PAUL J. FISHMAN

United States Attorney

ANNE B. TAYLOR

Assistant U.S. Attorney

401 Market Street

P.O. Box 2098

Camden, NJ 08101

(856) 757-5031

Attorneys for Defendants

Eric Kfir Yahav, M.D. and

Camcare Health Corporation

Document Electronically Filed

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

:

RAMONA ESTRELLA,

: HONORABLE

Plaintiff,

.

v.

: Civil Action No.

:

ERIC KFIR YAHAV, M.D., et al.

: NOTICE OF REMOVAL

:

Defendants.

.

TO: Michael T. Rooney, Esquire Celia Ann Rooney, Esquire

ROONEY & ROONEY

1515 Market Street, Suite 1200

Philadelphia, PA 19102

Attorneys for Plaintiff

Paul J. Cosgrove, Esquire
Ulmer & Berne LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202-2409
Attorney for Defendant Teva Pharmaceuticals USA, Inc.

PLEASE TAKE NOTICE that this case, previously pending in the New Jersey Superior Court, Law Division, Cumberland County, Docket No. L-3331-14, is hereby removed to the United States District Court for the District of New Jersey, pursuant to 42 U.S.C. § 233(c). The United States of America is hereby substituted for removing Defendants Eric Kfir Yahav, M.D. and Camcare Health Corporation (collectively "Federal Defendants"), pursuant to 42 U.S.C. § 233(c) and (g), with respect to all of the claims set forth against those parties in the Complaint. The United States of America, by and through its undersigned attorneys, respectfully state the following in support of the removal of this matter:

- 1. The Complaint was filed in the New Jersey Superior Court, Law Division, Cumberland County, on or about August 25, 2014. See Exhibit A (State Court Docket). The trial has not yet occurred. See Docket, Ex. A. Service of process has not been effected upon the Federal Defendants in the manner specified in and required under Fed. R. Civ. P. 4(i).
- 2. Plaintiff has filed this civil action seeking damages from the Federal Defendants for personal injuries she allegedly sustained as the direct and proximate result of the Federal Defendants' alleged negligence (i.e., medical malpractice). See Exhibit B (Complaint).
- 3. At all times relevant to this Complaint, the Federal Defendants were deemed employees of the United States pursuant to 42 U.S.C. § 233(g). <u>See</u> Exhibit C (Declaration of Erica Gibson).
- 4. This action is deemed to be an action against the United States because the Federal Defendants were acting within the scope of employment as employees of the United States pursuant to 28 U.S.C. § 2679(d) and 42 U.S.C. § 233(c). <u>See</u> Exhibit D (Certification of Scope of Employment).

- 5. Sections 233(a) and (g) of Title 42 of the United States Code, as amended by the Federally Supported Health Centers Assistance Act of 1995 (Public Law 104-73) provide that the Federal Tort Claims Act ("FTCA") is the exclusive remedy for tort claims against the United States.
- 6. The United States District Courts have exclusive jurisdiction over tort actions filed against the United States under the FTCA. 28 U.S.C. § 1346(b).
- 7. Counsel for co-Defendant Teva Pharmaceuticals USA, Inc. has consented to the removal of this matter to federal court.
- 8. This Notice of Removal will be filed with the Clerk of the New Jersey Superior Court, Law Division, Cumberland County, and will be served on all parties in accordance with 28 U.S.C. § 1446(d). <u>See</u> Exhibit E (Letter to Clerk of New Jersey Superior Court).

PAUL J. FISHMAN United States Attorney

s/Anne B. Taylor

By: ANNE B. TAYLOR Assistant U.S. Attorney

Dated: June 23, 2015

SJS 44 (Rev. 12/07, Case 1:15-cv-04286-JHR-JS: Decument 1:1 Stilled 06/23/15 Page 1 of 1 PageID: 4

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating

the civil docket sheet. (SEE II	NSTRUCTIONS ON THE REVERSE OF THE FORM.)	ī, ī						
I. (a) PLAINTIFFS		DEFENDANTS	DEFENDANTS					
(b) County of Residence	of First Listed Plaintiff	NOTE: IN LAN	of First Listed Defendant ID CONDEMNATION CASES, US INVOLVED.	SE THE LOCATION OF THE				
II. BASIS OF JURISI	DICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF P	PRINCIPAL PARTIES					
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party)		TF DEF 1 1 Incorporated or Pr of Business In Thi					
☐ 2 U.S. Government Defendant	☐ 4 Diversity (Indicate Citizenship of Parties in Item III)	Citizen of Another State	1 2	•				
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CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES				
 □ 110 Insurance □ 120 Marine □ 130 Miller Act □ 140 Negotiable Instrument □ 150 Recovery of Overpayment & Enforcement of Judgment □ 151 Medicare Act □ 152 Recovery of Defaulted Student Loans (Excl. Veterans) □ 153 Recovery of Overpayment of Veteran's Benefits □ 160 Stockholders' Suits □ 190 Other Contract □ 195 Contract Product Liability □ 196 Franchise ■ REAL PROPERTY □ 210 Land Condemnation □ 220 Foreclosure □ 230 Rent Lease & Ejectment □ 240 Torts to Land □ 245 Tort Product Liability □ 290 All Other Real Property 	□ 330 Federal Employers' Liability □ 340 Marine □ 345 Marine Product Liability □ 370 Other Fraud Liability □ 370 Other Fraud □ 350 Motor Vehicle □ 355 Motor Vehicle Product Liability □ 380 Other Personal Property Damag Product Liability □ 385 Property Damag	Geo Other Food & Drug	□ 422 Appeal 28 USC 158 □ 423 Withdrawal 28 USC 157 PROPERTY RIGHTS □ 820 Copyrights □ 830 Patent □ 840 Trademark SOCIAL SECURITY □ 861 HIA (1395ff) □ 862 Black Lung (923) □ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g)) FEDERAL TAX SUITS □ 870 Taxes (U.S. Plaintiff or Defendant) □ 871 IRS—Third Party 26 USC 7609	400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 810 Selective Service 850 Securities/Commodities/Exchange 875 Customer Challenge 12 USC 3410 890 Other Statutory Actions 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Information Act 900Appeal of Fee Determination Under Equal Access to Justice 950 Constitutionality of State Statutes				
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VII. REQUESTED IN COMPLAINT:	CHECK IF THIS IS A CLASS ACTIO UNDER F.R.C.P. 23	N DEMAND \$	CHECK YES only JURY DEMAND:	if demanded in complaint: : □ Yes □ No				
VIII. RELATED CAS	(See instructions): JUDGE		DOCKET NUMBER					
Explanation:	-							
DATE	SIGNATURE (OF ATTORNEY OF RECORD						

PAUL J. FISHMAN
United States Attorney
ANNE B. TAYLOR
Assistant U.S. Attorney
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Camden, NJ 08101
(856) 757-5031
Attorneys for Defendants
Eric Kfir Yahav, M.D. and
Camcare Health Corporation

Document Electronically Filed

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

RAMONA ESTRELLA,

: HONORABLE

Plaintiff,

:

v. : Civil Action No.

•

ERIC KFIR YAHAV, M.D., et al. : **CERTIFICATE OF SERVICE**

:

Defendants. :

I hereby certify that on June 23, 2015, I caused a copy of Defendants Eric Kfir Yahav, M.D. and Camcare Health Corporation's Notice of Removal and Exhibits attached thereto, Civil Cover Sheet, and this Certificate of Service to be placed in the United States mail, first class, postage prepaid, addressed to the following:

Michael T. Rooney, Esquire Celia Ann Rooney, Esquire ROONEY & ROONEY 1515 Market Street, Suite 1200 Philadelphia, PA 19102 Attorneys for Plaintiff

Paul J. Cosgrove, Esquire Ulmer & Berne LLP 600 Vine Street, Suite 2800 Cincinnati, OH 45202-2409 Attorney for Defendant Teva Pharmaceuticals USA, Inc.

> PAUL J. FISHMAN United States Attorney

s/ Anne B. Taylor
By: ANNE B. TAYLOR
Assistant U.S. Attorney

EXHIBIT A







END OF LIST

Page: 1

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EXHIBIT B

ROONEY & ROONEY
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Celia Ann Rooney, Esq.
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Philadelphia, PA 19102
Email: mrooney47@comcast.net

Email: croonev12: a comcast net

Phone: 215.854.4085 Attorneys for Plaintiff

-AND-

SUPERIOR COURT OF THE STATE OF NEW JERSEY CAMDEN COUNTY

RAMONA ESTRELLA : CIVIL ACTION 1229 N. 22nd Street :

Camden, New Jersey 08105 DOCKET NO. 2-3331-14

PLAINTIFF.

-V- : CODE: <u>604</u>

ERIC KFIR YAHAV, M.D. : MEDICAL NEGLIGENCE

1 Alpha Avenue, Suite 27
Voorhees, New Jersey 08043

CAMCARE HEALTH CORPORATION: 817 Federal Street: :

Camden, NJ 08103
-AND-

TEVA PHARMACEUTICALS USA, INC. : 1090 Horsham Road : North Wales, PA 19454 :

-AND-BAYER HEALTHCARE PHARMACEUTICALS,

INC.
100 Bayer Boulevard

Whippany, New Jersey 07981

-AND-JOHN DOE CORPORATIONS A through J,

-AND-JOHN DOES A through J, (fictitiously named entities and persons whose identities

are unknown to Plaintiff),

Defendant(s).

COMPLAINT

Plaintiff RAMONA ESTRELLA, by and through her undersigned attorney, by way of her

Complaint, states as follows:

THE PARTIES:

- Plaintiff RAMONA ESTRELLA is an adult individual residing at the address in the caption and a citizen of the Commonwealth of Pennsylvania for purposes of diversity jurisdiction.
- 2. Defendant ERIC KFIR YAHAV, M.D., is an adult individual whose principal place of business is at the address in the caption, where he may be served with summons, and who, at all times relevant herein, was a licensed physician in the State of New Jersey and held himself out to the public as a specialist in obstetrics and gynecology in the State of New Jersey.
- 3. Defendant CAMCARE HEALTH CORPORATION, INC., is a domestic non-profit corporation or other business entity established under the laws of the State of New Jersey, with its principal place of business at the address in the caption, and which was the actual or ostensible employer, master or principal of certain individual persons as set forth below, and which may be served with summons at the address in the caption.
- 4. Defendant TEVA PHARMACEUTICALS USA, INC., is a corporation or other business entity organized under the laws of the State of Delaware, with its principal place of business at the address in the caption, and which may be served with summons at the address of its registered service agent in the State of New Jersey as follows: Corporate Creations Network, 811 Church Road, Suite 105, Cherry Hill, NJ 08002; this Defendant manufactured, marketed and sold the intrauterine device (IUD) with the brand name "Paragard."
- 5. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a corporation or other business entity organized under the laws of the State of Delaware, with its principal place of business at

the address in the caption, and which may be served with summons at the address of its registered service agent in the State of New Jersey as follows: Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628; this Defendant manufactured, marketed and sold the intrauterine device (IUD) with the brand name "Mirena."

- 6. Defendant(s) JOHN DOE CORPORATIONS A through J, are fictitiously named corporations or other business entities whose identities are not presently known to the Plaintiff RAMONA ESTRELLA and may be known to the named Defendants which participated in the care and treatment of Plaintiff in one or more of the following capacities: actual or ostensible employers, masters, staffing agencies, or principals, or actual or ostensible agents, servants and/or employees of any of the named Defendants; suppliers or distributors of goods and/or services to the Plaintiff during her care and treatment at the times complained of herein; manufacturers, sellers, designers, packagers, marketers, or distributors of certain surgical products or supplies implanted, replaced, or removed from the Plaintiff; or in any other way participated in the care and treatment of the Plaintiff and who are or may be liable to the Plaintiff for injuries and harm and damages caused to her as alleged hereinafter.
- 7. Defendant(s) JOHN DOES A through J, whether male or female, are fictitiously named individuals whose identities are not presently known to the Plaintiff RAMONA ESTRELLA and who may be known to the named Defendants, who participated in the care and treatment of Plaintiff in one or more of the following capacities: health care assistants or professionals; pre-operative, operative or recovery room personnel; nurses, nurses' assistants or CNA's; interns, residents or fellows; actual or

ostensible agents, servants and/or employees of any of the named Defendants or any of the John Doe Corporations or individuals, whether known or unknown to the Plaintiff at the present time, or who otherwise participated in the care and treatment of the Plaintiff, including the provision or supply of any services or products, and who are or may be liable to the Plaintiff for the injuries and harm and damages caused to her under the theories of liability as alleged hereinafter.

THE MEDICAL EVENTS AND PERSONAL INJURIES AND BACKGROUND:

- 8. Prior to the events complained of, Plaintiff RAMONA ESTRELLA came under the care and treatment of Defendant ERIC KFIR YAHAV, M.D. (hereinafter "YAHAV" or "Dr. Yahav"), a specialist in obstetrics and gynecology, for general gynecological services, prenatal care and childbirth, and follow up gynecological care including placement of an intrauterine device, its later removal and replacement with a different IUD, as set forth in more detail below.
 - 9. Defendant Yahav was aware of Plaintiff's medical history.
- 10. Prior to the subject procedures in August of 2012, Plaintiff, then a minor child of 17, was in relative good health and had a healthy child born on July 5, 2012, without complication, after which she sought contraception by means of an IUD.
- 11. There is no indication in the records or reports of Defendant YAHAV that he adequately advised Plaintiff concerning the risks and dangers as well as benefits of using a contraceptive intrauterine device, or that he could misplace it, or that it could malfunction, or that he could mistakenly insert a Paragard IUD (which contains copper as a method of spermicide) rather than a Mirena IUD which contains

hormones as the method of preventing conception; furthermore, it does not appear in the records that he warned her about the possibility of becoming unable to bear children as a consequence of using an IUD.

- 12. On August 27, 2012, Defendant Yahav performed a procedure in the CAMCARE Health facility in which he reportedly inserted a Paragard IUD in the Plaintiff's uterus rather than a Mirena IUD, which is what Plaintiff requested and consented to; Dr. Yahav did not advise plaintiff of the change in device.
- 13. Following the August 27, 2012, procedure in which the Paragard IUD was inserted, which was not the device which Plaintiff selected, Plaintiff complained of ongoing and extreme and worsening pain in her abdomen and further experienced severe internal hemmorraging and bleeding.
- 14. On August 30, 2012, following a phone call to the CAMCARE facility to describe her pain and symptoms, a physician told her through the nurse to go directly to the Emergency Room at Cooper University Hospital in Camden, New Jersey, which she did.
- 15. On August 30, 2012, Dr. Yahav met Plaintiff at the hospital and performed a laparascopic procedure in which the Paragard IUD, described grossly as a "copper T" IUD by a pathologist, was removed; the device was found behind the uterus in the intra-abdominal cavity.
- 16. In the records, the device was described as having been "misplaced" and having "malfunctioned."
- 17. Prior to each of Plaintiff's procedures, Dr. YAHAV and others involved in her medical care failed to develop an adequate differential diagnosis, failed to adequately examine and order diagnostic studies, and otherwise failed to give her adequate pre-operative assessment and care.

- 18. As a direct and proximate result of the negligence and medical malpractice of the healthcare Defendants and all Defendants, and in combination and concurrence with the unreasonable dangerousness and defectiveness of the medical and surgical products which malfunctioned or were otherwise defective including the failure to adequately warn physicians and patients when they left the control of the manufacturing/distributing Defendants, and also due to the breaches of warranty of fitness for a particular purpose, Plaintiff sustained serious, permanent, incurable, and disabling injuries to the organs in her pelvic and abdominal areas, including internal abdominal scarring and other injuries and conditions, which place her in greater risk of harm in the future, and in all probability, have harmed her in making her unable to have children in the future.
- 19. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Manufacturing Defendants, Plaintiff has sustained substantial special damages including medical bills in the past and future, and incurred additional liens and subrogation interests which have to be accounted for out of any recovery made from responsible Defendants herein, including a substantial Medicare or Medicaid lien.
- 20. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Manufacturing Defendants, Plaintiff has sustained in the past and will sustain in the future lost wages and lost earning capacity.
- 21. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Manufacturing Defendants, Plaintiff has sustained substantial general damages for severe and continuing pain and suffering, loss of enjoyment of life in the past and future, disability,

physical deformity, scarring, impairment of functional abilities, embarrassment, inconvenience, humiliation, and other unliquidated damages for the harm caused to her.

- 22. The negligent acts and omissions of all of the Defendants, breaches of warranty, and the defectiveness of the products and other conduct, combined and commingled to cause, contributed to cause and were substantial factors in causing the harm, injuries and damages to the Plaintiff.
- 23. Defendants are or may be liable to the Plaintiff on theories of direct liability as well as vicarious liability for the acts and omissions of their actual or ostensible agents, servants and employees, and the doctrine of respondent superior is claimed herein.
- 24. The healthcare Defendants at all times relevant, had sole custody and control of all instrumentalities used in the surgeries upon Plaintiff, while Plaintiff was under anesthesia, and otherwise unable to help herself or avoid the harm being caused, and the harm complained of normally does not occur without acts or omissions in negligence, and therefore, the doctrine of **res lpsa loquitor** is claimed herein.
- 25. At all times relevant herein, Dr. YAHAV was in charge as the surgeon during the procedures and surgeries on Plaintiff which took place in August of 2012, and had a duty to adequately train, instruct and supervise the physician's assistant, residents, interns nurses, and other assistants so as to properly care for Plaintiff.
- 26. At all times relevant herein, Dr. YAHAV and his assistants were employees, agents and/or servants of Defendant CAMCARE HEALTH CORPORATION, INC., and therefore, that Defendant is or may be liable for their negligent acts and omissions and other misconduct.

- 27. At all times relevant herein, there were involved in the activities of the healthcare Defendants and in the activities of the manufacturing Defendants, unidentified individuals and businesses entities, herein fictitiously named as "John Doe Corporations A through J" and "John Does A through J", who are or may be liable to the Plaintiff along with the named Defendants on the basis of each of the Counts below, and each Count is intended to include such business entities and individuals, reserving Plaintiff's right to discover their identities and amend her pleading to name them when revealed.
- 28. The negligent conduct of the named and fictitiously named Defendants, their fraud and misrepresentation, breaches of warranty, and the defective product combined and commingled to cause, contributed to cause and were substantial factors in causing harm to the plaintiff.

COUNT I: NEGLIGENCE: MEDICAL MALPRACTICE: PLAINTIFF V. DEFENDANT ERIC KFIR YAHAV, M.D., AND DEFENDANT CAMCARE HEALTH CORPORATION, INC.

- 29. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.
 - 30. At all times relevant herein, Defendants YAHAV, M.D., and the hospital medical staff, and others present in and participating in the incidents complained of, were agents, employees or servants of the Defendant CAMCARE HEALTH CORPORATION, INC., and as such, their employers and/or principals are vicariously liable for their employees', agents' and/or servants' negligent acts and omissions and other misconduct.
 - 31. At all times relevant herein, the Healthcare Defendants and the Manufacturing

 Defendants are also directly liable for their own negligent acts and omissions to the extent that they

participated in the decisions, actions and conduct which caused, contributed to cause, or were substantial factors in causing the harm to Plaintiff as alleged herein.

- 32. Defendant YAHAV had duties to the Plaintiff as her gynecologist, attending physician, and surgeon, first, to do no harm, and otherwise, to perform the subject surgeries and procedures and examinations in a manner which met the standards of professional care for a specialist in his field and which was not performed in a manner to the detriment of the best interests of his patient.
 - 33. Defendant YAHAV breached his duties to the Plaintiff, causing her irreparable harm.
- 34. The negligent acts and omissions of Defendant YAHAV included but were not limited to the following:
- a) Performing a procedure and a surgery in a negligent and careless manner;
- b) Doing inadequate investigation into the potential risks and consequences of performing the procedures in the manner which he performed them;
- c) Using the wrong device in the initial IUD insertion, to-wit: inserting a Paragard device in the Plaintiff instead of a Mirena IUD as requested by and consented to by the Plaintiff:
- d) Inserting the Paragard IUD in the wrong place and in the wrong manner, resulting in its migration outside of the uterus and into the intra-abdominal cavity;
- e) Negligently perforating the Plaintiff's uterus while using a HUMI manipulator device;
- f) Misplacing, misaligning, or mal-positioning the IUD device so that it was not properly inserted into the uterus and was found to be outside and behind the uterus;
- h) Replacing a misplaced, malfunctioning IUD with a different device which also caused problems;
- Permitting an incompetent surgical assistant to participate in Plaintiff's procedures;

- j) Failing to adequately supervise assistants and nurses in the operating room;
- k) Failing to obtain adequate consultations before performing surgery;
- Using improper technique and performance of a procedure for which the device was contraindicated;
- m) Knowingly violating the product safety warnings mandated by the United States Food and Drug Administration;
- n) Failing to take into account the condition of the Plaintiff, the contra-indications she had at the time of the initial insertion, failing to note and document the critical physical details of the examination such as the presentation of the uterus prior to insertion, and failure to do an ultrasound.
- o) Being otherwise negligent, grossly negligent and careless in the care and treatment of plaintiff.
- 35. The above negligent acts and omissions fell below the acceptable standards of care for a gynecologist and gynecological surgeon in the field and were substantial factors in causing the harm to the Plaintiff set forth above.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s), jointly and severally, in an amount in excess of \$15,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT II: BATTERY: LACK OF INFORMED CONSENT: PLAINTIFF V. DEFENDANT ERIC KLIF YAHAV, M.D.

- 36. Plaintiff incorporates by reference all of the previous paragraphs as though fully set forth herein.
- 37. Defendant YAHAV had a duty to advise Plaintiff of all of the significant risks and side effects of the subject procedures, including the risks of failure or negligence in placement of the implanted devices which he selected and placed, and including the increased risk of harm from improper sizing and

placement of such hardware, the increased risk to her of the use of the products in ways not approved by the FDA, and the harm which would likely be caused to her by the contraindicated procedure and use of such medical devices.

- 38. Defendant failed to advise Plaintiff that he was not inserting the Mirena IUD which she had requested and consented to, and instead inserted a Paragard IUD, depriving Plaintiff of the opportunity of giving fully informed consent to the procedure.
- 39. Defendant YAHAV and the other medical Defendants failed to advise Plaintiff that the procedures she would undergo were either unnecessary or contraindicated.
- 40. As a result of these failures of the Defendants to fully inform plaintiff and obtain her informed consent, Dr. YAHAV and the other Defendants committed a medical battery upon the Plaintiff, thereby causing her harm.
- 41. A reasonable person in Plaintiff's position would not have consented to the procedures had she been fully informed of the matters a person would expect the physician to disclose about the benefits and risks of the device, the specific use of the device, which device was being used, the alternatives available to the patient, the "off-label" and/or experimental use of the device and attendant risks, the safety warnings provided which restricted the usage of the device to certain procedures which did not include the procedure selected by Defendants.
- 42. Plaintiff would not have consented to the surgeries complained of had she been fully apprised of all material and significant risks withheld from her knowledge and of the financial dealings of Dr.

YAHAV with the Manufacturing Defendants including, upon information and belief, the presence of sales representative(s) in the locations where she expected to receive care from competent and qualified medical personnel only.

43. The undisclosed risks of the treatment, the misplacement of the device, the malfunctioning of the device and the selection and improper insertion of a different device than the one which Plaintiff requested and consented to, did in fact happen and caused irreparable harm to the Plaintiff.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s), jointly and severally, in an amount in excess of \$15,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT III: LIABILITY OF HEALTH CARE PROVIDERS FOR MEDICAL DEVICES UNDER THE NJ PRODUCT LIABILITY ACT: § 2A:58C-11 PLAINTIFF V. DEFENDANTS YAHAV AND CAMCARE HEALTH CORPORATION

- 44. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.
- 45. Defendants YAHAV and CAMCARE HEALTH CORPORATION are health care providers as defined by the New Jersey Product Liability Act, § 2A:58C-1 et seq.
 - 46. The IUD products identified in this complaint are "medical devices."
- 47. The health care providers named herein knowingly violated the product safety Warning(s) mandated by the U.S. Food and Drug Administration.

- At all times relevant hereto, the medical Defendants named herein and others not presently known to Plaintiff but described as John Doe Corporations A through J and John Does A through J, and including the sales representative(s) in the operating room(s) or procedure rooms during Plaintiff's surgeries or procedures participated in the sale and distribution of medical products into the stream of commerce when they knew or should have known that the manner of use and selection of such products in the surgical procedures upon Plaintiff were used in violation of the Act.
- 49. At all times relevant hereto, Defendants YAHAV and CAMCARE HEALTH CORPORATION:

 (1) exercised some significant control over the design, manufacture, packaging or labeling of the medical device relative to the defect in the medical device which caused the Plaintiff's injuries, and/or

 (2) knew or should have known of the defective nature of the medical device when used in violation of the product warnings, which caused the Plaintiff's injuries, and/or (3) created a defect in the medical device which caused the Plaintiff's injuries; all in violation of the Act, 2A:58C-11, and all as specified above.
- 50. The products and medical devices as used for this Plaintiff were adulterated due to the Defendants' failure to comply with federal regulations.
- 51. The medical products and medical devices as used for this Plaintiff were misbranded due to the Defendants' failure to comply with federal regulations.
- 52. The medical products and medical devices as used for this Plaintiff deviated from the device's approved design and manufacturing processes.

- 53. Plaintiff was unaware of the defects in the products and devices which made them unreasonably unsafe and unfit for their use and unfit for the particular use in Plaintiff, and she was not in a position to recognize or control or avoid the unreasonably unsafe defect in the products.
- 54. As a direct and proximate result of the foregoing activities and conduct and defective uses of the products herein, the Plaintiff has suffered the injuries, damages and losses as set forth herein.

WHEREFORE, the Plaintiff demands judgment in her favor and against the Defendants, jointly and severally, for an amount in excess of \$15,000.00 which will fully and adequately compensate her, together with such interest, attorney's fees, costs of suit and such other relief as this Honorable Court may deem her entitled.

COUNT IV: PRODUCT LIABILITY UNDER THE NEW JERSEY PRODUCT LIABILITY ACT, N.J.STAT. § 2A:58C-1 et seq.: PLAINTIFF V. DEFENDANTS TEVA PHARMACEUTICALS AND BAYER HEALTHCARE PHARMACEUTICALS

- 55. Plaintiff incorporates by reference each of the foregoing paragraphs as though fully set forth herein.
- 56. The New Jersey Legislature promulgated the Product Liability Act in order to clarify certain aspects of product liability law in the state and not to supercede or abrogate provisions of the common law or commercial law which provide remedies for and protect consumers from the hazards of unreasonably dangerous products under claims for express warranty and warranty for a particular purpose.

- 57. The New Jersey common law and statutory law claims herein parallel federal requirements as to medical devices and therefore are not pre-empted.
- 58. Section 2A:58C-2 of the Act states that a manufacturer or product seller shall be liable to the plaintiff if the plaintiff shows by a preponderance of the evidence that the product was "not reasonably fit, suitable or safe for its intended purpose" because it (a) deviated from design specifications or from other units (manufacturing defect); and/or (b) failed to contain adequate warnings or instructions.
- 59. The Manufacturing Defendants are liable to Plaintiff in this case as manufacturers, sellers, designers, marketers, labelers, packagers and distributors of the products which caused plaintiff personal injuries, damages and harm.
- 60. The Manufacturing Defendants participated in the manufacture, packaging, labeling, distribution, and sale of surgical products implanted in the plaintiff including the Paragard IUD and the Mirena IUD which were defective and unreasonably dangerous to the Plaintiff in that they failed or malfunctioned and were not fit for the purpose for which they were intended.
- 61. The subject products were defective in that they were not accompanied by adequate warnings and instructions concerning the hazards they posed to patients as required by the FDA requirements for Class II and III devices of this nature.
- 62. The subject products were defective in that they were not fit, suitable, or reasonably safe as manufactured and sold and used in a manner not approved by the FDA with the knowledge and encouragement of the Manufacturing Defendant.

- 63. The defects in the products existed at the time they left the control of the manufacturers, distributors, marketers and sellers and entered into the stream of commerce and the condition of the product remained substantially the same until the time of the events complained of herein.
- 64. The products did not contain adequate warnings of the dangers of use in the manner in which the IUDs were used in Plaintiff.
- 65. The above-described defects, singly or in combination, directly and proximately caused the harm to plaintiff alleged herein.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of \$15,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT V: FRAUDULENT CONCEALMENT: PLAINTIFF V. DEFENDANTS YAHAV AND CAMCARE HEALTH CORPORATION INC.

- 66. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.
- 67. Under New Jersey law, healthcare providers are required to produce a true, unaltered, and complete copy of a patient's chart or records upon request by the patient or patient's representative within 30 days of such request.
- 68. Plaintiff's representatives herein requested copies of the medical records and diagnostic films on her behalf from Defendants YAHAV, CAMCARE HEALTH CORPORATION, and third party COOPER UNIVERSITY HOSPITAL by and through STAR-MED CORPORATION.

- 69. To date, Plaintiff's representative has not received true, unaltered, and complete copies of the requested records or complete diagnostic films in response to Plaintiff's proper requests, including an executed HIPAA-compliant authorization for the release of the records and tender of payment and has not received an affidavit of any custodian.
- 70. It is believed and therefore averred that the named providers are fraudulently concealing the records and films in order to deprive plaintiff of her rights to investigate thoroughly and pursue her potential claims against them, individually or in combination.
 - 71. Said records and films were and are material to the proper pursuit of this litigation.
 - 72. Said records and films were and are in the possession of Defendants.
- 73. Defendants have intentionally withheld, altered and/or destroyed the evidence to prevent plaintiff's representatives from a thorough and accurate investigation into her claims.
- 74. Plaintiff preserves her rights to present evidence of her damages, amend her pleadings, and to present additional causes of action which may be revealed in the records and films in the underlying actions for medical negligence and/or product liability as the litigation progresses and additional information is discovered.

WHEREFORE, Plaintiff respectfully requests the appropriate instructions to the jury at the appropriate time and upon appropriate proof of fraudulent concealment as to each or all of the named defendants or those fictitiously named individuals or corporations later identified and for such damages as have been caused to Plaintiff by such fraudulent concealment and such other and further relief as this Court deems

appropriate.

ADDITIONAL CLAIM FOR PUNITIVE DAMAGES FOR COUNTS I through V:

- 75. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.
- 76. Punitive damages claims are not a separate cause of action but an additional claim for damages above and beyond compensatory damages, which are separately demanded as a convenience and for clarity, should the evidence warrant an instruction by the Court to the jury under the heightened standard of judging the conduct of defendants.
- 77. The conduct of the Defendants was outrageous in that it was malicious, wanton, willful, oppressive and/or showed a reckless indifference to the interests, life, and safety of the Plaintiff, entitling Plaintiff to an award of punitive damages, over and above her compensatory damages in order to punish the Defendants for their outrageous misconduct and to deter the Defendants and others from committing similar acts.
- 78. The specific act(s) or omission(s) warranting an award of punitive damages include, but are not limited to:
- a) Inserting the wrong IUD without advising Plaintiff or obtaining her consent;
- b) Concealing and minimizing adverse events from the public, patients, physicians, and facilities;
 in off-label experimental ways;
- c) Taking advantage of patients by experimenting on the patients without their knowledge or consent.

79. Under the New Jersey Punitive Damages Act, 2A:15-5.9 et seq., Defendant(s) acts and

omissions caused the harm suffered by plaintiff and they were actuated by actual malice or accompanied

by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or

omissions, and/or defective products, in that there was a significant likelihood that serious harm would

arise from the conduct or products, and that Defendant(s) was/were highly aware that such reckless

disregard would result in serious harm to patients, and the conduct of the Defendant(s) continued for an

unreasonable period of time even after it/they knew of the harm being caused by its/their conduct and/or

products.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court issue judgment in her favor and

against all Defendants, individually, jointly, and severally, in a sum in excess of the jurisdictional limit

of this court, exclusive of interest and costs, over and above compensatory damages, as and for punitive

damages, to punish defendants' outrageous and reckless disregard of the lives and safety of others, and

to deter others from similar conduct, together with such other relief as this Court may deem appropriate.

JURY OF 12 DEMANDED FOR TRIAL.

Attorneys' Lien Requested.

Dated: August 25, 2014

Respectfully submitted.

/s/Michael Tr Roomey

Michael T. Rooney, Esq

Celia Ann Rooney, Esq.

Attorneys for Plaintiff

DESIGNATION OF TRIAL COUNSEL

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Michael T. Rooney, Esq., and Cella Ann Rooney, Esq., are hereby designated trial counsel for Plaintiffs in the captioned matter.

Attorney for Plaintiff

CERTIFICATION

I certify that the matter in controversy is not the subject of any other action or arbitration hearing, now or contemplated and that no other parties need be joined in this action. I recognize my continuing obligation to file and serve on all parties and the court an amended certification if there is a change in the facts stated in this original certification.

Attorney for Plaintiff

JURY DEMAND

The plaintiffs demand trial by a jury on all of the triable issues of this complaint, pursuant to New Jersey Court Rules 1:8-2(b) and 4:35-1(a).

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Ramona Estrella,	
Plaintiff,	
v.)	Case No.
Eric Kfir Yahav, M.D., Camcare Health Corporation, Teva Pharmaceuticals USA, Inc., Bayer Healthcare Pharmaceuticals, Inc.,) John Doe Corporation A through J and John Does A through J,	
Defendants.	

DECLARATION OF ERICA GIBSON

- I am a Staff Attorney in the General Law Division, Office of the General Counsel,
 Department of Health and Human Services (the "Department"). I am familiar with the official
 records of administrative tort claims maintained by the Department as well as with the system by
 which those records are maintained.
- 2. The Department has a Claims Branch that maintains in a computerized database a record of administrative tort claims filed with the Department, including those filed with respect to federally supported health centers that have been deemed to be eligible for Federal Tort Claims Act malpractice coverage.
- 3. As a consequence, if a tort claim had been filed with the Department with respect to Camcare Health Corporation, its approved delivery sites, or its employees or qualified contractors, a record of that filing would be maintained in the Claims Branch's database.

- 4. I caused a search of the Claims Branch's database to be conducted and found no record of an administrative tort claim filed by Ramona Estrella or an authorized representative relating to Camcare Health Corporation and/or Eric K. Yahav, M.D.
- 5. I have also reviewed official agency records and determined that Camcare Health Corporation was deemed eligible for Federal Tort Claims Act malpractice coverage effective January 1, 2011, and that its coverage has continued without interruption since that time. The Secretary of Health and Human Services' authority to deem entities as Public Health Service employees under 42 U.S.C. § 233(g) has been delegated to the Associate Administrator, Bureau of Primary Health Care, Health Resources and Services Administration. Copies of the notifications by the Associate Administrator, Bureau of Primary Health Care, Health Resources and Services Administration, Department of Health and Human Services, to Camcare Health Corporation are attached to this declaration as Exhibit 1.
- 6. Official agency records further indicate that Eric K. Yahav, M.D., was an employee of Camcare Health Corporation at all times relevant to the complaint in this case.

I declare under penalty of perjury that the foregoing is true and correct. 28 U.S.C. § 1746.

Dated at Washington, D.C., this

_, 2015.

ERICA GIBSON

Staff Attorney, Claims and Employment Law Branch

General Law Division

Office of the General Counsel

Department of Health and Human Services

EXHIBIT D

PAUL J. FISHMAN
United States Attorney
ANNE B. TAYLOR
Assistant U.S. Attorney
401 Market Street
P.O. Box 2098
Camden, NJ 08101
(856) 757-5031
Attorneys for Defendants
Eric Kfir Yahav, M.D. and
Camcare Health Corporation

Document Electronically Filed

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

RAMONA ESTRELLA,

: HONORABLE

Plaintiff,

v.

: Civil Action No.

ERIC KFIR YAHAV, M.D., et al.

: CERTIFICATION OF SCOPE OF

: FEDERAL EMPLOYMENT

Defendants.

I, Caroline Sadlowski, Chief, Civil Division, United States Attorney's Office for the District of New Jersey, acting pursuant to the provisions of 42 U.S.C. § 233(c), as amended by Public Law 104-73, and by virtue of the authority vested in me by 28 C.F.R. § 15.4, certify that I have read the Complaint in this action and all attachments thereto. On the basis of the information now available with respect to the allegations therein, I find that Defendants Eric Kfir Yahav, M.D. and Camcare

Health Corporation were acting within the scope of their employment as employees of the United States at the time of the conduct alleged in the Complaint.

PAUL J. FISHMAN United States Attorney

By:

Caroline Sadlowski Chief, Civil Division

Dated: June _//___, 2015

EXHIBIT E



U.S. Department of Justice

United States Attorney District of New Jersey

Anne B. Taylor Assistant United States Attorney anne.taylor@usdoj.gov Camden Federal Building & U.S. Courthouse 856.757.5031 401 Market Street, 4th Floor Fax: 856.757.5416 P.O. Box 2098 Camden, NJ 08101-2098

June 23, 2015

Via Federal Express

New Jersey Superior Court Clerk, Law Division Camden County Hall of Justice 101 South 5th Street, Suite 150 Camden, NJ 08103-4001

Re:

Ramona Estrella v. Yahav, et al.

Docket No.: CAM-L-3331-14 (N.J. Super. Ct.)

Dear Sir or Madam:

Pursuant to 28 U.S.C. § 1446(d), I enclose two copies of the Notice of Removal filed in this matter with the United States District Court for the District of New Jersey at Camden. Kindly file the Notice, thereby effecting removal of this action to the District Court, and return a stamped copy to this Office in the enclosed self-addressed stamped envelope.

Effective upon the filing of the Notice in the New Jersey Superior Court, the action is removed to the District Court and by statutory directive the state court "shall proceed no further" <u>Id.</u> Consequently, any <u>future</u> filings in this matter should be forwarded to the Clerk of the United States District Court, at Camden, for filing. Thank you for your assistance in this regard.

If you have any questions, please call me at (856) 757–5031.

Respectfully submitted,

PAUL J. FISHMAN United States Attorney

By: ANNE B. TAYLOR Assistant U.S. Attorney

Enclosures

cc: Michael T. Rooney, Esquire (via regular mail w/o encls.) Celia Ann Rooney, Esquire (via regular mail w/o encls.) Paul J. Cosgrove, Esquire (via regular mail w/o encls.)