Lessons learned from public private partnerships in the counterfeit medicines arena

October 18, 2018
PSM is one of many public private partnerships in the patient safety space.

- Perform much of the public documentation of counterfeit incidents.
- Conduct research faster than U.S. government agencies.
- Has the ability to operate without restrictions that constrain government agencies.
Publicizing successes and influencing outcomes

Internet pharmacy pioneer's licence reinstated, just days after it was suspended

Kris Thorkelson's Manitoba licence was pulled on same day his Canada Drugs reached tentative plea deal in U.S.

By Karen Pauls, CBC News   Posted: Dec 21, 2017 5:03 PM CT   Last Updated: Dec 21, 2017 5:14 PM CT

Terms of pending plea deal with U.S. Department of Justice for Kris Thorkelson
- Six months house arrest and four and a half years of probation;
- a $250,100 fine; and
- Turn over records and cooperate in future investigations.

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 is not prohibited from holding any kind of pharmacy license or starting a new pharmacy business to export to America.

Thorkelson’s company, CanadaDrugs, continues to hold provincial wholesale pharmacy licenses and a Canadian Federal manufacturing pharmacy license.
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.
Part of the FDA’s Alert network that circulates alerts about drug recalls

Dietary Supplement Aimed at Weight-loss Recalled Due to Presence of Undeclared Sibutramine

October 17, 2018

This is a reprint of an FDA Alert.

Fat Burners Zone is voluntarily recalling 1 lot of Zero Xtreme, capsules to the consumer level. FDA analysis has found Zero Xtreme to be tainted with sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. The presence of Sibutramine in Zero Xtreme renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Risk Statement: Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and...
Materials to help educate consumers and healthcare professionals that interact with them.

Distribute our materials to consumers and pharmacists (we print them at cost for you!)

Re-share our materials on social media

Print materials: editors@safemedicines.org
Every head of HHS and FDA for the last 18 years refused to certify the safety of drug importation.

Donna Shalala (1993–2001)

“flaws and loopholes... make it impossible for me to demonstrate that it is safe and cost effective.”

- Donna Shalala


“It’s impossible for us to certify that these drugs are safe.”

- Tommy G. Thompson

2003 MEDICARE MODERNIZATION ACT


Kathleen Sebelius (2009–2014)


Alex M. Azar II (2018–)

2000

2004

2008

2012

2016

2018


Scott Gottlieb, M.D. (2017–)

“Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient. Taking these drugs can pose a danger to consumers.”

- Margaret A. Hamburg, M.D.

It’s not a Republican or Democrat issue. It’s a safety issue.
PHARMACY

THESE ILLEGAL ONLINE PHARMACIES ARE SELLING MEDICINES FOR A CHEAPER RATE...

IF I MADE A SITE THAT FOCUSED ON DRUGS USED BY SERIOUS AND CHRONIC DISEASES, I COULD MAKE A LOT OF $$!

IT WILL BE EASY IF CUSTOMERS THINK THE DRUGS ARE FROM CANADA.

IN 2001, STREMPLER BUILT A WEBSITE.

RxNorth.com by MediPlan

In compliance with Canadian, U.K., and U.S. regulations.

About Us  Drug Information  Cancer in Drugs  For Patients  For Doctors  Contact Us

Specializing in medication for:
- Cancer
- HIV
- Chronic disease
- Age-related conditions

See Our Canadian Drugs

LEGITIMATE CANADIAN PHARMACIES ONLY FULFILL PRESCRIPTIONS LEGALLY ISSUED BY A CANADIAN DOCTOR.

A LIE

CONTRARY TO POPULAR BELIEF, CANADA DOES NOT ACTUALLY HAVE A LARGE ENOUGH INVENTORY OF LEGITIMATE DRUGS TO SUPPLY AMERICAN NEED.

ANDREW STREMPLER
PIONEERED THE CANADIAN FAKE PHARMACY INDUSTRY.
CONNED AMERICANS INTO BUYING FAKE DRUGS.

GUILTY!
FENTANYL 101
An introduction to the Fentanyl crisis in the U.S.

What are fentanyl and fentanyl analogues?

Fentanyl is a synthetic opioid that is 50–100 times more potent than morphine. Doctors prescribe fentanyl in medical settings, but drug traffickers manufacture black market fentanyl and sell it illegally.

There are over 40 analogues (variations) of fentanyl.

To evade prosecution, chemists alter the fentanyl molecule to create new analogues.
Pills have been found in 43 states, with deaths reported in 22 – March 2018

Full report: “Forty Three States and Counting” at www.safemedicines.org
Tosh Ackerman of Aptos, CA

The evening of October 27, 2015, 29-year-old Aptos, California resident Tosh Ackerman took a benadryl and part of a Xanax pill to help him sleep. He never woke up, and his girlfriend found him dead the next day.

Investigation showed that Ackerman’s Xanax was counterfeit. It contained a fatal dose of fentanyl.

Carrie is an active speaker to schools and the media. You can reach her at ToshsStory@gmail.com
Teach consumers how to save money safely so they don’t buy off the black market.

47 of the 50 most frequently prescribed medications in the U.S. are available in cheaper generic form.

Americans **pay less** for most commonly prescribed generic medications than Canadians do.
The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs to improve quality and safety by reducing the incidence of events that adversely affect patients.
A secure place to improve quality and safety

The Patient Safety Act and Rule makes PSWP privileged and confidential. Subject to certain specific exceptions, Patient Safety Work Product may not be used in criminal, civil, administrative, or disciplinary proceedings.

It is usually de-identified, but can sometimes be identifiable health information subject to the same HIPAA (healthcare privacy) rules.
Thank you