Counterfeit medicines in America: 2021

Learn how criminals ply their trade and how to recognize their scams.

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Conflict of interest and disclosure

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18 years studying safety (and counting!)

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Agenda

- The four waves of counterfeits in America to date.
- Deep dive into specific criminal cases.
- What’s happening with importation.

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Closed Secure Drug Supply

FDA-approved Supplier
- FDA regulates U.S. manufacturers & facilities globally

State Rules
- Each state regulates U.S. wholesalers with individual rules and cross-licenses

License
- State regulated doctors and pharmacies purchase from licensed wholesalers

Rx Order
- Result: Closed secure drug supply chain for patients

Unregulated Foreign Drug Supply

Unknown Conditions of Manufacture
- Safe?
- Sterile?
- Effective?

No Rules
- States do not regulate foreign wholesalers.

States do not regulate foreign wholesalers.
- Thousands of criminal organizations across the world produce counterfeit and substandard medicines.
- U.S. regulators cannot prosecute rogue, foreign drug manufacturers, leaving them accountable to no one.

Fake Pharmacies
- Fake pharmacies already sell Americans unregulated drugs online.

Fraud Pharmacies
- In a survey of 11,686 online pharmacy websites, less than 500 met regulators’ standards for safe pharmacies.

In a survey of 11,686 online pharmacy websites, less than 500 met regulators’ standards for safe pharmacies.

Jail
- Americans will be left wondering: “Is my medicine working? Is it even medicine?”

Result: Patients cannot rely on the quality, sterility or effectiveness of their medication.

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US-regulated manufacturer imports its medications

Foreign entities import a variety of medications. They are not regulatable by US entities and often not extraditable.
2002: Counterfeit Procrit / Epogen

Timothy Fagan
(New York. Photo from Dangerous Doses)

Maxine Blount (STL Post-Dispatch obituary photo)
Behind the scam

Source: Baptist Health Drug Images Health Library
Behind the scam: How did they do it?

“Dangerous Doses” by Katherine Eban

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Behind the scam: Obfuscating the source
Behind the scam: paper pedigree

Paper pedigrees are a difficult-to-manage and easy-to-forge method of securing the medicine supply chain.

These sales and other fraudulent sales during this era generated a good looking paper trail.
Behind the scam: medication testing

Basic testing such as with Raman Spectrometry checks for presence of medication, not quantity.

Source: Sulaf Assi / Bournemouth Univ.
Behind the scam: medication testing

First level screening is used by Customs and Border Protection at International Mail Facilities.
Behind the scam: medication testing

**CONTENT UNIFORMITY**
- Is the API CONSISTENT across the batch?
- Is the medicine EVENLY DISTRIBUTED if the pill is broken in half?

**DISSOLUTION RATE**
- **REAL:** able to dissolve into a patient’s bloodstream.
- **COUNTERFEIT:** doesn’t dissolve, gets flushed out of the patient’s body.

**ASSAY**
- Confirms that a pill has the stated amount of ACTIVE PHARMACEUTICAL INGREDIENT (API).
- **REAL:** API must be PRESENT and in THERAPEUTIC QUANTITIES.
- **COUNTERFEIT:**

**PURITY**
- Contaminants can harm or kill patients.
- **REAL:** medication free of bacteria lead mercury mold PCBs...
- **COUNTERFEIT:**

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Behind the scam: medication testing

Testing a single sample can cost: $2,500 - $4,100.

Finished product testing is an expensive supply chain security strategy.
Behind the scam: packaging

Credit: Amgen and FDA
Behind the scam: packaging

Credit: Amgen and FDA
Behind the scam: packaging

**Authentic PROCRIT vial P004677.** Vial is taller by approx. 1/16 inch with slightly smaller diameter. Black portion of label indicating LOT and EXP is secured to vial and does not appear to be pulling away. Font is larger, there is no strike-thru on number "7". Label is secured to vial.

**Counterfeit product vial P004677.** Vial is shorter by approx. 1/16 inch with slightly wider diameter. Black portion of label indicating LOT and EXP is not secured to vial and may appear to be pulling away. Font is smaller, and there may be a strike-thru on number "7".

Credit: International Pharmaceutical Federation

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Behind the scam: packaging

Vials of PROCRIT labeled as 40,000 U/mL in four-pack boxes, lot number P002641, expiration date: 9/03, have been found to be counterfeit. The active ingredient is approximately 20 times lower than the authentic product.

Credit: The Counterfeit Report
Behind the scam: aftermath

Kevin Fagan (Timothy’s father) and Max Butler (Maxine Blount’s brother)

“Dangerous Doses” by Katherine Eban

Credit: C-SPAN
Behind the scam: policy aftermath

- November 27, 2013: DSCSA Enacted
- May 1, 2015: T3 enforcement discretion ends
- July 1, 2015: Dispensers receive T3
- March 1, 2016: T3 enforcement discretion ends
- November 27, 2017: Manufacturers serialize product (note: enforcement delayed to November 27, 2018)
- November 27, 2018: Repackers serialize product
- November 27, 2019: Wholesalers receive and ship serialized product
- November 27, 2020: Dispensers receive and ship serialized product

- NDC: 59148 011 13
- SN: 10000000001
- EXP: AUG 22 2015
- Lot: AB100613

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Audience poll question

The Fagan family filed litigation against everyone in the supply chain including the legitimate manufacturers, uplabelers, the criminal wholesalers, and the pharmacy. What do you think happened to the pharmacy?

1. Nothing, they were unwitting victims.
2. Nothing, they dispensed fake product but didn’t know.
3. Moderate judgment, as they had a hand in dispensing fake product that caused harm.
4. Significant sanction, they dispensed a counterfeit product and were held responsible for patient harm.
5. None of the above.
What is the role of the pharmacist?

- Recall management didn’t work well in 2002, it’s likely better today.
- Safety is a combination of regulatory enforcement and technology.
- Pharmacy liability is an unexplored problem.
Second wave: The rise of the Canadian entrepreneurs, 2001 to the present

Kris Thorkelson, Canada Drugs
Andrew Strempler, RxNorth

Credit: Winnipeg Free Press / The Canadian Press
Blister packs of counterfeits, 2001 to the present

Andrew Strempler, Canadian pharmacist / entrepreneur

1999: Founded Canadian web pharmacy Mediplan / RxNorth
2005: Manitoba Pharmacists Association sanctions Strempler and orders him to surrender his license. He has sales of $100mm / yr.
2006: US FDA warns Americans Strempler’s company is shipping counterfeit product. Strempler flees Canada and continues business in the Caribbean.
2012: Strempler is arrested when his plane makes a stop in Florida. He is sentenced to 4 years in prison and fined $325,000.
2015: Strempler is released.

Credit: Winnipeg Free Press
"Basically, all my competition started selling drugs they were sourcing overseas from, in my opinion, unsafe countries and marketing them as Canadian. I couldn't compete with that," he said. (CBC 6/20/2017)

Canada’s drug supply would be drained in 201 days, should just 20% of U.S. prescriptions shift to dispensing out of Canada. (Shepherd, Health Econ Outcome Res Open Access 2018, 4:1)

Credit: CBC

Daren Jorgensen opened one of the first Canadian Internet fake pharmacies in 2001, and exited in 2008.
Illinois’ Experience With ISaveRX, 2003–2006

A “whitelisted” online pharmacy program of 28 online drug sellers dispensing from Canada, the United Kingdom, Australia, and New Zealand to IL, WI, KS, MO, and VT.

Select IG findings:
• Operating in violation of federal law with unapproved federal funds.
• Dispensing entities in the program in violation of IL pharmacy practice law.
• 40% of the inspections records (32 of 80) were not completed.
• State did not monitor that only approved pharmacies participated.
• Significant labor costs of $488,000 for 26 employees (19 months).
• High expenses, incl. $111,000 for international travel and over $350,000 for contract management, marketing, and legal services.
• Uptake of the program was small and it was eventually cancelled.
An online pharmacy regulation program started by Gov. Tim Pawlenty. After launch, the FDA cited a number of patient safety issues, including several found during a pre-announced visit by Minnesota’s own inspectors:

- Pharmacy techs, not pharmacists, entering prescriptions.
- Having pharmacists check 100 prescriptions / hour or refill 300 prescriptions / hour.
- Cold-chain drugs shipped not refrigerated / no historic thermometers in refrigerators.
- Allowing pharmacy techs instead of pharmacists contact U.S. medical providers
- Allowing faxed prescriptions.
- Failed to meet minimum lighting standards as set by MN pharmacy law.
- Uptake of the program was small and it was eventually cancelled.

Credit: Star Tribune
2007-2008: The Heparin Crisis

Timeline of the heparin crisis

Heparin (top) and chondroitin sulfate (bottom)

Credit: Chinese chemical vendor website (as named)
Maine’s passage of LD 171 in 2013

In 2013 Maine passed a law facilitating foreign mail order pharmacies from Canada, the UK, Northern Ireland, Australia, and New Zealand.

Dr. McCall ordered three medications from Canada Drug Center, operated by Quantum Solutions. They all arrived from other countries not on the approved list, and lab testing showed them to have insufficient API. The Maine Board of Pharmacy asked the AG to shut them down. The AG was powerless.

Credit: Mainebiz.biz
Martin Paul Bean of Boca Raton, FL purchased US$7mm oncology medications from Pakistan, India, and Turkey and repackaged them to appear to be FDA approved medications.

When pressed by physicians who worried about the medicine’s integrity, he would assure them they were Canadian. He was sentenced to two years in prison in 2013.
Wholesale lots of counterfeits, 2008-present
Since 2012, smugglers caught selling fake drugs sold up to 63 medications to over 3,000 doctors, clinics and hospitals across the U.S.
In 2017, Dr. Ona Colasante of Gainesville, FL was finally convicted and sentenced for 162 counts including purchasing black market non-FDA-approved medicines at a discount and administering them to her patients. She received one year in prison and three years probation.

Dr. Colasante at her clinic in 2012 (Photo credit Gainesville Sun)
Dr. Norbergs of *Palm Harbor, FL* bought oncology products from a ring of unlicensed wholesalers operating out of Canada with offices in Montana and Tennessee at a steep discount, gave them to at least 66 of her patients, and billed insurance for higher amounts.

Wanda Colgan, a patient, passed away in 2011 during the time of the crime. Her daughter Lori Ann Reed said at sentencing, “I’ll spend the rest of my life wondering if my mother would have lived longer if she’d gotten the treatment she deserved.”
Select medical clinics that received FDA warning letters
Doctors and clinics in NM have been warned by the FDA for doing business with unlicensed Canadian wholesalers.
Wave of wholesale counterfeit medicines in America, 2008-present

Late stage lung cancer Betty Hunter was treated with counterfeit Avastin in 2011. Ms. Hunter died three months later.

Source: Medicin der Dræber

Source: FDA
Wave of wholesale counterfeit medicines in America, 2008-present
One of many convictions over a multi-year period.
Prosecuting foreign nationals for selling counterfeit drugs is hard, which makes a poor deterrent.

2014: DOJ indicted 5 CanadaDrugs.com executives for selling $78 million of fake cancer drugs


2018: Plea bargain approved
Audience poll question

Canadian citizen Kris Thorkelson, a licensed pharmacist and founder of CanadaDrugs.com, was indicted along with co-conspirators for distributing US$78mm in misbranded medications (including oncology meds) into the US. What happened to him?

1. Nothing, big time criminals always go free.
2. He lost his pharmacists license, paid a fine, but did not serve any jail time.
3. He lost his license, paid a fine, and served time in jail in Canada.
4. He was extradited to the U.S. to face the families he harmed, lost his license, paid a fine, and did time in US prison before extradition.
Terms of plea deal
- Six months house arrest and four and a half years of probation;
- a $250,100 fine; and
- Turn over records and cooperation.

The plea agreement does not require him to:
- serve any jail time;
- surrender his pharmacy license;
- enter a guilty plea of selling counterfeit drugs.

He began his house arrest and subsequent probation while still holding his pharmacy license.
UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA,
v.
MAKSYM NIENADOV,
a/k/a Maksim Nenadov, and
VOLODYMR NIKOLAENKO,
Defendants.

Criminal No. H-19-365
18 U.S.C. § 2
18 U.S.C. § 371
18 U.S.C. § 545
18 U.S.C. § 2320(a)(4)
21 U.S.C. § 331(a)
21 U.S.C. § 331(i)
21 U.S.C. § 333(b)(8)
21 U.S.C. § 353
Behind the scam: Healthy Nation (Ukraine)

Epclusa (Hepatitis C)

Abraxane (advanced breast cancer)

Keytruda (Hodgkins Lymphoma)

Credit: Original manufacturer photos
Behind the scam: Healthy Nation (Ukraine)

May 2018: Criminal referral from Merck brand security to Immigrations and Customs Enforcement.

June-July 2018: ICE negotiates over whatsapp a purchase of Keytruda and Abraxane. They wire them the money and receives the medication in the states. It’s lab tested to be fake.
Behind the scam: Healthy Nation (Ukraine)

July 2018: Conversation moves to gmail and the investigators hit the jackpot.

Revlimid (chemotherapy)

Soliris (paroxysmal nocturnal hemoglobinuria)

Vial capping machine

Credit: Original manufacturer photos

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Dec. 2018 ICE undercover requests the Ukrainians come for a meeting in Houston Texas and offer to arrange visas.

Credit: Ukrainian-passport.com
Behind the scam: Healthy Nation (Ukraine)
What’s the pharmacists role in this case?

- Supply chain breaks require two parties to break the rules.
- Checking a validity of the wholesale license ends this scam immediately.
- Pharmacists are more likely to know how to check a wholesale license than an unlicensed medical practice manager.
- In pharmacy settings, these entities never make it very far. Even less so in Health-System contexts.
What were the warning signs?

- No state-issued wholesale license.
- Prices too good to be true.
- Fake lot numbers / no DSCSA data.
- Communication through whatsapp and unbranded email.

<table>
<thead>
<tr>
<th>Product</th>
<th>Avg. wholesale price (USD)</th>
<th>Ukrainian price (USD)</th>
<th>Discount vs AWP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keytruda 50mg</td>
<td>$2,190.37 / box</td>
<td>$1,180 / box</td>
<td>53%</td>
</tr>
<tr>
<td>Epclusa (28 tbl 400mg/100mg)</td>
<td>$24,920 / btl</td>
<td>$3,000 / btl</td>
<td>12%</td>
</tr>
<tr>
<td>Abraxane 100mg</td>
<td>$1,378.01 / dose</td>
<td>$400 / dose</td>
<td>29%</td>
</tr>
</tbody>
</table>
Learning Assessment Question #1

What is the best way to confirm that a wholesaler has a license?

1. Ask them to scan a copy of the license and send it to you.
2. Ask them to mail a copy of their license with their next invoice.
3. Ask them to confirm verbally that they have a license.
4. Ask them to confirm the legal name of the entity and look up their license with your state board of pharmacy.
5. You don’t need to confirm they have a license.
Learning Assessment Question #2

Can a U.S. licensed pharmacy import medication from a wholesaler only licensed in another country?

1. Yes, but only a licensed wholesaler in Canada.
2. Yes, but only from a foreign licensed wholesaler that has the same name as one that is licensed in the U.S.
3. Yes, but only from Tier 1 countries that have mutual recognition agreements with the U.S. FDA.
4. Yes, but only if you can match the imported product with a prescription. It’s legal because of the exception for “personal importation.”
5. None of the above.
Learning Assessment Question #3

What are the warning signs of an unlicensed wholesaler?

1. Contact phone numbers or other indications that the wholesaler is not located in the U.S.
2. No website.
3. No record of the wholesaler license with your state board of pharmacy.
4. Payment is accomplished through Western Union.
5. Offers to sell you product from another country’s drug supply.
6. Offers to sell you a generic that isn’t available in the U.S. but is in Canada or Europe.
7. All of the above.
On June 3, 2021, NABP warned of a scam involving nonprescription insulin.

OTC insulin manufactured for a chain pharmacy and marked “ONLY FOR RETAIL SALE BY [CHAIN]” was bought by mules, aggregated, and sold to a wholesaler who then sold it to a mail order pharmacy.

Risks to patients are significant: improperly handled or adulterated insulin.

Risks to purchasing / distributing pharmacies are both legal and financial.
Are we doing Canadian drug importation yet?

Where is importation today?

What do the Canadians think about it?
Where did this idea come from?

Pathway #1 importation provisions attached to 2003 Medicare Modernization Act signed by President Bush.

After it became law, a task force that included current HHS Sec’y. Alex Azar studied the proposal and found it was **unlikely to deliver savings or safety**. For the next 16 years, HHS and FDA heads appointed by both Republicans and Democrats have refused to certify safety and savings to Congress (a necessary step).
How is importation supposed to work?

- A state identifies a **Canadian wholesaler**, a U.S. wholesaler, and a medicine they want to import.
- They file a request to HHS to allow them to run a program to import medicine. This program is called a SIP and lasts for 2 years. They need to file a pre-importation application before they can bring any medicine into the country.
- Once medicine has been purchased, the manufacturer has to test it or the state has to pay for testing a statistical valid sample for purity and degradation.
- The medicine must then be relabeled and repackaged at a facility within thirty miles of a port of entry.
- The state bears all burden for licensing, inspections and compliance of all SIP participants including foreign entities.
- The state bears all burden for managing issues related to medical adverse events, product recalls, etc.
Does that sound expensive?

To date Florida has contracted with a vendor for ~US$8.9mm to setup a warehouse, setup an IT system for inv. management, design a recall management system, and hire staff to run their program.

No medicine to be imported has been identified, and no manufacturer has agreed to sell medicine to the program.

This is an empty warehouse.
## Status of importation in the states

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>States authorized to import medicine from Canada / Safety and Savings certification made to Congress</td>
<td>0: None.</td>
</tr>
<tr>
<td>Passed a law and submitted a request to HHS</td>
<td>2: FL, NM</td>
</tr>
<tr>
<td>Passed a law or appropriated funds to submit a request to HHS / officially studying the issue</td>
<td>6: CO, CT, ME, ND, NH, VT</td>
</tr>
</tbody>
</table>
Having each state “figure it out”

Pathway #1 throws all the logistics to the states.

Forcing American states to fend for themselves in a global market is not a remedy.

500,000 counterfeit masks seized by CBP (Sep 14, 2020)

He Removed Labels That Said “Medical Use Prohibited,” Then Tried to Sell Thousands of Masks to Officials Who Distribute to Hospitals June 25, 2020

Vendors scamming state purchasers
Unmasked: At the height of the pandemic, West Virginia equipped first responders with counterfeit respirators. Here's how it happened.
Having each state “figure it out”

U.S. Customs in Baltimore say they’ve seized thousands of unapproved or counterfeit coronavirus tests, masks and medications.

Coronavirus fuels a surge in fake medicines

The Conversation
How smugglers are shifting staggering amounts of contraband despite the pandemic

Italian police seized 14 tons of counterfeit medicine made with methamphetamine made in Syria. Sales proceeds were traced back to Islamic State finance groups. (July 1, 2020)
Population differences and drug shortages

Respective population - 2018

- 37 million
- 327 million

Breast cancer survivor says Tamoxifen drug shortage is at 'crisis point'

Pharmacists being asked to limit each patient to 1-month supply of drug, rather than normal 3-month supply

Aly Thomson - CBC News - Posted: Nov 15, 2019 6:00 AM AT | Last Updated: an hour ago
Shortage issues

**Totals**

- **Shortage reports**: 10789
  - **Actual shortage**: 1673 (16%)
  - **Anticipated shortage**: 51 (0%)
  - **Avoided shortage**: 305 (3%)
  - **Resolved**: 8760 (81%)

**Discontinuation Reports**

- **To be discontinued**: 2062
  - **180 (9%)**
  - **1856 (90%)**
  - **Reversed**: 26 (1%)

**Late reports**: 1873

**Overdue reports**: 396

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**Drug shortages homepage**

Welcome to Drug Shortages Canada, the website for reporting drug shortages and discontinuations in Canada. The Food and Drug Regulations require drug sellers to report when they are not able to meet demand for a product or when they stop selling a product. Information about the website and the regulations can be found on the [About & Resources Page](#).

A shortage means, in respect of a drug, a situation in which the manufacturer to whom a document was issued under subsection C 01 014.0 (1) that sets out the drug identification number assigned for the drug is unable to meet the demand for the drug.

Below are the newest and most recently updated Shortage and Discontinuation reports.

**Shortage Reports**

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Company Name</th>
<th>Status</th>
<th>Strength</th>
<th>Update</th>
<th>Date Updated</th>
<th>View Report</th>
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<td>AURO PHARMA INC</td>
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<td>800MG</td>
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How vulnerable is the Canadian supply chain?

“the 2018 Canadian prescription drug supply will last approximately 182 days if 20% of U.S. prescriptions were sourced from Canada”

Canada’s wholesalers have said no.

"The drug supply is insufficient for the Canadian market, let alone trying to divert it to a much larger market like the U.S.,” said Daniel Chiasson, president of the Canadian Association for Pharmacy Distribution Management, a trade group that represents drug distributors. "We're not supportive of any policy initiative or policy proposal that has the capacity to threaten the stability of medications available to Canadians."

“Trump proposes rule for importing prescription drugs from Canada”, (CBC) Dec 2019
“The Canadian drug market and manufacturing capacity are too small to meet the demand of both Canadian and American consumers for prescription drugs. [...] Canada will employ all necessary measures to safeguard access for Canadians to needed drugs.”

GOVERNMENT OF CANADA COMMENTS ON THE PROPOSED RULE 'IMPORTATION OF PRESCRIPTION DRUGS' (DOCKET NO. FDA-2019-N-5711)
Other issues with Canadian importation

American companies are not entitled to Canadian medicine pricing. Even if we found a seller in Canada, they are likely to mark it up further reducing as-yet unproven savings.
Other issues with Canadian importation

Imported Canadian medicine is not entitled to manufacturer rebates. Medicaid experts in Maine, Vermont, and Colorado have all raised this as an issue. With rebates, their prices are better than Canadian prices.
There is no track-and-trace system in Canada. Today, track-and-trace serialization is required on all U.S. medicine except for a small amount of grandfathered inventory. Imported Canadian medicine will be less safe.

Tracking starts at manufacturing time and stops at pharmacy shelf.
Four FDA commissioners doubt safety and savings.

Former FDA commissioners appointed by both Republican and Democratic administrations jointly signed a letter:

“we believe that such importation represents a complex and risky approach—one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation’s medical products.”

March 16, 2017

To Members of Congress:

As former Commissioners of the U.S. Food and Drug Administration, we have been following with concern the recently renewed debate about the importation of therapeutic drugs as a means to reduce the cost of prescription medications. Innovative proposals seek to make lower-cost but genuine, safe, and effective drugs available to U.S. consumers. However, this is not such a straightforward task. In fact, we believe that such importation represents a complex and risky approach—one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation’s medical products.

One of the FDA’s most important responsibilities is to ensure that medications used by Americans are safe, effective, and reliable. For nearly 80 years, the Federal Food, Drug, and Cosmetic Act (FFDCA) has granted the FDA the authority that allows it to take needed action to protect consumers. The “market” distribution system undertaken by the FDA under the direction of broadly supported drug safety regulations, provides assurance that good manufacturing practices are used and that the necessary supply chain, including shipment and storage, is carefully monitored to ensure the quality and safety of approved medications.

The American public and members of Congress have expressed serious concerns about access to and costs of prescription drugs, particularly innovative therapies with major benefits for people with serious diseases. We share these concerns, and believe we need better systems that enable affordable access to life-saving medicines.

However, routine importation from foreign countries is not the right approach. Allowing importation of drugs prepared in non-inspected facilities and drugs purported to be manufactured domestically for export to other countries and re-imported from those countries to the United States can not meet the requirements under the existing closed drug manufacturing and distribution system because the drugs could not be tracked and certified by the manufacturer.

Such a program would be very different from importation of consumer products like watches or clothing, where consumers can more easily discern quality and where there are no health consequences of failed products. It could lead to a host of unintended consequences and unenvisaged effects, including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs. It could also undermine American confidence in what has proven to be a highly successful system for assuring drug safety. The major shortcomings of a broad-based importation scheme include:

- Serious risks to patients and consumers. Current law permits drug importation if the FDA demonstrates it can be done safely. In unusual circumstances, such as a major

March 16, 2017 letter

PDF online

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Has anyone analyzed cost of these programs? Yes.

“While pharmaceutical importation plans are politically attractive, the numbers demonstrate that they fail to deliver cost savings when implemented safely. These schemes can be cheap, or they can be safe, but not both.”

What’s the risk to pharmacists?

- Pharmacy/Pharmacist liability for dispensing counterfeits has never been addressed. Who will be responsible? Who will pay for the added liability from practice insurance?
- Prime wholesaler contracts do not allow significant purchases from outside sources except in the case of exception circumstances. Will dispensing these violate these contracts?
- In it’s application to HHS, NM DOH said that they are willing to shame pharmacies that don’t participate in distributing these medicines.
- How does New Mexico plan to handle sanctioning a foreign-sourced counterfeit? How will they make harmed patients whole?