

FDA Issues Letters to Doctors Who May Have Purchased Counterfeit or Unapproved Prescription Drugs

For years FDA has responded to several breaches in the U.S. drug supply chain by rogue distributors who target doctors' offices and clinics offering unapproved, counterfeit, or otherwise unsafe prescription drugs. Doctors who purchase and administer these drugs are putting their **patients at risk** (</Drugs/NewsEvents/ucm446918.htm>) because these drugs may:

- Be fake, contaminated, ineffective, or otherwise unsafe;
- Not have been evaluated by FDA for safety and efficacy;
- Not contain the appropriate amount of active ingredients; or
- Contain harmful ingredients.

To reduce the public health threat posed by these potentially dangerous drugs FDA issues letters to inform doctors that may have obtained counterfeit or unapproved drugs from a rogue distributor, and provide tips on safe purchasing practices. For information on safe purchasing practices, see **FDA's Know Your Source campaign** (</Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm>).

Under the **Drug Supply Chain Security Act** (<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>), as of January 1, 2015, all health care providers who dispense or administer prescription drugs to patients are required to purchase their prescription drug products only from authorized trading partners

licensed by or registered with the state or federal government, as applicable. This will help ensure that these prescription drugs are purchased from legitimate sources who are subject to oversight by the state or federal government. To verify a wholesale drug distributor is licensed in the state(s) where it is conducting business, see **[Verify Wholesale Drug Distributor Licenses](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm)** (**[/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm)**).

FDA encourages health care professionals to report any suspected criminal activity to **[FDA's Office of Criminal Investigations \(OCI\)](http://www.fda.gov/ICECI/CriminalInvestigations/default.htm)** (**<http://www.fda.gov/ICECI/CriminalInvestigations/default.htm>**).

- For historical information, see **[FDA Issues Letters to Doctors Who May Have Purchased Counterfeit or Unapproved Prescription Drugs, 2012-2014](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm519702.htm)** (**[/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm519702.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm519702.htm)**) [A]

Counterfeit Botox Distributed by TC Medical

On March 21, 2016, FDA issued more than 1,300 letters to medical practices in the United States that purchased unapproved prescription drugs and/or injectable devices from TC Medical, an unlicensed supplier that distributed counterfeit Botox found in the United States. On May 7, 2015, TC Medical pleaded guilty to orchestrating a multi-year conspiracy to smuggle misbranded prescription products into the United States.

- **[March 21, 2016 Letter](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522030.pdf)** (**[/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522030.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522030.pdf)**) (PDF - 54KB)
- **[List of Medical Practices that were Issued a March 21 Letter](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522038.pdf)** (**[/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522038.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522038.pdf)**) (PDF - 1.4MB)

On March 30, 2016, FDA issued approximately 100 letters to medical practices in the United States that purchased from TC Medical and had also purchased from a different unlicensed distributor previously. On that same date, FDA also issued a letter to one U.S. doctor who purchased from TC Medical and who had also purchased from two other unlicensed distributors previously.

- **[March 30, 2016 Letter](#)**
[\(/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522034.pdf\)](#) (PDF - 187KB)
- **[Letter to Dr. Peter N. Bogdan](#)**
[\(/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522036.pdf\)](#) (PDF - 76KB)
- **[List of Medical Practices that were Issued a March 30 Letter](#)**
[\(/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM522224.pdf\)](#) (PDF - 235KB)

Criminal Cases

- **[November 10, 2016: Nurse Who Operated Spa in Laguna Niguel Agrees to Plead Guilty to Illegally Dispensing Botox Not Approved for Use in United States](#)**
[\(/ICECI/CriminalInvestigations/ucm562579.htm\)](#)

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More than 39 Unapproved Drugs Purchased from Gallant Pharmaceutical International or Gallant Medical International

On April 1, 2015, FDA sent more than 300 letters to medical practices in the United States that may have purchased unapproved prescription drugs, or unapproved/uncleared injectable devices, from a foreign supplier, Gallant Pharmaceutical International, Inc., also known as Gallant Medical International, Inc. Several individuals associated with Gallant, including a doctor and an office manager, have been convicted for their roles in distributing illegal drugs and devices.

- **[Letter to Doctors about the Risks of Purchasing Unapproved Drugs from Gallant Pharmaceutical International](#)**
[\(/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM446811.pdf\)](#) (PDF - 104KB)

- **[List of Doctors \(/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM446900.pdf\)](#)** (PDF - 56KB)

Criminal Cases

- **[May 9, 2014: Illegal Drug Company Gallant Pharma and Co-Founder Sentenced \(/ICECI/CriminalInvestigations/ucm562585.htm\)](#)**
- **[March 7, 2014: Co-Leader of Illegal Drug Company Gallant Pharma Sentenced to 3 Years \(/ICECI/CriminalInvestigations/ucm391732.htm\)](#)**
- **[December 2, 2013: Gallant Pharma Company and Co-Owner Plead Guilty to Sixteen Charges of Prescription Drug Fraud \(/ICECI/CriminalInvestigations/ucm377434.htm\)](#)**
- **[June 6, 2014: Supplier of Non-FDA Approved Chemotherapy and Cosmetic Drugs Sentenced to 15 Months \(/ICECI/CriminalInvestigations/ucm400389.htm\)](#)**
- **[August 7, 2013: Eleven Charged in Alleged Illegal Pharmacological Import and Distribution Scheme \(/ICECI/CriminalInvestigations/ucm436202.htm\)](#)**

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[More in Drug Supply Chain Integrity \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm\)](#)

[FDA Leads Effort to Create a Supply Chain Security Toolkit for Medical Products \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm559053.htm\)](#)

[Drug Supply Chain Security Act \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm\)](#)