WILSON SONSINI

BCLT Advanced Life Sciences Institute: *Anti-Counterfeiting and Patient Safety*

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Firm Overview

Focus

- Provide value-added legal services to life sciences, technology, and growth enterprises worldwide, as well as the investors that finance them
- Represent multi-billion-dollar global enterprises as well as venture-backed start-up companies
- Serve the principal challenges faced by management and board of directors of business enterprises
- Act as a strategic business partner to a diversified client base
- Exceptional understanding of the financial, regulatory, and industry environments important to our clients

Footprint

1961 Established | **19** Offices worldwide | **1,000+** Attorneys | **3,000+** Private clients | **300+** Public clients

Track Record

- Advise more than 300+ public and 3,000+ private enterprises
- Named Delaware Powerhouse (Law360)
- Named Capital Markets Practice Group of the Year (Law360)
- Named “Venture Capital Firm of the Year” LMG Life Sciences in recent years
- Ranked as one of Law360's "Life Sciences Groups of the Year"
- Ranked No. 1 in the Life Sciences Law Firm Index published by Lake Whillans, based on research conducted by Breaking Media
- Named "Hatch-Waxman Litigation Firm of the Year – Generic," and recognized under "Hatch-Waxman Impact Cases of the Year" for its work on *Celgene v. Mylan* (Federal Circuit, 2021), "Patent Impact Cases of the Year" for its work on *ModernaTx v. Arbutus* (Federal Circuit, 2021), and "Impact Deals of the Year – United States" for its role in Sanofi’s $6.15 billion collaboration with IGM Biosciences (LMG Life Sciences)
- Nationally ranked in the top 20 firms for number of patent lawsuits defended (ALM Corporate Counsel)
- Recognized in Law360’s 2023 Diversity Snapshot, ranked No. 2 among firms with more than 601 attorneys. The firm also ranked No. 2 for the highest representation of minorities in its partnership among large firms

Comprehensive Life Sciences Representation

Business Advisory
Guidance navigating typical and complex challenges as entities grow, by applying proven business, transactional, and strategic expertise

Corporate Finance
Broad commercial awareness, deep technical expertise, and seamless execution

Mergers & Acquisitions
Strategic and tactical advice, project management, and team coordination

Capital Markets
Broad commercial awareness, deep technical expertise, and seamless execution

Intellectual Property
More than 180 patent attorneys, agents, and advisors assist clients in leveraging their intellectual property, defend against claims of others, and establish a competitive position for the future

Collaborations
More than 65 dedicated attorneys with substantial experience developing, negotiating, and implementing commercial agreements

Employment Law/ Employee Benefits
Thoughtful and practical advice on compensation, incentivization, retention of executives and employees, and employment litigation matters

FDA Regulatory
Advise clients of all sizes, and at all stages of development, on critical aspects of FDA regulation and healthcare matters

Privacy and Cybersecurity
Highly skilled practitioners and former agency veterans provide comprehensive global advice

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FDA & Regulatory Approaches

Drug Supply Chain and Potential Threats

Drug Components → Finished Dosage Forms → Finished Drug Products

Suppliers → **Manufacturer, Importer, Wholesalers** → **Manufacturer, Wholesaler, Pharmacies, Providers** → **Patients**

- Stolen products re-introduced into the supply chain
- Counterfeit/falsified drugs sold to suppliers
- Diverted drugs resold
- Adulterated/misbranded drugs
- Internet – illegitimate drug sellers
  - Fraudulent online pharmacies
  - Drugs of unknown origin

What is an illegitimate product?

An illegitimate product is a product for which credible evidence shows that the product:

- is counterfeit, diverted or stolen;
- is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- is the subject of a fraudulent transaction; or
- appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

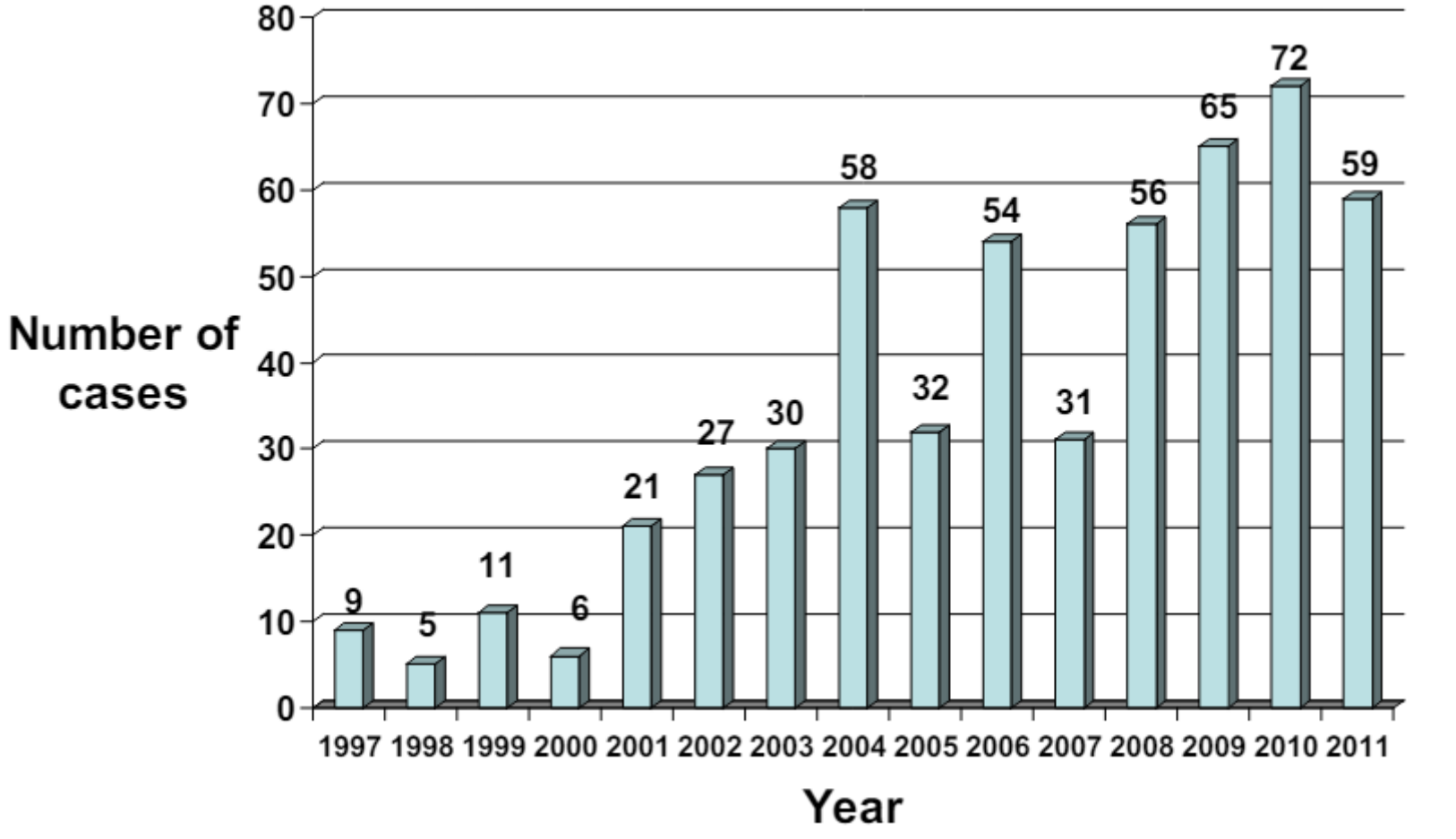
Drug Supply Chain Security Act (DSCSA)

- Enacted by Congress in November 2013
- Outlines steps to achieve interoperative, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Improves detection and removal of potentially dangerous drugs from the drug supply chain
- Establishes national licensure standards for wholesale drug distributors and third-party logistics providers (3PLs)

Key Supply Chain Security Requirements

- **Authorized Trading Partner**
  - Licensure and Registration
  - Annual Reporting
- **Product Tracing**
- **Product Identifiers**
- **Verification**
  - Respond to requests for verification of the product identifier
  - Verify product identifier of saleable return product
  - Determine that product is suspect product
  - Investigate and quarantine suspect product
  - Submit cleared product notifications
  - Quarantine and disposition illegitimate product
  - Submit notifications of illegitimate product and product with a high risk of illegitimacy

Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations



Impacts on Patient Safety

- Counterfeits
  - No/wrong active ingredients
- Stolen or diverted products
  - Improper/unknown storage and handling
- Expired products
  - Lost efficacy
- Adulterated products
  - Contamination, diluted
- Importation of unapproved or sub-standard products
  - Safety and efficacy have not been reviewed by FDA

Enforcement by Multiple Agencies

- ***FDA's Office of Drug Security, Integrity, and Recalls (ODSIR)***
  - Enhanced and targeted resources to address supply chain threats
  - New and coordinated approaches, policies and enforcement strategies
- ***FDA's Office of Criminal Investigations***
  - Report suspected criminal activity
- ***FDA's MedWatch Program***
  - Report suspect counterfeit medical products or quality issues
- ***Department of Justice, Drug Enforcement Administration***
- ***Federal Trade Commission***
  - Guideline on buying health products and services online
- ***Operation Pangea – global collaborations***
  - INTERPOL led global operation targeting internet websites supplying illegal and dangerous drugs

Counterfeit Prescription Drug Distributor Sentenced to Federal Prison

Department of Justice
U.S. Attorney's Office
Western District of Tennessee

FOR IMMEDIATE RELEASE
December 18, 2023

Memphis, TN – A federal judge has sentenced a Texas man to more than 17 years in prison for his involvement in a counterfeit prescription drug distribution operation. Kevin Olando Ombisi, 34, of Katy, Texas, has been sentenced to 210 months in federal prison for conspiring to distribute methamphetamine and related offenses. U.S. District Court Judge Mark S. Norris also ordered Ombisi to serve three years of supervised release upon completion of his prison term.

There is no parole in the federal system.

United States Attorney Kevin G. Ritz of the Western District of Tennessee made the announcement today along with Acting Assistant United States Attorney Nicole M. Argentieri of the Department of Justice's Criminal Division; Special Agent in Charge J. Todd Scott of the Drug Enforcement Administration (DEA) Louisville Field Division; Special Agent in Charge Charles L. Grinstead of the Food and Drug Administration Office of Criminal Investigation (FDA-OCI) Kansas City Field Office; Special Agent in Charge Francisco B. Burrola of Homeland Security Investigations (HSI) El Paso Division; and Inspector in Charge Scott Fix of the United States Postal Inspection Service (USPIS) Houston Division.

According to information presented in court, Ombisi used a marketplace on the Darknet and an encrypted messaging service called Wickr to sell pills made to resemble Adderall in exchange for bitcoin cryptocurrency. The pills that Ombisi distributed were not Adderall; instead, they contained methamphetamine. He mailed the methamphetamine pills through the U.S. Postal Service.

Content current as of:
12/18/2023

Regulated Product(s)
Drugs
Prescription Drugs

PRESS RELEASE

Ohio Man Pleads Guilty to Mail and Wire Fraud

Wednesday, February 2, 2011

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For Immediate Release

Office of Public Affairs

Sold Prescription Drugs Obtained from Unauthorized Dealers to Licensed Wholesalers

WASHINGTON – Gregory Pfizenmayer of Foley, Ala., has pleaded guilty before Senior U.S. District Court Judge Herman J. Weber in Cincinnati to one count of conspiracy to commit mail and wire fraud in connection with a drug diversion scheme in which he was involved, the Justice Department announced today.

The government information alleged that a co-conspirator supplied Pfizenmayer with prescription drugs, including, among others, Lupron, Procrit and Neulasta. Pfizenmayer subsequently sold these drugs to licensed drug wholesalers. Governing regulations require sales of prescription drugs to be accompanied by certifications identifying each prior sale or purchase of the drugs. The certifications accompanying the drugs that Pfizenmayer sold falsely stated that they had been obtained from dealers authorized by the relevant drug manufacturer.

In reality, according to the information, the drugs were not obtained from authorized dealers, nor were they obtained from the companies listed as sources in the documents accompanying the drugs. In fact, many of the prescription drugs sold by Pfizenmayer were obtained by physicians who, as health care entities, receive discounts when purchasing prescription drugs.

PRESS RELEASE

Mansfield man indicted for sale of counterfeit prescription pills

Thursday, June 18, 2015

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For Immediate Release

U.S. Attorney's Office, Northern District of Ohio

A grand jury returned a two-count indictment charging a Mansfield man with crimes related to the purchase and sale of counterfeit prescription drugs, said Steven M. Dettelbach, U.S. Attorney for the Northern District of Ohio.

Tamacio Walls, 23, was indicted on one count of introducing misbranded drugs into interstate commerce and one count of trademark violations.

Walls purchased, warehoused, dispensed and offered for sale, counterfeit versions of Viagra (active ingredient Sildenafil), Cialis (active ingredient Tadalafil) and Levitra (active ingredient Vardenafil) to consumers without requiring consumers to provide any form of prescription from a licensed medical practitioner, as required by law, according to the indictment.

The indictment also charges that Walls did not inform consumers that said drugs were prescription drugs and that they should seek medical advice before consuming the drugs, and that Walls failed to provide any warnings to consumers concerning potential dangers associated with taking the drugs. Walls obtained the drugs from unauthorized sources in China and India. The customs declarations for the shipments to Walls typically misrepresented the package contents in an attempt to avoid detection and seizure by U.S. Customs officials, according to the indictment.

FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain

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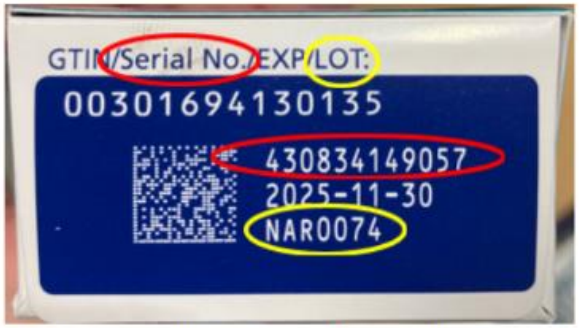
Español

[12/21/2023] FDA continues to investigate counterfeit Ozempic (semaglutide) injection 1 milligram (mg) in the legitimate U.S. drug supply chain and has seized thousands of units of the product. The agency advises wholesalers, retail pharmacies, health care practitioners and patients to check the product they have received and not distribute, use, or sell products labeled with lot number NAR0074 and serial number 430834149057 as pictured below. Some counterfeit products may still be available for purchase.



FDA and Novo Nordisk (manufacturer of Ozempic) are testing the seized products and do not yet have information about the drugs' identity, quality, or safety.

Additionally, analysis found the needles from the samples are counterfeit. Accordingly, the sterility of the needles cannot be confirmed, which presents an increased risk of infection for patients who use the counterfeit products. Based on analyses completed to date, other confirmed counterfeit components within the seized products are the pen label, accompanying health care professional and patient information, and carton.

Authentic Ozempic® Needle	Counterfeit Needle
	

Authentic Ozempic® Needle	Counterfeit Needle