

RE: Periodic Review of Existing Regulations 13563,
U.S. Food and Drug Administration, Docket No. FDA-2011-N-0259

Attention: Lisa Helmanis
Office of Policy
Food and Drug Administration
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I. Revise and improve the accuracy of consumer information found on the FDA's website, as it pertains to buying medications online and from online pharmacies.

One of the most critical responsibilities of the U.S. Food and Drug Administration is protecting American consumers from dangerous medication. That responsibility includes warning consumers about dangerous online pharmacies that may sell fake medication, medication with harmful ingredients, real medication without a prescription, or wrongfully use a patient's personal information and/or steal financial information. FDA's consumer information is helpful in alerting consumers to the threats of dangerous online pharmacies; however some of its assertions contradict the facts about non-U.S. online pharmacies that sell prescription drugs to Americans and could inadvertently prevent Americans from getting safe and medically necessary medication.

On the FDA's website - <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm> - a page called Buying Prescription Medicine Online: A Consumer Safety Guide misleads Americans about non-US online pharmacies. FDA's communication leads a consumer to believe that:

1. Only U.S. based online pharmacies are safe;
2. All medication sold in licensed U.S. online pharmacies is safe;
3. Only "FDA-approved" medication is tested for safety and efficacy.

The above assertions are inaccurate and should be revised. Claim number one above is made using the following language on the FDA site:

"Some Web sites sell medicine that may not be safe to use and could put your health at risk.

Some Web sites that sell medicine:

- aren't U.S. state-licensed pharmacies or aren't pharmacies at all"

A person reading the above communication might wrongly believe that all websites that are not U.S. state-licensed pharmacies are not “safe to use”, but if a consumer orders from a U.S. state-licensed pharmacy the medication purchased and ingested will definitely be safe and not harm the patient. Studies show that some websites that are not U.S. state-licensed pharmacies are safe to use.ⁱ ⁱⁱ Foreign and domestic online pharmacies that fill orders from licensed pharmacies, require a valid prescription, based on an in-person consultation with a licensed U.S. doctor, and provided verifiable contact information on their websites, safely dispense genuine medication. A consumer is almost certain to receive proper care and medications from one that meets the aforementioned criteria and is certified by the National Association of Boards of Pharmacy (NABP) VIPPS program or the PharmacyChecker.com Verification Program.ⁱⁱⁱ In fact, U.S. Government Accountability Office studies have shown the relative safety of Canadian online pharmacies compared to U.S. online pharmacies.^{iv}

Another false claim on the FDA website is that only FDA-approved medications are checked for safety and effectiveness. Such a claim communicates that drugs sold in all other countries, including highly developed countries, such as Australia, Canada, New Zealand and the United Kingdom, do not check that pharmaceutical products sold in those countries are safe and effective. This inaccurate position is put forth on the FDA website in the following manner:

“Some medicines sold online:

- are fake (counterfeit or “copycat” medicines)
- are too strong or too weak
- have dangerous ingredients
- have expired (are out-of-date)
- **aren’t FDA-approved (haven’t been checked for safety and effectiveness)”**

The last bullet point communicates that if a product isn’t FDA-approved then it has not been checked for safety and effectiveness. That is inaccurate and should be corrected. Most well-known drug manufacturers, such as Pfizer, GlaxoSmithKline, and Merck sell products in the aforementioned countries, which, due to differences in labeling or the color of the pill, may not meet the technical definition of “FDA-approved” but are still tested for safety and effectiveness, and are often the exact same drug as the one sold in the United States.

Another example of information on the FDA site that could mislead American consumers involves its recommendation that consumers consult the NABP and its VIPPS program regarding online pharmacy information. There’s no question that the NABP is a qualified authority on many pharmacy safety issues but its Internet Drug Outlet Identification Program, while useful, is highly misleading for consumers who are looking online for affordable medication. This program was started in 2008 with a grant from a large pharmaceutical company that stands to gain financially from NABP’s consumer education campaign that dissuades consumers from buying medication in other countries – where drug prices are lower.^v Very simply, the NABP categorizes online pharmacies in two ways: Recommended and Not Recommended.^{vi} VIPPS-approved sites, which are U.S. retail, pharmacy benefit, and some specialty pharmacy websites,

populate the Recommended List. The Not Recommended list includes any online pharmacy that does not dispense from the U.S., and, or, is involved in dangerous pharmacy practices. Regardless of the reason, all are defined as “rogue” by NABP. Here are two examples of online pharmacies one might find on this list:

1. Canadian-based online pharmacies that require valid prescriptions, dispense genuine medication from highly regulated licensed pharmacies in many countries, and have ethically served American patients for over a decade and;
2. Websites that will sell prescription drugs and controlled substances without a prescription and/or counterfeit drugs, misuse personal information and commit identity theft.

These efforts to educate and protect consumers wrongly combine safe online pharmacies that help people affordably obtain medication they need with dangerous online pharmacies that prey on Americans who want to buy medication without a prescription, including drugs of addiction. It is part of the FDA’s administrative practices to partner with third parties in an appropriate manner to most efficiently fulfill its mandate. And there are clearly good reasons to partner with the NABP. However, FDA should make sure such third parties are not misleading consumers, especially through programs sponsored by corporations. It is recommended that FDA ask NABP to revise its policies on public education about online pharmacies to provide an accurate distinction between dangerous pharmacy websites and reputable non-U.S. online pharmacies.

One reason this author believes that the FDA’s website contains inaccuracies and misleading statements, as described above, is that, under most circumstances, it is illegal for Americans to personally import prescription medication and therefore external communications should discourage the practice. However, the goal of preventing Americans from breaking the law through buying drugs from a non-U.S. online pharmacy should not be achieved through inaccurate or misleading statements. Americans deserve full honesty and clarity from their government when it comes to access to safe and affordable medication.

II. As a matter of public health, revise FDA’s personal drug importation policy to explicitly disallow government officials from seizing personally imported prescription orders destined for Americans that they know are genuine and dispensed pursuant to a prescription - SEC. 801. [21 USC §381]; Section 9.2 of the FDA Regulatory Procedures Manual Imports and Exports

FDA should revise Section 9.2 of its Regulatory Procedures Manual to ban government officials from seizing genuine medication en route by mail to Americans who have a valid prescription for that medication. Americans who do not receive their medication due their product being seized at a U.S. mail facility may not have other options to obtain that medication and could, as a result, become sick or die. If a U.S. Customs and Border Patrol or FDA official has a reasonable basis for determining that a personally imported prescription drug is made by the manufacturer licensed to sell that prescription drug then it should be allowed to reach the patient.

Unlike the dangers of buying counterfeit drugs online, about which we have very little data on negative effects in the United States (but still know it to be a serious problem), we have hard data to show the negative health and economic effects of non-adherence to prescription medication. First, it's reported that 121,000 people die each year due to prescription non-adherence^{vii}. Second, according to the FDA, non-adherence to prescription medication costs the country \$290 billion in additional health care costs^{viii}. Third, numerous studies have shown that cost is either the number one reason, or a major factor in, why people do not take their medication^{ix}. And the problem is getting much worse. According to the U.S. Centers for Disease Control and Prevention, from 1997 to 2009 the percentage of Americans not taking their medications due to cost nearly doubled from - increasing from 4.8 to 8.4%^x: that's 25 million Americans who did not take their prescribed medication due to cost in 2009. For the reasons stated above, preventing safe prescription drugs from reaching patients threatens the public health and leads to higher health care costs for the nation. Therefore, FDA should manage its enforcement discretion in a manner supportive of Americans receiving the medication they need.

III. Ban enforcement actions against foreign companies known to operate safe international mail-order pharmacy practices and websites - SEC. 801. [21 USC §381]; Section 9.2 of the FDA Regulatory Procedures Manual Imports and Exports

FDA should revise Section 9.2 of its Regulatory Procedures Manual to ban enforcement actions that would cut off access by Americans to safe and affordable medication. For the reasons stated in Part II above, FDA and other government agencies should take no actions that would reduce access to safe and affordable medication, including enforcement against safe non-US online pharmacies. This would allow FDA to continue its enforcement focus on wholesale importation and dangerous companies and websites that sell fake and/or dangerous pharmaceutical products to Americans or real prescription medication but without requiring a prescription. As mentioned above, studies show that unaffordable medication causes 25 million Americans to not take their medications^{xi}. Despite the technical illegality of the practice, Americans safely import prescription medications from properly verified international online pharmacies and the FDA does not take enforcement actions against individuals for doing so. Therefore, with its limited resources, FDA should exercise its enforcement actions against only foreign companies and people that clearly threaten the public health. There is no ethical basis for the FDA to spend taxpayer money on any effort designed to deny taxpayers access to prescribed medications.

ⁱ Bate, R. and Hess, K. "Assessing Website Pharmacy Drug Quality: Safer Than You Think?". *Public Library of Science One*. August 13, 2010. See <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0012199> (last accessed November 11, 2010).

ⁱⁱ U.S. Government Accountability Office. *Some Internet Pharmacies Pose Safety Risks For Consumers*, GAO-04-820. Washington, DC. Government Accountability Office June 2004. See <http://www.gao.gov/new.items/d04820.pdf> (last accessed June 26th, 2011).

ⁱⁱⁱ Ibid, Bate, R. and Hess K.

^{iv} U.S. Government Accountability Office. *Some Internet Pharmacies Pose Safety Risks For Consumers*, GAO-04-820. Washington, DC. Government Accountability Office June 2004. See <http://www.gao.gov/new.items/d04820.pdf> (last accessed June 26th, 2011).

^v “NABP Names 79 Internet Drug Outlets Operating in Conflict with Patient Safety and Pharmacy Practice Standards”. *National Associations of Boards of Pharmacy*. May 20, 2010. See <http://www.nabp.net/news/nabp-names-79-internet-drug-outlets-operating-in-conflict-with-patient-safety-and-pharmacy-practice/> (last accessed November 11, 2010).

^{vi} See NABP’s discussion on Buying Medicine Online, and its “lists” here: <http://www.nabp.net/programs/consumer-protection/buying-medicine-online/>. (last accessed June 26, 2011).

^{vii} Cut Copayments to Bolster Adherence”, *The Center for Medicine in the Public Interest*, See <http://www.cmpi.org/in-the-news/in-the-news/cut-drug-copayments-to-bolster-adherence/> (last accessed July 27, 2011).

^{viii} Campaign to Improve Poor Medication Adherence (U18), A Notice by the Food and Drug Administration on 03/09/2011, See <http://www.federalregister.gov/articles/2011/03/09/2011-5287/campaign-to-improve-poor-medication-adherence-u18#p-13>, (last accessed July 27, 2011).

^{ix} For more information see: <http://www.federalregister.gov/articles/2011/03/09/2011-5287/campaign-to-improve-poor-medication-adherence-u18>; http://www.nclnet.org/images/PDF/adherence_focus_groups.pdf; <http://www.hsph.harvard.edu/news/press-releases/2008-releases/poll-usa-today-kaiser-harvard-prescription-drugs.html> (last accessed July 27, 2011)

^x National Center for Health Statistics. Health, United States, 2010: With Special Feature on Death and Dying. Hyattsville, MD. 2011.

^{xi} *Ibid.*