

PharmacyChecker.com Public Comments on FDA’s proposed regulations to implement Section 708 of the Food and Drug Administration Safety and Innovation Act (FDASIA)

Proposed Rule: Administrative Destruction of Certain Drugs Refused Admission to the United States

Agencies: Department of Health and Human Services and the U.S. Food and Drug Administration

Docket No. FDA-2014-N-0504

Date: July 4th, 2014

Primum non nocere

Prescription drug prices are often eight times more expensive in U.S. pharmacies than in foreign pharmacies.¹ About five million Americans import prescription drugs for personal use each year due to lower drug prices outside the U.S.² As part of a petition on Change.org launched in April of this year, almost 2000 self-identifying Americans left comments stating why they import prescription medication for their own use and their serious concerns about Section 708. The relevant FDA personnel should [read them](#) before drafting the final regulation to put Section 708 into effect.³

Founded in 2003, PharmacyChecker.com verifies online pharmacies, provides drug price comparisons among verified online pharmacies and prescription discount cards, and advocates for expanding access, online and off, to safe and affordable medication. Online pharmacies verified in our program meet critical licensure, prescription, and privacy requirements that safeguard the health of their consumers.⁴ We are a stakeholder in the online business community seeking an open Internet environment that promotes innovation and new business models, especially those that serve the public health.

¹See http://www.pharmacychecker.com/news/online_pharmacy_prescription_savings_obamacare_2013.asp [Last accessed 7/6/2014].

² Cohen RA, Kirzinger WK, Gindi RM, “Strategies used by adults to reduce their prescription drug costs,” NCHS data brief, no 119. April 2013. Hyattsville, MD: National Center for Health Statistics. 2013, <http://www.cdc.gov/nchs/data/databriefs/db119.pdf>, [Last accessed 7/22/2013]. NCHS data shows that approximately 2% of the adult U.S. population imports prescription medication for personal use on an annual basis.

³ Change.org petition comments posted here: <http://www.pharmacychecker.com/pdf/comments-by-americans-concerned-section-708-fdasia.pdf>.

⁴ Bate, Roger, Ginger Zhe Jin, and Aparna Mather, “In Whom We Trust: The Role of Certification Agencies in Online Drug Markets,” The B.E. Journal of Economic Analysis & Policy. Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI: [10.1515/bejeap-2013-0085](https://doi.org/10.1515/bejeap-2013-0085),

We strongly support and wish to assist FDA in their actions to protect the public health against dangerous drug-selling websites. When Section 708 of the Food and Drug Administration Safety and Innovation Act (FDASIA) goes into effect it can protect the public health by deterring drug-selling websites that do not care about patient safety, but, without appropriate safeguards, it could also hurt patients if it curtails access by Americans to safe and affordable medications.

There are many prescription drugs (“drugs”) that are imported for personal use that may not meet the technical requirements of the Food, Drug and Cosmetic Act (the “Act”) but are still shown to be safe and effective. Those drugs include ones that can be legally prescribed in the U.S. that are either manufactured here, under U.S. regulations, or in other countries under U.S regulations and/or the regulations of the exporting country.⁵ When alerting Americans that their imported prescription orders are detained at an international mail facility (IMF), the FDA often informs them that the products don’t comply with the Act, and the Act “is designed to protect you from products that have not been shown to be safe and effective and that are not labeled in a truthful, accurate and non-misleading manner.”⁶ No doubt the Act was designed to protect consumers, but it’s not perfect: sometimes FDA will detain prescription drug orders for personal use that are safe and effective, labelled truthfully, and prescribed by a licensed practitioner in the U.S.

Without proper regulatory restraint, more Americans who order prescription medication for personal use from licensed pharmacies in Canada and other countries will face serious potential adverse health effects if their medications are detained in the first place, not to mention refused import and destroyed, pursuant to Section 708. To avoid adverse health effects and encourage compliance with prescribed medication use, the FDA should and can permit greater enforcement discretion to allow safe prescription drug orders for import that clearly don’t represent an unreasonable risk.

The proposed rule does not commit FDA to an “appropriate” standard of due process, as required under Section 708, one that gives individuals an appropriate opportunity to provide testimony to challenge FDA’s decision to destroy their drug imports for personal use. Since the enforcement actions envisioned under Section 708 potentially affect the life of an individual, in terms of whether or not their prescription drug order will be destroyed by the federal government, the standard for creating due process should be very high. As currently in effect and under the proposed rule’s revision, C.F.R. 1.94 only appears to provide a due process to challenge FDA detentions and refusals of large drug imports

⁵ Supra note 3. The data in Bate, et al, combines two studies involving prescription drug purchases and quality testing of those purchases, one in 2009 the other in 2011, including 195 orders from international online pharmacies approved by PharmacyChecker.com. All prescription orders received by PharmacyChecker.com approved international online pharmacies, which came from a variety of countries (not just Canada) were real medications (all but one marketed by Pfizer and AstraZeneca: 90.3% (177) was were identical to drugs sold in the U.S. by the same manufacturer; 8.7% (17) were foreign versions made by Pfizer or AstraZeneca; less than 1% (1) was a generic substitution, which according to Mr. Bate contained the right active ingredient and dosage. Those safe medications may be subject to refusal and destruction pursuant to Section 708.

⁶ U.S. FDA Regulatory Procedures Manual – April 2013 Chapter 9 Import Operations and Actions: See <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM179501.pdf> [Last accessed 7/3/2014].

valued over \$2500 by commercial entities such as drug companies, wholesale pharmacies, hospitals, and their agents – but not individuals. Since the proposed rule identifies individuals – not commercial entities or their agents – as the main, or likely, importers affected – people who are awaiting medications for their own use – **the FDA must create an administrative procedure for providing testimony for individual consumers to defend their prescription drug orders for personal use.**

The proposed rule does not meet the requirements of Executive Order 13563 (EO), which mandates that regulations are based on an examination of costs and benefits – including those affecting public health.⁷ The proposed rule only quantifies *benefits* but not the *costs to public health* of Section 708. Americans who may have to forgo medication that is detained, refused or destroyed can become sick, not get better, and even die. Those “costs” were ignored in the proposed rule.

In the proposed rule, FDA misattributes to a GAO report on Internet pharmacies what is a useful but still imperfect definition of “rogue Internet pharmacy.”⁸ The definition puts the emphasis on “fraudulent enterprises” that sell medications and don’t protect patient safety. We strongly support shutting down dangerous pharmacy websites that endanger patients by selling falsified drugs, or real drugs without a prescription. Shutting down those sites will protect the public health and reduce the need for FDA to spend its limited resources on imported drug refusals and destructions. In contrast, safe and effective medications, ones ordered on safe international online pharmacies, such as those approved in the PharmacyChecker.com Verification Program, serve the public health, and should not be inadvertently or purposefully refused entry or destroyed. In the comments below, we offer a concrete and useful definition of rogue online pharmacy to help FDA avoid enforcement actions against safe international online pharmacies.

As a reminder, Congress was warned about the language of Section 708, which was included in a related drug bill, by former Congresswoman Jo Ann Emerson:

This language threatens a critical, cost-effective supply of medications and pharmaceuticals. These drugs are exactly the same as their counterparts sold in America. I urge further discussion of this critical issue in conference and a full examination of the consequences of passing this provision into law.⁹

⁷ Exec. Order No. 13563, FR Doc. 2011–1385, January 21, 2011. See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

⁸ The GAO report cited in the proposed rule does not define rogue online pharmacy in the manner attributed to it in the proposed rule by the FDA. The GAO does use the phrase “fraudulent enterprise” in discussing rogue online pharmacies. Read through the Government Accountability Office. “Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad,” (GAO-13-560), 2013. <http://www.gao.gov/products/GAO-13-560>

⁹ Floor Statement of Congresswoman Jo Ann Emerson, May 30, 2012, during debate on the Food and Drug Administration Reform Act of 2012, a bill related to FDASIA: <http://votesmart.org/public-statement/702416/food-and-drug-administration-reform-act-of-2012#.U7I3mufD-FF>.

I. Safe drug imports and access to medicines are not protected under the proposed rule

Expanded authorities under Section 708 could serve the public health by preventing illnesses and deaths avoided because FDA destroyed counterfeit, adulterated or otherwise dangerous medicines in route to Americans who ordered them online, but they can also inadvertently **harm the public health by preventing Americans from receiving safe and effective, genuine medication, ordered online from safe international online pharmacies.** “Safe international online pharmacies” are those that process orders for genuine prescription drugs, filled by licensed pharmacists and pharmacies pursuant to a valid prescription.

Drug importation laws were essentially created to affect companies and their agents who import quantities of drugs for re-sale within the U.S., usually valued at a value of \$2500 or more – often called *wholesale drug importation*. In contrast, Section 708 targets prescription drug packages valued at \$2500 or less, many, if not most, of which are prescription drug orders in route to individuals for their own use - also known as *personal drug importation*. Wholesale drug importers that face regulatory actions in which their imports are detained, refused and destroyed are not waiting to personally take their purchased, imported drugs. In contrast, FDA’s refusal and destruction of personally imported prescription drugs poses a serious risk to the individuals because they may not receive and take medication that they ordered.

The proposed rule states: “A drug that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD Act if, among other reasons, it is or appears to be adulterated, misbranded, or unapproved in violation of section 505 of the FD Act ([21 U.S.C. 355](#)).” Whether the drugs are safe or effective or not, most personally imported medicine is “misbranded” or “unapproved” and therefore subject to refusal and destruction. Safe and effective, genuine medications imported for personal use from licensed pharmacies in Canada and other countries, such as Lipitor, are usually considered “misbranded or “unapproved” due to the differences in the product’s packaging and labelling from the products sold in U.S. pharmacies. **The FDA should identify a reasonable and compassionate policy so that genuine medications are not destroyed but reach the consumers who ordered them.**

According to the FDA, the illegality of personal drug importation is due to the fact that the agency cannot ensure the imported drug’s safety and efficacy, not that the drug is not safe and effective.¹⁰ Since personally imported drugs that were purchased from safe international online pharmacies are safe and effective, it’s incumbent upon the FDA, working with U.S. Customs and Border Patrol, to be very discerning about which imports should be detained. Using its enforcement discretion, the FDA can determine whether an imported drug is a safe, legally manufactured, medication, one checked for safety

¹⁰ On its website, the FDA informs consumers: In most circumstances, it is illegal for individuals to import drugs into the United States for personal use. This is because drugs from other countries that are available for purchase by individuals often have not been approved by FDA for use and sale in the United States. See

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm> [Last accessed 7/6/2014].

and efficacy, and the importer has a prescription for that medication, before refusing a prescription drug for personal import.

Safe imported drugs

To avoid unnecessary drug import refusals, ones that do not protect but threaten the public health, FDA needs to define the term “safe personal drug import” as part of its final regulation. We offer the following definition: A ‘safe personal drug import’ is a finished drug product approved for sale in a country, union, or economic area referred to in section 802(b)(1)(A) for which there is a corresponding U.S. drug subject to sections 505 or section 503(b) of the Act, other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)).¹¹ Essentially this would be any non-controlled drug that is legally prescribed in the U.S. and approved for sale in countries with the strongest pharmaceutical regulations.

Since safe personal drug imports are the *same* as the medications sold in U.S. pharmacies, they do not pose a public health risk, and there are no public health benefits to refusing such imports in route to individual patients with valid prescriptions. In the previous sentence, “same” means that the safe imported drugs are either identical, bioequivalent, or contain the same active ingredient or ingredients, route of administration, dosage form, and strength as their U.S. Label Drug counterpart, and have undergone regulatory scrutiny for safety and efficacy in a country, union, or economic area referred to in section 802(b)(1)(A). Those are drugs that, when prescribed, are almost certainly (if not definitely) as safe and effective for the patient who ordered them as those sold in U.S. pharmacies, and definitely do not represent an unreasonable risk to the public health.

FDA is encouraged to permit for import safe and effective medications for personal use as widely as possible. To that end, we recognize that there are many safe and effective drugs sold in other countries not included in the above definition of safe personal drug import, such as those available for sale in Turkey, which has a track and trace system to prevent counterfeit drugs.¹² Track and trace is still not implemented in the U.S. and may not be for the next decade.

Prescription requirement

In addition to drug quality, the main concern to PharmacyChecker.com and regulators about consumers ordering prescription medication online for personal import is that the patients do not have valid prescriptions for the products they ordered. If a personal drug import is accompanied by a valid prescription from the importer’s U.S. licensed prescriber, then the FDA knows the patient is under

¹¹ These are prescription drugs approved for sale in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

¹² Barlas, Stephen, “Track and Trace Drug Verification: FDA Plans New National Standards, Pharmacies Tread With Trepidation,” *U.S. National Library of Medicine*, April 2011. “Turkey and France already have requirements for drug packages to be printed with 2D data matrix codes when they leave a manufacturer’s plant.” See <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086119/> [Last accessed 7/6/2014].

appropriate medical supervision. Safe personal drug imports that are detained and inspected at IMFs can be checked for a prescription before permitting them for importation.

Focusing refusals of personally imported drug orders to those that are not accompanied by a prescription and appear to be counterfeit and/or adulterated, while allowing import to lawfully prescribed and safe drugs, will maximize the benefits of Section 708 in terms of protecting the public health.

II. Consumers are not provided due process under FDA's proposed regulation

The traditional focus of and legislative intent of America's drug importation laws are geared toward *wholesale not personal drug importation* and quantities.¹³ For clarity: according to a speech given by FDA Commissioner Margaret Hamburg, FDASIA expands federal authorities to destroy small imported drug packages to deter foreign Internet pharmacies.¹⁴ Thus, Section 708 is focused on small quantities of prescription drugs usually ordered online for personal use. The proposed rule does not meet the law's requirement that *appropriate* due process be made available to importers because it doesn't respond to the unique circumstances of *personal drug importation*. Consumers must be provided clarity on exactly how they can "introduce testimony" to challenge the FDA's decision to destroy their medications.

Specifically, the FDA's proposed language to amend C.F.R. 1.94 is neither practical for consumers to defend their personal use drug imports, nor does it meet a standard of "appropriate" due process. The current administrative process for importers to provide testimony to the FDA when their shipments are refused are geared toward large quantities of prescription drugs and active pharmaceutical ingredients in route to drug companies, wholesale pharmacies, retail pharmacies, hospitals, and other healthcare providers and their agents – but not individuals. Those commercial entities and their agents are not awaiting a refused drug import for personal use, and thus will not suffer adverse health consequences if their refused drug imports are destroyed. Not so for individuals awaiting medications for their own use.

To allow for appropriate due process, the FDA should provide a practical solution for consumers to contest the refusal and destruction of their prescription drug orders. FDA should provide a dedicated online submission platform to which consumers can provide timely testimony.

We propose the following language for C.F.R. to be included in the final rule:

"C.F.R 1.94 Hearing on refusal of admission or destruction for wholesale and personal imports

¹³ For example, the Prescription Drug Marketing Act of 1987, which restricted re-importation of prescription drugs to the manufacturer of those drugs, was a reaction to safety problems related to diversion in the wholesale market. See 99th CONG., 2nd SESS. DANGEROUS MEDICINE: THE RISK TO AMERICAN CONSUMERS FROM PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING, 22 (Comm. Print 1986). The law's intent was not focused on personal drug importation.

¹⁴ FDA Commissioner Margaret Hamburg, keynote speech and Partnership for Safe Medicines 2012: <http://www.c-span.org/video/?c4003702/section-708&newclip=>.

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application

(c) Drug imports for re-sale

If the article is a drug that may be subject to destruction under 801 (a) of the Federal Food, Drug and Cosmetic Act, and one that the importer intends for resale in the U.S., the district director may give the owner or consignee a single written notice that provides the notice on refusal of admission with the hearing on the destruction of the article described in paragraph (a) of this section.

(d) Drug imports for personal use

If the article is a drug imported by an individual for personal use that may be subject to destruction under 801 (a) of the Federal Food, Drug and Cosmetic Act, then the district director will give the owner or consignee a single written notice that includes the following information:

- 1) Notice on refusal of admission and the reasons for such refusal.
- 2) Notice that under federal law the owner or consignee has the right to “appropriate due process” to challenge the decision to destroy the drug by providing testimony.
- 3) Notice that testimony can be provided through an online platform, email, regular mail, or fax. The website, email address, mail address, and fax number for providing testimony will be provided.
- 4) The notice should include a dedicated attached document called “How to Provide Testimony to the FDA to Prevent the Destruction of Your Prescription Drug Order.” **SEE EXHIBIT A.** This document should make the process of providing testimony easy for most consumers. If they can’t afford their medication then it could be a matter of life and death.

III. Proposed Regulation Does Not Adhere to Executive Order 13564

Executive Order 13563 mandates that regulations take into account “costs and benefits” of a proposed regulation, including those affecting public health.¹⁵ The proposed rule quantifies the potential health benefits but not the potential costs to the public health. The proposed rule states: “The primary public health benefit from adoption of the proposed rule would be the value of the illnesses and deaths avoided because FDA destroyed a drug valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that posed a public health risk.” The FDA, to comply with Executive Order 13563, must also measure public health costs as the value of the illnesses and deaths caused because FDA destroyed a drug valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that did not pose a public health risk.

Access to affordable medicine is not a minor inconvenience but a serious public health crisis.¹⁶ Americans often buy medication internationally for import because they can’t afford the drug domestically.¹⁷ Twenty-five million Americans reported becoming sicker because they are not taking medication due to its cost.¹⁸ Americans who skip medication due to cost are almost twice as likely to experience a significant decline in overall health over two years of follow up.¹⁹ The final regulation, thus, must account for the fact that import refusals and destructions of safe medications for personal use serve to exacerbate the public health crisis of medication non-adherence.

IV. Revise FDA’s Personal Drug Importation Policy

In implementing Section 708, and amending C.F.R 1.94 as proposed above, which seeks to avoid refusing for personal import certain genuine and lawfully prescribed medications, it is necessary to update FDA’s Personal Drug Importation Policy [**See Exhibit B**]. The new policy should expressly instruct its personnel to use discretion in allowing for import three-month quantities of personal prescription drug orders containing medications approved for sale in a country, union, or economic area referred to in section

¹⁵ Supra Note 6. See <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf> [Last accessed 7/5/2014].

¹⁶ “Medication adherence: A call for action,” American heart journal 1 September 2011 (volume 162 issue 3 Pages 412-424 DOI: 10.1016/j.ahj.2011.06.007). Authors: Hayden B. Bosworth, Bradi B. Granger, Phil Mendys, Ralph Brindis, Rebecca Burkholder, Susan M. Czajkowski, Jodi G. Daniel, Inger Ekman, Michael Ho, Mimi Johnson, Stephen E. Kimmel, Larry Z. Liu, John Musaus, William H. Shrank, Elizabeth Whalley Buono, Karen Weiss, Christopher B. Granger. See <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/> [Last accessed 7/5/2014].

¹⁷ Supra Note 1. CDC’s data cites “cost” as the reason about five million Americans buy medication outside the U.S. each year.

¹⁸ USA Today/Kaiser Family Foundation/ Harvard School of Public Health, *Health Care Costs Survey*, 2005. The survey finds that 20% of respondents, adult Americans, report not filling a prescription due to cost; 54% of those respondents said their condition got worse as a result. Extrapolated to the 2012 population of adults 18 and older, which is 234,564,071, the number is approximately 25 million people. See <http://kff.org/health-costs/poll-finding/health-care-costs-survey-summary-and-chartpack/> [Last accessed 7/5/2014].

¹⁹ Heisler et. al, The Health Effects of Restricting Prescription Medication Use Because of Cost. Medical Care, Volume 42, Number 7, July 2004.

802(b)(1)(A), which can be legally prescribed in the United States, to individuals with a prescription for their orders. That policy will help prevent patients from going without prescribed medication.

CBP and FDA should focus on personal drug imports that have a reasonable probability of causing serious adverse health consequences or death, such as counterfeit and adulterated drugs and medications that are not accompanied by a prescription. New scanning technologies may be useful in refusing dangerous drug imports for personal use while, through enforcement discretion, allowing genuine medications to reach those who ordered them.²⁰

V. Shutting down rogue online pharmacies

The FDA affirms in its proposed rule that the target of its Section 708 enforcement efforts will be online pharmacies considered “rogue.” FDA wrongly attributes to a GAO report on Internet pharmacies a certain definition of “rogue Internet pharmacy.”²¹ This is not academic: the GAO did not define “rogue online pharmacy” in its report but mentioned in different contexts attributes common to many rogue online pharmacies.²² In citing the GAO report, FDA describes a “rogue Internet pharmacy” as a “fraudulent enterprise” that does one or more of the following: 1) operates in violation of Federal and/or State law; 2) offers cheap drugs for sale without a prescription that meets Federal and State requirements; or 3) operates without a pharmacy license in the United States.” We all agree that shutting down fraudulent enterprises that endanger patient safety is a great idea. In doing so FDA can reduce the need to spend its limited resources to destroy dangerous personally imported prescription drugs arriving at IMFs because they won’t be ordered in the first place.

So that the FDA does not mistakenly conflate safe international online pharmacies with rogue online pharmacies in its consideration of a final rule and implementation of Section 708, clarity on the lexicon of what is and is not a “rogue online pharmacy” is of the utmost importance to the public health.²³ Raising this issue serves to remind FDA that the National Association of Boards of Pharmacy (NABP), which FDA promotes for purposes of consumer education²⁴, conflates some safe international online pharmacies with “rogue online pharmacies” in its public outreach, programs, reports and website.²⁵ Just

²⁰ “FDA goes its own way with counterfeit detection device,” *Securing Industry*, September 14th, 2012. See http://www.securindustry.com/pharmaceuticals/fda-goes-its-own-way-with-counterfeit-detection-device/s40/a1405/#.U7jIM_ldWSo [Last accessed July 5th, 2014].

²¹ See Supra note 8.

²² See Supra note 7.

²³ “Scare Tactics Over Foreign Drugs,” *New York Times*, March 25th, 2014, Gabriel Levitt, Page 27. See http://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html?_r=0 [Last accessed July 5th, 2014].

²⁴ FDA promotes NABP’s VIPPS program: <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm235684.htm>.

²⁵ “NABP Lumps Real and Rogue Pharmacies Together,” RxRights.org, November 14th, 2013. See <http://www.rxrights.org/nabp-report-lumps-real-and-rogue-pharmacies-together/> [Last accessed July 5th, 2014].

See Peter Maybarduk, Public Citizen, comment to the Internet Corporation for Assigned Names and Numbers, March 13, 2013: <https://gtldcomment.icann.org/comments->

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as refusing import to and destroying genuine prescription drug orders threatens the public health, so does discouraging them from obtaining medicine through safe international online pharmacies that they will otherwise go without.

A reasonable definition of “rogue online pharmacy” is *a drug-selling website that does one or more of the following: 1) intentionally sells falsified, adulterated, or illegally manufactured medication; 2) sells real, genuine, legally manufactured medication but that is not dispensed by a licensed pharmacist and/or pursuant to a valid prescription, or 3) contains fraudulent content to mislead consumers.* That definition focusses on the combined factors of public health protection, legal compliance in drug manufacturing, dispensing, and prescription requirements, and access to affordable medication.

It should not be overlooked that the author of the GAO Report about Internet pharmacies referenced in the proposed rule, Marcia Crosse, advises during an interview that it is “fine” to order a prescription drug internationally and online but only under certain circumstances.²⁶ Her example is one where a consumer with a prescription has conducted “some kind of verification” and knows that her online prescription drug order will be filled by a licensed pharmacy in Canada. PharmacyChecker.com conducts the very “verification” described by Ms. Crosse.²⁷

Appropriate detentions, refusals and destructions of dangerous drugs imported for personal use; an appropriate due process that most Americans will understand and use to defend their personal drug imports when FDA detains and refuses them; transparent and honest public education about buying medicines online, combined with shutting down real rogue online pharmacies through enforcement measures will protect the public health.

In using the reasonable regulatory restraint and discretion recommended above, FDA will serve the public health while not harming Americans who choose to order safe imported drugs from foreign pharmacies because they can’t afford the much higher drug prices domestically.

Thank you for allowing us the opportunity to comment.

Gabriel Levitt
Vice President
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[feedback/applicationcomment/commentdetails/12145](#). [Last accessed 7/5/2014]. See Gabriel Levitt, Statement to the House Judiciary Committee, Subcommittee on the Courts, Intellectual Property and the Internet, Hearing on the Role of Voluntary Agreements in the U.S. Intellectual Property System, September 18th, 2013. See <http://docs.house.gov/meetings/JU/JU03/20130918/101316/HHRG-113-JU03-Wstate-LevittG-20130918-U1.pdf>.

²⁶ See Ask GAO Live: <http://www.tubechop.com/watch/1407272>.

²⁷ See Supra note 23.

EXHIBIT A

How to Provide Testimony to the FDA to Prevent the Destruction of Your Prescription Drug Order

As explained in the FDA Action Notification, the prescription drug that you have imported does not meet the requirements of the Food, Drug and Cosmetic Act and its entry was therefore refused. Additionally, we have reason to believe that the prescription drug import is not safe or effective and therefore we are concerned that it may be harmful to you. We are concerned that even if the medication is safe and effective that you do not have a prescription. Taking prescribed drugs without proper medical supervision can be very dangerous to your health. We also recognize that you may not be able to obtain your medication domestically due to cost and we do not wish you to go without prescribed treatments.

In consideration of the above, please submit responses to the following information requests that will serve to explain why you believe we are not justified in destroying the refused prescription drug and instead should send it to you. Your submissions can be submitted online [www.fda.gov/\[dedicated URL\]](http://www.fda.gov/[dedicated URL]), at [\[Dedicated Email\]@fda.gov](mailto:[Dedicated Email]@fda.gov), [\[Dedicated Fax Number\]](tel:[Dedicated Fax Number]), [\[Dedicated Mailing Address\]](#):

Prescription Order Details

Name of the drug:

Other name: [generic name, other brand name]

Strength:

Quantity:

Form: [pill, tablet, capsule, inhaler]

Country of Pharmacy Origin:

Pharmacy or Online Pharmacy (website) ordered from:

Drug Company that makes and/or markets the product:

- 1) Certify that the drug is for personal use.
- 2) Provide a copy a valid prescription, pursuant to which the drug was dispensed, and your prescriber's name, address and phone number.
- 3) Provide evidence that the drug is an approved drug under the regulations of another drug regulatory authority (FDA's counterpart in Canada, the UK, India, etc.) for which there is a corresponding drug approved in the U.S.
- 4) Provide an explanation why the drug does not pose a risk to your health.
- 5) If applicable, testify that the drug cannot be obtained domestically for reasons of cost.
- 6) Provide other reasons you believe FDA should re-consider its decision to refuse entry of and destroy your drug import.

The FDA ensures the confidentiality of the medical information you submit. We will respond to you within 10 days of your submission.

Exhibit B

Revised Personal Drug Importation Policy

FDA personnel is encouraged to exercise discretion to permit for personal use the importation of a three month or less quantity of a prescription drug or device that is not a controlled substance, can be legally prescribed in the United States, is accompanied by a prescription, and is approved for sale in one of the following countries: Australia, Canada, Israel, Japan New Zealand, Switzerland, South Africa or a country if the European Economic Area (countries listed in Section 802(b)(1)(A) of the Act).

In other circumstances, in deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel should consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; and
2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion of treatments not available in the U.S. to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.