Health Professions Legal Service Unit
JOB ASSIGNMENT REQUEST FORM

PARALEGALS

To:
- [x] Carolynn Bradley
- [ ] Debi Young
- [ ] Gail Banning
- [ ] _____

ADMIN SUPPORT

To:
- [ ] Britanny Reed
- [ ] Debbie Sloan
- [ ] Donna Thorson
- [x] Erika Quinn-Ellenbecker
- [ ] Joleen Karl
- [ ] Russ Holm
- [ ] Sonja Craddock
- [ ] _____

OTHER

- [ ] _____

STAFF ATTORNEY / PARALEGAL	RESPONDENT	CASE NUMBER
TDL	Gelnette, Marilyn	04-07-B-1063 UR 02-09-0004
RESPONDENT'S ATTORNEY	**REVIEWING MEMBER**	**AAG** McCartan
Stephan O. Fjelstad, 1424 Fourth Ave, 909 PLLC Seattle 98101-2217	—	**PROGRAM CONTACT** Miller-Smith
DATE REQUESTED	**DATE DUE**	
11-April-05	1-June-05	

- [ ] BAP
- [ ] Copy ☐File ☐Materials For: ☐RM, ☐MC, ☐AAG ☐ Expert
- [ ] Default / Waiver
- [ ] Expert Contract & File Preparation
- [ ] Interim Order –Forms & Records Preparation
- [ ] Modification / Reinstatement
- [ ] Notice of Correction
- [ ] Pre-Hearing Memo
- [ ] RAGS
- [ ] Schedule Settlement Conference
- [x] Service after program signature
- [ ] Settlement
- [ ] SOC
- [ ] STID & Agreed Order
- [ ] Summary Limitation / Suspension
- [ ] Transfer of Case to AGO
- [ ] Triage / Legal Review
- [x] Other Mtn/Cert

ADDITIONAL INSTRUCTIONS / COMMENTS:

4/13 - Made changes - ID Erika.

Health Professions Legal Service Unit
JOB ASSIGNMENT REQUEST FORM

PARALEGALS

To:
- ☐ Carolynn Bradley
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- ☐ _____

ADMIN SUPPORT

To:
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- ☐ Erika Quinn-Ellenbecker
- ☐ Joleen Karl
- ☐ Russ Holm
- ☐ Sonja Craddock
- ☐ _____

OTHER

- ☐ _____

STAFF ATTORNEY / PARALEGAL	RESPONDENT	CASE NUMBER / DOCKET NUMBER
TM	Gelnette, M	02-09-00044 UI / 04-07-B-1063 UR
RESPONDENT'S ATTORNEY	**REVIEWING MEMBER**	**AAG / PROGRAM CONTACT**
(sort of) Fjelstad		McLaran
DATE REQUESTED	**DATE DUE**	**DATE COMPLETED**
6-June-05		

- ☐ BAP
- ☐ Copy ☐File ☐Materials
  For: ☐RM, ☐MC, ☐AAG, ☐ Expert
- ☒ Default / Waiver
- ☐ Expert Contract & File Preparation
- ☐ Interim Order –Forms & Records Preparation
- ☐ Modification / Reinstatement
- ☐ Notice of Correction
- ☐ Pre-Hearing Memo
- ☐ RAGS
- ☐ Schedule Settlement Conference
- ☐ Service
- ☐ Settlement
- ☐ SOC Packet
- ☐ STID or Agreed Order
- ☐ Summary Limitation / Suspension
- ☐ Transfer of Case to AGO
- ☐ Triage / Legal Review
- ☐ Letter and _____
- ☐ Other _____

SOA: _____ hours _____ # of violations

ADDITIONAL INSTRUCTIONS / COMMENTS:

Staff Assignment Worksheet

Respondent Name: Gelvette, Marilyn

Case#(s): 2002-09-0002-UL Docket No.:

Program: Program contact:

Reviewing Member:

☐ Bahn, Mike	P or B	☐ Hoehn, Karl	P or B	☐ Weinstein, Elyette	P or B
☐ Berg, Larry	P or B	☐ Jensen, Karen	P or B	☐ Weisman, Mike	P or B
☐ Evans-Cordts, Barb	P or B	☐ Kelly, Trent	P or B	☐ Young, Judy	P or B
☐ Farrell, Mike	P or B	☒ Landreau, Teresa	P or B		
☐ Gilbert, Margaret	P or B	☐ McLaughlin, Jim	P or B	☐ Banning, Gail	P or B
☐ Hanley, Patrick	P or B	☐ Staiger, Janet	P or B	☒ Bradley, Carolynn	P or B
☐ Harris, Peter	P or B	☐ Weeks, Kristi	P or B	☐ Young, Debi	P or B

P = Primary B = Back-up

Received through ☐ IRP ☐ CMT ☐ ISU or ☐ Re-assigned on:

File to Staff Attorney or Paralegal on:

ACTION REQUESTED:

☐	Legal Review / Triage	☐	NOC
☐	Mental Evaluation	☐	NOD / BAP
☐	SOA / STID	☐	SOC
☐	Cease & Desist	☐	Other:
☒	Default / Waiver		

☐ SUMMARY	☐ Task Force Case

****

INITIAL WHEN SYSTEM IS UPDATED

6/9 ASI 6/6 TIMELINES 6/8 TALLY 6/8 Excel

Department of Health
Health Professions Quality Assurance Division
MS: 47873

2nd REQUEST FOR ATTORNEY GENERAL SERVICES

TO: Assigned AAG

FROM: Erika Quinn-Ellenbecker, Legal Secretary

RE: Marilyn Gelnette
Our File #: 2002-09-0004
Docket #: 04-07-B-1063MD
Staff Att: Teresa Landreau

DATE: March 17, 2005

Brief Statement of Legal Problem and Type of Assistance Requested

Attached for your review and approval are the draft Statement of Charges concerning the above-mentioned respondent.

CASE PRIORITY: 1____ 2____ ✓ 3___

1. If action is not taken immediately there is a substantial risk of significant injury to the public.

2. The requested response/legal action is needed no later than **April 17, 2005**.

3. The requested response/legal action is needed within a reasonable time, suspense date _____.

Enclosures: C&D
File

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine of:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE,	)	NOTICE OF INTENT TO ISSUE CEASE AND DESIST ORDER
Respondent.	)	

David Magby, Manager of the Unlicensed Practice Program (Program), on designation by the Secretary of Health, makes the allegations below, which are supported by evidence contained in program case file no. 2002-09-0004.

Section 1: FACTUAL ALLEGATIONS

1.1 Marilyn Gelnette (Respondent) has never held a credential to practice as a health care professional in the state of Washington.

1.2 During the time frame including the period between November 5, 2002 through January 9, 2003, Respondent worked at a hair removal and skin rejuvenation clinic known as Laser Works of Seattle (Laser Works), located in Tukwila, WA, where the activities described herein occurred.

1.3 Respondent offered laser treatment to human patients as a cure for and to ameliorate excessive hair, wrinkles and unsightly veins.

1.4 Respondent advised prospective patients that the laser energy she applied was "medical treatment" with anticipated "clinical results" and potentially harmful side effects.

ORIGINAL

1.5 Respondent applied penetrating laser energy to human patients at for hair removal, wrinkle reduction, and improvement in the appearance of leg veins. Such applications caused color changes, blisters and welts in the patients' tissue.

1.6 Respondent provided antibiotic ointment to one or more patients who suffered tissue damage from the laser applications and advised patients as to methods of treatment for such damage.

Section 2: ALLEGED VIOLATIONS

2.1 The conduct described in Sections 1.1 through 1.6 constitutes the unlicensed practice of medicine in violation of RCW 18.71.011(1), (2), and (3) and RCW 18.71.021.

> **RCW 18.71.011 Definition of practice of medicine -- Engaging in practice of chiropractic prohibited, when.** A person is practicing medicine if he does one or more of the following:
>
> (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
>
> (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
>
> (3) Severs or penetrates the tissues of human beings;
>
> . . .
>
> **RCW 18.71.021 License required.** No person may practice or represent himself or herself as practicing medicine without first having a valid license to do so.

2.2 The violation described in paragraph 2.1 constitutes grounds for issuance of a cease and desist order pursuant to RCW 18.130.190.

RCW 18.130.190 Practice without license -- Investigation of complaints -- Cease and desist orders -- Injunctions -- Penalties.

(1) The secretary shall investigate complaints concerning practice by unlicensed persons of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. In the investigation of the complaints, the secretary shall have the same authority as provided the secretary under RCW 18.130.050.

(2) The secretary may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed practice of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. The person to whom such notice is issued may request an adjudicative proceeding to contest the charges. The request for hearing must be filed within twenty days after service of the notice of intention to issue a cease and desist order. The failure to request a hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine. All proceedings shall be conducted in accordance with chapter 34.05 RCW.

(3) If the secretary makes a final determination that a person has engaged or is engaging in unlicensed practice, the secretary may issue a cease and desist order. In addition, the secretary may impose a civil fine in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed practice of a business or profession for which a license is required by one or more of the chapters specified in RCW 18.130.040. The proceeds of such fines shall be deposited to the health professions account.

(4) If the secretary makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the secretary may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the secretary. The failure to request a prompt or regularly scheduled hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine.

(5) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. The cease and desist order is conclusive proof of unlicensed practice and may be enforced under RCW 7.21.060. This method of enforcement of the cease and desist order or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

(6) The attorney general, a county prosecuting attorney, the secretary, a board, or any person may in accordance with the laws of this state governing injunctions, maintain an action in the name of this state to enjoin any person practicing a profession or business for which a license is required by the chapters specified in RCW 18.130.040 without a license from engaging in such practice or operating such business until the required license is secured. However, the injunction shall not relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy by injunction shall be in addition to any criminal liability.

(7) Unlicensed practice of a profession or operating a business for which a license is required by the chapters specified in RCW 18.130.040, unless otherwise exempted by law, constitutes a gross misdemeanor for a single violation. Each subsequent violation, whether alleged in the same or in subsequent prosecutions, is a class C felony. All fees, fines, forfeitures, and penalties collected or assessed by a court because of a violation of this section shall be remitted to the health professions account.

. . .

2.3 Pursuant to RCW 18.130.190 the Secretary of Health is authorized to issue a cease and desist order against a person upon a determination that such person has engaged in or is engaging in unlicensed practice of medicine and may impose a fine of up to one thousand dollars ($1,000.00) for each day of unlicensed practice.

Section 3: NOTICE TO RESPONDENT

David Magby, Manager of the Unlicensed Practice Program, alleges that the conduct referenced herein affects the public health, safety, and welfare; that a notice should be issued and served as provided by law to the Respondent giving the Respondent the opportunity to respond to the charges that she practiced as a physician without the proper license, and that if the Respondent fails to defend against these matters a permanent Cease and Desist Order may be issued and a civil fine imposed without further notice or opportunity for a hearing.

DATED this _____day of _____2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

_____
DAVID MAGBY
Unlicensed Practice Program Manager

_____
, WSBA #
Assistant Attorney General Prosecutor

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

Health Professions Legal Service Unit
JOB ASSIGNMENT REQUEST FORM

PARALEGALS

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- ☐ _____

ADMIN SUPPORT

To:
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- ☒ Erika Quinn-Ellenbecker
- ☐ Joleen Karl
- ☐ Russ Holm
- ☐ Sonja Craddock
- ☐ _____

OTHER

- ☐ _____

STAFF ATTORNEY / PARALEGAL	RESPONDENT	CASE NUMBER
TDL	Gefrette, M	02-09-000401 04-07-B-1063 UR
RESPONDENT'S ATTORNEY	**REVIEWING MEMBER**	**AAG** McCartan
Fjelstad, S.		**PROGRAM CONTACT** Chyma 11-5
DATE REQUESTED	**DATE DUE**	
16-Mar-05		

- ☐ BAP
- ☐ Copy ☐File ☐Materials
  For: ☐RM, ☐MC, ☐AAG☐ Expert
- ☐ Default / Waiver
- ☐ Expert Contract & File Preparation
- ☐ Interim Order –Forms & Records Preparation
- ☐ Modification / Reinstatement
- ☐ Notice of Correction
- ☐ Pre-Hearing Memo
- ☒ RAGS – 2nd

- ☐ Schedule Settlement Conference
- ☐ Service
- ☐ Settlement
- ☐ SOC
- ☐ STID & Agreed Order
- ☐ Summary Limitation / Suspension
- ☐ Transfer of Case to AGO
- ☐ Triage / Legal Review
- ☒ Other ~~2nd~~ revised NOPIC+D version 4

ADDITIONAL INSTRUCTIONS / COMMENTS:

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 02/23/2005 11:50:55 AM

Printed By GOTHOM\GLB0303 02/23/2005 11:50:57 AM

Profession: Unlicensed | License #: MD90000918 | Name : Gelnette, Marilyn

Case #: 2002-09-0004 | Description: Unlicensed Practice | Docket #: 04-07-B-1063 UR

Date Opened: 09/06/2002 | Date Closed: | Total Days As of 02/23/2005: 901

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	09/06/2002	09/06/2002	09/27/2002	21	0	0	21	Investigation
Investigation	09/06/2002	02/27/2003	02/23/2003	170	0	174	-4	Case Disposition
Case Disposition	02/27/2003		06/01/2005	140	685	727	98	

Banning, Gail

From: Latsch, Patricia
Sent: Wednesday, February 23, 2005 11:31 AM
To: Banning, Gail
Cc: Hoehn, Karl
Subject: RE: Staff Atty_Teresa L_16 cases_Timelineselectronic 022205.xls

approved. PbL

From: Banning, Gail
Sent: Wednesday, February 23, 2005 10:37 AM
To: Latsch, Patricia
Subject: Staff Atty_Teresa L_16 cases_Timelineselectronic 022205.xls

HTTS Extensions (16)

Case Name (Last, First)	Case Number (02-03-0004DE)	What is the cause of the delay? (Keep explanation to 5 to 15 words)	What is the work plan to con this Step (include dates f deliverables)?
Hernandez, Ernie	2003-04-0002DN 2003-09-0003DN 2003-09-0002DN 2004-01-0003DN 2004-06-0001DN 2004-08-0002DN 2004-10-0001DN	Re-assigned to SA on 11/22/04 for complex legal review of 7 cases; task request made 1/28/05; legal review to RBM 2/2/05; exhibits requested by RBM and forwarded 2/22/05.	RAGS to AAG after receipt of I recommendations.
White, Stanley	2004-11-0002DN	No whistleblower, task request on 1/14/05 and again on 2/3/05.	If whistleblower forthcoming, fc RAGS; if not, close as insuffici evidence.
Gelnette, Marilyn	2002-09-0004UR	AAG delay in addressing RAGS sent on 7/27/04.	Meeting with AAG set for 2/23/ independent expert is under contract.
Tasker, Joyce	2003-06-0016UR	AAG delay in addressing RAGS sent on 6/28/04.	Ongoing reminders to AAG.
Great Wall Medical & Dental	2003-02-0019UR	AAG delay in addressing RAGS sent on 7/27/04.	Ongoing reminders to AAG.
Bennett, Richard	2003-08-0009UR	AAG delay in addressing 2nd RAGS sent 7/27/04.	Ongoing reminders to AAG.
Lucich, William	2003-12-0010UR	AAG delay in addressing our injunction request of 4/16/04.	Filed as of 2/15/05; service per
Dahl, Carole	2003-11-0010UR	AAG delay in addressing our injunction request.	Filed as of 2/15/05; service per
Castleberry, Lynne	2003-10-0013UR	AAG delay in addressing RAGS of 8/16/04; novel laser issue.	Meeting with AAG set for 2/23/ independent expert is under contract.
Winterstein, Sherry	2002-08-0019UR	AAG delay in addressing RAGS of 8/4/04; novel laser issue.	Meeting with AAG set for 2/23/ independent expert is under contract.
Shoengarth, Shaney	2002-12-0013UR	AAG delay in addressing RAGS of 8/4/04; novel laser issue.	Meeting with AAG set for 2/23/ independent expert is under

			contract.
Aiello, Shelly	2004-04-0014UR	AAG delay in addressing RAGS of 8/4/04; novel laser issue.	Meeting with AAG set for 2/23/ independent expert is under contract.
Hernandez, Esteban	2003-01-0009UR	RAGS out 6/9/04; signed C&D rcvd 1/3/05; revision needed for typo.	2nd RAGS out 2/3/05 with e-m reminder.
Dubey, Eleanor	2003-01-0011UR	Re-assigned to SA on 1/3/05; drafting delayed by other priority cases.	Drafting will be completed with days.
Rivas, Marcy	2004-05-0005UR	Re-assigned to SA on 1/3/05; RAGS out on 2/16/05.	AAG suggested deadline of 3/
Marino Salon & Spa	2004-05-0016UR	Re-assigned to SA for legal review in light of task results 2/17/05; laster issues.	Draft within 2 weeks of assignr independent expert identified f other laser cases already.

MEMORANDUM

TO: BRANDITH IRWIN, MD

FROM: TERESA LANDREAU, WA STATE DEPT OF HEALTH

SUBJECT: UNLICENSED LASER PRACTITIONER CASES

DATE: 03/01/2005

CC: *AIELLO, CASTLEBERRY, GELNETTE, SHOENGARTH, WINTERSTEIN* FILES

Transmitted to you along with this cover are investigative materials regarding the five matters named above, for your use in connection with your service as an expert consultant for the Department of Health.

These documents may contain private health information and attorney work product which should not be disclosed to third parties. Please contact me before responding to any requests for information contained within these materials.

Thank you.

Department of Health
Health Professions Quality Assurance Division
MS: 47873

REQUEST FOR ATTORNEY GENERAL SERVICES

TO: Assigned AAG

FROM: Sonja Craddock, Legal Secretary

RE: Marilyn Gelnette
Our File #: 2002-09-0004
Docket #: 04-07-B-1063MR
Staff Att: Teresa Jordan

DATE: July 27, 2004

Brief Statement of Legal Problem and Type of Assistance Requested

Attached for your review and approval are the draft Statement of Charges concerning the above-mentioned respondent.

CASE PRIORITY: 1____ 2____✓ 3__

1. If action is not taken immediately there is a substantial risk of significant injury to the public.

2. The requested response/legal action is needed no later than **August 27, 2004**.
3. The requested response/legal action is needed within a reasonable time, suspense date _____.

Enclosures: C&D
File

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine of:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE,	)	NOTICE OF INTENT TO ISSUE CEASE AND DESIST ORDER
Respondent.	)	

Dave Magby, Manager of the Unlicensed Practice Program (Program), on designation by the Secretary of Health, makes the allegations below, which are supported by evidence contained in program case file no. 2002-09-0004.

Section 1: FACTUAL ALLEGATIONS

1.1 Marilyn Gelnette, Respondent, has never held a credential to practice as a health care professional in the state of Washington.

1.2 During the time frame that the treatment described herein occurred, Respondent was employed at Laser Works of Seattle to apply tissue penetrating laser energy to patients. On November 5, 2002, November 5, 2002, November 7, 2002, November 25, 2002, December 2, 2002, December 20, 2002, December 26, 2002, December 27, 2002, December 28, 2002, December 31, 2002, January 4, 2003, January 4, 2003, January 8, 2003, and January 9, 2003, Respondent used a printed "Informed Consent Form" to advise patients 3, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, and 16, respectively, the laser energy application was "medical treatment" with anticipated "clinical results" and known harmful side effects.

ORIGINAL

1.3 On July 18, 2002 Respondent applied penetrating laser energy to the torso of patient 1, causing redness and welts.

1.4 On September 4, 2002 Respondent applied penetrating laser energy to the face of patient 2, causing redness and blisters. Respondent then gave patient 2 a white antibiotic cream to treat his facial injury.

1.5 On November 4, 2002 Respondent applied penetrating laser energy to the lip and chin of patient 3, causing increased pink coloration.

1.6 On November 6, 2002 Respondent applied penetrating laser energy to the torso and lip of patient 4, causing redness and welting.

1.7 On December 11, 2002 and on January 2, 2003 Respondent applied penetrating laser energy to the face and legs of patient 5 for purposes of treating facial wrinkles and leg veins, causing blanching and coloration changes in Patient 5.

1.8 On December 27, 2002 Respondent applied penetrating laser energy to the torso and lip of patient 6, causing an increased pink coloration.

1.9 On January 4, 2003 Respondent applied penetrating laser energy to the neck of patient 7, causing a very pink skin reaction.

//

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Section 2: ALLEGED VIOLATIONS

2.1 The conduct described in Sections 1.1 through 1.5 constitutes the unlicensed practice of medicine in violation of RCW 18.71.011(1), (2), and (3) and RCW 18.71.021.

> **RCW 18.71.011 Definition of practice of medicine -- Engaging in practice of chiropractic prohibited, when.** A person is practicing medicine if he does one or more of the following:
>
> (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
>
> (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
>
> (3) Severs or penetrates the tissues of human beings;
>
> . . .
>
> **RCW 18.71.021 License required.** No person may practice or represent himself or herself as practicing medicine without first having a valid license to do so.

2.2 The violation described in paragraph 2.1 constitutes grounds for issuance of a cease and desist order pursuant to RCW 18.130.190.

> **RCW 18.130.190 Practice without license -- Investigation of complaints -- Cease and desist orders -- Injunctions -- Penalties.**
>
> (1) The secretary shall investigate complaints concerning practice by unlicensed persons of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. In the investigation of the complaints, the secretary shall have the same authority as provided the secretary under RCW 18.130.050.
>
> (2) The secretary may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed practice

of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. The person to whom such notice is issued may request an adjudicative proceeding to contest the charges. The request for hearing must be filed within twenty days after service of the notice of intention to issue a cease and desist order. The failure to request a hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine. All proceedings shall be conducted in accordance with chapter 34.05 RCW.

(3) If the secretary makes a final determination that a person has engaged or is engaging in unlicensed practice, the secretary may issue a cease and desist order. In addition, the secretary may impose a civil fine in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed practice of a business or profession for which a license is required by one or more of the chapters specified in RCW 18.130.040. The proceeds of such fines shall be deposited to the health professions account.

(4) If the secretary makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the secretary may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the secretary. The failure to request a prompt or regularly scheduled hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine.

(5) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. The cease and desist order is conclusive proof of unlicensed practice and may be enforced under RCW 7.21.060. This method of enforcement of the cease and desist order or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

(6) The attorney general, a county prosecuting attorney, the secretary, a board, or any person may in accordance with the laws of this state governing injunctions, maintain an action in the name of this state to enjoin any person practicing a profession or business for which a license is required by the chapters specified in RCW 18.130.040 without a license from engaging in such practice or operating such business until the required license is secured. However, the injunction shall not relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy by injunction shall be in addition to any criminal liability.
(7) Unlicensed practice of a profession or operating a business for which a license is required by the chapters specified in RCW 18.130.040, unless otherwise exempted by law, constitutes a gross misdemeanor for a single violation. Each subsequent violation, whether alleged in the same or in subsequent prosecutions, is a class C felony. All fees, fines, forfeitures, and penalties collected or assessed by a court because of a violation of this section shall be remitted to the health professions account.

. . .

2.3 Pursuant to RCW 18.130.190 the Secretary of Health is authorized to issue a cease and desist order against a person upon a determination that such person has engaged in or is engaging in unlicensed practice of medicine and may impose a fine of up to one thousand dollars ($1,000.00) for each day of unlicensed practice.

Section 3: NOTICE TO RESPONDENT

Dave Magby, Manager of the Unlicensed Practice Program, alleges that the conduct referenced herein affects the public health, safety, and welfare; that a notice should be issued and served as provided by law to the Respondent giving the Respondent the opportunity to respond to the charges that she practiced as a physician without the proper license, and that if the Respondent fails to defend against these

matters a permanent Cease and Desist Order may be issued and a civil fine imposed without further notice or opportunity for a hearing.

DATED this _____day of _____2004.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

_____
DAVE MAGBY
Unlicensed Practice Program Manager

_____
, WSBA #
Assistant Attorney General Prosecutor

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

CONFIDENTIAL SCHEDULE

This information is confidential and is NOT to be released without the consent of the individual or individuals named herein. RCW 2.17.310(1)(d).

Patient 1:

Patient 2:

Patient 3

Patient 4:

Patient 5:

Patient 6:

Patient 7:

Patient 8

Patient 9

Patient 10

Patient 11

Patient 12

Patient 13

Patient 14

Patient 15

Patient 16

LEGAL REVIEW WORKSHEET

July 8, 2004

To: Chyma Miller-Smith
Program Manager, Unlicensed Practice, via CMT

From: Teresa Jordan
Staff Attorney

Subject: MARILYN GELNETTE
Program File No. 2002-09-0004UI
(related cases Shaney Shoengarth & Sherry (Cheri) Winterstein)
02-12-0013UI 02-08-0019UI

BASIC LICENSING DATA: Respondent is unlicensed in WA.

INVESTIGATION SUMMARY:

Laser Works of Seattle, LLC offered laser hair removal, skin rejuvenation, and vein treatment to the public in Tukwila, WA. Respondent Gelnette is one of several unlicensed employee technicians there who routinely administered laser hair removal treatments. Selected patient files obtained by our health care investigator Gayle M. Crowley identify the individual technician by name or initial, and include their notations of varying patients' skin reactions to the application of laser energy, including redness, pain, swelling, welting and blisters. Laser Works staff, including Gelnette, routinely administered remedies for the skin reactions, including ice, comfrey, aloe, "neova cream", "neeva", "rejuvano", "differin gel", "emla" and "lasercaine". Some files document recommendations to patients to use certain medicines at home such as ibuprofen and lidocaine.

Gelnette used lasers on 12-11-02 and 1-22-03 to treat a patient's facial wrinkles and leg veins.

Before and during the investigation, Gelnette worked with no licensed medical supervision, although Laser Works hired a figure-head medical director who took no part in training or oversight of the day-to-day operations.

DOH received an e-mailed complaint 9-4-02 from a patient about facial hair removal by Gelnette on 8-28-02 which left blisters and redness on his cheek lasting a week. Treatment records reflect co-respondent Shaney Shoengarth as the patient's technician that day, but include notes in handwriting similar to Gelnette's.

LEGAL ANALYSIS:

1 - Attorney Work Product - RCW 42.56.290

[i] **RCW 18.71.011 Definition of practice of medicine -- Engaging in practice of chiropractic prohibited, when.**

1 - Attorney Work Product - RCW 42.56.290

1 - Attorney Work Product - RCW 42.56.290

RECOMMENDATION:

1 - Attorney Work Product - RCW 42.56.290

Correspondence from respondent's counsel after our investigation had commenced indicates the company subsequently hired licensed medical staff, including Dr. Bianci (located physically in Spokane), nurse supervisor Bonnie Schmidt and registered nurse Linn Drynildson.

1 - Attorney Work Product - RCW 42.56.290

OTHER CONSIDERATIONS:

A person is practicing medicine if he does one or more of the following:

(1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

(2) Administers or prescribes drugs or medicinal preparations to be used by any other person;

(3) Severs or penetrates the tissues of human beings;

(4) Uses on cards, books, papers, signs or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation "doctor of medicine", "physician", "surgeon", "m.d." or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license: PROVIDED HOWEVER, That a person licensed under this chapter shall not engage in the practice of chiropractic as defined in RCW 18.25.005.

Licensed professional health care providers, such as Dr. Bianchi and Nurses Schmidt and Dynildson, are mentioned in correspondence.

1 - Attorney Work Product - RCW 42.56.290

Department Of Health
Health Professions Quality Assurance Division
Washington State
Medical Quality Assurance Commission
Policy Statement

Title	Use of Lasers in Skin Care and Treatment	Number MD2003-03
Reference		
Contact	George Heye MD	
Effective Date	November 21, 2003	
Supersedes		
Approved	Hampton Irwin MD, Chair	

BACKGROUND

The U.S. Food and Drug Administration regulate the sale of lasers[1]. Lasers are prescription devices that can be sold only to licensed practitioners with prescriptive authority. Complications from the use of lasers for skin care and treatment include visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

POLICY

1. The use of a laser to treat or alter the skin is the practice of medicine under RCW 18.71.011.

2. A physician using a laser should be appropriately trained in the physics, safety and techniques of using lasers. Prior to initiating laser treatment, the physician should take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent which includes informing the patient that a non-physician may operate the laser, provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

3. A physician who meets the above requirements may delegate a laser procedure to an allied health professional, provided such delegation falls within the allied health professional's scope of practice. A physician making such delegation must prepare a written protocol for the allied health professional to follow in administering the laser treatment.
4. The supervising physician should ensure that the allied health professional has appropriate documented training in the area of basic dermatology and

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 07/27/2004 9:54:54 AM

Printed By GOTHOM\SMC0303 07/27/2004 9:54:57 AM

Profession: Unlicensed
Case #: 2002-09-0004
Date Opened: 09/06/2002

License #: MD90000918
Description: Unlicensed Practice
Date Closed:

Name : Gelnette, Marilyn
Docket #: 04-07-B-1063 MD
Total Days As of 07/27/2004: 690

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	09/06/2002	09/06/2002	09/27/2002	21	0	0	21	Investigation
Investigation	09/06/2002	02/27/2003	02/23/2003	170	0	174	-4	Case Disposition
Case Disposition	02/27/2003		06/16/2004	140	335	516	-41	

Health Professions Section 2 – Legal Service Unit

REQUEST FOR ADMINISTRATIVE SERVICES

Date Requested : 7/16, 2004 **(10 Day Due Date:)**

Staff Attorney: MJG EMW JLY PFH KLW LRP PJH TLJ

Reviewed if necessary: Yes MG **No**

Respondent: Gelnette, Marilyn

Program No(s): 02-09-000401 **Docket No(s):**

Respondent Attorney: Stephan O. Fjelstad PLLC

Attorney Address: 1424 Fourth Ave, Suite 909, Seattle 98101-2217

RCM/RBM: **HTTS DUE DATE:**

SOC ☒ 1ST RAGS ☐ 2ND RAGS ☐ SERVE SOC ☐ SIGNED A/O

SOA ☐ SOA/STID ☐ SERVE SOA ☐ SIGNED STID

# of ____ Violations ____ SA Hours

OTHERS ☐ MODIFICATION ☐ REINSTATEMENT ☐ BAP

☐ DEFAULT ☐ NOC ☐ LETTER and _____

SPECIAL INSTRUCTIONS:

* *

ADMINISTRATIVE TRACKING

File to Program for Signature: _____ **File returned from Program:** _____

Admin completed request: _____ **Formatted by:** SMC JAK JLO

aff Attorney Assignment Worksl i

Respondent Name: Gelinette, Marilyn

Case No.: 2002-09-0004 Program: unlicensed

Assigned Staff Attorney: ☐ EMW ☐ JLY ☐ KLW ☐ LRP ☐ PFH ☐ MJG ☐ PJH ☒ TJ

INCOMING:

Received through CMT: 7-15-04 Delivered to SA: 7-15-04

☒ HTTS ☒ ASI ☒ DCTRS

ADDITIONAL INVESTIGATION

Return to ISU Through CMT: _____

Return to LSU through CMT: _____

☐ **LEGAL REVIEW**

Review due (14 days): _____

Review Completed: _____ Returned to CMT _____

☐ **NOC**

Draft due (30 days): _____

Drafting completed, to admin _____

Admin complete _____ Return to CMT _____

☐ **SOA/STID**

Draft due (30 days): _____

Drafting completed, to admin _____

Admin complete _____

Serve _____

Signed STID received _____

Signed STID presented to disc authority _____

Presented to CMT/Board/Commission for alternate disposition _____

☒ **SOC** C & D

Draft due (30 days) 8-14-04

Drafting completed, to admin _____

File to copy _____

Copies back _____

Admin complete RAGS sent _____

AAG return date _____

Assigned AAG: _____

Service date _____

Signed AO received _____

Signed AO presented to disc authority _____

Return completed file through CMT: _____

*******Remove this form before returning to CMT*******

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 07/15/2004 2:22:50 PM

Printed By GOTHOM\CRL9303 07/15/2004 2:22:53 PM

Profession: Unlicensed | License #: MD90000918 | Name : Gelnette, Marilyn

Case #: 2002-09-0004 | Description: Unlicensed Practice | Docket #: N/A

Date Opened: 09/06/2002 | Date Closed: | Total Days As of 07/15/2004: 678

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	09/06/2002	09/06/2002	09/27/2002	21	0	0	21	Investigation
Investigation	09/06/2002	02/27/2003	02/23/2003	170	0	174	-4	Case Disposition
Case Disposition	02/27/2003		06/16/2004	140	335	504	-29	

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 04/02/2004 2:35:19 PM

Printed By GOTHOM\SMC0303 04/02/2004 2:35:22 PM

Profession: Unlicensed | License #: MD90000918 | Name : Gelnette, Marilyn

Case #: 2002-09-0004 | Description: Unlicensed Practice | Docket #: N/A

Date Opened: 09/06/2002 | Date Closed: | Total Days As of 04/02/2004: 574

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	09/06/2002	09/06/2002	09/27/2002	21	0	0	21	Investigation
Investigation	09/06/2002	02/27/2003	02/23/2003	170	0	174	-4	Case Disposition
Case Disposition	02/27/2003		06/16/2004	140	335	400	75	

STAFF ATTORNEY ASSIGNMENT

Respondent Name: Delapette, Marilyn

Case #(s): 2002-09-0004 UI

Program: UI

Received through CMT on: 2-27-03

REQUESTED ACTION:

☐ **INITIAL ASSESSMENT** Due Date (7 days): _____, 2003

☒ **LEGAL REVIEW** Due Date (14 days): 3-13, 2003

☐ **BELOW THRESHOLD**
Drafting: Due Date (7 days): _____, 2003

☐ **NOC**
Drafting: Due Date (30 days): _____, 2003

☐ **DRAFT SOA/STID**
Drafting: Due Date (30 days): _____, 2003

☐ **DRAFT SOC**
Drafting: Due Date (30 days): _____, 2003

☐ **OTHER:** _____, 2003

Staff Attorney Assigned: EW JY KW LP MG WR

Other Assigned: LLM

Date Assigned: FEB 28 2003, 2003

☐ **CASE LOG** updated?

☐ **ASI** updated ☐ **TIMELINES** updated ☐ **DCTRS** updated

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 02/28/2003 2:28:13 PM

Printed By GOTHOM\DSJ0303 02/28/2003 2:28:21 PM

Profession: Unlicensed | License #: MD90000918 | Name : Gelnette, Marilyn

Case #: 2002-09-0004 | Description: Unlicensed Practice | Docket #: N/A

Date Opened: 09/06/2002 | Date Closed: | Total Days As of 02/28/2003: 175

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	09/06/2002	09/06/2002	09/27/2002	21	0	0	21	Investigation
Investigation	09/06/2002	02/27/2003	02/23/2003	170	0	174	-4	Case Disposition
Case Disposition	02/27/2003		07/17/2003	140	0	1	139	

REQUEST FOR TIMELINE EXTENSION

Instructions:

1. Please **Type** or **Print** Clearly
2. Review HTTS Manual and applicable Policies to determine the appropriate Requesting level, Approval level and time limits for your Extension Request.
3. Be sure to attach a copy of the Case Summary Report to the Request **before** forwarding for approval.
4. Ensure that there is adequate time to process your Request **prior** to timelines running out.
5. Check only one block within the appropriate Step for "Reason for Extension".
6. Use commentary from Block VI-a of this form in the "Comments" box when entering the approved Extension on HTTS.
7. Keep the original form of the approved Extension Request with the case file; send a copy of the completed approved form – with Case Summary Report – to the Operations and Support Services Office.

I. CASE INFORMATION

Health Unit/Program:	Case #:	Docket #: (If Applicable)
Unlicensed	2002-09-0004	N/A

Respondent Name (Last, First, MI)	Step Start Date	Previous Extensions This Step	No. Days Requested
Gelnette, Marilyn	09/06/2002	N/A	7

II. REASON FOR DELAY (Check the current Step, and the reason for the Delay)

☐ Initial Assessment	X Investigation	☐ Disposition	☐ Adjudication (SOA)
☐ BMA - Board/Commission Member Availability	☐ MAI -	☐ - Outside Expert Review	☐ DPC - Due Process Continuance
☐ OTR - Other	☐ ICC - Add to File.	☐ Inter-related Concurrent Cases	☐ KPA - Key Personnel Availability
☐ KPA - Key Personnel not Available	☐ KPA -	☐ Key Personnel not Available	☐ CCC - Conflicting Concurrent Cases
	☐ RAI -	☐ Board/Commission Member not Available	☐ OTR - Other
	☐ OER -	☐ - Other	
	X OTR – [illegible]		

III. JUSTIFICATION FOR EXTENSION REQUEST: (All items must be addressed)

a. What is the cause of the delay?

Investigation consists of allegations with three different respondents. These are all companion cases. All three cases involved reviewing a large number of patient treatment files.

b. What is the workplan to complete this Step (include dates for deliverables)?

Finish the Investigative Report. Anticipate completion and submission to program no later than 2/21/2003.
This Case is Completed and will be Submitted to Cmt on 2/27/03 DC

c. Other factors the Approving Authority should consider?

This case is a companion case file to two other unlicensed cases.

IV. REQUESTOR AUTHENTICATION: (Name and authorization of person requesting the extension)

Gayle M. Crowley	Health Care Investigator		2/20/2003
NAME OF REQUESTOR	TITLE/DUTY POSITION OF REQUESTOR	ED's Initials (If Applicable)	DATE

V. APPROVAL/DISAPPROVAL: **(Check box indicating whether or not the request is granted. If granting, indicate number of days allowed.)**

☑ Good Cause Demonstrated – Extension Granted	No. Days Granted _____
☐ Good Cause Not Demonstrated – Extension Not Granted	

VI. RATIONALE: **(Describe the basis for your decision, and means of ensuring compliance within time granted.)**

a. Basis for Decision:

b. Management Oversight to be Imposed: **(Mandatory when extension granted)**

VII. SIGNATURE:

NAME OF APPROVING AUTHORITY	SIGNATURE OF APPROVING AUTHORITY	DATE
David Mazby	David Mazby	

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In the Matter of the Unlicensed Practice of Medicine by: MARILY GELNETTE, Respondent.	Docket No. 04-07-B-1063UR ORDER DENYING REQUEST FOR EXTENSION

A Statement of Charges alleging unprofessional conduct under RCW 18.130.180, a Notice of Opportunity to Defend, and an Answer to Statement of Charges form were served by mail on the Respondent on April 20, 2005 and re-served on April 27, 2005. The Respondent's Answer to Statement of Charges and request for hearing were due within 20 days of service, by May 17, 2005. On May 13, 2005, Stephen O. Fjelstad, Attorney at Law, filed a letter requesting an extension of time to file an answer. Mr. Fjelstad indicates that he met with the Respondent early in the investigation state. There was no response from the Department.

Mr. Fjelstad acknowledges that he is not filing a Notice of Appearance in this matter. If he's not the Respondent's attorney, he is not representing the Respondent and cannot speak for her. Thus, his request for an extension is denied. The rule indicates that the Respondent has ten days from service of the order denying the extension or twenty days from service of the initiating documents, whichever is longer, to file an application for adjudicative proceeding. WAC 246-10-203(3)(c).

The Presiding Officer concludes the Mr. Fjelstad does not have standing to make an extension request.

Dated this 19th day of May, 2005.

LAURA FARRIS, Senior Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL
I declare that today I served a copy of this document upon the following parties of record:
MARILYN GELNETTE AND RICHARD MCCARTAN, AAG by mailing a copy properly addressed with postage prepaid.

DATED AT OLYMPIA, WASHINGTON THIS 19th DAY OF MAY, 2005.

Darlene Wallace
Adjudicative Service Unit

cc: **CHYMA MILLER-SMITH**
LEGAL UNIT
STEPHEN O. FJELSTAD, ATTORNEY AT LAW

FOR INTERNAL USE ONLY: (Internal tracking numbers)
Program No. 2002-09-0004

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In the Matter of the Unlicensed Practice of Medicine:	)	Docket No. 04-07-B-1063UR
MARILYN GELNETTE,	)	NOTICE OF FAILURE TO RESPOND
Respondent.	)	

TO: Richard McCartan, Assistant Attorney General
Office of the Attorney General
P. O. Box 40109
Olympia, WA 98504-0109

THIS NOTICE is to advise you that as of this date the Respondent in the above-entitled matter has not responded to the Notice of Intent to Issue Cease and Desist Order served April 27, 2005.

DATED THIS 3rd DAY OF JUNE, 2005

Darlena Wallace

Darlena Wallace, Hearings Scheduler
PO Box 47879
Olympia, WA 98504-7879
(360) 236-4671

DECLARATION OF SERVICE BY MAIL

I declare that today, at Olympia, Washington, I served a copy of this document upon the following parties of record: Richard McCartan, Assistant Attorney General, by mailing a copy properly addressed with postage prepaid.

DATED THIS 3rd DAY OF JUNE, 2005.

Darlena Wallace

Adjudicative Service Unit

c: Marilyn Gelnette, Respondent
1001 4th Ave Ste 3200
Seattle WA 98154-1003

Chyma Miller-Smith, Program Manager
Teresa Landreau, Legal Unit

"Aurora" by Syneron
"Cool Glide" by Altus Medical
"Alexanderite" by ESC Sharp Plan
"IPL"L by Luminous

two may be pulsed light machines,. Used to cut or pierce human skin or tissues as surgical lasers? -+ may be.
"Aurora" incorporates radio frequency and reduces optical light energy emitted by about ½, may not be either intense pulsed light or a laser.

RCW 18.16.010
Intent.

The legislature recognizes that the practices of cosmetology, barbering, manicuring, and esthetics involve the use of tools and chemicals which may be dangerous when mixed or applied improperly, and therefore finds it necessary in the interest of the public health, safety, and welfare to regulate those practices in this state.

[2002 c 111 § 1; 1984 c 208 § 1.]

NOTES:

Effective date -- 2002 c 111: "This act takes effect June 1, 2003." [2002 c 111 § 18.]

RCW 18.16.020
Definitions.

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

(6) "The practice of cosmetology" means arranging, dressing, cutting, trimming, styling, shampooing, permanent waving, chemical relaxing, straightening, curling, bleaching, lightening, coloring, waxing, tweezing, shaving, and mustache and beard design of the hair of the face, neck, and scalp; temporary removal of superfluous hair by use of depilatories, waxing, or tweezing; manicuring and pedicuring, limited to cleaning, shaping, polishing, decorating, and caring for and treatment of the cuticles and nails of the hands and feet, excluding the application and removal of sculptured or otherwise artificial nails; esthetics limited to toning the skin of the scalp, stimulating the skin of the body by the use of preparations, tonics, lotions, or creams; and tinting eyelashes and eyebrows.
(12) "Practice of esthetics" means care of the skin by application and use of preparations, antiseptics, tonics, essential oils, or exfoliants, or by any device or equipment, electrical or otherwise, or by wraps, compresses, cleansing, conditioning, stimulation, pore extraction, or product application and removal; the temporary removal of superfluous hair

by means of lotions, creams, mechanical or electrical apparatus, appliance, waxing, tweezing, or depilatories; tinting of eyelashes and eyebrows; and lightening the hair, except the scalp, on another person.

Marilyn Gelnette, is described by the previous medical director as being licensed in CA in electrolysis and cosmetology in CA, and as working w/ laser, pulsed light and microdermabrasion for over 2 years as a licensed cosmetologist in CA (& electrolysis).

The definition of an esthetician is under the Practice of esthetics" in RCW 18.16.020:

Care of the ski by application and use of preparations, antiseptics, tonics, essential oils, or exfoliates, or by any device o equipment, electrical or otherwise, or by wraps, compresses, cleansing, conditioning, stimulation, pore extraction, or product application and removal, by temporary removal of superfluous hair by means of lotions, creams, mechanical or electrical apparatus, appliance, waxing, tweezing, or depilatories . . . on another person."

CONSIDER; Referral to DOL since this licensing occurs now under their bailiwick per statute, and Gelnette may not be licensed by them currently

Referal to Medicine program for aid and abet charge for nominal medical director Dr. John Fisher/ unprofessional conduct for lack of supervision while in nominal title of medical director

Consider practice medicine w/o license on 8-28-02 on behalf of Jason Kagihara from 8/28/03.

Referral on RN INSTRUCTOR forsame

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1001 FOURTH AVENUE, SUITE 3200
SEATTLE, WASHINGTON 98154
VOICE: (206) 340-6100
FAX: (206) 340-6105
EMAIL: sfjelstad@northstarlaw.com

DATE: MAY 12, 2005
TIME: 3:58 PM
NUMBER OF PAGES WITH COVER: 3

FACSIMILE COVER SHEET

TO: **Teresa Landreau**
Staff Att'y; Dept. of Health

FAX NO.: (360) 236-4930
TELE. NO: (360) 236-4845

FROM: Stephan O. Fjelstad PLLC

RE: Winterstein/Shoengarth/Gelnette

CLIENT REF.:
If any of these pages are not legible or you do not receive all the pages, please call (206) 340-6100.

COMMENTS:

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

April 27, 2005

Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188

Marilyn Gelnette
c/o Stephan Fjelstad
Attorney at Law
1001 4th Ave Ste 3200
Seattle, WA 98154-1003

Dear Ms. Gelnette:

Enclosed please find a copy of the following documents issued to you:

- Notice of Intent to Issue Cease and Desist Order
- *Notice of Opportunity for Settlement and Hearing*
- Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing
- Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (proposed)

Please be advised that the Answer to the Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing form must be completed and received by the Adjudicative Service Unit no later than twenty (20) days from the date it was mailed to you.

After reviewing the investigative files and conferring with the Program Manager for the Unlicensed Practice Program, we think an appropriate way to resolve this matter is by a Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (Agreed Order). The disciplinary authority has authority to enter this Agreed Order. This is a way of resolving this matter without a hearing.

If you agree that this is an amicable way to resolve this matter, please sign the Agreed Order and return it to me by **May 17, 2005**, and I will present the Agreed Order to the disciplinary authority for its acceptance. If I do not receive this document from you on or before **May 17, 2005**, I will assume that you have rejected this manner of resolution.

You do have the right, and are encouraged, to obtain private counsel to advise and instruct you concerning this matter. If you have any questions regarding the enclosed documents or the adjudication's process, please contact me at (360) 236-4845.

Sincerely,

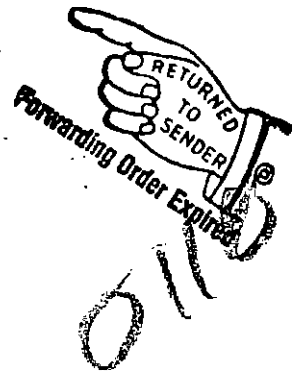
TERESA LANDREAU
Staff Attorney

TL/eqe

Enclosures

cc: Chyma Miller-Smith, Program Manager

Washington State
DEPARTMENT OF HEALTH
PO Box 47873
Olympia, WA 98504-7873



CONFIDENTIAL

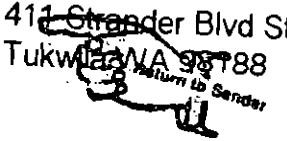
Marilyn Gelnette
c/o Stephan Fjelstad
Attorney at Law
1424 Fourth Ave Ste 909
Seattle WA 98101-2217

CONFIDENTIAL

Washington State
DEPARTMENT OF HEALTH
PO Box 47873
Olympia, WA 98504-7873

CONFIDENTIAL

Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188



RECEIVED
APR 25 2005
DEPARTMENT OF HEALTH
LEGAL UNIT

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

April 20, 2005

Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188

Marilyn Gelnette
c/o Stephan Fjelstad
Attorney at Law
1424 Fourth Ave, Ste 909
Seattle, WA 98101-2217

Dear Ms. Gelnette:

Enclosed please find a copy of the following documents issued to you:

- Notice of Intent to Issue Cease and Desist Order
- Notice of Opportunity for Settlement and Hearing
- Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing
- Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (proposed)

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After reviewing the investigative files and conferring with the Program Manager for the Unlicensed Practice Program, we think an appropriate way to resolve this matter is by a Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (Agreed Order). The disciplinary authority has authority to enter this Agreed Order. This is a way of resolving this matter without a hearing.

If you agree that this is an amicable way to resolve this matter, please sign the Agreed Order and return it to me by **May 10, 2005**, and I will present the Agreed Order to the disciplinary authority for its acceptance. If I do not receive this document from you on or before **May 10, 2005**, I will assume that you have rejected this manner of resolution.

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

May 13, 2003

Margaret Gilbert
Legal Unit
Health Professsion Quality Assurance
Department of Health
P.O. Box 47873
Olympia, WA 98504-7873

Re: Laser Works of Seattle Employees—Investigation; Recent Hiring of Nurse

Dear Ms. Gilbert:

This is to provide you another update on matters related to the Department of Health's ongoing investigation of my clients, the employees of Laser Works of Seattle (Shaney Shoengarth, Marilyn Gelnette and Cheri Winterstein). Laser Works has recently hired a new nurse on its staff, Linn Drynildson. Ms. Drynildson is a registered nurse licensed to practice in Washington State.

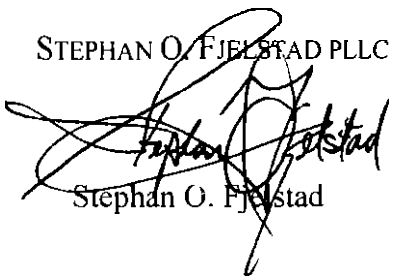
Bonnie Schmidt, also a nurse licensed in Washington, is supervising Ms. Drynildson and the other Laser Works employees. I described Ms. Schmidt's many years of extensive experience in matters of laser and intense pulsed light procedures and equipment in my letter of February 26, 2003 addressed to Chyma Miller-Smith, which letter I presume is part of your file. As I mentioned in my February 26th letter, Ms. Schmidt has been on-site at Laser Works in her supervisory and consulting capacity on a regular weekly basis. Should you wish to speak with Ms. Schmidt regarding the ongoing procedures at Laser Works, please feel free to call her at the Laser Works telephone number: (206) 575-8300.

Please contact me concerning the status of the investigation, as we remain committed to cooperating with the DOH with respect to any information we can supply you or further measures deemed advisable.

Thank you for your consideration.

Very truly yours,

STEPHAN O. FJELSTAD PLLC



Stephan O. Fjelstad

SOF:sof
clients

telnet (GothomCity)

Margaret -
I cannot find Linn Dreyfildson as a licensed nurse on ASI or garfield CIMS - We show Bonnie living in California

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BOARD OF NURSING ASSESSMENT SYSTEMS, INC. 05-15-03
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LAST SCHMIDT SOC SEC NUM 2 - DOH Licensee Social S...
FIRST BONNIE
MIDDLE JEAN

RESIDENCE INFORMATION
7928 GRADO EL TUPELO
CARLSBAD CA 92009

PHONE: ( ) - COUNTY: 51
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NOTES

+-ADDITIONAL INFORMATION-----------+
| SEX F = MARRIED = |
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| OTHER NAME |
| CORP. OFFICER = |
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STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

February 26, 2003

Chyma Miller-Smith
Health Care Investigator
Unlicensed Practice Program
Department of Health
PO Box 47874
Olympia, WA 98504-7874

Re: Investigation of Laser Works of Seattle Employees by Department of Health

Dear Ms. Miller-Smith:

As you know, I represent the three employees of the company Laser Works of Seattle, namely Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein (collectively, the "employees") regarding the Department of Health (DOH) investigation as to whether these individuals have practiced medicine. My understanding is that your program is now coordinating the investigation for DOH.

I previously wrote a letter dated January 15, 2003, to Gayle M. Crowley, the initial Health Care Investigator assigned to this case, explaining our preliminary position on the issue of whether we believe the employees have practiced medicine. I presume that letter is part of the file Ms. Crowley forwarded to your office and it gives a detailed background of the nature of Laser Works and the work its employees perform. (If for any reason my letter to Ms. Crowley has not reached you or is not part of the file, please let me know and I will supply another copy immediately.) Our position in the letter to Ms. Crowley is that we do not believe the employees have practiced medicine. Regardless of how that question may ultimately be resolved, however, I wish to emphasize on behalf of my clients that our singular aim is to ensure that they and Laser Works are in compliance with the provisions set forth in the recent Medical Quality Assurance Commission (MQAC) 10-25-02 policy statement entitled "Use of Lasers in Skin Care and Treatment" (the Policy). I write to you now to explain additional actions that have been taken to ensure compliance, to provide additional information not contained in my previous letter to Ms. Crowley and to seek your guidance in achieving satisfactory compliance if additional measures are **needed.**

As you know, the Policy allows the use of a laser for dermatologic purposes, such as hair removal, to be delegated with appropriate oversight by a physician. The Policy discusses the scope of "appropriate oversight" and lists three prerequisite skills the physician should possess:

1) The physician must be skilled in the diagnosis, selection and treatment of patients with skin conditions being considered for treatment with a laser.
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Until very recently, Laser Works had retained Dr. John Fisher as its medical director to provide physician oversight and be available to consult with the employees or to assist Laser Work's customers should any physical problems arise. Dr. Fisher unfortunately resigned late last December 2002 as medical director. His resignation was one of the primary concerns Ms. Crowley emphasized to me in a meeting we held on January 15, 2003 to discuss the DOH investigation.

Following Dr. Fisher's resignation, Laser Works had immediately sought the assistance of a new medical director, and on the same day as the meeting with Ms. Crowley, January 15, 2003, Dr. Elizabeth Bianchi agreed to act as Laser Work's new medical director effective immediately. Dr. Bianchi contacted Dr. George Heye of MQAC within a few days of her appointment as Laser Works' new medical director to discuss the Policy and his insights on the requirements for compliance. Dr. Bianchi is committed to working with the DOH and MQAC as closely as possible to satisfy any concerns raised in the investigation.

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We believe Dr. Bianchi's credentials and experience more than satisfy the various physician skill and oversight guidelines prescribed in the Policy. She has been board certified in family practice since 1998 and is generally qualified concerning the various skin condition

analyses and skills set forth in points 1) and 2) quoted above from the Policy. More specifically, Dr. Bianchi has served as the medical director for another cosmetic laser hair removal and skin rejuvenation center, Skin Nuvo of Spokane, since October 2002. This center offers most of the same services as those provided by the Laser Works employees. It also utilizes very similar laser or pulsed light equipment to that used by the Laser Works employees. In short, this prior experience and familiarity with procedures, equipment and typical customer skin concerns (including potential risks and effects) of a cosmetic laser hair removal and skin care center give Dr. Bianchi an ideal background to provide physician oversight for Laser Works.

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We believe Dr. Bianchi's cumulative experience, specialized training and credentials make her exceptionally qualified to provide the employees of Laser Works with physician oversight and to act as Laser Works' medical director. We are also confident that her location in Spokane will not impede her ability to handle any issues that may arise. As mentioned above, she will schedule regular visits to Laser Works' office, will be always accessible for consultation by telephone and, if special trips are ever necessary, has ready access by airline shuttles that leave for Seattle every one-and-one-half hours.

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In my letter to Ms. Crowley, I describe in detail the background of the employees in the various procedures they perform at Laser Works (*see* pages 2-3). Suffice here to say that each of them is well experienced, skilled and competent, as Dr. Bianchi agrees. We are confident that they compare favorably with other persons who provide the same services in this industry.

The consistent lack of harm or injury to Laser Works customers over the years is perhaps the best testament to the employees' high level of professional competence as a group. Now in its fourth year of operation, Laser Works has not once received a complaint evidencing any type of serious or permanent injury caused to a Laser Works customer by any of the employees during their tenures at the company. Laser Works' owners estimate that the company treats approximately three to five hundred customers each month; roughly four to five thousand yearly. Despite these numbers, customer complaints of any type are extraordinarily rare. As is explained to customers prior to treatment, some redness, puffing of the skin and other minor irritations sometimes follow treatment, conditions that are transient and strictly temporary. To the knowledge of Laser Works' management and employees, there has not been a single incident of serious or permanent burning, scarring or skin disfigurement caused by Laser Works' during its entire existence.

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dissatisfaction with treatment by the employees or Laser Works. In fact, not one of them contacted said they had complained in any fashion about Laser Works' treatments. To the contrary, these customers complimented Laser Works' services, indicated they would use its services again, and even volunteered to attest to this satisfaction in writing. We would very much like to know the nature of whatever contact or communication triggered the current DOH investigation, as the details of such communication have not been shared with us. If some customer of Laser Works has indeed been injured, Laser Works would certainly like to hear this and take whatever measures are necessary or that you would recommend to avoid this happening again. Until we learn otherwise, Laser Works remains unaware of a single incidence in which its employees have caused customer harm.

On a different topic, we would also like to address the question of whether the laser and pulse light systems used at Laser Works are equipment that can only be sold to persons with prescriptive authority such as medical doctors. Again, this subject is dealt with in the letter to Ms. Crowley in detail, but since the time that letter was written we have continued to look into this issue and would appreciate information and guidance from you.

The Policy indicates that the MQAC regards most lasers used for medical or medical like purposes as restricted for sale to medical personnel with prescriptive authority. Whether the particular machines used by Laser Works (identified in the letter to Ms. Crowley, p. 3) can only be purchased by such persons under FDA regulations, and whether the particular manufacturers of the systems do so restrict their sale, remain issues that may or may not have an impact on the DOH investigation of Laser Works, but which in any event we would like to better understand. None of the manufacturers of the four machines Laser Works uses informed Laser Works that the systems could only be purchased by a physician with prescriptive authority because of FDA, state or any other regulatory or other constraints. Two of them insisted that a doctor be on the leases as a matter of financial security. As a result, Laser Works purchased two of its systems with Dr. Fisher's name and assistance, and two of them without his name or any involvement by Dr. Fisher or by anyone with prescriptive authority.

Specifically, Lumines Medical Systems is one of the companies that have made its lasers available for purchase to the owners of Laser Works without any restriction or even inquiry about persons with prescriptive rights. No such restriction was mentioned in the documents that accompany the equipment. The Lumines lasers have been made available *via* personal payment and/or financing through conventional banks or other means with no involvement of a physician whatsoever. Nonetheless, when I met with Ms. Crowley, she asserted the view that the various manufacturers, including Lumines, can only sell their systems to persons with prescriptive authority.

The point is simply that Laser Works and its employees were never aware that its laser and intense pulse light systems might have been subject to such restrictions. Particularly if this is true and may have some impact on the employees, and also for purposes of Laser Works'

current and future dealings with industry laser or IPL manufacturers, we would very much appreciate information and direction from you on this matter.

Please contact me at your earliest convenience in response to this letter. On behalf of the employees, it is our continuing commitment to cooperate with all involved in this investigation and to initiate any changes the DOH believes are necessary. Dr. Bianchi also makes this a priority matter and is available to you at any time.

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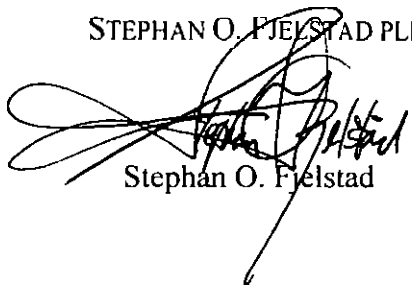

Stephan O. Fjelstad

SOF:sof
cc: clients

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

DATE: FEBRUARY 26, 2003
TIME: 3:33 PM
NUMBER OF PAGES WITH COVER: 7

FACSIMILE COVER SHEET

TO: Chyma Miller-Smith
Unlicensed Practice Program
DOH

FAX NO.: (360) 586-0123
TELE. NO: (360) 236-4659

FROM: Stephan O. Fjelstad

RE: DOH Investigation of Laser Works of Seattle—Letter

CLIENT REF.:
If any of these pages are not legible or you do not receive all the pages, please call (206) 903-0664.

COMMENTS:

Legal – 2/27/03
This letter came after Gayle Junaka left report + sent the file down from Kent.
I sent a copy of the letter to Medical Mayella) to review + respond to
Chyma

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STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

SOF:sof
cc: clients

Health Professions Quality Assurance Division
Investigation Service Unit

MEMORANDUM TO FILE

DATE: **February 27, 2003**

TO: **Maryella**

FROM: **Chyma** CNW
Unlicensed Practice Program

SUBJECT: **Laser Works of Seattle**

Attached is a letter from Stephan Fjelstad, Attorney for the Respondents in three of our unlicensed cases concerning performing laser hair removal by unlicensed persons and inappropriate or lack of supervision by a medical doctor.

Mr. Fjelstad is in receipt of the MCAQ policy dated 10/25/02 developed by Dr. Heye on "Use of Lasers in Skin Care and Treatment". He is looking for technical assistant in understanding the policy and classification of lasers and pulse light systems as equipment (medical) and the necessity to have prescriptive authority to purchase.

It appears Mr. Fjelstad is attempting to work at complying with MQAC policy but is asking for some assistance. For your information, Medical Investigation is currently looking at Dr. Bianchi and her involvement, (supervision) of the Spokane clinic, Skin Nuvo of Spokane, owned by the same group that owns Laser Works of Seattle.

Please have someone review and respond to Mr. Fjelstad letter.

Thanks.

Margaret -
This is just FYI
for the file to
document we (unit)
responded to the
(R)'s attorney for
technical assistance

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

February 27, 2003

Stephan O. Fjelstad
Attorney At Law
1424 Fourth Avenue Suite 090
Seattle, WA 98101-2217

RE: Laser Works of Seattle

Dear Mr. Fjelstad:

I am in receipt of your February 26, 2003, letter as follow up concerning our current unlicensed investigation into Laser Works of Seattle. Your letter has been added to the unlicensed investigation files of Gelnette, Winterstein, and Shoengarth, all employees of Laser Works of Seattle.

Due to your request for technical assistance concerning the Medical Quality Assurance Commission's (MQAC) policy on Laser Treatments, I am referring your February 26, 2003, letter to Maryella Jansen, Deputy Executive Director for MQAC for review and response. I am sure MQAC will be able to address the other issues you have raised concerning the classification of lasers and pulse light systems as equipment (medical) and the necessity to have prescriptive authority to purchase.

In the meantime, the investigation files against your clients have been sent to the Unlicensed Practice Program legal staff for review. The department policy allows the case disposition, which includes legal review up to 140 days to complete.

If you have any further questions related to Unlicensed Practice Program or checking the on status of your client's case, please feel free to contact me at the telephone number listed below.

Sincerely,

Chyma Miller-Smith

Chyma Miller-Smith
Unlicensed Practice Program
PO Box 47874
Olympia WA 98504-7874
360.236.4659

C: Maryella Jansen
Deputy Executive Director
Medical Quality Assurance Commission

Health Professions Quality Assurance Division
Investigation Service Unit

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FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

February 26, 2003

Chyma Miller-Smith
Health Care Investigator
Unlicensed Practice Program
Department of Health
PO Box 47874
Olympia, WA 98504-7874

Re: Investigation of Laser Works of Seattle Employees by Department of Health

Dear Ms. Miller-Smith:

As you know, I represent the three employees of the company Laser Works of Seattle, namely Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein (collectively, the "employees") regarding the Department of Health (DOH) investigation as to whether these individuals have practiced medicine. My understanding is that your program is now coordinating the investigation for DOH.

I previously wrote a letter dated January 15, 2003, to Gayle M. Crowley, the initial Health Care Investigator assigned to this case, explaining our preliminary position on the issue of whether we believe the employees have practiced medicine. I presume that letter is part of the file Ms. Crowley forwarded to your office and it gives a detailed background of the nature of Laser Works and the work its employees perform. (If for any reason my letter to Ms. Crowley has not reached you or is not part of the file, please let me know and I will supply another copy immediately.) Our position in the letter to Ms. Crowley is that we do not believe the employees have practiced medicine. Regardless of how that question may ultimately be resolved, however, I wish to emphasize on behalf of my clients that our singular aim is to ensure that they and Laser Works are in compliance with the provisions set forth in the recent Medical Quality Assurance Commission (MQAC) 10-25-02 policy statement entitled "Use of Lasers in Skin Care and Treatment" (the Policy). I write to you now to explain additional actions that have been taken to ensure compliance, to provide additional information not contained in my previous letter to Ms. Crowley and to seek your guidance in achieving satisfactory compliance if additional measures are needed.

As you know, the Policy allows the use of a laser for dermatologic purposes, such as hair removal, to be delegated with appropriate oversight by a physician. The Policy discusses the scope of "appropriate oversight" and lists three prerequisite skills the physician should possess:

1) The physician must be skilled in the diagnosis, selection and treatment of patients with skin conditions being considered for treatment with a laser.
2) The physician must know the indications for and against the various treatments available for the specific skin condition to be treated with a laser and be familiar with the risks, effects and side effects of the proposed laser treatment.
3) The physician must be certifiably trained in the theory and use of medical lasers and have sufficient practical hands on experience in the use of a laser to make the oversight of another laser user real and meaningful.

Until very recently, Laser Works had retained Dr. John Fisher as its medical director to provide physician oversight and be available to consult with the employees or to assist Laser Work's customers should any physical problems arise. Dr. Fisher unfortunately resigned late last December 2002 as medical director. His resignation was one of the primary concerns Ms. Crowley emphasized to me in a meeting we held on January 15, 2003 to discuss the DOH investigation.

Following Dr. Fisher's resignation, Laser Works had immediately sought the assistance of a new medical director, and on the same day as the meeting with Ms. Crowley, January 15, 2003, Dr. Elizabeth Bianchi agreed to act as Laser Work's new medical director effective immediately. Dr. Bianchi contacted Dr. George Heye of MQAC within a few days of her appointment as Laser Works' new medical director to discuss the Policy and his insights on the requirements for compliance. Dr. Bianchi is committed to working with the DOH and MQAC as closely as possible to satisfy any concerns raised in the investigation.

After her appointment as medical director, Dr. Bianchi quickly got up to speed on the procedures followed by the Laser Works employees and the equipment they use through telephone calls and spent extensive time visiting the office to meet personally with the employees and review procedures and treatments followed. She concluded based on her personal observations that the employees are well experienced and competent in performing the services and treatments offered at Laser Works. At this time, it is anticipated that Dr. Bianchi will make regular personal visits to Laser Works' office at least twice monthly and has been and will remain available by telephone (including cell phone) to the employees should any special need arise at any time.

We believe Dr. Bianchi's credentials and experience more than satisfy the various physician skill and oversight guidelines prescribed in the Policy. She has been board certified in family practice since 1998 and is generally qualified concerning the various skin condition

analyses and skills set forth in points 1) and 2) quoted above from the Policy. More specifically, Dr. Bianchi has served as the medical director for another cosmetic laser hair removal and skin rejuvenation center, Skin Nuvo of Spokane, since October 2002. This center offers most of the same services as those provided by the Laser Works employees. It also utilizes very similar laser or pulsed light equipment to that used by the Laser Works employees. In short, this prior experience and familiarity with procedures, equipment and typical customer skin concerns (including potential risks and effects) of a cosmetic laser hair removal and skin care center give Dr. Bianchi an ideal background to provide physician oversight for Laser Works.

Dr. Bianchi has also received and continues receive specialized training and certification in cosmetic medicine, laser hair removal and other skin rejuvenation treatments. Last year she successfully completed an advanced certification course in California for *FotoFacial* and multi-application of pulsed optical light and radio frequency technology. This course was provided by Stephan Mulholland, MD and Patrick Bitters, MD, who are widely known and published in as specialists in the area of cosmetic laser, intense pulsed light and pulsed light/radio frequency treatments (credit for the course applied toward the Physician's Recognition Award of the American Medical Association).[1] Dr. Bianchi's training related to cosmetic medicine includes her certification for intensive hands-on Botox injection training through the Perfect Skin Laser Center with Dr. Ivyl W. Wells in Boise, Idaho. She is also registered for an intensive two-day Aesthetics Workshop in approximately two weeks (March 2003) that includes advanced training in hair removal, the role of lasers in aesthetics, skin resurfacing, micro-dermabrasion, Botox, collagen injection and other procedures. (We would be happy to provide you copies of certification and coursework documentation of Dr. Bianchi's training, as well as her resume, should you request it.)

We believe Dr. Bianchi's cumulative experience, specialized training and credentials make her exceptionally qualified to provide the employees of Laser Works with physician oversight and to act as Laser Works' medical director. We are also confident that her location in Spokane will not impede her ability to handle any issues that may arise. As mentioned above, she will schedule regular visits to Laser Works' office, will be always accessible for consultation by telephone and, if special trips are ever necessary, has ready access by airline shuttles that leave for Seattle every one-and-one-half hours.

Laser Works has also always had available for consultation a registered nurse, Bonnie J. Schmidt. Ms. Schmidt has been a registered nurse since 1978 and is currently licensed in Washington, California, Oregon, Nevada, Arizona and New York. She currently acts as a medical laser consultant to various medical doctors and laser clinics throughout Washington, Oregon, California and Nevada.

[1] It bears mention that two of the four machines used by the Laser Works employees are intense pulsed light and pulsed light/radio frequency devices rather than lasers.

Ms. Schmidt's experience with laser technology is extensive. She was first certified as a laser technician in 1998. She assisted in pioneering the Alexanderite laser for ESC Medical Systems in 1998 and established starting parameters and protocols for ESC training manuals. She also assisted in pioneering the 1094 YAG laser and established starting parameters and protocols for Altus Medical laser training manuals. Ms. Schmidt is also certified in the use of intense pulse light systems manufactured by Syneron (the Aurora) and Lumines Medical Systems (the Quantum) for hair removal and Photo rejuvenation. She also obtained certification from Dr. Patrick Bitters (mentioned above regarding Dr. Bianchi's training); from Altus Medical for the 1064 YAG laser for treatment of veins and advance training in hair removal for dark skin types 3, 5 and 5; and from Biomedic for Obagi. She also has advanced training in micro-dermabrasion. Ms. Schmidt has personally performed over 4000 laser treatments with various lasers and intense pulse light systems for hair removal, photo facial, vein treatment, sun damage and age spot treatments.

Although she is not located in Washington, Ms. Schmidt has occasionally visited the Laser Works office in Seattle and has always been a resource available by telephone. Laser Works has now determined that she will increase the time she spends at Laser Works and be on site at the Laser Works office one day each week. She will also continue to be available at all times by telephone should any need arise.

In my letter to Ms. Crowley, I describe in detail the background of the employees in the various procedures they perform at Laser Works (*see* pages 2-3). Suffice here to say that each of them is well experienced, skilled and competent, as Dr. Bianchi agrees. We are confident that they compare favorably with other persons who provide the same services in this industry.

The consistent lack of harm or injury to Laser Works customers over the years is perhaps the best testament to the employees' high level of professional competence as a group. Now in its fourth year of operation, Laser Works has not once received a complaint evidencing any type of serious or permanent injury caused to a Laser Works customer by any of the employees during their tenures at the company. Laser Works' owners estimate that the company treats approximately three to five hundred customers each month; roughly four to five thousand yearly. Despite these numbers, customer complaints of any type are extraordinarily rare. As is explained to customers prior to treatment, some redness, puffing of the skin and other minor irritations sometimes follow treatment, conditions that are transient and strictly temporary. To the knowledge of Laser Works' management and employees, there has not been a single incident of serious or permanent burning, scarring or skin disfigurement caused by Laser Works' during its entire existence.

When Ms. Crowley of the DOH initially visited Laser Works, she collected charts on several of Laser Works' customers. We assumed these charts might have somehow been related to a communication or complaint to DOH that triggered the investigation. Laser Works contacted the persons whose charts Ms. Crowley had taken. Not one of them indicated

dissatisfaction with treatment by the employees or Laser Works. In fact, not one of them contacted said they had complained in any fashion about Laser Works' treatments. To the contrary, these customers complimented Laser Works' services, indicated they would use its services again, and even volunteered to attest to this satisfaction in writing. We would very much like to know the nature of whatever contact or communication triggered the current DOH investigation, as the details of such communication have not been shared with us. If some customer of Laser Works has indeed been injured, Laser Works would certainly like to hear this and take whatever measures are necessary or that you would recommend to avoid this happening again. Until we learn otherwise, Laser Works remains unaware of a single incidence in which its employees have caused customer harm.

On a different topic, we would also like to address the question of whether the laser and pulse light systems used at Laser Works are equipment that can only be sold to persons with prescriptive authority such as medical doctors. Again, this subject is dealt with in the letter to Ms. Crowley in detail, but since the time that letter was written we have continued to look into this issue and would appreciate information and guidance from you.

The Policy indicates that the MQAC regards most lasers used for medical or medical like purposes as restricted for sale to medical personnel with prescriptive authority. Whether the particular machines used by Laser Works (identified in the letter to Ms. Crowley, p. 3) can only be purchased by such persons under FDA regulations, and whether the particular manufacturers of the systems do so restrict their sale, remain issues that may or may not have an impact on the DOH investigation of Laser Works, but which in any event we would like to better understand. None of the manufacturers of the four machines Laser Works uses informed Laser Works that the systems could only be purchased by a physician with prescriptive authority because of FDA, state or any other regulatory or other constraints. Two of them insisted that a doctor be on the leases as a matter of financial security. As a result, Laser Works purchased two of its systems with Dr. Fisher's name and assistance, and two of them without his name or any involvement by Dr. Fisher or by anyone with prescriptive authority.

Specifically, Lumines Medical Systems is one of the companies that have made its lasers available for purchase to the owners of Laser Works without any restriction or even inquiry about persons with prescriptive rights. No such restriction was mentioned in the documents that accompany the equipment. The Lumines lasers have been made available *via* personal payment and/or financing through conventional banks or other means with no involvement of a physician whatsoever. Nonetheless, when I met with Ms. Crowley, she asserted the view that the various manufacturers, including Lumines, can only sell their systems to persons with prescriptive authority.

The point is simply that Laser Works and its employees were never aware that its laser and intense pulse light systems might have been subject to such restrictions. Particularly if this is true and may have some impact on the employees, and also for purposes of Laser Works'

current and future dealings with industry laser or IPL manufacturers, we would very much appreciate information and direction from you on this matter.

Please contact me at your earliest convenience in response to this letter. On behalf of the employees, it is our continuing commitment to cooperate with all involved in this investigation and to initiate any changes the DOH believes are necessary. Dr. Bianchi also makes this a priority matter and is available to you at any time.

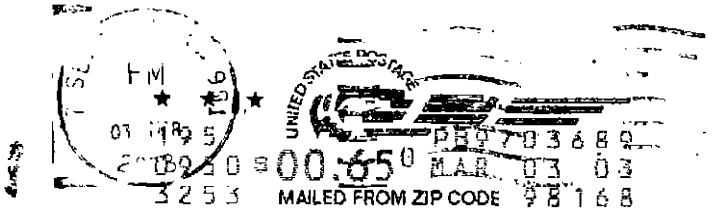
Very truly yours,

STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

SOF:sof
cc: clients

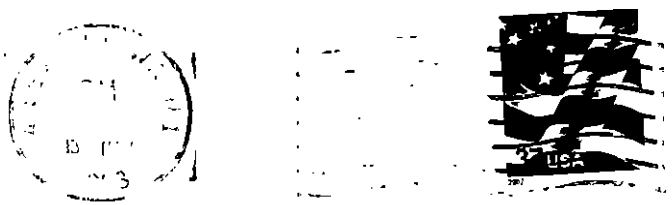
Stephan O. Fjelstad PLLC
1424 Fourth Ave., Suite 909
Seattle, WA 98101



Chyma Miller-Smith
Health Care Investigator
Unlicensed Practice Program
Department of Health
PO Box 47874
Olympia, WA 98504-7874

98504-7874

Stephan O. Fjelstad PLLC
1424 Fourth Ave., Suite 909
Seattle, WA 98101



Margaret Gilbert
Legal Unit
Health Professsion Quality Assurance
Department of Health
P.O. Box 47873
Olympia, WA 98504-7873

98504-7873 01

Landreau, Teresa

From: Landreau, Teresa
Sent: Tuesday, April 26, 2005 8:36 AM
To: 'fjelstad@winstarmail.com'
Subject: Laser Works staff Gelnette, Shoengarth, Winterstein

April 26, 2005
Stephan O. Fjelstad PLLC
Attorney at Law
Dear Mr. Fjelstad,
I'm writing to you from the Department of Health, Health Professional Quality Assurance division, because our mail sent to your Fourth Avenue, Seattle address regarding the subject line above was returned to us marked "forwarding order expired". Please advise as to your current mailing address, and/or if you have questions, please give me a call. I'll be away from my desk part of this morning, so if you call and miss me please leave a suggested time for my return call.
Thank you.
Sincerely,

Teresa Landreau
Staff Attorney, Dept of Health
Mail stop 47873
Olympia, WA 98504-7873
(360) 236-4845
Public Health – Always Working for a Safer and Healthier Washington

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In the Matter of the Unlicensed Practice of Medicine by:	)	Docket No. 04-07-B-1063UR
MARILYN GELNETTE	)	DECLARATION OF SERVICE BY MAIL
Respondent.	)	

I declare under penalty of perjury, under the laws of the state of Washington, that the following is true and correct:

On August 23, 2005, I served a true and correct copy of the Findings of Fact, Conclusions of Law and Final Order on Default (Failure to Respond), signed by the Health Law Judge on August 22, 2005, by placing same in the U.S. mail by 5:00 p.m., postage prepaid, on the following parties to this case:

Marilyn Gelnette
1001 4th Ave Ste 3200
Seattle WA 98154-1003

Richard McCartan, AAG
Office of the Attorney General
PO Box 40109
Olympia, WA 98504-0109

DATED: This 23rd day of August, 2005.

Darlena Wallace

Darlena Wallace, Adjudicative Service Unit
Hearing Scheduler

cc: Chyma Miller Smith, Program Manager
Teresa Landreau, Legal Unit

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47879 • Olympia, Washington 98504-7879

August 23, 2005

Marilyn Gelnette
1001 4th Ave Ste 3200
Seatle WA 98154-1003

RE: Docket No. 04-07-B-1063UR

Dear Ms. Gelnette:

Enclosed please find Declaration of Service by Mail and Findings of Fact, Conclusions of Law, and Final Order on Default (Failure to Respond) dated August 22, 2005.

Any questions regarding the terms and conditions of the Order should be directed to Chyma Miller Smith, Program Manager at (360) 236- 4659.

Sincerely,

Darlena Wallace
Hearing Scheduler
Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

cc: Richard McCartan, AAG
Chyma Miller Smith, Program Manager
Teresa Landreau, Legal Unit

Enclosure

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine by:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE	)	FINDINGS OF FACT, CONCLUSIONS OF LAW, AND FINAL ORDER OF DEFAULT (Failure to Respond)
Respondent.	)	

This matter comes before the Senior Health Law Judge, Presiding Officer, for final Order of Default. Based on the record, the Presiding Officer, on designation by the Secretary of Health now issues the following:

Section 1: FINDINGS OF FACT

1.1 On April 20, 2005, the Program issued a Notice of Intent to Issue a Cease and Desist Order (Notice of Intent) alleging unlicensed practice of medicine by Respondent. A Notice of Opportunity for Settlement Hearing, and Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing were also issued at that time. These documents were served by U.S. Mail at Respondent's last known addresses on June April 20, 2005.

1.2 On June 3, 2005, the Adjudicative Service Unit served upon Respondent a Notice of Failure to Respond.

1.3 To date, the Adjudicative Service Unit has not received an Answer to the Notice of Intent to Issue Cease and Desist Order.

1.4 The Secretary has no reason to believe Respondent is in active military service or is a dependent of a member of the military in active military service.

ORIGINAL

1.5 The Department of Health has filed the Declaration of Unlicensed Program Manager, David Magby, with attached exhibits.

1.6 Marilyn Gelnette, Respondent, has never held a credential to practice as a health care professional in the state of Washington.

1.7 During the timeframe including the period between November 5, 2002 through January 9, 2003, Respondent worked at a hair removal and skin rejuvenation clinic known as Laser Works of Seattle (Laser Works), located in Tukwila, WA, where the activities described herein occurred.

1.8 Respondent offered laser treatment to human patients as a cure for and to ameliorate excessive hair, wrinkles and unsightly veins.

1.9 Respondent advised prospective patients that the laser energy she applied was "medical treatment" with anticipated "clinical results" and potentially harmful side effects.

1.10 Respondent applied penetrating laser energy to human patients for hair removal, wrinkle reduction, and improvement in the appearance of leg veins. Such applications caused color changes, blisters and welts in the patients' tissue.

1.11 Respondent provided antibiotic ointment to one or more patients who suffered tissue damage from the laser applications and advised patients as to methods of treatment for such damage.

Section 2: CONCLUSIONS OF LAW

2.1 The Secretary of Health has jurisdiction over Respondent and over the subject matter of this proceeding.

2.2 Respondent is subject to the provisions of RCW chapters 18.71.011 and 18.71.021.

2.3 Respondent did not file a response to the Notice of Intent to Issue Cease and Desist Order within the time allowed by WAC 246-10-203. Pursuant to RCW 18.130.090(1) and RCW 34.05.440, Respondent is in default and the Secretary may issue a dispositive order based on the evidence presented to it.

2.4 Based upon the Findings of Fact in Section 1, Respondent engaged in the unlicensed practice of medicine in violation of RCW 18.71.011(1), (2), (3) and RCW 18.71.021.

2.5 The Secretary determines that sufficient grounds exist to issue a Cease and Desist Order to Respondent, pursuant to RCW 18.130.190.

Section 3: ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Secretary of Health hereby makes the following FINAL ORDER.

3.1 Respondent shall permanently **CEASE AND DESIST** from engaging in any and all conduct constituting practice of medicine unless she has obtained appropriate licensure or otherwise meets an exemption

3.2 Respondent shall pay a civil fine in the amount of one thousand dollars ($1,000.00). The fine shall be paid by certified or cashier's check or money order within sixty (60) days of the filing of this order, payable to the Department of Health, Unlicensed Practice Program, P.O. Box 1099, Olympia WA 98507-1099.

3.3 The effective date of this Final Order is the date the original bearing the judge's signature is filed with the Adjudicative Service Unit. The Respondent shall not submit any fees or compliance documents until after the effective date of this Final Order.

Section 4: NOTICE TO PARTIES

As provided in RCW 34.05.461(3), RCW 34.05.470, and WAC 246-11-580, either party may file a petition for reconsideration. The petition must be filed with the Department of Health, Adjudicative Service Unit, P.O. Box 47879, Olympia, WA 98504-7879, within ten (10) days of service of this Final Order. The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration shall not stay the effectiveness of this Final Order. The petition for reconsideration is deemed to have been denied twenty (20) days after the petition is filed if the Secretary of Health has not acted on the petition or served written notice of the date by which action will be taken on the petition.

"Filing" means actual receipt of the document by the Adjudicative Service Unit, RCW 34.05.010(6) and WAC 246-10-102. This Final Order was "served" upon you on the day it was deposited in the United States mail, RCW 34.05.010(18).

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Proceedings for judicial review may be instituted by filing a petition in the superior court in accord with the procedures specified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. The petition for judicial review must be filed within thirty (30) days after service of this Final Order, as provided by RCW 34.05.542.

DATED August 22nd, 2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

JOHN F. KUNTZ, HEALTH LAW JUDGE
PRESIDING OFFICER

Presented by:

TERESA LANDREAU, WSBA# 9591
Department of Health Staff Attorney

August 5, 2005
Date

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine by:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE	)	DECLARATION OF PROGRAM MANAGER FOR FAILURE TO RESPOND
Respondent.	)	

The Program Manager of the Unlicensed Practice Program (Program) declares as follows:

1. I am the Manager of the Unlicensed Practice Program (Program).

2. I am familiar with the program file regarding Marilyn Gelnette (Respondent).

3. On April 20, 2005, the Program issued a Notice of Intent to Issue Cease and Desist Order alleging unlicensed practice of medicine by Respondent. A Notice of Opportunity for Settlement Hearing, and Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing were also issued at that time. On April 20, 2005, these documents were served to Respondent's last known address of: 411 Strander Blvd, Suite 108, Tukwila, WA 98188 and to Respondent's counsel at 1424 Fourth Ave, Suite 909, Seattle, WA 98101-2217. On April 27, 2005, these documents were re-served to a corrected address for Respondent's counsel at: 1001 4th Ave., Suite 3200, Seattle, WA 98154-1003.

4. There is no information in the file to suggest that Respondent is in active military service or is a dependent of a member of the military in active military service.

//

5. Respondent has not filed a response to the Notice of Intent to Issue a Cease and Desist Order.

6. The attached documents are true and accurate copies of the following documents contained in the program file 2002-09-0004UI.

6.1 Email complaint, dated September 4, 2002, page 1. **(Exhibit 1)**

6.2 Internal DOH Memorandum to file of the telephone interview with Dr. Fisher, page 31. **(Exhibit 2)**

6.3 Internal DOH Memorandum to file of the interview with Mr. Moore, pages 32-33. **(Exhibit 3)**

6.4 A digital picture taken at Laser Works, Inc., page 34. **(Exhibit 4)**

6.5 A digital picture taken at Laser Works, Inc., page 37. **(Exhibit 5)**

6.6 A digital picture taken at Laser Works, Inc., page 38. **(Exhibit 6)**

6.7 A digital picture taken at Laser Works, Inc. page 39. **(Exhibit 7)**

6.8 A digital picture taken at Laser Works, Inc. page 41. **(Exhibit 8)**

6.9 A copy of a form entitled "Reminders and Referrals" from Laser Works, Inc., page 44. **(Exhibit 9)**

6.10 A copy of Laser Works, Inc., "Informed Consent" form, page 45. **(Exhibit 10)**

6.11 A copy of Laser Works, Inc., "Patient Medical History" form, page 46. **(Exhibit 11)**

6.12 A copy of a form from Laser Works, Inc., page 50. **(Exhibit 12)**

6.13 A copy of "Post Treatment-Vascular" instructions from Laser Works, Inc., page 51. **(Exhibit 13)**

6.14 A copy of Laser Works, Inc., "Informed Consent-Microdermabrasion" form, page 55. **(Exhibit 14)**

6.15 A copy of Laser Works, Inc., "Informed Consent-Skin Rejuventation" form, page 56. **(Exhibit 15)**

6.16 A copy of a patient's treatment records from Laser Works, Inc., pages 64-69. **(Exhibit 16)**

6.17 Patient records. **(Exhibit 17)**

6.18 Pages 6-10 of the DOH Investigative Report. **(Exhibit 18)**

6.19 Declaration and Curriculum Vitae of Brandith G. Irwin, MD, dated July 26, 2005. **(Exhibit 19)**

I declare under penalty of perjury of the laws of the state of Washington that the foregoing is true and correct.

DATED this 10 day of August, 2005.

DAVID MAGBY
Unlicensed Practice Program Manager

EXHIBIT 1

Miller-Smith, Chyma

From: 4 - Identity - Whistleblower Regarding Health Care Provider - RC...
Sent: Wednesday, September 04, 2002 11:59 AM
To: Miller-Smith, Chyma
Subject: hair removal treatment

hello chyma,

my name is 4 - Identity - Whistleblower... and I am writing in regards to a hair removal treatment that I received @laser works on Aug 28th. I was told by Marilyn Gelnette that if I did treatment on my check area she could garentee 100% that I would not get any redness or burns after the treatment and I would be able to go to work and be fine. so i let her perform the treatment only on my left cheek because the laser broke before she could finish the other side. And after the treatment my cheek was red and i received blisters, only today is my cheeks starting to get back to there normal color(9/4/02). I was wondering what could be done to stop this from happening to me or another person. No one should go through this treatment. Fell free to give me a call if you have any questions(4 - Identity - Whistleblo... .thank you for your time in this delectate matter.

4 - Identity - Whistleblower Regarding ...

EXHIBIT 2

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Dr. John Fisher

On December 17, 2002, an interview was conducted with Dr. John Fisher. He is identified as the Medical Director of Laser Works. Dr. Fisher says he has not been in contact with Eric Moore and has no idea why I would be contacting him.

Dr. Fisher says he became their medical director to help them with financing of the laser, etc. He says he really hasn't had much contact with the business, but receives a monthly check for $500 from them to use him as the medical director.

Dr. Fisher states in the 3 years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least 6 months and has not worked with or know any of the employees working at the business.

Dr. Fisher says he is employed full time as the Public Medical Doctor. He works for King County in the jail systems at different locations. Dr. Fisher says it is his understanding Eric Moore and Jeff Schmidt have nurses providing treatment at their office. He was very surprised to hear no medical personnel are working at the office.

Dr. Fisher then explained he a short time ago (month or so) he ordered 4% Lidocaine prescription for the office and it was mailed. He expressed his concern that these complaints were going to affect him and his license to practice.

Dr. Fisher also explained he just finished probation for a complaint with MQAC and the FDA for selling Viagra over the Internet for $19.99. He doesn't want more problems and said he would cooperate fully in our investigation. Dr. Fisher said he would be preparing a resignation letter to Eric Moore and Laser Works of Seattle. He will fax me a copy. (The resignation letter was received later this same date)

December 20, 2002: On this date, I met with Dr. Fisher. He signed a Witness Notification form and said he will prepare and provide a statement for this investigation. Dr. Fisher was shown the forms obtained from and being used by Laser Works. He became emotional and said he was concerned with the wording used in the forms. He states he never has seen these forms or was involved in the preparation of the forms. He says he had very little to do with the business, but did receive a check monthly.

EXHIBIT 2

EXHIBIT 9

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Eric Moore

On December 17, 2002, an interview was conducted with Eric Moore, owner of Laser Works. Also present at this interview was Jim Voiland, HC Investigator. Mr. Moore states his employees are not performing medical treatment to patients/clients/customers.

Mr. Moore says they did not hire Dr. Fisher to be the Medical Director out of necessity. They hired Dr. Fisher and had him order the lasers as they (he and Jeff (co-owners) could obtain easier better financing on the lasers. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business. They have not written agreement between Dr. Fisher, Jeff Schmidt, and himself. He says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse.

Mr. Moore identified one of the respondent's as a cosmotologist (Marilyn Gelnette). He says she started working here June 2002. He explained he is in the process of merging and forming a new company. He identified three employees that perform the laser treatments, etc. They are Sherry Winterstein, Shaney Shoengarth, and Marilyn Gelnette. He says he does not perform the treatments.

Mr. Moore says he or Marilyn Gelnette usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs. He says anyone being seen sign a disclosure form as part of the intake process. He used to have an esthetician names Sandra Lee Murillo, but he let her go in July or August 2002 as she wasn't doing her job.

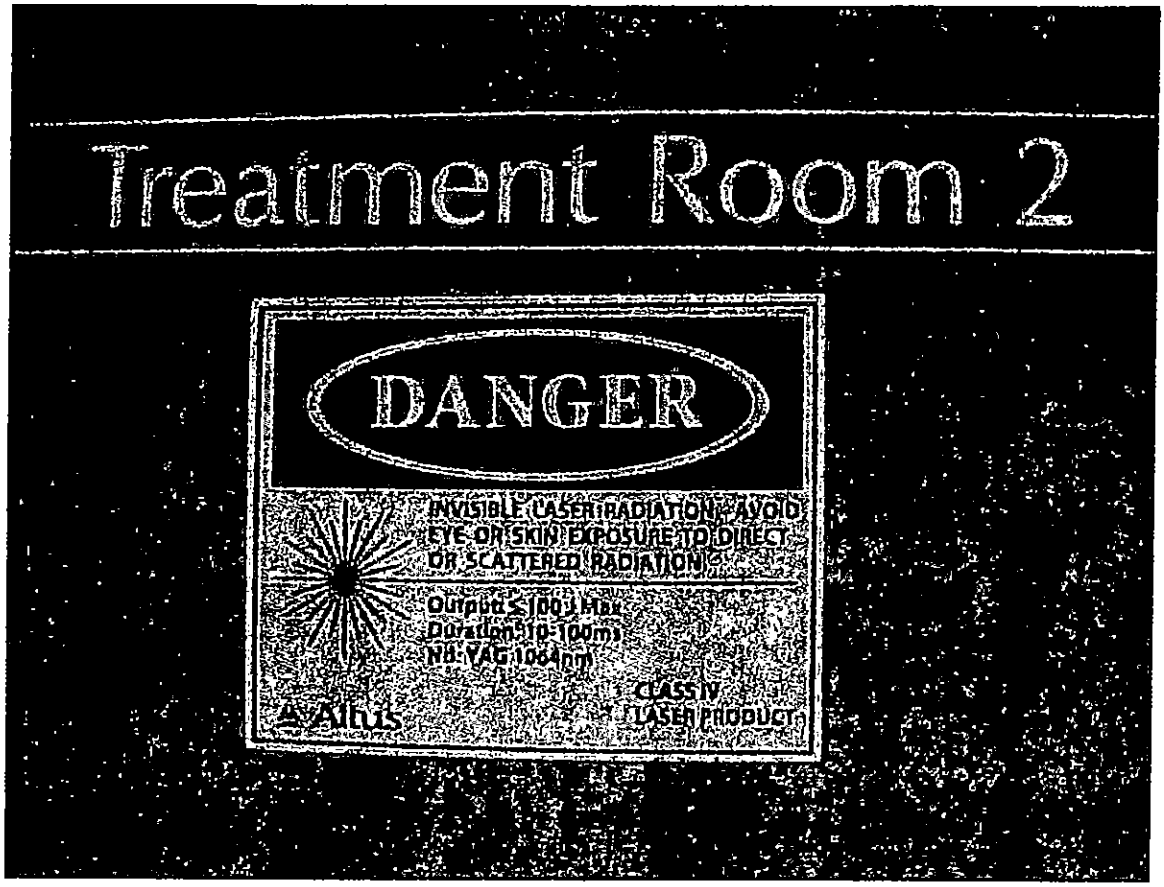
Mr. Moore says as far as Lidocaine being used by the employees, it is only given to someone in pain who requests it. He says it is not a big deal. He can't remember the last time they received any, but says it is very rarely used. He will provide the information. Mr. Moore described how they order it. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail. When we requested to see where the Lidocaine is kept, Mr. Moore was unable to show any of it to us. He couldn't find it.

The four lasers used here are identified as YAG; QUANTUM IPL; ALEXANDRITE; and SYNERON IPL. All four were viewed and pictures were taken of the treatment rooms, etc. Also, copies of the forms given to patients/clients/customers were obtained at this visit. Mr. Moore states that even though Botox treatments are listed on forms, this office does not perform these treatments. He says they do have a microdermabrasion machine, but do very few treatments.

A review was made of the appointment book and records were obtained. Files were obtained or alleged burned individuals and copied.

Mr. Moore says he will be providing evidence and statements that the three employees are not providing medical treatment or performing any unlicensed practice.

MVC-0015



MVC-0025

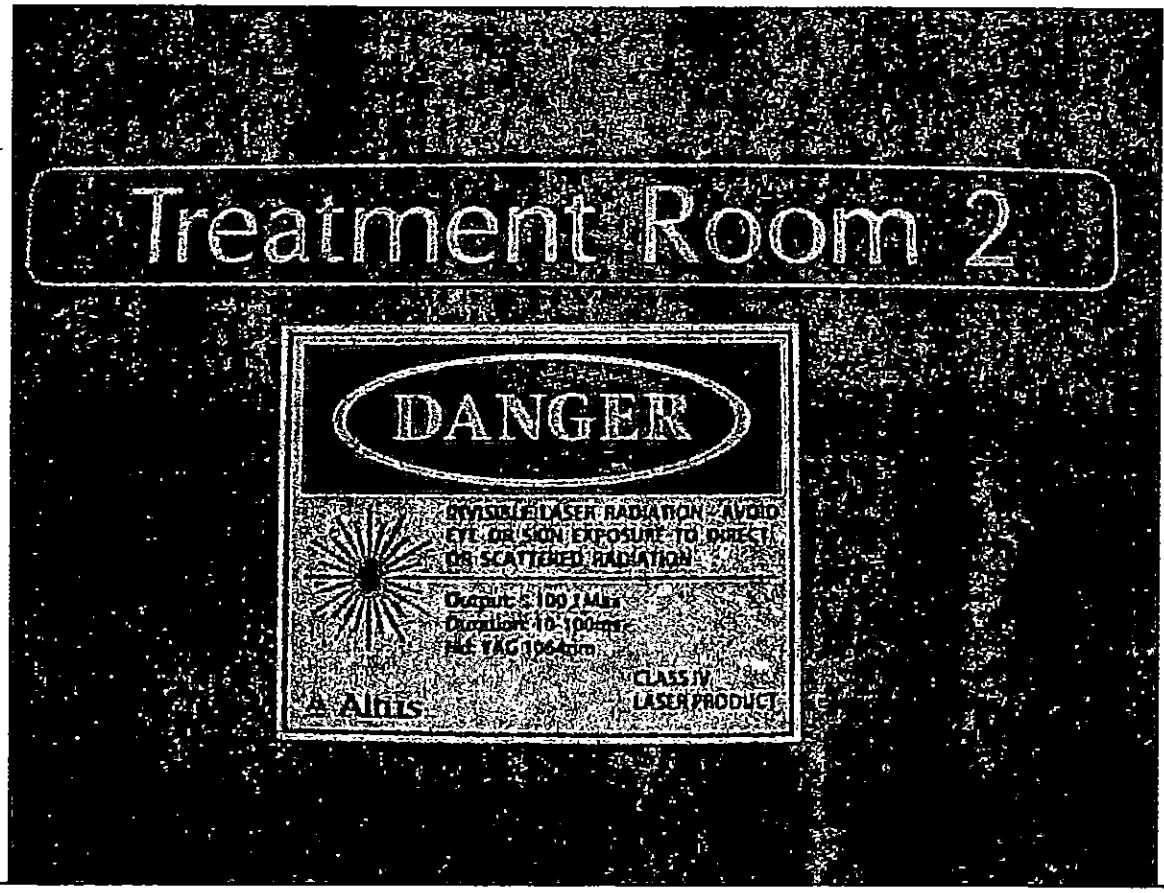
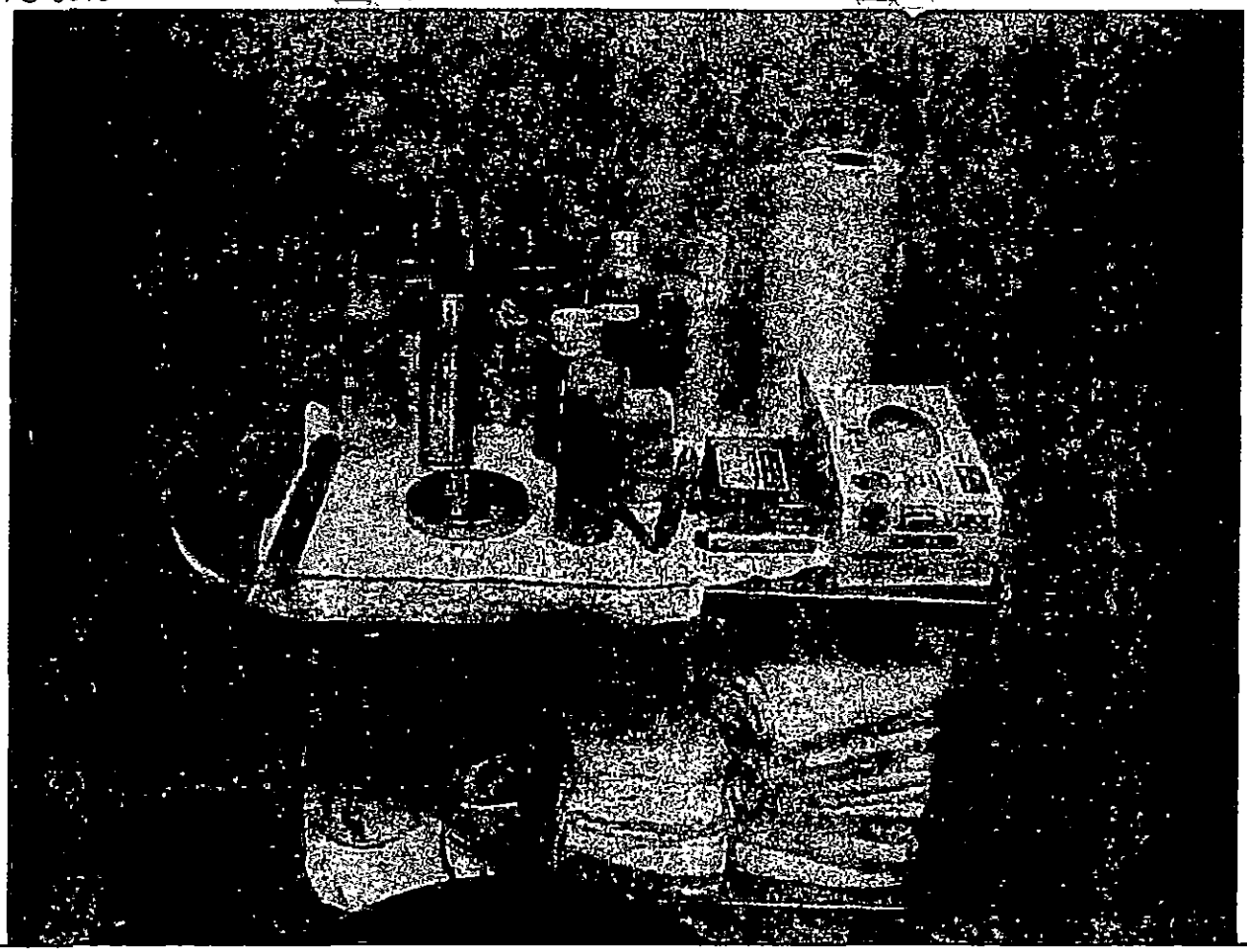


EXHIBIT 4

EXHIBIT 4

MVC-0075



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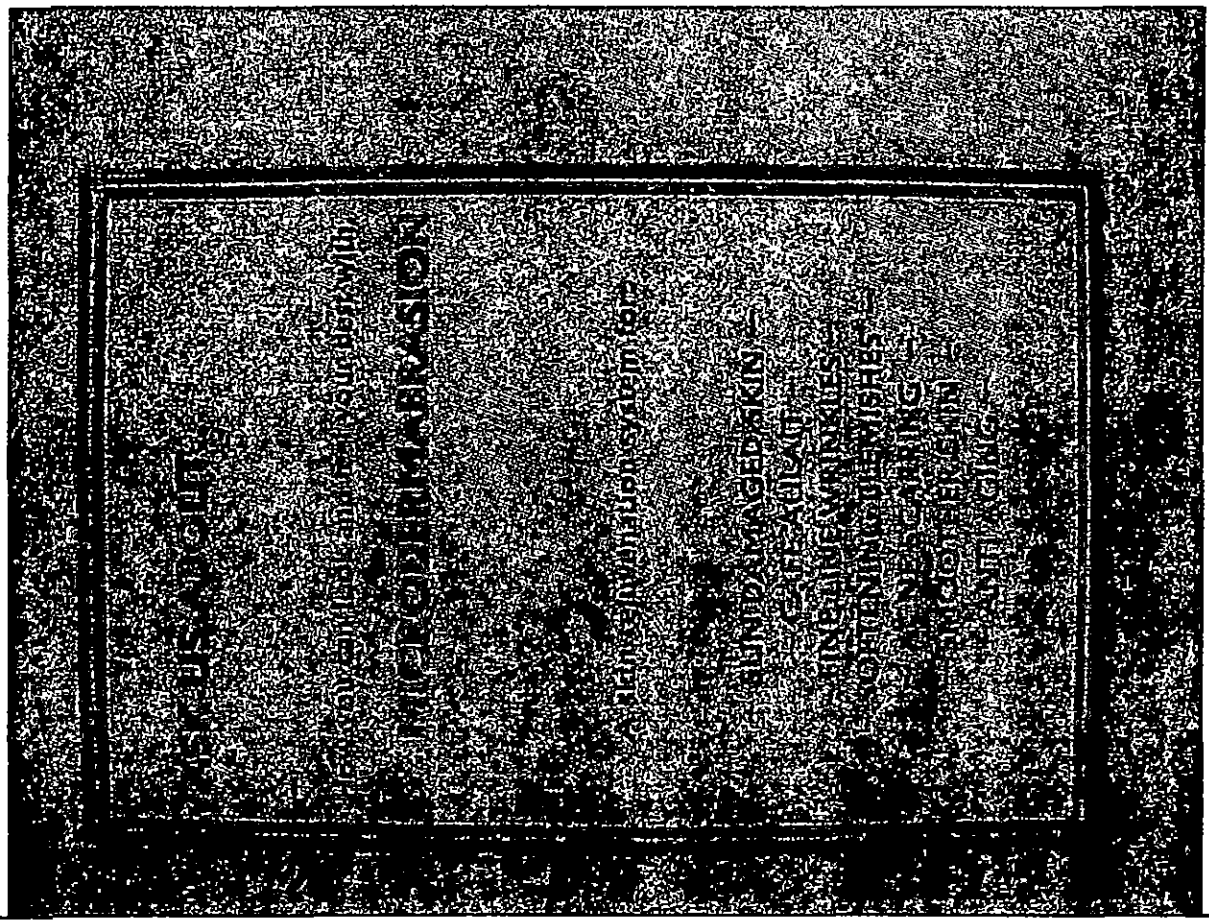
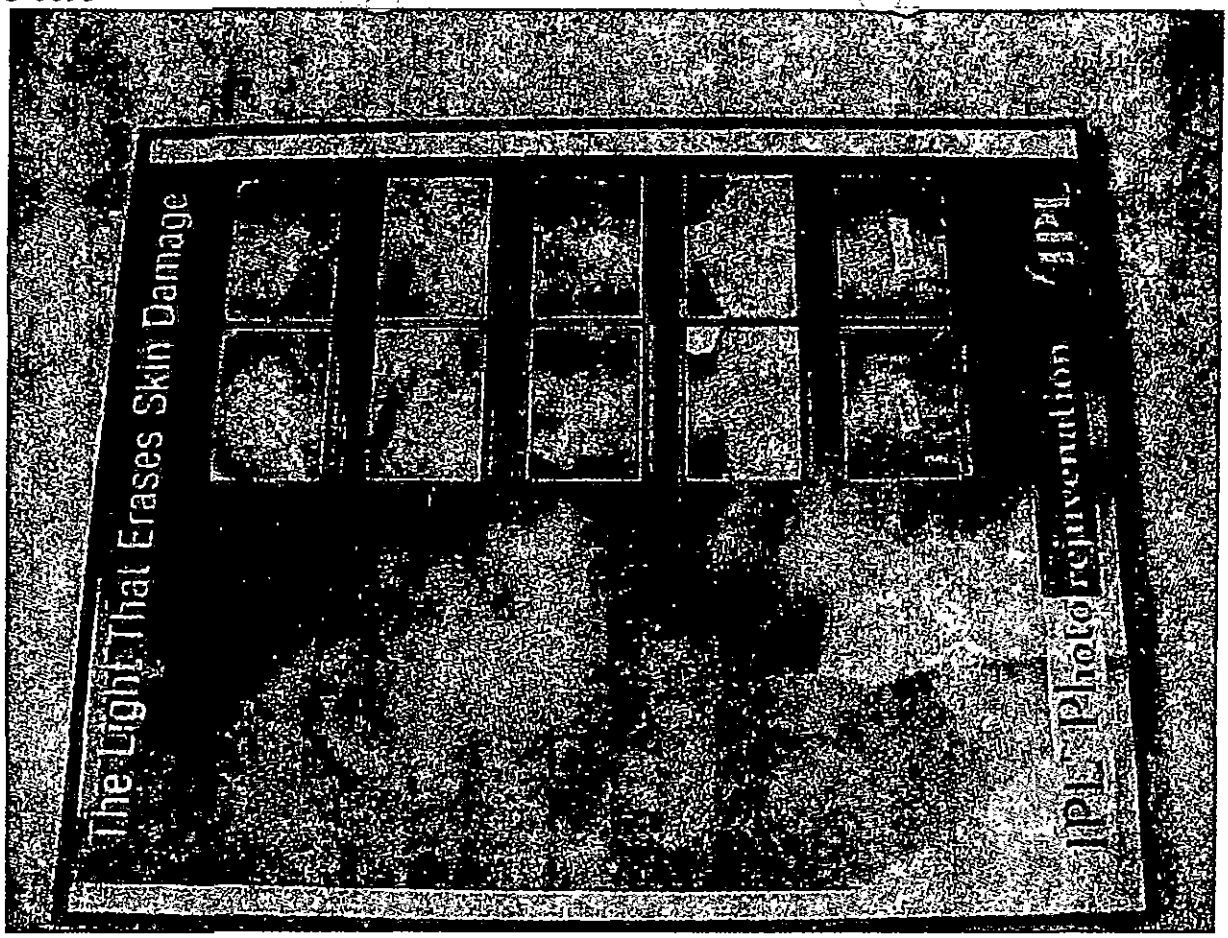


EXHIBIT 5

EXHIBIT 5

MVC-0095



MVC-0105

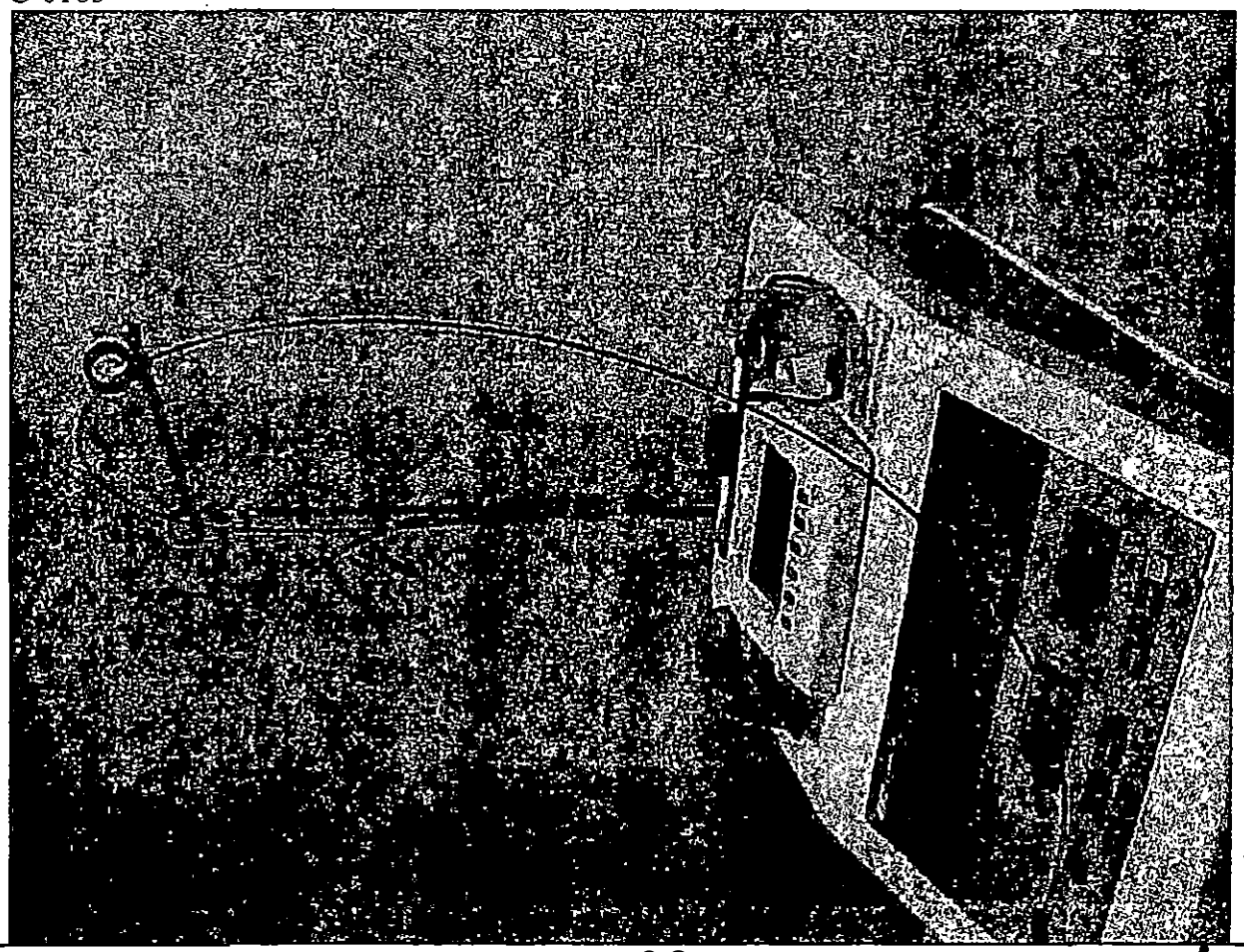
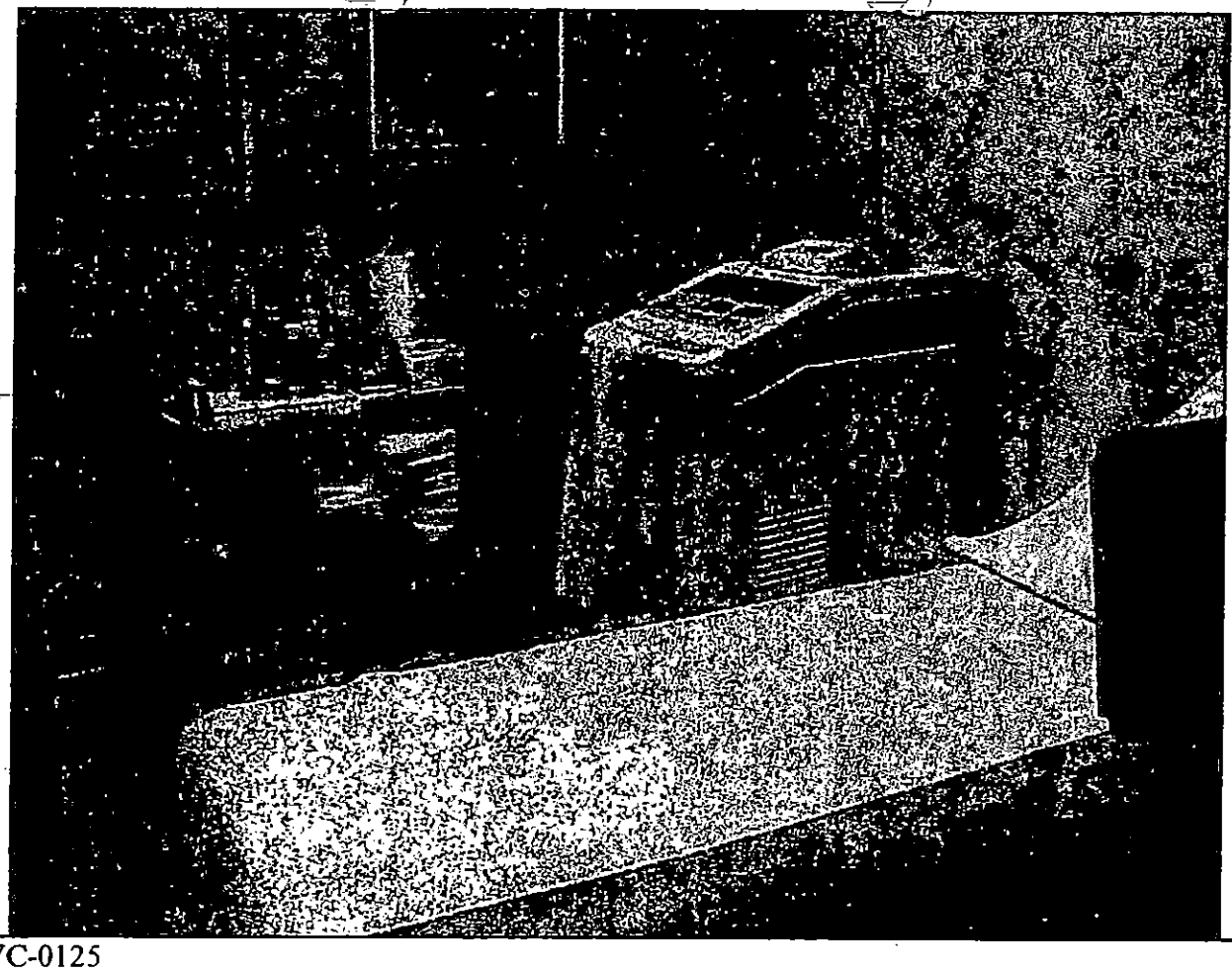


EXHIBIT 6

MVC-0115



MVC-0125

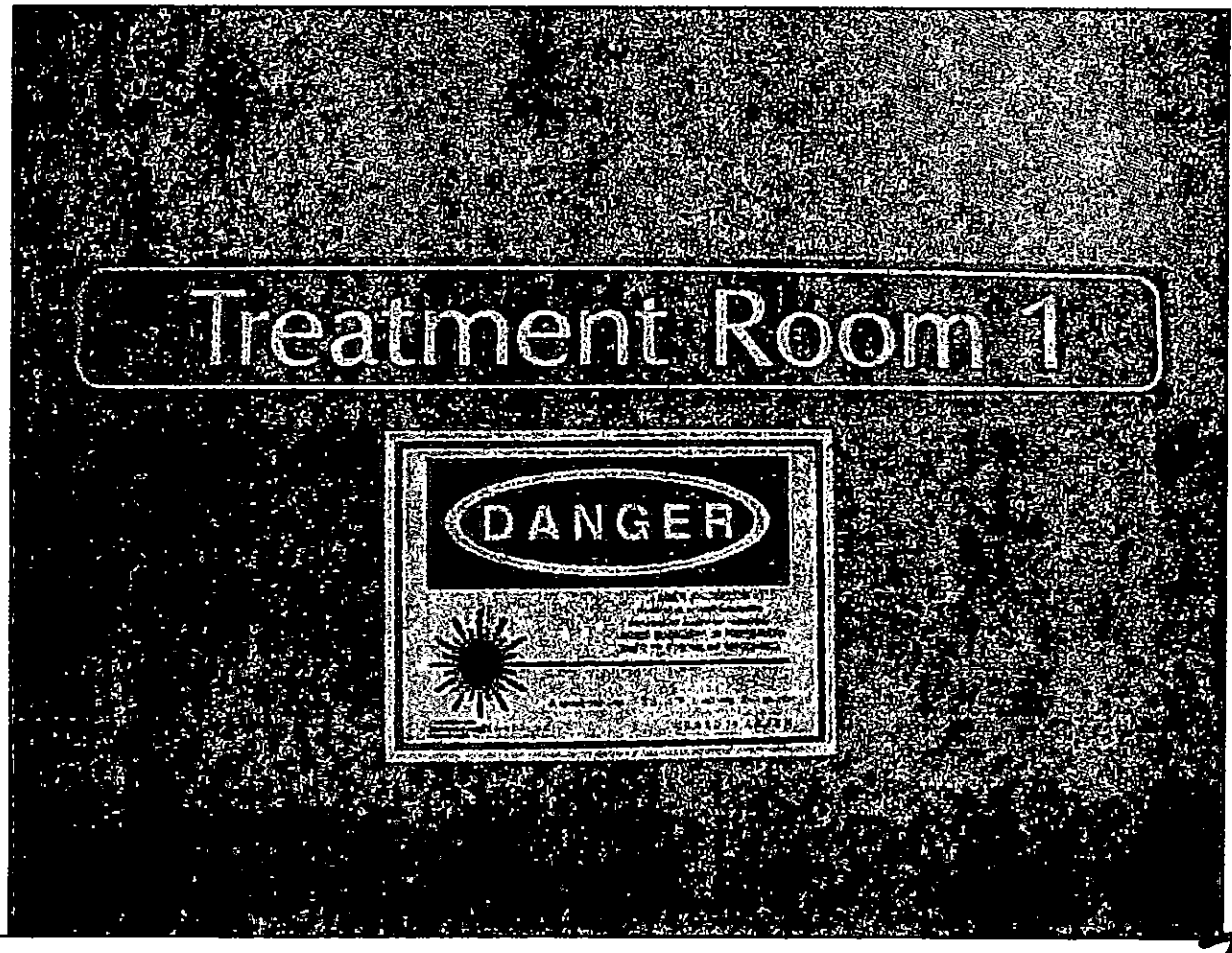
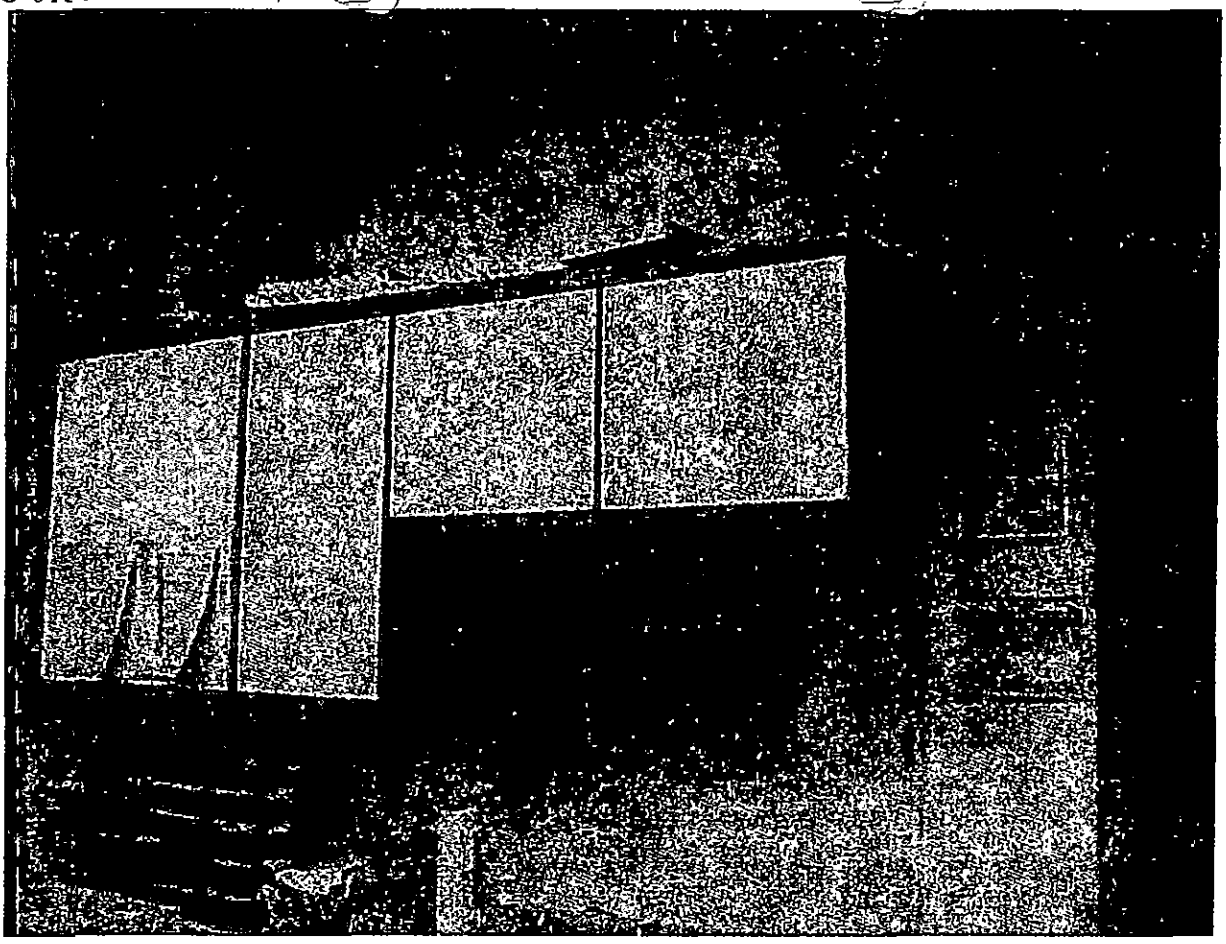


EXHIBIT 7

EXHIBIT 7

MVC-0155



MVC-0165

EXHIBIT 8

Laser~Works

Reminders And Referrals

* For hair removal treatments remember your hair may not shed for 14-28 days following your treatment.
* For skin enhancement treatments, although you'll see some immediate changes and improvements, collagen stimulation gradually increases 14-28 days after your treatment. Skin texture and clarity will gradually improve 10-30 days following your treatment. Following a botox treatment you should see improvements within 72 hours, with gradual improvements for up to 30 days.
*Following a treatment, avoid exposure to the sun for about a week. If you need to be in the sun, you should apply sun block (SPF 30) in the areas you have treated.
* Temporary side effects such as blister are rare, however should a blister occur, apply an antibiotic ointment and notify our office at 206.575.8300 or 888.395.9990

* Your follow up treatment should be in the next 4-8 weeks depending on the type of treatment or area treated. We'll be calling you to confirm your appointment 24-48 hrs. in advance.

*If you have any further questions or concerns, please do not hesitate to call us. Thank you

The Staff at Laser~Works of Seattle

Remember: Refer family and friends for their free treatment

Name of referral: _____ Referred by: _____

EXHIBIT 9

EXHIBIT 9

LASER~WORKS OF SEATTLE

INFORMED CONSENT FORM

I understand that I will receive medical treatment from Laser~Works of Seattle. I also understand that clinical results may vary with different skin types, hair color and the location on the body for the treatments by Laser~Works of Seattle. The various treatments Laser~Works of Seattle provides include: laser hair removal and intense pulse light (epilation); intense pulse light and laser skin rejuvenation; Botox tm injections; micro dermabrasion; and treatment of vascular lesions and of visual veins with the use of intense pulse light and lasers. I further understand that there is a possibility of unusual side effects from any of these treatments such as scarring and permanent discoloration. There can also be short-term effects of any of these treatments such as reddening, mild burning, temporary discoloration of the skin. These possible effects have been fully explained to me: _____ (please initial).

I have made Laser~Works of Seattle aware of my use of tanning beds, sunless tanning products and any unprotected exposure to the sun in the last 14 days: _____ (please initial).

I will not hold Laser~Works of Seattle, its owners or its employees responsible for the hair reduction or skin treatment results I experience. I realize that my skin and hair is an organ unique to me and that therefore results may vary: But Laser~Works of Seattle has made me aware of their Guarantees _____ (please initial)

I understand that there are other options for hair removal and or skin rejuvenation such as electrolysis, waxing and chemical preparations rather than laser treatment. With this in mind, I choose laser treatment with Laser~Works of Seattle as a non-invasive treatment for epilation and or skin rejuvenation: _____ (please initial).

I understand that my treatments by Laser~Works of Seattle require payment and the prices and fee structure for treatment have been explained to me. **There are no refunds on treatments, or on treatments paid in advance:** _____ (please initial).

I further understand that Laser~Works of Seattle's quoted price for treatment is the price for each individual treatment or session, unless otherwise specified in writing by Laser~Works of Seattle. I understand that the services Laser~Works of Seattle provides sometimes require more than one treatment session, depending on the individual, and that the price quoted to me for treatment is the price for each individual treatment session, unless, again, otherwise specified in writing: _____ (please initial).

I am aware that Laser~Works of Seattle requires 24 hours notice of a cancellation or of a need to reschedule and that it is my responsibility to provide that notice. I agree to pay a minimum of $75.00, or half the scheduled treatment cost, if I fail to give the required 24 hours notice. If I choose to prepay my treatment session or sessions, I understand that I may forfeit one of my future sessions if I do not provide Laser~Works of Seattle proper notice (24 hours).

I have read and fully understand all the terms of this informed consent form, all my questions have been answered to my satisfaction and I agree to terms of this agreement:

Print patient name: _____

Signature: _____ Date: _____

Witness: _____ Date: _____

EXHIBIT 10

Laser~Works!

Patient Medical History

Name: _____ D.O.B. _____

Address: _____ City: _____ Zip:_____

Home Phone: _____ Business Phone: _____

Referred By: _____

Ethnic Origin: _____(For skin reaction to Laser)

Have you ever been diagnosed with the following?

Heart condition: _____ Bleeding Disorder: _____ Fainting Spells: _____
Diabetes: _____ Type? _____ Insulin Controlled? _____
Herpes: _____ Keloid Scars: _____ _____

Are you pregnant? _____
What medications are you taking? (including aspirin) _____
Are you taking any herbal preparations? (St Johns Wort) _____
How often do you use alcohol? _____ x-day _____ x-week ___ x-month
Allergies: _____

Skin type (when exposed to the sun **without protection** for about 1 hour)

1. Always burns, never tans _____
2. Usually burns, sometimes tans _____
3. Sometimes burns, sometimes tans _____
4. Always tans _____

When were you last exposed to the sun? (including tanning booth) _____
Do you use chemical tanning products? _____
Are you planning a holiday in the sun? _____

Reason for visit (areas to be treated) _____

Prior Treatment (if any)
Waxing _____ Body Part(s): _____
Electrolysis _____ Body Part(s): _____
Depilatory _____ Body Part(s): _____
Laser _____ Body Part(s): _____

EXHIBIT 11

EXHIBIT 11

Patient Medical History
Vascular Treatment

Name:_____D.O.B._____

Address:_____City:_____ State___Zip:_____

Home Phone:_____Business Phone:_____

Referred By:_____

Ethnic Origin:_____ (For skin reaction to Laser)

Have you ever had the following?

Heart Condition:_____
Diabetes:_____ Type:_____Insulation Controlled:_____
_____
Bleeding Disorder:_____ Fainting Spells:_____
Keloid Scarring:_____ Herpes_____
Are you pregnant?_____ Hz skin cancer:_____
What medications are you taking (including aspirin)_____
_____
_____

Are you on any blood thinners?_____
Are you taking any herbal preparations? (St. John's Wort)_____
If yes, List:_____
_____

How often do you use alcohol?_____x-day_____x-week_____x-month
Allergies:_____

Skin type (when exposed to the sun without protection for about 1 hour)

1. Always burn, never tans_____
2. Always burns, sometimes tans_____
3. Sometimes burns, sometimes tans_____
4. Always tans_____

When were you last exposed to the sun (including tanning booths)?_____
Do you use chemical tanning lotions?_____
Are you planning a holiday in the sun?_____

Reason for visit (area to be treated)_____

Prior treatment (if any) Stripping_____ Body Part (s)_____
Ligation_____ Body Part (s)_____
Injection_____ Body Part (s)_____
Laser_____ Body Part (s)_____

EXHIBIT 12

POST TREATMENT- VASCULAR

- Apply ice, cold compresses as needed.
- Avoid strenuous exercise for 3 days.
- If blister occurs apply an anti-biotic ointment such as Neosporin and call clinic at 206-575-8300. Keep the area clean and lubricated.
- Changes in skin color may occur, notify clinic for treatment advice.
- It takes 2 to 6 weeks for coagulated vessels to dissipate.
- Compression stockings may be worn during the day for up to 3 days after.
- SPF 20 minimum should be worn.

EXHIBIT 13

LASER ~ WORKS!

Informed Consent – Microdermabrasion

I, _____consent to and authorize Laser ~ Works!, and it's staff, to perform microdermabrasion skin exfoliation and other services. My signature and initials below acknowledges that I have read the following precautions and understand the risks. I agree to receive the treatments or series of treatments listed as follows:

Areas to be treated: _____

_____

_____

_____ The nature and purpose of the treatment has been explained to me, and any question I have regarding this procedure have been explained to my satisfaction.

_____ I understand that with any treatment certain risks are involved and that any complications or side effects from known or unknown causes could occur. I freely assume these risks.

_____ Possible side effects include, but are not limited to: Mild redness, extreme redness, bruising, local swelling, stinging, tenderness, dry skin, flaking, lightening or darkening of the skin, infections, pimples, bumpy appearance, and cold sores. Most side effects are temporary and generally subside within 72 hours.

_____ If I am prone to Herpetic outbreaks, I have been advised to see my physician about a prescription for acyclovir, zovirax, or to take supplements of L-Lysine, Beta-Carotene and Folic Acid daily.

_____ I have been advised to discontinue all AHA's, Glycolics, Rentin-A, Renova, or any exfoliating products for up to 72 hours post-procedure. I understand that I must use hydrating and soothing antioxidants for healing, and ice for swelling and inflammation reduction. Also, I understand there should be no sun exposure for 72 hours and the use of an SPF 30 at all times during treatment is advised.

_____ I have been advised and agree to avoid collagen injections for up to 10-14 days before any microdermabrasion treatment and 7 days after treatment.

_____ I am over 18 years of age or I have parental consent co-signed below.

_____ I will call to inform my practitioner of any complications or concerns I may have as soon as they occur.

Date _____

Patient Signature _____

Parental Signature _____

Witness _____

EXHIBIT 14

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

January 25, 2003

Via Hand Delivery

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Department of Health (DOH) Investigation of Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein—Documents in Response to Subpoena

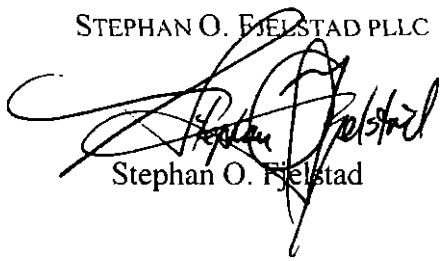
Dear Ms. Crowley:

Accompanying this letter are the documents produced by my clients in response to the DOH subpoena served on January 15, 2003. In our telephone discussion on Wednesday, January 22, 2003, you clarified the scope of the documents to be produced under the subpoena: 1) copies of Laser Works' actual handwritten daily client appointment books from December 17, 2002 forward (through the date of the subpoena); 2) all records concerning all clients who received treatments at Laser Works on December 23, 2002; and 3) all records concerning two clients who received treatments at Laser Works on each day from December 17, 2002 forward (through the date of the subpoena), on the condition that the clients selected under this latter category received various types of treatments at Laser Works (as opposed to only clients who received one particular type of treatment exclusively, dermabrasion, for example). The files produced reflect all three of these categories of documents.

Also, as I previously informed you, Dr. Elizabeth Bianchi agreed as of the same date of the subpoena and our meeting at my office on January 15, 2003, to act as a medical director for Laser Works to provide additional medical consultation and oversight as needed during this period.

Very truly yours,

STEPHAN O. FJELSTAD PLLC



Stephan O. Fjelstad

SOF:sof
enclosures
cc: clients

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

January 27, 2003

Via Hand Delivery

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Department of Health (DOH) Investigation of Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein—Additional Documents

Dear Ms. Crowley:

Attached for the records in your investigation are copies of revised forms that Laser Works and the above-named employees are now using for Laser Works clients.

Very truly yours,

STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

SOF:sof
enclosures
cc: clients

000084

Date: _____

Customer Comments and Concerns

Name of client: _____

Phone #: ____ - _____

Call returned by: _____ Date: _____

Date of Last Treatment: _____

Notes: _____

Laser-Works of Seattle

INFORMED CONSENT FORM

I understand that I will receive non medical treatment from Laser~Works of Seattle. I also understand that clinical results may vary with different skin types, hair color and the location on the body for the treatments by Laser~Works of Seattle. The various treatments Laser~Works of Seattle provides include: laser hair removal and intense pulse light (epilation); intense pulse light and laser skin rejuvenation and micro dermabrasion. I further understand that there is a possibility of unusual side effects from any of these treatments such as scarring and permanent discoloration. There can also be short-term effects of any of these treatments such as reddening, mild burning, temporary discoloration of the skin. These possible effects have been fully explained to me: _____ (please initial).

I have made Laser~Works of Seattle aware of my use of tanning beds, sunless tanning products and any unprotected exposure to the sun in the last 14 days: _____ (please initial).

I will not hold Laser~Works of Seattle, its owners or its employees responsible for the hair reduction or skin treatment results I experience. I realize that my skin and hair is an organ unique to me and that therefore results may vary: _____ (please initial).

I understand that there are other options for hair removal and or skin rejuvenation such as electrolysis, waxing and chemical preparations rather than laser treatment. With this in mind, I choose laser treatment with Laser~Works of Seattle as a non-invasive treatment for epilation and or skin rejuvenation: _____ (please initial).

I understand that my treatments by Laser~Works of Seattle require payment and the prices and fee structure for treatment have been explained to me. **There are no refunds on treatments, or on treatments paid in advance:** _____ (please initial).

I further understand that Laser~Works of Seattle's quoted price for treatment is the price for each individual treatment or session, unless otherwise specified in writing by Laser~Works of Seattle. I understand that the services Laser~Works of Seattle provides sometimes require more than one treatment session, depending on the individual, and that the price quoted to me for treatment is the price for each individual treatment session, unless, again, otherwise specified in writing: _____ (please initial).

I am aware that Laser~Works of Seattle requires 24 hours notice of a cancellation or of a need to reschedule and that it is my responsibility to provide that notice. I agree to pay a minimum of $75.00, or half the scheduled treatment cost, if I fail to give the required 24 hours notice. If I choose to prepay my treatment session or sessions, I understand that I may forfeit one of my future sessions if I do not provide Laser~Works of Seattle proper notice (24 hours).

I have read and fully understand all the terms of this informed consent form, all my questions have been answered to my satisfaction and I agree to terms of this agreement:

Print patient name: _____

Signature: _____ Date: _____

Witness: _____ Date: _____

Laser - Works

Client Medical History

Name: _____ D.O.B. _____

Address: _____ City: _____ Zip: _____

Home Phone: _____ Business Phone: _____

Referred By: _____

Ethnic Origin: _____(For skin reaction to Laser)

Have you ever been diagnosed with the following?

Heart condition: _____ Bleeding Disorder: _____ Fainting Spells: _____
Diabetes: _____ Type? _____ Insulin Controlled? _____
Herpes: _____ Keloid Scars: _____ HIV/AIDS: _____

Are you pregnant? _____
What medications are you taking? (including aspirin) _____
Are you taking any herbal preparations? (St Johns Wort) _____
How often do you use alcohol? _____ x-day _____ x-week ____ x-month
Allergies: _____

Skin type (when exposed to the sun **without protection** for about 1 hour)

1. Always burns, never tans _____
2. Usually burns, sometimes tans _____
3. Sometimes burns, sometimes tans _____
4. Always tans _____

When were you last exposed to the sun? (including tanning booth) _____
Do you use chemical tanning products? _____
Are you planning a holiday in the sun? _____

Reason for visit (areas to be treated) _____

Prior Treatment (If any)
Waxing _____ Body Part(s): _____
Electrolysis _____ Body Part(s): _____
Depilatory _____ Body Part(s): _____
Laser _____ Body Part(s): _____

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

In the Matter of the Investigation of:	)	
	)	No. 2002-09-0004UI
MARILYN GELNETTE	)	SUBPOENA DUCES TECUM
Licensee	)	

THE STATE OF WASHINGTON: To: LASER WORKS OF SEATTLE
411 Strander Blvd., Suite 108
Tukwila, WA 98188

On behalf of the Secretary of the Department of Health and pursuant to the authority granted to same in RCW 18.130.050(3), you are ordered to produce and furnish to the Department of Health, Health Professions Quality Assurance Division, 20435 72nd Ave., S, Suite 200, Kent, WA 98032, or to the Department of Health Investigator, Gayle M. Crowley, or other authorized agent on or before the 27th day of January 2003 at 5pm, copies of the following documents and records:

1. **Copies of all appointment schedules from December 17, 2002 to present.**

2. **Records for all patients receiving treatment from December 17, 2002 to present.**

You are hereby given notice and informed that in the case of willful and intentional failure of any person to comply with this subpoena, application to the appropriate court of this or any other jurisdiction, or other suitable administrative action pursuant to the authority granted to the Secretary in Chapter 18.130. RCW will be taken.

DATED this 15 day of January 2003.

Mary Selecky
Secretary

By: David E. Magby
DAVID E. MAGBY
Chief Investigator

American Society for Laser Medicine and Surgery, Inc.

EDUCATIONAL RECOMMENDATIONS FOR LASER USE BY NON-PHYSICIANS

1) Individual should be a licensed medical professional, and carry adequate malpractice insurance.

2) Individuals should be trained appropriately in laser physics, tissue interaction, laser safety, clinical application, and pre and post operative care of the laser patient.

3) Prior to the initiation of any patient care activity the individual should have read and signed the facilities' policies and procedures regarding the safe use of lasers.

4) Continuing education of all licensed medical professionals should be mandatory and be made available with reasonable frequency (including outside the office setting) to help insure adequate performance. Specific credit hour requirements will be determined by the state, and/or individual facility.

5) A minimum of TEN procedures of precepted training should be required for each laser procedure and laser type to assess competency. Participation in all training programs, acquisition of new skills and number of hours spent in maintaining proficiency should be well documented.

6) After demonstrating competency to act alone, the designated licensed medical professional may perform limited laser treatments on specific patients as directed by the supervising physician.

(Please also refer to the Principles for Non-Physician Laser Use)

Approved by the Board of Directors
American Society for Laser Medicine and Surgery, Inc.
April 15, 1999

2404 Stewart Square • Wausau, WI 54401 • Telephone: (715) 845-9283 • FAX: (715) 848-2493
E-Mail: aslms@dwave.net • Home Page: http://www.aslms.org

Patty O

American Society for Dermatologic Surgery

930 North Meacham Road • Schaumburg, IL • 60173-5016
847/330-9830 • Fax 847/330-1135

POSITION STATEMENT
ON THE USE OF NON-PHYSICIAN PERSONNEL IN A DERMATOLOGIC SURGERY PRACTICE

1. Dermatologic surgeons shall be trained appropriately in all dermatologic surgical procedures, including pre-and post-operative care, that they provide in their practices. Any physician who delegates a surgical procedure to a non-physician must be qualified to do the procedure themselves by virtue of having received appropriate training in those surgical techniques.

2. Any allied health professional employed by a dermatologic surgeon to perform any surgical procedure must have received appropriate documented training and education in that procedure, be properly licensed in their state, and be adequately insured for the procedure to be performed.

3. Each patient should be evaluated by the dermatologic surgeon and descriptive orders for appropriate treatment should be documented and reviewed with non-physician personnel.

4. A properly trained and licensed allied health professional may carry out a specifically designated surgical procedure only under direct supervision by the dermatologic surgeon following established written procedures which are immediately available for reference at the specific location where the procedure is to be performed.

→ don't dictate whom: RN, LPN, HCA, MA...

5. The ultimate responsibility for medical judgment and for properly performing any procedure lies with the physician. Therefore, the supervising dermatologic surgeon shall be physically present and immediately available to respond promptly to any question or problem that may occur while the procedure is being performed, and to be able to assume direct performance of the procedure if required.

The guiding principle for all dermatologic surgeons is to practice ethical medicine with the highest possible standards to ensure that the best interests and welfare of each patient are guaranteed. The ASDS endorses the concept that use of properly trained and licensed allied health professionals under appropriate direct physician supervision allows certain surgical procedures to be performed safely and effectively.

Draft: October 26, 1998

Facsimile

A L VOSS ASSOCIATES

To: Patty Owens

From: Alan L. Voss

Date: June 8, 2000

Subject: Washington Laser Regulations

Pages:

Patty:

Here are some of the various state citations that I could find. As I mentioned, there are roughly 40+ states that allow delegation of laser hair removal (LHR) to licensed or unlicensed allied health care providers. In most states these individuals are only identified as someone the physician feels is adequately trained so as to ensure a safe and effective treatment. There are only 6 or 7 states that allow only a physician to perform this therapy. Since they do not want, nor can afford to do the procedure themselves, they either break the law and delegate or the public will not have access to this new technology.

In this market the electrologist currently owns the patients, and in most instances has a long standing relationship more as a friend than a patient. This happens because needle electrology is such a slow procedure that it often takes years to complete. Most electrologists will tell you they have started treating many backs, but never finished any of them because of the length of time that it takes.

The states regulatory organizations are very confused because this is the first time that a supposed surgical device is being used by a non-physician in the vanity marketplace. They look on lasers as all being the same, and treat them accordingly. Education and training are needed by both the users and regulators.

I hope this data is helpful.

P.O. Box 405, Angels Camp, CA 95221, Phone (209) 736-9292
Fax (209) 736-1930 E-mail - alvoss@calnet.com

The Use of Medical Assistants by Physicians

There is a popularly held myth that medical assistants may perform any procedure in a doctor's office if supervised by a physician. This is not true, as medical assistants are unlicensed, and can only legally perform certain duties allowed by law and technical supportive services enumerated in regulations. This does not include functions outside of the law and those covered by other practice acts.

Section 2069 of the Business & Professions Code defines a medical assistant as an unlicensed person who performs basic administrative, clerical, and technical supportive services under the supervision of a physician. A medical assistant may administer medication only by intradermal, subcutaneous, or intramuscular injections, perform skin tests, and other technical supportive services described in regulation. Some of those services included in the regulation are: applying and removing bandages and dressings, removing sutures or staples from superficial incisions or lacerations, removing ear wax, collecting urine and stool specimens, and shaving and disinfecting treatment sites. Under some circumstances, medical assistants may draw blood. The law specifically prohibits medical assistants from applying topical anesthetic agents, and they may not be employed for inpatient care in a licensed general acute care hospital.

Medical assistants are not licensed, and it is not legal to use them to replace highly trained, licensed professionals. They are there to assist and perform support services in the physician's office appropriate with their training ...

Recently, the Medical Board's regulations relating to the technical supportive services of medical assistants were challenged in Superior Court in California Optometric Association vs. The Division of Licensing of the Medical Board of California. The COA sued the Division over its amendments to Section 1366 of Division 13 of Title 16 of the California Code of Regulations, which added simple ophthalmic testing to the list of activities that may be legally performed by medical assistants.

The primary issue of contention was the addition of Section 1366(b)(4), which stated: *Perform ophthalmic testing not requiring interpretation by the medical assistant in order to obtain test results.* After filing suit in April 1996, COA ultimately won. On June 12, 1997, Superior Court Judge Earl Warren, Jr. declared this regulation invalid and ineffective, and restrained the Medical Board from enforcing it. In compliance with the court's order, the Division is repealing the disputed language through the Office of Administrative Law.

Another issue that recently has come to the attention of the Medical Board is the use of lasers by non-physicians. It has been suggested that some doctors are employing unlicensed medical assistants to use lasers for tattoo removal, spider vein treatments, or hair removal. This practice is not legal. The physician, of course, may use the laser in his or her office, but only a licensed nurse or physician assistant may use it under the physician's supervision, following protocols appropriate to their licenses. Similarly, it is not legal to employ electrologists to perform laser hair removal, as laser use is not permitted by the barbering and cosmetology license they possess.

In summary, medical assistants are not licensed, and it is not legal to use them to replace highly trained, licensed professionals. They are there to assist and perform support services in the physician's office appropriate with their training, which cannot be compared with licensed nurses or other health professionals who must meet rigorous educational and examination requirements.

Physicians who would like additional information may fax requests to (916) 263-2387.

United States Medical Licensing Examination (USMLE) Step 3 Date:

Examination Date	Application Deadline
May 12-13, 1998	February 2, 1998
December 1-2, 1998	August 21, 1998

For additional information, contact:

Medical Board of California
Licensing Program
1426 Howe Avenue, Suite 54
Sacramento, CA 95825-3236
(916) 263-2499

G000220

American Society for Dermatologic Surgery

930 North Meacham Road • Schaumburg, IL • 60173-6016
847/330-9830 • Fax 847/330-1135

August 20, 2001

AUG 2 1 2001

Washington State Board of Osteopathic Medicine & Surgery
Robert Nicoloff, Executive Director
PO Box 47870
Olympia, WA 98504

Dear Robert Nicoloff

The American Society for Dermatologic Surgery (ASDS) is the largest medical specialty society comprised of dermatologic surgeons. As such, we represent the interests of patients, our physician members, and the specialty, in every state across the country. I am writing on behalf of the ASDS regarding an important patient safety issue.

The ASDS has become increasingly concerned about the proliferation of non-physicians practicing medicine and its impact on patient safety. In a recent survey of the Society's 2400 members regarding this issue, approximately 45% of respondents indicated an increase in the number of patients requesting treatment for complications from non-physicians such as burns, splotching, irreversible pigmentation or scarring due to:

- → Laser or light-based hair removal
- → Chemical peeling
- → Microdermabrasion
- → Microdermabrasion and chemical peel combinations
- → Non-ablative, sub-surface laser and light-based skin rejuvenation
- → Misdiagnosis and delayed treatment of rosacea

(Photographs illustrating these complications are included in the enclosed packet.)

Complications may occur in the best of circumstances. However, they are happening in two primary arenas: 1) individuals, such as cosmetologists and estheticians, who perform increasingly aggressive, invasive procedures without direct physician supervision; and 2) employees of physicians, who perform procedures outside their scope of training (e.g. laser and light-based surgeries, combination peels, botulinum toxin, filler substances) with inadequate or no direct physician supervision. These individuals are not qualified or trained to diagnose skin conditions, perform these procedures and manage resulting complications. In Florida, for instance, the non-physician practice of medicine resulted in a death from the injection of a non-approved substance. Moreover, patients who are treated by non-physician personnel for cosmetic dermatologic services are deprived of correct diagnosis and treatment of skin disease, most notably skin cancers.

American Society for Dermatologic Surgery

The problem is exacerbated by the ill-defined and inconsistent definitions and policies from state to state, as well as by the efforts of individuals and entities to encourage the use of medical devices and the practice of medical procedures by non-physicians.

In order to provide assistance to the state boards of medicine and bring about more consistent policy-making, the ASDS has developed position statements defining appropriate levels of physician supervision and what constitutes the practice of medicine. You'll find these documents included with a packet of information containing photographs of complications, survey results, marketing materials promoting "rent a medical director" and other related activities, and press releases supporting our public awareness campaign. We urge you to examine this issue in your state and consider these documents as a basis for future policy-making.

If you have questions regarding any of the material enclosed, please do not hesitate to contact Katherine Svedman, ASDS Executive Director at 847/240-1429 or ksvedman@aad.org. A dermatologic surgeon and member of the ASDS will be in touch with you shortly regarding this very important patient safety issue.

Sincerely,

Harold J. Brody, MD
President

Enclosures

American Society for Dermatologic Surgery

Position on the Practice of Medicine and Use of Non-Physician Office Personnel

The guiding principle for all dermatologic surgeons is to practice ethical medicine with the highest possible standards. Physicians should be properly trained in all procedures performed to ensure the highest level of patient care and safety. A physician should be fully qualified by residency training and preceptorship or appropriate course work. Training should include an extensive understanding of cutaneous medicine and surgery, the indications for each procedure, and the pre- and post-operative care involved in treatment. It is the position of the ASDS that only active and properly licensed doctors of medicine and osteopathy shall engage in the practice of medicine.

Under the appropriate circumstances, a physician may delegate certain procedures to certified or licensed non-physician office personnel (e.g. RN, CMA, LPN, PA, NP, CORT). Specifically, the physician must directly supervise the non-physician office personnel to protect the best interests and welfare of each patient. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed. It is the physician's obligation to ensure that, with respect to each procedure performed, the non-physician office personnel possess the proper training in cutaneous medicine, the indications for the procedure, and the pre- and post-operative care involved.

Approved by the ASDS Board of Directors
April, 2001

For more information, contact the ASDS at 847/330 9630

American Society for Dermatologic Surgery

Position on the Definition of the Practice of Medicine

The practice of medicine involves diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities whether physical or mental, by any means, methods, devices, or instruments. The practice of medicine includes, but is not limited to:

a. Undertaking to perform any surgical operation upon any person; and

b. Performing any act or procedure that uses a biologic or synthetic material, chemical application, mechanical device, or displaced energy form of any kind if it alters or damages or is capable of altering or damaging *living tissue*.

(i) Such acts or procedures include, for example, the use of all lasers, light sources, microwave energy, electrical impulses, chemical application, particle sanding, the injection or insertion of foreign or natural substances, or soft tissue augmentation.

(ii) Living tissue is any layer below the dead cell layer (stratum corneum) of the epidermis. The epidermis, below the stratum corneum, and dermis are living tissue layers.

(iii) Certain FDA-approved Class I and II devices, by their intended or improper use, can alter or cause biologic change or damage below the stratum corneum. Therefore, their use and the diagnosis and treatment surrounding their use, constitutes the practice of medicine.

Approved by the ASDS Board of Directors
April, 2001

For more information, contact the ASDS at 847/330-9830.

American Society for Dermatologic Surgery

Position on The Use of Lasers, Intense Pulsed Light, Radio Frequency, and Medical Microwave Devices

Physicians shall be trained appropriately in the physics, safety, and surgical techniques involved in the use of lasers, intense pulsed light, radio frequency, and medical microwave devices prior to performing procedures using such devices. Training should include an extensive understanding of cutaneous medicine and surgery, the indications for such surgical procedures, the pre- and post-operative care involved in treatment, as well as the treatment of complications associated with these devices.

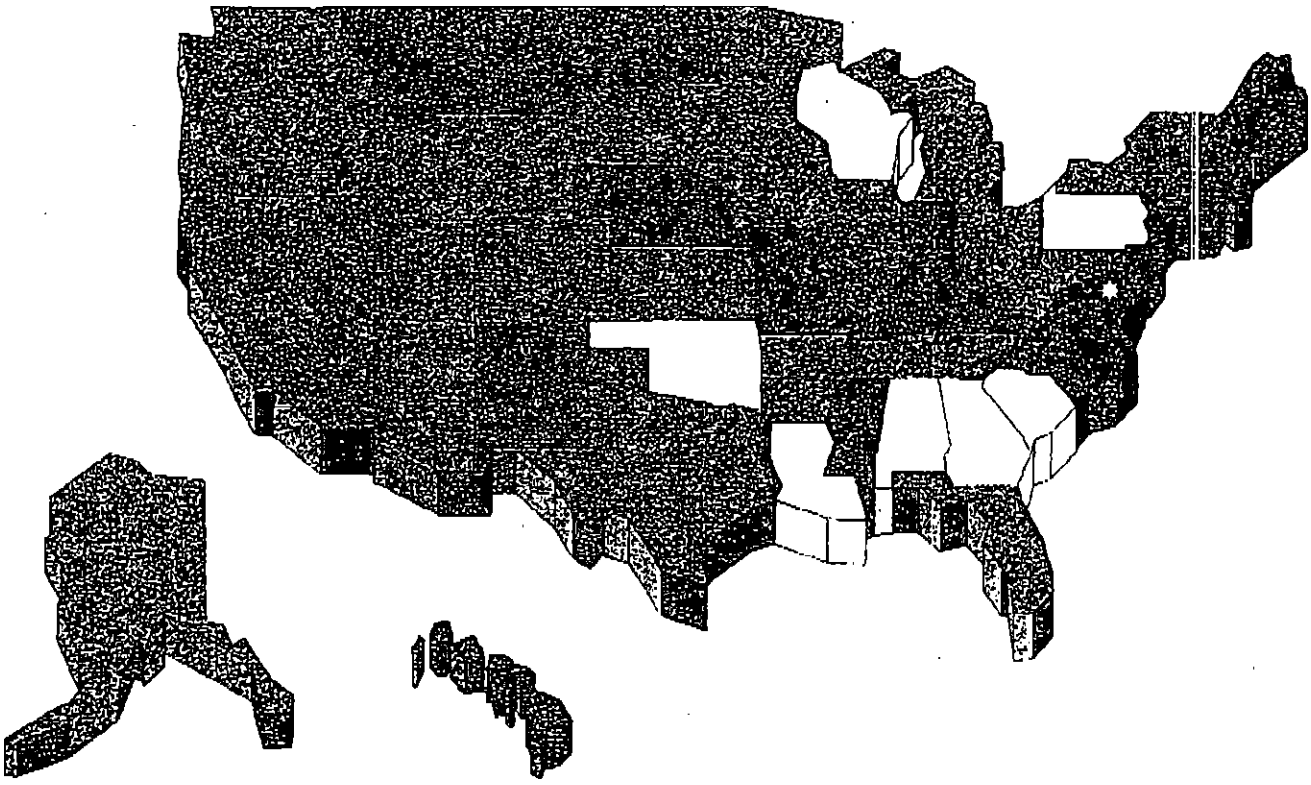
A physician who delegates such procedures should be fully qualified by residency training and preceptorship or appropriate course work prior to delegating procedures to licensed or certified non-physician office personnel and should directly supervise the procedures. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed.

Any non-physician office personnel employed and designated to perform a procedure by a physician must be under the direct supervision of the physician. For each procedure performed, the non-physician office personnel must have appropriate documented training in the physics, safety, and surgical techniques of each system. The non-physician office personnel should also be appropriately trained by the delegating physician in cutaneous medicine, the indications for such surgical procedures, and the pre- and post-operative care involved in treatment.

Approved by the ASDS Board of Directors
April, 2001

For more information, contact the ASDS at 847/330-9830.

State Boards of Medicine Regulations on the Practice of Laser Procedures



States permitting only MDs to perform laser procedures.
(Delaware, Hawaii, Indiana, Kentucky, Maine, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, and Virginia)

States permitting MDs to delegate laser procedures under direct supervision.
(Alabama, Georgia, Louisiana, Oklahoma, Pennsylvania, South Carolina, Wisconsin, and the District of Columbia)

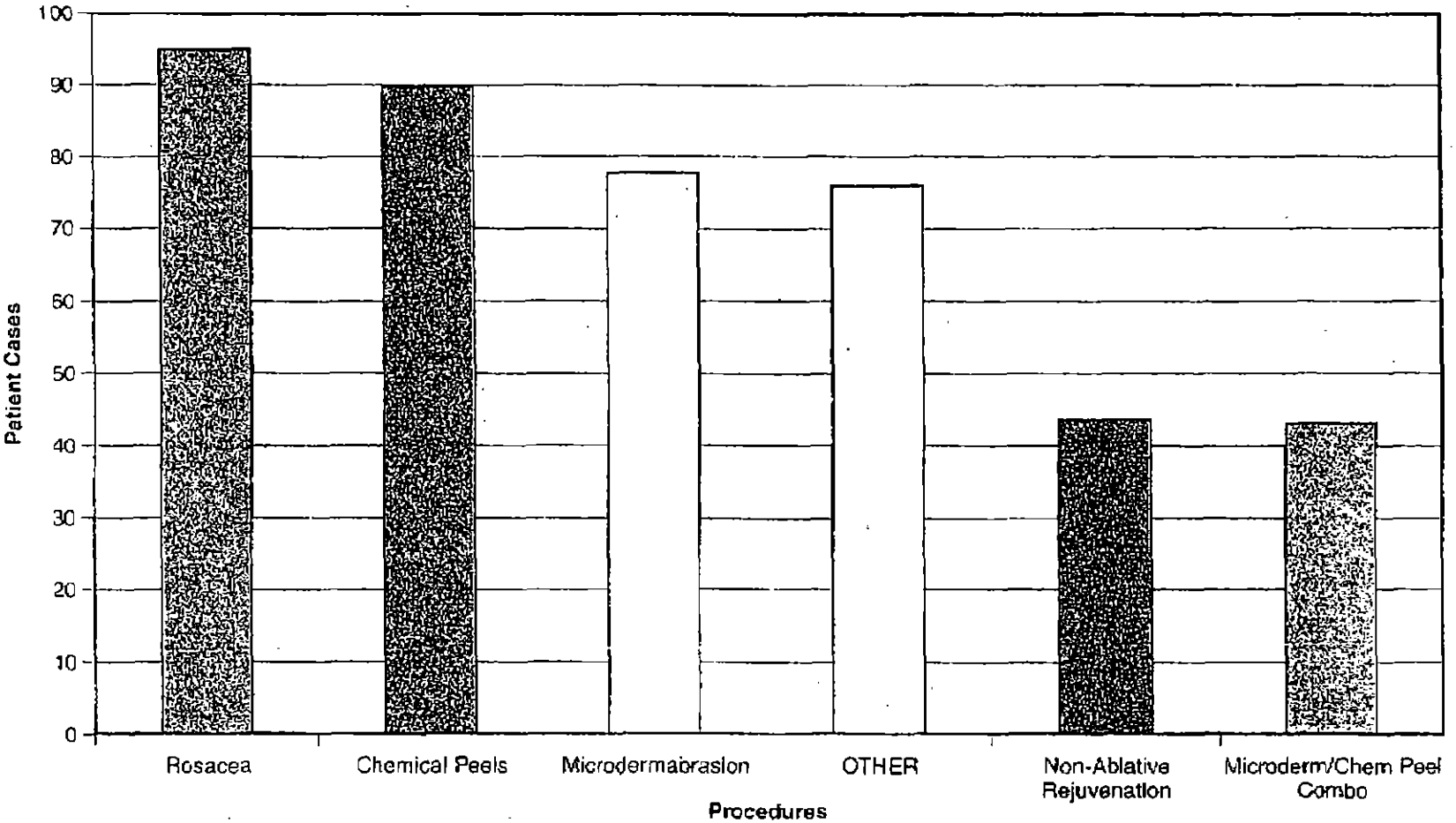
States permitting MDs to use their discretion when delegating laser procedures, but with various definitions of supervision.
(Connecticut, Colorado, California, Florida, Illinois, Maryland, Massachusetts, New York, Texas and Washington)

States having no regulations regarding laser procedures.
(Alaska, Arizona, Arkansas, Idaho, Iowa, Kansas, Michigan, Minnesota, Nevada, Ohio, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wyoming)

State regulations are subject to change, and the specific language varies extensively.

Source: The American Electrology Association (June of 2001)
Dr. David Goldberg

2001 ASDS Member Survey of Patient Complications Due to Non-Physician Practice of Medicine



The data was compiled in July, based on a survey of 2400 ASDS members.
Nearly 45% of respondents reported an increase in patient complications treated during the past year.

American Society for Dermatologic Surgery
930 North Meacham Road
Schaumburg, IL 60173

For more information, contact:
Nadine Tosk, ASDS, at (504) 483-6957 or
Nadine Woloshin, Rubenstein Associates, Inc., at (212) 843-8041

AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY WARNS CONSUMERS TO BE WARY OF COSMETIC PROCEDURES PERFORMED BY NON-PHYSICIANS

* * *

ASDS Launches Patient Awareness Campaign After Member Survey Reveals Alarming Rise In Patients Seeking Corrective Treatment For Complications

August 10, 2001 - Schaumburg, IL. The American Society for Dermatologic Surgery (ASDS) has launched a campaign warning consumers that many procedures being offered at spas, salons and "walk-in" clinics should only be performed by physicians or under direct physician supervision. The patient safety campaign was prompted by the alarming increase in the number of patients seeking corrective treatment due to complications from laser and light-based hair removal, subsurface laser/light rejuvenation techniques, chemical peels, microdermabrasion, injectables, and other medical procedures performed by non-physicians without adequate training or supervision

The announcement was made by ASDS President Harold J. Brody, M.D., who said the campaign is being initiated because of growing concern by the Society about the proliferation of non-physicians practicing medicine and its impact on public health, safety and welfare.

"Consumers need to be aware that cosmetic skin treatments using lasers, high-tech light devices, chemical peels, soft tissue fillers, botulinum toxin, and microdermabrasion are surgical procedures that can be invasive, carry potential side effects and should be performed by a qualified physician or under direct physician supervision," says Dr. Brody. "Furthermore, consumers who are treated by non-physicians for cosmetic dermatologic services are often deprived of correct diagnosis and treatment for serious, sometimes life threatening skin conditions, including skin cancers and rosacea."

- more -

In a recent survey of the Society's 2,400 members, approximately 45 percent of the respondents reported an increase in the number of patients treated over the past year for complications such as burns, splotching, irreversible pigmentation and scarring. The disturbing results were attributed primarily to estheticians, cosmetic technicians and employees of physicians who perform various medical procedures outside their scope of training or with inadequate or no physician supervision.

The Society's recently issued position statement on the non-physician practice of medicine recognizes that complications can occur in the best of circumstances. However, the vast majority of complications are due primarily to the practice of increasingly aggressive, invasive medical procedures by para-professionals who are not qualified to diagnose, treat or correct human conditions and disease, putting the unsuspecting public at risk.

"The bottom line is simply that marketing and price should not supplant logic and sound judgment when it comes to the practice of medicine and public health," notes Dr. Brody.

According to the ASDS, the incidence of complications reflected in the survey may just be the "tip of the iceberg." In many cases, complications go unreported because patients are in litigation or are reluctant to seek curative treatment. In some cases, patents may not even realize they have been misdiagnosed.

The issue is further complicated by laws regulating the use of laser/light sources by non-physicians, which vary from state to state, are often vague and are rarely enforced. Currently, only 15 states require an MD to operate a laser. Seventeen (17) other states and the District of Columbia differ greatly on which categories of non-physicians (e.g., RN, LPN, PA, ARNP) are permitted to perform procedures and whether they require "supervision," "direct supervision," or "on-site supervision" by physicians. The remaining 18 states do not have positions on laser procedures.

Apart from new regulations in Florida, there are virtually no laws that require physicians or non-physicians to report complications.

- more -

ASDS believes that under *appropriate circumstances and in accord with state statutes* physicians may delegate certain procedures to certified or licensed non-physician personnel, but the physicians must provide direct, on-site supervision and be available to respond immediately to any problems or queries.

Consumers seeking additional information about skin surgery treatments and referrals to board-certified dermatologic surgeons are urged to contact the ASDS consumer hotline at 1-800-441-ASDS (2737) during weekday business hours or log on to www.aboutskinsurgery.com.

The American Society for Dermatologic Surgery was founded in 1970 to promote excellence in the subspecialty of dermatologic surgery and foster the highest standards of patient care. With more than 2,400 members, the ASDS is the nation's primary resource and advocate for education, research and practice enhancement related to cosmetic, therapeutic and reconstructive dermatologic surgery.

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Editor's Note: Photos of patient complications are available upon request.

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Dr. John Fisher

On December 17, 2002, an interview was conducted with Dr. John Fisher. He is identified as the Medical Director of Laser Works. Dr. Fisher says he has not been in contact with Eric Moore and has no idea why I would be contacting him.

Dr. Fisher says he became their medical director to help them with financing of the laser, etc. He says he really hasn't had much contact with the business, but receives a monthly check for $500 from them to use him as the medical director.

Dr. Fisher states in the 3 years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least 6 months and has not worked with or know any of the employees working at the business.

Dr. Fisher says he is employed full time as the Public Medical Doctor. He works for King County in the jail systems at different locations. Dr. Fisher says it is his understanding Eric Moore and Jeff Schmidt have nurses providing treatment at their office. He was very surprised to hear no medical personnel are working at the office.

Dr. Fisher then explained he a short time ago (month or so) he ordered 4% Lidocaine prescription for the office and it was mailed. He expressed his concern that these complaints were going to affect him and his license to practice.

Dr. Fisher also explained he just finished probation for a complaint with MQAC and the FDA for selling Viagra over the Internet for $19.99. He doesn't want more problems and said he would cooperate fully in our investigation. Dr. Fisher said he would be preparing a resignation letter to Eric Moore and Laser Works of Seattle. He will fax me a copy. (The resignation letter was received later this same date)

December 20, 2002: On this date, I met with Dr. Fisher. He signed a Witness Notification form and said he will prepare and provide a statement for this investigation. Dr. Fisher was shown the forms obtained from and being used by Laser Works. He became emotional and said he was concerned with the wording used in the forms. He states he never has seen these forms or was involved in the preparation of the forms. He says he had very little to do with the business, but did receive a check monthly.

MEMO TO FILE

December 17, 2002

CASE NO.: 2002-08-0019UI; 2002-09-0004UI

SUBJECT: Eric Moore

On December 17, 2002, an interview was conducted with Eric Moore, owner of Laser Works. Also present at this interview was Jim Voiland, HC Investigator. Mr. Moore states his employees are not performing medical treatment to patients/clients/customers.

Mr. Moore says they did not hire Dr. Fisher to be the Medical Director out of necessity. They hired Dr. Fisher and had him order the lasers as they (he and Jeff (co-owners) could obtain easier better financing on the lasers. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business. They have not written agreement between Dr. Fisher, Jeff Schmidt, and himself. He says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse.

Mr. Moore identified one of the respondent's as a cosmotologist (Marilyn Gelnette). He says she started working here June 2002. He explained he is in the process of merging and forming a new company. He identified three employees that perform the laser treatments, etc. They are Sherry Winterstein, Shaney Shoengarth, and Marilyn Gelnette. He says he does not perform the treatments.

Mr. Moore says he or Marilyn Gelnette usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs. He says anyone being seen sign a disclosure form as part of the intake process. He used to have an esthetician names Sandra Lee Murillo, but he let her go in July or August 2002 as she wasn't doing her job.

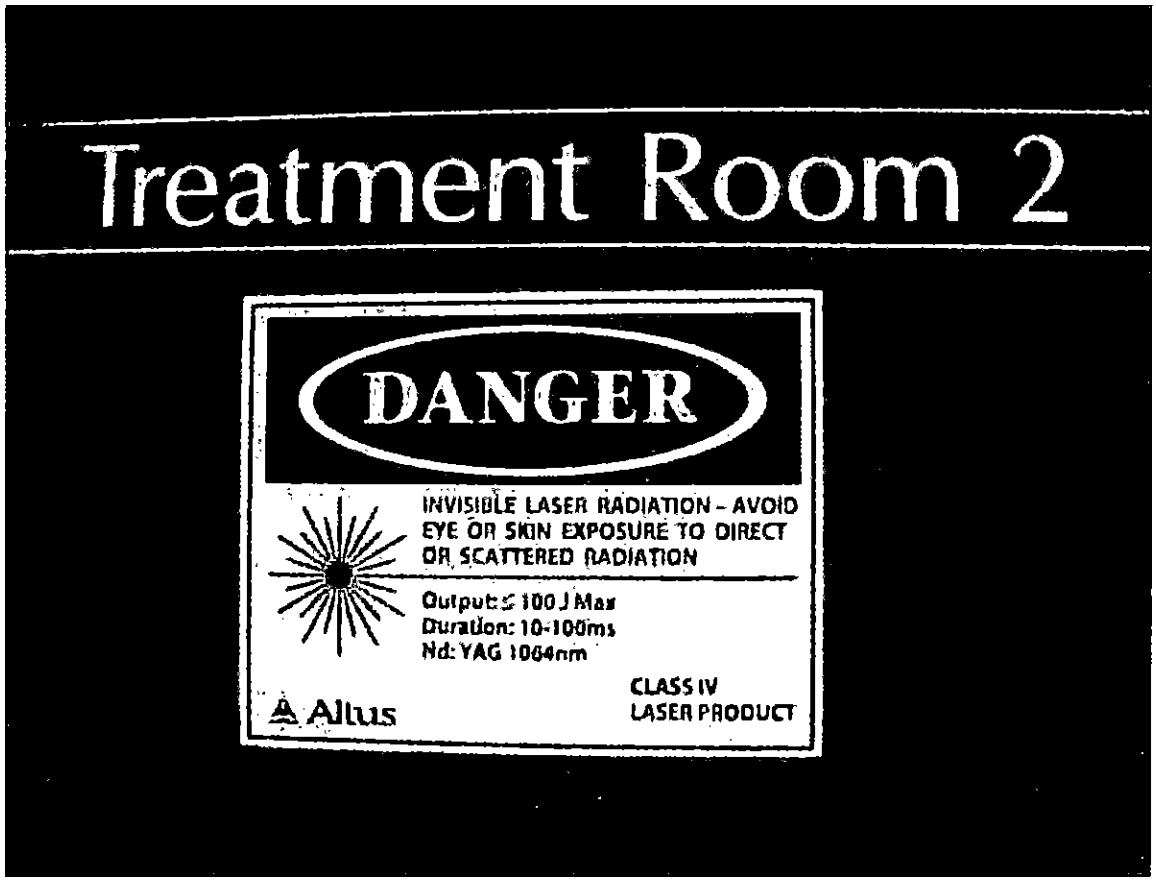
Mr. Moore says as far as Lidocaine being used by the employees, it is only given to someone in pain who requests it. He says it is not a big deal. He can't remember the last time they received any, but says it is very rarely used. He will provide the information. Mr. Moore described how they order it. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail. When we requested to see where the Lidocaine is kept, Mr. Moore was unable to show any of it to us. He couldn't find it.

The four lasers used here are identified as YAG; QUANTUM IPL; ALEXANDRITE; and SYNERON IPL. All four were viewed and pictures were taken of the treatment rooms, etc. Also, copies of the forms given to patients/clients/customers were obtained at this visit. Mr. Moore states that even though Botox treatments are listed on forms, this office does not perform these treatments. He says they do have a microdermabrasion machine, but do very few treatments.

A review was made of the appointment book and records were obtained. Files were obtained or alleged burned individuals and copied.

Mr. Moore says he will be providing evidence and statements that the three employees are not providing medical treatment or performing any unlicensed practice.

MVC-0015



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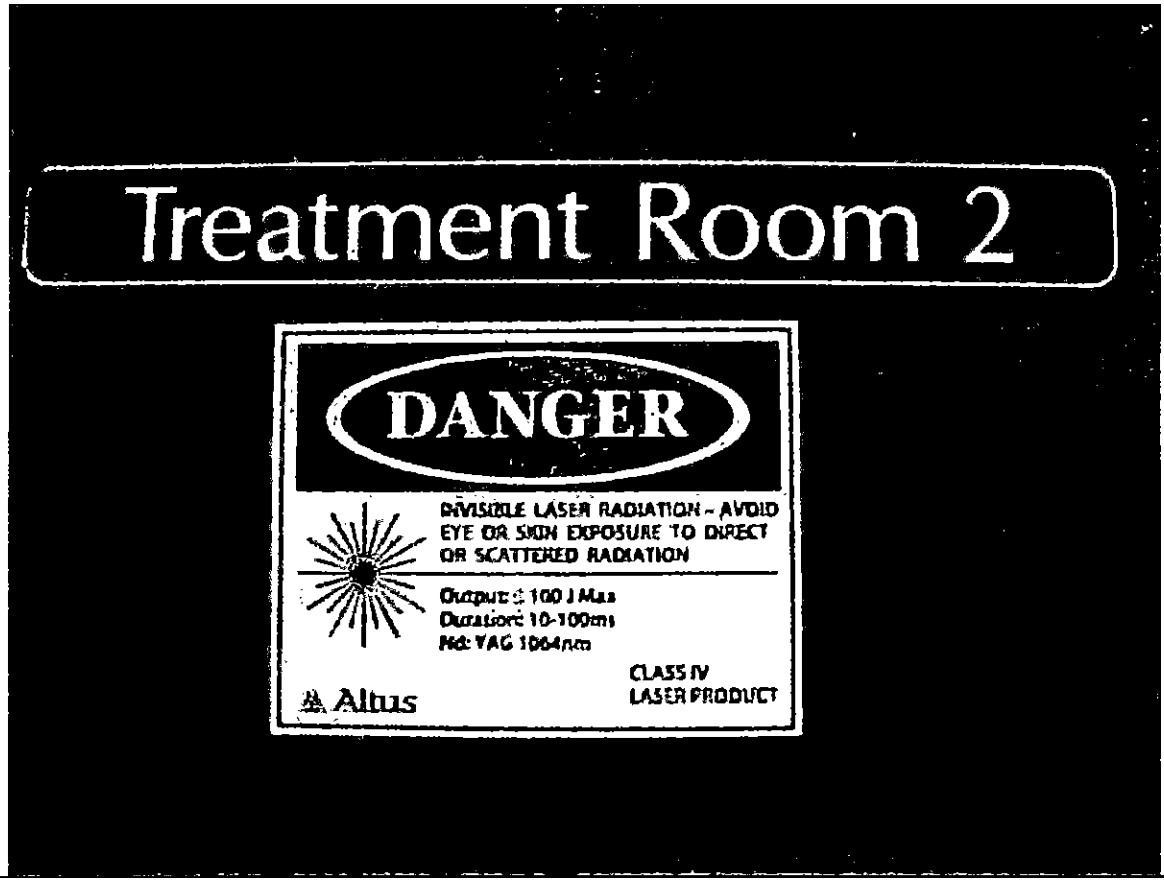

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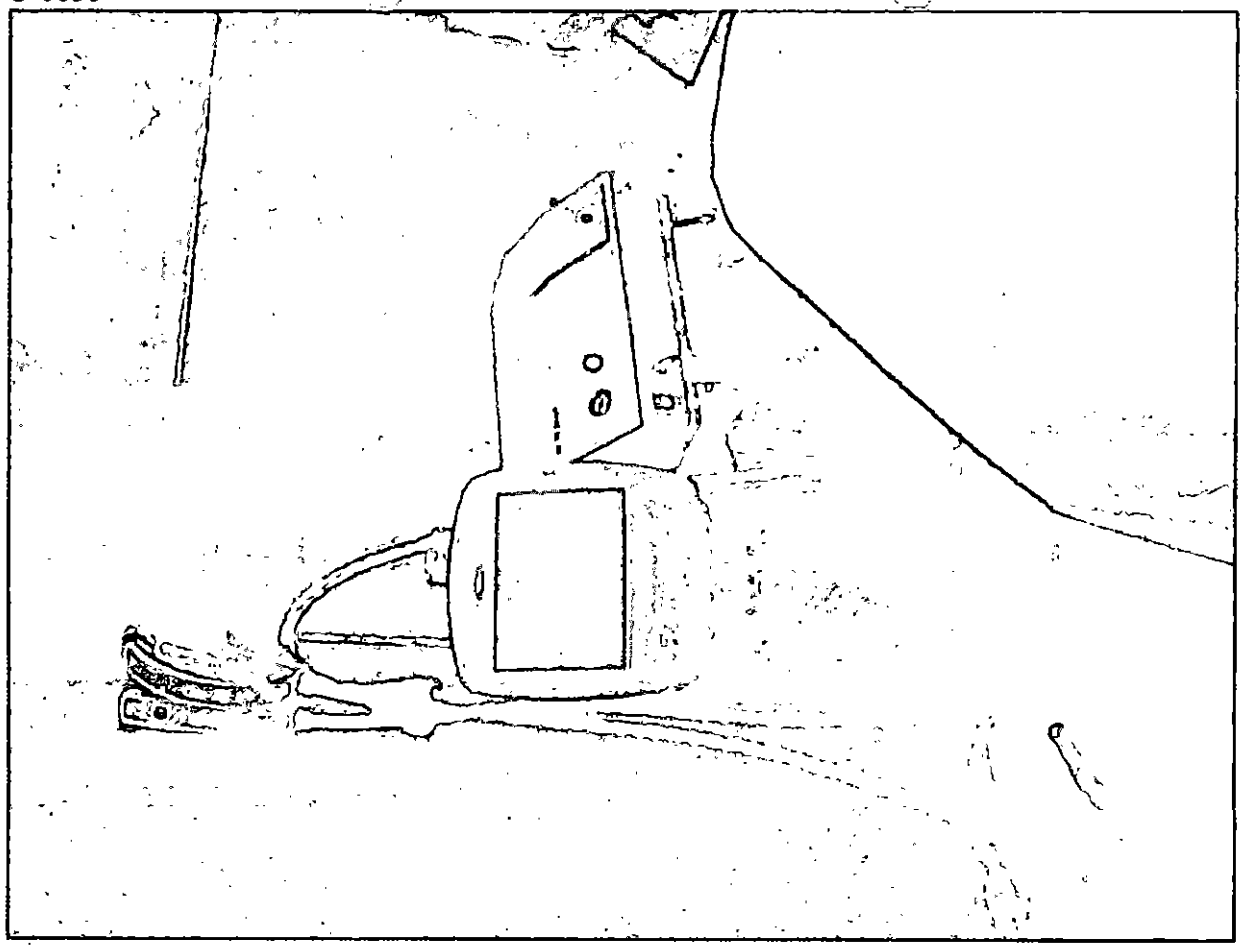

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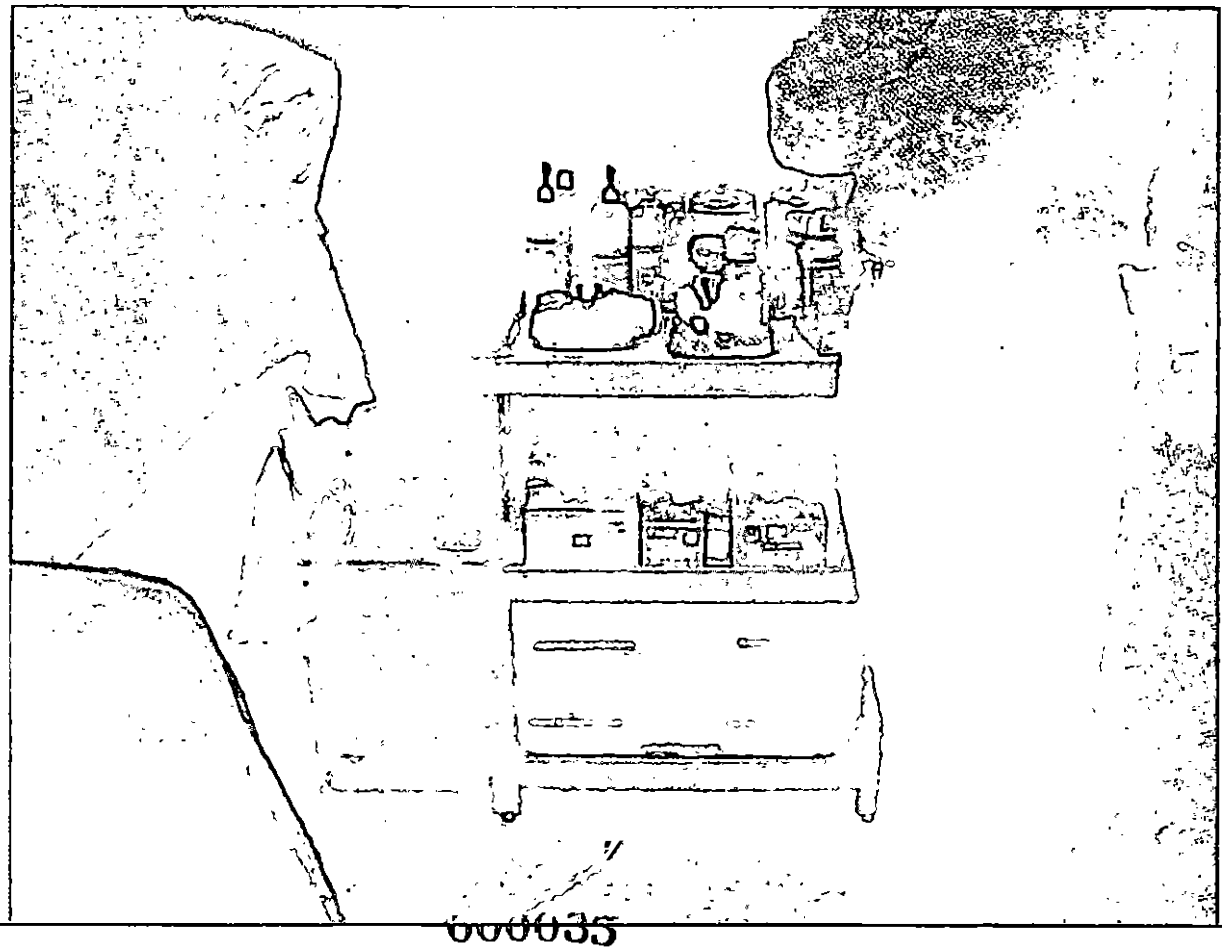

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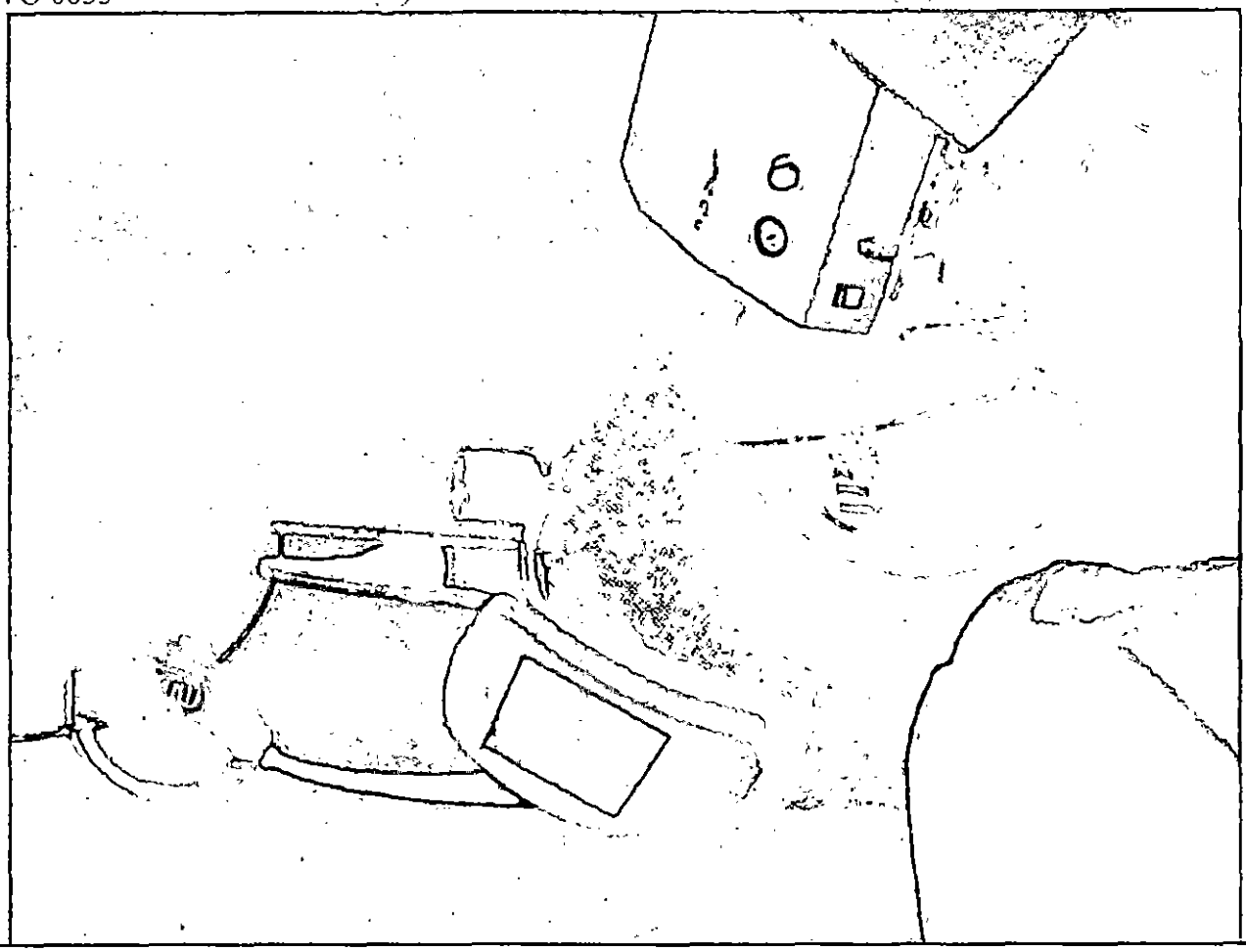

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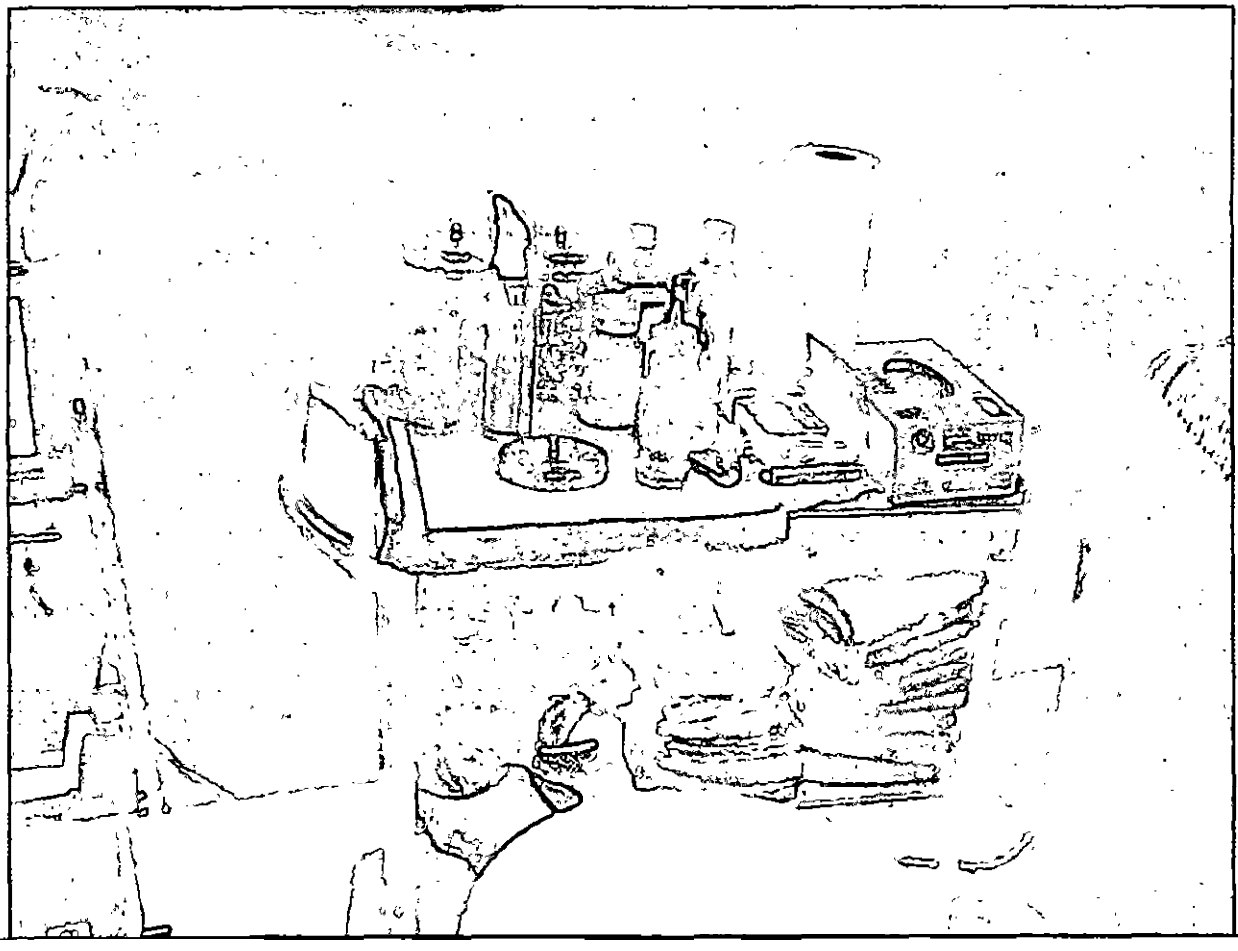

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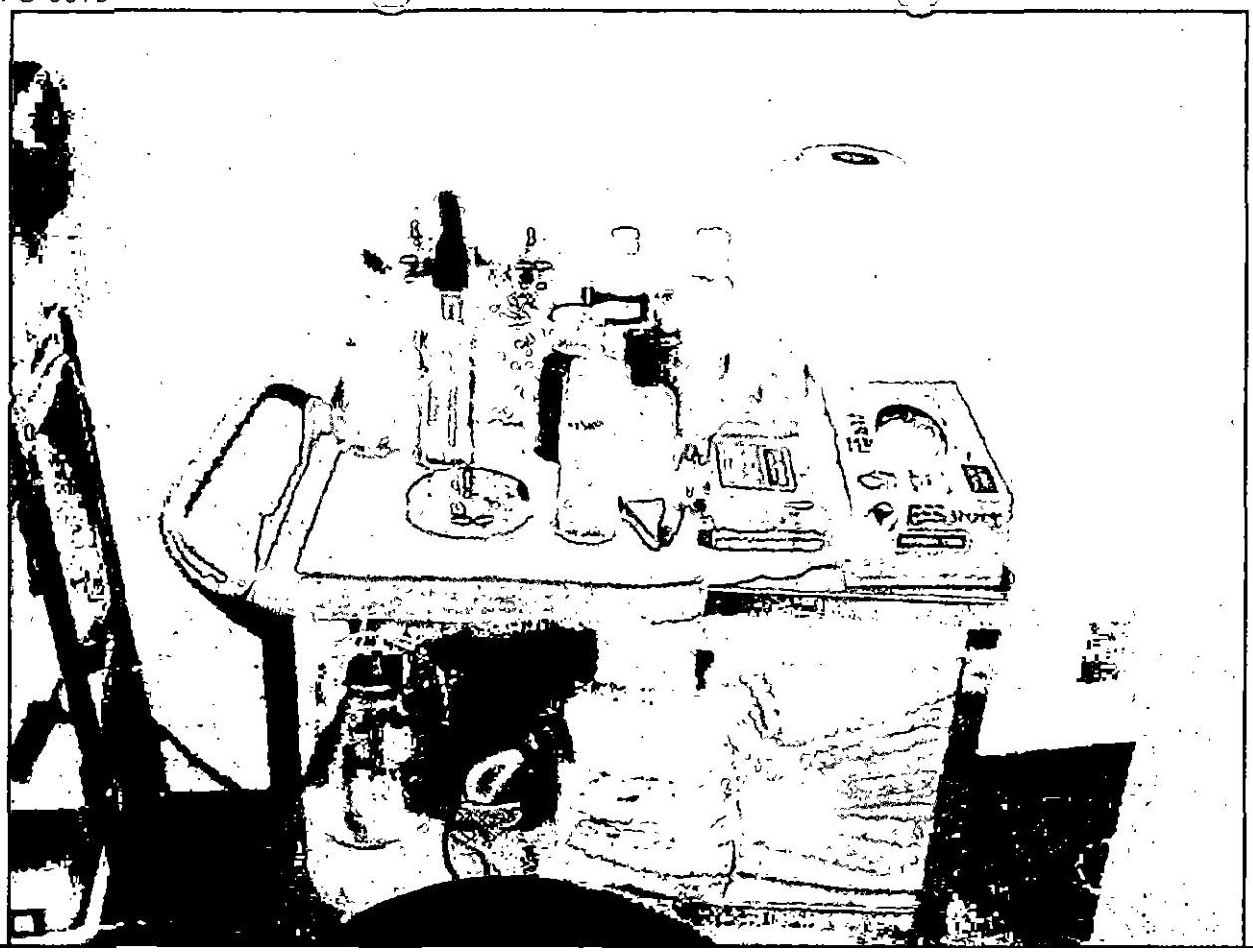

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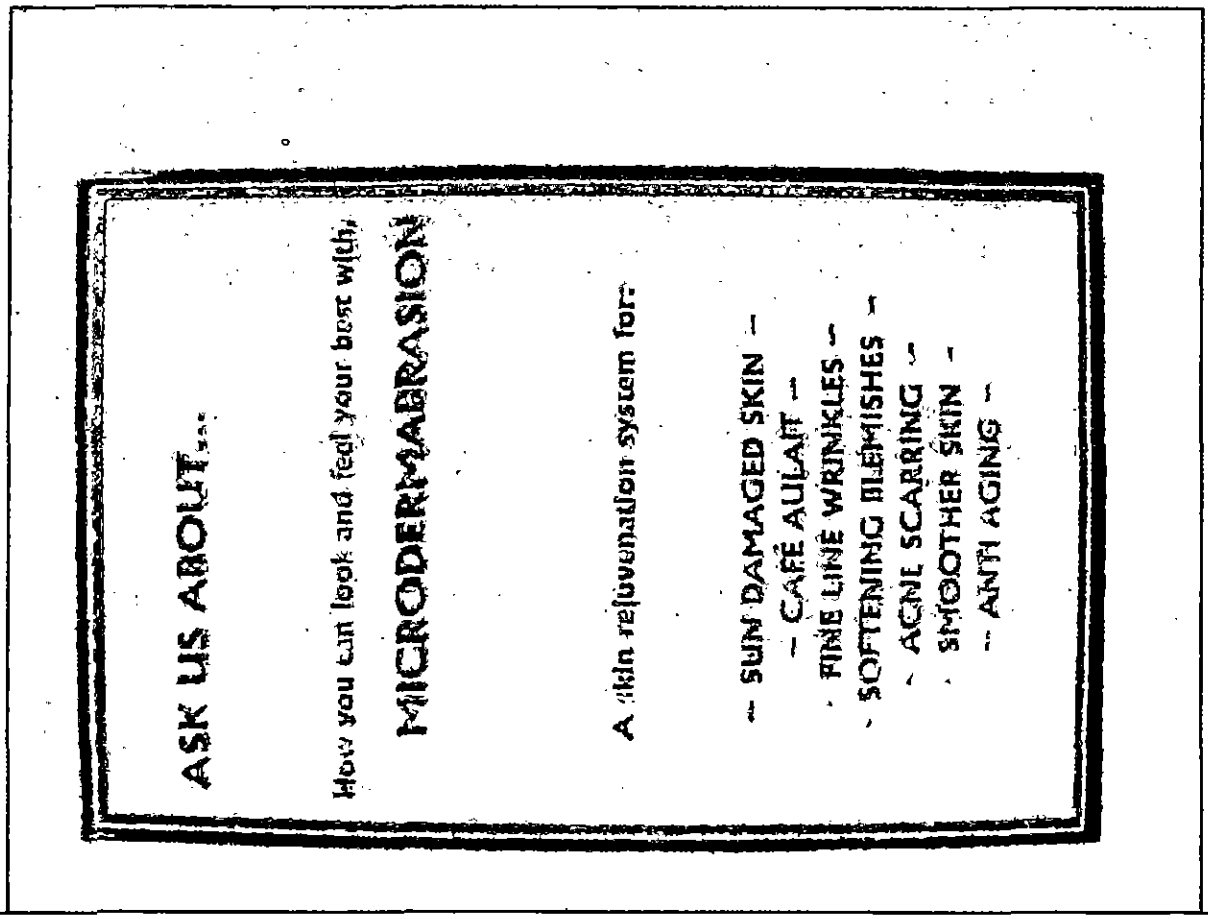

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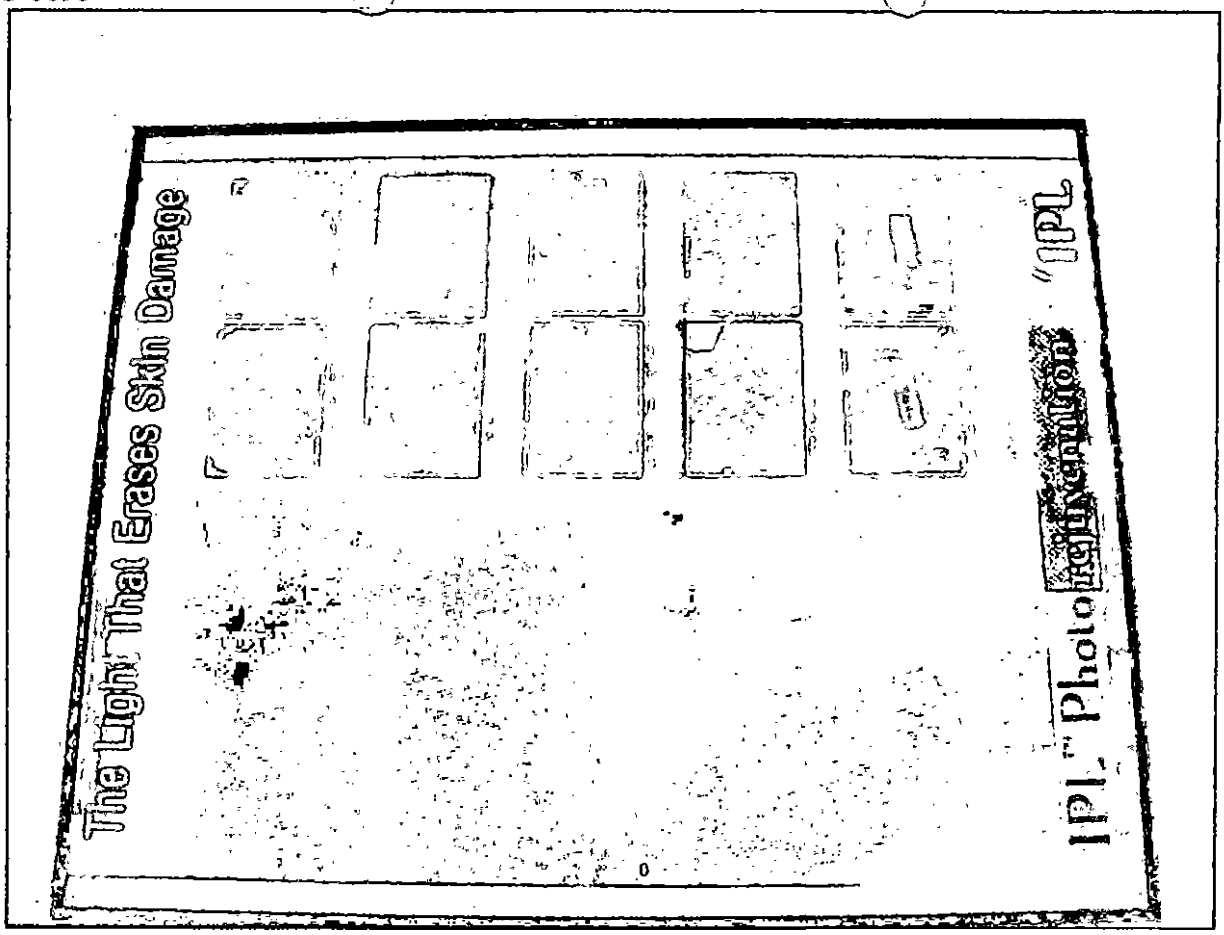

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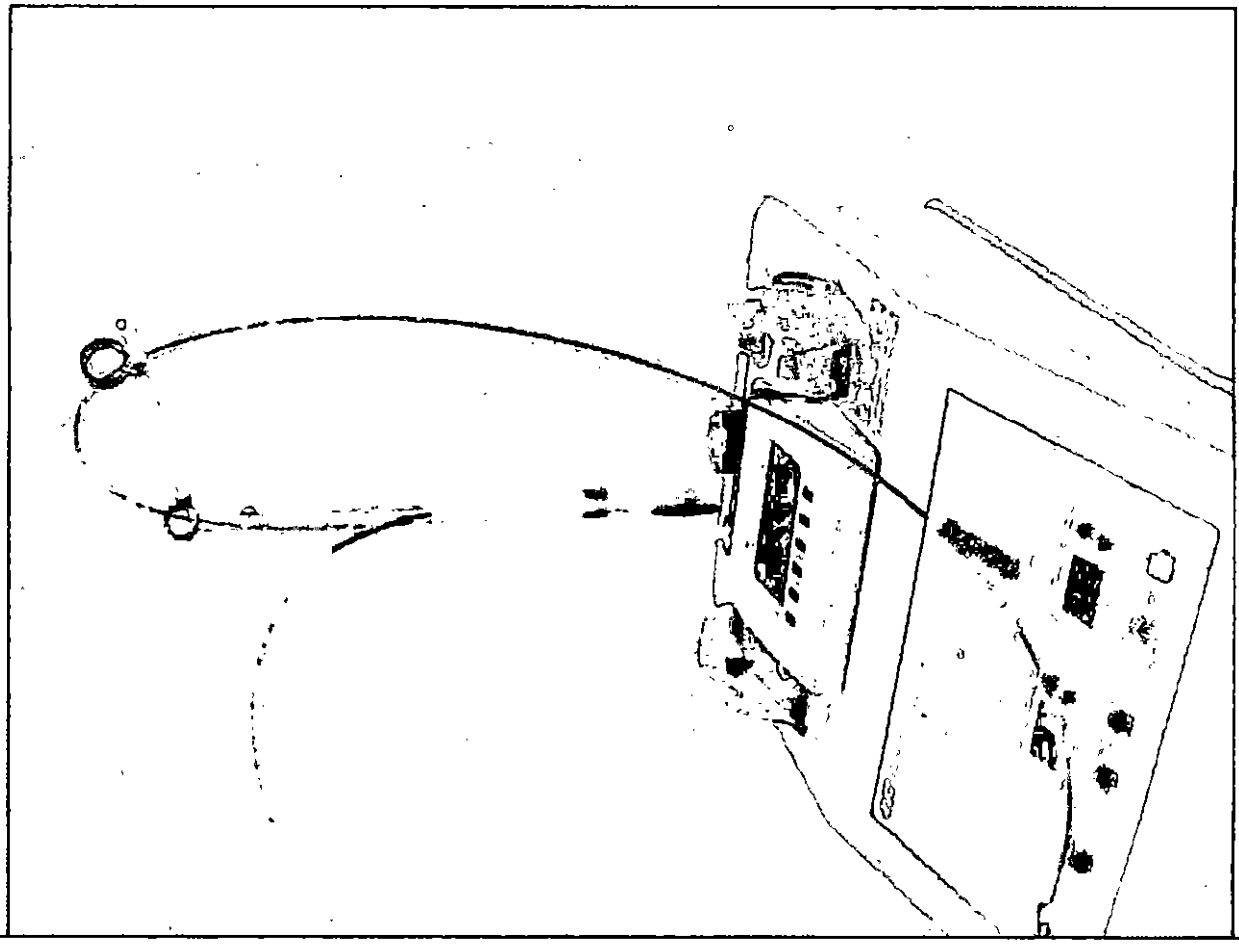

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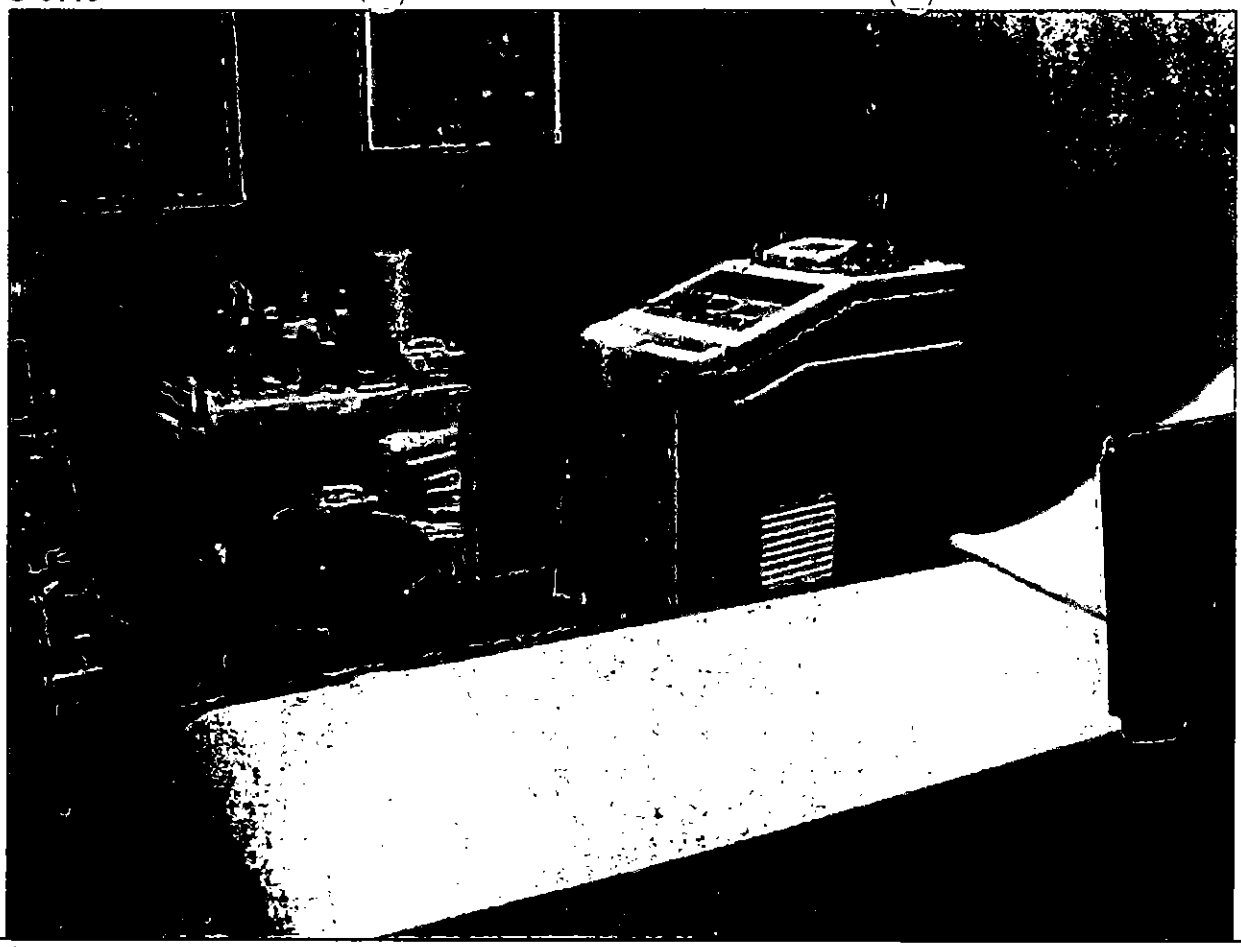

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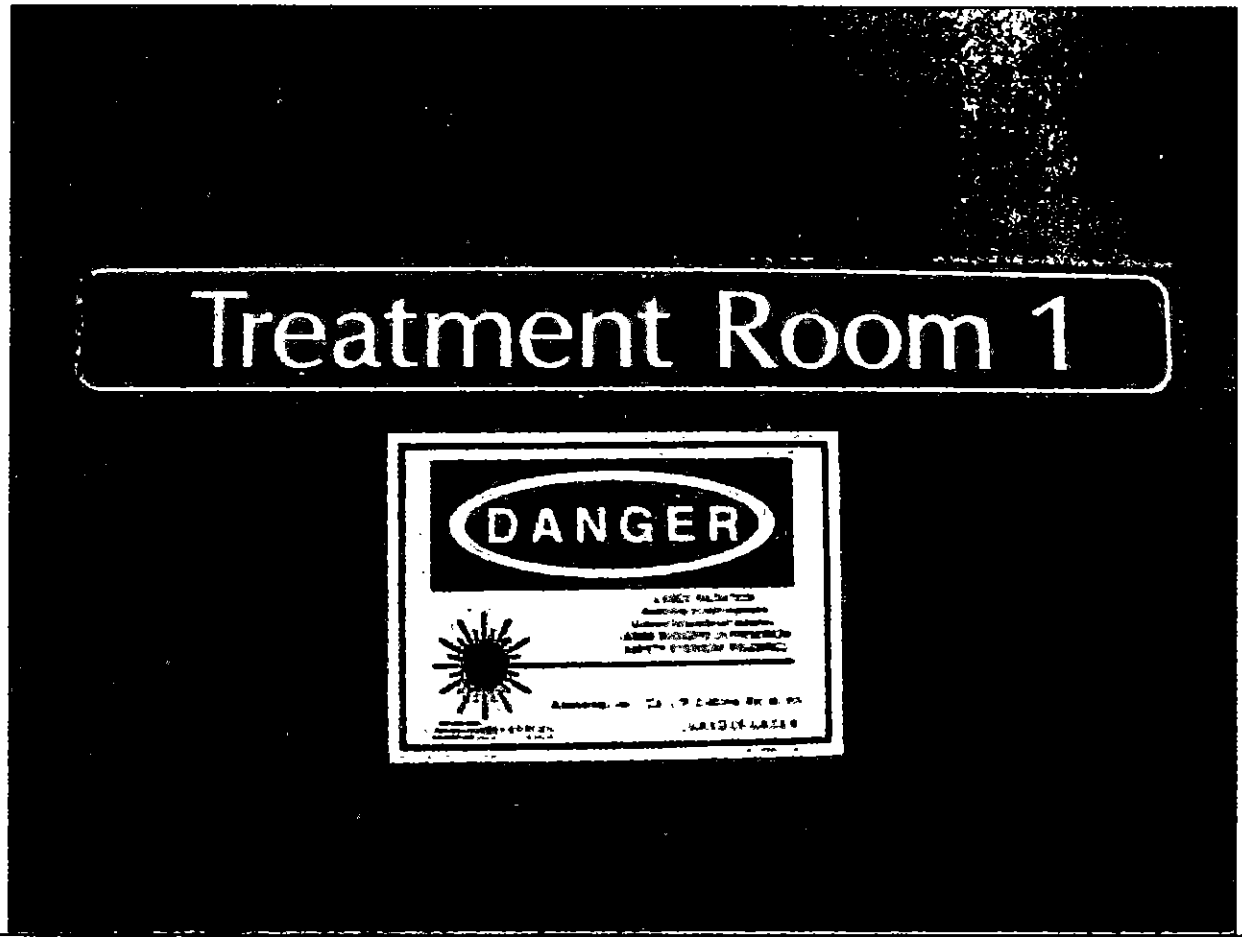

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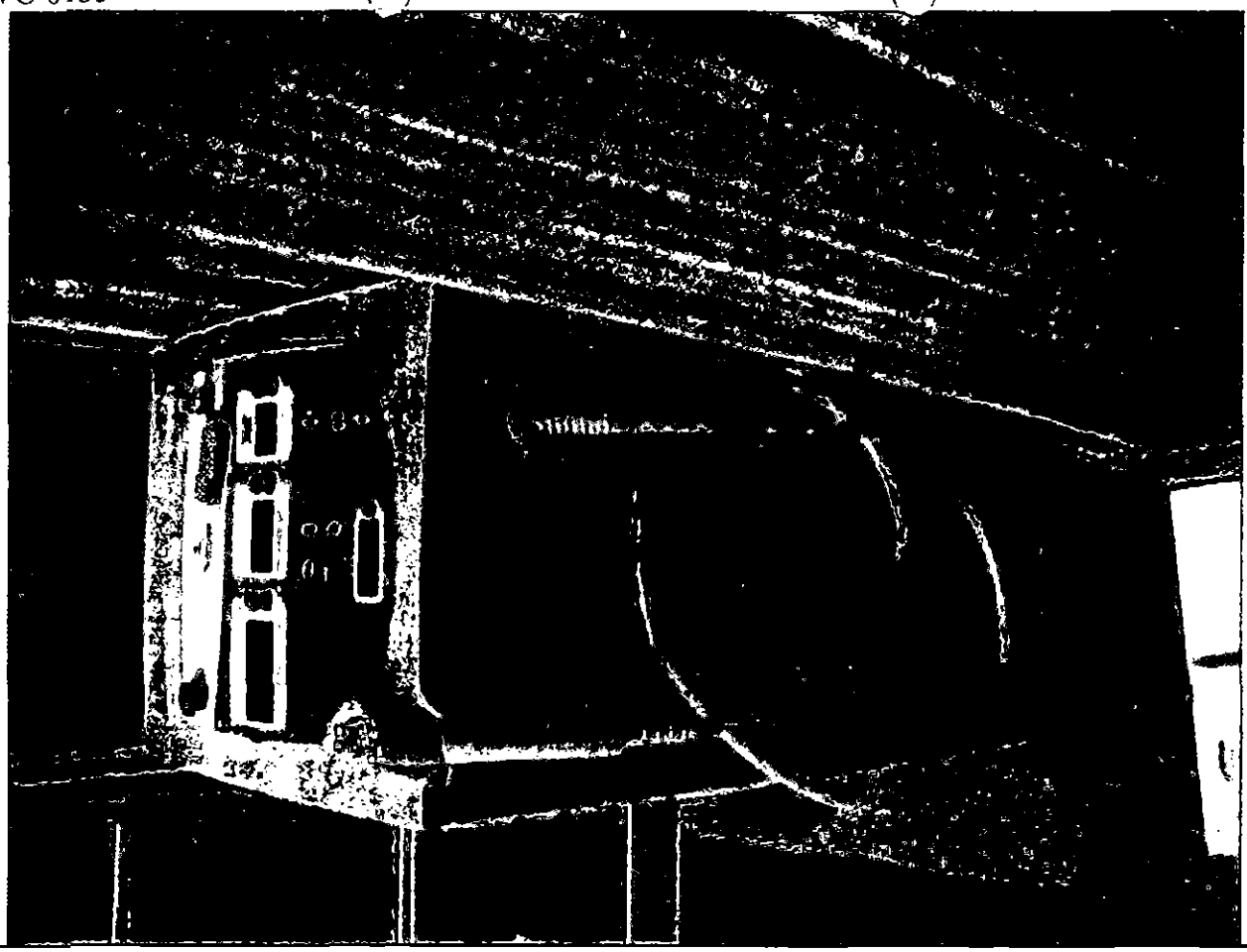

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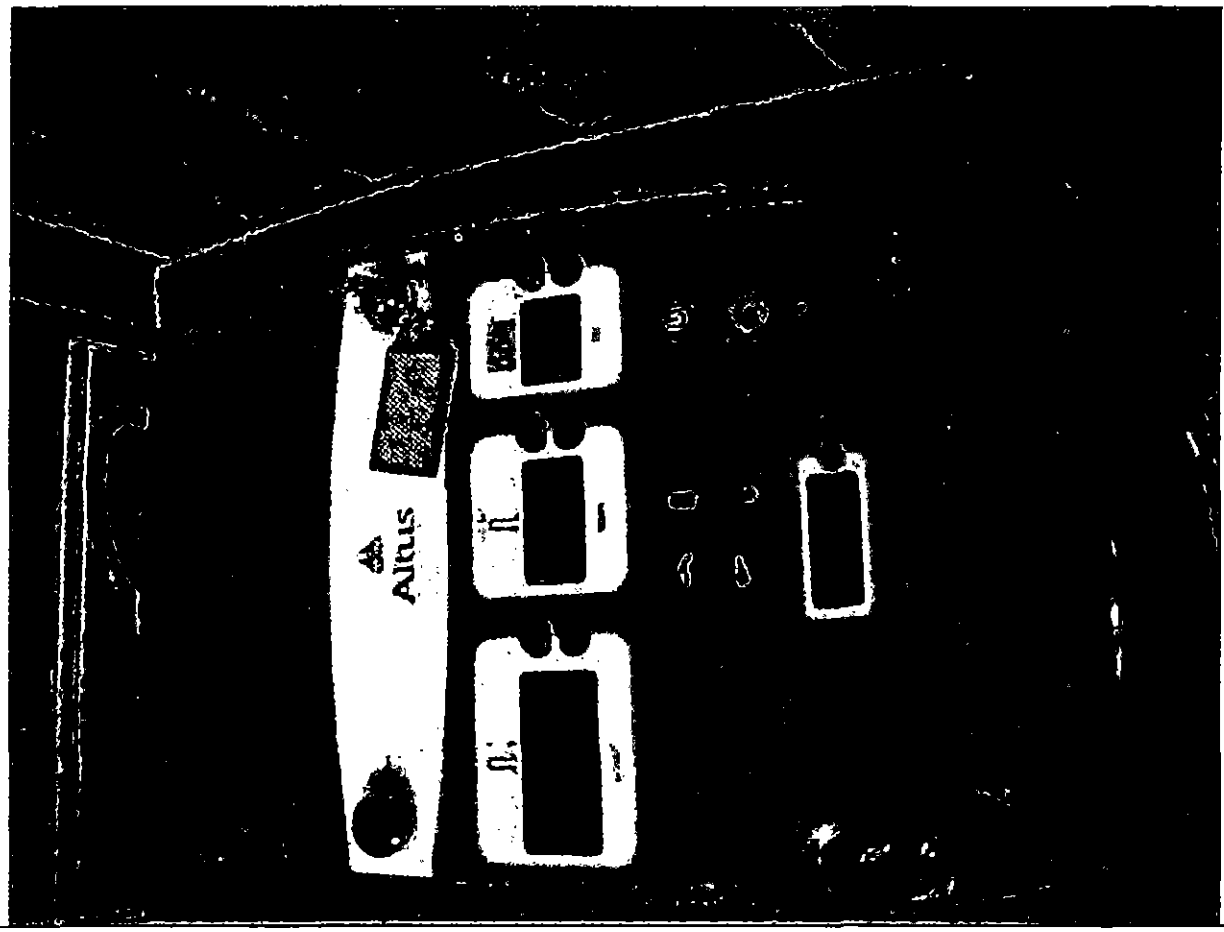

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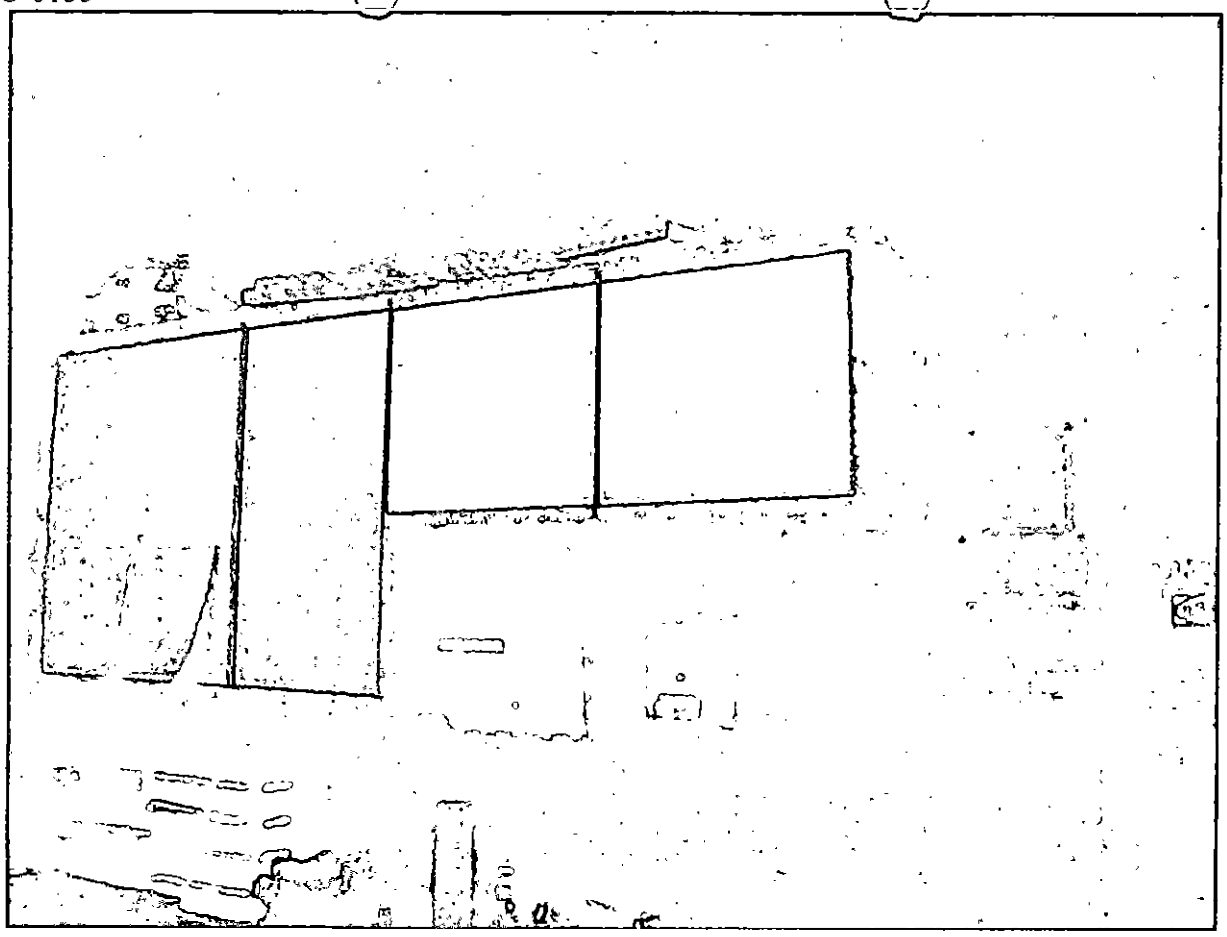

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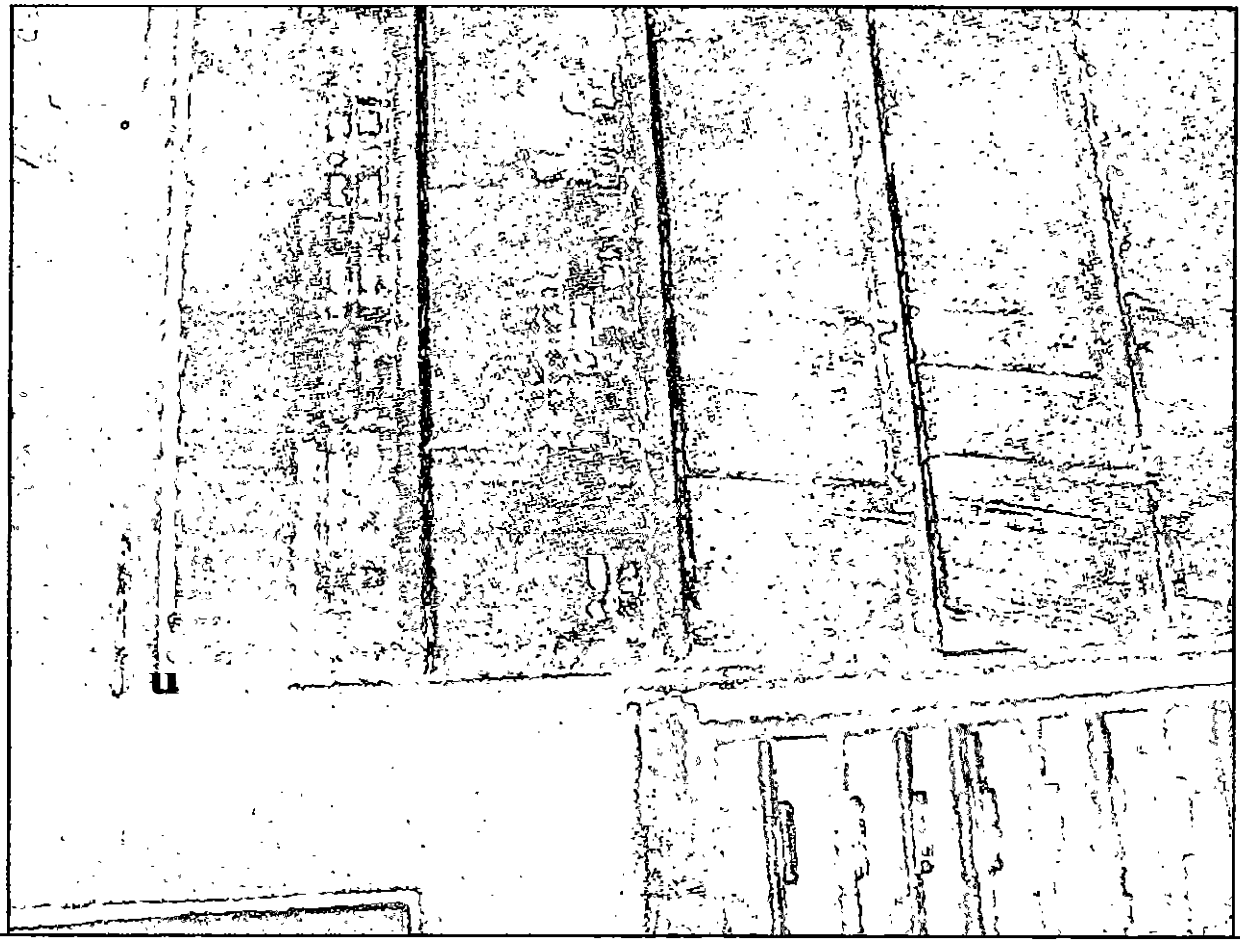

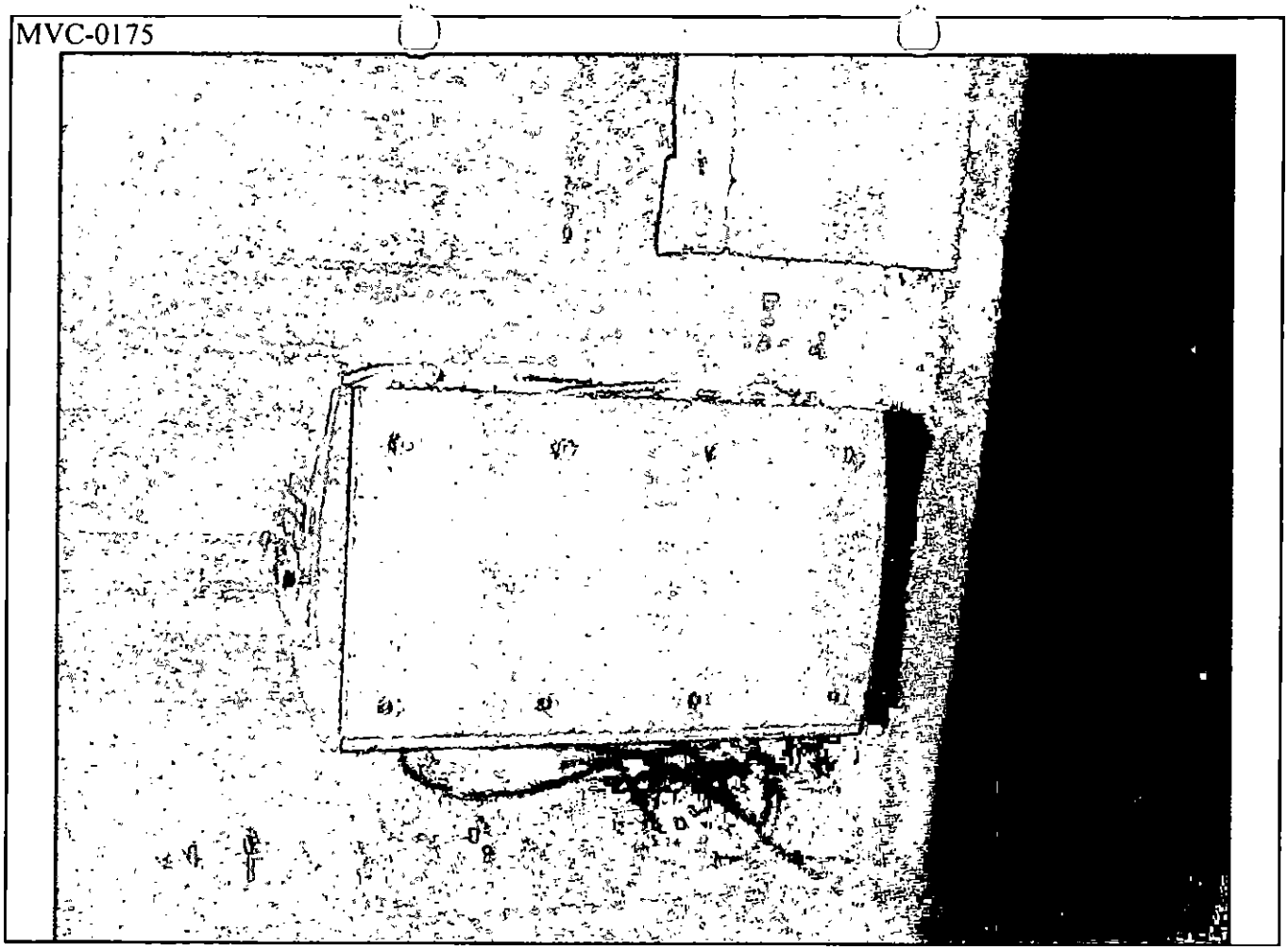
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Laser~Works

Reminders And Referrals

* For hair removal treatments remember your hair may not shed for 14-28 days following your treatment.
* For skin enhancement treatments, although you'll see some immediate changes and improvements, collagen stimulation gradually increases 14-28 days after your treatment. Skin texture and clarity will gradually improve 10-30 days following your treatment. Following a botox treatment you should see improvements within 72 hours, with gradual improvements for up to 30 days.
*Following a treatment, avoid exposure to the sun for about a week. If you need to be in the sun, you should apply sun block (SPF 30) in the areas you have treated.
* Temporary side effects such as blister are rare, however should a blister occur, apply an antibiotic ointment and notify our office at 206.575.8300 or 888.395.9990

* Your follow up treatment should be in the next 4-8 weeks depending on the type of treatment or area treated. We'll be calling you to confirm your appointment 24-48 hrs. in advance.

*If you have any further questions or concerns, please do not hesitate to call us. Thank you

The Staff at Laser~Works of Seattle

Remember: Refer family and friends for their free treatment

Name of referral: _____ Referred by: _____

LASER~WORKS OF SEATTLE

INFORMED CONSENT FORM

I understand that I will receive medical treatment from Laser~Works of Seattle. I also understand that clinical results may vary with different skin types, hair color and the location on the body for the treatments by Laser~Works of Seattle. The various treatments Laser~Works of Seattle provides include: laser hair removal and intense pulse light (epilation); intense pulse light and laser skin rejuvenation; Botox tm injections; micro dermabrasion; and treatment of vascular lesions and of visual veins with the use of intense pulse light and lasers. I further understand that there is a possibility of unusual side effects from any of these treatments such as scarring and permanent discoloration. There can also be short-term effects of any of these treatments such as reddening, mild burning, temporary discoloration of the skin. These possible effects have been fully explained to me: _____ (please initial).

I have made Laser~Works of Seattle aware of my use of tanning beds, sunless tanning products and any unprotected exposure to the sun in the last 14 days: _____ (please initial).

I will not hold Laser~Works of Seattle, its owners or its employees responsible for the hair reduction or skin treatment results I experience. I realize that my skin and hair is an organ unique to me and that therefore results may vary: But Laser~Works of Seattle has made me aware of their Guarantees _____ (please initial)

I understand that there are other options for hair removal and or skin rejuvenation such as electrolysis, waxing and chemical preparations rather than laser treatment. With this in mind, I choose laser treatment with Laser~Works of Seattle as a non-invasive treatment for epilation and or skin rejuvenation: _____ (please initial).

I understand that my treatments by Laser~Works of Seattle require payment and the prices and fee structure for treatment have been explained to me. **There are no refunds on treatments, or on treatments paid in advance:** _____ (please initial).

I further understand that Laser~Works of Seattle's quoted price for treatment is the price for each individual treatment or session, unless otherwise specified in writing by Laser~Works of Seattle. I understand that the services Laser~Works of Seattle provides sometimes require more than one treatment session, depending on the individual, and that the price quoted to me for treatment is the price for each individual treatment session, unless, again, otherwise specified in writing: _____ (please initial).

I am aware that Laser~Works of Seattle requires 24 hours notice of a cancellation or of a need to reschedule and that it is my responsibility to provide that notice. I agree to pay a minimum of $75.00, or half the scheduled treatment cost, if I fail to give the required 24 hours notice. If I choose to prepay my treatment session or sessions, I understand that I may forfeit one of my future sessions if I do not provide Laser~Works of Seattle proper notice (24 hours).

I have read and fully understand all the terms of this informed consent form, all my questions have been answered to my satisfaction and I agree to terms of this agreement:

Print patient name: _____

Signature: _____ Date: _____

Witness: _____ Date: _____

Laser~Works!

Patient Medical History

Name: _____ D.O.B. _____

Address: _____ City: _____ Zip:_____

Home Phone: _____ Business Phone: _____

Referred By: _____

Ethnic Origin: _____(For skin reaction to Laser)

Have you ever been diagnosed with the following?

Heart condition: _____ Bleeding Disorder: _____ Fainting Spells: _____
Diabetes: _____ Type? _____ Insulin Controlled? _____
Herpes: _____ Keloid Scars: _____ _____

Are you pregnant? _____
What medications are you taking? (including aspirin) _____
Are you taking any herbal preparations? (St Johns Wort) _____
How often do you use alcohol? _____ x-day _____ x-week ___ x-month
Allergies: _____

Skin type (when exposed to the sun **without protection** for about 1 hour)

1. Always burns, never tans _____
2. Usually burns, sometimes tans _____
3. Sometimes burns, sometimes tans _____
4. Always tans _____

When were you last exposed to the sun? (including tanning booth) _____
Do you use chemical tanning products? _____
Are you planning a holiday in the sun? _____

Reason for visit (areas to be treated) _____

Prior Treatment (if any)
Waxing _____ Body Part(s): _____
Electrolysis _____ Body Part(s): _____
Depilatory _____ Body Part(s): _____
Laser _____ Body Part(s): _____

After reading this article ***you may never shave or wax again!*** *New, break* **through** ***technology*** now coupled with pricing so affordable it doesn't make sense to remove hair any other way! Now for about the price of most hair removal methods that are only temporary you can ***permanently*** remove hair anywhere on the body. ***Nuvo laser skin clinics*** a national laser hair removal and skin rejuvenation service company is now offering state of the art laser hair removal treatments with the newest most advanced lasers, all at a price point that has the public lined up to finally get the solution to their unwanted hair! Laser hair removal is the process of covering an area with gentle pulses of light energy that are so safe that they are actually recognized as being beneficial to the skin. It is these gentle pulses of light that systematically and permanently treat hair follicles so that you can throw away the razors, creams, and hot wax forever!!

Nuvo laser skin clinics is challenging a traditionally overpriced and often times inconvenient service market with a common sense approach that has people thinking twice about their investment of money and time with only temporary hair removal methods. With pricing on small body parts only **$59.95** and large body parts only **$89.95**, Nuvo laser skin clinics has many people changing their hair removal habits as well as their minds about becoming hair free in areas they never before thought about maintaining with shaving or waxing.

Nuvo laser skin clinics uses only the newest, patented and FDA approved lasers combining the best hair removal technology of electrolysis with the best traditional hair removal lasers. This allows for treatment of all hair colors even gray and blondes and on any skin type even tanned skin!

The most amazing part of the process is that all of the treatments are performed with virtually no discomfort or pain, allowing clients to resume their activities immediately after treatment. There is simply no better way to achieve permanently that sleek, smooth, maintenance and worry free look then to walk into a ***Nuvo*** clinic and get started. With the procedure being so safe, the price affordable and the process so simple, you won't need a lengthy or sometimes embarrassing consultation. All of your personal needs and issues can be addressed in privacy with our highly skilled and trained technicians, however there are always treatment specialists at **Nuvo** on duty to quickly answer all of your questions and set up a program for each client.

If you're like many people who have struggled with embarrassing unwanted hair or would just like to keep your ***"look"*** without the hassle of constant hair removal maintenance you'll certainly be pleasantly surprised. ***Nuvo laser skin clinics*** are so sure of their client's results that they guarantee customer satisfaction. Talk to a treatment specialist today, get scheduled, and get started. ***Remember, you have everything to gain including your time, your confidence, and your freedom with nothing to lose except hair!!***

LASER~WORKS

HAIR REMOVAL AND SKIN REJUVENATION CLINICS

Small Body Parts at Only $59.95

Bikini Line
Chin
Under Arms
Sides of Face
Upper Lip
Front of Neck
Back of Neck
Navel
Hands
Feet
Brows

Large Body Parts at Only $89.95

Back
Shoulders
Chest
Abdominals
Upper Legs
Lower Legs
Extended Bikini
Buttocks
Upper Arms
Lower Arms

Call today to take advantage of our new pricing structure!

411 Strander Blvd, STE 107 • Tukwila, WA • 98188
Phone: 206-575-8300 • Fax: 206-575-6816

PHONE CONSULT QUESTIONS-LASER

Date:_____

Name: _____

Address: _____

City: _____ State: ____ Zip: _____

Phone: HM: _____ WK: _____ Cell: _____

Hair Color: _____ Complexion: _____

Have you been exposed to the sun or a tanning bed recently? **Y / N**

Have you waxed or used a chemical depilatory in the past 2 weeks? **Y / N**

What area(s) are you interested in treating? _____

How did you hear about us?
(publication, radio, TV, internet) _____

EVALUATION SET FOR: _____ **TIME:** _____

TREATMENT SET FOR: _____ **TIME:** _____

Patient Medical History
Vascular Treatment

Name:_____D.O.B._____

Address:_____City:_____ State___Zip:_____

Home Phone:_____Business Phone:_____

Referred By:_____

Ethnic Origin:_____ (For skin reaction to Laser)

Have you ever had the following?

Heart Condition:_____
Diabetes:_____ Type:_____Insulation Controlled:_____
_____
Bleeding Disorder:_____ Fainting Spells:_____
Keloid Scarring:_____ Herpes_____
Are you pregnant?_____ Hz skin cancer:_____
What medications are you taking (including aspirin)_____
_____
_____

Are you on any blood thinners?_____
Are you taking any herbal preparations? (St. John's Wort)_____
If yes, List:_____
_____

How often do you use alcohol?_____x-day_____x-week_____x-month
Allergies:_____

Skin type (when exposed to the sun without protection for about 1 hour)

1. Always burn, never tans_____
2. Always burns, sometimes tans_____
3. Sometimes burns, sometimes tans_____
4. Always tans_____

When were you last exposed to the sun (including tanning booths)?_____
Do you use chemical tanning lotions?_____
Are you planning a holiday in the sun?_____

Reason for visit (area to be treated)_____

Prior treatment (if any) Stripping_____ Body Part (s)_____
Ligation_____ Body Part (s)_____
Injection_____ Body Part (s)_____
Laser_____ Body Part (s)_____

POST TREATMENT- VASCULAR

- Apply ice, cold compresses as needed.
- Avoid strenuous exercise for 3 days.
- If blister occurs apply an anti-biotic ointment such as Neosporin and call clinic at 206-575-8300. Keep the area clean and lubricated.
- Changes in skin color may occur, notify clinic for treatment advice.
- It takes 2 to 6 weeks for coagulated vessels to dissipate.
- Compression stockings may be worn during the day for up to 3 days after.
- SPF 20 minimum should be worn.

PRE-TREATMENT- VASCULAR

- No sun or tanning bed exposure at least 3 days prior to treatment.
- No aspirin or blood thinning medication within 1 week.
- No history of coagulapathies (blood clots), diabetes, keloid scarring, history of skin cancer or herpes in treatment area.
- Pregnancy.
- Topical anesthetic may be purchased and applied prior to treatment (Lasercaine).
- Ice and cool-tip laser will cool the area.
- If prior treatment by injection or vein stripping, we do not recommend treatment with laser.
- Treatment may be repeated up to 3 times with laser; then other alternatives should be considered i.e. vein stripping or injections.

Laser~Works of Seattle

TREATMENT LOG

PATIENT NAME:_____TECHNICIAN:_____DATE:_____

AREAS TREATED _____TX # _____

PATIENT SKIN TYPE I___II___III___IV___V___ HAS TANNING CHANGED PATIENT'S SKIN TYPE UP THE FITZPATRICK CLASSIFICATION? ____YES____NO

LASER/EQUIPMENT **TIME ELAPSED DURING TX**_____

***AURORA** HR___OR SR___? OPTICAL ENERGY #_____ RF ENERGY#_____
IMPEDANCE SAFETY LIMIT (ISL) #____ SKIN TEMP. AVG. #____ HIGH #____ LOW #___

***QUANTUM/IPL** HR___OR SR___? PROGRAM 1, 2, 3 ? ___ WHICH HEAD? _____560 ,640,

695, 755 OPTICAL ENERGY/J'S #_____ MILLISECONDS#_____ PULSE COUNT#_____

* **ALEX** J'S#_____ MS#_____ 7MM___ 10MM___ ***ALTUS** J'S#_____ MS#_____

***MICRO DERMABRASION** AREA TREATED_____ POWER USED#_____

SKIN REACTION (TODAY'S TREATMENT)_____
_____

DOCUMENT % OF REDUCTION (HAIR REMOVAL ONLY) FROM BEFORE FIRST TREATMENT TO CURRENT % OF REDUCTION. %_____
SKIN REACTION FROM THE TREATMENT PRIOR TO TODAY'S(HAIR SHEDDING?, IMPROVEMENTS IN SKIN TEXTURE AND TONE?, ETC.) _____
_____

DID YOU MAKE THE PATIENT AWARE OF THE SERVICES AVAILABLE TO THEM AT LASER~WORKS THAT THEY ARE'NT CURRENTLY USING? DID YOU ASK A QUESTION VERY SIMILAR TO THIS ONE? "HAVE YOU HAD THE OPPORTUNITY TO LEARN ABOUT OUR LASER TREATMENTS FOR SKIN ENHANCEMENT, SPIDER VEINS, OR HAIR REMOVAL?" ____YES____NO
DID YOU ASK THE PATIENT ABOUT TREATING EXTRA AREAS, NOW (TIME PERMITTING) OR SCHEDULING THEM WHEN MORE TIME IS AVAILABLE? ____YES ____NO
*ANY ADDITIONAL NOTES ON THIS CLIENTS TREATMENT(S) _____
_____
_____
_____
_____

NEXT APPOINTMENT:___/____/____ BALANCE DUE:_____

LASER ~ WORKS!
Medical History
Skin Rejuvenation

1. What type of problem are you consulting for:

   - ☐ Sunspots
   - ☐ Wrinkles
   - ☐ Distended blood vessels (red spots that may be spidery in appearance)
   - ☐ Flushing of the skin
   - ☐ Large Pores

2. How many years have you noticed this problem?_____

3. At what age did your skin problem occur?_____

4. Are your present skin problems getting more pronounced? Y / N

5. Have you ever been treated for this problem? Y / N

6. Are you currently taking medication for your skin problem? Y / N

7. Are you pregnant, nursing or planning a pregnancy soon? Y / N

8. Do you have a history of keloid scarring? Y / N

9. Do you have a history of:

   - ☐ Septicemia
   - ☐ Herpes Sores
   - ☐ Easy brusability
   - ☐ Skin injury
   - ☐ Heart disorders
   - ☐ Bleeding disorders
   - ☐ Dark spots after pregnancy

10. Have you had any allergic reactions to anesthesia? Y / N

11. Do you have any allergies, especially skin related? Y / N
    If yes, please specify_____

12. Do you have any allergy to medication Y / N
    If yes, please specify_____

13. Are you taking any medication?

    - ☐ Aspirin
    - ☐ Hormones/contraceptive
    - ☐ Thyroid medication
    - ☐ Sedatives
    - ☐ Appetite depressants
    - ☐ Anti-coagulants
    - ☐ Cortisone
    - ☐ Insulin
    - ☐ Tranquilizers
    - ☐ Other (please specify) _____

Client Signature_____Date:_____

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LASER ~ WORKS!

Informed Consent – Microdermabrasion

I, _____consent to and authorize Laser ~ Works!, and it's staff, to perform microdermabrasion skin exfoliation and other services. My signature and initials below acknowledges that I have read the following precautions and understand the risks. I agree to receive the treatments or series of treatments listed as follows:

Areas to be treated: _____

_____

_____

_____ The nature and purpose of the treatment has been explained to me, and any question I have regarding this procedure have been explained to my satisfaction.

_____ I understand that with any treatment certain risks are involved and that any complications or side effects from known or unknown causes could occur. I freely assume these risks.

_____Possible side effects include, but are not limited to: Mild redness, extreme redness, bruising, local swelling, stinging, tenderness, dry skin, flaking, lightening or darkening of the skin, infections, pimples, bumpy appearance, and cold sores. Most side effects are temporary and generally subside within 72 hours.

_____If I am prone to Herpetic outbreaks, I have been advised to see my physician about a prescription for acyclovir, zovirax, or to take supplements of L-Lysine, Beta-Carotene and Folic Acid daily.

_____I have been advised to discontinue all AHA's, Glycolics, Rentin-A, Renova, or any exfoliating products for up to 72 hours post-procedure. I understand that I must use hydrating and soothing antioxidants for healing, and ice for swelling and inflammation reduction. Also, I understand there should be no sun exposure for 72 hours and the use of an SPF 30 at all times during treatment is advised.

_____ I have been advised and agree to avoid collagen injections for up to 10-14 days before any microdermabrasion treatment and 7 days after treatment.

_____ I am over 18 years of age or I have parental consent co-signed below.

_____ I will call to inform my practitioner of any complications or concerns I may have as soon as they occur.

Date _____

Patient Signature _____

Parental Signature _____

Witness _____

LASER ~ WORKS!

Informed Consent

Skin Rejuvenation

I understand that the IPL Quantum SR is an IPL device used for skin rejuvenation and that clinical results may vary in different skin types. I understand that there is a possibility of rare side effects such as scarring and permanent discoloration as well as short-term effects such as reddening, mild burning, temporary bruising and temporary discoloration of the skin. These effect have all been fully explained to me _____ (please initial)

Based on the clinical experience and discussion with other physicians we have found that those people who tend to sunburn rather than tan usually obtain good results on the first and subsequent visits. On the other hand, those who tan more easily tend to have more variation in their results. Some patient in this category will experience partial results and some will experience no improvement at all.

I understand that the treatment by the IPL Quantum SR system involves a series of treatments and the fee structure has been fully explained to me.

I also understand that there are options for cosmetic skin treatment that are available and each of these other options have fully been explained to me _____ (Please initial)

With this in mind, I am choosing to try the IPL Quantum SR non-invasive treatment for Photorejuvenation.

I have read and understand this agreement and all my questions have been addressed and answered to my satisfaction. I agree to the terms of this agreement.

I understand that there is a 24-hour cancellation policy, and a $75.00 minimum fee or half of the treatment cost will be charged. _____ (Please initial).

I understand that Laser – Works! Does not offer a money back policy. If for some reason I am unsatisfied with the results of my IPL treatment I realize that there will be no cash refunds._____ (Please initial)

Client's name (please print):_____

Signature:_____

Date:_____

Witness:_____

Laser~Works of Seattle

TREATMENT LOG

PATIENT NAME:_____TECHNICIAN:_____DATE:_____

AREAS TREATED _____TX # _____

PATIENT SKIN TYPE I__ II__ III__ IV__ V__ HAS TANNING CHANGED PATIENT'S SKIN TYPE UP THE FITZPATRICK CLASSIFICATION? ___YES___NO

LASER/EQUIPMENT **TIME ELAPSED DURING TX_____**

***AURORA** HR__OR SR__? OPTICAL ENERGY #_____ RF ENERGY#_____
IMPEDANCE SAFETY LIMIT (ISL) #____ SKIN TEMP. AVG. #____ HIGH #____ LOW #___

***QUANTUM/IPL** HR__OR SR__? PROGRAM 1, 2, 3 ? ___ WHICH HEAD? _____560 ,640,

695, 755 OPTICAL ENERGY/J'S #_____ MILLISECONDS#_____ PULSE COUNT#_____

* **ALEX** J'S#_____ MS#_____ 7MM__ 10MM__ ***ALTUS** J'S#_____ MS#_____

***MICRO DERMABRASION** AREA TREATED_____ POWER USED#_____

SKIN REACTION (TODAY'S TREATMENT)_____
_____

DOCUMENT % OF REDUCTION (HAIR REMOVAL ONLY) FROM BEFORE FIRST TREATMENT TO CURRENT % OF REDUCTION. %_____
SKIN REACTION FROM THE TREATMENT PRIOR TO TODAY'S(HAIR SHEDDING?, IMPROVEMENTS IN SKIN TEXTURE AND TONE?, ETC.) _____
_____

DID YOU MAKE THE PATIENT AWARE OF THE SERVICES AVAILABLE TO THEM AT LASER~WORKS THAT THEY ARE'NT CURRENTLY USING? DID YOU ASK A QUESTION VERY SIMILAR TO THIS ONE? "HAVE YOU HAD THE OPPORTUNITY TO LEARN ABOUT OUR LASER TREATMENTS FOR SKIN ENHANCEMENT, SPIDER VEINS, OR HAIR REMOVAL?" _____YES_____NO
DID YOU ASK THE PATIENT ABOUT TREATING EXTRA AREAS, NOW (TIME PERMITTING) OR SCHEDULING THEM WHEN MORE TIME IS AVAILABLE? ____YES ____NO
*ANY ADDITIONAL NOTES ON THIS CLIENTS TREATMENT(S) _____
_____
_____
_____
_____

NEXT APPOINTMENT:___/_____/____ BALANCE DUE:_____

CLIENT INFORMATION

Skin Rejuvenation

The following is some general information that may answer questions you might have with regard to treatment with the IPL Quantum SR.

1. Pain- some patients feel discomfort during treatment. Exposure is limited to an extremely short pulse. Patients report the treatment feels like a rubber band snap. This discomfort may range from mild to moderate and does not last long. A mild burning sensation may last for up to one hour. A cold compress or ice pack may be used if desired.

2. Heating- There is always the slight possibility of developing a crust or blister. This is superficial, and rarely results in any scarring and is treated like sunburn or any other blister.

3. Pigment Changes- The treated area will probably heal without any pigment changes, however, there is always the chance that hyper pigmentation (darker) or hypo pigmentation (lighter) areas may occur. These are temporary and will fade within 1 to 6 months. Sun exposure *must* be avoided 3 to 4 weeks prior to therapy and after, as exposure to the sun may intensify hyper pigmentation. It is rare that a change is ever permanent.

4. Scarring- it is vary rare and it is important to follow all the post treatment instructions carefully in order to prevent infection.

5. Excessive Swelling- May occur immediately after treatment especially if the face has been treated. This is temporary and not harmful. Cold packs or a hydrocortisone preparation may reduce the swelling.

6. Fragile Skin- The skin that has been treated should be treated gently for a few days. It should not be rubbed and when applying makeup, pat gently. Makeup can be applied immediately after treatment as long as the skin is not broken.

7. Bruising- May or may not occur. If bruising occurs it will normally clear up in 1 to 7 days.

8. We start with test areas to see how clients react to treatment. If the tests are satisfactory a session of treatments will follow.

SKIN REJUVINATION (IPL)
POST TREATMENT CARE

1. Quick warm showers are recommended. If areas are treated other than the facial area, hot baths are not advised for 24 hours.

2. If the skin is broken or a blister appears apply an antibiotic ointment. The area should be kept lubricated to prevent crusting or scabbing of tissue.

3. Cold compacts; aloe Vera or any other cooling preparation may be used to ease temporary discomfort.

4. Prolonged sun exposure is to be avoided for 3 weeks before treatment and then for the following 3 weeks. A total sun block, not a sunscreen; should be applied if it is impossible to comply. If further treatment is needed a commitment to stay out of the sun is necessary. If there is sun exposure there are certain minor complications that might occur.

5. Any questions or concerns please contact the clinic without hesitation.

6. Makeup can be applied as long as the skin is not broken. Makeup will also serve as an additional sun block.

Laser~Works of Seattle

TREATMENT LOG

PATIENT NAME:_____TECHNICIAN:_____DATE:_____

AREAS TREATED _____TX # _____

PATIENT SKIN TYPE I___II___III___IV___V___ HAS TANNING CHANGED PATIENT'S SKIN TYPE UP THE FITZPATRICK CLASSIFICATION? ____YES____NO

LASER/EQUIPMENT **TIME ELAPSED DURING TX_____**

***AURORA** HR___OR SR___? OPTICAL ENERGY #_____ RF ENERGY#_____
IMPEDANCE SAFETY LIMIT (ISL) #____ SKIN TEMP. AVG. #____ HIGH #____ LOW #___

***QUANTUM/IPL** HR___OR SR___? PROGRAM 1, 2, 3 ? ___ WHICH HEAD? _____560 ,640,

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***MICRO DERMABRASION** AREA TREATED_____ POWER USED#_____

SKIN REACTION (TODAY'S TREATMENT)_____
_____

DOCUMENT % OF REDUCTION (HAIR REMOVAL ONLY) FROM BEFORE FIRST TREATMENT TO CURRENT % OF REDUCTION. %_____
SKIN REACTION FROM THE TREATMENT PRIOR TO TODAY'S(HAIR SHEDDING?, IMPROVEMENTS IN SKIN TEXTURE AND TONE?, ETC.) _____
_____

DID YOU MAKE THE PATIENT AWARE OF THE SERVICES AVAILABLE TO THEM AT LASER~WORKS THAT THEY ARE'NT CURRENTLY USING? DID YOU ASK A QUESTION VERY SIMILAR TO THIS ONE? "HAVE YOU HAD THE OPPORTUNITY TO LEARN ABOUT OUR LASER TREATMENTS FOR SKIN ENHANCEMENT, SPIDER VEINS, OR HAIR REMOVAL?" _____YES_____NO
DID YOU ASK THE PATIENT ABOUT TREATING EXTRA AREAS, NOW (TIME PERMITTING) OR SCHEDULING THEM WHEN MORE TIME IS AVAILABLE? ____YES ____NO
*ANY ADDITIONAL NOTES ON THIS CLIENTS TREATMENT(S) _____
_____
_____
_____
_____

NEXT APPOINTMENT:___/_____/____ BALANCE DUE:_____

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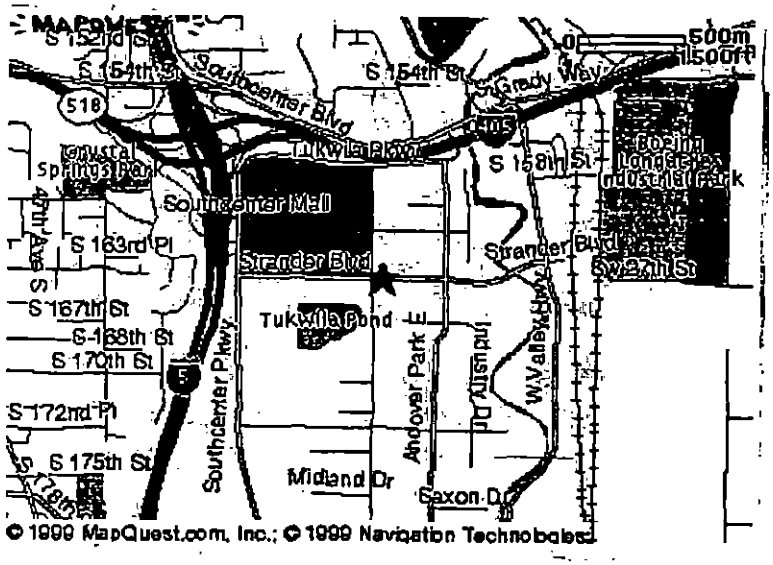
Laser~Works!

411 Strander Blvd. suite #107
Tukwila, WA 98188
Southcenter Professional Plaza
206.575.8300



From I-5 Southbound:

Take the Southcenter exit. At the end of the exit, go left on Southcenter Parkway. Stay in the right lane, and go right on 61st Ave. Turn left at the first light on Tukwila Parkway. Take a right at the second light on Andover Park West. At the second light on Andover Park West go left on Strander Blvd. Our office is located one block up on the right side. Southcenter Professional Plaza, in suite #107

From I-5 Northbound:

Take the Southcenter exit, and stay to the right of the Y. Take a right at the yield sign onto Southcenter Parkway. Then a left at the first light onto Strander Blvd. Follow the road past the mall, and the entrance to our lot is directly behind Barnes and Noble. Our office is located in the Southcenter Professional Plaza, suite #107.

From I-405 Southbound:

Take the West Valley Hwy. exit. At the bottom of the exit take a right heading south. Take a right on Strander Blvd. At the first light on Strander take a left on Andover Park East. Our parking lot is the first on the right.

Laser~Works!

Common Questions & Concerns

How does it feel?

Most patients tolerate the treatment very well and report that it is more comfortable than some of the other hair removal methods that they have tried. Patients who do feel discomfort during treatment often report the sensation feels like a rubber band snap ranging from mild to moderate. A warm sunburn feeling can also occur which usually subsides in less than an hour. For people who are extremely sensitive we have a topical anesthetic available to be applied before treatment.

What happens to my skin?

Your skin should not show any sign that you've had treatment for unwanted hair. Temporary side effects such as redness and slight swelling usually disappear within one half hour. The redness in the skin is caused by both the heat of the intense light and by the ice applied immediately following treatment. These side effects are again temporary and disappear quickly after treatment. Side effects such as a blister or pigment change are rare and easily treatable.

Is this permanent?

Yes, it is true. The follicles that have been effectively treated will not be able to produce new hair. It is also true that the follicles that produce your unwanted hair are only vulnerable to the lasers energy when they are actively growing. Therefore, a particular body part will usually require a series of treatments to treat follicles that were once dormant as they become active. This should produce a thinner re-growth of hair after each treatment.

If you have any further questions or to set up your first appointment, please call (206) 575-8300 or (888) 395-9990.

*Help us fit your schedule by calling and booking in advance of when you'd like to start your treatment as we are often booked out 2 weeks or longer.

Pre Treatment Instructions

*Please do not wax, bleach, tweeze, or use a chemical depilatory 2 weeks prior to and during laser treatment. Shaving is OK.

*Avoid tanning or sun exposure prior to treatment for a minimum of 7 days in treatment area. If light sun exposure is unavoidable prior to treatment, apply sun block (minimum SPF 30) in areas to be treated.

*Prior to treatment, the area should be shaved. If you are unable to shave the area that is to be treated, shaving can be performed here normally for a $25.00 fee.

*Please wear white cotton undergarments as the laser is potentially attracted to dark colors.

*Please notify our office if there has been any change in your health status, or if you have been prescribed antibiotics or steroids so we can reschedule treatment.

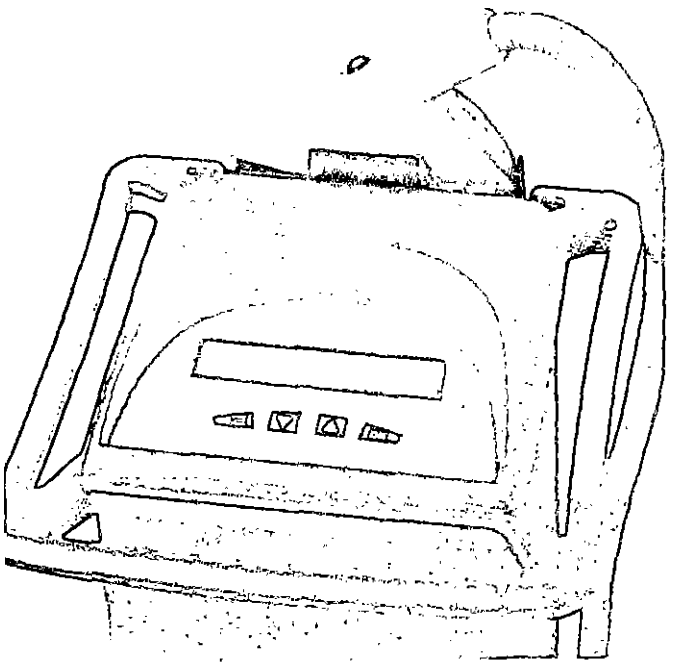
*We have provided directions to our office and a map on the reverse side for your convenience.

What makes Aurora different?

Aurora is based on a unique technology, called ELOS™, which utilizes the synergy of electrical energy and light to remove hair more gently, more effectively than any other system.

Aurora:

- Uses less energy, which means more safety (particularly if you have dark skin)
- Causes fewer, milder side-effects
- Is more comfortable before and after treatment
- Removes more hair in fewer treatments



The Aurora hair removal system is provided by:

Syneron Inc.
100 West Beaver Creek Rd. Unit 6
Richmond Hill, Ontario, Canada
L4B 1H2

Tel : (905) 886-9235
Fax : (905) 886-7046
Toll free: (866) 259-6661

email: gordonp@syneron.com
www.syneron.com

For more information, contact:

Syneron

AURORA

Say goodbye to unwanted hair

Gentle

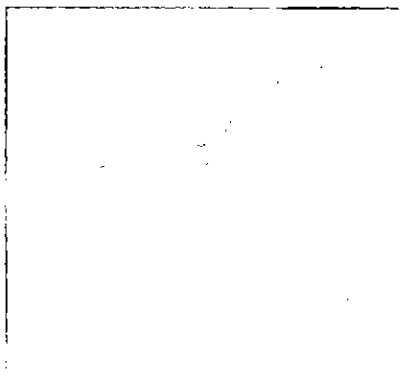
long-lasting hair removal

For men and women

000062

Syneron

Safe, effective hair removal is now within your reach



Removing unwanted hair from your face or body is now easier and more comfortable than ever before. Instead of shaving, tweezing, or waxing, and instead of going through painful electrolysis or laser treatments, you can now enjoy comfortable, long-term hair removal.

The Aurora™ hair removal system utilizes advanced technologies based on proven science. It treats unwanted hair safely, quickly and very effectively, eliminating the hair at root level and severely reducing re-growth.

Please talk to your doctor to answer any questions and to discuss your hair removal goals. Your doctor is best qualified to assess your suitability for this treatment.

Aurora Hair Removal System

How does Aurora work?
Aurora is a faster, gentler way to remove unwanted hair, with long-term results. It applies precisely controlled pulses of energy (electrical and light, with cooling), reaching into the hair follicles that lie beneath the skin. The energy heats the hair, right down to the bottom of the root, destroying it without damaging surrounding tissue or skin.

What does it feel like?
Each pulse, which lasts less than one second, produces a slight tingling feeling. In particularly sensitive areas, such as the upper lip, it may feel like a quick, light pinch.

Is it suitable for everyone?
Aurora enables your doctor to customize the treatment to exactly match your hair and skin color and type. As long as there is some color in your hair (even blond hair has enough color), then Aurora will be effective.

What about side effects?
The energies used by Aurora (electrical and light) are both commonly used in a range of medical and cosmetic procedures and have proven to be safe. Most people experience no side effects at all, though a few exhibit some short-term local reddening of the surrounding skin. You can return to your regular activities immediately after treatment, although it is advisable to keep the skin protected from exposure to direct sunlight for a short period of time.

How many treatments will I need?
Similar to other technologies, Aurora destroys hairs that are in the active growth phase, so repeat treatments will be needed to target hair that was not affected at the time of the previous treatments. The number of treatments you will need depends on your hair and skin color and type, and the part of your face or body treated. Your doctor can advise you about how long it will take to reach your hair removal goals. (Usually, four to six treatments are required.)

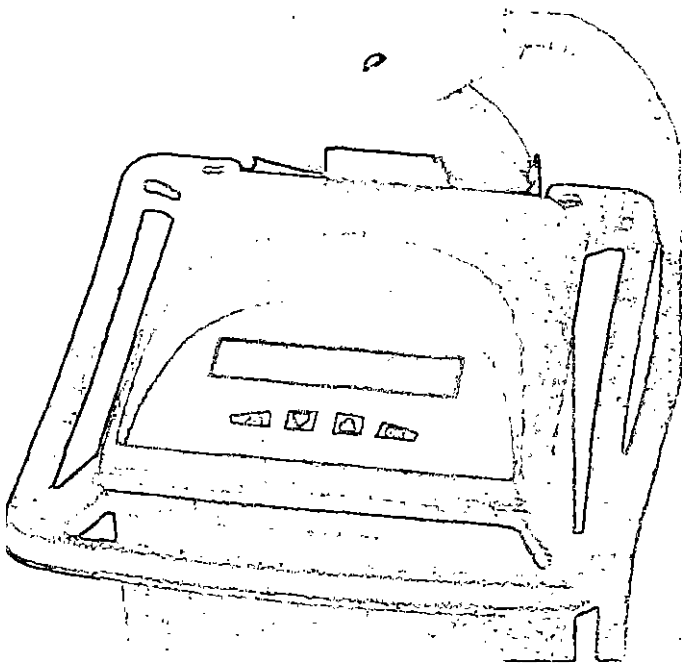
What results can I expect?
Aurora has been proven to be effective for long-term hair reduction with each individual treatment. At the end of the treatment program you can expect your skin to remain smooth.

What makes Aurora different?

Aurora is based on a unique technology, called ELOS™, which utilizes the synergy of electrical energy and light to improve the appearance of your skin more gently, more effectively than any other system.

Aurora:

- Uses less energy, which means more safety (particularly if you have dark skin)
- Causes fewer, milder side-effects
- Is more comfortable before and after treatment
- Treats a greater range of lesions



The Aurora skin rejuvenation system is provided by:

Syneron Inc.
100 West Beaver Creek Rd. Unit 6
Richmond Hill, Ontario, Canada
L4B 1H2

Tel : (905) 886-9235
Fax : (905) 886-7046
Toll free: (866) 259-6661

email: gordonp@syneron.com
www.syneron.com

For more information, contact:

Syneron

AURORA

Skin Rejuvenation

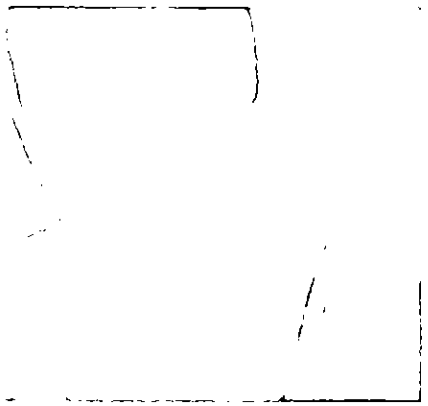
Enjoy

a smoother
more youthful
appearance

000063

Syneron

Skin renewal is now safer, gentler and more effective



Removing unattractive lesions is now easier, more comfortable than ever before. Instead of enduring painful procedures that use intense heat, light or laser, you can now enjoy comfortable, long-lasting skin renewal that produces the results you truly want.

The Aurora™ skin rejuvenation system utilizes advanced technologies based on proven science. It uses a unique combination of electrical energy, light and cooling to treat vascular lesions (facial telangiectasias, rosacea, etc.) and superficial pigmented lesions (such as age spots, solar lentigo, and others) safely, quickly and very effectively.

Please talk to your doctor to answer any questions and to discuss your skin renewal goals. Your doctor is best qualified to assess your suitability for this treatment.

Aurora Skin Rejuvenation System

How does Aurora work?
Aurora is a safer, gentler way to smooth and remove many types of facial skin imperfections. It applies precisely controlled pulses of energy (electrical energy and light, combined with cooling), removing a wide variety of vascular lesions and pigmented lesions without damaging surrounding tissue or skin.

What does it feel like?
Each pulse, which lasts less than one second, produces a slight tingling feeling. In particularly sensitive areas it may feel like a quick, light pinch.

Is it suitable for everyone?
Aurora can be effective on all types of skin and on a wide variety of lesions and skin irregularities. Your doctor will customize the treatment to exactly match your skin type and treatment goal.

What about side effects?
The energies used by Aurora (electrical and light) are both commonly used in a range of medical and cosmetic procedures and have been proven to be safe. Most people experience no side effects at all, though a few exhibit some short-term local reddening of the surrounding skin. You can usually return to your regular activities immediately after treatment, although it is advisable to keep the skin protected from direct sunlight for a short period of time.

How many treatments will I need?
Excellent results can be achieved in a single session. If multiple types of lesions are to be treated, several treatments, spaced three to four weeks apart, may be required. Your doctor can advise you about how long it will take to reach your skin renewal goals.

What results can I expect?
Aurora has been proven to permanently remove vascular lesions and superficial pigmented lesions. At the end of the treatment program you can expect your skin to be smoother and clearer.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

1511 3rd Ave., Suite 321 • Seattle, WA 98101

December 16, 2002

Marilyn Gelnette
411 Strander Blvd, Suite 108
Tukwila, WA 98188

RE: Unlicensed Practice of 2002-09-0004UI

Dear Ms. Gelnette,

The Washington State Department of Health (Department) is authorized under RCW 18.130 to investigate complaints concerning the alleged practice of Medicine by unlicensed persons. The Department has received information and an allegation you are advertising and practicing in medicine by providing treatment at "Laser Works," in Tukwila, WA.

It is the Department's position that if you are engaging in such conduct, as alleged, you must have a license to practice Medicine under chapter 18.71 RCW. According to our records, you are not licensed or certified to practice medicine in the state of Washington. Based on the above, an investigation has been initiated into the complaint we have received against you.

If found in violation, the Secretary of the Department of Health (Secretary) is authorized under RCW 18.130.190 to take the following actions against any person engaging in the unlicensed practice of a health care business or profession:

- *Issue a Cease and Desist Order to that person;*
- *Impose a civil fine in an amount up to **ONE THOUSAND DOLLARS** ($1,000.00) **per day** for each day that the person engages in unlicensed practice;*
- *Seek an injunction in Superior Court with regard to the unlicensed practice.*

Furthermore, please be advised that the unlicensed practice medicine is a criminal violation (RCW 18.130.190(7) and constitutes a gross misdemeanor for a single violation. Each subsequent violation, whether alleged in the same or in subsequent prosecutions, is a class C felony.

In some cases, we find that individuals are unaware of the need for a license or are unaware that what they are doing constitutes unlicensed practice. In such situations, once they have been advised of the legal requirements they have chosen to either become properly licensed or discontinue the illegal practice.

Further, you may feel that the conduct you are engaged in may not be a violation of state law. **We would encourage you to submit a letter to us in which you fully explain your practice so that we may better evaluate the complaint**. You are free to consult with and engage an attorney at your expense to represent you in this matter prior to making your written response. Your response(s) may be used if disciplinary action is deemed necessary. If you wish to have an attorney represent you, please have the attorney file a Notice of Appearance at the address listed below.

At this time, no formal charges have been filed against you as an unlicensed Health Care Provider. This is a preliminary investigation only. We have included a licensing requirement notification form and ask that you sign and return this form to us within **fourteen days from the date of this letter**. This may preclude further investigation on our part.

Thank you in advance for your cooperation. If you have any questions, please feel free to contact me at (253) 395-6709.

Sincerely,

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S, Suite 200
Kent, WA 98032

Enclosure

DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

LICENSING REQUIREMENT NOTIFICATION

I, Marilyn Gelnette, have been advised that the practice of Medicine within the state of Washington requires proper licensing by the Department of Health. By signing my name below and returning this notification to the Department, I acknowledge receipt of the necessity to be licensed to practice Medicine in the state of Washington. Furthermore, my signature below does not constitute an admittance that I have practiced without the proper licensure or certification.

Signed: _____
Marilyn Gelnette

Dated: _____, 200__.

12/17/18

Eric Moore
Laser Works of Seattle
411 Strander Blvd
Tukwila, WA 98188

Dear Eric:

The purpose of this letter is to advise you of my resignation as Medical Director for the LaserWorks clinic in Tukwila. My resignation is effective today.

At this time, I am unable to fulfill the true requirements nor accept the degree of responsibility that is associated with this position.

Sincerely

John Fisher MD
Seattle

10-25-02
MQAC Policy

Use of Lasers in Skin Care and Treatment

Most lasers used for medical or medical like purposes carry an FDA classification that restricts their sale and therefore use to someone with prescriptive authority such as an MD or Dentist. For our purposes here we are addressing only physicians. The Medical Commission holds that the use of a laser for treating or altering skin is the practice of medicine. The Commission however has allowed that the use of a laser for dermatologic purposes, such as hair removal, may be delegated provided a physician provides appropriate oversight.

One may not assume that an MD degree and a valid medical license qualifies a physician to provide appropriate oversight for the dermatologic use of a laser. "Appropriate oversight" here presumes and indeed requires that a physician possess a variety of prerequisite skills:

1) The physician must be skilled in the diagnosis, selection and treatment of patients with skin conditions being considered for treatment with a laser.
2) The physician must know the indications for and against the various treatments available for the specific skin condition to be treated with a laser and be familiar with the risks, effects and side effects of the proposed laser treatment.
3) The physician must be certifiably trained in the theory and use of medical lasers and have sufficient practical hands on experience in the use of a laser to make the oversight of another laser user real and meaningful.

Before delegating the use of a laser to another person the overseeing physician must also assure that that individual as well has both appropriate training in the area of basic dermatology, and demonstrable training and experience in the use of a laser. While this training and experience need not be identical to the physician's, it must be of sufficient similarity and scope to assure that the designee can provide laser based dermatologic services with skill and safety.

Skill in laser based hair removal does not imply skill with other laser cosmetic procedures such as the treatment of congenital and vascular conditions or tattoos. As the complexity of a skin condition increases so does the risk to the patient, and the involvement of a physician in the care of that patient must increase concomitantly. Procedures which carry unusual or significant risks based on age, diagnosis or location on the body should either not be delegated at all or should be delegated only to those individuals whose skills and experience are commensurate with the problem. Such individuals should ideally have a significant background of medical training as a nurse or physician assistant.

Finally the physician must be available to those he or she is overseeing. In this matter availability means that the physician is sufficiently available to the staff to assure appropriate patient selection and treatment. Availability may mean that the physician is in the office proper or in the building, or, it may mean that the physician is available by phone, depending on the facility, the patient, the diagnosis, the person providing the treatment and the nature of the treatment being provided. Again reasonable care and safety, not physician convenience, is the standard.

George Heye, MD
Medical Consultant
Medical Quality Assurance Commission
360-236-4795

(LR 12-18-02)

D CONCENTRATIONS AND
.Y AS A GUIDE. OTHER
NTRATIONS MAY BE USED
MAXIMUM RECOMMENDED

E AND TECHNICAL PROCEDU-
containing heavy metals, which
ions (mercury, zinc, copper, etc.)
r mucous membrane disinfection
incidents of swelling and edema.
n of multi-dose vials is desired,
91%) or ethyl alcohol (70%) is
nercially available brands of rub-
itions of ethyl alcohol not of U.S.P.
ls which are injurious to rubber
e used.
locaine-MPF indicate single dose
Paraben Free (MPF).

receding page.)

1/92 (13)
dentification Guide, page 304

℞

USP)
IRHYTHMIAS

l Injection, USP) is a sterile non py-
antiarrhythmic agent administered
direct injection or continuous infu-

are composed of aqueous solutions
ide. Lidocaine HCl ($C_{14}H_{22}N_2O \cdot HCl$)
d acetamide, 2-(diethylamino)-N-(2, 6
ohydrochloride.
ons, dosage and administration, pre-
reactions, see circular in package.)

Injection, Xylocaine (lidocaine HCl
ut preservatives is supplied in 5 mL, 50
ded Syringes and in 5 mL, 100 mg Am-

and for intravenous infusions, Xylo-
Injection, USP) without sodium chlo-
supplied in one and two gram 25 and
Vials are available with or without

ored at controlled room temperature

8/95

MPF™ (lidocaine HCl) ℞

HCl) Sterile Solution (Methyl-
local anesthetic agent and is ad-
jection. See INDICATIONS for

solution contains lidocaine HCl,
acetamide, 2-(di-
)-monohydrochloride.
(supplied in 5 mL ampules may be

and administration, pre-
(circular in package.)

Sterile Solution
100 mg, and sodium hy-
just pH to 5.0–7.0. A

Solution, 5 mL
prefilled sterile dispos-
unit containing a la-

30°C (59°–86°F).
8/90 (7)

XYLOCAINE® (lidocaine HCl) ℞
[zī'lo-caine]
4% TOPICAL SOLUTION
For topical application

DESCRIPTION

Xylocaine (lidocaine HCl) 4% Topical Solution contains a local anesthetic agent and is administered topically. See INDICATIONS for specific uses.
Xylocaine 4% Topical Solution contains lidocaine HCl, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride.
The 50 ml screw-cap bottle should not be autoclaved, because the closure employed cannot withstand autoclaving temperatures and pressures. Composition of Xylocaine (lidocaine HCl) 4% Topical Solution: Each ml contains lidocaine HCl, 40 mg, methylparaben, and sodium hydroxide and/or hydrochloric acid to adjust pH to 6.0 – 7.0.
An aqueous solution. NOT FOR INJECTION

HOW SUPPLIED

Xylocaine (lidocaine HCl) 4% Topical Solution 50 ml screw-cap bottle, cartoned (NDC 0186-0320-01). NOT FOR INJECTION.
Store at controlled room temperature: 15°-30°C (59°-86°F).
021802R01 Rev. 7/84 (1)

1.5% XYLOCAINE®-MPF ℞
with Dextrose 7.5%
(lidocaine HCl and dextrose Injection, USP)
For Spinal Anesthesia
in Obstetrics.

(For details of indications, dosage and administration, precautions, and adverse reactions, see circular in package.)

HOW SUPPLIED

Xylocaine-MPF 1.5% with Dextrose 7.5% (lidocaine HCl and dextrose Injection, USP), NDC 0186-0212-03, is supplied in 2 mL ampules in packages of 10.
Store at controlled room temperature 15°–30°C (59°–86°F).
021836R08 9/94(8)

5% XYLOCAINE®-MPF ℞
[zī'lo-cain]
(lidocaine HCl and dextrose Injection, USP)
WITH GLUCOSE 7.5%

(For details of indications, dosage and administration, precautions, and adverse reactions, see circular in package.)

HOW SUPPLIED

Xylocaine-MPF 5% with Glucose 7.5% (lidocaine HCl and dextrose Injection, USP), NDC 0186-0225-03, is supplied in 2 mL ampules in packages of 10.
Store at controlled room temperature 15°–30°C (59°–86°F).
021564R12 Rev. 4/95

XYLOCAINE® 2% Jelly (lidocaine hydrochloride) ℞
[zī'lo-caine]
A Topical Anesthetic
for Urological Procedures
and Lubrication
of Endotracheal Tubes

DESCRIPTION

Xylocaine (lidocaine HCl) 2% Jelly is a sterile aqueous product that contains a local anesthetic agent and is administered topically. (See INDICATIONS for specific uses.)
Xylocaine 2% Jelly contains lidocaine HCl which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride.
Xylocaine 2% Jelly also contains hydroxypropylmethylcellulose, and the resulting mixture maximizes contact with mucosa and provides lubrication for instrumentation. The unused portion should be discarded after initial use. Composition of Xylocaine 2% Jelly: Each mL contains 20 mg of lidocaine HCl. The formulation also contains methylparaben, propylparaben, hydroxypropylmethylcellulose, and sodium hydroxide and/or hydrochloric acid to adjust pH to 6.0–7.0.
(For details of indications, dosage and administration, precautions, and adverse reactions, see circular in package.)

HOW SUPPLIED

Xylocaine (lidocaine HCl) 2% Jelly is supplied in the listed dosage forms. NDC 0186-0330-01, 30 mL aluminum tube, Box of 1.
A detachable applicator cone and a key for expressing the contents are included.
NDC 0186-0330-36 5 mL aluminum tube, Box of 25

Store at controlled room temperature 15°–30°C (59°–86°F).
021838R14 Rev. 3/96
Shown in Product Identification Guide, page 304

5% XYLOCAINE®(lidocaine) ℞
[zī'lo-caine]
Ointment
A Water-Soluble Topical Anesthetic Ointment

DESCRIPTION

Xylocaine (lidocaine) 5% Ointment contains a local anesthetic agent and is administered topically. See INDICATIONS for specific uses.
Xylocaine 5% Ointment contains lidocaine, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-.
Composition of Xylocaine 5% Ointment
Each gram of the plain and flavored ointments contains lidocaine, 50 mg, polyethylene glycol 540 blend, polyethylene glycol 3350 and propylene glycol. The flavored ointment contains sodium saccharin, peppermint oil and spearmint oil.
(For details of indications, dosage and administration, precautions, and adverse reactions, see circular in package.)

HOW SUPPLIED

Xylocaine (lidocaine) 5% Ointment (NDC 0186-0315-21) is available in 35 gm tubes.
Xylocaine (lidocaine) 5% Ointment Flavored for application within the oral cavity, is dispensed in 3.5 gram tubes, 10 tubes per carton (NDC 0186-0350-03), and in 35-gram jars (NDC 0186-0350-01).
KEEP CONTAINER TIGHTLY CLOSED AT ALL TIMES WHEN NOT IN USE.
Store at controlled room temperature 15°–30°C (59°–86°F).
021709R13 1/94(13)

XYLOCAINE ® (lidocaine) OTC
[zī'lo-cain]
2.5% OINTMENT

(See PDR For Nonprescription Drugs.)

XYLOCAINE® (lidocaine) ℞
[zī'lo-caine]
10% Oral Spray
Flavored Topical Anesthetic Aerosol
For Use In The Oral Cavity

WARNING—CONTENTS UNDER PRESSURE

DESCRIPTION

Xylocaine (lidocaine) 10% Oral Spray contains a local anesthetic agent and is administered topically in the oral cavity. See INDICATIONS for specific uses.
Xylocaine 10% Oral Spray contains lidocaine, which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-.
Composition of Xylocaine (lidocaine) 10% Oral Spray:
Each actuation of the metered dose valve delivers a solution containing lidocaine, 10mg, cetylpyridinium chloride, absolute alcohol, saccharin, flavor, and polyethylene glycol.
And as propellants: trichlorofluoromethane/dichlorodifluoromethane (65%/35%).

WARNING

Contains trichlorofluoromethane and dichlorodifluoromethane, substances which harm public health and environment by destroying ozone in the upper atmosphere.
(For details of indications, dosage and administration, precautions, and adverse reactions, see circular in package.)

HOW SUPPLIED

NDC 0186-0356-01: A 26.8 mL aerosol container provides a total amount of 3.3 g (w/w) of the active ingredient lidocaine. Each actuation of the metered dose valve delivers 10 mg of lidocaine.
Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F. Avoid contact with the eyes. Inhalation and swallowing should be avoided.
Keep out of the reach of children.
Use only as directed; intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
STORE AT CONTROLLED ROOM TEMPERATURE 15°–30°C (59°–86°F).
Manufactured by Armstrong Laboratories, Inc., West Roxbury, MA 02132.

Continued on next page

About Lumenis™

A Strategic Partnership

Lumenis™, the leader in laser and light-based technologies for medical and aesthetic applications, is the product of a powerful union. When ESC™ Medical Systems Ltd. and Coherent Medical Group joined forces, we dramatically enhanced our ability to produce quality products and a new paradigm of service. Our separate innovations in laser and light-based technology produced a whole new category in healthcare; now our merged research and development paths promise to transform the future of life-enhancing science.

A History of Innovation

Our partnership brings together two long-term pioneers in the application of light to aesthetic and medical procedures. ESC, founded in 1991, introduced IPL™ (Intense Pulsed Light™) technology for medical and aesthetic treatments. In 1998 it acquired Sharplan Laser Industries, also a strong force in the medical laser industry since 1973. ESC's earliest systems used IPL technology to treat vascular and pigmented lesions on the face and leg. Physicians around the world quickly adopted this technique. Today, the company supplies more than 35 main-line products and some 600 accessories to customers in more than 75 countries. Coherent, founded in 1966, has a rich heritage of excellence in engineering, and its lasers are considered the "gold standards" for both medical and aesthetic applications.

Coherent pioneered the use of lasers in ophthalmology; it introduced the first holmium laser for use in orthopedics and urology, including the treatment of kidney stones and Benign Prostate Hyperplasia (BPH); and it has consistently led in the use of CO_2 lasers for cosmetic skin resurfacing.

A Commitment To Our Customers

Lumenis maintains a strong commitment to customer service and support. Its commitment to research and development is exemplified by the largest R&D budget in the industry and through strategic alliances with world recognized research organizations.

Lumenis is well-positioned to continue and even improve upon both of these traditions.

The Ultimate Consolidation

We intend to be a potent force for innovation - providing quality products, responding to the needs of the medical community and its patients and, above all, keeping the promises we make. As pioneers in the field of laser and light-based medical science, we now strive to meet our leadership obligations through innovation, superior service and a commitment to excellence.

Aesthetic

LUMEN

FAQs | VALUE ADDED | NEWS | SERVICE & SUPPORT | LINKS | CONTA

The Science of Light | Clinical Applications | Product Solutions | Workshops & Conferenc

Enhancing Life. Advancing Technology.™

Aesthetic Medicine has made dramatic advances in the past twenty years, and Lumenis™ laser and light-based technologies have been there every step of the way. By uniting the research excellence, clinical innovations and powerful products of ESC™ Medical Systems, Ltd. and Coherent Medical Group, we dramatically enhanced our ability to develop dynamic new products and to create a new paradigm of customer service.

Please Select Area of Interest

PRODUCT SOLUTIONS:

Select a Product

CLINICAL APPLICATIONS:

Select an Application

Latest News

* Attend our Webinar on treating Pseudofolliculitis Barbae!
* Lumenis Announces Lawsuits Against Syneron Unfair Trade Practices and Patent Infringement
* Lumenis Receives FDA Marketing Clearance fo ReLume

PATIENT INFORMAT

powered b

LightSheer

VascuLight

IPL Quantum SR

IPL Quantum DL

UltraPulse Encore

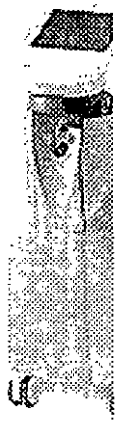
ClearLight

SkinScape

BClear

ReLume

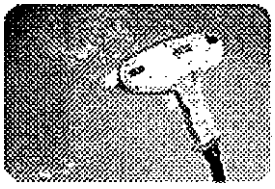
IPL™ Quantum DL



UPGRADEABLE AND AFFORDABLE Nd:YAG SYSTEM

Clinically proven for the effective treatment of deeper and other vascular lesions.

- Leg veins
- Larger telangiectasias
- Hemangiomas
- Extended life handpiece--at least 10 times longer life than older designs--means cost-effective operation
- Integrated contact cooling for optimal control of treatment site cooling
- Multiple Synchronized Pulsing™ Nd:YAG technology controls the effect of high energy by interspersed cooling periods, maximizing heating of the vessel while protecting the epidermis
- Can be upgraded to perform IPL Skin Treatments using Photorejuvenation and/or IPL Photoepilation
- Fast, easy operation. Two-second repetition rate for rapid treatment; easy-to-use touch screen, and user-friendly software with advanced user capabilities



The new IPL Quantum DL system incorporates proven, highly effective Nd:YAG technology with the reliability and simplicity you expect from Lumenis' IPL Quantum series. Its modular, upgradeable design protects your investment by allowing you to step up to IPL skin treatment, hair removal and other upgrades as they become available.

Unique, Multiple Synchronized Pulsing and integrated cooling permits optimal safety, efficacy and patient comfort.

RESULTS

Click for a larger view

Before After

Click for a larger view

Before After

Click for a larger view

Before After

MORE DETAILS

- Leg Veins FAQ

SPECIFICA

Specific English

Klicken Deutscher In Zusätzliche [Informatione

L'inform français L'information supplémenta

Informa: Informazioni supplementa

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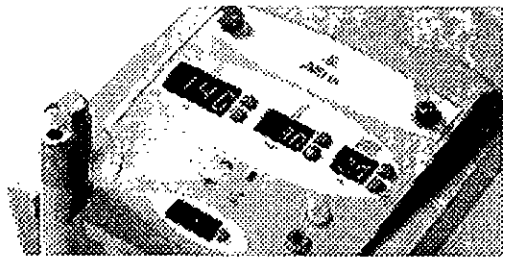

Market Overview

Market Overview

Laser Genesis

CoolGlide® Family

CoolGlide® Vantage

CoolGlide® Excel

CoolGlide®

Genesis

Medlite C Series

Clinical Studies

Laser Genesis Pre & Post

Hair Removal Pre & Post

Vascular Pre & Post

Leg Veins:
Approximately 50% to 60% of men and women worldwide have unsightly leg veins. sclerotherapy is still considered the treatment of choice for the removal of super leg veins, there are known side effects, and some veins will not respond. CoolGli and CoolGlide® Excel can provide a safe and effective method of treatment that requires no painful injections.

Facial Telangiectasia:
Facial telangiectasia or unsightly blood vessels on the face also affect both men a women. This condition may be due to sun damage, smoking, heredity, hormones even steroid therapy. Treatment for such a condition is typically for cosmetic rea and multiple treatments are usually necessary but not always effective.

Hair Removal:
The removal of unwanted hair has traditionally been achieved with techniques su shaving, waxing, tweezing, electrolysis, or the use of depilatory creams and lotio these, the only technique that provides a long-lasting solution is electrolysis. Hov this is performed on one hair follicle at a time and makes the treatment of even areas very time consuming.

Laser-based solutions were first introduced in the United States in 1995 with the promise of long-lasting hair removal achieved in a much more rapid manner than electrolysis. Lasers are well suited for the removal of unwanted hair, because wi right selection of parameters, they can be used as a non-invasive method to disal hair structure without damaging the surrounding dermis and epidermis. Numerou follicles can be treated simultaneously allowing for rapid coverage of large areas

Even though laser hair removal has generated great enthusiasm and experienced growth, many limitations remained prior to the introduction of the CoolGlide® aesthetic laser system. Existing products were not well suited to treat a broad ra the population, typically had a high ownership cost, and had other significant performance limitations as well. The laser-based hair removal market was in nee affordable system that allowed the safe treatment of a wider range of skin types the ability to effectively and rapidly treat large areas. Such a product would serv catalyst to make this superior treatment available to a greater patient populatio worldwide.

CoolGlide® Cleared For Permanent Reduction

The CoolGlide® and CoolGlide® Excel are the first long pulse ND:YAG laser syster receive clearance to claim permanent hair reduction. According to the FDA, perm hair reduction can be defined as the long-term stable reduction in the number of re-growing after a treatment regimen.This capability has been demonstrated in a term clinical study.

Format for printing. Email this article to an associate.

Laser Facts

Introduction
Hair Removal
Wrinkle Treatment
Dental Treatment
Eye Surgery
Other Medical Uses
Practitioners
Biostimulation Lasers
Laser Radiation Safety

Medical lasers have been used for dermatology applications such as removal of port wine stains, dark spots, tattoos, acne scars and other blemishes for over a decade. Lasers are used for a growing number of cosmetic procedures including hair removal, treatment of wrinkles, and tooth whitening. For risk information on the specific laser treatment that you are considering, ask your physician or operator for the patient labeling for the laser device.

HAIR REMOVAL

The popularity of laser hair removal has increasingly grown, prompting many laser manufacturers to conduct research and seek FDA clearance for their lasers for this indication. The market is growing so quickly that FDA cannot maintain an up-to-date list of all laser manufacturers whose devices have been cleared for hair removal, as this list continues to change. To learn if a specific manufacturer has received FDA clearance, you can check FDA's Website at http://www.fda.gov/cdrh/databases.html under the 510(k) database. You will need to know the manufacturer or device name of the laser. You can also call FDA's Center for Devices and Radiological Health, Consumer Staff, at 1-888-INFO-FDA or 301-827-3990, fax your request to 301-443-9535 or send an e-mail to: DSIMCA@cdrh.fda.gov.

Manufacturers should be aware that receiving an FDA clearance for general permission to market their devices does not permit them to advertise the lasers for either hair removal or wrinkle treatment, even though hair removal or wrinkle treatment may be a by-product of any cleared laser procedure. Further, manufacturers may not claim that laser hair removal is either painless or permanent unless the FDA determines that there are sufficient data to demonstrate such results. Several manufacturers received FDA permission to claim, "permanent reduction," NOT "permanent removal" for their lasers. This means that although laser treatments with these devices will permanently reduce the total number of body hairs, they will not result in a permanent removal of all hair. The specific claim granted is "intended to effect stable, long-term, or permanent reduction" through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing after a treatment regime, which may include several sessions. The number of hairs

regrowing must be stable over time greater than the duration of the complete growth cycle of hair follicles, which varies from four to twelve months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treatment area.

FDA does not make comparisons between systems or how well or safely they work compared to another company's system. FDA does not recommend one laser system over another.

Lasers cleared for body hair removal are also cleared for facial hair removal.

WRINKLE TREATMENT

Lasers are also being used to treat wrinkles. Several manufacturers have received FDA clearance to claim treatment of wrinkles, while others may claim skin resurfacing. Patients have reported reddening of the skin, which lasted from one to four months. Pain was mild and could be treated with over-the-counter analgesics. Consumers should bear in mind that skin abrasion, whether achieved by lasers, chemicals or abrasive materials, means removing one or more layers of skin, which can be painful and could cause redness, swelling or scarring, depending on how each person heals.

People considering this procedure should consult a dermatologist or the manufacturer to determine whether or not they would be good candidates. Be sure to ask your dermatologist for a copy of the patient labeling for the specific laser device used to understand the risks.

DENTAL TREATMENTS

Several manufacturers have received clearance for argon and carbon dioxide lasers to activate tooth-bleaching solutions and to treat gum disease. Several lasers have clearance for hard tissue use on teeth. On May 7, 1997 FDA cleared the first laser system for treating tooth decay, an erbium YAG laser made by Premier Laser Systems. Recently, American Dental Technologies received FDA clearance to market its laser for caries removal; it is not cleared to remove tooth enamel.

Studies conducted by the manufacturers showed that the laser is as safe and effective as a high-speed drill for removing dental decay and preparing a cavity for a filling. The manufacturer's study indicated that fewer patients needed anesthetic for pain. Any inquiries regarding this method of cavity treatment should be directed to your dentist, who can provide you with patient labeling including risks for the specific laser.

EYE SURGERY

Lasers may be used to remove tissue in eye surgery as well. This may include removing tumors, cataracts, or proliferating blood vessels common to diabetic retinopathy. Several manufacturers have lasers cleared for photorefractive keratectomy (PRK) and Laser-Assisted In Situ Keratomileusis (LASIK), two procedures for correcting nearsightedness, farsightedness, and astigmatism. The laser is used to reshape the cornea and focus images correctly on the retina. For information on eye surgery and which lasers have received clearance, you can access FDA's Website at: http://www.fda.gov/cdrh/LASIK. As with the other types of patient labeling, be sure to ask the surgeon for the patient labeling for the specific laser device being used.

OTHER MEDICAL USES

Some lasers have been cleared for medical uses such as removing tissue. Because heat from lasers cauterizes blood vessels, there is less bleeding compared to scalpel use. Usually, FDA gives manufacturers general surgical clearances; in order to promote the laser for a specific surgical procedure, manufacturers must first provide FDA with clinical evidence that their lasers are safe and effective for that specific procedure. If you wish to learn whether a specific laser has been cleared for a specific indication, you may contact FDA's Consumer Staff. You will need to provide the name of the manufacturer and the specific product name of the device before contacting the Consumer Staff.

PRACTITIONERS

States regulate who can use lasers for various therapeutic procedures. Medical lasers are prescription devices available for sale only to licensed practitioners. You should check with your state medical licensing board to determine who qualifies as a licensed practitioner in your state.

BIOSTIMULATION LASERS

Biostimulation lasers, also called low level laser therapy (LLLT), cold lasers, soft lasers, or laser acupuncture devices, were cleared for marketing by FDA through the Premarket Notification/510(k) process as adjunctive devices for the temporary relief of pain. These clearances were based on the presentation of clinical data to support such claims. FDA will consider similar applications for these and other claims with the decision to require clinical data being made on an individual basis, taking into consideration both the device and the claim. Please note that FDA law and regulations contain provisions that permit limited distribution of unapproved devices for use in clinical investigations. There are numerous clinical investigations being conducted in this and other countries to determine safety and efficacy with these devices for the intended uses that are proposed.

Certain unapproved, nonsignificant risk Class III medical devices, including biostimulation lasers, may only be distributed in the U.S. to individual practitioners who have approval from an Institutional Review Board (IRB) for the investigational clinical use of the device, or to investigators participating in a study under an Investigational Device Exemption (IDE) approved by the Center for Devices and Radiological Health (CDRH), as specified in the Code of Federal Regulations (CFR), 21 CFR 812. Even with IRB approval, a sponsor must comply with IDE requirements such as monitoring investigations, maintaining records, making reports, and complying with prohibitions on promotion and commercialization of investigational devices. The investigators would have similar responsibilities, also covered in 21 CFR 812.

LASER RADIATION SAFETY

All laser devices distributed for both human and animal treatment in the U.S. are subject to Mandatory Performance Standards. They must be meet the Federal laser product performance standard and must submit an "initial report" to CDRH's Office of Compliance prior to distributing the product (see 21 CFR 1000-1040.11). This performance standard specifies the safety features and labeling that all laser products must have in order to provide adequate safety to users and patients. A laser product manufacturer must certify that each model complies with the standard before introducing the laser into U.S. commerce. This includes distribution for use during clinical investigations prior to device approval.

Certification of a laser product means that each unit has passed a quality assurance test and that it complies with the performance standard. The firm that certifies a laser product assumes responsibility for product reporting, recordkeeping, and notification of defects, noncompliances, and accidental

radiation occurrences, as specified in sections 21 CFR 1000-1010. A certifier of a laser product is required to report the product via a Laser Product Report submitted to CDRH. Reporting guides and related regulatory information are available from the DSMA web site at: http://www.fda.gov/cdrh/devadvice. Distribution of any certified laser products internationally would also require submission of the report.

Updated 5/17/2002

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Overview of Regulations

Introduction

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. A description of device classification and a link to the Product Classification Database can be found at: http://www.fda.gov/cdrh/devadvice/313.html

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:

- Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA),
- Establishment registration on form FDA-2891,
- Medical Device Listing on form FDA-2892,
- Quality System (QS) regulation,
- Labeling requirements, and
- Medical Device Reporting (MDR)

Premarket Notification 510(k) - 21 CFR Part 807 Subpart E

If your device requires the submission of a Premarket Notification 510(k) you can not commercially distribute the device until you receive a letter of substantial equivalence from FDA authorizing you to do so. A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent. Information on preparing a 510(k) submission can be found at: http://www.fda.gov/cdrh/devadvice/314.html.

Most Class I devices and some Class II devices are exempt from the Premarket Notification 510(k) submission. A list of exempt devices is located at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

If you plan to send a 510(k) application to FDA for a Class I or Class II device, you may find 510(k) review by an Accredited Persons beneficial. FDA accredited 12 organizations to conduct a primary review of 670 types of devices. By law, FDA must issue a final determination within 30 days after receiving a recommendation from an Accredited Person. You can find information on the Accredited Persons Program at http://www.fda.gov/cdrh/thirdparty.

Premarket Approval (PMA) - 21 CFR Part 814

Product requiring PMAs are Class III devices are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device. The PMA is an actual approval of the device by FDA. A description of the process and instructions for filing a PMA application can be found at: http://www.fda.gov/cdrh/devadvice/316.html. In addition the PMA Manual can be found at: http://www.fda.gov/cdrh/dsma/pmaman/front.html

Investigational Device Exemption (IDE) - 21CFR Part 812

Clinical trials using unapproved medical devices on human subjects are performed under an Investigational Device Exemption (IDE). Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of nonsignificant risk must be approved by the IRB only before the study can begin.

A description of the IDE process and information on FDA requirements for conducting a clinical study of an unapproved medical device can be found at:
http://www.fda.gov/cdrh/devadvice/ide/index.shtml

Establishment Registration form FDA-2891 - 21 CFR Part 807

Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. A description of the establishment registration process and instructions for completion of the Establishment Registration form FDA-2891 can be found at:
http://www.fda.gov/cdrh/devadvice/341.html

Once a year, FDA sends the registration form FDA-2891(a) to all registered firms to be verified, corrected, and returned by the firm as a yearly registration.

In addition to registration, foreign manufacturers must also designate a U.S. Agent. Information on U.S. Agents can be found at http://www.fda.gov/cdrh/usagent/

Medical Device Listing form FDA-2892 - 21CFR Part 807

All medical devices that are manufactured and imported into the U.S. are required to be listed with the FDA on Medical Device Listing form FDA-2892. Firms that are required to list their devices are those that:

- manufacture,
- repackage and relabel,
- develop specifications,
- reprocess single-use devices,
- remanufacture
- manufacture accessories and components sold directly to the end user

A separate device listing form must be submitted for each type of device.

A description of the medical device listing process and instructions for how to obtain and submit a device listing for your firm can be found at: http://www.fda.gov/cdrh/devadvice/342.html

Quality System Regulation (QS)/Good Manufacturing Practices (GMP) -
21 CFR Part 820

The quality system regulation includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements.

The quality system regulation includes design controls which must complied with during the design and development of the device. Information on design controls can be found in the following guidance documents:

Design Control Guidance for Medical Device Manufacturers
http://www.fda.gov/cdrh/comp/designgd.html
http://www.fda.gov/cdrh/comp/designgd.pdf

Do It By Design - An Introduction to Human Factors in Medical Devices
http://www.fda.gov/cdrh/humfac/doit.html
http://www.fda.gov/cdrh/humfac/doitpdf.pdf

The guidance document, "Medical Device Quality Systems Manual: A Small Entity Compliance Guide" is available on the Internet at: http://www.fda.gov/cdrh/dsma/gmp_man.html

Additional information on the QS requirements can be found at the following websites:
http://www.fda.gov/cdrh/devadvice/32.html or http://www.fda.gov/cdrh/dsma/cgmphome.html.

Labeling - 21 CFR Part 801

Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device. Labeling requirements can be accessed on the web at:
http://www.fda.gov/cdrh/devadvice/33.html

Medical Device Reporting - 21 CFR Part 803

Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA under the Medical Device Reporting program. In addition, certain malfunctions must also be reported. The MDR regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner. Further information on the Medical Device Reporting process can be found at:
http://www.fda.gov/cdrh/devadvice/351.html

Updated 3/13/02

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Classify Your Medical Device

- Introduction
- How To Determine Classification

Introduction

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

Device Class and Regulatory Controls

1. Class I General Controls
    - With Exemptions
    - Without Exemptions
2. Class II General Controls and Special Controls
    - With Exemptions
    - Without Exemptions
3. Class III General Controls and Premarket Approval

The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. If your device is classified as Class I or II, and if it is not exempt, a 510k will be required for marketing. All devices classified as exempt are suspect to the limitations on exemptions. For Class III devices, a premarket approval application (PMA) will be required unless your device is a preamendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMA's have not been called for. In that case, a 510k will be the route to market.

Device classification depends on the *intended use* of the device and also upon *indications for use*. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in Premarket Notification Review Program K86-3 which is Appendix C of the Premarket Notification [510(k)] Manual.

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

As indicated above all classes of devices as subject to General Controls. General Controls are the baseline

requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

How to Determine Classification

To find the classification of your device, as well as whether any exemptions may exist, you need to find the regulation number that is the classification regulation for your device. There are two methods for accomplishing this: go directly to the classification database and search for a part of the device name, or, if you know the device panel (medical specialty) to which your device belongs, go directly to the listing for that panel and identify your device and the corresponding regulation. You may make a choice now, or continue to read the background information below. If you continue to read, you will have another chance to go to these destinations.

If you already know the appropriate panel you can go directly to the CFR and find the classification for your device by reading through the list of classified devices, or if you're not sure, you can use the keyword directory in the PRODUCT CODE CLASSIFICATION DATABASE. In most cases this database will identify the classification regulation in the CFR. You can also check the classification regulations below and the Precedent Correspondence for information on various products and how they are regulated by CDRH.

Each classification panel in the CFR begins with a list of devices classified in that panel. Each classified device has a 7-digit number associated with it, e.g., 21 CFR 880.2920 - Clinical Mercury Thermometer. Once you find your device in the panel's beginning list, go to the section indicated: in this example, 21 CFR 880.2920 . It describes the device and says it is Class II. Similarly, in the Classification Database under "thermometer", you'll see several entries for various types of thermometers. The three letter product code, FLK in the database for Clinical Mercury Thermometer, is also the classification number which is used on the Medical Device Listing form, FDA-2892.

Once you have identified the correct classification regulation go to What are the Classification Panels below and click on the correct classification regulation or go to the CFR Search page. Some Class I devices are exempt from the premarket notification and/or parts of the good manufacturing practices regulations. Approximately 572 or 74% of the Class I devices are exempt from the premarket notification process. These exemptions are listed in the classification regulations of 21 CFR and also has been collected together in the Medical Device Exemptions document.

Descriptions of each class of devices

Updated 2/9/2000

Choose another topic: Select a topic

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Crowley, Gayle M

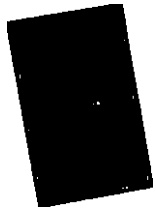
From: Kathy Maynor [kmaynor@altusmedical.com]
Sent: Friday, December 20, 2002 3:50 PM
To: Crowley, Gayle M
Cc: Robert Shine; Kevin Connors
Subject: FDA information on lasers

Hello Gayle -

I was just checking to see if you received my rather lengthy fax yesterday regarding the FDA and lasers. Hopefully that helps explain how the lasers are categorized, who can buy them, and who can use them. I did try to look up the requirements for the state of Washington. From what I can see, the state of Washington does not have any specific rules or regulations regarding aesthetic lasers or light devices at this time. The Medical Quality Assurance Board has taken a position that they believe that the use of these devices constitutes the practice of medicine, and therefore the operation of these lasers/light devices can only be done by certain medical personnel. The type of medical personnel is not defined at this time.

If you need any other info, please call me at 650-259-5586 or email at kmaynor@altusmedical.com

Regards,
Kathy Maynor



Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010
kmaynor@altusmedical.com
650-259-5586

Altus MEDICAL

December 19, 2002

Gayle Crowley
Department of Health
Washington State

Dear Gayle:

The purpose of this letter is to respond to your phone call of this afternoon regarding who can buy and use aesthetic lasers. You also asked about three specific lasers: the Quantum IPL from Lumenis, the CoolGlide from Altus, and the Epitouch from Sharplan.

I have provided the following attachments to address your inquiry:

- Regulatory/legal position paper on who can buy and use aesthetic lasers/IPLs. This will give you an overview on the relevant federal and state rules, and what they mean to manufacturers and laser/IPL purchasers.
- Xerox copy of the pertinent page from the FDA rules and regulations that states the requirement for manufacturers to sell only to licensed practitioners.
- Copies of the FDA 510k clearance letters for the three lasers you are interested in. These letters will show you that all of them have been categorized by the FDA as prescription use devices only. That means that we can only sell to someone licensed by their state to write prescriptions.

Each state controls who can use the laser, and the rules are quite different from state to state. Some states are very strict, and others allow non-medical personnel to operate these devices. Many states still do not have any rules directly regulating these devices, and I believe that Washington is one of those states. The State Medical Board has adopted the position that the use of these devices constitutes the practice of medicine, and therefore only certain medical personnel should operate them. However, as far as I can tell, the board has not published any rules stating specifically which medical personnel are allowed to operate them, or what the physician's role is for oversight

I hope this information helps, and if there is anything else you need, please feel free to contact me directly at 650-259-5586.

Sincerely,

Kathy Maynor
Vice President of Regulatory and Quality

Regulatory/Legal Position Paper on Who Can Buy and Use Aesthetic Lasers

First, the state and federal laws governing aesthetic lasers are complex. Just to make it more fun, the states have widely varying rules, and there is no chance whatsoever that the states will ever agree on one set of rules. They are not required to do that, and all states like to have their own unique laws.

There are two separate and distinct sets of rules regulating who can buy a laser and who can operate one. The federal government, through the FDA, controls who can buy the laser. The individual state governments, generally through their state medical boards, control who can operate the laser. We use the analogy of a car manufacturer to explain this difference to our customers. For example, when you buy a Ford Explorer, in general you must be over the age of eighteen, you must have the funds, and you must have the mental capacity (you cannot be either an idiot or a lunatic) to enter into a contract for sale. Those are the contract rules that the Ford Motor Company would follow. However, that does not mean that you will be able to obtain a license to drive the car. If you have a physical infirmity, have too driving infractions, etc., then the state will not permit you to drive. The Ford Motor Company is not involved in providing the buyer with an operating license, and the company has no influence over the state government agency that sets the licensing rules. Our situation is much the same. We have a set of rules to follow to ensure that the buyer can obtain a laser. However, we have no involvement or control over who is allowed to operate the laser in each state.

Who Can Buy A Hair Removal Laser

To place a medical device on the market in the USA, a medical manufacturer must obtain an FDA clearance or approval before marketing their product. First, we have to determine the classification of our device by the FDA. There are three classes of devices (defined in 21 CFR 860.3), and this classification is based on the design, manufacturing and service controls needed to ensure that the device is safe and effective. This classification is not based on whether a physician must operate the device. All laser hair removal devices are considered as class II devices.

When the FDA gives their clearance or approval, they indicate on their clearance letter whether the device is considered as a prescription device or an over the counter device. On page 3 of our FDA clearance letter, in the bottom left hand corner, you can see that the FDA has determined that our hair removal laser is a prescription device. **All laser hair removal devices on the market are considered as prescription devices.** Please note that this includes the intense pulsed light devices currently on the market. Although these devices are not technically lasers, the FDA treats them the same as laser hair removal devices, and we believe that state medical boards should also consider them in their regulations.

The FDA law, section 21 CFR 801.109 defines a prescription device as:

> *"A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device ..."*

In plain language this means that the device requires specialized knowledge to use it correctly, and it is not safe for use by the general public. Because the specialized knowledge is not something that everyone can learn, the federal government has elected to limit the people who can purchase a hair removal laser to "a practitioner licensed by law."

This does not mean that the buyer has to be a doctor or a physician. That is a common misconception that many people have. The FDA law goes on to say that:

"...Federal law restricts this device to sale by or on the order of a _____, the blank to be filled in with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the device...."

Therefore it is up to each state to determine who is a "licensed practitioner." In some states this means physicians only, in some states chiropractors are included, and in other states electrologists are included. In the state of Florida for example, there are 26 categories of health care professionals, excluding doctors and nurses, who are also considered as licensed practitioners. Unless there is another state law to the contrary, any of these licensed practitioners can purchase a hair removal laser.

As a manufacturer, it would be extremely difficult for us to keep up with the rules in all of the 50 states, much as it would impose a burden for the Ford Motor Company to keep up with the licensing provisions for drivers in each of the 50 states. Therefore, Altus Medical decided to require that our customers have a medical director (physician) associated with them when they purchase the laser. A physician is considered as a licensed practitioner by every state. Adopting this more restrictive policy ensures that Altus meets all state requirements.

The Altus Medical, Inc. policy is to inform every potential customer of our requirement for a medical director, and we print the excerpt of the FDA regulation cited above in our operator manual. We used to rely on the customer's representation that they had a medical director prior to completing a sale. However, with the changing legal landscape, we are now requiring a signed document from the customer positively stating that they have a medical director.

Who Can Use the Laser

It is solely up to each state to determine who can operate a laser or any other prescription device. The federal government does not have any input into this decision, nor does any medical device manufacturer.

Most states do not regulate hair removal lasers at this time, although more states are in the process of developing new rules and regulations for them. The first decision that a state needs to make is whether the practice of hair removal represents the practice of medicine. Usually a state will look to its Business and Professions Code for a definition of the practice of medicine.

Some states have tried to make this decision based on the FDA designation of hair removal lasers as class II devices. This is a legally flawed argument. As stated previously, the class II designation has nothing to do with who is potentially qualified to use the device. For example, the devices below are also classified as class II devices, and they are not controlled by doctors:

a) HEPA air cleaners (21 CFR 880.5045) - Any air cleaner that purports to help allergy sufferers must be reviewed and approved by the FDA. These are considered as class II devices by the FDA, which is the same classification as the laser hair removal devices. However, these devices are available at many drugstores and are frequently used in homes by the general public. I own one myself.

b) AC powered adjustable hospital beds (21 CFR 880.5100) - These beds are considered as class II devices by the FDA. These beds can be purchased and used by non-physicians.

c) Powered wheelchairs (21 CFR 890.3860) - These are also class II devices, and they are operated solely by disabled patients.

A better indicator is whether the FDA has classified the device for either prescription use or over the counter use. The devices listed above are class II, but they are classified for over the counter use. There are some exceptions even to this indicator. For example, the wearable programmable insulin pumps for diabetics are class II devices classified for prescription use. But the devices are operated and programmed by the diabetic, not the physician. The physician is involved in providing training and monitoring services only to the diabetic. Also, until quite recently, the epilators used by electrologists were classified as class II

prescription devices. Very few states ever enforced any requirements for physician involvement in electrolysis. Based on the long successful history of electrology, the FDA recently down classified these devices to class I and class II over the counter.

This problem is compounded by the definition of the scope of practice for other licensed practitioners such as cosmetologists and estheticians. Often the relevant Business and Professions Code lists "removing superfluous hair from the body of any person" as part of the scope of practice for cosmetologists, estheticians and electrologists. This implies that hair removal is not part of the practice of medicine.

State Resolutions

Most states do not have regulations directly on point for hair removal lasers. However, state medical boards have started to push for more regulations in this area. Their concerns are a curious mix of safety considerations and a desire to protect revenue streams from intrusion by other specialties such as aestheticians, cosmetologists, electrologists, etc. Due to this conflict of interests, in my opinion the state medical board should not be allowed to make the final decision.

The state of Florida is the most recent state to establish regulations for the operation of hair removal lasers (regulation 64B8-56.002). They permit physicians, physician assistants, special categories of nurses, and electrologists to operate the laser. We believe that the inclusion of electrologists is proper because of their extensive knowledge of skin and hair, their existing experience base with electromechanical devices for hair removal, and the fact that the CDRH section of the FDA controls both their devices as well as the lasers.

It can take several hours of research to determine what the state requirements are, particularly if there is no explicit law or regulation. Legally, the responsibility for such a law rests with the state legislative bodies, so you check there first to see if the state has passed any laws on the subject. Some states have searchable web based directories, and other states do not.

If there are no specific laws, then you have to see whether the responsibility has been delegated by the state legislative body to the state medical board. If so, then you need to check the rules and regulations of the state medical board. If there are no regulations, then you have to check to see if there are any position papers on the topic or any pending regulations.

Then you need to check the state boards of cosmetology, nursing and estheticians as well as the business professions boards to see if any of those bodies have passed any pertinent regulations, or if they have any position papers.

Lastly, you have to check recent legal cases and state medical board actions against medical practitioners to see if any rules have been set by court cases.

Kathy Maynor
Vice President of Regulatory/Quality
Altus Medical, Inc.

practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

§ 801.63 Medical devices; warning statements for devices containing or manufactured with *chlorofluorocarbons and other class I ozone-depleting substances.*

(a) All over-the-counter devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall carry one of the following warnings:

(1) The EPA warning statement:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The alternative statement:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or other class I substance, if applicable]:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL, OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE OF THIS PRODUCT.

(b) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. This provision does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

[61 FR 20101, May 3, 1996]

Subpart D—Exemptions From Adequate Directions for Use

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented:

Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it i on or within a package from which th device is to be dispensed, distributed b or on behalf of the manufacturer, pack er, or distributor of the device, tha furnishes or purports to furnish infor mation for use of the device contair adequate information for such use, in cluding indications, effects, route methods, and frequency and duratic of administration and any releva hazards, contraindications, side effect and precautions, under which practi tioners licensed by law to employ t device can use the device safely and f the purposes for which it is intende including all purposes for which it advertised or represented. This inf mation will not be required on called reminder—piece labeling whi calls attention to the name of the vice but does not include indications other use information.

(e) All labeling, except labels a cartons, bearing information for use the device also bears the date of issuance or the date of the latest re sion of such labeling.

§ 801.110 Retail exemption for scription devices.

A device subject to § 801.109 shall exempt at the time of delivery to ultimate purchaser or user from tion 502(f)(1) of the act if it is deliv by a licensed practitioner in the co of his professional practice or upo prescription or other order lawf issued in the course of his professi practice, with labeling bearing name and address of such licensed titioner and the directions for use cautionary statements, if any, tained in such order.

FDA REGULATIONS – CHAPTER 21, CODE OF FEDERAL REGULATIONS

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George J. Hattub
Director Regulatory Affairs/Quality Assurance
Sharplan Lasers, Incorporated
33 Plan Way
Warwick, Rhode Island 02886

DEC - 4 1997

Re: K973354
Trade Name: Sharplan Model 5000 Alexandrite Laser System
Regulatory Class: II
Product Code: GEX
Dated: September 4, 1997
Received: September 5, 1997

Dear Mr. Hattub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K973354

Device Name: Sharplan Model 5000 Alexandrite Laser System

Indications For Use:
The Sharplan Model 5000 Alexandrite Laser System is intended for use in dermatology for the removal of unwanted dark body hair.

(Please Do Not Write Below This Line - Continue on Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973354

Prescription Use X
(Per 21 CFR 801.109) OR Over-The-Counter Use ____

(Optional Format 1-2-96)

K973354

DEC - 4 1997

510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Model 5000 Alexandrite Laser System

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of Sharplan Model 5000 Alexandrite Laser System is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which are the Cynosure Alexandrite Laser for Hair Removal and the Sharplan Model 5000 Alexandrite Laser System for Dermatology.

1. Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
George J. Hattub, Director of Regulatory Affairs/Quality Assurance
August 22, 1997

2. **Model:** Sharplan Model 5000 Alexandrite Laser System

3. **Predicate Devices:** The Cynosure Alexandrite Laser (cleared by FDA, August, 1997), and the Sharplan Model 5000 Alexandrite Laser System for Dermatology (K971874)

4. **Description:** The Sharplan Model Alexandrite Laser System is a medical device which capable of emitting an invisible pulsed treatment laser beam at a wavelength of 755 nm under the guidance of an visible aiming beam. This laser can be utilized in either the continuous or timed exposure modes of operation

5. The Sharplan Model 5000 Alexandrite Laser System is intended for use in dermatology for the removal of dark, unwanted body hair. Clinical data on 40 subjects was presented.

6. From both a design and clinical perspective, the predicate and candidate devices, are of the same technology and have the same intended use. Based upon an analysis of the overall performance characteristics for the devices, Sharplan Lasers, Inc. believes that no significant differences exist. Therefore, the Sharplan Model 5000 Alexandrite Surgical Laser should not raise any concerns regarding its overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ms. Anne C. Worden
Acting Vice President, Regulatory
and Quality Assurance
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Quantum - Lumenis

Re: K020839
Trade/Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems and the Real Time Chiller
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 11, 2002
Received: July 15, 2002

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

000169

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K020839

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL Systems and Nd:YAG Laser Systems and the Real Time Chiller

Indications For Use:

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

- Intense Pulsed Light Energy/Wavelengths (515 - 1200 nm):

  The 515 – 1200 nm intense pulsed light wavelengths are indicated for:
  - The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars and striae;
  - The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
  - The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[a], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

- Nd:YAG Laser Wavelength (1064 nm):

  The 1064 nm wavelength produced by the Nd:YAG laser is indicated for:
  - The coagulation and hemostasis of vascular lesions and soft tissue, including:
    - Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 – 4.0 mm diameter) of the leg.

[a] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

*** Continued on Following Page***

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
K020839
510(k) Number

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number (if Known): K020839

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL Systems and Nd:YAG Laser Systems and the Real Time Chiller

Indications For Use: ***Continued from Previous Page***

➢ Real Time Chiller:

The Real Time Chiller is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number K020839

K020879 1/3

Attachment 25 OCT 11 2002

510(k) Summary Statement for the
Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Anne C Worden Acting VP, Regulatory & QA
Summary Preparation Date:	March 11, 2002

II. Names

Device Names:	Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- ESC Medical Systems EpiLight (K991935, K994014);
- ESC Medical Systems MultiLight (K994014);
- ESC Medical Systems Photoderm HR (K991935);
- ESC Photoderm Nd:YAG Accessory (K980537);
- ESC Photoderm PL (K960772);
- ESC Photoderm VL (K950493);
- Candela SPTL-1e Pulsed Dye laser system (K011092);
- Candela Dynamic Cooling Devices (K001589, K951033);
- MedArt 520 Cooling System (K000503);
- OptoMed DermaCool Skin Cooling Device (K990417); and
- Coherent Epidermal Chiller Tip (K960032).

IV. Product Description

Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems are comprised of the following main components:

- A light/laser system console (including software and control electronics);
- A control and display panel;
- One or two attached handpiece(s);
- A skin cooling device integrated into the handpiece (on some handpieces);
- A trigger button integrated into the handpiece;
- A remote interlock connector (disables light/laser when treatment room door is opened).

K020839 2/3

V. Indications for Use

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology. The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems is indicated for the treatment of tattoos and benign pigmented epidermal and cutaneous lesions, including warts, scars and striae, and the treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations, and the removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[8], hair reduction in skin types I-V through selective targeting of melanin in hair follicles (515 – 1200 nm), and for the coagulation and hemostasis of vascular lesions and soft tissue (1064 nm).

In addition, the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) is safe and effective when indicated for coagulation and hemostasis of vascular lesions and soft tissue, including, the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg.

The *Real Time Chiller is indicated for use in cooling the epidermis at the treatment site* prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling), to reduce discomfort during and/or associated with light or laser treatment, to minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation, to allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions), to reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions), and to protect the skin from thermal necrosis, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation.

VI. Rationale for Substantial Equivalence

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems share the same general indications for use, and therefore is substantially equivalent for use in surgical, aesthetic and cosmetic applications to the ESC Medical Systems EpiLight intense pulsed light systems (K991935, K994014), the ESC Medical Systems MultiLight intense pulsed light systems (K994014), the ESC Medical Systems Photoderm HR intense pulsed light systems (K991935), the ESC Medical Systems Photoderm Nd:YAG Accessory (K980537), the ESC Medical Systems Photoderm PL intense pulsed light systems (K960772), the ESC Medical Systems Photoderm VL intense pulsed light system (K950493), the Candela SPTL-1e Pulsed Dye laser system (K011092), the Candela Dynamic Cooling Devices (K001589 & K951033), the MedArt 520 Cooling System (K000503), the OptoMed DermaCool System and Handpieces (K990417), and the Coherent Epidermal Chiller Tip (K960032). In addition, clinical data demonstrated that

K020839 3/3

the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective when indicated for use in specific applications in the medical specialties of general and plastic surgery, and dermatology.

VII. Safety and Effectiveness Information

Clinical data was provided to demonstrate that the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective, when indicated in specific applications in the medical specialties of general and plastic surgery, and dermatology. Performance data was provided to demonstrate that the Cooling Head integrated into the Treatment Head of the delivery handpiece for the Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems operates in accordance with its specifications.

VIII. Conclusion

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems were found to be substantially equivalent to the predicate ESC Medical Systems EpiLight intense pulsed light systems (K991935, K994014), the ESC Medical Systems MultiLight intense pulsed light systems (K994014), the ESC Medical Systems Photoderm HR intense pulsed light systems (K991935), the ESC Medical Systems Photoderm Nd:YAG Accessory (K980537), the ESC Medical Systems Photoderm PL intense pulsed light systems (K960772), the ESC Medical Systems Photoderm VL intense pulsed light system (K950493), the Candela SPTL-1e Pulsed Dye laser system (K011092), the Candela Dynamic Cooling Devices (K001589 & K951033), the MedArt 520 Cooling System (K000503), the OptoMed DermaCool System and Handpieces (K990417), and the Coherent Epidermal Chiller Tip (K960032). The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems shares similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

Clinical data was provided to demonstrate that the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective, when indicated in specific applications in the medical specialties of general and plastic surgery, and dermatology.

Q00175

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Altus Medical, Inc.
Michael Levernier
Vice President, Clinical Development
821 Cowan Road
Burlingame, California 94010

Re: K022226
Trade/Device Name: Family of Altus Medical CoolGlide Aesthetic Lasers
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 5, 2002
Received: July 10, 2002

Dear Mr. Levernier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050,

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K022226

Device Name: **Family of Altus Medical CoolGlide Aesthetic Lasers**

Indications For Use:

The family of Altus Medical CoolGlide Aesthetic Lasers are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

1064nm:

Dermatology:

The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022226

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the Altus CoolGlide laser handpiece is to provide cooling of the skin, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:
The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endoscopy/laproscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022226

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

532nm:

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022226

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

OCT 0 8 2002

K022226

Attachment 17
510(k) Summary for the
Family of Altus Medical CoolGlide Aesthetic Lasers

I. General Information

Submitter: Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010

Contact Persons: Kathy Maynor
Mike Levernier

Summary Preparation Date: July 5, 2002

II. Names

Device Names: Family of Altus Medical CoolGlide Aesthetic Lasers

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Family of CoolGlide Aesthetic Lasers, manufactured by Altus Medical (K991798, K991234, K003202 and K014040);
- NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461);
- Vbeam and Clearbeam Pulsed Dye Lasers, manufactured by Candela (K013043 and K013748);
- PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806);
- CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715); and
- Smoothbeam Diode Laser, manufactured by Candela (K013825).
- Lyra Surgical Laser System, manufactured by Laserscope (K020021)

IV. Product Description

Family of Altus Medical CoolGlide Aesthetic Lasers are comprised of the following main components:

- a laser system console (including software and control electronics);
- a control and display panel;
- a permanently attached fiberoptic-coupled handpiece;
- a skin cooling device integrated into the handpiece;
- a footswitch (or finger-operated exposure switch (handswitch) option integrated into the handpiece)
- a remote interlock connector (disables laser when treatment room door is opened).

V. Indications for Use

The family of Altus Medical CoolGlide Aesthetic Lasers are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

1064nm:

Dermatology:
The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the Altus CoolGlide laser handpiece is to provide cooling of the skin, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:
The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endoscopy/laproscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

Indications for use (532nm):

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

VI. Rationale for Substantial Equivalence

The family of Altus Medical CoolGlide Aesthetic Lasers share the same general indications for use, and therefore is substantially equivalent to the currently marketed Altus Medical family of CoolGlide Aesthetic Nd:YAG Lasers (K991798, K991234, K003202 and K014040), the NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461), the Vbeam and Clearbeam Pulsed Dye Lasers, manufactured Candela (K013043 and K013748), the PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806), the CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715), the Smoothbeam Diode Laser, manufactured by Candela (K013825), and the Lyra Surgical Laser System, manufactured by Laserscope (K020021).

VII. Safety and Effectiveness Information

The new **indications for use** in dermatology, endoscopic/laproscopic general surgery, gastroenterology, general surgery, gynecology, otorhinolaryngology, neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary.thoracic surgery, and urology are based upon the indications for use for predicate laser systems.

Technologically, the CoolGlide family of aesthetic lasers is identical to the previous predicate CoolGlide family (K014040). Therefore the risks and benefits for the CoolGlide laser family are comparable to the predicate devices.

We therefore believe that there are no questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The family of Altus Medical CoolGlide Aesthetic Lasers were found to be substantially equivalent to the currently marketed Altus Medical family of CoolGlide Aesthetic Nd:YAG Lasers (K991798, K991234, K003202 and K014040), the NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461), the Vbeam and Clearbeam Pulsed Dye Lasers, manufactured Candela (K013043 and K013748), the PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806), the CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715), the Smoothbeam Diode Laser, manufactured by Candela (K013825), and the Lyra Surgical Laser System, manufactured by Laserscope (K020021). The family of Altus Medical CoolGlide Aesthetic Lasers share similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

telnet (GothomCity)

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MEDICAL BOARD             ASSESSMENT SYSTEMS, INC.                    12-20-02
gmc1303                         REAL SYSTEM          V2.5.74          10:34:01 AM
INDIVIDUAL NAME                  (JR,SR,III)          REFERENCE # MD00031593
   LAST FISHER                                        SOC SEC NUM  2 - DOH Licensee Social S...
  FIRST JOHN                          +-ADDITIONAL INFORMATION----------------+
 MIDDLE A                             |           SEX M =      MARRIED Y =     |
                                      |                                        |
RESIDENCE INFORMATION                 |   OTHER NAME                           |
33 C ETRURIA STREET                   |CORP. OFFICER                        =  |
SEATTLE WA  98109                     |TRUST ACCOUNT                           |
                                      |                                        |
                                      |  BIRTH PLACE CANADA                    |
                                      |        DATE 02-11-1963                 |
PHONE: (   )     -       COUNTY:   17 |                                        |
       (   )     -       LGL ST: WA   |SCHOOL CODE 60.01                       |
                                      |   CE UNITS    0.00 REQD BY 02-11-2005  |
NOTES                                 +----------------------------------------+
REFER INQUIRIES TO MDB
+-------------------------------------------------------------------------------+
|CURRENT STATUS: ALD  EXPIRATION DATE: 02-11-2003  FIRST ISSUE DATE: 02-14-1994|
|RENEWAL STATUS: M   LAST ACTIVE DATE:   -  -     LAST RENEWAL DATE: 01-12-2001|
|COMPLAINTS O/C:  0/ 1      AUTHORITY:                                          |
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Subj: **Fwd: proposed agreement**
Date: 11/19/99 10:27:24 AM Pacific Standard Time
From: ICEGROUP1
To: JFisher577

Forwarded Message:
Subj: **proposed agreement**
Date: 11/19/99 10:26:42 AM Pacific Standard Time
From: ICEGROUP1
To: JFisher

John, take a look at the agreement I have outlined and let me know if we need to make changes. I look forward to your response! Jeff

---

Forwarded Message:
Subj: **changes to agreement**
Date: 11/19/99 10:15:28 AM Pacific Standard Time
From: Babbittks
To: ICEGROUP1

The following agreement is between Dr. John Fisher, Eric Moore and Jeff Schmidt.
It is agreed that Dr. Fisher and Eric Moore will sign together a lease agreement for the purchase of one Alexandrite laser through ESC Medical Systems. Laser Works of Seattle accepts full responsibility in paying this monthly obligation. If in the event laser works is unable to fulfill this obligation both Eric Moore and Jeff Schmidt (Laser Works, Principles) accept full personal responsibility for the payment of this lease.
Dr. Fisher will receive compensation as follows: after the first 30 days of operation Dr. Fisher will receive 1000.00, 60 days 1500.00, and 90 days 2500.00.
Laser works will continue to pay Dr. Fisher 2,500.00 per month or 5 % of net profits which ever is the greater for the remainder of the 9 month agreement. If after 9 months either party wishes to cancel the agreement they may do so with 60 days notice. In the event of a cancellation Laser Works is to secure alternative financing and has 60 days to do so. Dr. Fisher will receive his normal compensation until the Laser lease has expired and is no longer in his name. During this agreement Dr. Fisher agrees that from time to time it is necessary to speak with patients that may experience minor side effects to Laser treatment, and to also prescribe topical medications for pain relief.

Laser~Works

11501 SW Pacific Hwy Suite 102
Portland Ore 97223
USA

Phone 503-244-8600
Fax 503-244-1554
Email icegroup1@aol.com

June 04, 2000

Altus
821 Cowan Road
burlingame, CA 94010

As a condition to the sale of the Coolglide laser system , such condition being incorporated by reference in the purchase agreement, Laser~works! hereby certifies that:

1. Laser~Works has identified and retained a Medical Director who has a current and valid medical license issued by an accredited state medical licensing board.

2. All use of the Coolglide System will be in full compliance with all statues, laws, regulations and rules applicable in the state (Washington) where the procedure is performed.

Signature of Medical Director John Iske MD.

Medical license number MD 315983 . WA

Signature of Laser~Works! President

GUARANTY/INDEMNITY AGREEMENT

This Guaranty and Indemnity Agreement ("Agreement") is entered into as of March 31, 2000, by and between John Fisher, MD, an individual ("Fisher"), on the one hand, and Eric Moore ("Moore"), an individual and Jeffery Brent Schmidt ("Schmidt"), an individual, on the other hand. Collectively, Fisher, Moore, and Schmidt are referred to herein as the "Parties" and each individually as a "Party".

Recitals

WHEREAS, on or about March 31, 2000, Fisher and Moore entered into that certain Lease Agreement (the "Lease") calling for the lease of a medical device described as one "Altus CoolGlide Laser System" ("Laser") financed through Standard Capital Corporation ("Lessor"), a Massachusetts entity;

WHEREAS, Fisher and Moore are jointly and severally liable for the obligations arising under the Lease;

WHEREAS, Fisher agreed to execute the Lease in exchange for the promise of Moore and Schmidt to be fully responsible for the obligations and liability arising out of and relating to the Lease and/or the Laser;

WHEREAS, it has always been and remains the intent of the Parties that Moore and Schmidt shall be together and each personally Liable, and that Fisher shall not be liable in any manner whatsoever, for any and all obligations relating to the Lease and the Laser;

WHEREAS, Fisher desires, and Moore and Schmidt would like to provide, this written Agreement exonerating, indemnifying, subrogating, and holding harmless Fisher from and against any and all liability associated with the Lease and/or the Laser.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Moore and Schmidt hereby confirm the guarantee and indemnity, and the Parties agree to the following:

Terms and Conditions

1. **Moore and Schmidt's Guaranty**. Moore and Schmidt, jointly and severally, hereby unconditionally and irrevocably guarantee the full and punctual payment by Moore and Schmidt of all fees and all other sums payable under the Lease and the full and punctual performance and observance by Moore and Schmidt of each and every one of the terms, conditions and covenants of the Lease to be kept and performed by Moore and Schmidt. The Parties understand that the Lease requires

payments and/or other obligations by Fisher, notwithstanding, Moore and Schmidt shall be solely responsible for all obligations arising out of or relating to the Lease or the Laser.

2. **Indemnity/Exoneration.** Moore and Schmidt together, and each of them, jointly and severally, and their respective heirs, beneficiaries, and estates hereby agree to indemnify, defend, and hold harmless Fisher, his spouse, estate, beneficiaries, heirs, agents, and attorneys from and against any and all liability, losses, costs, damages, claims, suits, actions, judgments, and expenses whatsoever, including, but not limited to, costs and attorneys, fees (which attorneys shall be selected and hired at the sole discretion of Fisher), arising out of, relating to, or in connection with the Lease and/or the Laser, or any breach by Moore or Schmidt of this Agreement. Moreover, to the extent legally possible, Moore and Schmidt hereby exonerate and shall subrogate Fisher from any liability under or related to the Lease or the Laser.

3. **Fisher's Rights and Remedies** Fisher shall be entitled to require Moore and Schmidt to fully perform and observe each and every one of the terms, conditions and covenants of the Lease. Fisher may proceed joint and severally against Moore and/or against Schmidt (or their respective heirs, beneficiaries, or estates) following breach or default by Moore and/or Schmidt of Lease , this Agreement, or concerning the Lease. Upon notice of breach or default, Fisher shall be entitled to collect immediately from Moore and/or Schmidt all fees and all other sums payable under the Lease for the remainder of the term of the entire Lease. Fisher shall be entitled to assert any and all defenses and counterclaims that Fisher would have against Moore and Schmidt under the Lease or this Agreement. Fisher shall not be Liable for any amounts owed by Moore and/or Schmidt under the terms of the Lease and/or this Agreement.

4. **Notice of Withdrawal and Release of Liability.** Approximately nine (9) months after the execution of the Lease, a review shall be made by Fisher, on the one hand, and Moore and Schmidt, on the other hand, along with Lessor calling for an assignment and delegation to Moore and Schmidt of Fishers rights and responsibilities under the Lease, thereby releasing Fisher from any and all apparent obligations and liabilities under the Lease.

5. **Notices** Whenever any -notice or demand is to be given under this Agreement the notice shall be in writing and addressed to the Parties at their respective addresses as set forth below. Notices delivered by overnight courier service (e.g., U.S. Express Mail or Federal Express) shall be deemed delivered on the business day following mailing. Notices mailed by U.S. Mail, postage prepaid, registered or certified with return receipt requested, shall be deemed delivered four (4) days after mailing. Notices delivered by any other method shall be deemed given upon receipt. Notices by facsimile transmission are acceptable under this Agreement provided that they are transmitted to the other Party's then current facsimile number, and are deemed delivered one (1) hour after transmission if sent during the recipient's business hours, or 9:00 a.m. (recipient's time) the next business day. Any Notice given to Moore shall be deemed to provide constructive notice to Schmidt; any Notice given to Schmidt shall be deemed to provide constructive notice to Moore.

If to Fisher:.	John Fisher, MD 55 Bell Street #203 Seattle, Washington 98121 Tel. No. (206) 728-1630 Fax No. (206) 728-1596
If to Moore:	Eric Moore 4008 171 Avenue SW Seattle, Washington 98106
If to Schmidt:	Jeffrey Brent Schmidt 3663 SE Rockwood Street Milwaukie, Oregon 97222

6. **Applicable Law; Arbitration.** This Agreement shall be governed by and interpreted in accordance with the domestic laws of the State of Washington applicable to contracts made and performed solely in Washington, without regard to conflict of law principles. Any action related to, to enforce, construe, or interpret this Agreement shall be settled by arbitration in the city of Seattle, Washington in accordance with the rules and regulations governing commercial arbitration promulgated by the American Arbitration Association before a neutral arbitrator(s) (i.e., individual(s) who, to the best of a Parties knowledge, do not have a bias in favor of, or against, any Party) having experience in matters involving equipment leasing. The decision of the arbitrator(s) shall be final and binding on the Parties, and judgment upon the award rendered by the arbitrators may be entered in the Superior Court of the State of Washington in and for the County of King. Any arbitration award shall include attorneys' fees and costs (including costs of filing fees, expert witnesses, discovery, etc.) for the prevailing Party. However, notwithstanding the foregoing, if any action is commenced against Fisher by a third party relating to the Agreement, the Lease, or the Laser, the Parties hereto shall be required to join in such action, and the arbitration compulsion will not apply, at the sole discretion of Fisher.

7. No Assignment. None of Moore, Schmidt, or their respective heirs, beneficiaries, or estates shall have the right to sell, assign, transfer or hypothecate (all hereinafter referred to as "assign" or an "assignment) any right or interest pursuant to the Laser, the Lease, or this Agreement, nor delegate any obligations under the Lease and/or this Agreement voluntarily or by operation of law, without the prior express written consent of Fisher. Any such purported assignment of rights or delegation of duties without such prior written consent shall be null and void *ab initio* and given no force or effect. Any such purported assignment or delegation without such prior express written consent shall be considered a breach and default of this Agreement entitling Fisher to pursue any and all rights and remedies provided in this Agreement and entitling Fisher to collect from Moore and/or Schmidt the greater of the entire balance owned on the Lease, or the market value of the Laser.

S. No Waiver. The failure of either Party at any time to enforce any right or remedy available to it under this Agreement with respect to any breach or failure by the other Party shall not be

construed to be a waiver of such right or remedy with respect to any other breach or failure by the other party.

9. **Severability.** If any provision of this Agreement is held invalid, unenforceable or void, the remainder of the Agreement shall not be affected thereby and shad continue m full force and effect.

10. **Entire Agreement; Prior Agreements Superseded; Modification.** This Agreement is the entire agreement between the Parties relating to the Lease and Laser, and this Agreement replaces any and all contemporaneous or prior negotiations, understandings, representations, or agreements between the Parties, whether oral or written. The Parties acknowledge that they have not relied on any promise, representation, or warranty, express or implied, not contained in this Agreement. No amendment modification or supplement to this Agreement shall be effective unless it is in writing and either signed by all Parties, or signed by one Party if such Party is the Party to be charged.

It. **Counterparts** The Parties may execute " Agreement in two or more counterparts, which shall, in the aggregate, be signed by each party. Each counterpart shall be deemed an original instrument as against any party who has signed it. Facsimile copies of this Agreement are acceptable as original copies.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date set forth below, effective as of the date first set forth in the first paragraph of this Agreement:

JOHN FISHER
an individual

_____
John Fisher

Date: _____

ERIC MOORE
an individual

Eric M. Moore
Eric Moore

Date: 5/12/00

JEFFERY BRENT SCHMIDT
an individual

_____
Jeffery Brent Schmidt

Date: _____

INSURANCE CONFIRMATION

Date: March 31, 2000
Lease Number:

FROM:
New Vista Ventures d/b/a Laser Works of Seattle
411 Strander Boulevard
Tulewila, WA 98188

2984

TO: Agent
Agent's/Broker's Name: Don Brown
Broker Insurance Company: Red Shield Insurance Co
Street Address: 1934 NE Sandy Blvd
City, State Zip: Portland, OR / 97232
Area Code/Phone Number: 503 / 226 - 4146
FAX: 503 / 234 - 9665

Gentlemen:

We have entered into a Lease Agreement (or an Equipment Financing Agreement) for an **Altus CoolGlide Laser System with all accessories thereto,** with a value of **$65,000.00**:

The equipment is located at: New Vista Ventures d/b/a Laser Works of Seattle, 411 Strander Boulevard , Tulewila, WA 98188

This is a net lease or finance and we are responsible for the insurance cost. Please see that we have immediate coverage and notify the company shown below at once in the form of a copy of the insurance policy or a Certificate of Insurance. If the latter is sent, please provide therein for thirty (30) days written notice in the event of cancellation or alteration.

☑ **PHYSICAL DAMAGE:** Insurance is to provide for fire, theft, extended coverage, vandalism and malicious mischief for the full value of the equipment. _____ is to be named a Loss Payee, as its interests may appear.

☑ **LIABILITY:** Coverage should be written with minimum limits of $1,000,000 for BODILY INJURY. _____ is to be named an Additional Insured.

THANK YOU,

By: [signature] MD

TITLE: Medical Director

John A. Fisher

SCOH(02/1997)

000192

STANDARD CAPITAL CORPORATION
Corporate Place 93 • 100 Burtt Road • Andover, MA • 01810
Phone: 800-995-3273 • Fax: 978-749-3665

LEASE AGREEMENT:

VENDOR / SUPPLIER OF EQUIPMENT:

NAME: Altus Medical CONTACT: John Connors
ADDRESS: 821 Cowan Road CITY: Burlingame STATE: CA ZIP: 94010
PHONE: 650-552-9700

NOTE: VENDOR IS NOT AN AGENT OR REPRESENTATIVE OF THE LESSOR, AND IS NOT AUTHORIZED TO MODIFY ANY OF THE TERMS OF THIS LEASE

SCHEDULE OF PAYMENTS

Term: Number of payments: 63
1 @ $ 1,419.60 per month*
3 @ $ 0.00 per month*
1 @ $ 1,419.60 per month*
*Except as otherwise indicated ☐ QUARTERLY ☐ OTHER

(Note: Applicable taxes and insurance may be added, see Paragraphs 10 and 12)

EQUIPMENT DESCRIPTION, (include serial numbers):

Equipment Description	Serial Numbers
An Altus CoolGlide laser System with all accessories thereto	

PAYABLE AT SIGNING OF LEASE (check one)

☐ Security Deposit (see paragraphs 6 and 15) $
☑ First only 1 Total Payment $ 1,419.60
☐ Other $

EQUIPMENT LOCATION (IF OTHER THAN BELOW)

(Attach additional schedule if locations differ for each item of equipment)

ADDRESS
CITY STATE ZIP PHONE

ACCEPTANCE OF LEASED EQUIPMENT

As Lessee, you acknowledge that the equipment covered by this Lease has been completely and satisfactorily delivered, and after full inspection is accepted for all purposes of the Lease. Your acceptance shall be deemed effective and irrevocable forty-eight (48) hours after delivery of the Equipment if you do not notify us of nonacceptance, or on the date you sign the Deliver & Acceptance of Leased Equipment, whichever is earlier. We will not fund the lease without a signed Delivery & Acceptance.

ACCEPTED BY LESSOR: Standard Capital Corporation

BY _____
AUTHORIZED SIGNATURE TITLE

_____
DATE

Corporate Place 93
100 Burtt Road
Andover, MA 01810
Phone (800) 995-3273
Fax (978) 749-3665

ACCEPTED BY LESSEE:

FULL LEGAL NAME OF LESSEE: New Vista Ventures d/b/a Laser Works of Seattle
FEDERAL TAX I.D. OR SOCIAL SECURITY #: 912011905
BILLING ADDRESS: 411 Strander Boulevard
CITY: Tulewila STATE: WA ZIP: 98188

THE UNDERSIGNED HEREBY AGREES TO ALL OF THE TERMS AND CONDITIONS AS SET FORTH ON BOTH SIDES OF THIS LEASE AGREEMENT (AND ANY SCHEDULE TO THIS LEASE), AND CERTIFIES THAT THE EQUIPMENT SHALL BE USED FOR BUSINESS PURPOSES ONLY.

X _____ 4/3/00
John A. Fisher DATED
TITLE:

PERSONAL GUARANTY

I hereby acknowledge that I am receiving a benefit from this lease, and I jointly & severally unconditionally guarantee the prompt payment in full of all obligations of the Lessee under this Lease. I further acknowledge that this lease may be amended from time to time by execution of lease schedules and that by signing below I represent and acknowledge that a "continuing guaranty" is being given, which shall be in full force and effect and apply to all such future schedules. This guaranty shall remain and continue in full force and effect as to any renewal, modification or extension of the lease, and shall further apply to any additional leases entered into between the lessor and the lessee from the date of this guaranty forward, whether or not I have received notice of or consented to such renewal, modification extension or additional leases. I understand that the lessor in entering into such renewals, modifications, extensions or additional lease transactions, shall be relying upon my guarantee herein. I also agree that you, the lessor may make other arrangements with the lessee, such as releasing or compromising the lessee's obligations, and I will still be responsible for those payments and other obligations. You do not have to notify me if the Lessee fails to meet all of its obligations under the lease. If the lessee fails to meet all of its obligations, I will immediately pay in accordance with the default provisions of the Lease all sums due under the original terms of the Lease, and I will perform all other obligations of the Lessee under the Lease, and I agree that you do not have to proceed first against the Lessee or exhaust other collateral before I am required to satisfy my obligations under this guaranty. I will reimburse you for all the expenses you incur in enforcing any of your rights against the Lessee or me, including attorneys fees. **THIS GUARANTY SHALL BE GOVERNED BY THE LAWS OF THE STATE OF ILLINOIS. I AGREE AND CONSENT TO THE JURISDICTION OF THE FEDERAL AND STATE COURTS LOCATED IN COOK COUNTY, ILLINOIS, FOR THE DETERMINATION OF DISPUTES BETWEEN US.** However, you agree that we will have the right to commence any action in any Court having the proper jurisdiction for that action. I agree and consent that you may serve me by registered or certified mail, which will be sufficient to obtain jurisdiction. No payment by me under this guaranty shall entitle me, by subrogation or otherwise, to any payment from the Lessee or out of the property or other assets of the Lessee. **I WAIVE TRIAL BY JURY IN ANY ACTION BETWEEN US.**

X _____ X _____ 4/3/00
WITNESS SIGNATURE DATE John A. Fisher, AN INDIVIDUAL (No titles) DATED

X _____ 4/3/00 X _____ 4/4/00
WITNESS SIGNATURE DATE Eric W. Moore, AN INDIVIDUAL (No titles) DATED

Dear Lessee: Please read your copy of this Lease carefully and feel free to ask us any questions you may have about it. We use the words you and your to mean the Lessee indicated below. The words we, us, and our refer to the Lessor indicated below.

1. **LEASE AGREEMENT:** You agree to lease from us and we agree to lease to you, the equipment listed above or on any schedule to this Lease. You unconditionally promise to pay us the sum of all of the rental payments indicated above or on any schedule. The amount of each rental payment shown above or on any schedule is based on our estimated total cost of the equipment including, if applicable, installation costs. The rental payment shall be raised or lowered, in a proportionate manner, if the actual total cost of the equipment is greater than or less than the estimate, and you authorize us to adjust the rental payment by up to ten percent (10%) if it is necessary. You authorize us to insert in this Lease any serial numbers and other identification data about the equipment, as well as any other omitted factual matters.

2. **UCC-ARTICLE 2A:** You agree that this Lease is a "Finance Lease" under Article 2A of the Uniform Commercial Code ("UCC"). You acknowledge that: (a) we did not select, manufacture or supply the equipment, but at your request we have purchased the equipment for lease to you, and (b) based on your own judgment, you have selected the vendor or supplier of the equipment (indicated above), and you have selected the particular equipment that you are leasing from us. You agree that you have approved any purchase or supply contract between us and the vendor before signing this Lease; or, if you have entered into a purchase contract for the equipment, you agree to assign it to us effective when we pay for the equipment. You may have rights under the supply or purchase contracts, and you may contact the supplier for a description of those rights or any warranties. To the extent permitted by applicable law, you waive any and all rights and remedies conferred upon you under UCC Sections 2A-303 and 2A-508 through 522.

3. **NO WARRANTIES:** We are leasing the equipment to you "AS IS". **WE MAKE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OR ORDINARY USE IN CONNECTION WITH THIS LEASE. YOU UNDERSTAND AND AGREE THAT WE ARE INDEPENDENT FROM THE VENDOR OR SUPPLIER OF THE EQUIPMENT, AND THAT NEITHER THE VENDOR NOR ANY OTHER PERSON IS OUR AGENT, NOR ARE THEY AUTHORIZED TO WAIVE OR CHANGE ANY TERM OR CONDITION OF THIS LEASE. YOU AGREE THAT NO REPRESENTATION, GUARANTEE OR WARRANTY BY THE VENDOR OR OTHER PERSON IS BINDING ON US.** So long as you are not in default under any of the terms of this Lease, we transfer to you any warranties made to us, as the owner of the equipment, by the Vendor, manufacturer or supplier. **YOU AGREE THAT ANY BREACH BY THE VENDOR OR OTHER PERSON WILL NOT RELIEVE OR EXCUSE YOUR OBLIGATIONS TO US.** Regardless of cause, you will not assert any claim whatsoever against us for loss of profits you expected to make or any other direct, consequential, special or indirect damages. If you have entered into a maintenance agreement for the equipment, and the cost of the maintenance is included in your

STANDARD CAPITAL CORPORATION

RE: **Lease Number:**

Dear Customer:

Reference is made to the above lease between you as Lessee and Standard Capital Corporation ("Lessor"). All terms used herein, which are defined in the lease, shall have the same meaning herein.

Provided you shall have promptly complied with all provisions of the lease to be performed by you, you shall have the option to purchase all, but not less than all, of the Equipment " as is, where is," at the end of the Initial Term (or at the end of any renewal or extended term if the lease has been renewed or extended) at 10% of original cost plus all applicable taxes.

The option shall be exercised by your giving written notice of exercise, delivered personally to Lessor or mailed to Lessor, postage prepaid, certified U.S. mail return receipt requested. Notice must be received not less than 90 days nor more than 150 days prior to the scheduled termination date (or any renewal or extended term if the lease has been renewed or extended) at the address set forth above or at such other address as Lessor may specify.

In the event this option is not exercised by you, your responsibility will be stated in the Lease. Should you have any questions, please call customer service at (800) 995-3273.

Very Truly Yours,

Standard Capital Corporation

Lessee: New Vista Ventures d/b/a Laser Works of Seattle

By: _____

John A. Fisher

Title: Medical Director

Date: 4/3/00

100 Burtt Road • Andover, MA 01810
Phone: 800-995-3273 • Fax 978-749-3665

DELIVERY AND ACCEPTANCE RECEIPT

Lease #

Instructions: upon receipt and inspection of the Equipment from the Vendor, this receipt must be signed by Lessee and mailed or otherwise delivered to Lessor

To: LESSOR; Lease Number:

Re: **Altus CoolGlide Laser System with all accessories thereto**

Date: April 4th, 2000

The undersigned Lessee certifies that:

1. Lessee has received the equipment directly from the Vendor, and not from LESSOR as agent or otherwise.

2. Lessee has inspected and tested the above equipment, which is also all of the Property to be leased under the lease referred to above, and found such equipment to be satisfactory in all respects. If the equipment is only part of the Property specified in the Lease, refer to LESSOR for special instructions.

3. Lessee accepts the equipment for all purposes under the lease.

4. Lessee understands that Lessee's signature and delivery of this document to LESSOR starts the lease, which cannot later be canceled by Lessee for any reason.

5. Lessee requests LESSOR to pay the Vendor for the equipment.

6. Lessee will supply insurance certificates to LESSOR within ten (10) days if not already delivered. Failure to deliver insurance certificates is a lease default and LESSOR may charge an additional risk fee until such certificates are furnished as required.

Lessee: New Vista Ventures d/b/a Laser Works of Seattle

(signature)

Printed Name: John A. Fisher

Title:

STANDARD
CAPITAL CORPORATION

March 31, 2000

New Vista Ventures d/b/a Laser Works of Seattle
411 Strander Boulevard
Tulewila, WA 98188

Re: Lease No.

DUE DATE: March 31, 2000

		Monthly Rent
First Month		
Lease Payment (First Month)		$1,419.60
Sales Tax (8.60% WA)		$122.09
Other Fees		
State & Local Filing Fees; Credit Investigation Costs; Documentation & Processing Costs		$250.00
	TOTAL DUE	$1,791.69

Please remit payment payable to **"Standard Capital Corporation"** and a copy of this invoice with contract documentation to: 100 Burtt Road; Andover, MA 01810.

monthly payments, you acknowledge that we are not responsible for any service, repairs, or maintenance of the equipment, and that we are not a party to the maintenance agreement; if you have a dispu regarding maintenance or service, you will nevertheless continue to pay us all payments due under this Lease and any schedules to this Lease.

4. **NON-CANCELABLE LEASE:** THIS LEASE CANNOT BE CANCELED BY YOU FOR ANY REASON.

5. **DELIVERY OF EQUIPMENT:** You request that we arrange delivery to you at your expense. If the equipment has not been delivered, installed, and accepted by you within forty-five (45) days from t date that we ordered the equipment, we may on ten (10) days written notice to you terminate the Lease and our obligations to you.

6. **TERM OF LEASE, ADMINISTRATIVE FEE:** The Lease term will start on the date that any equipment is delivered to you or your agent ("the Commencement Date") and will continue until you ha met all of your obligations under the Lease. Advance rentals are not refundable if the Lease does not begin for any reason. The payments of rent are payable periodically in advance as stated above or on a schedule to this Lease. The first payment is due on the Commencement Date. You will be notified in writing if we change your first payment date, and we may charge you interim rent for any adjustment per Thereafter, your payments will be due on the same day of each month (or other period indicated on the reverse side). All payments will be made to us at our address on this Lease, or at the address which designate in writing. We will apply your payments to late charges, taxes, fees and lease payments due and payable at our discretion. YOUR OBLIGATION TO PAY RENTALS TO US IS UNCONDITION AND IS NOT SUBJECT TO ANY REDUCTION, SET-OFF, DEFENSE, OR COUNTERCLAIM FOR ANY REASON WHATSOEVER. If you paid a security deposit to us, it will be held by us to secure performance under this Lease, and will be applied or returned pursuant to paragraph 15.) On the Commencement Date of this Lease, you shall pay to us a one-time administrative fee, not to $250.

7. **ASSIGNMENT:** You may not sell, transfer, assign or sublease the equipment without our prior written approval. We may sell, assign or transfer this Lease and ownership of equipment without notifying you; and you agree that if we do, the new lessor will have the same rights and benefits that we now have, and will not have to perform any of our obligations. agree that the rights of the new lessor will not be subject to any claims, defenses or setoffs that you may have against us. However, any such assignment, sale, or transfer of this Lease or equipment will not relieve us of our obligations to you under this Lease.

8. **OWNERSHIP, RIGHTS, AND QUIET ENJOYMENT:** Except with regard to any computer software which may be covered by this Lease, you agree that we are the owner of and have title to equipment. If the Equipment includes computer software, with respect to that software, you acknowledge and agree that (a) we do not have, have not had, nor will in the future have any title to or ownership the software; and (b) you have executed or will execute a separate Software License Agreement with the Licensor of the software, and we are not a party to and shall have no responsibilities whatsoever regards to that Software License Agreement. You agree, at your expense, to protect and defend our title or other rights to the equipment. Further, you agree that you will at all times keep the equipment from any legal process or lien whatsoever, and you shall give us immediate notice if any legal process or lien is asserted or made against the equipment. You shall have the right to quiet use and enjoymen the equipment for the term of this Lease, provided you are not in default.

9. **CARE, USE AND LOCATION; LOSS OF EQUIPMENT:** You are responsible for installing and keeping the equipment in good working order and repair. You will keep and use the equipment onl your address shown on the reverse side, or on any attached schedule, and you will only use it for business or commercial purposes and in compliance with all applicable laws. You will not make any alterati to the equipment without our prior written consent, nor will you permanently attach the equipment to your real estate. At the end of the Lease term, you will return the equipment to us at your expense. You responsible for protecting the equipment from damage, except for ordinary wear and tear, and from any other kind of loss while you have the equipment or while it is being delivered to you. In the event equipment is lost or damaged, so long as you are not in default under this Lease, then you shall have the option to: (a) repair or replace the equipment, or (b) pay to us both the unpaid balance of the remai rent under the Lease and our residual interest in the equipment, present valued using a discount rate of six (6%) percent per year.

10. **TAXES AND FEES:** You agree to pay when due all taxes, fines and penalties relating to this Lease.

11. **INDEMNITY:** We are not responsible for any injuries or losses to you or any other person caused by the installation or use of the equipment. You agree to reimburse us for and to defend us aga any claims for such losses or injuries, including those arising out of negligence, tort or strict liability claims. This indemnity shall continue even after the term of this Lease has expired.

12. **INSURANCE:** You agree that we have the right (but not the obligation) to place, at your expense, property insurance against loss, theft, damage or destruction of the equipment, for up to the replacement value, unless you provide us with written evidence of your own insurance coverage which is satisfactory to us and which identifies us as the loss payee. You also agree to provide and main public liability insurance naming us as an additional insured. If we place insurance for you, you agree to pay the expenses for that insurance in equal installments allocated to each rental payment (plus inte on such amount at 1.5% per month, or the highest rate permitted by law); the expenses shall include the full premium for the insurance and service fees which we or our designee customarily charge for plac insurance. If any insurance proceeds are paid, you shall apply the insurance proceeds toward your total obligations under this Lease; or, if you are not in default under this Lease or any other obligation to and we otherwise consent in writing, you shall have the option to use the insurance proceeds to repair or replace the equipment. **If we place insurance for you, you shall cooperate with our insuran agent in connection with the placement and the processing of any claims. Nothing in this Lease shall create any insurance relationship of any type whatsoever between us and any other pers or party. You agree that we are not required to secure or maintain in force any insurance, in any amounts or upon any specific terms and conditions. We reserve the right to terminate insurance coverage which we may arrange, and we may allow any such insurance coverage to lapse without having any liability to you. You hereby appoint us as your attorney-in-fact to ma claims for, receive payment of, and execute and endorse all documents, checks, or drafts for loss or damage under any insurance policies.**

13. **DEFAULT AND REMEDIES:** If you do not pay rent when due, or if you break any of your promises under this Lease or under any other agreement with us, or you become insolvent, assign y assets for the benefit of your creditors, or enter (voluntarily or involuntarily) into a bankruptcy proceeding, you will be in default. If you default we can require that you return the equipment to us and pay to us remaining balance of all of the rental payments due under this Lease or under any other obligation you may have now or in the future with us ("Other Obligations"), present valued using a six (6%) percent year discount rate. If you fail to return the equipment to us, in addition we can also require that you pay to us our residual interest in the equipment, present valued as noted above. You also agree to pay interest on all sums due us from the date of default until paid at the rate of one and one-half (1-1/2%) percent per month, but only to the extent permitted by law. If you default, we shall also be entitled to reco from you all damages caused by that default. We can also use any of the remedies available to us under the Uniform Commercial Code or any other law. **If we refer this Lease to an attorney enforcement or collection, you agree to pay our reasonable attorney's fees of at least 20% of the remaining balance of all the rental payments, plus our actual costs.** If we have to take possessio the equipment, you agree to pay the cost of repossession, storing, shipping, repairing and selling the equipment. Although you agree that we are not obligated to do so, if we decide to sell the equipment, we are able to sell the equipment for a price that exceeds the sum of (a) our cost of repossession and sale of the equipment and (b) the residual value of the equipment, present valued as calculated above, we shall give you a credit for the amount of such excess. You agree that we do not have to notify you that we are selling the equipment. In any jurisdiction where such action is permitted by law, upon yo breach of this Lease or under any Other Obligation, you hereby irrevocably authorize any attorney of our choosing to appear in any court of record to confess judgment against you for all amounts hereunder, without stay of execution. You waive issuance by us of service of process, all rights, if any, to notice of default, demand, presentment, notice of intent to accelerate, notice of acceleration, notice protest, notice of dishonor, all rights of appeal and relief from any and all appraisement, stay or exemption laws then in effect. **No remedy given in this paragraph is intended to be exclusive and ea shall be cumulative, but only to the extent necessary to permit us to recover amounts you owe us.**

14. **OTHER RIGHTS:** You agree that any delay or failure to enforce our rights under this Lease (or under any schedule(s) to this Lease or any other agreements) shall not prevent us from enforcing rights at a later time. Both parties intend this Lease to be a valid and legal document, and agree that if any part is determined to be unenforceable, all other parts will remain in full force and effect. If document is found not to be a Lease, then you grant us a security interest in the equipment. You also give us the right to immediately file, at your expense, any Uniform Commercial Code ("UCC") financ statements or related filings and you appoint us your attorney-in-fact to sign your name to any such filings that we make.

15. **REDELIVERY OF EQUIPMENT; RENEWAL:** You shall provide us with written notice, by certified mail, sent not less than 90 days nor more than 150 days prior to the expiration of the Lease term, your intention either to exercise any option to purchase all but not less than all of the equipment (if we grant you such an option) or to return the equipment to us at the end of the Lease term. For this notice be effective, you must not be in default of any of your obligations to us. If you elect to return the equipment to us at the expiration of the original or any renewal term of the Lease, you shall disconnect, prepa package for shipping, and return all the equipment to us, insured and freight prepaid by you, in good repair, condition and working order to a location designated by us. Upon your purchase or return of equipment, we may charge you a title transfer or lease termination fee of up to $250.00. If we have not received written notice from you of your intention to purchase or return the equipment, this Lease automatically renew for succeeding one-year periods, commencing at the expiration of the original Lease term. If this Lease is renewed, the advance payment of the last month's lease payment (as set forth the reverse side) shall apply to the last month of the renewal period, and shall not apply to the last month of the initial term. Any security deposit held by us shall continue to be held to secure your performanc for the renewal period. If you specifically request in writing, and provided you have fulfilled all of your obligations to us (including, if you elect, the return of all of the equipment in good repair, condition an working order), we will refund your security deposit to you without interest within 90 days after the end of the original or renewed lease term (or as otherwise required by applicable law), or at your direction may apply the security deposit toward your purchase of the equipment (if we grant you a purchase option).

16. **LATE CHARGE:** If any part of a payment is not made by you when due, you agree to pay us a late charge of ten (10%) percent of each such late payment to cover our additional internal collectio overhead (to the extent permitted by law). You agree to pay us the late charge not later than one month following the date that the original payment was due.

17. **ENTIRE AGREEMENT; CHANGES:** This Lease contains the entire agreement between you and us, and it may not be altered, amended, modified, terminated or otherwise changed except in writi and signed both by you and us. A limiting endorsement on a check or other form of payment will not be effective to modify your obligations or any of the other terms and conditions of this Lease, and we ma apply any payments received without being bound by such limiting endorsements. Other than this Lease, we are not party to, or not bound by, and will not honor the terms of any purchase order or oth agreement regarding the equipment or any financing therefor.

18. **COMPLIANCE; NOTICES:** In the event you fail to comply with any part of this Lease, we can, but we do not have to, take any action necessary to affect your compliance upon ten (10) days pri written notice to you. If we are required to pay any amount to obtain your compliance, the amount we pay plus all of our expenses in causing your compliance, shall become additional rent and shall be paid you at the time of the next due rental payment. If any notices are required under this Lease, they shall be sufficient if given personally or mailed to the address set forth in this Lease by certified or registere mail, postage prepaid. This Lease is for the benefit of and is binding upon you and your personal representatives, successors and assigns.

19. **CHOICE OF LAW; JURISDICTION: YOU AND WE AGREE THAT THIS LEASE SHALL BE BINDING WHEN ACCEPTED IN WRITING BY US AT OUR OFFICES, AND SHALL BE GOVERNED B THE LAWS OF THE STATE OF ILLINOIS. YOU AND WE EACH CONSENT TO THE JURISDICTION OF THE FEDERAL AND STATE COURTS LOCATED IN COOK COUNTY, ILLINOIS FOR TH DETERMINATION OF ALL DISPUTES ARISING UNDER THIS LEASE. HOWEVER, YOU AGREE THAT WE WILL HAVE THE RIGHT TO COMMENCE ANY ACTION IN ANY COURT HAVING TH PROPER JURISDICTION FOR THAT ACTION.** You agree and consent that we may serve you by registered or certified mail, which shall be sufficient to obtain jurisdiction. **YOU AND WE WAIVE TRIAL B JURY IN ANY ACTION BETWEEN US.**

20. **REPRESENTATIONS AND COVENANTS OF LESSEE:** You represent that all financial and other information furnished to us was, at the time of delivery, true and correct. During the term of t Lease, you shall provide us with such interim or annual financial statements as we request.

GLOBEX
Capital Group

Facsimile

Date 5/29/02

Number of pages including cover sheet 6

TO: *Eric Moore*
John Fisher, M.D & Eric Moore

Phone

Fax *206-937-5180*

CC:

From *Lorraine Brooks*
Globex Capital Group
112 Main Street
East Rockaway, NY 11518

Phone *(516) 599-2100 ext 117*

Fax Phone *(516) 599-5337*

At the request of Lumenis, The Globex Capital Group has attached the following set of lease documentation for signature. The lease is for $91,600.00 for a Quantum SR HR. Sales Tax will be billed monthly.

1. US Bancorp Lease Agreement - please sign where indicated. Personal Guaranty is located on the bottom of the lease, please have each person sign by their respective name. Please sign bottom of 2nd page as well.
2. Invoice – please remit.
3. Certificate of Acceptance - Please sign where indicated
4. Authorization Letter - Please sign where indicated.
5. Drivers License - Please include a copy of the front and back of Dr. Fisher and Mr. Moore's Drivers License.

Please fax signed documents to (516) 599-5337.
Please Overnight original documents & make check payable to:

Globex Capital Group
112 Main Street
East Rockaway, NY 11518
Attn: Lorraine Brooks
Our Federal Express Account # is **2073-5047-8**

Please call me if you have any questions.

Thank you.

112 Main Street, East Rockaway, NY 11518 (516) 599-2100

May 29, 2002

John Fisher M.D. and Eric Moore
411 Strander Blvd.
Tukwila, WA 98188

INVOICE

First and Last Months Payment	$ 3,960.00
8.8 Sales Tax	$ 348.48
Documentation Fee	$ 300.00
TOTAL DUE	**$ 4,608.48**

Please make check payable to:

Globex Capital Group
112 Main Street
East Rockaway, NY 11518

May 29, 2002

Lumenis
2400 Condensa Street
Santa Clara, CA 95051

This letter hereby authorizes you to forward our deposit made via check/credit card of $ 5,000.00 for equipment ordered to the appropriate leasing company, with the understanding that these funds will be applied to the advance rentals, sales tax and applicable fees on our lease for the equipment.

Thank you for your assistance in this matter.

Best regards,

(X) _____
John Fisher, M.D.

(X) Eric Moore
Eric Moore

John Fisher, M.D. and Eric Moore
Print Name of Lessee

U.S. Bancorp Business Equipment Finance Group
Two Appletree Square, Suite 330 • Minneapolis, MN 55425
Tel: 800-941-7456 • Fax: 800-571-7371

CERTIFICATE OF ACCEPTANCE

The undersigned John Fisher, M.D. and Eric Moore ("Lessee") under the Lease Agreement dated _____, 2002 the "Lease") between Lessee and **U.S. Bancorp** ("Lessor") hereby acknowledges receipt of all the Equipment described in the Lease. Said Equipment has been received in good order and working condition. Lessee hereby accepts the same in accordance with all the terms and conditions of the Lease, and agrees that Lessor has fully and satisfactorily performed all covenants to be performed by Lessor pursuant to the Lease. Lessee acknowledges the fact that upon signature of this document, all terms and conditions of the Lease, including noncancellability clause, will come into full force and effect.

Lessee warrants that the present location of the equipment is:

411 Strander Blvd.
Tukwila, WA 98188

Lessee: John Fisher M.D. and Eric Moore
By: (X) (X) Eric Moore
Title: _____
Date: _____

(Form2/01)

1. **LEASE AGREEMENT:** You agree to lease from us personal property described under "ITEM DESCRIPTION" as modified by supplements to this Master Agreement from time to time signed by you and us (such property and any upgrades, replacements, repairs and any additions referred to as "Equipment") for business purposes only. You agree to all the terms and conditions contained in this Agreement and any supplement, which together are a complete statement of our Agreement regarding the listed Equipment ("Agreement") and supersedes any purchase order or outstanding invoice. This Agreement may be modified only by written agreement and not by course of performance. This Agreement becomes valid upon execution by us and will begin on the Lease Commencement Date shown and will continue from the first day of the following month for the number of consecutive months shown. The term will be extended month-to-month unless you send us written notice that you do not want it renewed at least ninety (90) days before the end of any term and then you must exercise one of the other two options. Leases with $1.00 purchase option will not be renewed. If any provision of this Agreement is declared unenforceable in any jurisdiction, the other provisions herein shall remain in full force and effect in that jurisdiction and all others. The lease payable from the month of lease commencement shall be prorated from the monthly Lease Payment Amount set forth.

2. **RENT:** Rent will be payable in installments, each in the amount of the basic rental payment shown plus any applicable sales tax, use tax, plus 1/12th of the amount estimated by us to be personal property tax on the Equipment for each year of this Agreement. If we pay any tax on your behalf, you agree to reimburse us promptly. You will pay the advance payment on the date you sign this Agreement. Subsequent installments will be payable on the first day of each rental payment period shown beginning after the first rental payment period. We will have the right to apply all sums received from you, to any amounts due and owed to us under the terms of this Agreement.

3. **COMPUTER SOFTWARE:** Notwithstanding any other terms and conditions of the Agreement, you agree that as to software only: a) We have not had, do not have, nor will have any title to such software, b) you have executed or will execute a separate software license agreement and we are not a party to and have no responsibilities whatsoever in regards to such license agreement, c) you have selected such software and as per lease paragraph 6, WE MAKE NO WARRANTIES OF MERCHANTABILITY, DATA ACCURACY, SYSTEM INTEGRATION, OR FITNESS FOR A PARTICULAR USE AND TAKE ABSOLUTELY NO RESPONSIBILITY FOR THE FUNCTION OR DEFECTED NATURE OF SUCH SOFTWARE. WE ARE FINANCING THE ACQUISITION OF THE SOFTWARE ONLY AND ARE NOT RESPONSIBLE FOR ANY UPGRADES OR SUPPORT.

4. **OWNERSHIP OF EQUIPMENT:** We are the owner of the Equipment and have sole title to the Equipment (excluding software).

5. **WARRANTY DISCLAIMER:** WE MAKE NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING THAT THE EQUIPMENT IS FIT FOR A PARTICULAR PURPOSE OR THAT THE EQUIPMENT IS MERCHANTABLE. YOU AGREE THAT YOU HAVE SELECTED THE SUPPLIER AND EACH ITEM OF EQUIPMENT BASED UPON YOUR OWN JUDGMENT AND DISCLAIM ANY RELIANCE UPON ANY STATEMENTS OR REPRESENTATIONS MADE BY US OR ANY SUPPLIER. WE DO NOT TAKE RESPONSIBILITY FOR THE INSTALLATION OR PERFORMANCE OF THE EQUIPMENT. THE SUPPLIER IS NOT AN AGENT OF OURS AND NOTHING THE SUPPLIER STATES CAN AFFECT YOUR OBLIGATION UNDER THE AGREEMENT. YOU WILL CONTINUE TO MAKE ALL PAYMENTS UNDER THIS AGREEMENT REGARDLESS OF ANY CLAIM OR COMPLAINT AGAINST SUPPLIER OR THE EQUIPMENT.

6. **LOCATION OF EQUIPMENT:** You will keep and use the Equipment only at your address shown above and you agree not to move it unless we agree to it. At the end of the Agreement term, you will return the Equipment to a location we specify at your expense, in retail resalable condition, full working order and in complete repair.

7. **LOSS OR DAMAGE:** You are responsible for the risk of loss or destruction of or damage to the Equipment. No such loss or damage relieves you from the payment obligations under this Agreement. You agree to promptly notify us in writing of any loss or damage and you will pay us the present value of the total of all unpaid payments for the full lease term plus the estimated fair market value of the Equipment at the end of the originally scheduled term, all discounted at six percent (6%) per year. Any proceeds of insurance will be paid to us and applied, at our option, against any loss or damage.

8. **COLLATERAL PROTECTION AND INSURANCE:** You agree to keep the Equipment fully insured against loss with us as loss payee in amount not less than the replacement cost until this Agreement is terminated. You also agree to obtain a general public liability insurance policy from anyone who is acceptable to us and to include us as an insured on the policy. You agree to provide us certificates or other evidence of insurance acceptable to us before this Agreement begins or, we will enroll you in our property damage program and bill you a property damage surcharge as a result of our increased credit risks and administrative costs. As long as you remain current, in the event of a loss, (excluding losses resulting from an act of God), the replacement value of the Equipment will be applied against any loss or damage as per paragraph 7. YOU MUST BE CURRENT TO BENEFIT FROM THIS PROGRAM. NOTHING IN THIS PARAGRAPH WILL RELIEVE YOU OF YOUR RESPONSIBILITY FOR LIABILITY INSURANCE COVERAGE ON THE EQUIPMENT.

9. **INDEMNITY:** We are not responsible for any loss or injuries caused by the installation or use of the Equipment. You agree to hold us harmless and reimburse us for loss and to defend us against any claim for losses or injury caused by the Equipment.

10. **TAXES AND FEES:** You agree to pay when due all taxes (including personal property tax, fines, and penalties) and fees relating to this Agreement or the Equipment. If we pay any of these fees for you, you agree to reimburse us and to pay us a processing fee for each payment we make on your behalf. In addition, you agree to pay us any filing fees prescribed by the Uniform Commercial Code (UCC) or other law and reimburse us for all costs and expenses involved in documenting and servicing this transaction. You further agree to pay us $129.00 on the date the first lease payment is due to cover the expense of originating this Agreement.

11. **ASSIGNMENT:** YOU HAVE NO RIGHT TO SELL, TRANSFER, ASSIGN OR SUBLEASE THE EQUIPMENT OR THIS AGREEMENT. We may sell, assign, or transfer this Agreement without notice to you. You agree that if we sell, assign or transfer this Agreement, the new owner will have the same rights and benefits that we have now and will not have to perform any of our obligations. You agree that the rights of the new owner will not be subject to any claims, defenses, or set-offs that you may have against us.

12. **DEFAULT AND REMEDIES:** If you do not pay any lease payment or other sum due to us or any other party when due or if you break any of your promises in the Agreement or any other agreement with us, you will be in default. If any part of a payment is late, you agree to pay a late charge of 15% of the payment which is late or if less, the maximum charge allowed by law. If you are ever in default, at our option, we can terminate or cancel this Agreement and require that you (1) pay the unpaid balance of this Agreement (discounted at 6%); (2) pay the amount of any purchase option and if none is specified, 20% of the original Equipment cost which represents our anticipated residual value in the Equipment; and (3) return the Equipment to us to a location designated by us. We may recover interest on any unpaid balance at the rate of 8% per annum. We may also use any of the remedies available to us under Article 2A of the Uniform Commercial Code as enacted in the State of Minnesota or any other law. If we refer this Agreement to an attorney for collection, you agree to pay our reasonable attorney's fees and actual court costs. If we have to take possession of the Equipment, you agree to pay the cost of repossession. The net proceeds of the sale of any repossessed Equipment will be credited against what you owe us under this Agreement. YOU AGREE THAT WE WILL NOT BE RESPONSIBLE TO PAY YOU ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES FOR ANY DEFAULT BY US UNDER THIS AGREEMENT. You agree that any delay or failure to enforce our rights under this Agreement does not prevent us from enforcing any rights at a later time. You agree this is a finance lease under Article 2A of the UCC and your rights and remedies are governed exclusively by this Agreement and you waive any and all other rights and remedies.

13. **UCC FILINGS:** You grant us a security interest in the Equipment if this Agreement is deemed a secured transaction and you authorize us to record a UCC-1 financing statement or similar instrument, and appoint us your attorney-in-fact to execute and deliver such instrument, in order to show our interest in the Equipment.

14. **LESSEE GUARANTY:** You agree to submit the original master lease documents with the advance payment to the Lessor via overnight courier the same day of the facsimile transmission of the lease document. Lessee waives the right to challenge in court the authenticity of a faxed copy of this Agreement and the faxed copy shall be considered the original and shall be the binding Agreement for the purposes of any enforcement action under paragraph 12.

15. **LAW:** This Agreement will be deemed fully executed and performed in the state of Minnesota upon signing by U.S. Bancorp and will be governed by and construed in accordance with Minnesota law. You expressly consent to jurisdiction and venue of any state or federal court in the state of Minnesota and waive the right to object on the basis of Forum Non Convenicns. You waive the right to trial by jury for any claim or action arising out of or relating to this Agreement or the Equipment.

Signature (X) John Fisher M.D.

Signature (X) Eric Moore

Agreement # _____

U.S. Bancorp Business Equipment Finance Group
Two Appletree Square, Suite 330 • Minneapolis, MN 55425
Tel: 800-941-7456 • Fax: 800-571-7371

Corporate Headquarters: 115 W College Drive, Marshall, MN 56258

U.S. bancorp. Healthcare Finance Services

'E-Z' Lease Agreement

Agreement #:

This document is written in "Plain English". The words you and your refer to the customer. The words we, us, and our refer to U.S. Bancorp. Every attempt has been made to eliminate confusing language and create a simple, easy-to-read agreement.

Customer	Supplier
Legal Business Name John Fisher, M.D. and Eric Moore	Supplier's Name Lumenis
	Address 2400 Condensa Street
Address 411 Strander Blvd	City, State, Zip Santa Clara, CA 95051
City, State, Zip Tukwila, WA 98188	Salesperson
Phone # Fax #	Phone # 800-635-1313 Fax #
E-mail Address	E-mail Address

1. Specify Equipment

Quantity	Equipment Description	Serial Number
1	Quantum SR HR	

2. Provide us with some basic information

Social Security #: Federal Tax ID #:

Business Type: ☐Partnership ☐Proprietorship ☐Corporation—if Corporation, State of Incorporation: Years in Business:

Your Present Bank: Branch: Phone #:

3. Select your Lease Term (Applicable taxes are in addition to the payment shown)

Lease Term in Months: 60 Monthly Payments: $ 1,980.00 Advance Payment: $ 3,960.00

You shall have the following options at the end of the original Agreement term, provided the Agreement has not terminated early and no event of default under the Agreement has occurred and is continuing.
1) Purchase the Equipment for the following purchase option: One Dollar ($1.00)
2) Renew the Agreement per paragraph 1. 3) Return the Equipment per paragraph 6.

4. Sign the acceptance/delivery agreement.

By signing below, you acknowledge and accept all terms and conditions on the back of this Agreement. Upon our verbal confirmation of delivery and acceptance of the Equipment indicated above, your promises herein will be irrevocable and unconditional in all respects. You understand and agree that we have purchased the Equipment from the Supplier, and you may contact the above Supplier for your warranty rights, if any, which we transfer to you for the term of this Agreement. You understand and agree that in the event that you are not satisfied with the delivery, installation, or performance of the Equipment, you shall only look to entities other than U.S. Bancorp such as the manufacturer, installer, or carrier, and shall not assert against U.S. Bancorp any claim or defense that you may have with reference to the Equipment or its installation. Your approval as indicated by your verbal confirmation is a condition precedent to the effectiveness of this lease. By signing below, the undersigned consents to and authorizes the use of his/her consumer credit report by us from time to time as may be needed in the credit and collection process and further authorizes banks, trade references, credit bureaus, and financial institutions the right to provide personal and business information via fax or over the phone to U.S. Bancorp for purposes of reviewing this application for business credit. **THIS IS A NONCANCELLABLE/IRREVOCABLE AGREEMENT. THE AGREEMENT CANNOT BE CANCELLED OR TERMINATED.**

John Fisher, M.D. and Eric Moore

Company Name

John Fisher, MD — Eric Moore — Date

5. Sign the guaranty (please do not include a title)

As additional inducement for us to enter into the Agreement, the undersigned ("you") unconditionally personally guarantees that the customer will make all payments and meet all obligations required under this Agreement and any supplements fully and promptly. You agree that we may make other arrangements including compromise or settlement with the customer and you will waive all defenses and notice of those changes and will remain responsible for the payment and obligations of this Agreement. We do not have to notify you if the customer is in default. If the customer defaults, you will immediately pay in accordance with the default provision of the Agreement all sums due under the original terms of the Agreement and will perform all other obligations of the Agreement. If it is necessary for us to proceed legally to enforce this guaranty, you expressly consent to the jurisdiction of the court set out in paragraph 16 and agree to pay all costs, including attorneys fees incurred in enforcement of this guaranty. It is not necessary for us to proceed first against the customer or the Equipment before enforcing this guaranty. By signing this guaranty, the undersigned consents to and authorizes the use of his/her consumer credit report by us from time to time as may be needed in the credit and collection process and further authorizes banks, trade references, credit bureaus, and financial institutions the right to provide personal and business information via *fax or over the phone to U.S. Bancorp for purposes of reviewing this application for business credit.*

Signature of Personal Guarantor — Date	Signature of Personal Guarantor — Date
John Fisher, M.D.	Eric Moore
Print Name — Home Phone Number	Print Name — Home Phone Number
Home Address (Not P.O. Box)	Home Address (Not P.O. Box)

U.S. Bancorp Business Equipment Finance Group - Acceptance

Lessor: U.S. Bancorp Business Equipment Finance Group — Title — Lease Commencement Date

0001203

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

20435 72nd Avenue South, Suite 200 • Kent, Washington 98032

Health Systems Quality Assurance Division
Investigation Service Unit

WITNESS NOTIFICATION FORM

PLEASE BE ADVISED THAT ANY WRITTEN STATEMENT YOU MAKE MAY BE RELEASED TO THE PERSON UNDER INVESTIGATION IF A STATEMENT OF CHARGES IS ISSUED.

Signature

12/20/07
Date

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

December 24, 2002

Via Facsimile and Mail

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Letter of Representation and Notice of Appearance for Marilyn Gelnette

Dear Ms. Crowley:

This is to give you notice that I represent Marilyn Gelnette concerning the Department of Health's investigation and related issues set forth in your letter to Ms. Gelnette dated December 16, 2002. My appearance on her behalf concerns matters related to her work as an employee of Laser Works of Seattle located in Tukwilla, Washington.

Please feel free to call me regarding the Department's investigation of Ms. Gelnette.

Very truly yours,

STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

SOF:sof

12/23/02

The 11/19/1999 Laser leasing agreement between Jeff Schmidt, Eric Moore (Owners of LaserWorks) and John Fisher states that the agreement can be terminated with 60days notice from either party, and that laserworks is to find alternative financing for the lasers.

This is to notify Jeff Schmidt and Eric Moore of my request to be removed from the lease of the ESC Alexandrite laser, and the Altus Coolglide lasers within 60 days.

John Fisher MD
Seattle

Received, Eric Moore Representing LaserWorks of Seattle Date 12/23/02

Crowley, Gayle M

From: John Fisher [j_anthony_fisher@yahoo.com]
Sent: Monday, December 23, 2002 4:40 PM
To: Crowley, Gayle M
Subject: Statement

Just following up to make sure you received my faxed statement. If you have any other questions, please contact me.

John Fisher MD
Seattle
206 680-7752

Crowley, Gayle M

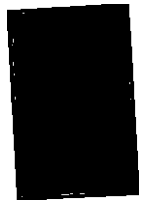
From: John Fisher [j_anthony_fisher@yahoo.com]
Sent: Tuesday, January 14, 2003 5:01 PM
To: Crowley, Gayle M
Subject: Re: Read: Statement

Dear Ms. Crowley:

As we discussed, on 12/23/02 I went into the LaserWorks facility at South Center to give them written notice of my request to be taken off of the leases for the lasers. You may recall that I resigned as medical director the week previously.

I was surprised to find that there appeared to be treatments still going on at the time of my visit on the 23rd. I saw one patient that appeared to have a facial sun burn which was weaping openly and appeared to have vaseline or antibiotic ointment on it.. I was quite surprised by the extent of the damage. I asked him if he had been sun burned, as it was in a distribution that a skier might get on the face. He said no, 'he was having some treatments done'. It was my assumption that he was having treatment at the Laserworks center, but he did not say directly, and I did not ask any further questions.

Please let me know if you have any other questions.



Sincerely, John Fisher
----- Original Message -----

From: Crowley, Gayle M
To: 'john fisher'
Sent: Tuesday, January 14, 2003 9:22 AM
Subject: RE: Read: Statement

Thanks, Dr. Fisher, for your cooperation in this matter. I'm trying to get this case wrapped up by next Tuesday, Jan 21st. If it's possible to get those documents and your statement to me by the end of the week, I would appreciate it.

Also, thank you for responding to my E-mail so quickly. Have a good day.

-----Original Message-----
From: john fisher [mailto:j_anthony_fisher@yahoo.com]
Sent: Tuesday, January 14, 2003 9:02 AM
To: Crowley, Gayle M
Subject: RE: Read: Statement

Hello Gayle:

I have not had any further contact with Laser works since we last spoke. I am sorry I have not faxed you my request to be taken off the leases yet, I will do that this week, and make a brief statement about my vist there.

Sincerely,

John Fisher<*Gayle.Crowley@DOH.WA.GOV*> wrote:

Good morning, Dr. Fisher. Have you had any further contact with Laser Works? Do you know if they still have you listed as their "Medical Director?" Also, you were going to E-mail me a statement regarding your observations when you went in and saw Eric. I never received it. If you could please give me an update.

Thank you,

Gayle Crowley

-----Original Message-----
From: John Fisher [mailto:j_anthony_fisher@yahoo.com]
Sent: Tuesday, December 24, 2002 6:07 PM
To: Crowley, Gayle M
Subject: Read: Statement

This is a receipt for the mail you sent to
"'John Fisher'" at 12/24/2002 1:45 PM

This receipt verifies that the message has been displayed on the recipient's computer at 12/24/2002 6:06 PM

John Fisher
33C Etruria Street,
Seattle, WA 98109

Crowley, Gayle M

From: Stephan O. Fjelstad [fjelstad@winstarmail.com]
Sent: Wednesday, January 15, 2003 9:42 AM
To: Crowley, Gayle M
Subject: Letter Re: Practice of Medicine

Gayle:

Attached is the letter we have discussed previously for your review prior to our meeting this afternoon. I look forward to meeting you.

Stephan Fjelstad

Crowley, Gayle M

From: john fisher [j_anthony_fisher@yahoo.com]
Sent: Friday, January 17, 2003 7:47 AM
To: Crowley, Gayle M
Subject: Re: Laser Works

"Crowley, Gayle M" <Gayle.Crowley@DOH.WA.GOV> wrote:

> Good morning, Dr. Fisher. Do you remember the name of the pharmaceutical company the Lidocaine was ordered from? Did you make a copy of the prescription? Do you remember how many times you ordered Lidocaine for Laser Works? I am trying to find out this information. Eric was unable to show me any of the containers or information.
>
> Have you had any contact with anyone from Laser Works?
>
> Gayle Crowley
> Health Care Investigator
> Department of Health
> 20435 72nd Ave. S, Suite 200
> Kent, WA 98032
> (253) 395-6709
> (253) 395-6724 FAX
>
> "The Department of Health works to protect and improve the health of people in Washington State."

I believe the product was Lasercaine. I do not have copies of the order. The company was faxed a copy of my DEA with my permission. It never occured to me that this was a prescription product. Some of the skin products carried by Laserworks are not prescription, but the distributor wants to see one, just to prove it is being used in a professional office, and not a beauty salon.

I have had no further contact with Laserworks.

Good luck. Let me know if there is anything else.

JOhn

I found this on the internet, and I believe this is the place (Arizona) the DEA number was sent. They will have my name on record if so. I have no other information. I believe they only ordered once from this place. The order was actually shipped to my work place, and I took it over myself. There were about 15, 15g containers in the shippment.

- LaserCaine Forte (lidocaine and tetracaine) Supplied in a one pound jar, 15Gm or 7.5Gm tube. Apply

by rubbing onto desired area with sufficient layers such that skin is not visible through cream. Repeat every 15 minutes. No occlusive dressing necessary. Onset varies with skin thickness: thin skin: 25-40 min. medium skin: 44-55 min. thick skin: 55-65 min. LaserCaine becomes clear as it reaches skin temperature. Re-apply until it becomes opaque again and then add small amounts, as needed, to cover bare spots. Unit dose package ordered by calling 1-808-262-9938 (Phoenix, AZ.) (I think this is the place)

John Fisher
33C Etruria Street,
Seattle, WA 98109

Crowley, Gayle M

To: Fisher, John

Subject: RE: Checking in.

Good morning, Dr. Fisher. The statement and information you provided to the Department of Health in this investigation would be accessible by any attorney for Laserworks if a statement of charges is issued and discover is requested. Certain information you provided may be redacted depending on a legal review by a Department of Health staff attorney. As a licensed medical physician you were required to cooperate in the investigation under the UDA, 18.130.180. You have been forthright with cooperating with this investigation and the Investigative Report will note such.

-----Original Message-----
From: Fisher, John [mailto:John.Fisher@METROKC.GOV]
Sent: Tuesday, February 11, 2003 9:23 AM
To: Crowley, Gayle M
Subject: RE: Checking in.

Gayle:
I am concerned that I will be a 'witness for the prosecution' in this matter. I have nothing personal against the clinic. They also have my name on the leases still. I do not want to get these guys angry, and risk being stuck with lasers. Is the information that I have provided you confidential?

JOhn

-----Original Message-----
From: Crowley, Gayle M [mailto:Gayle.Crowley@DOH.WA.GOV]
Sent: Friday, February 07, 2003 2:27 PM
To: 'Fisher, John'
Subject: RE: Checking in.

Thank you for all of your help. I would like to just ask you one more question, Dr. Fisher. Do you know approximately what time you were in Laserworks on the 23rd of December and saw the patient with the male patient/client/customer with a raw face? I am trying to identify the patient you saw. Any help would be great.

Other than that, I'm just about finished with my investigation. Hope all is well with you.

-----Original Message-----
From: Fisher, John [mailto:John.Fisher@METROKC.GOV]
Sent: Tuesday, February 04, 2003 10:41 AM
To: Crowley, Gayle M
Subject: Checking in.

How is the investigation progressing?
I have had no further contact with Laserworks.

John Fisher, MD
Seattle

Crowley, Gayle M

To: Fisher, John

Subject: RE: Checking in.

Thanks so much, Dr. Fisher. I obtained all the records for that day and can now narrow things down. Have a good day.

-----Original Message-----
From: Fisher, John [mailto:John.Fisher@METROKC.GOV]
Sent: Friday, February 14, 2003 2:24 PM
To: Crowley, Gayle M
Subject: RE: Checking in.

Gayle:

I am sorry that I forgot to answer your question in my reply to your email:

It was in the afternoon, around 3pm I believe that I saw that patient at the clinic. Looked like a young man in his mid twenties.
John

-----Original Message-----
From: Crowley, Gayle M [mailto:Gayle.Crowley@DOH.WA.GOV]
Sent: Friday, February 07, 2003 2:27 PM
To: 'Fisher, John'
Subject: RE: Checking in.

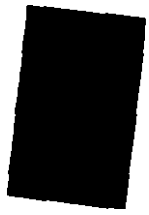
Thank you for all of your help. I would like to just ask you one more question, Dr. Fisher. Do you know approximately what time you were in Laserworks on the 23rd of December and saw the patient with the male patient/client/customer with a raw face? I am trying to identify the patient you saw. Any help would be great.

Other than that, I'm just about finished with my investigation. Hope all is well with you.

-----Original Message-----
From: Fisher, John [mailto:John.Fisher@METROKC.GOV]
Sent: Tuesday, February 04, 2003 10:41 AM
To: Crowley, Gayle M
Subject: Checking in.

How is the investigation progressing?
I have had no further contact with Laserworks.

John Fisher, MD
Seattle



12/22/02

Statement of: John A. Fisher MD
Location where statement is taken: Seattle, Washington.

STATEMENT:

Approximately October of 1999, I was approached by Jeff Schmidt and Eric Moore with a proposition. They had a laser hair removal business in Portland, Oregon and wanted to expand into the Seattle market. Jeff had also been in the hair removal business in the past in Seattle. He had sold his interest in a clinic already, and wanted to start his own up now.

My friend was their medical director in Portland. He had given them my name as an MD that they might be able to work with. My friend told me that Jeff and Eric had been reliable to work with and that there was very little work involved.

They proposed that I have the position of medical director. There was no formal agreement, contract or actual job description. The position was mainly for the purposes of getting better financing for the project. The job description was to:

"...speak to patients that may experience minor side effects to Laser treatment, and to also prescribe topical medications for pain relief.."

Based on the experience that Jeff and Eric had in the business, and the fact a colleague of mine was working with them, I agreed to take their offer. Both Eric and Jeff agreed to sign personal guarantees also, should something happen to the company. I never had any ownership in the company.

I was to be paid primarily to compensate me for the risk of putting my name on the lease of the ESC Alexandrite laser. I was never contacted by the salesman or the company in this transaction. I simply faxed signed documents to the company as requested.

I was never involved in any planning of the clinic set up, the day to day running, training of staff etc. I did not sign off on any of the forms etc that were being used in the treatment of their clients. It was my understanding that the laser work was done by RNs.

In the several years of our relationship, I was called only one time. It was in the first year of the operation. A young woman had some irritation following a procedure done at the clinic. I spoke directly with the patient, and agreed to meet with her to assess her condition. I met her at the clinic and found that she had some minor follicular irritation that required no treatment at that time.

I was called only one other time. In the middle of 2002, I was called about a prescription for LazerCaine, a topical anesthetic of 5% lidocaine. This product was apparently a prescription product, and the supplying pharmacy needed a copy of my DEA number. I called Costco pharmacy in Seattle to see if they had a product like this. They said they did not, and that it must be a proprietary product or formulation done by the specific pharmacy that laser works was dealing with. I agreed to provide the information requested to the pharmacy that Laserworks was using, so that they could get the product. I was not sure if the product was really a prescription item, or that the pharmacy was just being very cautious where they sent the product. My DEA number was also requested for a line of skin care products, that were also non-prescription. The company that was marketing the products, just wanted to keep them in professional settings so they requested proof of a medical director. I do not recall the names of those products.

In April of 2000, I was approached by Jeff and Eric to sign on another laser, for financing purposes once again. They wanted to open a clinic in Lynnwood, Washington. I agreed to this second laser, and was again compensated for my signing. I never saw the Lynnwood office, nor was I involved in the staffing of the office. My understanding was that they also had an RN in the Lynnwood office doing the procedures. Ultimately, it was my understanding that this second office was sold to the RN herself, for her to run on her own.

On Tuesday the 17th, I received a call from Gayle Crowley, an investigator for the Department of Health in Washington. She told me that she had serious concerns about the practices going on at Laserworks in Southcenter. I was surprised to hear that she had spoken to Eric Moore the night before to ask about the services performed at Laserworks, and who was performing them.

Ms. Crowley informed me that I could be held responsible for the actions of the laser works staff, and that as medical director, I was responsible for the training and oversight of their practice. This was certainly not my understanding of the responsibility of the position.

I agreed to meet with Ms. Crowley to cooperate fully with her investigation. After hanging up the phone, I immediately contacted Eric Moore, to discuss my conversation with Ms. Crowley. I advised him of my intent to resign my position as medical director. I faxed a signed resignation to him immediately.

The following Friday am, I met with Ms. Crowley to provide her with some documents that I had pertaining to the leases of the lasers. I was shown several forms that are used in the Laserworks offices for the intake of their clients. I was shocked to see the very medical nature of these forms.

I certify under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct:

Signed: [signature] 12/22/02 3 pm

Name: John Fisher

Address: 33C Etruria Street, Seattle, WA 98109

Telephone: 206 680-7752

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

January 15, 2003

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Department of Health Letters to Marilyn Gelnette, Shaney Shoengarth and Cheri Winsterstein

Dear Ms. Crowley:

As you know, I represent three employees of the company Laser Works of Seattle, namely Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein (collectively, the "employees"). You forwarded letters to Ms. Shoengarth and Ms. Winterstein dated December 19, 2002, and an identical letter to Ms. Gelnette of December 16, 2002, indicating that the Department of Health (DOH) had received a complaint against these individuals and has initiated a preliminary investigation into the allegation DOH apparently received that they may be advertising and practicing in medicine. This responds to the invitation in your letters to the employees for an explanation of their work as it relates to the issue of whether they are actually violating state law by practicing medicine. Certainly it has never been their intent or understanding that they were practicing medicine in any respect.

I would like to emphasize preliminarily that Laser Works has been operating at its location in Tukwilla, Washington for nearly four years now. Prior to opening Laser Work's doors, the principals of the company diligently explored the question of whether their business was subject to any statutory licensing or other regulations in Washington. They concluded that no such statutes or regulations applied; if they had thought any such requirements existed, they would have gladly made application and complied. Their due diligence involved analysis of existing laws and discussions with other members of the same industry. In this effort, they also contacted representatives of the laser equipment manufacturers to determine whether there existed any special restrictions or laws pertinent to Washington State applicable to this industry, and again were informed of no such laws or restrictions.

I know you previously spent time at Laser Works' premises, but certain aspects of the services the company offers and the employees' roles in providing those services bear emphasis. It is important to stress first that the nature of Laser Work's services is strictly cosmetic. People do not come to Laser Works complaining about health concerns or seeking treatment for any type of ailment, injury or sickness. Neither the employees nor anyone at Laser Works diagnoses or offers advice related to health problems. Laser Work's customers simply want to enhance their appearance by reducing the amount of hair on some portion of their physique or by improving the appearance of their skin.

In short, Laser Works provides cosmetic, non-invasive treatments for hair reduction and skin rejuvenation. By non-invasive, we mean that Laser Works' treatments never involve the breaking, cutting or piercing of the skin, or, of course, the cutting or severing of underlying tissues. The treatments are dermatologic and surficial, contained to the outer layer of the skin or dermis and no blood results from the process. No needles or injections of any kind are used. The treatments are performed using light, non-surgical laser or pulsed light equipment. This process allows the neutralization of hair follicles to reduce hair on the body and the rejuvenation of skin by eliminating or reducing age spots, tiny surface vein capillaries and minimization of fine skin lines and wrinkles.

Laser Works also includes micro-dermabrasion among its services, as do many of the local beauty salons and spas. Micro-dermabrasion is another strictly cosmetic, very mild procedure that essentially provides a light skin scrub to clean skin pores and exfoliate or clean away dead cells from the outer layer of the surface of the skin. It is not a skin resurfacing technique. The main purpose is simply to soften the skin. It is tantamount to receiving a "facial." Again, the process is strictly non-invasive, involving no piercing or cutting of the skin. And, again, micro-dermabrasion is a very common skin rejuvenation procedure and practiced by numerous beauty salons, spas and cosmetologists generally.

None of the employees has ever practiced Botox or tattoo removal procedures at Laser Works; Laser Works does not now offer and has never offered these procedures.

Each of the employees participates in operating the laser and pulsed light equipment and providing the related treatments for hair removal and skin rejuvenation. Although we are unaware of any licensing or certification options for operation of laser or pulsed light machinery, each of the employees is very skilled in operating the equipment. Shaney Shoengarth, has been with Laser Works for nearly three years and has close to four years of experience with laser and pulsed light equipment. Marilyn Gelnette has worked with laser and pulsed light technology for over two-and-one-half years and also does microdermabrasion at Laser Works. She holds a license in electrolysis and cosmetology in California where she lived formerly. She also participates in in-take and evaluation of Laser Works customers, including ensuring that they fully understand the company's disclosure and information form regarding treatments. Cheri Winterstein has done laser and pulsed light treatments now for over one year, and also does

dermabrasion at Laser Works. Laser Works has never received a complaint that any of these employees has ever caused any kind of serious or permanent injury to any Laser Works customer in providing treatments during their tenures at the company.

Neither the employees nor anyone at Laser Works has ever prescribed or dispensed any type of drug or medicine for internal use to any customer. Laser Works is not in the business of prescribing or supplying drugs or medicines and does not advertise itself in that manner. I have also investigated the company's past use of lydocaine. Lydocaine is a strictly external, topical crème applied to partially numb the skin. It can be purchased over-the-counter in nonprescription strength.

For some time, neither Laser Works and nor any of the employees have stored or supplied any lydocaine at the premises, and have no intention of acquiring more lydocaine for any purpose. There simply is no real need for lydocaine in Laser Works' services. The last time Laser Works received any lydocaine was several months ago when it ordered a small shipment of about fifteen small containers. It was supplied to a tiny fraction of Laser Works' customers to be applied to their skin prior to treatments. Since that time, no one at Laser Works has ordered any more lydocaine and will not do so. No other crème or other substance similar to lydocaine, nor any other external or internal drug or medicine has ever been supplied to anyone at Laser Works. (We also note that none of the persons who have supposedly complained to the DOH, which led to this investigation, had used lydocaine.)

Laser Works and the employees currently use four machines for the various hair removal and skin rejuvenation services. The trade names and manufacturers of the equipment include the "Aurora" manufactured by Syneron, the "Cool Glide" by Altus Medical, the "Alexanderite" by ESC Sharp Plan and the "IPL" by Luminous. Our understanding is that two of these machines are more properly described as intense pulsed light systems rather than lasers because the light energy they emit is not sufficiently concentrated to be classified as lasers. None of these machines is a surgical laser as they are not designed or used to cut or pierce human skin or tissues.

In fact, the latest generation of "laser" equipment, including the Aurora used at Laser Works, now incorporates radio frequency (as used in electrolysis) and reduces the amount of optical light energy emitted by approximately one-half. It is questionable that such mild energy light emissions even qualify these systems as intense pulsed light or lasers at all.

Laser Works purchased two of its machines without the assistance or involvement of its medical director, Dr. John Fisher, or of any other physician. No such assistance by medical personnel was requested or required. The other two machines were purchased with Dr. Fisher's assistance and signature. Although Dr. Fisher may have suggested otherwise to you, the singular reason for purchasing the initial two machines through Dr. Fisher is that having a physician's signature in the transactions allowed Laser Works to procure favorable financing

arrangements from the manufacturers. Our understanding is that because they are all non-surgical lasers, none of the machines, including the two purchased with Dr. Fisher's assistance, is technically restricted to be sold only to medical physicians by the federal or Washington state law or regulations. We have not yet found any reference in the literature or purchase documentation accompanying the equipment (or on the equipment itself) any notice that the machines are restricted to purchase or use only by licensed physicians or medical personnel. As such, none of the employees has been operating equipment that can, by law, only be sold to (or operated by) medical personnel with prescriptive authority.

We do understand that certain manufacturers have a company preference or policy to sell laser equipment to medical physicians and the involvement of a doctor facilitates purchase and financing. We have found no definitive authority, based on our research thus far, however, that a physician's involvement is absolutely required by federal or Washington law to buy the equipment. If you are aware of FDA prohibitions or other federal or Washington laws that do restrict the machines Laser Works uses only to purchase by medical professionals, please advise us. (We have also reviewed the MQAC Policy of 10/25/02 regarding use of lasers as a separate matter and will address it below.) We do know that the type of laser and pulsed light equipment Laser Works uses is freely sold and purchased on the resale market without any restriction whatever; anyone with the money can repurchase these machines, and we are unaware of any regulation or restriction in that market. We are further aware that other industries, such as beauty salons, use the less expensive laser or pulse light technology in their own skin rejuvenation services.

We continue to research the numerous FDA classifications and regulations, as well as state law, to determine whether these machines are necessarily prescription devices that can only be sold to medical personnel with prescriptive rights, and regardless of whether they will be put to a "medical" use or application. Again, we would welcome information you may have in this inquiry that we have not yet uncovered. Clearly the FDA regulates lasers pursuant to 21 CFR Part 1000.15 as "radiation emitting products" and "medical devices" under the Federal Food, Drug and Cosmetic Act (the FD&C), Section 201. CFR 1040 et seq., moreover, contains elaborate performance standards and designation and warning information that is to accompany certain classifications of lasers. The FDA's Center for Devices & Radiological Health, however, also says that not all radiation-emitting products come with medical applications and claims such as to meet the definition of a "medical device." Certainly the FDA, under the FD&C subjects medical devices to premarketing (and some postmarketing) regulatory controls. Whether the machines purchased by Laser Works' are necessarily medical devices that can only be sold to licensed physicians for the uses to which Laser Works puts them remains a question, particularly under Washington state law.

With respect to other activities by Dr. Fisher in his role as medical director for Laser Works, he has never, to our knowledge, prescribed drugs or medicines to Laser Works's

customers related to services or treatments provided by Laser Works. As a precaution, he has been available to Laser Works as an on-call consultant and for oversight.

In our telephone conversations, you have also mentioned that one of Laser Works' forms given to its customers contains the following language: "I understand that I will receive medical treatment...." This form does not correctly portray the nature of any services Laser Works offers and by no means is a representation that Laser Works or its employees actually believe that the services they have been providing are actually medical treatments. The form containing this language is a very recently revised document. The only reason it indicates "medical" treatments is that at the time the form was recently changed, Laser Works was considering eventually offering Botox treatments, which it would have done through a medical physician, and simply wanted its form to accommodate that potential treatment along with its other services. This would negate the need to offer multiple forms.

Laser Works' previous form, including the version used immediately before this recently revised one, had no language at all suggesting Laser Works offered any sort of "medical" treatment. Prior to contemplating Botox, Laser Works, as is reflected in the old form, did not consider its hair removal or skin rejuvenation procedures related to "medical" treatments. This new form literally contains an error in drafting because Laser Works has, since the printing of the new form, elected not to offer Botox treatments. Accordingly, the form will be revised again so that it does not indicate to customers that they will receive medical treatments.

You also mentioned that Laser Works uses a form called "Patient Medical History." Again, Laser Works has never used this form with the intent or belief that its customers are medical "patients" and that it is providing medical services. I would point out that another of Laser Works' standard forms is entitled "Customer Comments and Concerns," which emphasizes that Laser Works views and refers to the users of its services as "customers" or "clients" rather than as medical "patients" who receive medical treatments. I would also emphasize that using a form asking a few questions pertinent to a person's medical history does not in itself mean that the services the employees provide are indeed medical practices. The aim of the medical history form is simply to discern any conditions that might affect a customer's skin, and does not involve some sort of medical diagnosis. The same questions would be pertinent to many other practices in other non-medical industries, such as cosmetology, esthetics or electrolysis. In any event, so as not to convey to its customers the wrong impression that it is engaging in medical practices, Laser Works will also revise this form so that it uses the word "customer" or "client" rather than "patient."

Similarly, the print advertisements Laser Works uses do not use the word "medical" or otherwise indicate that customers will receive medical treatments. Those advertisements emphasize "hair removal" and "laser facials" to reduce hair, age and sun spots and other dermatological blemishes—in the same manner that innumerable spas, salons, cosmetologists

and other non-medical practitioners advertise their services to accomplish the same cosmetic goals.

We do not believe that the services provided by Laser Works and its employees qualify as the practice of medicine under the relevant state statutes and case law interpreting those statutes. The practice of medicine under Washington law is defined in RCW 18.71.011:

> A person is practicing medicine if he does one or more of the following:
>
> (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
>
> (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
>
> (3) Severs or penetrates the tissues of human beings;
>
> (4) Uses on cards, books, papers signs or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation "doctor of medicine," "physician," "surgeon," "m.d." or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license...

We believe subpart (3) does not apply to Laser Work or the employees' practices because none of the services or treatments they provide involves severing or piercing the tissues of their customers. As described above, all methods practiced by the employees involve no cutting of the skin, much less underlying tissues.

Subpart (4) also does not apply to Laser Works' practices because none of the company's advertising marketing or other forms of supplying written information to the public uses the terms doctor of medicine, physician, surgeon, or M.D. as defined by the statute. Similarly, in *State v. Pollman*, 51 Wash. 110, 98 P. 88 (1908), the only case discussing this statutory prohibition (under the predecessor statute to RCW 18.71.011), the court prohibited conduct by an individual who actually printed the words "physician" and "doctor" on his office doors. Laser Works engages in no such conduct. Nowhere in its printed materials, moreover, does Laser Works hold itself out as practicing medicine in any way or otherwise offering services involving the diagnosis or treatment of human disease, injury or ailments of any kind.

With respect to subpart (2) concerning drugs, neither Laser Works nor the employees have ever prescribed any drug to any customer and has never provided any drug to anyone for internal use. As mentioned earlier, Laser Works previously had small amounts of lydocaine that a few customers were given as a mild, topical and external application prior to treatments. The lydocaine was not a medicine or drug for treatment of any disease, ailment or any particular condition. It simply provided a mild analgesic for customers who expressed concern about potential pain. Lydocaine is no longer provided by anyone at Laser Works for any purpose, and has not been available for some time, because it is simply not necessary given the nature of treatments offered by Laser Works and the employees. No one at Laser Works will order any more Lydocaine or any type of similar external or topical substance. No other drugs or medicines of any kind, whether prescription or non-prescription, are available to customers at Laser Works. I would note also that it is questionable whether lydocaine as previously used at Laser Works qualifies necessarily as a "drug" for purposes of defining medical practice, at least under case law. In *Kelly v. Carroll*, 36 Wash.2d 482, 488, 219 P.2d 79 (1950), the court observed that a "drug" is a substance "used as a medicine," and that a "medicine" is a substance used "in treating disease." In this matter, none of the employees used lydocaine to treat any disease or illness.

We believe subsection (1) does not apply because no one at Laser Works purports to "diagnose," "cure" or "prescribe" anything to anyone. Nor do they advise any customer concerning any "disease, ailment, injury, infirmity, deformity, pain" or any other "condition" related to health or healing. The curing or prevention of some sickness or injury or the restoration of health is clearly the underpinning of both the letter and spirit of this statute and the meaning of the "practice of medicine."

The services the employees provide at Laser Works are strictly cosmetic in nature and that is how they are advertised. Particularly given the non-invasive nature of the procedures used at Laser Works, we do not believe the legislature intended or a court would find that these procedures should be regulated as the practice of medicine. For example, one court, interpreting the predecessor statute to RCW 18.71.021, ruled that the type of "advice" that constitutes "practicing medicine" included prescriptions and advising a diabetic to discontinue use of insulin and to restrict his diet to exclude carbohydrates. *State v. Karsusky*, 197 Wash. 87, 84 P.2d 390 (1938). In another case, the unlicensed individual "diagnosed" a person's "ailments," employed manual manipulations to give medical advice and prescribed diet as a cure. *State v. Greiner*, 63 Wash. 46, 114 P. 897 (1911). Cases such as these (and we have found no contrary cases under the current version of the statute) involve circumstances critically distinct from Laser Works' procedures.

We also note that several other industries routinely practicing much more invasive, painful and risky procedures than Laser Works are not regulated as the practice of medicine. Electrologists, for example, pierce the skin with needles in order to neutralize hair follicles. Similarly, tattoo artists and body piercers use needles to break the human skin and deeper into

body tissues. The practice of esthetics involves the use of electrical appliances, waxings and chemical compounds—often referred to as "chemical peels"—that are frequently much more disruptive to skin surfaces, resulting in serious redness and skin peeling, than Laser Works' procedures. Numerous salons and cosmetology shops also perform chemical perms that present similar risks, and use less expensive laser technology in their services.

Certain of these and similar industries are regulated (*e.g.*, RCW 18.16 for cosmetologists, barbers and manicurists), others are not. Certainly none of them, however, is regulated as the practice of medicine. By analogy, we believe Laser Works' procedures also should not require a medical license. It may be time for the state legislature to pass laws requiring licenses and regulations for Laser Works' industry, or deem it appropriate to include this business under, for example, RCW 18.16. In that event, Laser Works and the employees will gladly comply with any requirements. It seems inappropriate and inequitable, however, to simply declare that the employees are practicing medicine given the nature of their services and the fact that other industries are not so regulated.

On the topic of regulations, we further note that at a broader regulatory level, neither the procedures Laser Works employs nor those of the industries listed under RCW 18.16 are included among the numerous industries defined as "health professions" under RCW 18.120.020(4) or as "health care services" under RCW 48.44.010(1). We believe this is appropriate precisely because of the non-medical and cosmetic nature of Laser Works' services and those governed by RCW 18.16—it simply is not about a person's health, is not a health care service or healing art, but instead concerns purely a person's appearance.

We recognize that despite our interpretation of applicable statutes and case law, the Medical Quality Assurance Commission ("MQAC") very recently issued a policy statement entitled "Use of Lasers in Skin Care and Treatment" (the "policy statement"). Although we do not believe the policy statement necessarily means Laser Works' services are the practice of medicine, we want to assure you that the employees and Laser Works fully intend to cooperate with the DOH and to bring their procedures into compliance with the MQAC as deemed necessary through this investigation process.

We note initially that the first paragraph of the policy statement assumes most lasers are restricted for sale only to persons with "prescriptive authority." As we noted above, our research continues on the question of whether the laser and pulsed light equipment used at Laser Works is conclusively restricted in that manner. What the MQAC does make clear in the same paragraph, however, is that "the use of a laser for dermatologic purposes, such as hair removal" can be delegated to persons without prescriptive authority. For all of the reasons discussed above, we believe the procedures used at Laser Works by the employees are all for "dermatologic purposes" and therefore can be performed by non-physicians. All of Laser Works services are dedicated to the singular purpose of improving the appearance of its customers' skin.

Nonetheless, Laser Works and the employees are committed to working with the DOH and to achieving compliance with the MQAC's policy statement. We recognize that the policy statement sets forth a number of recommendations for "appropriate oversight" by a physician regarding the procedures that may be delegated regarding the use of lasers. Please be assured that the employees and Laser Works intend to address these provisions and comply with them to the extent possible to ensure proper continued oversight by a physician. We have some concern that certain of the requirements may be difficult to achieve immediately. For example, we are unaware of whether physicians can acquire actual certification in the "theory and use" of lasers, as seems to be recommended for the oversight physician in subpart (3) of the second paragraph of the policy statement. We will, however, explore that issue with the MQAC as well as any other topics the DOH believes need to be addressed concerning Laser Works' practices.

We would like to underscore that we believe Dr. Fisher has provided the proper availability as is emphasized in the policy statement, as he has always been accessible by phone if needed. To the extent the DOH believes more or different involvement by a physician is necessary to comply with the policy statement, Laser Works will work to provide such additional oversight immediately. We also underscore that the employees are highly skilled with years of experience in using the laser and/or pulsed light machines as is also underscored in the policy statement. We are generally confident that the skill and experience level of the employees compares well with other businesses performing the same services throughout the state.

Again, the employees and Laser Works are committed to working with the DOH to satisfy its concerns and will make adjustments to Laser Works' procedures to ensure compliance with any requirements deemed necessary. We look forward to the process of exchanging information with you and of identifying any such necessary changes. We believe there are additional facts and evidence that may be pertinent to your investigation. As we receive such evidence and facts we will supply them to you and request that you do not at this time finalize your report until we have had that opportunity.

Very truly yours,

STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

SOF:sof
cc: clients

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DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

LICENSING REQUIREMENT NOTIFICATION

I, Marilyn Gelnette, have been advised that the practice of Medicine within the state of Washington requires proper licensing by the Department of Health. By signing my name below and returning this notification to the Department, I acknowledge receipt of the necessity to be licensed to practice Medicine in the state of Washington. Furthermore, my signature below does not constitute an admittance that I have practiced without the proper licensure or certification.

Signed: Marilyn Gelnette
Marilyn Gelnette
Dated: 12/31/02, 200_

By signing this document, I understand that I am not admitting that I now practice, or ever have practiced medicine working for Laser Works of Seattle. My belief has always been that my work for this company has never involved the practice of medicine.

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

December 26, 2002

Via Facsimile and Mail

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Department of Health Investigation of Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein

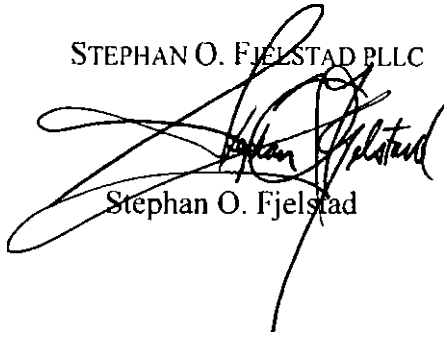
Dear Ms. Crowley:

This is simply to confirm our agreement made on the telephone on December 24, 2002 to extend the deadline by one week for my clients to return the licensing requirement notification forms you previously forwarded to them with your letters of December 16 (Ms. Gelnette) and 19, 2002 (Ms. Shoengarth and Ms. Winterstein). By my calendar, the due date for Ms. Gelnette was previously December 30, 2002, which makes her deadline now January 6, 2003, with the responses for Ms. Shoengarth and Ms. Winterstein now due by January 9, 2003. Your December 16th and 19th letters also invited my clients to respond in writing regarding their work and whether they believe they have violated state law. We intend to submit at least preliminary written responses on this subject by the same dates as now set for the licensing notification forms (January 6th and 9th), and presume those timeframes will work for you. Please let me know right away if any of this does not meet with your approval.

I thank you for your courtesy in extending these deadlines. As we also discussed on the phone, in the meantime I am attempting to get up to speed as quickly as possible on the background facts so that we can meet soon as you suggested. I will be in touch with you on that topic. Feel free also to telephone me with any matters you would like to discuss further.

Very truly yours,

STEPHAN O. FJELSTAD PLLC



Stephan O. Fjelstad

SOF:sof
clients

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1424 FOURTH AVENUE, SUITE 909
SEATTLE, WASHINGTON 98101-2217
VOICE: (206) 903-0664
FAX: (206) 903-6144
EMAIL: fjelstad@winstarmail.com

January 7, 2003

Via Facsimile and Mail

Gayle M. Crowley
Health Care Investigator
Department of Health
20435 72nd Ave., S., Suite 200
Kent, WA 98032

Re: Department of Health Investigation of Marilyn Gelnette, Shaney Shoengarth and Cheri Winterstein

Dear Ms. Crowley:

This is simply to confirm the contents our telephone discussion on January 3, 2003 in which we agreed to meet at my office on January 15, 2003 at 2:00pm to discuss the DOH investigation involving my clients. We also agreed that the licensing requirement notification forms you provided my three clients as well as an initial letter on behalf of all three in response to the issues raised in your letters of December 16 and 19, 2002 to them, will not need to be forwarded to you until the time of our meeting on January 15, 2003.

I look forward to our meeting.

Very truly yours,

STEPHAN O. FJELSTAD PLLC

Stephan O. Fjelstad

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EXHIBIT 15

LASER ~ WORKS!

Informed Consent

Skin Rejuvenation

I understand that the IPL Quantum SR is an IPL device used for skin rejuvenation and that clinical results may vary in different skin types. I understand that there is a possibility of rare side effects such as scarring and permanent discoloration as well as short-term effects such as reddening, mild burning, temporary bruising and temporary discoloration of the skin. These effect have all been fully explained to me _____ (please initial)

Based on the clinical experience and discussion with other physicians we have found that those people who tend to sunburn rather than tan usually obtain good results on the first and subsequent visits. On the other hand, those who tan more easily tend to have more variation in their results. Some patient in this category will experience partial results and some will experience no improvement at all.

I understand that the treatment by the IPL Quantum SR system involves a series of treatments and the fee structure has been fully explained to me.

I also understand that there are options for cosmetic skin treatment that are available and each of these other options have fully been explained to me _____ (Please initial)

With this in mind, I am choosing to try the IPL Quantum SR non-invasive treatment for Photorejuvenation.

I have read and understand this agreement and all my questions have been addressed and answered to my satisfaction. I agree to the terms of this agreement.

I understand that there is a 24-hour cancellation policy, and a $75.00 minimum fee or half of the treatment cost will be charged. _____ (Please initial).

I understand that Laser – Works! Does not offer a money back policy. If for some reason I am unsatisfied with the results of my IPL treatment I realize that there will be no cash refunds._____ (Please initial)

Client's name (please print):_____

Signature:_____

Date:_____

Witness:_____

EXHIBIT 15

EXHIBIT 116

EXHIBIT 17

EXHIBIT 18

APPENDIX D

GENERAL SUMMARY

THE INFORMATION CONTAINED IN THIS REPORT, WITH IT'S ACCOMPANYING EVIDENCE AND EXHIBITS, SHOULD BE CONSIDERED IN CONJUNCTION WITH THAT INFORMATION INCLUDED IN THE COMPANION CASE FILES FOR THE MATTER REFERENCED ABOVE ON THE COVER PAGE OF THIS REPORT.

This investigation was initiated by receipt of a complaint at the Unlicensed Program of the Department of Health, from 4 - Identity - Whistleblower ... on September 4, 2002. 4 - Identity - Whistleblower ..., complainant, says he received treatment for hair removal from the respondent on August 28, 2002. He alleges the respondent, Marilyn Gelnette, told him she could guarantee him 100% that if he had treatment on his cheek, he would be able to go to work and be fine. He says he let her perform the treatment. He alleges she only treated his left cheek because the laser broke before she could finish the other side. He alleges after the treatment, his cheek was red and he received blisters. At the date of this E-mail complaint, September 4, 2002, he alleges his cheek is starting to get back to their normal color.

The complainant is wondering what can be done to stop this from happening to him or another person. He says no one should go through this treatment. **Page 1**

On September 9, 2002, the Unlicensed Program requested a field investigation be conducted to verify if the respondent is providing any type of medical services for which requires licensure. **Page 2**

On September 17, 2002, a telephone interview was conducted with the complainant of the companion case file. She provided names of patients and also gave information regarding Laser Works and how the business is run.

On October 22, 2002, information was obtained from the Internet website for the State of Washington Cosmetology Board, including the requirements for licensure. **Pages 3-12**

On December 17, 2002, information about laser treatment and equipment from various agencies was obtained from the Department of Health, Unlicensed Program Manager. **Pages 13-30**

On December 17, 2002, a telephone interview was conducted with Dr. John Fisher, medical director of Laser Works, Inc. Dr. Fisher was not aware an investigation was open. He became the medical director to help the company with financing of the laser. He doesn't have much contact with the business, but does receive a monthly check for $500 for them to use him as their medical director.

Dr. Fisher states in the three years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least six months and has not worked with or know any of the employees working at the Laser Works.

Dr. Fisher is full time employed as the Public Medical Doctor for King County, in the jail systems at different locations. It is his understanding the owners of Laser Works, Inc. have nurses

providing treatment in their offices. He is unaware of any non-medical personnel providing treatment to patients.

Dr. Fisher explained he ordered Lidocaine (later identified as 5% topical) for the business and the prescriptions were mailed directly to Laser Works. A Memo To File was prepared from this interview. **Page 31**

On December 17, 2002, a field visit was made to the respondent's place of employment, Laser Works, Inc., with health care investigator Jim Voiland. Pictures were taken of the front reception office, treatment rooms, equipment being used for treatment, and framed posters.

An interview was conducted with owner Eric Moore. Mr. Moore states his employees are not performing any medical treatment to individuals who come in for their services. He identified these individuals as clients or customers.

Mr. Moore says they did not hire Dr. Fisher to be the medical director out of necessity. They hired Dr. Fisher so they could have him order the lasers and obtain easier and better financing. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business.

Mr. Moore says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse. He identified the respondent as being a cosmetologist and that she started working her in June 2002. He and the respondent usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs.

When Mr. Moore was asked about the respondent and companion case respondents using prescription strength Lidocaine on patients/clients/customers, he says Lidocaine is only given to someone in pain that requests it. He says it's not a big deal. He couldn't remember the last time they received any Lidocaine, but says it is rarely used. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail to the business. Mr. Moore was unable to show us a container of Lidocaine or where it is stored in the office, when asked, but walked around the office and opened cabinet doors.

Mr. Moore described the four lasers being used. He says they do have a microdermabrasion machine, but do very few treatments. Even though botox treatments are listed on Laser Works forms, he says this office does not perform these treatments. A Memo to File was prepared from this interview.

A copy of all Laser Works forms and brochures, located in the front reception office, were obtained. A review of these forms included the following:

- Reminder and Referrals – This form includes the following comment: "Following a botox treatment you should see improvements within 72 hours..."
- Informed Consent Form – Per owner Eric Moore, this is the new form they are using. This form first sentence reads, "I understand that I will receive medical treatment From Laser Works of Seattle."
- Patient Medical History

- Patient Medical History – Vascular Treatment
- Post Treatment – Vascular
- Pre-Treatment – Vascular
- Treatment Log
- Medical History – Skin Rejuvenation
- Informed Consent – Microdermabrasion
- Informed Consent – Skin Rejuvenation
- Client Information Skin Rejuvenation
- Skin Rejuvenation (IPL) Post Treatment Care

A review was made of Laser Works appointment book. A sample of files were obtained, including individuals previously identified by the complainant and companion case file complainant. **Pages 32-134**

On December 17, 2002, a letter was delivered to the respondent and an interview was conducted. The respondent denied she is performing any type of medical treatment or practicing medicine. The respondent did not want to sign the Licensing Requirement Notification at this time. **Pages 135-137**

On December 17, 2002, Dr. Fisher faxed a copy of his resignation as Medical Director for Laser Works, Inc. A telephone message for Dr. Fisher verified this letter was also faxed to Eric Moore at his home, per Mr. Moore's request. **Page 138**

On December 18, 2002, a copy of the Medical Quality Assurance Commission's Policy was obtained from Dr. Heye. **Pages 139-140**

On December 19, 2002, information regarding the drug, 5% Xylocaine (Lidocaine) was obtained from the 1997 Edition of the Physicians' Desk Reference. **Page 141**

On December 19, 2002, information was obtained from several Internet Websites, including the Federal Drug Administration (FDA), and copies printed. Further contact was made with Kathy Maynor at Altus Medical. Ms. Maynor faxed laser FDA information. She also provided the explanations showing how the lasers are categorized, who can buy them, and who can use them. **Pages 142-184**

On December 20, 2002, an interview was conducted with Dr. John Fisher. Dr. Fisher provided documents he had pertaining to his association and agreements with owners Eric Moore and Jeff Schmidt of Laser Works. These documents include copies of laser lease agreements.

During this interview, Dr. Fisher signed a Witness Notification Form. He expressed his concern about the investigation and how it could affect his license to practice. **Pages 185-204**

On December 23, 2002, a Notice of Appearance was received from the respondent's attorney, Stephan Fjelstad. Mr. Fjelstad is also representing the two companion case file respondents. **Page 205**

During the course of conducting this investigation, Dr. Fisher provided correspondence by E-mail. Dr. Fisher also faxed a copy of the termination of the laser leasing agreement between himself, Jeff Schmidt, and Eric Moore. **Pages 206-214**

On January 15, 2003, Dr. Fisher provided a statement. He described in detail how he became the medical director of Laser Works, Inc. Dr. Fisher said he was paid primarily to compensate him for the risk of putting his name on the lease of the ESC Alexandrite laser.

Dr. Fisher says he was never involved in the planning or set up of the clinic or the day-to-day running of the clinic. It was his understanding the laser work was to be done by RN's. In the several years he has been the medical director, Dr. Fisher says he has been called only once, during the first year of operation.

Dr. Fisher also discusses his ordering of the prescription for Lazercaine, a topical anesthetic of 5% lidocaine. **Pages 215-216**

On January 15, 2003, the respondent's attorney provided the respondent's written response. This written response is the same one as for the two companion case file respondents. The respondent's attorney describes in detail how Laser Works, Inc. is performing its operations at the Tukwila location. He says prior to the business opening it's door, the principals diligently explored statutory licensing and regulations in Washington.

The respondent's attorney describes treatment provided by employees at Laser Works and says the nature of their services is strictly cosmetic. He says none of the employees diagnose or offer advice related to health problems. Customers simply want to enhance their appearance.

The respondent's attorney says the respondent has worked with laser and pulsed light technology for over two and one half years and also does microdermabrasion at Laser Works. He says she holds a license in electrolysis and cosmetology in California, where she lived formerly.

The respondent's attorney states none of the employees, including the respondent, have ever prescribed or dispensed any drug or medicine for internal use to any customer. He denies any employees have stored or supplied any lidocaine at the premises, and have no intention of acquiring more for any purpose. He says the last time Laser Works received lidocaine was several months ago when a small shipment of fifteen containers were ordered. The respondent's attorney says the lidocaine was supplied to a tiny fraction of Laser Works customers to be applied to their skin prior to treatments.

The respondent's attorney explains Dr. Fisher's role as medical director for Laser Works, Inc. He says Dr. Fisher has never, to their knowledge, prescribed drugs or medicines to any customers.

The respondent's attorney denies the services Laser Works and their employees are providing qualify as the practice of medicine under Washington State law.

The respondent completed the Licensing Requirement Notification form by signing and also providing a written statement. **Pages 217-229**

On January 27, 2003, patient treatment records were obtained by subpoena. These were a sampling of records for individuals receiving treatment from December 17, 2002 through January 15, 2003.

A review of the records indicates several patients/clients/customers were given lazercaine (lidocaine) during the treatment process. This is noted on Evidence Page #411, and Evidence Page #621. A comment from the treatment provider suggesting lidocaine is listed on Evidence Page #455. **Pages 230-683**

On January 27, 2003, the respondent's attorney provided copies of three forms that have been revised and are being used at Laser Works. They are as follows:

- Customer Comments and Concerns
- Informed Consent Form
- Client Medical History **Pages 684-687**

On January 31, 2003, a telephone interview was conducted with Dr. Elizabeth Bianchi. She states she is currently the medical director for Laser Works Inc. Dr. Bianchi states she is also the medical director of Nouveau (sp?) of Spokane. She says she lives and works in Spokane, but has made a visit to Laser Works. She also works for Planned Parenthood in Spokane. Dr. Bianchi said she understands she is responsible for the day to day treatment being provided at Laser Works, and is going to work with the Medical Quality Assurance Commission.

On February 18, 2003, a telephone interview was conducted with the complainant. The complainant says it took almost two weeks for his cheek to look normal again after receiving treatment from the respondent. He alleges the treatment was stopped because the laser broke before the respondent could finish. He was given a white antibiotic cream to put on his cheek by the respondent.

EXHIBIT 19

DECLARATION OF BRANDITH G. IRWIN, M.D.

Pursuant to RCW 9A.72.085, the undersigned certifies that:

1. I am a duly licensed and Board certified physician practicing dermatology in Seattle, Washington. My background and experience are summarized in the attached curriculum vitae.

2. The following statement is based upon my training and experience in the field of the application of laser energy to human tissue.

3. The use of laser for hair removal and for skin treatment involves the use of energy that penetrates the skin and underlying tissues and that such penetrating energy can be the cause of such symptoms such as redness, swelling, blistering, in-grown hair, and scarring.

4. Lasercaine and lidocaine (4% or greater) are topical numbing agents and are available by prescription only. They are capable of causing death if used improperly.

The undersigned certifies under penalty of perjury that the forgoing is true and correct.

Dated this 7/26/05 in Seattle, Washington. _____, MD.

CURRICULUM VITAE

Brandith Gail Irwin, M.D.

Address: 1101 Madison, Suite 1490, Seattle, WA 98104
Telephone: (206) 215-6600
Place of Birth: Seattle, Washington

EMPLOYMENT:

04/99 to present	Madison Skin and Laser Center, Brandith Irwin, M.D., PLLC
1991 to 1999	Minor & James Medical Group

BOARD CERTIFICATION:

Dermatology, 1991 (recertified 2001)

Internal Medicine, 1987

HONORS AND AWARDS:

Dermatology Foundation Leaders Society, 2002-Present

Appearance on Oprah Winfrey show to discuss aging skin

Alpha Omega Alpha Medical Honor Society

National Dermatology Foundation Research Fellowship Award, 1990

Seattle Magazine, 2001, 2002, 2004. Listed as a top dermatologist in the Puget Sound area.

LASER EDUCATION:

2000-2005	ASDS Meetings, AAD Meetings, International Conference on Aging Skin (Paris), Individual Preceptorships
1998-2000	Preceptorship EpiTouch Alexandrite Laser Workshop (Los Gattos, CA) Multi-Light Inservice (Seattle, WA 05/99) Multi-Light Preceptorship (Los Gattos, CA 02/99)
1996	UCSF Course: Techniques for facial rejuvenation
1995	Coherent CO^2 Ultra Pulse Training course (Seattle) Sripp's Institute/La Jolla (two-day practicum with Dr. Richard Fitzpatrick)
1993	Stanford Laser Course
1993 to present	Use of YAG, Candela, Multi-Light, Alexandrite, Epi-Touch, Erbium and CO^2 Ultra Pulse (1995) lasers, Elos and Thermage (RF)

PUBLICATIONS:

Your Best Face: Looking Your Best Without Plastic Surgery. Hay House 2002

CURRICULUM VITAE

Brandith Gail Irwin, M.D.

Address: 1101 Madison, Suite 1490, Seattle, WA 98104
Telephone: (206) 215-6600
Place of Birth: Seattle, Washington

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04/99 to present	Madison Skin and Laser Center, Brandith Irwin, M.D., PLLC
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Appearance on Oprah Winfrey show to discuss aging skin

Alpha Omega Alpha Medical Honor Society

National Dermatology Foundation Research Fellowship Award, 1990

Seattle Magazine, 2001, 2002, 2004. Listed as a top dermatologist in the Puget Sound area.

LASER EDUCATION:

2000-2005	ASDS Meetings, AAD Meetings, International Conference on Aging Skin (Paris), Individual Preceptorships
1998-2000	Preceptorship EpiTouch Alexandrite Laser Workshop (Los Gattos, CA)
	Multi-Light Inservice (Seattle, WA 05/99)
	Multi-Light Preceptorship (Los Gattos, CA 02/99)
1996	UCSF Course: Techniques for facial rejuvenation
1995	Coherent CO^2 Ultra Pulse Training course (Seattle)
	Sripp's Institute/La Jolla (two-day practicum with Dr. Richard Fitzpatrick)
1993	Stanford Laser Course
1993 to present	Use of YAG, Candela, Multi-Light, Alexandrite, Epi-Touch, Erbium and CO^2 Ultra Pulse (1995) lasers, Elos and Thermage (RF)

PUBLICATIONS:

Your Best Face: Looking Your Best Without Plastic Surgery. Hay House 2002

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine by: **MARILYN GELNETTE** Respondent.	)	**Docket No. 04-07-B-1063UR** FINDINGS OF FACT, CONCLUSIONS OF LAW, AND FINAL ORDER OF DEFAULT (Failure to Respond)

This matter comes before the Senior Health Law Judge, Presiding Officer, for final Order of Default. Based on the record, the Presiding Officer, on designation by the Secretary of Health now issues the following:

Section 1: FINDINGS OF FACT

1.1 On April 20, 2005, the Program issued a Notice of Intent to Issue a Cease and Desist Order (Notice of Intent) alleging unlicensed practice of medicine by Respondent. A Notice of Opportunity for Settlement Hearing, and Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing were also issued at that time. These documents were served by U.S. Mail at Respondent's last known addresses on June April 20, 2005.

1.2 On June 3, 2005, the Adjudicative Service Unit served upon Respondent a Notice of Failure to Respond.

1.3 To date, the Adjudicative Service Unit has not received an Answer to the Notice of Intent to Issue Cease and Desist Order.

1.4 The Secretary has no reason to believe Respondent is in active military service or is a dependent of a member of the military in active military service.

1.5 The Department of Health has filed the Declaration of Unlicensed Program Manager, David Magby, with attached exhibits.

1.6 Marilyn Gelnette, Respondent, has never held a credential to practice as a health care professional in the state of Washington.

1.7 During the timeframe including the period between November 5, 2002 through January 9, 2003, Respondent worked at a hair removal and skin rejuvenation clinic known as Laser Works of Seattle (Laser Works), located in Tukwila, WA, where the activities described herein occurred.

1.8 Respondent offered laser treatment to human patients as a cure for and to ameliorate excessive hair, wrinkles and unsightly veins.

1.9 Respondent advised prospective patients that the laser energy she applied was "medical treatment" with anticipated "clinical results" and potentially harmful side effects.

1.10 Respondent applied penetrating laser energy to human patients for hair removal, wrinkle reduction, and improvement in the appearance of leg veins. Such applications caused color changes, blisters and welts in the patients' tissue.

1.11 Respondent provided antibiotic ointment to one or more patients who suffered tissue damage from the laser applications and advised patients as to methods of treatment for such damage.

Section 2: CONCLUSIONS OF LAW

2.1 The Secretary of Health has jurisdiction over Respondent and over the subject matter of this proceeding.

2.2 Respondent is subject to the provisions of RCW chapters 18.71.011 and 18.71.021.

2.3 Respondent did not file a response to the Notice of Intent to Issue Cease and Desist Order within the time allowed by WAC 246-10-203. Pursuant to RCW 18.130.090(1) and RCW 34.05.440, Respondent is in default and the Secretary may issue a dispositive order based on the evidence presented to it.

2.4 Based upon the Findings of Fact in Section 1, Respondent engaged in the unlicensed practice of medicine in violation of RCW 18.71.011(1), (2), (3) and RCW 18.71.021.

2.5 The Secretary determines that sufficient grounds exist to issue a Cease and Desist Order to Respondent, pursuant to RCW 18.130.190.

Section 3: ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Secretary of Health hereby makes the following FINAL ORDER.

3.1 Respondent shall permanently **CEASE AND DESIST** from engaging in any and all conduct constituting practice of medicine unless she has obtained appropriate licensure or otherwise meets an exemption

3.2 Respondent shall pay a civil fine in the amount of one thousand dollars ($1,000.00). The fine shall be paid by certified or cashier's check or money order within sixty (60) days of the filing of this order, payable to the Department of Health, Unlicensed Practice Program, P.O. Box 1099, Olympia WA 98507-1099.

3.3 The effective date of this Final Order is the date the original bearing the judge's signature is filed with the Adjudicative Service Unit. The Respondent shall not submit any fees or compliance documents until after the effective date of this Final Order.

Section 4: NOTICE TO PARTIES

As provided in RCW 34.05.461(3), RCW 34.05.470, and WAC 246-11-580, either party may file a petition for reconsideration. The petition must be filed with the Department of Health, Adjudicative Service Unit, P.O. Box 47879, Olympia, WA 98504-7879, within ten (10) days of service of this Final Order. The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration shall not stay the effectiveness of this Final Order. The petition for reconsideration is deemed to have been denied twenty (20) days after the petition is filed if the Secretary of Health has not acted on the petition or served written notice of the date by which action will be taken on the petition.

"Filing" means actual receipt of the document by the Adjudicative Service Unit, RCW 34.05.010(6) and WAC 246-10-102. This Final Order was "served" upon you on the day it was deposited in the United States mail, RCW 34.05.010(18).

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Proceedings for judicial review may be instituted by filing a petition in the superior court in accord with the procedures specified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. The petition for judicial review must be filed within thirty (30) days after service of this Final Order, as provided by RCW 34.05.542.

DATED _____, 2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

_____

PRESIDING OFFICER

Presented by:

_____
TERESA LANDREAU, WSBA# 9591
Department of Health Staff Attorney

August 5, 2005
Date

STEPHAN O. FJELSTAD PLLC
ATTORNEY AT LAW
1001 FOURTH AVENUE, SUITE 3200
SEATTLE, WASHINGTON 98154
VOICE: (206) 340-6100
FAX: (206) 340-6105
EMAIL: sfjelstad@northstarlaw.com

May 12, 2005

Via Facsimile and Mail

Department of Health
Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

Re: *In the Matter of the Unlicensed Practice of Medicine by:*

Cheri Winterstein; Docket No. 04-08-B-1006UR; Program No. 2002-08-0019;
Shaney Shoengarth; Docket No. 04-08-B-1007UR; Program No. 2002-12-0013;
and
Marilyn Gelnette; Docket No. 04-07-B-1063UR; Program No. 2002-09-0004.

Dear Adjudicative Service Unit and Health Law Judge:

I recently received notices of intent to issue cease and desist orders and other documents from the Department of Health (DOH) for each of the above-named individuals. I previously represented these individuals concerning the initial phases of the DOH investigation. Because approximately two years has passed since we last heard from the DOH in these matters, however, we assumed the investigation had ended. I have not heard from or communicated with these individuals for approximately those same two years.

After now receiving the notices of intent to issue the cease and desist orders, I have attempted to contact all three of them and have been unsuccessful—I do not have and cannot find current addresses or telephone numbers for any of them. The company where they previously worked and where I contacted them previously is no longer in business. I did contact an individual who used to work with them years ago, who believes that Ms. Winterstein and Ms. Gelnette moved out of the State of Washington some time ago, and that all of them (including Ms. Shoengarth) retired from the type of work for which the DOH commenced its investigation. That is as much as I have been able to learn thus far.

I also do not believe the DOH notices sent to these individuals at their previous workplace address reached them; in other words, to my knowledge, they have as yet been notified of the DOH's cease and order or of their options for responding.

Given my inability thus far to contact these individuals, I cannot purport to represent them at this time, and I request that you not construe this letter as a notice of appearance. I do believe, however, that it would be in their best interest for me to request, on their behalf, an additional sixty (60) days for their responses to the cease and desist notice. Please accept this letter as that request. This will afford me time in which I will continue to attempt to contact the three respondents and determine whether they would like me to represent them again and, if so, whether they are amenable to signing the proposed stipulated findings of fact, conclusions of law and agreed orders to cease and desist, and otherwise submitting answers to the notice.

I would appreciate your forbearance in this matter as I believe it would be in everyone's best interest to give these individuals an opportunity to respond.

Very truly yours,

STEPHAN O. RIELSTAD PLLC

Stephan O. Rielstad

SOF:sof
cc:
Richard McCartan, AAG
Attorney General's Office
P.O. Box 40109
Olympia, WA 98504-0109

Teresa Landreau
Staff Attorney, Dept. of Health
P.O. Box 47873
Olympia, WA 98504-4845

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine: **MARILYN GELNETTE,** Respondent.	**Docket No. 04-07-B-1063UR** DECLARATION OF SERVICE BY MAIL **Program No. 2002-09-0004**

Under penalty of perjury under the laws of the state of Washington, I declare that the following is true and correct:

On April 20, 2005 I served a true and correct copy of a Notice of Intent to Issue Cease and Desist Order; Notice of Opportunity for Settlement and Hearing; Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing; and Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist by placing same in the U.S. mail postage prepaid, on the following parties to this case:

Richard McCartan, AAG
Attorney General's Office
P.O. Box 40109
Olympia, WA 98504-0109

Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188

Stephan Fjelstad
Attorney at Law
1424 Fourth Ave, Ste 909
Seattle, WA 98101-2217

Erika Quinn-Ellenbecker, Legal Assistant

Original filed with:
Department of Health
Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine: **MARILYN GELNETTE,** Respondent.	**Docket No. 04-07-B-1063UR** DECLARATION OF SERVICE BY MAIL **Program No. *2002-09-0004***

Under penalty of perjury under the laws of the state of Washington, I declare that the following is true and correct:

On April 27, 2005 I re-served a true and correct copy of a Notice of Intent to Issue Cease and Desist Order; Notice of Opportunity for Settlement and Hearing; Answer to Notice of Intent to Issue Cease and Desist Order and Request for Settlement and Hearing; and Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist by placing same in the U.S. mail postage prepaid, on the following parties to this case:

Richard McCartan, AAG
Attorney General's Office
P.O. Box 40109
Olympia, WA 98504-0109
(w/o enclosures)

Marilyn Gelnette
c/o Stephan Fjelstad
Attorney at Law
1001 4th Ave Ste 3200
Seattle, WA 98154-1003

Erika Quinn-Ellenbecker, Legal Assistant

Original filed with:
Department of Health
Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine by: **MARILYN GELNETTE,** Respondent.	**Docket No. 04-07-B-1063UR** NOTICE OF OPPORTUNITY FOR SETTLEMENT HEARING

You are notified that a Notice of Intent to Issue Cease and Desist Order has been issued by the Unlicensed Practice Program (Program), a copy of which is enclosed. The Notice of Intent to Issue Cease and Desist Order initiates the process by which the Office of Professional Standards, designee of the Secretary of Health, will determine whether you have engaged in the unlicensed practice of medicine pursuant to the meaning of RCW 18.108.030 as alleged in the Notice of Intent to Issue Cease and Desist Order. If you are found to have engaged in the unlicensed practice of medicine, the Presiding Officer may issue a permanent Cease and Desist Order and impose a civil fine, as provided in RCW 18.130.190.

You may request an adjudicative proceeding by filing an answer to the Notice of Intent to Issue Cease and Desist Order. Your answer to the Notice of Intent provides you the opportunity to request an adjudicative proceeding or to waive the opportunity for an adjudicative proceeding, pursuant to RCW 34.05.413 and WAC 246-10-203. An answer form is enclosed.

YOUR ANSWER TO THE NOTICE OF INTENT TO ISSUE CEASE AND DESIST ORDER MUST BE RECEIVED BY THE ADJUDICATIVE SERVICE UNIT WITHIN TWENTY (20) DAYS FROM THE DATE THIS NOTICE WAS MAILED TO YOU. If the

ORIGINAL

twenty (20) day limit results in a hardship upon you, you may request in writing an extension for good cause not to exceed sixty (60) additional days. A request for extension must be received by the Adjudicative Service Unit within twenty (20) days from the date this notice was mailed to you. The Presiding Officer will grant an extension for good cause.

Failure to file an answer within the twenty (20) day time limit or within the time limit established by a hardship extension constitutes a default. Pursuant to RCW 34.05.440 and WAC 246-10-204, a default will result in the loss of your right to an adjudicative proceeding, including a hearing, and resolution of the case without your participation. A default may result in the issuance of a permanent Cease and Desist Order and the imposition of a civil fine.

If you waive your opportunity for settlement and hearing, the case will be resolved without your further participation. Resolution of the case may include the issuance of a permanent Cease and Desist Order and the imposition of a civil fine. You may submit a written statement for consideration by the Presiding Officer, so long as that statement is received by the Adjudicative Service Unit within twenty (20) days of the date this notice was mailed to you or within the time limit established by a hardship extension.

If you request an adjudicative proceeding, you will have an opportunity to settle the matter prior to a hearing. In seeking a settlement, you may submit a written statement and any supporting materials for consideration. A written settlement offer may be included with the Notice of Intent to Issue Cease and Desist Order or may be sent to you at a later date. If a settlement cannot be achieved through written documents, a settlement conference will be held. If a settlement cannot be reached, then the matter will

proceed to a hearing.

Notice of the date, time, and location of the hearing will be sent to you at least seven (7) days in advance. At the hearing, you may appear personally and may be represented by counsel at your own expense. The hearing will be scheduled and conducted according to the requirements of the Administrative Procedure Act, chapter RCW 34.05, and the procedural rules of WAC 246-10.

If you request an adjudicative proceeding but fail to appear or participate in a hearing or other stage of the adjudicative proceeding, you may be held in default Pursuant to RCW 34.05.434, the names, addresses, and telephone numbers of the Presiding Officer, the parties to whom notice is given, and their representatives are attached and incorporated herein by reference.

Respondent shall inform the Unlicensed Practice Program and the Adjudicative Service Unit, in writing, of changes in residential or business address within **thirty (30) days** of any such change. Changes shall be sent to Department of Health, Unlicensed Practice Program, P.O. Box 47874, Olympia, WA 98504-7874 and Department of Health, Adjudicative Service Unit, P.O. Box 47879, Olympia, WA 98504-7879.

DATED this 12 day of April, 2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

David Magby

DAVID MAGBY
Unlicensed Practice Program Manager

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

Pursuant to RCW 34.05.434, the following parties, representatives, and officers have been given notice of this proceeding.

Adjudicative Service Unit
Department Of Health
P.O. Box 47879
Olympia, WA 98504-7879
Phone: 360-236-4677
Fax: (360) 586-2171

Unlicensed Practice Program
Department Of Health
Chyma Miller-Smith, Program Manager
Po Box 47874
Olympia, WA 98504-7874
Phone: 360-236-4659

Attorney For Unlicensed Practice Program
Richard Mccartan, AAG
Attorney General's Office
P.O. Box 40109
Olympia, WA 98504-0109
Phone: 360-664-4998

Representative Of The Secretary Profession For Purposes Of Settlement Negotiations
Teresa Landreau, Staff Attorney
Department Of Health
Legal Unit
P.O. Box 47873
Olympia, WA 98504-7873
Phone: 360-236-4845
Fax: 360-236-4930

Health Law Judge, Presiding Officer
Department Of Health
P.O. Box 47879
Olympia, WA 98504-7879
Phone: 360-236-4677
Fax: 360-586-2171

Respondent
Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188
Phone: (206) 575-8300

Attorney For Respondent
Stephan Fjelstad
1424 Fourth Ave, Ste 909
Seattle, WA 98101-2217
Phone: (206) 903-0664

1.5 Respondent applied penetrating laser energy to human patients for hair removal, wrinkle reduction, and improvement in the appearance of leg veins. Such applications caused color changes, blisters and welts in the patients' tissue.

1.6 Respondent provided antibiotic ointment to one or more patients who suffered tissue damage from the laser applications and advised patients as to methods of treatment for such damage.

Section 2: ALLEGED VIOLATIONS

2.1 The conduct described in Sections 1.1 through 1.6 constitutes the unlicensed practice of medicine in violation of RCW 18.71.011(1), (2), and (3) and RCW 18.71.021.

> **RCW 18.71.011 Definition of practice of medicine -- Engaging in practice of chiropractic prohibited, when.** A person is practicing medicine if he does one or more of the following:
>
> (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
>
> (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
>
> (3) Severs or penetrates the tissues of human beings;
>
> . . .
>
> **RCW 18.71.021 License required.** No person may practice or represent himself or herself as practicing medicine without first having a valid license to do so.

2.2 The violation described in paragraph 2.1 constitutes grounds for issuance of a cease and desist order pursuant to RCW 18.130.190.

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine of:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE	)	NOTICE OF INTENT TO ISSUE CEASE AND DESIST ORDER
Respondent	)	

David Magby, Manager of the Unlicensed Practice Program (Program), on designation by the Secretary of Health, makes the allegations below, which are supported by evidence contained in program case file no. 2002-09-0004.

Section 1: FACTUAL ALLEGATIONS

1.1 Marilyn Gelnette (Respondent) has never held a credential to practice as a health care professional in the state of Washington.

1.2 During the timeframe including the period between November 5, 2002 through January 9, 2003, Respondent worked at a hair removal and skin rejuvenation clinic known as Laser Works of Seattle (Laser Works), located in Tukwila, WA, where the activities described herein occurred.

1.3 Respondent offered laser treatment to human patients as a cure for and to ameliorate excessive hair, wrinkles and unsightly veins.

1.4 Respondent advised prospective patients that the laser energy she applied was "medical treatment" with anticipated "clinical results" and potentially harmful side effects.

//

RCW 18.130.190 Practice without license -- Investigation of complaints -- Cease and desist orders -- Injunctions -- Penalties.

(1) The secretary shall investigate complaints concerning practice by unlicensed persons of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. In the investigation of the complaints, the secretary shall have the same authority as provided the secretary under RCW 18.130.050.

(2) The secretary may issue a notice of intention to issue a cease and desist order to any person whom the secretary has reason to believe is engaged in the unlicensed practice of a profession or business for which a license is required by the chapters specified in RCW 18.130.040. The person to whom such notice is issued may request an adjudicative proceeding to contest the charges. The request for hearing must be filed within twenty days after service of the notice of intention to issue a cease and desist order. The failure to request a hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine. All proceedings shall be conducted in accordance with chapter 34.05 RCW.

(3) If the secretary makes a final determination that a person has engaged or is engaging in unlicensed practice, the secretary may issue a cease and desist order. In addition, the secretary may impose a civil fine in an amount not exceeding one thousand dollars for each day upon which the person engaged in unlicensed practice of a business or profession for which a license is required by one or more of the chapters specified in RCW 18.130.040. The proceeds of such fines shall be deposited to the health professions account.

(4) If the secretary makes a written finding of fact that the public interest will be irreparably harmed by delay in issuing an order, the secretary may issue a temporary cease and desist order. The person receiving a temporary cease and desist order shall be provided an opportunity for a prompt hearing. The temporary cease and desist order shall remain in effect until further order of the secretary. The failure to request a prompt or regularly scheduled hearing constitutes a default, whereupon the secretary may enter a permanent cease and desist order, which may include a civil fine.

(5) Neither the issuance of a cease and desist order nor payment of a civil fine shall relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy of a cease and desist order or civil fine shall be in addition to any criminal liability. The cease and desist order is conclusive proof of unlicensed practice and may be enforced under RCW 7.21.060. This method of enforcement of the cease and desist order or civil fine may be used in addition to, or as an alternative to, any provisions for enforcement of agency orders set out in chapter 34.05 RCW.

(6) The attorney general, a county prosecuting attorney, the secretary, a board, or any person may in accordance with the laws of this state governing injunctions, maintain an action in the name of this state to enjoin any person practicing a profession or business for which a license is required by the chapters specified in RCW 18.130.040 without a license from engaging in such practice or operating such business until the required license is secured. However, the injunction shall not relieve the person so practicing or operating a business without a license from criminal prosecution therefore, but the remedy by injunction shall be in addition to any criminal liability.

(7) Unlicensed practice of a profession or operating a business for which a license is required by the chapters specified in RCW 18.130.040, unless otherwise exempted by law, constitutes a gross misdemeanor for a single violation. Each subsequent violation, whether alleged in the same or in subsequent prosecutions, is a class C felony. All fees, fines, forfeitures, and penalties collected or assessed by a court because of a violation of this section shall be remitted to the health professions account.

. . .

2.3 Pursuant to RCW 18.130.190 the Secretary of Health is authorized to issue a cease and desist order against a person upon a determination that such person has engaged in or is engaging in unlicensed practice of medicine and may impose a fine of up to one thousand dollars ($1,000.00) for each day of unlicensed practice.

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Section 3: NOTICE TO RESPONDENT

David Magby, Manager of the Unlicensed Practice Program, alleges that the conduct referenced herein affects the public health, safety, and welfare; that a notice should be issued and served as provided by law to the Respondent giving the Respondent the opportunity to respond to the charges that she practiced as a physician without the proper license, and that if the Respondent fails to defend against these matters a permanent Cease and Desist Order may be issued and a civil fine imposed without further notice or opportunity for a hearing.

DATED this 18 day of April 2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

DAVID MAGBY
Unlicensed Practice Program Manager

RICHARD MCCARTAN , WSBA # 8323
Assistant Attorney General Prosecutor

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine by: **MARILYN GELNETTE,** Respondent.	**Docket No. 04-07-B-1063UR** ANSWER TO NOTICE OF INTENT TO ISSUE CEASE AND DESIST ORDER AND REQUEST FOR SETTLEMENT AND HEARING

TO:

Marilyn Gelnette
411 Strander Blvd Ste 108
Tukwila, WA 98188

Phone: (206) 575-8300

Correct Name: _____

Correct Address: _____

_____

Correct Phone: _____

INSTRUCTIONS: This form may be used to answer the Notice of Intent to Issue Cease and Desist Order and to request settlement and a hearing. Correct your name, address, and telephone number above, if necessary, enter your answers below, and sign and date this form. Return it to:

DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT
P.O. BOX 47879
OLYMPIA, WA 98504-7879
TELEPHONE: (360) 236-4677

THIS FORM MUST BE RECEIVED BY THE ADJUDICATIVE SERVICE UNIT WITHIN TWENTY (20) DAYS FROM THE DATE THIS NOTICE WAS MAILED TO YOU. If the twenty (20) day limit results in a hardship upon you, you may request in writing an extension for good cause not to exceed sixty (60) additional days. A request for

ORIGINAL

extension must be received by the Adjudicative Service Unit within twenty (20) days from the date this notice was mailed to you. The Presiding Officer will grant an extension for good cause. Failure to file an answer within the twenty (20) day time limit or within the time limit established by a hardship extension constitutes a default. Pursuant to RCW 34.05.440 and WAC 246-10-204, a default will result in the loss of your right to an adjudicative proceeding, including a hearing, and resolution of the case without your participation. A default may result in the issuance of a permanent Cease and Desist Order and the imposition of a fine.

Section 1: REQUEST FOR ADJUDICATIVE PROCEEDING

INSTRUCTIONS: Mark one (1) of the following:

☐ I waive my opportunity for settlement and hearing. I am enclosing my written statement and/or any materials I wish to have the Presiding Officer consider in disposition of the case.

☐ I request an opportunity for settlement and a hearing if settlement is not reached. I understand that a scheduling order will be issued and that I (or my attorney) will be required to participate in all stages of the adjudicative proceeding in accordance with WAC 246-10.

☐ I accept the settlement offer as proposed in the Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (Agreed Order). I have signed that settlement offer and am returning it. In the event that the settlement is not accepted by the Presiding Officer, I request a hearing.

Section 2: REPRESENTATION

INSTRUCTIONS: Mark the appropriate response and provide correct information:

☐ I will be represented by an attorney who must file a Notice of Appearance.

His/her name, address, and telephone number are:

Name: _____

Address: _____

_____

_____

Telephone: _____

☐ I will not be represented by an attorney.

Section 3: RESPONSE TO ALLEGATIONS

INSTRUCTIONS: Indicate below whether you admit, deny, or do not contest each of the alleged facts and alleged violations contained in the numbered paragraphs in the Notice of Intent to Issue Cease and Desist Order. Check one (1) response for each numbered paragraph.

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Paragraph Number	Admit	Deny	Do Not Contest
1.1			
1.2			
1.3			
1.4			
1.5			
1.6			
2.1			
2.2			
2.3			

INSTRUCTIONS: Mark the appropriate response:

☐ I have attached a sworn statement in my defense or in mitigation of charges.

☐ I have not attached a sworn statement.

Section 4: INTERPRETER REQUEST

INSTRUCTIONS: Complete the appropriate information if you request an interpreter because of a primary language other than English and/or because of a hearing or speech impairment. If you later determine that an interpreter will be necessary, you must notify the parties listed in the Notice of Opportunity for Settlement and Hearing. Costs for an interpreter will be paid pursuant to WAC 246-10-121.

☐ I request that a qualified interpreter be appointed to interpret for me or for my witness(es). My (or my witness(es)') primary language is

_____.

☐ I request that a qualified interpreter be appointed to interpret for me or for

my witness(es). My (or my witness(es)') hearing or speech impairment requires an interpreter able to communicate in the following language:

_____.

Section 5: PROCEDURAL RIGHTS

Pursuant to RCW 34.05, you have the right to demand a hearing, to be represented by an attorney at your own expense, to subpoena witnesses or the production of books or documents, and to otherwise defend against the allegations in the Notice of Intent to Issue Cease and Desist Order.

The Secretary of Health has adopted procedural rules for the exercise of these rights and for the conduct of any adjudicative proceeding you request. The rules are contained in WAC 246-10.

DATED: _____, 2005.

_____
MARILYN GELNETTE
Respondent

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

In the Matter of the Unlicensed Practice of Medicine of:	)	**Docket No. 04-07-B-1063UR**
MARILYN GELNETTE	)	STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND AGREED ORDER TO CEASE AND DESIST
Respondent.	)	

The Unlicensed Practice Program (Program) of the Department of Health (Department), by and through Teresa Landreau, Department of Health Staff Attorney, and Marilyn Gelnette, Respondent, represented by her attorney, Stephan Fjelstad, stipulate and agree to the following:

Section 1: PROCEDURAL STIPULATIONS

1.1 The Program of the Department has served on Respondent a Notice of Intent to Issue Cease and Desist Order (Notice), under the above docket number, which alleges that Respondent engaged in conduct constituting unlicensed practice of medicine.

1.2 Respondent understands that the state of Washington is prepared to proceed to a hearing on the allegations in the Notice.

1.3 Respondent understands that she has the right to defend herself against the allegations in the Notice by presenting evidence at a hearing.

1.4 Respondent understands that , should the State prove the allegations in the Notice, the Secretary of Health (Secretary) has the power and authority to issue a permanent Cease and Desist Order and impose a fine under RCW 18.120.190.

1.5 Respondent and the Program agree to expedite the resolution of this matter by means of this Stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist (Agreed Order).

1.6 Respondent waives the opportunity for a hearing on the Notice contingent upon signature and acceptance of the Agreed Order by the Secretary.

1.7 This Agreed Order is not binding unless and until it is signed and accepted by the Secretary.

1.8 Should this Agreed Order be rejected, Respondent waives any objection to the participation at hearing of the Health Law Judge who heard the Agreed Order presentation.

Section 2: STIPULATED FACTS

Respondent and the State stipulate and agree to entry of the following findings of fact:

2.1 Marilyn Gelnette (Respondent) has never held a credential to practice as a health care professional in the state of Washington.

2.2 During the timeframe including the period between November 5, 2002 through January 9, 2003, Respondent worked at a hair removal and skin rejuvenation clinic known as Laser Works of Seattle (Laser Works), located in Tukwila, WA, where the activities described herein occurred.

2.3 Respondent offered laser treatment to human patients as a cure for and to ameliorate excessive hair, wrinkles and unsightly veins.

2.4 Respondent advised prospective patients that the laser energy she applied was "medical treatment" with anticipated "clinical results" and potentially harmful side effects.

2.5 Respondent applied penetrating laser energy to human patients for hair removal, wrinkle reduction, and improvement in the appearance of leg veins. Such applications caused color changes, blisters and welts in the patients' tissue.

2.6 Respondent provided antibiotic ointment to one or more patients who suffered tissue damage from the laser applications and advised patients as to methods of treatment for such damage.

Section 3: CONCLUSIONS OF LAW

Respondent and the State stipulate and agree to entry of the following conclusions of law based on the stipulated findings of fact, above:

3.1 The facts above in Section 2 establish that Respondent has engaged in conduct constituting unlicensed practice of medicine in violation of RCW 18.71.011(1) (2) (3) and RCW 18.71.021.

3.2 The Secretary has jurisdiction over Respondent and over the subject matter of this proceeding under RCW 18.130.190.

3.3 The Secretary has the power and authority to issue a permanent Cease and Desist Order and impose a fine under RCW 18.130.190.

3.4 The stipulated findings of fact and conclusions of law herein constitute grounds for the issuance of a permanent Cease and Desist Order under RCW 18.120.190.

Section 4: AGREED ORDER

Based on the preceding stipulated Findings of Fact and Conclusions of Law, the State and Respondent hereby stipulate and agree to the terms and conditions of this Agreed Order:

4.1 Respondent shall permanently **CEASE AND DESIST** from engaging in any and all conduct constituting practice of medicine unless she has obtained appropriate licensure or otherwise meets an exemption.

4.2 Respondent shall pay a civil fine in the amount of ten thousand dollars ($10,000.00) within sixty (60) days of the filing date of the Agreed Order. Nine thousand dollars ($9,000.00) of the fine shall be stayed on condition Respondent complies with the terms of this order. The remaining one thousand dollars ($1000) shall be paid by certified or cashier's check or money order within six (6) months of the filing of this order, payable to the Department of Health, and mailed to the Department of Health, Unlicensed Practice Program, P.O. Box 1099, Olympia, WA 98507-1099.

4.3 The effective date of the Agreed Order is the date the original bearing the judge's signature is filed with the Adjudicative Service Unit. The Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

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I, Marilyn Gelnette, hereby certify that I have read this stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist in its entirety; that my counsel of record, Stephan Fjelstad, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Secretary without my appearance. If the Secretary accepts this stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist, I understand that I will receive a signed copy.

MARILYN GELNETTE
Respondent

Date

STEPHAN FJELSTAD, WSBA #
Attorney for Respondent

Date

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Section 5: ORDER

The Secretary of Health accepts and enters this stipulated Findings of Fact, Conclusions of Law, and Agreed Order to Cease and Desist.

DATED this_____day of _____2005.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
SECRETARY OF HEALTH
UNLICENSED PRACTICE PROGRAM

_____

Health Law Judge

Presented by:

_____
TERESA LANDREAU, WSBA #9591
Department of Health Staff Attorney

_____
Date

INTERNAL TRACKING NUMBER:	PROGRAM NO. 2002-09-0004

Health Professions Quality Assurance Division
Investigation Service Unit

MEMORANDUM

DATE: December 5, 2005

TO: Lisa Noonan
Disciplinary Manager

FROM: Robin Crowell-Pisano
Unlicensed Practice Unit

SUBJECT: Marilyn Gelnette
2002-09-0004UI

Attached is a copy of the investigation report and Cease and Desist Order for Marilyn Gelnette.

Ms. Gelnette was practicing medicine without a license.

If you have any questions, please feel free to contact Chyma at (360) 236-4659.

Thank you!

Enclosure

telnet (GothomCity)

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                      AAAAAAAA    SSS    SSS      III
MEDICAL BOARD               ASSESSMENT SYSTEMS, INC.                    10-13-05
rsp7303                           REAL SYSTEM           V2.5.74         01:22:08 P
INDIVIDUAL NAME                    (JR,SR,III)          REFERENCE # MD00035207
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 MIDDLE A                                |          SEX M =      MARRIED Y =
                                         |
RESIDENCE INFORMATION                    |   OTHER NAME
4708 S SCHAFER BRANCH RD                 |CORP. OFFICER                          =
SPOKANE WA  99206                        |TRUST ACCOUNT
                                         |
                                         |  BIRTH PLACE CALIFORNIA
                                         |         DATE 07-14-1951
PHONE: (509) 869-8951  COUNTY:   32      |
       (   )    -      LGL ST: WA       |SCHOOL CODE 011.03
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telnet (GothomCity)

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 MIDDLE A                                     |           SEX M =      MARRIED Y =
                                              |
RESIDENCE INFORMATION                         |   OTHER NAME
33 C ETRURIA STREET                           |CORP. OFFICER                          =
SEATTLE WA  98109                             |TRUST ACCOUNT
                                              |
                                              |  BIRTH PLACE CANADA
                                              |          DATE 02-11-1963
PHONE: (    )     -       COUNTY:   17        |
       (    )     -       LGL ST: WA          |SCHOOL CODE 60.01
                                              |   CE UNITS    0.00 REQD BY 02-11-2005
NOTES                                         +---------------------------------------
REFER INQUIRIES TO MDB
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|CURRENT STATUS: ELD  EXPIRATION DATE: 02-11-2005  FIRST ISSUE DATE: 02-14-1994
|RENEWAL STATUS: M   LAST ACTIVE DATE: 02-11-2005 LAST RENEWAL DATE: 01-24-2003
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DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

CONFIDENTIAL INVESTIGATION REPORT
PREPARED FOR THE
SECRETARY, DEPARTMENT OF HEALTH

****

Case # 2002-09-0004UI

RESPONDENT: MARILYN GELNETTE

(Companion Case #2002-08-0019UI Winterstein & #2002-12-0013UI Shoengarth)

****

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Investigator: Gayle M. Crowley
Health Care Investigator

APPROVED BY _____ DATE 6/21/03

APPENDIX A

RESPONDENT INFORMATION

NAME:	MARILYN GELNETTE
BUSINESS ADDRESS:	411 Strander Blvd., Suite 108 Tukwila, WA 98188
BUSINESS TELEPHONE #:	(206) 575-8300
RESIDENCE ADDRESS:	N/A
RESIDENCE TELEPHONE #:	N/A
LICENSE NUMBER:	Unlicensed
DATE ISSUED:	N/A
EXPIRATION DATE:	N/A
BIRTH DATE:	N/A
SPECIALIZATION:	N/A
PREVIOUS COMPLAINT HISTORY:	0/0
ATTORNEY IDENTIFICATION:	Stephan O. Fjelstad, PLLC

APPENDIX B

COMPLAINANT INFORMATION

NAME: 4 - Identity - Whistleblower...

BUSINESS ADDRESS:

BUSINESS TELEPHONE # : 4 - Identity - Whistleblower Regarding Health Care ...

RESIDENCE ADDRESS: N/A

RESIDENCE TELEPHONE # : N/A

ATTORNEY: N/A

ATTORNEY ADDRESS: N/A

ATTORNEY TELEPHONE # : N/A

APPENDIX C

CONTACT LIST

John A. Fisher, MD
33C Etruria Street
Seattle, WA 98109
(206) 680-7752 Home
(206) 205-2410 Work
(206) 680-7752 Pager

Eric Moore
Laser Works of Seattle
411 Strander Blvd., Suite 108
Tukwila, WA 98188
(206) 575-8300
(206) 501-7710 Cell

George Heye, MD
Medical Consultant
Medical QA Commission
1300 SE Quince
P. O. Box 47874
Olympia, WA 98504
(360) 236-4795

Kathy Maynor
Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010
((650) 259-5586

Rosie McGrew
Department of Licensing
Cosmetology
(360) 664-6625

Elizabeth Bianchi, MD
10808 46th Ave.
Spokane, WA
(509) 926-8462 Home
(509) 995-0368 Cell

Gayle M. Crowley
Health Care Investigator
20435 72nd Ave., S, Suite 200
Kent, WA 98032
(253) 395-6709

APPENDIX D

GENERAL SUMMARY

THE INFORMATION CONTAINED IN THIS REPORT, WITH IT'S ACCOMPANYING EVIDENCE AND EXHIBITS, SHOULD BE CONSIDERED IN CONJUNCTION WITH THAT INFORMATION INCLUDED IN THE COMPANION CASE FILES FOR THE MATTER REFERENCED ABOVE ON THE COVER PAGE OF THIS REPORT.

This investigation was initiated by receipt of a complaint at the Unlicensed Program of the Department of Health, from 4 - Identity - Whistleblower..., on September 4, 2002. 4 - Identity - Whistleblower ..., complainant, says he received treatment for hair removal from the respondent on August 28, 2002. He alleges the respondent, Marilyn Gelnette, told him she could guarantee him 100% that if he had treatment on his cheek, he would be able to go to work and be fine. He says he let her perform the treatment. He alleges she only treated his left cheek because the laser broke before she could finish the other side. He alleges after the treatment, his cheek was red and he received blisters. At the date of this E-mail complaint, September 4, 2002, he alleges his cheek is starting to get back to their normal color.

The complainant is wondering what can be done to stop this from happening to him or another person. He says no one should go through this treatment. **Page 1**

On September 9, 2002, the Unlicensed Program requested a field investigation be conducted to verify if the respondent is providing any type of medical services for which requires licensure. **Page 2**

On September 17, 2002, a telephone interview was conducted with the complainant of the companion case file. She provided names of patients and also gave information regarding Laser Works and how the business is run.

On October 22, 2002, information was obtained from the Internet website for the State of Washington Cosmetology Board, including the requirements for licensure. **Pages 3-12**

On December 17, 2002, information about laser treatment and equipment from various agencies was obtained from the Department of Health, Unlicensed Program Manager. **Pages 13-30**

On December 17, 2002, a telephone interview was conducted with Dr. John Fisher, medical director of Laser Works, Inc. Dr. Fisher was not aware an investigation was open. He became the medical director to help the company with financing of the laser. He doesn't have much contact with the business, but does receive a monthly check for $500 for them to use him as their medical director.

Dr. Fisher states in the three years he has been involved in the business, he was only called to see someone once, just after the business opened. He has not been to the business in at least six months and has not worked with or know any of the employees working at the Laser Works.

Dr. Fisher is full time employed as the Public Medical Doctor for King County, in the jail systems at different locations. It is his understanding the owners of Laser Works, Inc. have nurses

providing treatment in their offices. He is unaware of any non-medical personnel providing treatment to patients.

Dr. Fisher explained he ordered Lidocaine (later identified as 5% topical) for the business and the prescriptions were mailed directly to Laser Works. A Memo To File was prepared from this interview. **Page 31**

On December 17, 2002, a field visit was made to the respondent's place of employment, Laser Works, Inc., with health care investigator Jim Voiland. Pictures were taken of the front reception office, treatment rooms, equipment being used for treatment, and framed posters.

An interview was conducted with owner Eric Moore. Mr. Moore states his employees are not performing any medical treatment to individuals who come in for their services. He identified these individuals as clients or customers.

Mr. Moore says they did not hire Dr. Fisher to be the medical director out of necessity. They hired Dr. Fisher so they could have him order the lasers and obtain easier and better financing. Dr. Fisher was mainly a figurehead for the financing, and had little to do with the day-to-day operations of the business.

Mr. Moore says this office has seen 1,000's of people. The employees have been trained by the companies on how to work the lasers. He says nothing the employees do when working with the lasers require a physician or nurse. He identified the respondent as being a cosmetologist and that she started working her in June 2002. He and the respondent usually do the intakes on all incoming patients/clients/customers. They find out which areas and describe the process and costs.

When Mr. Moore was asked about the respondent and companion case respondents using prescription strength Lidocaine on patients/clients/customers, he says Lidocaine is only given to someone in pain that requests it. He says it's not a big deal. He couldn't remember the last time they received any Lidocaine, but says it is rarely used. He faxes a request to Dr. Fisher, who then orders it and it is delivered by mail to the business. Mr. Moore was unable to show us a container of Lidocaine or where it is stored in the office, when asked, but walked around the office and opened cabinet doors.

Mr. Moore described the four lasers being used. He says they do have a microdermabrasion machine, but do very few treatments. Even though botox treatments are listed on Laser Works forms, he says this office does not perform these treatments. A Memo to File was prepared from this interview.

A copy of all Laser Works forms and brochures, located in the front reception office, were obtained. A review of these forms included the following:

- Reminder and Referrals – This form includes the following comment: "Following a botox treatment you should see improvements within 72 hours..."

- Informed Consent Form – Per owner Eric Moore, this is the new form they are using. This form first sentence reads, "I understand that I will receive medical treatment From Laser Works of Seattle."

- Patient Medical History

- Patient Medical History – Vascular Treatment
- Post Treatment – Vascular
- Pre-Treatment – Vascular
- Treatment Log
- Medical History – Skin Rejuvenation
- Informed Consent – Microdermabrasion
- Informed Consent – Skin Rejuvenation
- Client Information Skin Rejuvenation
- Skin Rejuvenation (IPL) Post Treatment Care

A review was made of Laser Works appointment book. A sample of files were obtained, including individuals previously identified by the complainant and companion case file complainant. **Pages 32-134**

On December 17, 2002, a letter was delivered to the respondent and an interview was conducted. The respondent denied she is performing any type of medical treatment or practicing medicine. The respondent did not want to sign the Licensing Requirement Notification at this time. **Pages 135-137**

On December 17, 2002, Dr. Fisher faxed a copy of his resignation as Medical Director for Laser Works, Inc. A telephone message for Dr. Fisher verified this letter was also faxed to Eric Moore at his home, per Mr. Moore's request. **Page 138**

On December 18, 2002, a copy of the Medical Quality Assurance Commission's Policy was obtained from Dr. Heye. **Pages 139-140**

On December 19, 2002, information regarding the drug, 5% Xylocaine (Lidocaine) was obtained from the 1997 Edition of the Physicians' Desk Reference. **Page 141**

On December 19, 2002, information was obtained from several Internet Websites, including the Federal Drug Administration (FDA), and copies printed. Further contact was made with Kathy Maynor at Altus Medical. Ms. Maynor faxed laser FDA information. She also provided the explanations showing how the lasers are categorized, who can buy them, and who can use them. **Pages 142-184**

On December 20, 2002, an interview was conducted with Dr. John Fisher. Dr. Fisher provided documents he had pertaining to his association and agreements with owners Eric Moore and Jeff Schmidt of Laser Works. These documents include copies of laser lease agreements.

During this interview, Dr. Fisher signed a Witness Notification Form. He expressed his concern about the investigation and how it could affect his license to practice. **Pages 185-204**

On December 23, 2002, a Notice of Appearance was received from the respondent's attorney, Stephan Fjelstad. Mr. Fjelstad is also representing the two companion case file respondents. **Page 205**

During the course of conducting this investigation, Dr. Fisher provided correspondence by E-mail. Dr. Fisher also faxed a copy of the termination of the laser leasing agreement between himself, Jeff Schmidt, and Eric Moore. **Pages 206-214**

On January 15, 2003, Dr. Fisher provided a statement. He described in detail how he became the medical director of Laser Works, Inc. Dr. Fisher said he was paid primarily to compensate him for the risk of putting his name on the lease of the ESC Alexandrite laser.

Dr. Fisher says he was never involved in the planning or set up of the clinic or the day-to-day running of the clinic. It was his understanding the laser work was to be done by RN's. In the several years he has been the medical director, Dr. Fisher says he has been called only once, during the first year of operation.

Dr. Fisher also discusses his ordering of the prescription for Lazercaine, a topical anesthetic of 5% lidocaine. **Pages 215-216**

On January 15, 2003, the respondent's attorney provided the respondent's written response. This written response is the same one as for the two companion case file respondents. The respondent's attorney describes in detail how Laser Works, Inc. is performing its operations at the Tukwila location. He says prior to the business opening it's door, the principals diligently explored statutory licensing and regulations in Washington.

The respondent's attorney describes treatment provided by employees at Laser Works and says the nature of their services is strictly cosmetic. He says none of the employees diagnose or offer advice related to health problems. Customers simply want to enhance their appearance.

The respondent's attorney says the respondent has worked with laser and pulsed light technology for over two and one half years and also does microdermabrasion at Laser Works. He says she holds a license in electrolysis and cosmetology in California, where she lived formerly.

The respondent's attorney states none of the employees, including the respondent, have ever prescribed or dispensed any drug or medicine for internal use to any customer. He denies any employees have stored or supplied any lidocaine at the premises, and have no intention of acquiring more for any purpose. He says the last time Laser Works received lidocaine was several months ago when a small shipment of fifteen containers were ordered. The respondent's attorney says the lidocaine was supplied to a tiny fraction of Laser Works customers to be applied to their skin prior to treatments.

The respondent's attorney explains Dr. Fisher's role as medical director for Laser Works, Inc. He says Dr. Fisher has never, to their knowledge, prescribed drugs or medicines to any customers.

The respondent's attorney denies the services Laser Works and their employees are providing qualify as the practice of medicine under Washington State law.

The respondent completed the Licensing Requirement Notification form by signing and also providing a written statement. **Pages 217-229**

On January 27, 2003, patient treatment records were obtained by subpoena. These were a sampling of records for individuals receiving treatment from December 17, 2002 through January 15, 2003.

A review of the records indicates several patients/clients/customers were given lazercaine (lidocaine) during the treatment process. This is noted on Evidence Page #411, and Evidence Page #621. A comment from the treatment provider suggesting lidocaine is listed on Evidence Page #455. **Pages 230-683**

On January 27, 2003, the respondent's attorney provided copies of three forms that have been revised and are being used at Laser Works. They are as follows:

- Customer Comments and Concerns
- Informed Consent Form
- Client Medical History **Pages 684-687**

On January 31, 2003, a telephone interview was conducted with Dr. Elizabeth Bianchi. She states she is currently the medical director for Laser Works Inc. Dr. Bianchi states she is also the medical director of Nouveau (sp?) of Spokane. She says she lives and works in Spokane, but has made a visit to Laser Works. She also works for Planned Parenthood in Spokane. Dr. Bianchi said she understands she is responsible for the day to day treatment being provided at Laser Works, and is going to work with the Medical Quality Assurance Commission.

On February 18, 2003, a telephone interview was conducted with the complainant. The complainant says it took almost two weeks for his cheek to look normal again after receiving treatment from the respondent. He alleges the treatment was stopped because the laser broke before the respondent could finish. He was given a white antibiotic cream to put on his cheek by the respondent.

APPENDIX E

EVIDENCE & ATTACHMENTS

Page #'s	Description
1	Respondent's E-mail complaint letter received September 4, 2002.
2	Request for field investigation by Unlicensed Program Manager.
3-12	Information obtained from the Cosmetology Board.
13-30	Faxed information and documents received from the Unlicensed Program Manager.
31	Memo to File of telephone interview with Dr. Fisher.
32-33	Memo to File of interview with Eric Moore.
34-42	Digital pictures taken at Laser Works Inc.
43	Picture disk.
44-61	Laser Works forms.
62-63	Laser Works brochures.
64—69	Treatment records of 3 - Healthcare Informatio... .
70-79	Treatment records of 3 - Healthcare Inform... .
80-93	Treatment records of 3 - Healthcare Information Readily Id...
94-102	Treatment records of 3 - Healthcare Informatio... .
103-109	Treatment records of 3 - Healthcare Information Re... .
110-120	Treatment records of 3 - Healthcare Information ... .
121-129	Treatment records of 3 - Healthcare Information Readily... .
130-134	Treatment records of 3 - Healthcare Informatio...
135-137	Unlicensed letter delivered to respondent.
138	Faxed copy of Dr. Fisher's resignation letter to Eric Moore and Laser Works, Inc.
139-140	Medical Quality Assurance Commission's Policy on Use of Lasers in Skin Care and Treatment.
141	Physician's Desk Reference (1997 edition) of drug 5% Xylocaine (lidocaine).

142-148 Laser information obtained from various Internet websites.

149-157 Laser Facts information obtained from FDA Internet website.

158-184 Faxed information and E-mail received from Kathy Maynor, Altus Medical.

185 ASI printout of Dr. John Fisher's license information.

186-203 Records and documents obtained from Dr. Fisher.

204 Witness Notification form of Dr. Fisher.

205 Notice of Appearance from the respondent's attorney, Stephan Fjelstad.

206 Termination of the 11/19/1999 Laser leasing agreement received from Dr. Fisher, dated December 23, 2002.

207-214 E-mail correspondent with Dr. Fisher.

215-216 Statement of Dr. Fisher.

217-225 Respondent's written response signed and submitted by respondent's attorney.

226 Licensing Requirement Notification form signed by the respondent.

227-229 Correspondence from the respondent's attorney.

230-262 Daily appointment book records of Laser Works, Inc.

263-269 Treatment records of 3 - Healt... .

270-274 Treatment records of 3 - Healthcare Informati... .

275-283 Treatment records of 3 - Healthcare Infor... .

284-293 Treatment records of 3 - Healthcare Informati... .

294-297 Treatment records of 3 - Healthcare Informat... .

298-310 Treatment records of 3 - Healthc... .

311-313 Treatment records of 3 - Healthcare Informatio...

314-317 Treatment records of 3 - Healthcare Inform... .

318-324 Treatment records of 3 - Healthcare Information...

325-329 Treatment records of 3 - Healthcare Information Re... .

330-337 Treatment records of 3 - Healthcare Informati... .

338-349 Treatment records of 3 - Healthcare Information Readily I...

350-358	Treatment records of	
359-369	Treatment records of	
370-385	Treatment records of	
386-396	Treatment records of	
397-409	Treatment records of	
410-418	Treatment records of	
419-421	Treatment records of	
422-427	Treatment records of	
428-431	Treatment records of	
432-452	Treatment records of	
453-459	Treatment records of	
460-469	Treatment records of	
470-474	Treatment records of	
475-479	Treatment records of	3 - Healthcare Information R...
480-484	Treatment records of	
485-489	Treatment records of	
490-493	Treatment records of	
494-499	Treatment records of	
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508-511	Treatment records of	
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548-556	Treatment records of	
557-560	Treatment records of	
561-565	Treatment records of	

566-580	Treatment records of
581-583	Treatment records of
584-594	Treatment records of
595-597	Treatment records of
598-612	Treatment records of
613-618	Treatment records of
619-626	Treatment records of
627-635	Treatment records of
636-644	Treatment records of
645-652	Treatment records of
653-665	Treatment records of
666-668	Treatment records of
669-673	Treatment records of
674-677	Treatment records of
678-680	Treatment records of
681	Subpoena served requesting appointment schedules and patient treatment records.
682-683	Letter from respondent's attorney regarding the subpoena request and records.
684-687	Revised forms of Laser Works, Inc.

APPENDIX F

POSSIBLE VIOLATIONS

RCW 18.130.190

APPENDIX G

ACTIVITY REPORT

1.	09-16-2002	Received case file.
2.	09-16-2002	Reviewed case file. Field visit will be necessary. This case is companion to #0019 unlicensed case. Different respondents, but same business office.
3.	09-17-2002	Reviewed case and discussed with Lloyd and Jim.
4.	09-17-2002	Researched information.
5.	09-17-2002	T/C to C on companion case file. Conducted interview with C over the telephone. C does not want to sign a Whistleblower. She was actually an employee of the business. She gave information regarding the business and how it is run. Former employee.
6.	09-17-2002	Looked up on the Internet and other information on ASI and also telephone book.
7.	09-17-2002	T/C to business. Obtained business hours, etc.
8.	10-22-2002	T/C to Chyma. ?'s concerning what an unlicensed can do regarding Laser, Chemical Peels, etc. She has had a case before, but not the same as these.
9.	10-22-2002	Looked up on the Internet information about the Cosmetology Board, etc. Printed the information.
10.	10-22-2002	T/C to the Cosmetology Board. Left message for contact with someone here.
11.	10-22-2002	T/C from Rosie, Cosmetology Board.
12.	12-16-2002	Prepared unlicensed letter to deliver to R at unannounced field visit to Laser Works.
13.	12-17-2002	T/C to Chyma, unlicensed Program Manager. She will fax information to me on laser equipment and use, etc.
14.	12-17-2002	Received faxed information. Reviewed fax.
15.	12-17-2002	T/C to Jim Voiland, regarding meeting me this AM at Laser Works.
16.	12-17-2002	T/C to Dr. Heye, MQAC consultant. Discussed case, etc., and what information the MQAC has regarding any policy with lasers and who can

provide laser treatment. Made arrangements to obtain this information from him when I come down to Olympia on December 18, 2002.

17. 12-17-2002 T/C to the Medical Director, Dr. Fisher. Left a message for him to contact me.

18. 12-17-2002 T/C from Dr. Fisher. Conducted a partial telephone interview with Dr. Fisher regarding his role and part with Laser Works. Dr. Fisher is going to fax me a copy of the resignation he is sending to Laser Works and Eric Moore. Made arrangements to meet with Dr. Fisher on 12/20 at 6:15 AM.

19. 12-17-2002 Met up with Jim and conducted an unannounced F/V to Laser Works.

20. 12-17-2002 Met with Eric Moore and discussed information, etc. Viewed the offices and equipment and took pictures of the equipment.

21. 12-17-2002 Obtained evidence and documents from office. Obtained patient files from office to copy and return to the office.

22. 12-17-2002 Made copies back at the Kent office and returned the files to Laser Works. When I returned, Eric Moore had more ?'s.

23. 12-17-2002 Met with R and delivered unlicensed letter. Discussed case, etc.

24. 12-18-2002 Met with MQAC medical consultant, Dr. Heye and obtained copy of MQAC Policies of the use of Laser. Also met with MQAC Chief Investigator Jim Smith, discussed company's medical director and his part in the company, etc.

25. 12-18-2002 Reviewed MQAC Policy on the Use of Lasers in Skin Care and Treatment, dated October 25, 2002. Made notes of ?'s to ask Dr. Heye.

26. 12-19-2002 T/C to Chyma. ?'s after reviewing guidelines. Can I give Eric Moore a copy of this, etc. Per Chyma, yes, but to clear with Medical. Also, they are in process of opening complaint on other unlicensed practice re Shaney Shoengarth. She will call me back with case #, etc.

27. 12-19-2002 T/C to Dr. Heye. Left message for contact.

28. 12-19-2002 T/C to Jim Smith, Chief Investigator, MQAC. Per Jim, Guideline information is public record, and I can give him a copy of it.

29. 12-19-2002 T/C to Eric Moore. Left message for contact.

30. 12-19-2002 T/C from Eric Moore. Discussed MQAC guidelines and policies, etc. Explained to Eric I plan to come by his office. He is requesting information of how our department validates complaints, etc.

31. 12-19-2002 T/C to Dave. Explained case, etc.

32. 12-19-2002 F/V to Laser Works. Met with Eric Moore. Eric had ?'s. Per Eric, he says he is going to find a way to beat this. Explained that this is nothing personal and again what my position is as an investigator.

Per Eric, he states they are not providing medical treatment in any way and it should hot be considered medical treatment.

33. 12-19-2002 Researched the Internet re:lasers. T/C to the laser companies. Rep will fax me a copy of the FDA standards, etc.

34. 12-19-2002 Reviewed some of the Internet website information with Jim.

35. 12-19-2002 Obtained Lidocaine information from Joe in Pharmacy. Copied for case file.

36. 12-19-2002 T/C to Dr. Fisher to verify we are still meeting at 6:15 AM tomorrow morning.

37. 12-20-2002 Prepared for and met witness Dr. Fisher. Showed Dr. Fisher the forms being used at Laser Works. Dr. Fisher became emotional after reviewing the forms I showed him. Dr. Fisher signed the Witness Notification form and discussed how concerned he is with how this investigation could affect his license to practice. Dr. Fisher states he will prepare and provide a statement for these investigations.

38. 12-20-2002 After returning to the office. Discussed interview with unlicensed Program Manager, etc.

39. 12-20-2002 Received faxed documents from Kathy Maynor/Lumenis company. Looked over documents, which include FDA information.

40. 12-23-2002 Received Notice of Appearance from R's attorney.

41. 12-23-2002 T/C from R's attorney.

42. 12-23-3002 T/C to R's attorney. Discussed case. Attorney is requesting a 7-day extension. He states he still has not talked to the R.

Discussed case with Attorney and explained the complaint alleges all three respondents are practicing medicine without licensure. Attorney states he has not spoken with Dr. Fisher, only with Eric Moore, owner. He says Mr. Moore wants to cooperate and make things right. Attorney says he will speak with respondents and contact me.

43. 12-23-2002 Received statement of Dr. Fisher, witness, listed medical director of Laser Works. Reviewed statement.

44. 12-23-2002 Received E-mail from Kathy Maynor. Reviewed E-mail, etc.

45. 12-23-2002 T/C to Kathy Maynor. Left message for contact and thank her for the fax

46. 12-23-2002 Prepared memo to File of Interview conducted with Eric Moore, owner of Laser Works.

47. 12-23-2002 Prepared Memo to File of interview conducted with Dr. Fisher.

48. 12-23-2002 T/C to Chyma Miller-Smith, Unlicensed Program Manager. Discussed statement obtained.

49. 12-23-2002 Organized the file and reviewed all information obtained.

50. 12-24-2002 Received E-mail from Dr. Fisher. Reviewed and replied

51. 12-24-2002 T/C from Dr. Fisher. He says he went into Laser Works and brought a letter to Eric Moore personally to have his name removed as Medical Director. Dr. Fisher says he is concerned as he witnessed the employees appearing to still be treating patients/clients/customers. He is going to put this in writing.

52. 12-30-2002 Received original letter from R's attorney for all 3 R's. Reviewed letter.

53. 12-30-2002 T/C to Attorney. Left message. Placed in file.

54. 12-30-2002 T/C from R's attorney. He had a lot of ?'s. Attorney has never worked a case like this before. Explained the License Notification letter, etc. Attorney wanted to know process, etc. He also was requesting how Laser Works could get in compliance if found not in compliance. I explained he would have to contact the Medical Quality Assurance Commission, etc.

55. 01-03-2003 T/C from R's attorney on voice mail.

56. 01-03-2003 T/C to R's attorney. He had a lot of questions. Discussed case, etc. again. Gave him telephone numbers for Medical and Unlicensed Program, etc

57. 01-07-2003 T/C from R's attorney. ?'s.

58. 01-14-2003 E-mailed Dr. Fisher. He previously stated he would provide an additional statement from his office visit to Laser Works on 12/23/02. Received E-mail back from Dr. Fisher he would prepare statement and get to me by the end of the week.

59. 01-14-2003 Started the Investigative Report.

60. 01-15-2003 Received E-mail statement from Dr. Fisher. Reviewed statement. Replied to E-mail.

61. 01-15-2003 Prepared for meeting with R's attorney.

62. 01-15-2003 F/V to R's attorney's office. Went over R's written response, etc. Attorney had ?'s. Answered some questions, with Atty, contacted Chyma

Miller-Smith, unlicensed program manager. After telephone call. Again, discussed additional information with R's attorney. After leaving attorney's office, reviewed information obtained.

63. 01-21-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002.

Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages.

Atty asked do I only need the page of the treatment provided that day. Explained to Atty that I need the entire individual record.

64. 01-22-2003 T/C from R's attorney. Atty wanted to verify what I am requesting on the subpoena. Explained that I will need a variety of treatment provided, but he could give me an assortment of between 2-3 people seen per day from the date requested. Explained to Atty that I will need records and files for all people seen on December 23, 2002.

Atty asked if they could just provide a typed version of the appointment book so I can see the names of the patients. Explained I need the copies of the actual appointment book pages.

Atty asked do I only need the page of the treatment provided that day. Explained to Atty that I need the entire individual record.

65. 01-22-2003 T/C from R's attorney. Attorney gave the MD's information for Elizabeth Bianchi. Per Atty, MD is also the Medical Director for Nouveau of Spokane. Per Atty, he does not think Dr. Bianchi has an actual written contract and that contract is currently only verbal for Laser Works of Seattle. He says Dr. is aware of the complaints, etc. She may be difficult to reach today as she will be with patients most of the day.

66. 01-24-2003 T/C from R's attorney, early evening. R says he has all the information requested by subpoena ready. ? Of arrangements to meet and go over this information.

67. 01-24-2003 T/C on 1/26 to Attorney. Left message on his office # that I would be available to meet with him sometime on Monday, and to contact me.

68. 01-27-2003 T/C from R's attorney. Made arrangements to meet him and review requested subpoena documents.

69. 01-27-2003 F/V and met with R's attorney. Reviewed information obtained, etc. Attorney had ?'s.

70. 01-31-2003 T/C to new medical director, Dr. Bianchi. Discussed case and her involvement with Laser Works. Gave Dr. Bianchi web sites to obtain information regarding the lasers to include FDA information. She has the MQAC Guidelines she obtained from Eric, etc. Gave Dr. Bianchi the MQAC consultant's name and telephone number and also the Unlicensed Program Manager's name and # for contact. She says she is aware that she is responsible for the employees and what they are doing. She says she has reviewed the statements the three provided to me.

71. 02-13-2003 T/C from R's attorney on voice mail.

72. 02-13-2003 T/C to R's attorney. He had ?'s.

73. 02-18-2003 Worked on the Investigative Report.

74. 02-18-2003 T/C to C. Discussed his complaint.

75. 02-19-2003 Worked on the Investigative Report. Stamped evidence.

76. 02-19-2003 Reviewed all patient treatment records obtained from Laser Works, Inc.

77. 02-20-2003 Worked on the Investigative Report.

78. 02-21-2003 Finished the Investigative Report. Printed out the Investigative Report.

79. 02-21-2003 Prepared extension to program. Closed out case file.

APPENDIX H

REQUEST FOR INVESTIGATION

☐ Respondent Notification Letter
☐ AFH/NHA Notification Letter
☐ Malpractice Settlement Letter

☐ Complainant Notification Letter
☐ Whistleblower

Date received: 9/5
Date assigned: 9/6

Investigator: Gayle
Priority: 3

Comments: _____

☒ REV UPDATED ☐ TIMELINES UPDATED ☒ ASI UPDATED ☐ TIMEKEEPING UPDATED

CASE MANAGEMENT TEAM
Decision/Action Log

CMT Meeting Date: 09-04-02	**Case No. or ASI Candidate No:** 02-09-0004 41
Credential-holder or Applicant Name: Marilyn Gobrette	
Reason for CMT Review: Unlicensed	
CMT Decision and Basis for Decision:	
Field Inut. Pursue C & D.	

Note: This form is to be completed by program staff at CMT meetings and maintained in every disciplinary or application file reviewed.

CASE MANAGEMENT ASSESSMENT

DATE: September 4, 2002 **CASE NO:** 02-09-0004 UI

RESPONDENT ADDRESS:	**COMPLAINANT(S) ADDRESS:**
MARILYN GELNETTE	*4 - Identity - Whistleblower Regarding Health Care Provider - RCW 43....*

SUMMARY OF COMPLAINT: **Unlicensed Practice – Medicine**

PREVIOUS COMPLAINTS: YES ☐ NO ☒

BACKGROUND COMMENTS:

POSSIBLE VIOLATIONS RCW 18.130.180: 28 – Unlicensed Practice

COMMENTS:

09-04-02 Case file to Chyma for assessment...DW

ACTION:

☐ Draft Letter 1 & 2

☐ Legal Review
- ☐ Cease & Desist
- ☐ NOC
- ☐ SOC
- ☐ STID

☐ Request Field Investigation

DATE RECEIVED:	8/11/00
DATE ASSIGNED:	
PRIORITY:	1 ☐ 2 ☐ 3 ☐
INVESTIGATOR ASSIGNED:	

REQUEST FOR INVESTIGATIVE SUPPORT:

Please obtain the following information (waiver, patient records, respondent explanation, etc.):

_____

_____

_____

RETURNED FROM INVESTIGATIONS: _____

CLOSED:

How should case be closed?
- ☐ (CNAA) No Jurisdiction
- ☐ (CNAB) Below Threshold
- ☐ (CNAD) Insufficient Evidence
- ☐ (CNAX) Complaint Unique Closure-Check File
- ☐ (CNOC) Notice Of Correction

☐ Close, No Jurisdiction, Letter to Respondent
☐ Close, No Jurisdiction, Letter to Complainant
☐ Close, Insufficient Evidence, Letter to Respondent
☐ Close, Insufficient Evidence, Letter to Complainant

CASE MANAGEMENT ASSESSMENT

- ☐ Close, Assurance of Discontinuance Letter to Respondent
- ☐ Close, Assurance of Discontinuance Letter to Complainant
- ☐ Close, No Cause for Action Letter to Respondent
- ☐ Close, No Cause for Action Letter to Complainant

- ☐ Rev closed
- ☐ Timesheet (ISU data) closed
- ☐ ASI closed
- ☐ Timelines closed
- ☐ Timesheet (Unlicensed) closed

telnet (GothomCity)

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                     AAAAAAA    SSS  SSS   IIIIIIIIIII
UNLICENSED PRACTICE        ASSESSMENT SYSTEMS, INC.                  09-09-02
dtw0303                          REAL SYSTEM          V2.5.74        10:33:26 AM
INDIVIDUAL NAME                        (JR,SR,III)      REFERENCE # MD90000918
   LAST GELNETTE                                        SOC SEC NUM     -  -
  FIRST MARILYN                      +-ADDITIONAL INFORMATION----------------+
 MIDDLE                              |           SEX F =      MARRIED   =     |
                                     |                                        |
RESIDENCE INFORMATION                |   OTHER NAME                           |
                                     |CORP. OFFICER                       =   |
                                     |TRUST ACCOUNT                           |
                                     |                                        |
                                     |  BIRTH PLACE                           |
                                     |         DATE   -  -                    |
PHONE: (   )     -       COUNTY:     |                                        |
       (   )     -       LGL ST:     |SCHOOL CODE                             |
                                     |   CE UNITS    0.00 REQD BY   -  -      |
NOTES                                +----------------------------------------+

+-------------------------------------------------------------------------------+
|CURRENT STATUS: U    EXPIRATION DATE:    -  -      FIRST ISSUE DATE:    -  -  |
|RENEWAL STATUS:     LAST ACTIVE DATE:    -  -     LAST RENEWAL DATE:    -  -  |
|COMPLAINTS O/C:  0/ 0      AUTHORITY:                                          |
+-------------------------------------------------------------------------------+
1MENU #1  2INSP DAT 3COMP DAT 44        5         6         7         8
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telnet (GothomCity)

AAAAAA SSSSSS IIIIIIIIIII
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UNLICENSED PRACTICE ASSESSMENT SYSTEMS, INC. 09-09-02
dtw0303 REAL SYSTEM V2.5.74 10:33:13 AM

CASE NUMBER	COMPLAINANT	COMPLAINT DATE	INVESTIGATOR	TYPE	STATUS
2002090004	4 - Identity - Whistleblower Re...	09-04-2002		26	ASSESS

1GO BACK 2 MORE 3CNG ENTR 4NEW ENTR 5DEL ENTR 6 7 TOP 8PRT ENTR

Health Professions Quality Assurance Division
Investigation Service Unit

MEMORANDUM TO FILE

DATE: **September 9, 2002**

TO: **Dave Magby, Chief Investigator**
ISU

FROM: **Chyma Miller-Smith**
Unlicensed Practice Program

SUBJECT: **Request for Field Investigation**
on Marilyn Gelnette 02-09-0004UI

The Unlicensed Program received an e-mail complaint on Marilyn Gelnette who is using a laser to provide hair removal and is not a licensed Physician in the State of Washington.

I am requesting a field investigation to ascertain if Marilyn Gelnette is providing any type of medical services in which requires licensure. CMT decision was to pursue a Cease and Desist Order.

Attached is the investigation file and complaint information.

Access Washington

Department of LICENSING

DOL HOME
DRIVERS
CARS
TRUCKS
BOATS
BUSINESSES
PROFESSIONS
LIST OF LICENSES
FORMS
PRIVACY
LINKS
ABOUT DOL
SEARCH
Search DOL

Cosmetology

WELCOME to the Cosmetology Licensing Program administered by the Department of Licensing's Professional Licensing Support Services unit. This unit is responsible for all licensing and examination activities including regulatory compliance.

Professional Licensing Internet Query - An Internet-based application designed to give you access to Professional Licensing data. You can navigate the system using full and partial name, license number and other search criteria to perform searches for professional licensing information.

REQUIREMENTS FOR LICENSURE:

Application forms are available for download at the bottom of our website.

PROFESSION	REQUIREMENTS FOR LICENSURE
Cosmetologist	Completed application and completion of a 1600 hour course in cosmetology from a licensed school in Washington or certification of current licensure in good standing from other jurisdictions. Pass written examination and pay fee.
Barber	Completed application and completion of a 1000 hour course in barbering from a licensed school in Washington or certification of current licensure in good standing from other jurisdictions. Pass written examination and pay fee.
Manicurist	Completed application and completion of a 500 hour course in manicuring from a licensed school in Washington or certification of current licensure in good standing from other jurisdictions. Pass written examination and pay fee.
Esthetician	Completed application and completion of a 500 hour course in skin care from a licensed school in Washington or certification of current licensure in good standing from other jurisdictions. Pass written examination and pay fee.

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Salon/Shop	Completed application, liability insurance policy in the amount of $100,000, a currently licensed supervisor, and pay fee.
Booth Renter	Completed application, current individual license and liability insurance policy in the amount of $100,000, and pay fee.
Mobile Operator	Completed application, current individual license and liability insurance policy in the amount of $100,000, and pay fee.
Personal Service Operators	Completed application, current individual license and public liability insurance policy in the amount of $100,000, and pay fee.
Instructor	Completed application, current individual license and completion of 500 hours of instructor training, hold a degree in education from an accredited postsecondary institution, or certification of current licensure in good standing from other jurisdictions. Pass written examination and pay fee.
School	Completed application, School Tuition Certification, School Data Sheet, Surety Bond, all information referenced and required in RCW 18.16.140 and WAC 308-20-040 and pay fee.

Reciprocity: No reciprocity, however, if an applicant provides proof they are currently licensed in good standing in another state, territory or foreign country, and pay the fee, they are eligible for examination.

APPLICATION, EXAM, AND RENEWAL FEES:

PROFESSION	APPLICATION/EXAM FEES	RENEWAL FEES
Cosmetologist	$25.00	$20.00 per year (minimum of 2 years for each license)
Barber	$25.00	$20.00 per year (minimum of 2 years for each license)
Manicurist	$25.00	$20.00 per year (minimum of 2 years for each license)
Esthetician	$25.00	$20.00 per year (minimum of 2 years for each

		license)
Salon/Shop	$50.00	$50.00 per year
Booth Renter	$50.00	$50.00 per year
Mobile Service Operator	$50.00	$50.00 per year
Personal Service Operator	$50.00	$50.00 per year
Instructor	$30.00	$20.00 per year
School	$175.00	$175.00 per year

Exam Required For: Cosmetologist, Barber, Esthetician, Manicurist and Instructor.

Schedule of Exams: Every Wednesday, Thursday and Friday at designated Department of Licensing Service Offices.

Cosmetology Licensing Program Disciplinary Actions

Cosmetology Frequently Asked Questions

Forms: You can download the forms listed below to your own desktop or work-station.

Application for licensure as a Cosmetologist, Manicurist, Esthetician, Barber, or Instructor

Application for licensure as a Booth Renter, Mobile Operator, Personal Service Operator, or Salon/Shop

Instructions and application for a license to conduct a Cosmetology, Barbering, Esthetics and/or Manicuring School

School Data Sheet for licensure to conduct a Cosmetology, Barbering, Esthetics and/or Manicuring School

Application for Surety Bond

Application for School Tuition Certification

Please contact us if you have any questions. We look forward to hearing from you!

(24) "Mobile operator" means any person possessing a valid cosmetology, barbering, manicuring, or esthetician's license that provides services in a mobile salon/shop.

(25) "Personal service operator" means any person possessing a valid cosmetology, barbering, manicuring, or esthetician's license that provides services for clients in the client's home, office, or other location that is convenient for the client.

[1991 c 324 § 1; 1984 c 208 § 2.]

RCW 18.16.020
Definitions. ***(Effective June 1, 2003.)***
As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

(1) "Department" means the department of licensing.

(2) "Board" means the cosmetology, barbering, esthetics, and manicuring advisory board.

(3) "Director" means the director of the department of licensing or the director's designee.

(4) "The practice of cosmetology" means arranging, dressing, cutting, trimming, styling, shampooing, permanent waving, chemical relaxing, straightening, curling, bleaching, lightening, coloring, waxing, tweezing, shaving, and mustache and beard design of the hair of the face, neck, and scalp; temporary removal of superfluous hair by use of depilatories, waxing, or tweezing; manicuring and pedicuring, limited to cleaning, shaping, polishing, decorating, and caring for and treatment of the cuticles and nails of the hands and feet, excluding the application and removal of sculptured or otherwise artificial nails; esthetics limited to toning the skin of the scalp, stimulating the skin of the body by the use of preparations, tonics, lotions, or creams; and tinting eyelashes and eyebrows.

(5) "Cosmetologist" means a person licensed under this chapter to engage in the practice of cosmetology.

(6) "The practice of barbering" means the cutting, trimming, arranging, dressing, curling, shampooing, shaving, and mustache and beard design of the hair of the face, neck, and scalp.

(7) "Barber" means a person licensed under this chapter to engage in the practice of barbering.

(8) "Practice of manicuring" means the cleaning, shaping, polishing, decorating, and caring for and treatment of the cuticles and the nails of the hands or feet, and the application and removal of sculptured or otherwise artificial nails by hand or with mechanical or electrical apparatus or appliances.

(9) "Manicurist" means a person licensed under this chapter to engage in the practice of manicuring.

(10) "Practice of esthetics" means care of the skin by application and use of preparations, antiseptics, tonics, essential oils, or exfoliants, or by any device or equipment, electrical or otherwise, or by wraps, compresses, cleansing, conditioning, stimulation, pore extraction, or product application and removal; the temporary removal of superfluous hair by means of lotions, creams, mechanical or electrical apparatus, appliance, waxing, tweezing, or depilatories; tinting of eyelashes and eyebrows; and lightening the hair, except the scalp, on another person.

(11) "Esthetician" means a person licensed under this chapter to engage in the practice of esthetics.

(12) "Instructor-trainee" means a person who is currently licensed in this state as a cosmetologist, barber, manicurist, or esthetician, and is enrolled in an instructor-trainee curriculum in a school licensed under this chapter.

(13) "School" means any establishment that offers curriculum of instruction in the practice of cosmetology, barbering, esthetics, manicuring, or instructor-trainee to students and is licensed under this chapter.

(14) "Student" means a person sixteen years of age or older who is enrolled in a school licensed under this chapter and receives instruction in any of the curricula of cosmetology, barbering, esthetics, manicuring, or instructor-training with or without tuition, fee, or cost, and who does not receive any wage or commission.

(15) "Instructor" means a person who gives instruction in a school in a curriculum in which he or she holds a license under this chapter, has completed at least five hundred hours of instruction in teaching techniques and lesson planning in a school, and has passed a licensing examination approved or administered by the director. An applicant who holds a degree in education from an accredited postsecondary institution shall upon application be licensed as an instructor to give instruction in a school in a curriculum in which he or she holds a license under this chapter. An applicant who holds an instructional credential from an accredited community or technical college and who has passed a licensing examination approved or administered by the director shall upon application be licensed as an instructor to give instruction in a school in a curriculum in which he or she holds a license under this chapter.

(16) "Person" means any individual, partnership, professional service corporation, joint stock association, joint venture, or any other entity authorized to do business in this state.

(17) "Salon/shop" means any building, structure, or any part thereof, other than a school, where the commercial practice of cosmetology, barbering, esthetics, or manicuring is conducted; provided that any person, except employees of a salon/shop, who operates from a salon/shop is required to meet all salon/shop licensing requirements.

(18) "Crossover training" means training approved by the director as training hours that may be credited to current licensees for similar training received in another profession licensed under this chapter.

(19) "Approved security" means surety bond.

(20) "Personal services" means a location licensed under this chapter where the practice of cosmetology, barbering, manicuring, or esthetics is performed for clients in the client's home, office, or other location that is convenient for the client.

(21) "Individual license" means a cosmetology, barber, manicurist, esthetician, or instructor license issued under this chapter.

(22) "Location license" means a license issued under this chapter for a salon/shop, school, personal services, or mobile unit.

000007

(23) "Mobile unit" is a location license under this chapter where the practice of cosmetology, barbering, esthetics, or manicuring is conducted in a mobile structure. Mobile units must conform to the health and safety standards set by rule under this chapter.

(24) "Curriculum" means the courses of study taught at a school, set by rule under this chapter, and approved by the department. After consulting with the board, the director may set by rule a percentage of hours in a curriculum, up to a maximum of ten percent, that could include hours a student receives while training in a salon/shop under a contract approved by the department. Each curriculum must include at least the following required hours:

(a) Cosmetologist, one thousand six hundred hours;

(b) Barber, one thousand hours;

(c) Manicurist, six hundred hours;

(d) Esthetician, six hundred hours;

(e) Instructor-trainee, five hundred hours.

(25) "Student monthly report" means the student record of daily activities and the number of hours completed in each course of a curriculum that is prepared monthly by the school and provided to the student, audited annually by the department, and kept on file by the school for three years.

[2002 c 111 § 2; 1991 c 324 § 1; 1984 c 208 § 2.]

NOTES:

Effective date -- 2002 c 111: See note following RCW 18.16.010.

RCW 18.16.020

Definitions. ***(Effective until June 1, 2003.)***

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

(1) "Board" means the cosmetology, barbering, esthetics, and manicuring advisory board.

(2) "Director" means the director of the department of licensing or the director's designee.

(3) "The practice of cosmetology" means the practice of cutting, trimming, styling, shampooing, permanent waving, chemical relaxing or straightening, bleaching, or coloring of the hair of the face, neck, and scalp and manicuring and esthetics.

(4) "Cosmetologist" means a person licensed under this chapter to engage in the practice of cosmetology and who has completed sixteen hundred hours of instruction at a school licensed under this chapter.

(5) "The practice of barbering" means the cutting, trimming, arranging, dressing, curling, waving and shampooing hair of the face, neck and scalp.

(6) "Barber" means a person licensed under this chapter to engage in the practice of barbering.

(7) "Practice of manicuring" means the cleaning, shaping, or polishing of the nails of the hands or feet, and the application and removal of artificial nails.

(8) "Manicurist" means a person licensed under this chapter to engage in the practice of manicuring.

(9) "Practice of esthetics" means skin care of the face, neck, and hands involving hot compresses, massage, or the use of approved electrical appliances or nonabrasive chemical compounds formulated for professional application only, and the temporary removal of superfluous hair by means of lotions, creams, or mechanical or electrical apparatus or appliance on another person.

(10) "Esthetician" means a person licensed under this chapter to engage in the practice of esthetics.

(11) "Instructor-trainee" means a person who is currently licensed in this state as a cosmetologist, barber, manicurist, or esthetician, and is enrolled in an approved instructor-trainee program in a school licensed under this chapter.

(12) "School" means any establishment offering instruction in the practice of cosmetology, or barbering, or esthetics, or manicuring, or instructor-trainee to students and licensed under this chapter.

(13) "Student" means a person sixteen years of age or older who is enrolled in a school licensed under this chapter and receives any phase of cosmetology, barbering, esthetics or manicuring instruction with or without tuition, fee, or cost, and who does not receive any wage or commission.

(14) "Instructor-operator-cosmetology" means a person who gives instruction in the practice of cosmetology and instructor-training in a school and who has the same qualifications as a cosmetologist, has completed at least five hundred hours of instruction in teaching techniques and lesson planning in a school, and has passed an examination prepared or selected by the board and administered by the director. An applicant who holds a degree in education from an accredited postsecondary institution and

who is otherwise qualified shall upon application be licensed as an instructor-operator with a cosmetology endorsement.

(15) "Instructor-operator-barber" means a person who gives instruction in the practice of barbering and instructor training in a school, has the same qualifications as a barber, has completed at least five hundred hours of instruction in teaching techniques and lesson planning in a school, and has passed an examination prepared or selected by the board and administered by the director. An applicant who holds a degree in education from an accredited postsecondary institution and who is otherwise qualified shall upon application be licensed as an instructor-operator with a barber endorsement.

(16) "Instructor-operator-manicure" means a person who gives instruction in the practice of manicuring and instructor training in a school, has the same qualifications as a manicurist, has completed at least five hundred hours of instruction in teaching techniques and lesson planning in a school, and has passed an examination prepared or selected by the board and administered by the director. An applicant who holds a degree in education from an accredited postsecondary institution and who is otherwise qualified shall upon application be licensed as an instructor-operator with a manicurist endorsement.

(17) "Instructor-operator-esthetics" means a person who gives instruction in the practice of esthetics and instructor training in a school, has the same qualifications as an esthetician, has completed at least five hundred hours of instruction in teaching techniques and lesson planning in a school, and has passed an examination prepared or selected by the board and administered by the director. An applicant who holds a degree in education from an accredited postsecondary institution and who is otherwise qualified shall upon application be licensed as an instructor-operator with an esthetics endorsement.

(18) "Vocational student" is a person who in cooperation with any senior high, vocational technical institute, community college, or prep school, attends a cosmetology school and participates in its student course of instruction and has the same rights and duties as a student as defined in this chapter. The person must have academically completed the eleventh grade of high school. Every such vocational student shall receive credit for all creditable hours of the approved course of instruction received in the school of cosmetology upon graduation from high school. Hours shall be credited to a vocational student if the student graduates from an accredited high school or receives a certificate of educational competence.

(19) "Booth renter" means a person who performs cosmetology, barbering, esthetics, or manicuring services where the use of the salon/shop facilities is contingent upon compensation to the owner of the salon/shop facilities and the person receives no compensation or other consideration from the owner for the services performed.

(20) "Person" means any individual, partnership, professional service corporation, joint stock association, joint venture, or any other entity authorized to do business in this state.

(21) "Salon/shop" means any building, structure, or motor home or any part thereof, other than a school, where the commercial practice of cosmetology, barbering, esthetics, or manicuring is conducted.

(22) "Crossover training" means training approved by the director as training hours that may be credited to current licensees for similar training received in another profession licensed under this chapter.

(23) "Approved security" means surety bond, savings assignment, or irrevocable letter of credit.

WAC 308-20-080 Minimum instruction guidelines for cosmetology, barbering, manicuring and esthetics training. The minimum instruction guidelines for training required for a student to be eligible to take the license examination for the following professions shall include:

(1) For cosmetology:

(a) Theory of the practice of cosmetology, barbering, manicuring and esthetics services;

(b) At least 100 hours of skills in the application of manicuring and pedicuring services;

(c) At least 100 hours of skills in the application of esthetics services;

(d) Shampooing including draping, brushing, scalp manipulations, conditioning and rinsing;

(e) Scalp and hair analysis;

(f) Hair cutting and trimming including scissors, razor, thinning shears and clippers;

(g) Hair styling including wet, dry and thermal styling, braiding and styling aids;

(h) Cutting and trimming of facial hair including beard and mustache design and eyebrow, ear and nose hair trimming;

(i) Artificial hair that may include extensions and fitting;

(j) Permanent waving including sectioning, wrapping, preperm test curl, solution application, processing test curl and neutralizing;

(k) Chemical relaxing including sectioning, strand test, and relaxer application;

(l) Hair coloring and bleaching including predisposition test and strand test, and measurement, mixing, application and removal of chemicals;

(m) Disinfecting of individual work stations, individual equipment and tools and proper use and storage of linens;

(n) Diseases and disorders of the scalp, hair, skin and nails;

(o) Safety including proper use and storage of chemicals, implements and electrical appliances;

(p) First aid as it relates to cosmetology, barbering, manicuring and esthetics; and

(q) No more than twenty-five percent of skills training using mannequins.

(2) For barbering:

(a) Theory of the practice of barbering services;

(b) Shampooing including draping, brushing, scalp manipulations, conditioning and rinsing;

(c) Scalp and hair analysis;

(d) Hair cutting and trimming including scissors, razor, thinning shears and clippers;

(e) Hair styling, wet, dry and thermal styling and styling aids;

(f) Cutting and trimming of facial hair including shaving, beard and mustache design and eyebrow, ear and nose hair trimming;

(g) Artificial hair;

(h) Disinfecting of individual work stations, individual equipment and tools and proper use and storage of linens;

(i) Diseases and disorders of the skin, scalp and hair;

(j) Safety including proper use of implements and electrical appliances;

(k) First aid as it relates to barbering; and

(l) No more than twenty-five percent of skills training using mannequins.

(3) For manicuring:

(a) Theory in the practice of manicuring and pedicuring services;

(b) Artificial nails including silk, linen, fiberglass, acrylic, gel, powder, extensions and sculpting, preparation, application, finish and removal;

(c) Cleaning, shaping and polishing of nails of the hands and treatment of cuticles;

(d) Cleaning, shaping and polishing of nails of the feet;

(e) Disinfecting of individual work station, individual equipment and tools and proper use and storage of linens;

(f) Diseases and disorders of the nails of the hands and feet;

(g) Safety including proper use and storage of chemicals, implements and electrical appliances;

(h) First aid as it relates to manicuring and pedicuring; and

(i) No more than twenty-five percent of skills training using mannequins.

(4) For esthetics:

(a) Theory in the practice of esthetics services;

(b) Skin care of the face, neck and hands including hot compresses, massage, electrical or mechanical appliances or chemical compounds;

(c) Facials;

(d) Temporary removal of superfluous hair of the face, neck and hands by tweezing, waxing, tape, chemicals, lotions, creams, mechanical or electrical apparatus and appliances;

(e) Disinfecting of individual work stations, individual equipment and tools and proper use and storage of linens;

(f) Diseases and disorders of the skin of the face, neck and hands;

(g) Safety including proper use and storage of chemicals, implements and electrical appliances;

(h) First aid as it relates to esthetics; and

(i) No more than twenty-five percent of skills training using mannequins.

[Statutory Authority: RCW 18.16.030(2). 02-04-012, § 308-20-080, filed 1/24/02, effective 6/30/02. Statutory Authority: Chapter 18.16 RCW and RCW 34.05.220. 92-04-006, § 308-20-080, filed 1/23/92, effective 2/23/92. Statutory Authority: RCW 18.16.030. 91-11-042, § 308-20-080, filed 5/10/91, effective 6/10/91; 88-19-047 (Order PM 772), § 308-20-080, filed 9/14/88. Statutory Authority: 1984 c 208. 84-19-020 (Order PL 480), § 308-20-080, filed 9/12/84.]

5.1

HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION
P.O. BOX 47870, OLYMPIA, WA 98504-7870

September 8, 2000

TO: Podiatric Medical Board

FROM: Arlene Robertson, Program Manager

RE: Laser Treatments

ISSUE

The Nursing Commission has received a request for an interpretative statement to outline what type of license, if any, is needed to use lasers such as an Epilight for hair removal. The issue was determined to be more of a medical issue which has led the Department of Health to develop an interpretative statement that is applicable to those professions identified as using laser technology.

BACKGROUND

On June 12th staff from DOH representing MDs, DOs, DPMs, and nursing met with Pat Owens, RN, MHA, to get a better understanding of the use of lasers and the types of individuals conducting the procedures. Ms. Owens has been involved in operating and conducting training for several years and provided extensive background information on lasers.

Ms. Owens discussed the types of aesthetic lasers and treatment provided, laser regulating agencies and professional organizations, national laser standards, principles for non-physician laser use, educational recommendations for laser use by non-physicians, Washington laser regulations, and use of personnel and recommended educational and training requirements. A small portion of the information provided by Ms. Owens is included for review.

More information was to be gathered by some members of the Committee from other sources. Another meeting will be scheduled once that information has been obtained.

ACTION

None required at this time.

LASER REGULATORY AGENCIES & PROFESSIONAL ORGANIZATIONS

Food and Drug Administration
FDA regulations apply primarily to laser manufacturers and specifically labeling parameters for medical lasers. Labels and labeling regulations include not only the graphic material upon the laser, but also any materials such as manuals, support literature, letters and delivery systems packaging and inserts that accompany the laser. Therefore, the manufacturer is required to furnish complete information with respect to directions for use, indications, and cautions to the consumer.

American National Standards Institute
The first cohesive blueprint for building safe clinical laser services was the "American National Standard for the Safe Use of Lasers in Health Care Facilities" or "ANSL3." This advisory document (not a regulation of law) is intended as a guide to aid the consumer, laser producer and the general public. It has become the foundation for the majority of regulatory, professional and advisory standards. ANSL3 covers many areas of lasers and their safe use including terminology, hazard evaluation, classification, control measures and administrative controls.

Joint Commission on Accreditation of Health Organizations (JCAHO)
JCAHO does not currently recommend specific guidelines for laser use, however criteria may be based on ANSI recommendations.

Occupational Safety & Health Administration
OSHA is an advocate for workers on the job site, however it does not have specific legislated regulation governing laser safety in health care facilities. Publication 8-1.7 is an instruction handbook for OSHA investigators which basically copies ANSI standards.

Association of Operating Room Nurses
AORN's "Recommended Practices for Laser Safety in the Practice Setting" was first published in 1989. These broad recommended practices provided guidelines to assist perioperative nurses in developing policies and procedures for the safe use of lasers in their practice setting. These practices represent an acceptable level of practice. AORN's recommendations reflect nationally accepted standards for laser safety.

American Society for Laser Medicine & Surgery (ASLMS)
The ASLMS, in 1980, issued reports that were adopted as recommendations by the society's members. In 1990, the board of directors released nine recommended perioperative practices relating to patients undergoing laser procedures. This included assessment, nursing diagnosis, planning, implementation and evaluation of nursing care.

State Regulations
Including FDA, State Regulations are the only guidelines for laser safety that are backed by legislative action. The concern over laser safety is reflected in the increasing number of states that are enacting medical laser safety legislation. Regulations governing the safe use of lasers present health care personnel with a complex set of guidelines. Only FDA and individual state enactment's are supported by legislation. All other guidelines are recommended practices or standards, and are based on the ANSI Z136.3 practices.

NATIONAL LASER STANDARDS

Federal Laser Product Performance Standard (FLPPS)

- This standard is legally binding in the U.S., and is applicable to all laser products that are introduced or imported into commerce in the U.S.
- The U.S. Congress enacted the Radiation Control for Health and Safety Act of 1968 as Public Law 90-602. Its purpose was to control electromagnetic radiation emitted by electronic products, including x-ray machines, televisions, lasers, microwave ovens, etc. The Act was amended and renamed the United States Federal Food, Drug, and Cosmetic Act, Subchapter C, in November 1990.
- This Act enabled the U.S. Food and Drug Administration (FDA) under the Department of Health and Human Services (HSS) to promulgate federal regulations regarding laser product performance. The FDA agency responsible for administering and enforcing this standard is the Center for Devices and Radiological Health (CDRH). The standard was first issued in 1975, became effective in 1976, and was revised in 1982.
- The standard is alternatively known as the FLPPS, the FDA regulation, the CDRH standard, and 21CFR1040 (U.S. Code of Federal Regulations, Title 21, Subchapter J, Part 1040).
- This regulation is applicable only to laser products and their manufacturers. It requires that manufacturers certify the laser hazard classification and incorporate certain safety features into the laser product which depend upon that hazard classification.

American Society for Laser Medicine and Surgery, Inc.

PRINCIPLES FOR NON-PHYSICIAN LASER USE

1) Any physician who delegates a laser procedure to a non-physician must be qualified to do the procedure themselves by virtue of having received appropriate training in laser physics, safety, laser surgical techniques, pre and post operative care, and be able to handle the resultant emergencies or sequelae.

2) Any licensed medical professional employed by a physician to perform a laser procedure must have received appropriate documented training and education in the safe and effective use of each laser system, be a licensed medical professional in their state, and carry adequate malpractice insurance for that procedure.

3) A properly trained and licensed medical professional may carry out specifically designed laser procedures only under physician supervision and following written procedures and/or policies established by the specific site at which the laser procedure is performed.

4) Since the ultimate responsibility for performing any procedure lies with the physician, he supervising physician should be immediately available and shall be able to respond within f ve minutes to any untoward event that may occur. Ultimate responsibility lies with the supervising physician.

The guiding principle for all physicians is to practice ethical medicine with the highest possible standards to ensure the best interest and welfare of each patient is guaranteed. The ASLMS endorses the concept that use of properly trained and licensed medical professionals, under appropriate supervision, allows certain laser procedures to be performed safely and effectively.

5" response time : not necessarily in person : cell phone, pager.

manufacturers do the training physician + the person running the machine must be licensed & malpractice -

Approved by the Board of Directors
American Society for Laser Medicine and Surgery, Inc.
April 15, 1999

2404 Stewart Square • Wausau, WI 54401 • Telephone: (715) 845-9283 • FAX: (715) 848-2493
E-Mail: aslms@dwave.net • Home Page: http://www.aslms.org

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PRIORITY LEVEL _____
SUMMARY ACTION? _____

HEALTH PROFESSIONS QUALITY ASSURANCE
Case Disposition Worksheet

Back out - Same case as in 2002 -

Respondent_Bianchi, Elizabeth_ Case Number 2005-10-0073MD

Date Presented: 3/2/06 Profession: __Medical_____ Section: _#5_____

Presented by: Moat_ Staff Attorney: _Farrell Staff present at B/C Disposition:

Panel: A Pre-Assigned or Requested (circle one)[103] Bat/Dn

A. *REQUEST FOR LEGAL ACTION*:

☐ **Summary Action:** ___ *Suspension*
___ *Practice Restrictions* _____
☐ **Statement of Charges:** **(Complete Sanctions Worksheet)**
☐ **Statement of Allegations:** **(Complete Sanctions Worksheet)**
☐ **Notice of Correction:**
☐ **Notice of Determination:**
☐ **Withdrawal of SOC:** ☐ **Withdrawal of SOA:**

Alleged Violations—RCW 18.130.180:

____**(1)** Moral turpitude	____**(10)** Aiding and abetting	____**(19)** Treating by secret methods
____**(2)** Misrepresentation of facts	____**(11)** Violation of rules	____**(20)** Betrayal of patient privilege
____**(3)** False advertising	____**(12)** Practice beyond scope	____**(21)** Rebating
____**(4)** Incompetence	____**(13)** Misrepresentation or fraud	____**(22)** Interference w/ investigation
____**(5)** Out of state action	____**(14)** Failure to supervise	____**(23)** Current drug/alcohol misuse
____**(6)** Illegal use of drugs	____**(15)** Public health risk	____**(24)** Sexual contact/patient abuse
____**(7)** Violated state or fed law	____**(16)** Unnecessary or inefficacious drugs	____**(25)** Acceptance of more than nominal gratuity
____**(8)** Failure to cooperate	____**(17)** Criminal conviction	
____**(9)** Failure to comply	____**(18)** Criminal abortion	

Other Violations of Relevant State or Federal Law: _____
Or
RCW 18.130 .170: ___Mental Impairment ___Physical Impairment

Should not have been opened

B. *FILE CLOSED*:

☐ **CNAA** – No Jurisdiction	☐ **CNAE** – No violation determined	☐ **CNAI** – Care rendered was within standard of care	☒ **CNAX** – Complaint unique closure
☐ **CNAB** - Below Threshold	☐ **CNAF** – No violation at the time the event occurred	☐ **CNAJ** – Conduct was within standard of practice	☐
☐ **CNAC** – Evidence does not support a violation	☐ **CNAG** – Risk minimal, not likely to reoccur	☐ **CNAK** - Mistaken identity	☐
☐ **CNAD** – Insufficient evidence	☐ **CNAH** Complainant withdrew	☐ **CNAM** – No Whistleblower	☐

Further explanation (if any): _____

C. OTHER, EXPLAIN (Legal Review, Return to Investigation, etc.):

_____
_____

[103] Program may request a specific staff attorney who has prior experience with the file or the Respondent.

Washington State Department of Health

Health Profession Quality Assurance
Individual Case Summary Report
As of 02/03/2006 1:02:59 PM

Printed By sxc0303 02/03/2006 1:03:00 PM

Profession: Medical | License #: MD00035207 | Name : Bianchi, Elizabeth A

Case #: 2005-10-0073 | Description: Unprof - Aid/Abet Unlic Practice | Docket #: N/A

Date Opened: 10/26/2005 | Date Closed: | Total Days As of 02/03/2006: 100

Current Step = Case Disposition

Step Name	Step Start	Step End	Step Due	Auth Days	Extend Days	Days Used	Days Remain	Next Step
Intake/Assess	10/26/2005	11/22/2005	11/26/2005	21	10	27	4	Investigation
Investigation	11/22/2005	12/21/2005	05/11/2006	170	0	29	141	Case Disposition
Case Disposition	12/21/2005		05/10/2006	140	0	44	**96**	

DEPARTMENT OF HEALTH
INVESTIGATION SERVICE UNIT
MEMORANDUM TO FILE

DATE: December 14, 2005

CASE #: 2005-10-0073MD

RE: BIANCHI, Elizabeth MD

FROM: Gayle M. Crowley, Health Care Investigator

A telephone interview was conducted with the respondent on this date. When the allegations were explained, the respondent indicated she was previously investigated under Case #2002-12-0019MD. She had a letter in her possession from the Department of Health, Medical Quality Assurance Commission, stating her case was closed with no disciplinary action taken.

On December 14, 2005, a copy of the "Confidential Investigative Report" and "Initial Review Panel Case Summary" was obtained from the Medical Quality Assurance Commission. A review of this report indicated the respondent was previously investigated with regards to these same allegations, "Aiding or abetting unlicensed practice," under this #2002-12-0019MD case.

This case is being returned to the Medical Quality Assurance Commission for an additional review after contact with James H. Smith. The companion case file is also being returned for an additional review. A copy of the "Confidential Investigative Report" and "Initial Review Panel Case Summary" for Case #2002-12-0019MD is attached.

EVIDENCE/ATTACHMENTS

Page #'s	Description
1	Notice/WAC 246-15-030
2	Respondent notification letter
3-6	Confidential Investigative Report #2002-12-0019MD
7-9	Case Summary/Initial Review Panel #2002-12-0019MD

Initiate investigation and obtain records, including patient records:

Date: 11/15/05

Health Professions Quality Assurance Division
Investigation Service Unit

2005-10-0073

MEMORANDUM

DATE: October 13, 2005

TO: Lisa Noonan
Disciplinary Manager

FROM: Robin Crowell-Pisano
Unlicensed Practice Unit

SUBJECT:
2002-09-0004UI

Attached is a copy of the investigation report and Cease and Desist Order for

Ms. was providing treatment for acute and chronic pain to the public using the PAP-IMI device. Ms. does not have a medical license.

Also, a copy of the investigation and legal file has been copied. We believe the two physicians may be aiding and abetting unlicensed practice. These files have been given to you for review. The physicians in question are Dr. and Dr.

If you have any questions, please feel free to contact Chyma at (360) 236-4659.

Thank you!

Enclosure

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MQAC INTAKE REVIEW PANEL A
Incorporates DOH Database Information
Case Number: 2005-10-0073MD

MD/PA ___
AGE ____
FOP _____
TOM _____
C/C ___, ___, __
Disp _____

Date: November 7, 2005
Presented by: George Heye, MD

Respondent: Elizabeth A. Bianchi, MD **Spokane County**

Complainant: DOH

CASE SUMMARY

This case is cross-referenced with case no. 2005-10-0074MD

The Respondent:
Board Certified Internal Medicine
DOB: 7/14/1951
Licensed since: 7/14/1997

The Complainant:
Department of Health, Investigative Services Unit

Malpractice Settlement:
no

The Complaint:
During the course of an unlicensed practice investigation, the DOH Investigator felt that two physicians were aiding and abetting the unlicensed practice. Included with the complaint is a copy of the investigation and legal files.

Objective Abstract

The actual complaint is redacted and incorporated herein for review.

Prior Cases:
02-12-0019MD. Possible aiding or abetting unlicensed practice. Closed ncfa.

MQAC INTAKE REVIEW PANEL A
Incorporates DOH Database Information
Case Number: 2005-10-0073MD

MD/PA ___
AGE ____
FOP _____
TOM _____
C/C ___, ___, __
Disp _____

Date: November 7, 2005
Presented by: George Heye, MD

Respondent: Spokane County

Complainant: DOH

CASE SUMMARY

This case is cross-referenced with case no. 2005-10-0074MD

The Respondent:
Board Certified Internal Medicine
DOB: 7/14/1951
Licensed since: 7/14/1997

The Complainant:
Department of Health, Investigative Services Unit

Malpractice Settlement:
no

The Complaint:
During the course of an unlicensed practice investigation, the DOH Investigator felt that two physicians were aiding and abetting the unlicensed practice. Included with the complaint is a copy of the investigation and legal files.

Objective Abstract

The actual complaint is redacted and incorporated herein for review.

Prior Cases:
02-12-0019MD. Possible aiding or abetting unlicensed practice. Closed ncfa.

a7

DEPARTMENT OF HEALTH
HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION - SECTION 5

INTAKE SHEET

Respondent Information

Case No: 05-10-0073MD Case Opened: 10/26/2005

Name: Elizabeth A. Bianchi, MD Lic/Cert/Reg No: MD00035207 Issued: 7/14/1997

Address: 4708 S Schafer Branch Road D.O.B.: 7/14/1951 Expires: 7/14/2007

Soc Sec No: 2 - DOH Licens...

Spokane, WA 99206

School Attended: U of FL; Gainesville, FL Year Completed: 1995

Specialty: Internal Medicine Board Certified: Yes

Complainant Information

Name: DOH

Address:

Companion Case Information (other Respondent)

Previous Case Information (same respondent)

Case No: 02-12-0019MD Case Disposition: Closed Reason Closed: NCFA

Complainant: Confidential, MD

***Steps**

A=Assess
I=Investigating
LR=Legal Review
F=Final Action
RM = Reviewing Member
LD=Legal Drafting
LS = Legal Service
S=Settlement
LP=Legal Prehearing
RAG=Legal Support

AMA AMERICAN MEDICAL ASSOCIATION

AMA Physician Profile

Name and Mailing Address:

ELIZABETH ANN BIANCHI MD
4708 S SCHAFER BRANCH RD
SPOKANE VLY WA 99206-9225

Primary Office Address:

9116 E SPRAGUE AVE # 400
SPOKANE VLY WA 99206-3601

Phone: 1-509-869-8951

Birthdate: 07/14/1951
Birthplace: RIVERSIDE, CA UNITED STATES OF AMERICA

Physician's Major Professional Activity: OFFICE BASED PRACTICE

Practice Specialties Self Designated by the Physician*:

Primary Specialty: FAMILY MEDICINE

Secondary Specialty: UNSPECIFIED

**Self-Designated Practice Specialties/Areas of Practice (SDPS) listed on the AMA Physician Profile do not imply "recognition" or "endorsement" of any field of medical practice by the Association, nor does it imply, certification by a Member Medical Specialty Board of the American Board of Medical Specialties, or that the physician has been trained or has special competence to practice the SDPS.*

AMA membership: NON MEMBER

All Information from this Point Forward is Provided by the Primary Source

Current and/or Historical Medical School:

UNIV OF FL COLL OF MED, GAINESVILLE FL 32610

Degree Awarded: Yes

Degree Year: 1995

AMA
AMERICAN
MEDICAL
ASSOCIATION

AMA Physician Profile

Current and/or Historical Post Graduate Medical Training Programs Accredited by the Accreditation Council for Graduate Medical Education (ACGME):

Future training dates, as reported by the program, should be interpreted as "in progress" or "current" with projected date of completion. If the training program indicates that training for a physician in a particular specialty was not completed at their institution, the training segment will be identified as "INCOMPLETE TRAINING".

Institution: INLAND EMPIRE HP SERV ASSOC
Specialty : FAMILY PRACTICE

State: WASHINGTON
06/1995 - 06/1998
(VERIFIED)

Note: **If you have discrepant information, please submit a Request for Investigation to the AMA so that we may verify the information with the primary source(s). See the last page of this Profile for instructions on how to report a data discrepancy.**

Current and/or Historical Medical Licensure:

Jurisdiction	MD/ DO	Date Granted	Expiration Date	Status	License Type	Last Reported
WASHINGTON	MD	07/14/1997	07/14/2007	ACTIVE	UNLIMITED	10/19/2005

Note: **When the specific month and day are unknown, the date will display the default value of "01." Not all licensing boards maintain or provide full date values. Please contact the appropriate licensing board directly for this information.**

ECFMG Certfication:

Applicant Number:

Note: **The Educational Commission for Foreign Medical Graduates (ECFMG) applicant identification number does not imply current ECFMG certification status. To verify ECFMG status, contact the ECFMG Certification Verification Service in writing at P.O. Box 13679, Philadelphia, PA 19101.**

Federal Drug Enforcement Administration:

* *Only the last three characters of active DEA number(s) are displayed.*

DEA Number *	Schedule	Expiration Date	Last Reported
XXXXXX192	22N 33N 4 5	07/31/2007	10/11/2005
XXXXXX634	22N 33N 4 5	07/31/2006	10/11/2005

Note: **Many states require their own controlled substances registration/license. Please check with your state licensing authority for requirement information as the AMA does not maintain this information.**

AMA AMERICAN MEDICAL ASSOCIATION

AMA Physician Profile

Specialty Board Certification(s)*:

Specialty Board Certification(s) by one or more of the 24 boards recognized by the American Board of Medical Specialties (ABMS) and the American Medical Association (AMA) through the Liaison Committee on Specialty Boards, as reported by the ABMS:

The AMA Physician Profile has been designated by the ABMS as an Official ABMS Display Agent of Member Board Certification data. Therefore, the ABMS Board Certification information on the AMA Physician Profile is considered a designated equivalent source in regard to credentialing standards set forth by accrediting bodies such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and National Committee for Quality Assurance (NCQA).

Certifying Board: AMERICAN BOARD OF FAMILY MEDICINE
Certificate: FAMILY MEDICINE
Certificate Type: GENERAL

Duration	Effective	Expiration	Occurrence	Last Reported
TIME LIMITED	07/09/2004	12/31/2011	RE-CERT	10/06/2005
TIME LIMITED	07/10/1998	12/31/2005	INITIAL	10/06/2005

Note: For certification dates, a default value of "01" appears in the day or month field if data were not provided to AMA. Please contact the appropriate specialty board directly for this information. (**) Indicates an expired certificate.

Medicare/Medicaid Sanction(s):

TO DATE, THERE HAVE BEEN NO SUCH SANCTIONS REPORTED TO THE AMA BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

Other Federal Sanction(s):

TO DATE, THERE HAVE BEEN NO FEDERAL SANCTIONS REPORTED TO THE AMA BY ANY BRANCH OF THE US MILITARY, THE VETERAN'S ADMINSTRATION OR THE US PUBLIC HEALTH SERVICE.

AMA
AMERICAN
MEDICAL
ASSOCIATION

AMA Physician Profile

Additional Information:

TO DATE, THERE IS NO ADDITIONAL INFORMATION FOR THIS PHYSICIAN ON FILE.

The content of the AMA Physician Profile is intended to assist with credentialing. Appropriate use of the AMA Physician Masterfile data contained on this Profile by an organization would meet the primary source verification requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Accreditation HealthCare Commission/URAC. The Physician Masterfile meets the National Committee for Quality Assurance (NCQA) standards for verification of medical education, post graduate medical training, board certification, DEA status, and Medicare/Medicaid sanctions.

If you note any discrepancies, please log onto our web site (http://www.ama-assn.org/go/amaprofiles) and go to the order detail page, select the D following the physician's name and enter the data in question. Or you can mark the issues on a copy of the profile and mail or fax to:

Division of Database Products and Licensing
Attn: Credentialing Products
515 N. State Street
Chicago, IL 60610
800- 665-2882
312 464-5900 (fax)

If you have questions or need additional information, please call the AMA Profile Service customer support line at 800-665-2882.

crh0303 REAL SYSTEM V2.5.7 03:35:40 PM
INDIVIDUAL NAME (JR,SR,III) REFERENCE # MD00035207
LAST BIANCHI SOC SEC NUM 2 - DOH Licensee Soc...
FIRST ELIZABETH
MIDDLE A

RESIDENCE INFORMATION
4708 S SCHAFER BRANCH RD
SPOKANE WA 99206

PHONE: (509) 869-8951 COUNTY: 32
( ) - LGL ST: WA

NOTES
AC060605JDH*061305 RCVD $450-OVR PMT-RFND $140-061705 DC

+-ADDITIONAL INFORMATION-----+
SEX M = MARRIED Y =
OTHER NAME
CORP. OFFICER =
TRUST ACCOUNT
BIRTH PLACE CALIFORNIA
DATE 07-14-1951
SCHOOL CODE 011.03
CE UNITS 0.00 REQD BY 07-14-2009
+-----+

CURRENT STATUS: A D EXPIRATION DATE: 07-14-2007 FIRST ISSUE DATE: 07-14-1997
RENEWAL STATUS: Z LAST ACTIVE DATE: - - LAST RENEWAL DATE: 06-17-2005
COMPLAINTS O/C: 0/ 1 AUTHORITY:

2005-10-0073 MD 10/26/2003

22/10

Brd Cert - Internal Medicine
1995 / N of FL; Gainesville FL - aiding and abetting unlicensed practice

Complainant:

DOH

companion case:

→ Fisher, John A.
2005-10-0074 MD

→ genesis of these complaints ←
is: 2002-09-0004 UI

CASE NUMBER	COMPLAINANT	COMPLAINT DATE	INVESTIGATOR	TYPE	STATUS
2002120019	CONFIDENTIAL	12-10-2002		22	CNAE

Leak File

Miller-Smith, Chyma

From: 4 - Identity - Whistleblower Regarding Health Care Provider - RCW 4...
Sent: Wednesday, September 04, 2002 11:59 AM
To: Miller-Smith, Chyma
Subject: hair removal treatment

hello chyma,

my name is 4 - Identity - Whistleblow... and I am writing in regards to a hair removal treatment that I received @laser works on Aug 28th. I was told by Marilyn Gelnette that if I did treatment on my check area she could garentee 100% that I would not get any redness or burns after the treatment and I would be able to go to work and be fine. so i let her perform the treatment only on my left cheek because the laser broke before she could finish the other side. And after the treatment my cheek was red and i received blisters, only today is my cheeks starting to get back to there normal color(9/4/02). I was wondering what could be done to stop this from happening to me or another person. No one should go through this treatment. Fell free to give me a call if you have any questions(4 - Identity - Whistleblo... .thank you for your time in this delectate matter.

4 - Identity - Whistleblower Regarding Health C...

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

March 23, 2006

Elizabeth A. Bianchi, MD
4708 S Schafer Branch Rd
Spokane, WA 99206

SUBJECT: Elizabeth A. Bianchi, MD
MD00035207; Case No: 2005-10-0073MD

Dear Dr. Bianchi:

The Medical Quality Assurance Commission has closed its investigation regarding allegations of unprofessional conduct.

During the course of the investigation, it was determined that this issue was resolved in case number 2002-12-0019MD, which was closed no cause for action. Therefore, this case is being administratively closed.

As a reminder, you may submit an additional written statement if you wish it to be added to the case file. The file will be subject to release within the guidelines established by Washington public disclosure laws. Public disclosure requests usually come from insurance companies and employers.

Thank you very much for your cooperation in this matter. If you have any questions, please feel free to contact me at (360)236-4791 or Maryella Jansen, Deputy Executive Director, at (360)236-4792.

Respectfully,

LISA NOONAN, Case Management Manager
Medical Quality Assurance Commission
PO Box 47866
Olympia, WA 98504-7866

05-10-0073MD
BIANCHI, ELIZABETH A

- [x] Respondent Notification Letter
- [ ] NHA Notification Letter
- [ ] Malpractice Settlement Letter
- [ ] Special Letter (see comments below)
- [ ] Complainant Notification Letter
- [ ] Whistleblower
- [ ] Criminal History Letter
- [ ] Task Request

RECEIVED
DEC 5 2005
DEPARTMENT OF HEALTH
Investigation Service Unit

Date received: 11/22/05
Date assigned: 11/30/05

Investigator: G Crawley
Priority: 3

Comments: _____

- [x] REV UPDATED
- [x] TIMELINES UPDATED
- [x] ASI UPDATED
- [x] TIMEKEEPING UPDATED

NOTICE

WAC 246-15-030, procedures for filing, investigation, and resolution of whistleblower complaints.

(1)(b) Instructs that staff will affix a permanent cover to the letter of complaint or other form of notice in the complaint file, noting the statutory citation concerning protecting the identity of the complainant.

(3)(c) Ensure upon case closure, that the permanent cover affixed in subsection (1)(c) of this section will remain.

RCW 43.70 provides that the identity of a whistleblower who complains in good faith to the Department of health about the improper quality of care by a health care provider as defined in RCW 43.72.010 ***shall remain confidential***.

Pursuant to the above RCW and WAC it is staff's duty to see that the complainant's name or any information which may identify the complainant is not disclosed.

NOTICE

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

December 1, 2005

Elizabeth Bianchi, MD
4708 S Schafer Branch Road
Spokane, WA 99206

Dear Dr. Bianchi:

SUBJECT: Case No: 2005-10-0073MD

The purpose of this letter is to inform you that the Medical Quality Assurance Commission received a report concerning an allegation of unprofessional conduct as defined in RCW 18.130.180 (10), the Uniform Disciplinary Act. RCW 18.130.050, of the Uniform Disciplinary Act, authorizes the Medical Quality Assurance Commission to investigate complaints of unprofessional conduct.

A preliminary investigation to gather the facts will be conducted by an investigator from the Department of Health, Medical Assessment and Medical Investigations Unit. The investigator will contact you as soon as possible during the investigation if a statement or other information from you is required.

Please note that the Medical Quality Assurance Commission is bound by statute to comply with two different laws, which may seem to conflict. The first requires that we immediately notify a practitioner that a complaint has been filed. The second, the whistleblower law RCW 43.70.075, prohibits us from releasing the name of the complainant or any specific details about the report which could identify the complainant until we have received a signed waiver authorizing us to do so. We are sensitive to the fact that it can be very disconcerting to know a complaint has been filed against you, but not know any details about it. Therefore, once the waiver has been obtained, an investigator will contact you as soon as possible and all issues will be discussed as fully as allowed by law so that you will have an opportunity to respond. In a small percentage of cases, a statement from the Respondent will not be required and no investigator will contact the Respondent.

You may submit a written statement about the complaint at any time. However, you may choose to wait until after you have been contacted by an investigator and advised of the nature of the complaint. If the Commission receives any inquiries about the status of your license while this case is still open, only its existence will be disclosed. Once the review process has been completed, the case will either be closed or acted upon. The contents of the closed case file, including any statements submitted by you, will be subject to release according to Washington's public disclosure laws. Most public disclosure requests come from insurance companies and employers.

We have enclosed our informational brochure *What Happens Next?* along with a copy of RCW 18.130.180 Unprofessional Conduct. Please be aware that this process can take three to six months and in some cases longer. If you have questions, please contact Gayle Crowley, the assigned Investigator, at (253) 395-6709.

Respectfully,

Kay Nonnand

Kay Nonnand
Secretary Senior

Enc.: *What Happens Next?*; RCW 18.130.180
(R)Notify-RPT030.DOC

000002

DEPARTMENT OF HEALTH
HEALTH PROFESSIONS SECTION 5
INVESTIGATIONS UNIT

CONFIDENTIAL INVESTIGATIVE REPORT

PREPARED FOR THE

MEDICAL QUALITY ASSURANCE COMMISSION

****

CASE # 2002-12-0019MD

Respondent:

Elizabeth Bianchi, MD (Unknown.MD)
10808 46th Avenue
Spokane, WA 99206

H. (509) 926-8462 Cell: (509) 995-0368

Attorney:

None provided

Complainant:

Confidential

Attorney:

None Provided

Investigative Case File completed by Investigator: T.R. Heafey on May 23,2003

APPROVED BY:_____ DATE:_____

GENERAL CASE SUMMARY

COMPLAINT / ALLEGATIONS: A confidential complainant contacted the WA State Department of Health on 12-10-2002 concerned about a hair removal business at the Spokane Valley Mall that offers photo rejuvenation through the use of a pulsed light unit called "Aurora" manufactured by Syneron. Reportedly, none of the personnel are medically licensed but have been trained to operate the Aurora machines by the company.

CASE REVIEW: *Nuvo* of Spokane is located in the Spokane Valley Mall, managed by Jeff Gelnette. In addition to informational material including brochures (pp 4-7), an article in the *Spokane Magazine* provides a description of the services offered by the laser skin clinic. (pg 8) On April 25, 2003, Mr. Gelnette was provided with a Letter of Request (pp 9-10) asking for a copy of his business license; names, addresses & telephone numbers of current employees; copies of licenses or certifications; job descriptions; information about the equipment used; access to their appointment book and copies of random selected patient records (Attachment A). This information was provided (pp11-33) by a very cooperative Jeff Gelnette. According to Amy Gelnette, The (IPL) Intense pulse light laser operates with a radio frequency and is used for Tattoo removal, aging spots, sun spots, and hair removal such as bikini lines as well as microdermabrasion for stretch marks. She indicated that a topical anesthetic was applied if the patient was uncomfortable after the procedure. Jeff Gelnette says this practice was discontinued and the only medications applied are the ones the physician uses.

Chyma Miller-Smith of ISU was consulted in regard to a similar investigation she was involved with. Copies of documentation relating to this investigation were provided, also. (Attachment B). Dr. Elizabeth Bianchi was identified as the Medical Director for both Clinics (Seattle & Spokane Valley). Dr. Bianchi was sent a Letter of Cooperation on May 02, 2003. (pp 34-35) Her reply was received on May 21, 2003 (pp 36-43). The investigation was completed and forwarded to the Chief Investigator on May 23, 2003.

1. Contacts Made	3. Significant Activity
2. Key Evidence / Attachments	4. Prior Case History.

1) **Contacts**:

Thomas R. Heafey, Health Care Investigator III
Department of Health/Medical Investigations
1500 West Fourth Avenue, Suite 313
Spokane, WA 99204
(509) 458-3642

Jeff Gelnette, Manager
NUVO Laser Skin Clinic
Spokane Valley Mall
14700 E. Indiana, STE 1092
Spokane, WA 99216
(509) 927-9400
FAX: (509) 927-4955
Cell: (509) 869-8828

Chyma Miller- Smith
WA State Dept. of Health
Investigative Service Unit
(360) 236-4659

2) **Key Evidence / Attachments**:

Page	Description
1-3	Letters of Complaint, Notification and Acknowledgement.
4-7	Informational sheets obtained from *NUVO* of Spokane Valley
8	Article appearing in the *Spokane Magazine* regarding *NUVO*.
9-10	Letter of request to Jeff Gelnette, Manager of *NUVO*.
11-33	Response & requested data from Jeff Gelnette.
34-35	Copy of the Letter of cooperation sent to Dr. Elizabeth Bianchi.
36-43	Dr. Bianchi's response.

ATTACHMENTS:

Attachment A	Randomly selected Patient records from *NUVO*.
Attachment B	Investigative data obtained from ISU.

3) **Activity**:

Date	Activity
12-10-2002	Complaint received by the WA State Department of Health.
12-10-2002	Initial Assessment Review
12-11-2002	Request for Investigation received MIU/Olympia.
12-11-2002	Investigation assigned to T. Heafey.
12-16-2002	Request for Investigation received MIU/Spokane.
02-24-2003	T/C to Chyma Miller- Smith.
02-26-2003	Reports received from ISU (Attachment B).
02-29-2003	T/C from Chyma Miller-Smith

04-21-2003 T/C to NUVO.

04-25-2003 Letter of Request hand-delivered to business.

05-02-2003 Letter of Cooperation sent to Dr. Elizabeth Bianchi.

05-08-2003 T/C from Jeff Gelnette.

05-14-2003 Picked up documentation from Jeff Gelnette.

05-22-2003 Dr. Bianchi's response reviewed.

05-23-2003 Investigation completed and forwarded to the Chief Investigator

4) **Prior Case History**: None

INITIAL REVIEW PANEL
CASE PRESENTATION

Case Number:
02-12-0019MD

MD/PA _____
AGE _____
FOP _____
TOM _____
C/C ___, ___, ___
Disp _____

Date: May 29, 2003
Presented by: Bill N. Crowell, PA-C

Respondent:	**Elizabeth A. Bianchi, MD**	**Spokane County**

Complainant:	Confidential

CASE SUMMARY

The Respondent: Is a 51-year-old Board Certified Family Practice physician, who has been licensed in the State of Washington since July 14, 1997.

The Complainant: Confidential

Malpractice Settlement: N/A

The Complaint: Possible aiding or abetting unlicensed practice.

Complaint Review: On December 10, 2002, the MQAC Medical Consultant received a telephone call regarding a hair removal business advertising itself as removing not only hair, but also performing treatment of vascular lesions, i.e., leg veins, and superficial skin pigmentation problems. This was accomplished through the use of a pulsed light unit called an "Aurora" and the personnel performing the treatments were reportedly not medically licensed, although they may have been trained by the company that manufactured the machine. It was also alleged that while there may have been some medical supervision, no physician was on site.

The original complaint had been opened as an unknown physician. Upon visiting the business, named Nuvo Laser Skin Clinic, which is located in a large shopping mall in eastern Washington, the investigator learned it was managed by a Mr. JG. In an advertisement from a local newspaper with a large circulation, the offered services at the clinic included Botox injections, photo facials and photo rejuvenation to remove age spots and other blemishes, laser hair removal, micro dermabrasion, spider vein therapy, and tattoo removal. The MQAC Investigator learned at that time that the Respondent was the medical director of not only this clinic but also another in Seattle, and that the Seattle clinic had recently undergone an investigation by the Unlicensed Program of the Department of Health.

Review of that investigation reveals that a complaint had been received on September 4, 2002, from a patient who had undergone hair removal treatment from a different Respondent, a cosmetologist, and sustained blisters and redness of his left cheek. Two other complaints had also been received against two other cosmetologist, although they related more to technique rather than an adverse outcome or patient harm. During the investigation, it was

learned that the clinic did have a medical director, although it was not the Respondent. However, during the course of the investigation, and after the medical director was made aware there was an ongoing investigation of the clinic, he resigned. The medical director reported he had been approached three years prior by the owners of the clinic to help the company finance several lasers, under the impression that it would be easier for the company to obtain better financing of a laser with a physician listed as a member of the staff.

The medical director noted he was paid $500 a month to compensate him for the risk of putting his name on the lease, and that he had never been involved in the planning or set up of the day-to-day operations of the clinic. He did note that he had ordered, per the request of the clinic manager, topical Lidocaine 5% for the clinic. The medical director also pointed out that it was his impression that the laser work was to be performed by registered nurses. He also reported that he had only been called to the clinic once in the several years he had been listed as the medical director, and had not been in the clinic for the past six months. It is noted the medical director recently completed a Board Order.

Following the medical director's resignation in December 2002, the clinic obtained the services of the Respondent on January 15, 2003. The Respondent is now acting as the medical director for both clinics.

The Respondent replies that as the medical director of for NUVO, she is responsible in ensuring that client safety and supervision of procedures performed by the staff, including assessment of dermatological conditions, and training and use of the equipment for treatments. The Respondent notes she is available by phone and in person, if needed, for any medically related questions at either the Spokane or Seattle clinic.

The Respondent goes on to say the only invasive procedures she performs is Botox injections and sclerotherapy for small leg veins/telangiectasias. A copy of her training in Botox and sclerotherapy was provided, as well as additional training in the use of lasers. In answering the MQAC Investigator's question regarding what medications are used by her, the Respondent noted she only used Botox and 0.2 % or 0.3% Sodium Tetradecyl Sulfate for sclerotherapy. On a rare occasion, the Respondent notes she has written a prescription for 2% lidocaine gel for patients who experience difficulty in tolerating hair removal or *Photo Facial* treatments. The Respondent adds that she personally sees these patients in the clinic.

In continuing to answer the MQAC Investigator's question regarding how she supervises the operation in both the Seattle and Spokane clinics, the Respondent answers by saying she is available by phone or in person twenty-four hours a day, seven days a week. That if an emergent condition was to arise, 911 would be called and the patient transferred to the nearest hospital. For other non-emergent conditions, the client would be scheduled to see her.

The Respondent states there is now an RN at the Seattle office and she could arrange to fly to Seattle from Spokane if the need should arise. The Respondent goes on to say she provides routine services to the Spokane clinic and travels to Seattle at least monthly to communicate with the Seattle staff and management regarding medically related topics. In addition, the Respondent notes she has developed a relationship with a local dermatologist to assist her with any questions or referrals.

The Respondent notes her experience in this field of medicine includes elective rotations through plastic and dermatology and that she has taken post graduate training in FotoFacial (IPL) technology, extensive workshops in Botox injections and sclerotherapy with a noted physician in Boise, ID. The Respondent also notes that she completed a two day Aesthetics

workshop and seminar from the National Procedures Institute for procedures including cosmetic patient evaluation, Botox and collagen injection, skin resurfacing, lasers, hair removal, and office surgery. In addition, the Respondent notes that she continues to stay current with cosmetically related dermatology literature.

The Respondent goes on to say that the staff is well trained to distinguish when treatment is not indicated and what contradictions exist for cosmetic procedures, noting that they are outlined in the *Training and Treatment Manual* . The Respondent adds that she is available to see and or discuss any patients who may have a condition that requires evaluation. In addition, the Respondent notes that all patients fill out a general medical history and are evaluated prior to the procedure.

The Respondent, when asked the question by the MQAC Investigator, how many times she had been contacted by phone, related that she seldom gets contacted regarding a patient concern or injury, adding that the procedures are very safe, that the clients are given informed consent, and that all questions and expectations are addressed.

The Respondent answered the question if she had a written contract with the clinic by replying she did not, that she is compensated by salary, and has no ownership in the company.

A number of patient handout sheets and instructions were included with the Respondent's statement, regarding the different treatments, complications, frequency of treatments, and telephone numbers to call if problems were incurred. The Spokane clinic has 12 employees, including aestheticians, receptionists, office manager, and the Respondent.

Prior Cases: None

Case File_512482_pdf-r.pdf redacted on: 5/14/2015 11:23

Redaction Summary (51 redactions)

4 Privilege / Exemption reasons used:

1 -- "Attorney Work Product - RCW 42.56.290" (6 instances)

2 -- "DOH Licensee Social Security Number - RCW 42.56.350(1)" (6 instances)

3 -- "Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1)" (23 instances)

4 -- "Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1)" (16 instances)

Page 22, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 1 instance
Page 23, Attorney Work Product - RCW 42.56.290, 1 instance
Page 24, Attorney Work Product - RCW 42.56.290, 4 instances
Page 25, Attorney Work Product - RCW 42.56.290, 1 instance
Page 49, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 84, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 4 instances
Page 290, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 386, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 425, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 426, DOH Licensee Social Security Number - RCW 42.56.350(1), 1 instance
Page 429, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 432, Identity - Whistleblower Regarding Health Care Provider - RCW 43.70.075(1), RCW 42.56.070(1), 2 instances
Page 437, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 8 instances
Page 438, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 12 instances
Page 439, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 1 instance
Page 440, Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1), 1 instance
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