

The Honorable Jeremiah C. Lynch
Russell Smith Courthouse
201 E. Broadway, Suite 370
Missoula, MT 59802

March 12, 2018

Dear Honorable Jeremiah C. Lynch,

The Partnership for Safe Medicines represents over 60 organizations united in our concern for the dangers of counterfeit drugs in America. We write today to request that in the interest of protecting Americans you add key patient protections to the plea bargain, settlement, and probation of Kris Thorkelson and CanadaDrugs.com.

Once the investigation was completed, the U.S. Food and Drug Administration's Office of Criminal Investigation had identified 509 different medical practices across America that they suspected of having done business with the CanadaDrugs.com cancer drug supply chain. We are deeply grateful to the dedicated agents at the FDA's Office of Criminal Investigation and the attorneys at the U.S. Department of Justice for their hard work, over many years, to document the horrifying crime.

Counterfeiting oncology medications is a nearly untraceable and heinous health care crime. You put saline in a bottle, and when the cancer patient takes it, there is no evidence in the patient of the crime. If the patient dies, everyone just assumes they died because of an aggressive cancer. The only reason we know that there were actual counterfeits stems from the reaction one patient had to impurities in the counterfeit¹ which gave investigators an opportunity to seize it before it was destroyed or hidden².

Before even serving the condition of six months house arrest, it appears that Mr. Thorkelson has regained his license to practice pharmacy in Manitoba and since Manitoba has an active American pharmaceutical export industry, this means he can continue to export medicine into America as well³. We feel that being a part of a scheme to sell Americans fake cancer drugs while you profit from it should be sufficient grounds for a long-term revocation of a pharmacist's license. We are puzzled why the Province of Manitoba doesn't agree with our grave concerns.

¹ "Betty Hunter's Death Illustrates Danger Of Fake Drugs," *Safe Medicines*, February 2, 1027, <http://www.safemedicines.org/2017/02/sad-story-of-betty-hunters-death-illustrates-danger-of-fake-drugs.html>.

² "Pharmacy Exec Charged in Fake Drug Scheme," *Courthouse News Service*, August 18, 2015, <https://www.courthousenews.com/pharmacy-exec-charged-in-fake-drug-scheme/>.

³ Karen Paula, "Internet Pharmacy Pioneer's Licence Reinstated, Just Days after It Was Suspended," *CBC News Manitoba*, December 21, 2017, <http://www.cbc.ca/news/canada/manitoba/kris-thorkelson-pharmacy-licence-reinstated-1.4461387>.

Additionally, it appears that CanadaDrugs.com's license from the College of Pharmacists in Manitoba has another entity added to it, "PrarieRX". We are concerned that after CanadaDrugs shuts down, this would facilitate a strategy to transfer the license and select assets of the American pharmacy export business to a new entity that would continue shipping black market drugs into America. The Better Business Bureau cites a multitude of Doing Business As names associated with CanadaDrugs, including: Prairie RX, Jandrugs.ca, Americandrugsource.com, Ehealthpharmacy.com, Onlinecanadianmeds.com, Pharmacy-online.ca, Prescriptionwarehouse.com, Smartchoicepharmacy.com, Thecanadapharmacy.com, Mediplan Prescription Plus Pharmacy, Mediplan Health Consulting Inc., Rx North.com, Mediplan Health, Mediplan Pharmacy, Northcountryrx.com, Mediplan Global Health, CanadianDrugstore.com, Discount Canada Drugs, Prescription Warehouse, MedCenter Canada, Meds5000 Inc., Canadiandrugmeds.com, Meds4mail Inc., Well-Being Pharmacy, Canada Discount Rx.com, CDRX Inc., RX Counter, Prairie Meds, PrairieMeds.com, 4624450 Manitoba Ltd.

This would certainly violate the spirit of the settlement, if not the letter of it.

The ongoing danger to patients is not speculative. Previous individuals involved in the counterfeit drug trade have been caught, sentenced, and then returned to the pharmaceutical industry, operating companies that look to also be dealing in black market medications.

Andrew Strempler was the pioneer of the online Canadian black market pharmacy. He founded Mediplan Health Consulting, which frequently operated under the name RxNorth.com, in 1999⁴. By 2001, the U.S. FDA sent Strempler a letter⁵ informing him that he could not sell medications to American citizens because the drugs he was selling were not FDA-approved, but that did not stop him. As it became more difficult to operate in Canada, Strempler moved part of his business over to the United Kingdom and started using a warehouse in Freeport, Bahamas to fill orders. In 2006, the FDA issued a warning to the public⁶ saying that seized medications from RxNorth.com came back as counterfeit. It was around this time that Strempler took the most valuable thing his company had, its customer list, and sold it off to Kris Thorkelson⁷. Strempler hadn't given up on the online pharmacy industry⁸.

⁴ Christopher Rowland, "Where Drug Prices Head South," *The Boston Globe*, November 23, 2013, http://archive.boston.com/business/globe/articles/2003/11/23/where_drug_prices_head_south/.

⁵ U.S. Food and Drug Administration to Andrew Strempler, October 31, 2001, http://www.safemedicines.org/wp-content/uploads/2018/03/FDA_Warning_Letter_31Oct2001.pdf.

⁶ "Fake Drugs Among Purchases Linked to Canadian Firm," *The Washington Post*, August 31, 2006, <http://www.washingtonpost.com/wp-dyn/content/article/2006/08/30/AR2006083002987.html>.

⁷ "Bitter Pill: The rise and fall of Manitoba's Internet pharmacy pioneers", <https://www.winnipegfreepress.com/opinion/fyi/generation-rx-200693481.html>

⁸ Strempler, A. *User Profile*, LinkedIn, viewed February 11, 2018, <https://www.linkedin.com/in/andrew-strempler-0674337/>.

He already had a new company up and running in 2005: PharmaCheck⁹. This company sells medication online to customers in the Caribbean and South America. An indictment was finally brought against Strempler and he pleaded guilty in October of 2012. After his sentencing, Deputy Assistant Attorney General Stuart Delery said “The sentence handed down today serves as an effective deterrent to those who would peddle counterfeit pharmaceuticals — particularly those drugs trafficked over the Internet.” Andrew Strempler did not learn that selling drugs online is a bad business model. He just learned to move that model to countries that do not have the protections that the U.S. FDA offers American citizens.

Knowing that the executives were aware of Andrew Strempler’s prosecution, we think that it is clear that so far the U.S. is not levying punishments sufficient to discourage Canadians from going into the business of sending substandard and counterfeit medication to Americans.

Our recommendation - Prison time instead of house arrest

The Partnership for Safe Medicines is of the opinion that Kris Thorkelson being offered a plea deal for misprision of a felony does not hold him accountable for running a company that trafficked in counterfeit pharmaceutical products that were sold to and used to treat American citizens, especially with the assumption that he had knowledge of this crime. Under 18 USC 3553¹⁰, any sentence imposed by the court should “afford adequate deterrence to criminal conduct.” How does home confinement and probation act as a deterrent to dissuade others from attempting the same scheme in the future? How does home confinement illustrate to Thorkelson the error of his ways? How does it show him that knowingly importing and selling counterfeit medications that compromised and cut the lives of an unknown number of people just a fraction shorter than they would have had with the correct treatment is something no human being with a conscience should ever think of doing?

When the U.S. Department of Justice brought a case against Kansas City, MO pharmacist Robert Courtney in 2002 for selling misbranded, diluted medicines - including chemotherapy drugs - to his customers for over nine years, they held him legally accountable for his actions. Courtney confessed to authorities¹¹ to purchasing his chemotherapy drugs from the gray market for most of a decade and diluting them. It is estimated that he diluted 98,000 prescriptions that were provided to 4,200 patients. Courtney was sentenced to 30 years and is serving his sentence at Big Spring Federal Correctional Institution in Texas. All of his assets were sold off to create a \$10.4 million fund for his victims. CanadaDrugs.com has been in business for 16 years. Robert Courtney admitted to only defrauding his customers for nine. Where is there any justice or restitution in a sentence of probation for Kris Thorkelson’s victims?

⁹ “Canadian Pharmacy Operator Loses License,” *Securing Industry*, February 25, 2010, <https://www.securindustry.com/pharmaceuticals/canadian-pharmacy-operator-loses-license/s40/a387/>

¹⁰ <https://www.law.cornell.edu/uscode/text/18/3553>

¹¹ <http://www.nytimes.com/2003/06/08/magazine/the-toxic-pharmacist.html>

Our recommendation - Surrender and termination of pharmacy licenses for the duration of the sentence

We request that both Mr. Thorkleson and the CanadaDrugs.com entity voluntarily terminate all licenses to practice pharmacy, not allow those licenses to be transferred to any other entity, and not reapply for any new ones during the probationary period.

If profiting from providing fake cancer drugs to cancer patients isn't grounds for losing your license, we're not sure what is.

Our recommendation - Surrender of all domains for all related brand identities of CanadaDrugs.com

The Better Business Bureau of Manitoba says CanadaDrugs has several other market facing brands for doing business¹² that are not mentioned in the plea deal. We worry that these entities will be picked up and continue to do business selling misbranded and counterfeit medicine to Americans after the settlement. We request that these websites be terminated as well and their domains be surrendered to U.S. authorities as well. These entities are:

Prairie RX
Jandrugs.ca
Americandrugsource.com
Ehealthpharmacy.com
Onlinecanadianmeds.com
Pharmacy-online.ca
Prescriptionwarehouse.com
Smartchoicepharmacy.com
Thecanadapharmacy.com
Mediplan Prescription Plus Pharmacy
Mediplan Health Consulting Inc.
Rx North.com
Mediplan Health
Mediplan Pharmacy
Northcountryrx.com
Mediplan Global Health
CanadianDrugstore.com
Discount Canada Drugs
Prescription Warehouse
MedCenter Canada
Meds5000 Inc.
Canadiandrugmeds.com

¹²

<https://www.bbb.org/manitoba/business-reviews/online-pharmacy/canada-drugs-ltd-in-winnipeg-mb-1450>



Meds4mail Inc.
Well-Being Pharmacy
Canada Discount Rx.com
CDRX Inc.
RX Counter
Prairie Meds
PrairieMeds.com
4624450 Manitoba Ltd.

We want to highlight our appreciation for all the hard work over many years taken by agents at the FDA's Office of Criminal Investigation and the U.S. Department of Justice to bring this case to a close. We think all Americans are very fortunate and should be grateful to have such dedicated law enforcement working to protect them from heinous counterfeit criminals.

Respectfully submitted,

Shabbir Imber Safdar, Executive Director
Partnership for Safe Medicines

Appendix

Journal article, "USA criminal and civil prosecution associated with illicit online pharmacies: legal analysis and global implications": Camille Guerra, Timothy K. Mackey