In the United States District Court for Maryland

Food and Drug Administration v. Office of Regulatory Affairs HA-17-5-21

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To regulate the online pharmaceutical industry after extensive felony monopolization, theft from International Mail Facilities (IMF) and counterfeiting since the passage of An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes P.L. 113-54 of Nov. 27, 2013 and to provide compensation for personal suits for injury to online pharmaceutical deliveries under 15USC§15.

Repeal Section 801(u) of the FD&C Act under 21USC§381(u) as botched without differentiating counterfeit drugs by SUPPORT for Patients and Communities Act P.L. 115-271 of Oct. 24, 2018.

Insert online pharmacy consumer before pharmacist in Section 804(a)(1) of the FD&CA under 21USC§384(a)(1) as stricken and replaced by a conspiracy in restraint of trade with Canada in Sec. 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) Public Law 108-173 Dec. 8, 2003 and feloniously enforced by FDA final rule entitled “Importation of Prescription Drugs” on September 25, 2020.

Delete 'from Canada' from §384(b)

Replace 'to submit to the Secretary' with 'record' at §384(d)(1).

Insert 'foreign' before establishment and delete 'within Canada' under §384(f).

Repeal paragraphs i to end §384(i-m).

Work Cited

Alleged violations of the 1955 Treaty of Amity, Economic Relations, and Consular Rights (*Islamic Republic of Iran v. United States of America*) No. 175 3 October 2018

An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes P.L. 113-54 of Nov. 27, 2013

Buy American provisions 24USC§225h

Definitions. Controlled Substances Act 21USC§802

Felony monopolization 15USC§2

Definitions relating to the dispensing of controlled substances by means of the Internet 21CFR§1300.04 [74 FR 15619, Apr. 6, 2009]

Imports and exports 21USC§381

Importation of prescription drugs 21USC§384 amended Pub. L. 114–125, title VIII, § 802(d)(2), Feb. 24, 2016, 130 Stat. 210 [sic].

Medicare Prescription Drug, Improvement, and Modernization Act (MMA) Public Law 108-173 Dec. 8, 2003

National Commission on Electronic Fund Transfers 12USC§2404

Penalties. Food, Drug and Cosmetic Act 21USC§333

Personal suits for injury 15USC§15

Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy 21CFR§1301.11 [74 FR 15621, Apr. 6, 2009]

Postal policy 39USC§101

Prohibited Acts Acts A 21USC§841

Prohibited Acts. Food, Drug and Cosmetic Act 21USC§331

Registration of producers of drugs or devices 21USC§360

Registration requirements 21USC§823

Substances requiring special packaging 16CFR§1700.14

SUPPORT for Patients and Communities Act Public Law No: 115-271 of Oct. 24, 2018

Trusts, etc. in restraint of trade illegal; penalties 15USC§1

Importation of prescription drugs 21USC§384

An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes P.L. 113-54 of Nov. 27, 2013 created a situation whereby domestic wholesalers and compounders were facilitated to adulterate superior generic pharmaceuticals manufactured in India and purchased online and thereby discredit the competition violation of felony monopolization under 15USC§2 and adulteration, mislabelling and counterfeiting under 21USC§331. The Trump Administration extensively blocked international bank transaction so that an online pharmacy consumer would have to call their bank and pay a reasonable fee to pre-authorize an international transaction, or their card would be blocked, the transaction would not go through and they would need to call to reactivate their card so that it could be used at all. This has been somewhat mitigated by conscientious international vendors. The FDA FY 21 Justification of Estimates for Appropriations Committees reports an alarming increased in ORA international drug interceptions from International Mail Facilities (IMF) and Ports of Entry and destruction attributed to the, now

contested, SUPPORT Act Public Law No: 115-271 of Oct. 24, 2018. FY 19 the FDA increased the number of special agents and import investigators responsive to illicit activity involving FDA-regulated products arriving through International Mail Facilities (IMF) and Ports of Entry. FY 19 more than 17,000 violative drug products were destroyed across all nine IMF (an increase of 15,522 over FY 18) with a reported value of more than $1.5 million (an increase of more than $1 million over FY 18).

The FY 21 Budget provided $45 million for opioid activities at international mail facilities to increase enforcement. This investment will enable FDA to inspect 100,000 packages per year, many containing multiple products. As provided in sections 303(f) and 401(h) of the Act under 21USC§823(f) and §841(h)), it is unlawful for any person who falls within the definition of "online pharmacy" as set forth in section 102(52) of the Act under 21USC§802(52)) and 21CFR§1300.04(h)) to deliver, distribute, or dispense a controlled substance by means of the Internet under 21CFR§1301.11(b). It is inappropriate to target online pharmacies because they do not sell controlled substances. Shipments from legitimate online pharmacies registered under 21USC§360(i) should not be searched or delayed. Section 3022 of the SUPPORT Act Public Law No: 115-271 of Oct. 24, 2018 added Section 801(u) to the FD&C Act under 21USC§381(u) that needs to be repealed because it is unconstitutionally vague to abuse the term "drug" so that its effect is that any import may be deemed to be illicit, seized and counterfeited by aforementioned drug compounders, regardless of whether or not it is or was at time of entry into an International Mail Facility (IMF) counterfeit under (u)(2). The Budget provides an additional $4.5 million, $78 million total, to ostensibly strengthen the compounding scientific framework, develop a list of bulk drug substances approved for compounding by industry, bolster regulatory compliance, and expand policy development. The Budget will enable FDA to evaluate the over 300 unique bulk drug substances nominated for inclusion on the list of substances approved for compounding by industry. This ORA compounding program is highly suspected of being an organized high-tech counterfeit operation capable of repackaging adulterated and substandard drugs in fancy foil packages that look just like the quality generic Indian pharmaceutical, that were imported and destroyed.

For the past several years banks have infringed on international transactions so that they would need to be pre-authorized by the bank to prevent the account from being frozen since 2020 in conspiracy with India. The National Commission on Electronic Fund Transfers should hold a hearing to redress restraint of trade pursuant to 12USC§2404(a) and 15USC§1. For the most part this has affected +/-$10 billion annual online pharmaceutical imports to individuals residing in the United States. The delay in international mail deliveries due to the COVID-19 pandemic is adulterously long, up to 5-8 weeks for an express delivery that should not take longer than 5-8 days. These shipments of lifesaving must not be delayed or subjected to unlawful search and adulteration. The Postal Service shall provide prompt, reliable, and efficient services to patrons in all areas and shall render postal services to all communities under 39USC§101(a). States must remove any impediments arising to the free exportation of goods required for humanitarian needs, such as (i) medicines and medical devices; paragraph 98 of Alleged violations of the 1955 Treaty of Amity, Economic Relations, and Consular Rights (*Islamic Republic of Iran v. United States of America*) No. 175 3 October 2018.

The rule of law is that the prescriptions pharmaceutical drugs may be purchased without prescription. Pharmaceutical drugs manufactured in India's several full service generic pharmaceutical drug manufacturers tend to be of equal or higher quality than American pharmacy drugs. In general the foil packages sold by the online pharmacy are far safer from adulteration than the American child-proof cap under 16CFR§1700.14. There is a credible fear that there is an organized conspiracy to counterfeit the sealed packages and replace their contents with toxic substances. There is believed to be at least one

high tech online pharmacy counterfeit operation in business since at least 2014 that has opportunistically resurfaced to predate upon the delay in the international delivery of the mail. Pfizer forensic service to the US District Attorney is highly encouraged to pursue the up to $15,000 fine for each and any prohibited online pharmacy counterfeiting devices, up to $1 million, discovered by the Postal Service pursuant to the Food Drug and Cosmetic Act (FD&CA) under 21USC§333(f). To avoid the looming cost of devaluation it would be really nice to buy American foil wrapped antibiotics online without prescription by converting the online pharmaceutical counterfeiting machines to legitimate use pursuant to 24USC§225h.

US Attorneys prosecute pharmaceutical drug counterfeiting. On January 27, 2021 Antonio Walthour (28) was sentenced to three and a half years for conspiring to sell counterfeit drugs. These drugs were made with fentanyl to make pills and pressing them to look like legitimate pharmaceutical controlled substances with markings such as “Xanax,” “Lortab,” “Percocet,” or “Watson.” Eric and Holly Falkowski were sentenced in 2017 for their roles in the conspiracy to 188 months and 36 months, respectively. In 2020 U.S. Immigration and Customs Enforcement’s (ICE) Homeland Security Investigations (HSI) New Orleans seized 51,000 counterfeit items valued at more than $16.7 million during a holiday-related intellectual property rights surge operation. David Beckford was sentenced to more than 10 years in prison for his role in a conspiracy to manufacture counterfeit Xanax pills with a pill press. The problem seems to be that the FDA is not certifying online pharmacies who deliver from the high quality generic pharmaceutical manufacturers in India. US Attorneys and law enforcement infringe on this weakness to seize everything they can get their hands on. In cases where there are real manufacturing devices, these devices get into the hands of law enforcement and their health professional informants and are used to counterfeit drugs with the monopolistic intent to adulterate the non-DEA licensed competition, and thereby justify payments for their refusal to treat, improper ineffective and/or experimental prescriptions, and poisonous enforcement, but only generate more mistrust, chronic illness and death. The drug and product mislabelling and counterfeiting device operation is believed to be located in California using equipment seized by the federal police. The FDA has a responsibility to ensure online pharmacies get their products from Indian generic pharmaceutical manufacturers and their shipments are not intercepted and counterfeited pursuant to felony monopolization under 15USC§2 that describes why, due to her affiliation with the Permanent Select Committee on Intelligence, aggravated identity theft of voluntary Democrat, involuntary Republican, and citizens alike, Nancy Pelosi is disqualified, and it her who must be impeached, from her office of Speaker of the House.