

**NATIONAL CONSUMERS LEAGUE
HEALTH ADVISORY COUNCIL
4TH ANNUAL SPRING MEMBERSHIP MEETING**

COUNTERFEIT DRUGS PANEL DISCUSSION

Washington, DC
June 27, 2018

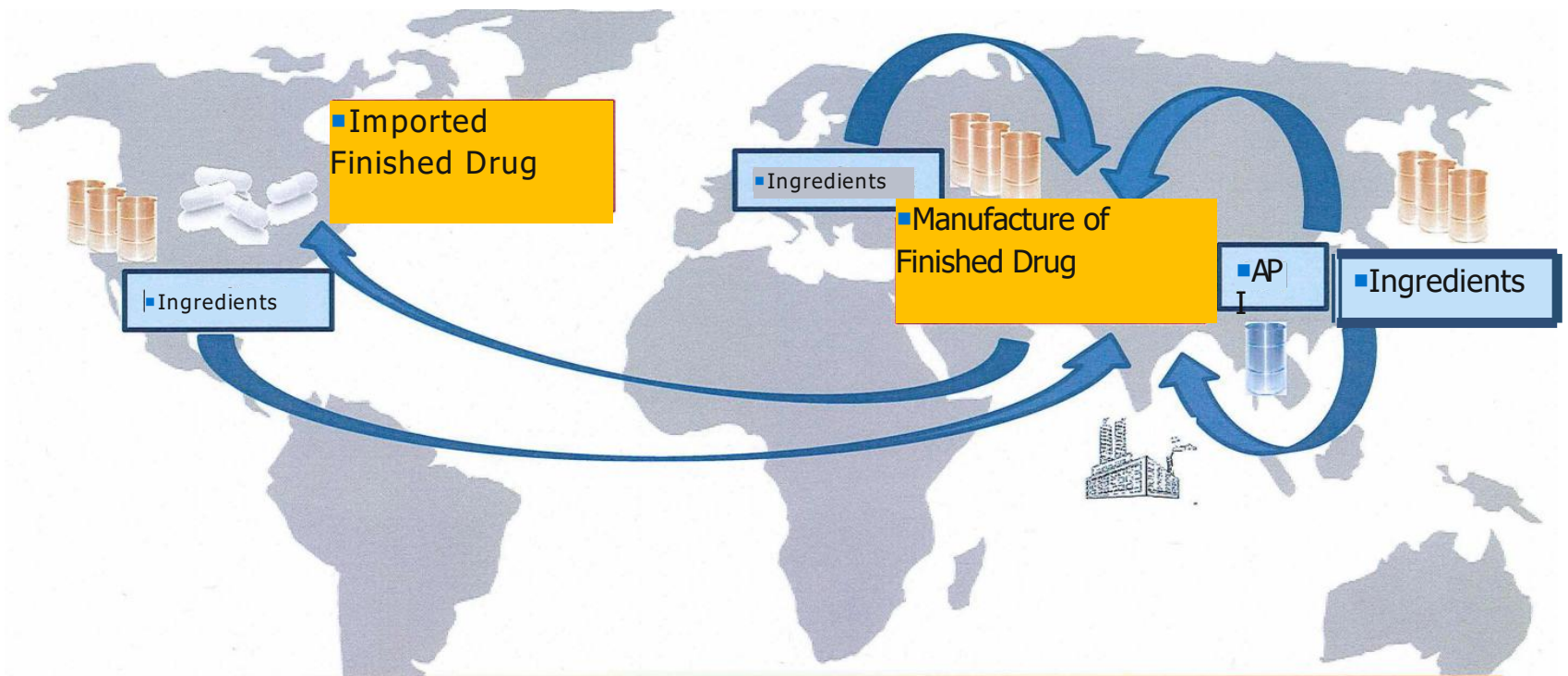


George M. Karavetsos
DLA Piper LLP

Drug Counterfeiting: Enforcement Challenges and Strategies to Combat the Problem

- **Increased Opportunity as Global Drug Supply Chain Becomes More Complex**
- **Illegal “Canadian” Internet Pharmacies Fuel a Global Counterfeit Drug Market**
- **Flood of Counterfeit and Dangerous Unapproved Drugs arrive at International Mail Facilities Daily**
- **High Profit Margins and Favorable Risk-Benefit Analysis: Canadadrugs.com**
- **Strategies to Stop the Flow of Counterfeit Drugs From Entering the U.S.**

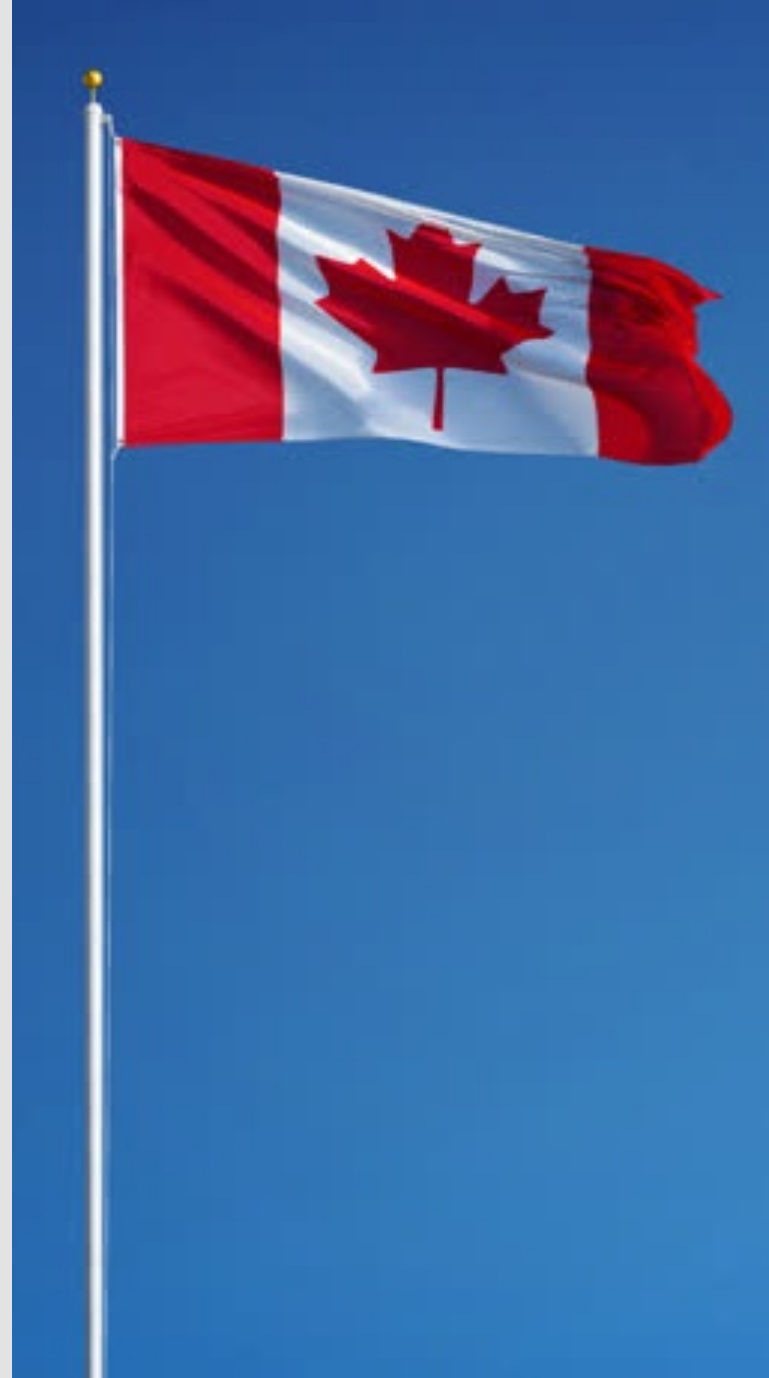
Increased Opportunity as Global Drug Supply Chain Becomes More Complex



- Illustration of drug manufacturing supply chain: A U.S. finished drug may be produced using an active pharmaceutical ingredient (API) made in China and ingredients made in Europe, Japan, or the U.S. These components may be shipped to India where the finished drug is manufactured and then imported into the U.S. for distribution.

Illegal Canadian Internet Pharmacies Fuel the Counterfeit Drug Market

- 96% of online pharmacies operate illegally, selling drugs without a prescription or distributing counterfeits
- Drugs that Americans import today are not coming from the Canadian drug supply, they are not sterile, they are not effective, and they are sometimes deadly
- Canadian authorities are not regulating prescription drugs exported to Americans and the FDA, CBP, and FBI do not have the resources to stop the flow of unapproved and counterfeit drugs



Counterfeit and Foreign Unapproved Drugs are not coming from Canada



No HHS Secretary or FDA Commissioner has certified that Importation from Canada is Safe



Clandestine Drug Laboratory



Unapproved Overseas Manufacturing Facility



Flood of Unapproved and Counterfeit Drugs arrive at International Mail Facilities Daily



Scott Gottlieb, M.D.
@SGottliebFDA

Follow

Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages



9:33 AM · 25 Aug 2017



Hard to Detect Counterfeit Drugs



High Profit Margins and Favorable Risk-Benefit Analysis: CanadaDrugs.com



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BUTTE DIVISION

UNITED STATES OF AMERICA,) CR _____
)
)
Plaintiff,)
)
vs.)
)
CANADADRUGS.COM LTD.)
PARTNERSHIP,)
THORKELSON)
CONSULTING, LTD.,)
4208081 CANADA, LTD.)
ROCKLEY VENTURES, LTD.,)
GLOBAL DRUG SUPPLY, LTD.,)
RIVER EAST SUPPLIES, LTD.,)
KRISTJAN THORKELSON,)
THOMAS HAUGHTON,)
RONALD SIGURDSON,)
TROY NAKAMURA,)
DARREN CHALUS,)
NARINDER KAULDER,)
JIM TRUEMAN,)
)
Defendants.)

Counterfeit Avastin

WARNING: COUNTERFEIT AVASTIN®

Printing defects found on counterfeit Avastin® vial labels

Printing defects found on counterfeit Avastin® vial labels

Poor quality double helix logo on vial flip off caps

Counterfeit crimp caps on vials are poor quality screen printing.

The printing and other defects on this flyer are unique to the counterfeit Avastin® vials depicted. These vials will be referred to as "Avastin_vial_1". Known counterfeit vial labels have been observed with lot B89017 (exp. 03 2013) which did not match lot on cartons. For this or any other flyers please reference the flyer version indicated here.

Avastin_vial_1_B89017_DCA

This warning flyer is for internal FDA investigative use only. The information contained in this warning flyer is based upon information at the time of publication and is subject to change. For more information contact Duane Setzler, Ph.D., FCC Director at (313) 479-2700 or dssetzler@fda.hhs.gov

Path of Counterfeit Drugs

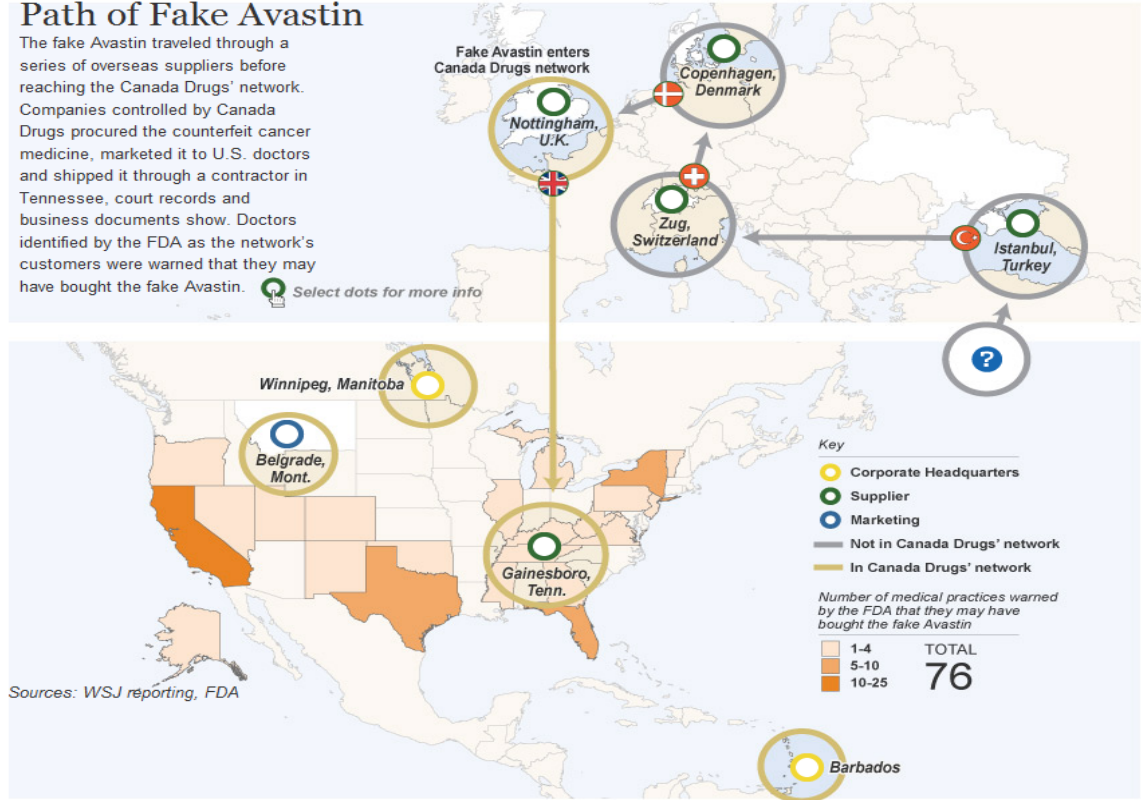


How Fake Cancer Drugs Entered U.S.

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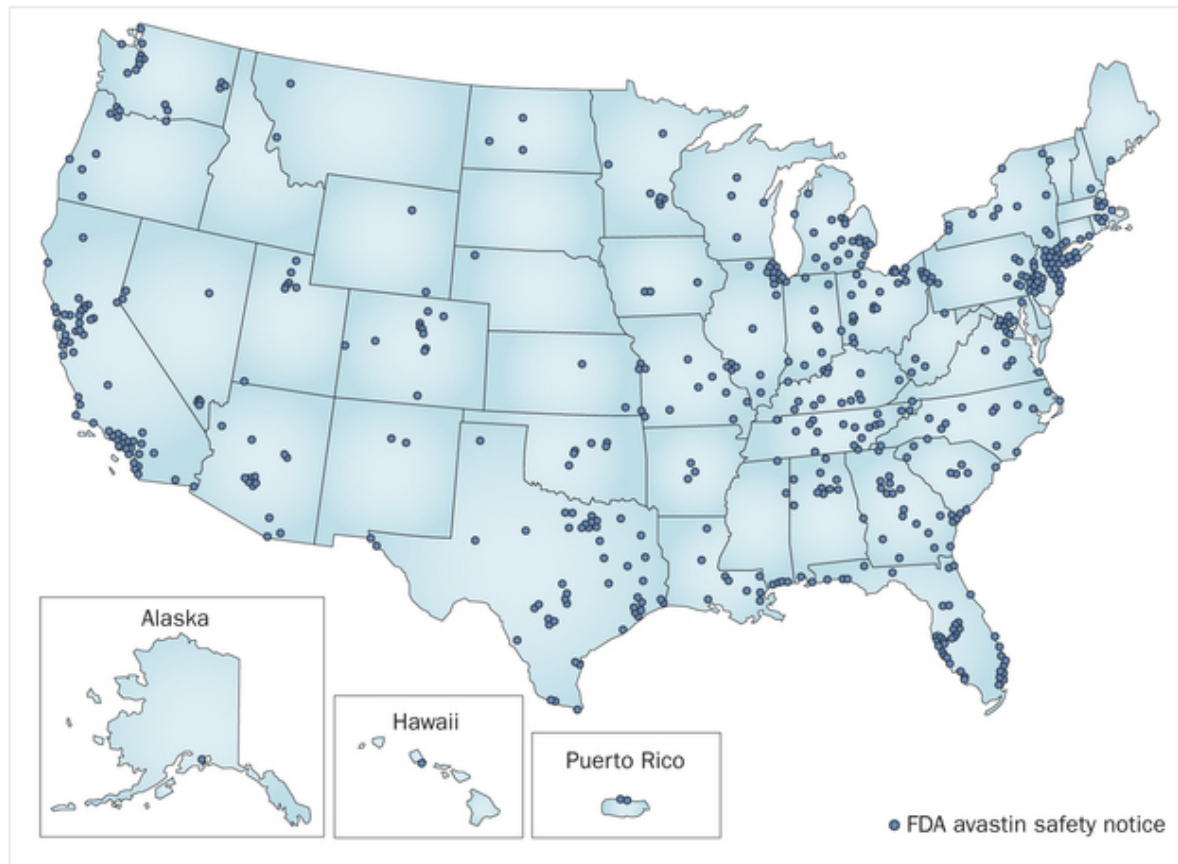
Path of Fake Avastin

The fake Avastin traveled through a series of overseas suppliers before reaching the Canada Drugs' network. Companies controlled by Canada Drugs procured the counterfeit cancer medicine, marketed it to U.S. doctors and shipped it through a contractor in Tennessee, court records and business documents show. Doctors identified by the FDA as the network's customers were warned that they may have bought the fake Avastin. [Select dots for more info](#)

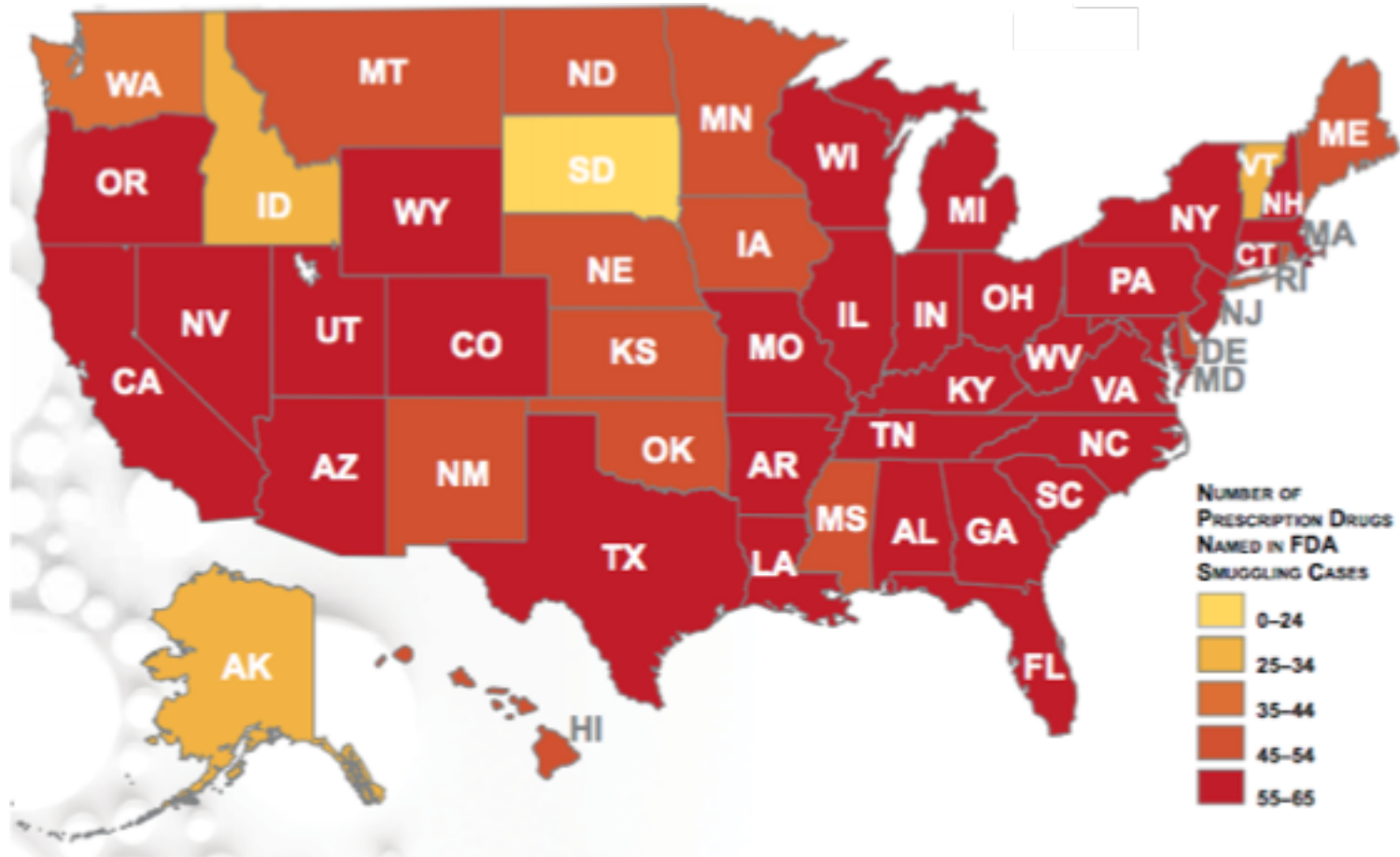


FDA Warning Notifications Sent to Doctors and Clinics

Figure 1: Visual depiction of a total of 949 FDA safety notifications that were sent to 932 physicians and/or clinics in 795 zip codes from 2012 to 2013.



Since 2012, smugglers caught selling fake drugs sold more than 63 different medications to over 3000 doctors, clinics, and hospitals in the U.S.



Strategies to Stop the Flow of Counterfeit and Unapproved Drugs from entering the U.S.

- Enhance coordination and collaboration with foreign regulatory and law enforcement partners to proactively investigate and dismantle transnational criminal organizations
- Educate medical practitioners and consumers about the dangers of ordering medications from illegal “Canadian” and other foreign internet pharmacies
- Increase inspectional resources at International Mail Facilities
- Utilize innovative technologies to detect counterfeit drugs
- Enact new legislation that will provide FDA regulators the legal authority to destroy counterfeit and unapproved drugs onsite



THANK YOU