

CHAD C. SPRAKER
Assistant U.S. Attorney
PAUL JOSEPH
Special Assistant U.S. Attorney
U.S. Attorney's Office
901 Front Street, Suite 1100
Helena, Montana 59626
Phone: (406) 457-5120
FAX: (406) 457-5130
Email: chad.spraker@usdoj.gov
Email: paul.joseph@fda.hhs.gov

ATTORNEYS FOR PLAINTIFF
UNITED STATES OF AMERICA

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

UNITED STATES OF AMERICA, Plaintiff, vs. KRISTJAN THORKELSON, Defendant.	14-CR-27-BU-DLC UNITED STATES' SENTENCING MEMORANDUM
---	---

Kristjan Thorkelson and his co-conspirators operated a large-scale unapproved and misbranded prescription drug smuggling scheme that included operations in Canada, the United Kingdom, Barbados, and the United States.

Thorkelson helped establish and support the smuggling and distribution scheme through several of his corporate entities operating under the name “Canada Drugs.” As the Chief Executive Officer of Canada Drugs, Thorkelson and others oversaw the distribution within the United States of substantial quantities of prescription drugs, including clinical cancer medications, that were not approved by the United States Food & Drug Administration (“FDA”) as required by law for sale in the United States, and were misbranded under the Food Drug and Cosmetic Act. Thorkelson was aware of the commission of the felony crime of introducing misbranded drugs into interstate commerce, he concealed the offense, and he failed to alert authorities of the crime in violation of 18 U.S.C. § 4. Additionally, the illegal smuggling and distribution scheme overseen by Thorkelson resulted in the distribution of counterfeit cancer drugs Avastin and Altuzan to physicians in the United States.

A plea hearing and sentencing hearing are scheduled in this case for April 13, 2018 (along with the plea and sentencing hearings for the related organizational defendants, Canadadrugs.com, Ltd., Partnership, Rockley Ventures, Ltd., and River East Supplies, Ltd.). The United States and Thorkelson jointly request that the Court accept Thorkelson’s plea and plea agreement, which is governed by Rule 11(c)(1)(C), *Federal Rules of Criminal Procedure*, and impose a sentence of 60

months probation, with the first 6 months to be served under home detention, a fine in the amount of \$250,000, a special assessment of \$100, and additional conditions of probation as detailed further below, which include causing the permanent cessation of the sale of all unapproved, misbranded, adulterated, or counterfeit drugs in the United States, and cooperating fully with the United States in this ongoing and future criminal prescription drug investigations.

THE CHARGE

In a one-count Superseding Information filed in this case on December 12, 2017, Thorkelson was charged in Count I with committing, between in or about 2011 through 2012, the felony crime of misprision of felony, namely, having knowledge of the commission of a felony crime, concealing the same, and failing as soon as possible to make known the same to authorities, in violation of 18 U.S.C. § 4. Specifically, the offense that Thorkelson had knowledge of, concealed, and failed to report was the felony crime of introducing, and delivering for introduction, into interstate commerce misbranded prescription drugs, with intent to defraud and mislead in violation of 21 U.S.C. §§ 331(a).

Misprision of felony listed in Count I carries a maximum punishment of three years imprisonment, a maximum term of probation of five years, a maximum fine of \$250,000, and a \$100 special assessment.

RELEVANT FACTS

In 2001, Manitoba, Canada-based Thorkelson founded Canada Drugs as an online pharmacy based in Winnipeg, Canada. PSR ¶¶ 37-38. Canada Drugs' business model was based on illegally importing unapproved and misbranded prescription pharmaceutical drugs into the United States from abroad and selling the drugs illegally to consumers throughout the United States in violation of 21 U.S.C. § 331(a). *Id.* The drugs were illegally imported into the United States through the systematic use of fraudulent customs declaration forms, which consistently undervalued the price of the drug products in order to avoid detection by United States regulatory and law enforcement authorities. *Id.* ¶¶ 49, 57-58. The drugs distributed in the United States by Canada Drugs were not approved by the FDA, and were misbranded as defined in the FDCA pursuant to 21 U.S.C. §§ 352(c), 352(o), and 352(f), as the products contained language on the labeling that was not in English, failed to contain adequate warnings and required statements, and lacked adequate directions for use. The United States has identified at least \$78 million in gross proceeds received by Canada Drugs and its related entities, as a result of the illegal prescription drug distribution scheme in the United States. *Id.* ¶ 48.

In addition to being the Canada Drugs CEO, Thorkelson was also listed as the Director of Global Drug Supply, a subsidiary of Canada Drugs. *Id.* ¶ 31. Ronald Sigurdson was the Chief Financial Officer of Canada Drugs, and he assisted in the management of distribution operations along with Canada Drugs Clinical Manager Troy Nakamura, and Director of Clinical Sales for Canada Drugs, Darren Chalus. James Trueman served as a liaison between Canada Drugs and the drop shippers used by the Canada Drug entities in the United States. *Id.* ¶¶ 31-34. Thomas Haughton was the President of two entities related to Canada Drugs, and he helped manage the operations of Canada Drugs' affiliate in the United Kingdom. *Id.*

After approximately eight years of operating this illegal scheme, in 2009, Thorkelson expanded the Canada Drugs market to include acquiring prescription drugs, including life-saving cancer medication, intended for sale in foreign countries, and illegally smuggling the drugs into the United States for distribution. *Id.* ¶¶ 38-39. As part of this expansion, Canada Drugs acquired other companies engaged in similar illegal prescription drug importation and distribution activities and used the brand names, drug inventories, and customer lists of those companies to further its illegal operation. *Id.* ¶¶ 38-40. Thorkelson was personally involved in the acquisition of other companies, including Montana Healthcare Solutions,

also known as MHCS. *Id.* ¶¶ 39-41, 46. A majority of the prescription drugs, including cancer medication that needed to be stored at consistently cold temperatures, was intended solely for foreign markets. *Id.*

In July 2009, Canada Drugs created a new entity, Rockley Ventures, Ltd., to operate its new clinical line of products. In 2009 and 2010, Thorkelson, Haughton, and Chalus, negotiated for the purchase of Montana Healthcare Solutions from Montana resident Paul Bottomley. The transaction was finalized in October 2010 when Bottomley sold Montana Healthcare Solutions to Canada Drugs and Rockley Ventures for \$5 million. *Id.* ¶ 39. As part of the sale of Montana Healthcare Solutions, all non-FDA approved pharmaceutical drugs were shipped from Montana to Canada or to a shipping company in the United States under contract with Canada Drugs. After the purchase, Canada Drugs continued to use Montana Healthcare Solutions' bank account at First Montana Bank to deposit funds from physicians for sales of unapproved and misbranded prescription drugs purchased in the United States. *Id.* ¶ 48. The funds from that account at First Montana Bank were then transferred by Bottomley to accounts of Canada Drugs entities in Canada and Barbados. *Id.* (In 2013, Bottomley pleaded guilty in the District of Montana to the felony crime of misprision of a felony, in violation of 18 U.S.C. § 4, in connection with his conduct related to the Defendants in this case.)

During the criminal investigation, it was discovered that entities affiliated with Canada Drugs had distributed in the United States counterfeit cancer drug Avastin (American version) and counterfeit cancer drug Altuzan (Turkish version). *Id.* ¶¶ 40-59. The counterfeit Altuzan was distributed in 2011 by River East Supplies, the subsidiary which conducted Canada Drugs' operations in the United Kingdom. Authorities were only able to track a portion of the counterfeit packs of Altuzan because River East Supplies did not maintain adequate drug tracing and transaction documents. *Id.* ¶ 44. Substance analysis conducted by the FDA revealed that the Altuzan vials were counterfeit as they contained no active ingredient.

The counterfeit Avastin distributed by Canada Drugs-affiliated entities was discovered in December 2011, when the United Kingdom Medicines and Healthcare Products Regulatory Agency notified the FDA of a potential counterfeit batch of the oncology drug which River East Supplies had purchased from a supplier in the European Union. *Id.* ¶ 43. Specifically, River East Supplies had acquired 167 packages of Avastin 400 mg and had transferred 41 of those vials to a drop shipper used by Canada Drugs in the United States. *Id.* That drop shipper confirmed that they had already distributed 36 of the 41 vials of Avastin to physicians in the United States. *Id.* Subsequent lab tests confirmed that the

Avastin was counterfeit and contained none of the active ingredient bevacizumab that is found in legitimate versions of the oncology drug. *Id.* ¶¶ 43, 50-51, 59.

By at least early 2012, Thorkelson and other employees and executives of Canada Drugs were aware that the Canada Drugs affiliated companies had sold packages of suspect Avastin and Altuzan to medical clinics in the United States. *Id.* ¶¶ 43-52. Yet, at that time, Thorkelson failed to notify any authorities regarding the suspect product. Further, Thorkelson and his co-conspirators took steps to conceal the same. For example, in March 2012, Thorkelson sent an email message to all Canada Drugs employees falsely stating that Canada Drugs had “absolutely no connection to selling or offering Avastin.” *Id.* ¶ 53. Thorkelson further falsely stated in that email message that Canada Drugs sold “only prescription maintenance medications to individuals.” *Id.* By the time that email message had been sent, employees and executives of Canada Drugs, including Thorkelson, were aware that the statements in that message were false, and that Canada Drugs and related entities had already taken efforts to recall the suspect Avastin from customers in the United States. *Id.* ¶¶ 41-59

Further, during this criminal investigation, FDA Office of Criminal Investigation agents learned that executives and employees of Canada Drugs had systematically undervalued the declared value of each shipment of pharmaceutical

drugs on customs forms in order to conceal the illegal importation of the unapproved and misbranded drugs into the United States. *Id.* ¶¶ 33, 39, 57. Even after the drop-shippers used by Canada Drugs questioned the valuation of the products on the customs forms as well as the listing of the contents of the packages, an executive of Canada Drugs falsely informed the drop shipper that Canada Drugs was following all legal requirements for the importation of the drugs into the United States. *Id.*

SENTENCING RECOMMENDATION

The Government believes that the following disposition of the case against Thorkelson per the plea agreement entered into pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure is supported by a fair assessment of the advisory guideline calculations as well as the factors set forth in 18 U.S.C. § 3553(a) and relevant case law:

- 1) The Defendant will be sentenced to a period of probation of 60 months, with the first six months to be served under home detention;
- 2) The Defendant will pay a fine of \$250,000;
- 3) The Defendant shall cause his co-defendants, their subsidiaries, and other related entities to permanently cease all sales of unapproved, misbranded,

- adulterated, and counterfeit drugs in the United States within 90 days of the sentencing date;
- 4) The Defendant shall cause his co-defendants, their subsidiaries, and other related entities to surrender to the United States all domain names and any legal rights to the use of the domain names used in the importation, sale, or distribution of unapproved, misbranded, adulterated, and counterfeit drugs;
 - 5) The Defendant agrees not to disclose any customer information of individuals residing in the United States to any other pharmacy or business outside of the United States;
 - 6) The Defendant agrees to fully cooperate with the United States in this ongoing criminal investigation and future criminal investigations of the importation, sale, or distribution of violative products;
 - 7) The Defendant will pay a special assessment of \$100;
 - 8) The Defendant agrees that the plea agreement is contingent on the Court's acceptance of the guilty pleas of the corporate co-defendants, Canadadrugs.com Ltd Partnership, River East Supplies, Ltd, and Rockley Ventures, Ltd; and

9) The Defendant agrees to waive any right to appeal the judgment and sentence and the right to bring any other post-conviction attack.

If Thorkelson pleads guilty to the charge discussed above, the United States will move to dismiss the criminal charges against the following corporate and individual co-defendants, Global Drug Supply, Thorkelson Consulting, 4208081 Canada, Thomas Haughton, Ronald Sigurdson, Troy Nakamura, Darren Chalus, Narinder Kaulder, and Jim Trueman.

The Court should impose the sentence on the defendant that the parties have agreed to pursuant to Rule 11(c)(1)(C) as it reflects the seriousness of the defendant's crime and provides just punishment for the offense, under 18 U.S.C. § 3553(a).

The United States believes that the above-referenced sentence is an appropriate one reflecting the seriousness of Thorkelson's conduct, the need for just punishment, and adequate deterrence to future criminal conduct. The United States believes that the sentence imposed on Thorkelson should be viewed as a whole taking into consideration the dispositions of the criminal cases of the related corporate and individual co-defendants.

The United States FDA is a federal agency whose critically important mission is to protect and promote the public health by assuring the safety, efficacy, and security of prescription drugs, among many other items. A significant goal of the FDA in protecting the prescription drug supply is to reduce the likelihood of

poor quality, unsafe, ineffective products from entering the legitimate United States drug supply chain. In contrast, it was the goal of Thorkelson's criminal scheme to breach the integrity of the drug supply chain for financial gain, resulting in the health of consumers in the United States being endangered. As a direct result of the illegal conduct of Thorkelson, consumers and patients, including those needing life-saving chemotherapy, were at risk of receiving drugs that were not approved by the FDA for use in the United States, were not in the proper supply chain, which had routes and storage that could not be verified, or were counterfeit.

The sentence agreed to by the parties is reasonable as it importantly shuts down Thorkelson's large network of businesses operating this vast drug importation and distribution scheme, disgorges substantial proceeds from Thorkelson's related entities, mandates assistance by Thorkelson in ongoing and future criminal investigations, and avoids the expenditure of significant additional time and resources by the United States in continuing to seek the extradition to the United States of individual co-defendants and continuing to litigate the receipt of evidence from abroad through pending mutual legal assistance treaty requests.

CONCLUSION

The defendant, Kristjan Thorkelson, operated an illegal business that placed profits ahead of the health and safety of consumers in the United States. The

United States respectfully requests imposition of the sentence listed herein as it will ensure that the goals of sentencing in the federal system are met.

DATED this 4th day of April, 2018.

KURT G. ALME
United States Attorney

/s/ Chad C. Spraker
Assistant United States Attorney
Attorney for Plaintiff

/s/ Paul Joseph
Special Assistant United States Attorney
Attorney for Plaintiff

CERTIFICATE OF COMPLIANCE

Pursuant to D. Mont. LR 7.1(d)(2) and CR 12.1(e), the attached United States' Sentencing Memorandum is proportionately spaced, has a typeface of 14 points or more, and has a body containing 2384 words.

/s/ Chad C. Spraker

Assistant United States Attorney
Attorney for Plaintiff

/s/ Paul Joseph

Special Assistant United States Attorney
Attorney for Plaintiff