# Online Pharmacies, Personal Drug Importation and Public Health

Ill-Considered Enforcement Prevents Access to Safe and Affordable Medication

Gabriel Levitt, Vice President, PharmacyChecker.com

*GAO Report on Internet Pharmacies Can Mislead Lawmakers and the Public about International Online Pharmacies*

For the Senate Committee on Health, Education, Labor and Pensions, and the House Committee on Energy and Commerce

February 2015

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February 12, 2015

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Palone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

**SUBJECT: The public record on Internet pharmacies, GAO report, drug safety and affordability**

In June of 2013, pursuant to Section 1127 of the Food and Drug Administration Safety and Innovation Act, your committee received a report from the GAO about Internet pharmacies – entitled "Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad" – that ignored evidence and analysis showing that safe international online pharmacies are a lifeline of affordable medication for millions of Americans. Instead, the GAO wrongly labels safe foreign online pharmacies as rogue online pharmacies. To correct the public record, we have prepared and are providing to your committee the enclosed holistic, consumer-focused, evidence-based analysis about online pharmacies within the important context of a health crisis caused by high drug prices in America. This report, entitled, "Online Pharmacies, Personal Drug Importation and Public Health," can more appropriately guide lawmakers on how to protect the public from counterfeit or substandard medication from rogue online pharmacies. The report is authored by Gabriel Levitt, Vice President of PharmacyChecker.com, who has been directly involved, on a daily basis, for the past 12 years with the evaluation of online pharmacies and prescription drug costs and has participated in multiple forums and published several articles as an expert on this topic, including providing testimony before the House Judiciary Committee's Subcommittee on Courts, Intellectual Property and the Internet.

**We urge you to read the enclosed report and include it in the public record to help prevent a completely unnecessary travesty in which millions of Americans are cut off from safe and affordable medication due to actions stemming from the flawed research and analysis in the GAO report**.

Legitimate public health concerns about *rogue* online pharmacies are being misused by the pharmaceutical industry to encourage legislative, regulatory, and private sector actions that curtail access to licensed pharmacies providing **s**afe and affordable medication. The consequence of overreach

could be millions more Americans facing economic hardship or having to forgo prescribed medication, which studies show can lead to more sickness and death. Already, tens of millions of Americans go without medications due to cost.

Despite federal prohibitions, according to the CDC, about five million Americans buy prescription drugs from foreign sources each year for reasons of cost. Many of these purchases are from safe international online pharmacies that require valid prescriptions. Yet the Obama administration and the FDA have worked in tandem with the pharmaceutical industry to educate consumers not to purchase more affordable, genuine medication from Canadian and other pharmacies that could save their lives. The well-documented facts of our report help provide a road map for action that is beneficial to regulators, lawmakers, private industry and, most importantly, millions of cash-strapped Americans who are struggling to afford life-saving medications.

We are available on short notice to answer your questions in writing or in person.

Sincerely,

Tod Cooperman, M.D., President
Gabriel Levitt, Vice President
PharmacyChecker.com

CC: By Email/PDF:

Reps. Rosa DeLauro, Keith Ellison, Darrell Issa, Nita Lowey, Carolyn Maloney, Nydia Velazquez
Sens. Susan Collins, Kristin Gillibrand, Charles Grassley, Dean Heller, Amy Klobuchar, John McCain, Rand Paul, Bernie Sanders, Charles Schumer, David Vitter

Stephen Barrett, MD, Quackwatch
Roger Bate, Ph.D., American Enterprise Institute
David Belk, MD, The True Cost of Healthcare
Kenneth G. Berge, M.D., Mayo Clinic
Robin A. Cohen, Ph.D.., U.S. Centers for Disease Control and Prevention
Gabrielle Cosel, Manager, Drug Safety, The Pew Charitable Trusts
Sara R. Collins, Ph.D., Commonwealth Fund
Allan Coukell, Senior Director, Health Programs, The Pew Charitable Trusts
Marcia Crosse, GAO
Laurie Garrett, Senior Fellow for Global Health, Council on Foreign Relations
Lee Graczyk, Lead Organizer, RxRights
Joe Graedon, People's Pharmacy
Peter Maybarduk, JD, Director, Global Access to Medicines, Public Citizen
Dena Mendelsohn, JD, MPH, Consumers Union
Lee Purvis, AARP
Elisabeth Rosenthal, New York Times
Ed Silverman, Wall Street Journal
Sean Vitka, Sunlight Foundation
Maria A. Villarroel, Ph.D., U.S. Centers for Disease Control and Prevention

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A GAO report entitled "Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad," contains critical inaccuracies and omits important peer-reviewed research that could lead lawmakers and their staffs to draw erroneous conclusions about international online pharmacies, potentially resulting in unnecessary enforcement actions that disadvantage consumers and threaten the public health. According to the U.S. Centers for Disease Control and Prevention (CDC) about five million Americans buy prescription drugs from foreign sources each year for reasons of cost. The evidence provided herein, including consumer testimonials and empirical data, shows that safe international online pharmacies are lifelines of affordable medication for many Americans. While rogue pharmacy sites can be very dangerous, overly broad and ill-considered Federal enforcement against safe international online pharmacies will lead to fewer Americans taking prescribed medication.

# Contents

## EXECUTIVE SUMMARY

The U.S. government relies on the Government Accountability Office (GAO) for objective and independent research and analysis of government programs and policies that affect public health. GAO's report entitled Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad (the "GAO report")[1] contains critical inaccuracies and omits important peer-reviewed research to the extent that lawmakers and their staffs will likely draw erroneous conclusions about international online pharmacies that could lead to overreaching and unnecessary enforcement actions that disadvantage consumers and threaten public health. The GAO report was written pursuant to Section 1127 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), a law dedicated to protecting public health.[2]

In contrast to the GAO report, the following holistic, consumer-focused, evidence-based analysis discusses online pharmacies within the important context of a health crisis caused by high drug prices in America, and can more appropriately guide lawmakers on how to protect the public from counterfeit or substandard medication. Legitimate public health concerns about rogue online pharmacies are being used to encourage legislative, regulatory, and private sector actions that curtail online access to safe and affordable medication.[3] The consequence of overreach could be millions more Americans facing economic hardship or having to forgo prescribed medication, which studies show can lead to more sickness and death.[4]

Fifty million Americans did not fill a prescription due to cost in 2012, according to the Commonwealth Fund.[5] According to the Harvard School of Public Health, over half of Americans who do not take prescription medication due to cost report becoming sicker.[6] That means potentially 25 million

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[1] *Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Abroad*, GAO-13-560 (Washington, D.C. July 2013). See http://www.gao.gov/assets/660/655751.pdf [Last accessed 10/7/2014].

[2] Pub. L. No. 112-144, § 1127, 126 Stat. 993, 1117-18 (2012).

[3] Graczyk, Lee, "Americans Can't Afford U.S. Medication, Need a Safe Alternative," November 12, 2014, *The Hill Congress Blog*, see http://thehill.com/blogs/congress-blog/healthcare/223650-americans-cant-afford-us-medication-need-a-safe-alternative [Last accessed 11/12/14]. See Gabriel Levitt, "Inconvenient Truths about Foreign Online Pharmacies," October 8, 2014, *The Hill Congress Blog*, see http://thehill.com/blogs/congress-blog/healthcare/220034-inconvenient-truths-about-foreign-online-pharmacies [Last accessed 10/30/2014]. See Roger Bate, "Google's Ad Freedom Wrongly Curtailed," September 28, 2011, RealClearMarkets.com, see http://www.realclearmarkets.com/articles/2011/09/28/googles_advertizing_freedom_is_curtailed_99281.html [Last accessed 10/19/2014].

[4] Brown, Marie T., and Jennifer K. Bussell, "Medication Adherence: WHO Cares?" *Mayo Clinic Proceedings* 86.4 (2011): 304–314 [Last accessed 1/19/2015] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/.

[5] S. R. Collins, R. Robertson, T. Garber, and M. M. Doty, "Insuring the Future: Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act", *The Commonwealth Fund*, April 2013. http://www.commonwealthfund.org/~/media/files/publications/fund-report/2011/mar/1486_collins_help_on_the_horizon_2010_biennial_survey_report_final_v2.pdf, [Last accessed 9/17/2014].

[6] Harvard School of Public Health/*USA Today*/Kaiser Family Foundation, *Health Care Costs Survey* (conducted April 25 –June 9, 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

Americans become sicker each year because they can't afford prescribed medication.[7] According to the U.S. Centers for Disease Control and Prevention (CDC), about five million Americans buy prescription drugs from foreign sources each year for reasons of cost.[8] Additional estimates show that between four and five million Americans get their imported prescription drugs through international online pharmacies due to their lower prices.[9].

As a government performance audit, the GAO report must abide by generally accepted government auditing standards (GAGAS). Those standards include a responsibility to meet stringent professional and ethical standards, including "…exercising reasonable care and professional skepticism. Reasonable care includes acting diligently in accordance with applicable professional standards and ethical principles. Professional skepticism is an attitude that includes a questioning mind and a critical assessment of evidence."[10]

The GAO report does not meet the appropriate performance audit standards because its conclusions are mostly based on consultations with stakeholders that have significant financial interests in the audit's outcome or the organizations they fund: the GAO seems to rely on their data and positions without a "questioning mind and a critical assessment of evidence." The GAO also misreports critical data it was provided by industry and government sources. GAO did not consult a wider range of available data, expert analyses, and stakeholders known to its authors that would have resulted in a more balanced analysis.[11] Central to the above, the GAO seems to neglect the public interest by completely omitting a discussion about Americans who rely on safe and effective prescription drug imports ordered from foreign Internet pharmacies, ones the GAO report mistakenly refers to as "rogue."

The GAO correctly presents the regulatory challenges to shutting down *rogue* online pharmacies, but *incorrectly* conflates such dangerous pharmacy websites with safe online pharmacies that sell medication from licensed pharmacies in Canada and other countries, which offer Americans a source of affordable medication ("safe international online pharmacies"). This conflation unnecessarily curtails access to safe medication because federal regulatory and private enforcement actions against rogue online pharmacies engulf safe international online pharmacies that Americans rely on.

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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].

[7] *ibid*

[8] Cohen RA, Kirzinger WK, Gindi RM, "Strategies used by adults to reduce their prescription drug costs," *National Center for Health Statistics data brief, no 119*, U.S. Centers for Disease Control and Prevention, April 2013, Hyattsville, MD: see http://www.cdc.gov/nchs/data/databriefs/db119.pdf, [Last accessed 7/22/2013].

[9] Consumer Reports National Research Center, "Best Buy Prescription Drug Tracking Poll 3," August 10, 2011. See http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/2011-BBD-Rx-poll-public-release.pdf [Last accessed 9/17/2014].

[10] *Government Auditing Standards*, GAO-12-331G (Washington, D.C., December 2011), see http://gao.gov/assets/590/587281.pdf [Last accessed 9/17/2014].

[11] Such as peer reviewed studies by Roger Bate and Aparna Mathur at the American Enterprise Institute; recommendations from studies funded by the California HealthCare Foundation; and earlier studies by GAO on Internet pharmacies, all of which are discussed in this report. Supporters of buying medications from international online pharmacies include Mature Voices Minnesota, Coalition of Wisconsin Aging Groups, the Congress of California Seniors, Third Power Age, and New York Statewide Senior Action Council; and non-governmental organizations such as RxRights.org and Demand Progress; and companies such as PharmacyCheceker.com, founded in 2002 to evaluate online pharmacies, U.S. and foreign, and compare their drug prices.

In part, the problem stems from different classification systems to define "rogue online pharmacy." The National Association of Boards of Pharmacy (NABP) and the GAO report wrongly refer to safe international online pharmacies as "rogue." LegitScript, a stakeholder that is repeatedly cited in the GAO report, classifies these safe online pharmacies as "unapproved," but not "rogue," a critical fact overlooked in the GAO report. A more useful and honest definition of "rogue online pharmacy" is *a drug-selling website that intentionally sells fake, adulterated, or unlicensed medication; genuine and regulated medication that is not dispensed by a licensed pharmacist and/or pursuant to a valid prescription; or engages in fraud."* This definition provides a clear framework to enable lawmakers and regulators to target dangerous foreign and domestic pharmacy websites without overreaching enforcement action against safe ones.

The GAO report asserts that most rogue online pharmacies operate from abroad. However, according to the data of industry stakeholders consulted by the GAO, it is actually not clear whether there are more rogue online pharmacies based in the United States or abroad. In its focus on pharmacies "abroad," the GAO report obfuscates technical violations of drug importation laws by Americans who import safe and effective medication for personal use with the use of dangerous web pharmacies, foreign and domestic.

The GAO report largely relies on data and analysis it obtained from pharmaceutical companies, U.S. pharmacies and organizations they fund, and federal agencies, particularly the U.S. Food and Drug Administration (FDA). The aforementioned entities do not recognize the public health benefits of online access to safe and more affordable pharmacies outside the U.S. Their positions are untenable because the public health benefits of safe, personally imported medication purchased online are indisputable – as explained below.

The National Consumers League (NCL) identifies 125,000 annual deaths due to prescription medication non-adherence, but that number only applies to non-adherence related to heart conditions and is based on data from a 1998 article.[12] It's unknown how many deaths are currently due to prohibitive drug costs, but given the prominence of cost as a barrier to access, the numbers are clearly unacceptable. A 2012 CVS survey found that 61% of U.S. pharmacists cite drug costs as the main reason Americans don't take their medications.[13]

For the past fifteen years Americans have ordered medication from Canada and many other countries over the Internet from licensed pharmacies that require a valid prescription[14], employ trained and

[12] McCarthy, R. "The Price You Pay for the Drug Not Taken," *Business Health* 1998.

[13] "CVS/Caremark Survey Says Cost is Biggest Barrier to Prescription Adherence," *CVS/Caremark Insights*, September 27th, 2012, see http://info.cvscaremark.com/cvs-insights/cvs-caremark-survey-says-cost-biggest-barrier-prescription-adherence [Last accessed 9/17/2014]; or See http://www.prnewswire.com/news-releases/cvs-caremark-survey-pharmacists-say-cost-is-biggest-barrier-to-medication-adherence-171516471.html [Last accessed 9/17/2014].

[14] This report concurs with the definition of "valid prescription" identified in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. A valid prescription is one written pursuant to a "valid patient-practitioner relationship" consultation between a licensed healthcare practitioner and a patient. "Valid Patient-Practitioner Relationship" means the following have been established:1) a patient has a medical complaint; 2) a medical history has been taken; 3) a face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and 4) some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

licensed pharmacists, and protect their patients' privacy.[15] There are no reported incidents of an American dying or experiencing a severe adverse reaction from taking a medication ordered online from a pharmacy outside the U.S. that requires a prescription from a licensed healthcare provider who has physically examined the patient.[16] There are also no reported deaths or serious illnesses due to dispensing errors committed by safe international online pharmacies, while dispensing problems in U.S. pharmacies are routine and have killed and sickened many Americans over the past decade.[17]

Thousands of Americans have publicly affirmed that they greatly benefit from lower cost medication available from international online pharmacies and that such access saves their lives, and prevents financial hardship.[18] [19] Here are a few examples of what Americans are saying:

**Morton Ross**, Palm Harbor, FL 2014-04-03, "The meds I take daily, are the difference between 'life and death'. I cannot afford the higher prices at local pharmacies."

**Darilyn Schlie**, Fort Worth, TX 2014-04-03, "Without the ability to go outside the U.S. I will not be able to afford the medication I need."

**James Marshall**, Nashville, TN 2014-04-03, "I have emphysema and could not afford my medications if not for being able to order some of them from outside the USA."

By failing to note that personal drug importation from safe international online pharmacies is a public health benefit, as exemplified by the above testimonials, the GAO report does not properly or fully inform Congress about foreign Internet pharmacies.

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[15] For example, such pharmacists have provided testimony before Congress. The Canadian International Pharmacy Association was founded in 2002. That association's vice president at the time, Dr. Andy Troszok, testified before the House Committee on Government Reform, Subcommittee on Human Rights and Wellness. He said: "I am a Canadian licensed pharmacist, and when I graduated I pledged an oath to take the health, safety, and well-being of my patients as a priority. I have the privilege of working in community pharmacy for 8 years, and also in academia, and I have had the ability to work with patients, and every time I did I took that to the strongest possible level. I think patient safety and overall patient health should be the priority of any pharmacist working in any kind of realm, be it hospital, retail, or innovative delivery of service such as distance-based delivery or mail order." U.S. House, Committee on Government Reform, Subcommittee on Human Rights and Wellness, *International Prescription Drug Parity: Are Americans Being Protected or Gouged*, Source, Hearing, April 3, 2003, Serial No. 108-12. Washington: Government Printing Office 2003. See http://webcache.googleusercontent.com/search?q=cache:ua5hIPDo8yYJ:https://bulk.resource.org/gpo.gov/hearings/108h/87228.txt+&cd=4&hl=en&ct=clnk&gl=us [Last accessed 9/17/2014].

[16] Neither the FDA nor any other federal or state agency, or group, whether for or non-profit, has reported a single death or serious adverse effect from personal drug importation in a situation where the importing consumer had a valid prescription. This is after about 15 years during which Americans have purchased medication online from foreign pharmacies.

[17] Cohen, Elizabeth, "Don't Be A Victim of Pharmacy Errors," *CNN Health*, October 30, 2007. See http://www.cnn.com/2007/HEALTH/10/25/pharmacy.errors/ [Last accessed 9/7/2014]. See Henry I Miller, "Medication Mistakes Are a Tough Pill to Swallow," *Forbes*, February 16, 2011: http://www.forbes.com/sites/henrymiller/2011/02/16/medication-mistakes-are-a-tough-pill-to-swallow [Last accessed 9/17/2014].

[18] Change.org Petition 2014 - over 2000 people, who identify their names and where they live in the U.S., comment about buying their medications internationally: http://www.pharmacychecker.com/pdf/comments-by-americans-concerned-section-708-fdasia.pdf. The comments were made on a petition of over 8000 signatures hosted on Change.org: http://www.change.org/p/kathleen-sebelius-please-don-t-stop-americans-from-getting-medicine-at-lower-cost-outside-the-u-s [Last accessed 9/19/2014].

[19] Also see RxRights.org consumer testimonials: http://www.rxrights.org/testimonials/.

The GAO report does not take into account pertinent data about international online pharmacy safety, which was published in two peer-reviewed studies. Those studies demonstrate that medication ordered from *credentialed* online pharmacies, foreign and domestic, were safe and effective, and that those credentialed online pharmacies all required valid prescriptions. The credentialing agencies were the National Association of Boards of Pharmacy (NABP), LegitScript, a private investigation and verification company contracted by the FDA[20], PharmacyChecker.com, a private pharmacy credentialing company and drug price comparison website, and the Canadian International Pharmacy Association (CIPA), a Canadian trade association of pharmacies and pharmacists that sell medication globally.[21] The medication purchased domestically in that study was about 50% more expensive than the same medication purchased from other countries.[22] That level of savings is substantial but much lower than Americans often save. PharmacyChecker.com price comparison data demonstrate that savings are often as high as 90% from credentialed international online pharmacies when consumers have access to online price comparisons and can find the lowest prices.[23] The FDA has relied on and cited PharmacyChecker.com's data for its own drug price analyses.[24]

The GAO report omits a central finding about the safety of Canadian Internet pharmacies found in an earlier GAO report.[25] Through test purchases of prescription drugs online, GAO's earlier report found that *all Canadian Internet pharmacies required prescriptions and sent genuine medication*, whereas some U.S. online pharmacies did not require valid prescriptions.[26] The earlier GAO report was written, at least in part, by the author of the new GAO report, Marcia Crosse.[27]

In addition to its previous, and more evidence-based report, the GAO might have considered independent analysis published by the Center for Studying Health System Change, funded by the California HealthCare foundation and the Robert Wood Johnson Foundation, which recommends that U.S. states provide their residents with, "A user's guide and price comparison tool for Canada-based or

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[20] U.S. Food and Drug Administration, Department of Health and Human Services, FDA Contract Solicitation Number: FDA-SOL-10-1068201-02; *Internet Monitoring and Support Services*; Contract award date, September 17th, 2010, Contract award dollar amount: $2,571,765.00; see https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=6e179a4b6e9d90bb5696dbfbc2edd065 [Last accessed 10/7/14].

[21] 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*. December 2013, Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI. See 10.1515/bejeap-2013-0085 [Last accessed 9/19/2014].

[22] *ibid*

[23] PharmacyChecker.com (September 30, 2013). *Online Pharmacies May Help Many Afford Prescription Medication Under Obamacare* [Press Release]. See http://www.pharmacychecker.com/news/online_pharmacy_prescription_savings_obamacare_2013.asp [Last accessed 9/20/14].

[24] "FDA: U.S. Generics Can Be a Better Bargain than Canadian Drugs," Associated Press in *St. Petersburg Times Online*, see http://www.sptimes.com/2004/01/18/news_pf/Worldandnation/FDA__US_generics_can_.shtml [Last accessed 9/23/2014].

[25] *Internet Pharmacies: Some Pose Safety Risks for Consumers*, GAO-04-820 (Washington, D.C.: June 17, 2004). See http://www.gao.gov/new.items/d04820.pdf [Last accessed 9/17/2014].

[26] *ibid*

[27] Marcia Crosse is an exceedingly talented and dedicated public servant. Her research and policy analysis have served Congress and the American public well for over 30 years. That Ms. Crosse is responsible for this report was surprising and disappointing. The flawed analysis of the GAO report is mostly a reflection of the legislative and regulatory capture by pharmaceutical commercial interests in this issue area – not Ms. Crosse's dedication and ability, which I admire.

other foreign-based online pharmacies, which would be particularly helpful to consumers who need brand-name drugs."[28]

The GAO could argue that the language of Section1127 neither expressly requests an independent analysis on the issue of online pharmacy safety and usage, nor asks the question whether safe non-U.S. online pharmacies are accessed by and help Americans. Indeed, Section 1127 contained nuanced biases to maintain a narrow line of inquiry favorable to the commercial interests of pharmaceutical and U.S. pharmacy companies. As evidence of that bias the record shows that a government relations advisor and lobbyist working with drug companies and a U.S. pharmacy trade association drafted Section 1127.[29] While this may explain the language of Section 1127 it does not excuse GAO from failing to: 1) consult sources that are not known to be hostile to American consumers buying medication from Canada and other countries, online or otherwise, and 2) engaging in an independent inquiry and analysis.

Even within the biased parameters of inquiry found in Section 1127, the GAO report is not sufficiently responsive. For instance, Section 1127 requests an analysis of "the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet Web sites" – referring to websites that "sell prescription medication in violation of federal and state laws."[30] The industry stakeholders consulted by the GAO have compiled data on this core issue of safety and found not a single example of patient harm resulting from purchasing medication outside the U.S. from international online pharmacies that require a valid prescription.[31] The GAO did not mention those findings, which are specifically responsive to the core issue of safety and lend further evidence that international online pharmacies requiring a prescription are safe.

The GAO report calls into question the appropriateness of the U.S Drug Enforcement Agency's efforts to combat dangerous web pharmacies. The DEA views the Internet as an insignificant source of illegally obtained controlled drugs, and online pharmacies are not a DEA priority.[32] As explained in greater detail below, the problem may be somewhat larger than DEA asserts but GAO appears to defend the position of one of its stakeholders, LegitScript, instead of analyzing the hard data. Specifically, the GAO report

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[28] Tu, Ha T. and Catherine Corey, "State Prescription Drug Price Websites: How Useful to Consumers," *Health System Change Research Brief #1*, February 2008, Center for Studying Health System Change, see http://www.hschange.com/CONTENT/966/ [Last accessed 9/20/14].

[29] Ms. Libby Baney is identified as a lobbyist for the Alliance for Safe Online Pharmacies in this lobbying disclosure report: http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=6B1B406C-D5C0-48C6-9484-B9FF3B372B1F&filingTypeID=51 [Last accessed 10/21/2014]. Ms. Baney, now executive director of the Alliance for Safe Online Pharmacies, is also now principal at FWD Strategies International. In marking her consulting firm Ms. Baney takes credit for drafting Sec. 1127, see http://fwdstrategies.com/services/ [Last accessed 9/20/14].

[30] Pub. L. No. 112-144, § 1127, 126 Stat. 993, 1117-18 (2012).

[31] The Alliance for Safe Online Pharmacies' Response to the U.S. Intellectual Property Enforcement Coordinator's Request for Public Comment on the Development of the Joint Strategic Plan on Intellectual Property Enforcement, August 2012, see http://safeonlinerx.com/wp-content/uploads/2012/08/ASOP-Response-to-IPEC.pdf [Last accessed 12/19/2013].

[32] DEA Agent Robert Hill presentation at the Partnership For Safe Medicines Interchange Conference in October 2010. See http://www.tubechop.com/watch/1046694 [Last accessed 9/20/14].

does not mention the source of the most extensive survey data relating to the nation's prescription abuse problem, which shows 0.2% of prescription narcotic abuse is attributed to the Internet.[33]

Despite the absence of any discussion about safe international online pharmacies in the GAO report, the lead author clearly recognizes that international online pharmacies can be safe, as evidenced by an online video in which Ms. Crosse discusses her report.[34] The key safety issue, according to Ms. Crosse, is that the dispensing pharmacy is "real" and that the patient has a prescription from a licensed health provider. She affirms the safety of personal drug importation when Americans buy online from licensed Canadian pharmacies pursuant to valid prescriptions.[35] In speaking to a consumer who orders from a Canadian online pharmacy, she states that if the patient has "done some kind of verification that it's a Canadian pharmacy, and she knows that the drug she has been receiving is the drug that has been prescribed, that's fine."[36]

Current federal and state laws that curtail access to safe and affordable medication from pharmacies outside the U.S. hurt American consumers. New regulations, executive branch initiatives, and private sector actions are now threatening that access completely. Section 708 of FDASIA gives the FDA new authority to destroy genuine and safe imported medication valued at $2500 or less, but only after creating regulations that allow people an appropriate due process to provide testimony to defend their prescription drug imports.[37] The GAO report mentions section 708 once in a footnote, but does not explore the unintended consequences of seizing and destroying medications imported for personal use.

In a floor statement in 2012 during debate on FDASIA, former Representative Jo Ann Emerson (R-MO) warned her colleagues about similar language to Section 708 that was in an earlier version of the bill: "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."[38]

More recently, Senators Charles Grassley (R-IA), Dean Heller (R-NV), Angus King (I-ME), David Vitter (R-LA) expressed serious concerns about the "potential health threat to hundreds of thousands of Americans" from Section 708.[39] Congressman Keith Ellison wrote the FDA about many of his

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[33] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013. See http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf [Last accessed 9/19/2014].

[34] For the relevant clip of an interview with Marcia Crosse, see *Ask GAO Live: Chat on Internet Pharmacies*, August 12th, 2013 at http://www.tubechop.com/watch/1407272; for the whole discussion, see https://www.youtube.com/watch?v=qzvVK6GhF5Q [Last accessed 9/19/14].

[35] *ibid*

[36] *ibid*

[37] Pub. L. No. 112-144, § 708 (2012).

[38] Representative JoAnn Emerson (MO), "Food and Drug Administration Reform Act." May 30th 2012. See http://votesmart.org/public-statement/702416/food-and-drug-administration-reform-act-of-2012#.UxVJN-co4s9 [Last accessed 9/22/14].

[39] U.S. Senator David Vitter, "Vitter Fights to Keep Prescription Drug Prices Affordable Through Reimportation," July 9, 2014 [press release], see http://www.vitter.senate.gov/newsroom/press/vitter-fights-to-keep-prescription-drug-prices-affordable-through-reimportation [Last accessed 9/20/14].

constituents expressing serious concerns with how Section 708 will impede their access to safe and affordable medication.[40]

Through its Office of the Intellectual Property Coordinator (IPEC), the Obama administration created and encouraged policies and actions affecting access to online pharmacies.[41] One of its focuses is on encouraging the private sector to take "voluntary" actions against rogue online pharmacies.[42] IPEC encouraged the formation of a business consortium, one now established as a non-profit called the Center for Safe Internet Pharmacies (CSIP). While CSIP helps curb access to rogue pharmacies, it also acts to discourage Americans from accessing safe, affordable pharmacies outside the U.S. The CSIP website is largely a clearing house for information from pharmaceutical industry-funded groups such as The Partnership for Safe Medicines, which is funded by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) and led by one of Pharma's vice presidents, and the National Association of Boards of Pharmacy, which runs Internet pharmacy programs that rely on funding from the pharmaceutical industry: an industry that engages in scare campaigns by labeling any pharmacy outside the U.S. that sells to Americans as rogue, thus conflating licensed pharmacies with dangerous pharmacy websites.[43]

Using funds provided by Eli Lilly, Merck, and Pfizer, the NABP applied to the Internet Corporation for Assigned Names and Numbers (ICANN) to operate a generic top-level domain (gTLD) called .pharmacy. The NABP will use the .pharmacy designation to identify any international online pharmacy as a rogue if it sells to people in the U.S. Pharmacies such as Walgreens, CVS, and Rite Aid can expect to obtain permission to register a .pharmacy web address, whereas the safest international online pharmacy will be prohibited from doing so.[44] NABP will launch public education campaigns urging consumers to avoid any drug-selling website that does not have .pharmacy at the end of it, which could scare more Americans away from safe and affordable medication. At the time of this writing, the .pharmacy string has been delegated to NABP, but ICANN is facing pressures from consumer groups and the ICANN community to delay its full implementation.[45]

The "voluntary" protocols encouraged by the Obama administration have now led online and physical "gatekeepers" such as credit card companies, mail carriers and domain registration to deny service to safe international online pharmacies. For example, VISA, a member of CSIP, recently adopted policies in

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[40] Letter to the U.S. Food and Drug Administration by Congressman Keith Ellison dated July 1st, 2014. See http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0504-0022 [Last accessed 9/20/14].
[41] "Obama Seeks Action on Online Pharmacies," *Securing Industry*, September 3, 2010, see http://www.securingindustry.com/pharmaceuticals/obama-seeks-action-on-online-pharmacies-domain-names/s40/a567/#.VB3d-OfD_ml [Last accessed 9/20/14].
[42] *ibid*
[43] Levitt, Gabriel, Statement to the House Judiciary Committee Subcommittee on the Courts, Intellectual Property and the Internet, September 18th, 2013, see http://docs.house.gov/meetings/JU/JU03/20130918/101316/HHRG-113-JU03-Wstate-LevittG-20130918-U1.pdf [Last accessed 10/21/2014]. Also by Gabriel Levitt, "Why is Google Supporting Big Pharma," January 6, 2014, in http://infojustice.org/archives/31846.
[44] According to the NABP's new registration program for .pharmacy gTLD, eligible applicants must have a pharmacy license "in the jurisdictions where they are based and where they serve patients." Since Canadian pharmacies that serve U.S. patients are licensed in Canada but not in a U.S. state they will all be banned from the program. See http://www.dotpharmacy.net/.
[45] "Your 24,349 Signature Petition Had an Impact," October 22, 2014, *RxRights.org*, see http://www.rxrights.org/24349-signature-petition-impact/ [Last accessed 11/6/2014].

coordination with LegitScript that restrict the use of Visa credit cards for prescription sales to U.S.-based consumers to U.S. pharmacies only.[46]

Coordination with gatekeepers is one way to protect consumers from rogue pharmacy websites but it need not and should not affect a consumer's ability to access a safe international online pharmacy. The way to shut down rogue online pharmacies is demonstrated in a series of coordinated federal and global actions called Operation Pangea, which bring together efforts by law enforcement and private industry.[47] According to Interpol's website, Pangea's "activities target the three principal components used by illegal websites to conduct their trade – the Internet Service Provider (ISP), payment systems and the delivery service."[48] Additionally, through Operation Pangea, counterfeiters (people who make counterfeit drugs) and those threatening public health through online drug sales have been arrested and imprisoned.[49]

**The question for lawmakers is this: which online pharmacies should be targeted by FDA and private sector enforcement operations?** A definition of "rogue online pharmacy" that focuses strictly on public health considerations, rather than technical restrictions on personal drug importation and intellectual property law, provides the answer. Those online pharmacies in the business of selling genuine medications, dispensed by a licensed pharmacy and pharmacist that require a patient's prescription should not be considered "rogue." In stark contrast, criminals in the business of intentionally selling fake, spurious, or adulterated medications online, or real prescription drugs without requiring a valid prescription are "rogue." Millions of Americans are buying genuine medications internationally, despite technical legal prohibitions, because they are much lower cost. Stopping them from doing so would be unethical and likely lead to more people becoming sick and dying.[50] Furthermore, actions that are necessary to protect one's health should not be sanctioned as criminal to begin with. Lawmakers should pass legislation to remove criminal penalties (even if they are never enforced) that can be applied to individuals who import small quantities of medication for their own use. Such laws are inimical to our basic rights of life and liberty.

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[46] "VISA Policies Curtail Consumer Access to Safe Medicines Online: Reminiscent of China or North Korea!!" *PharmacyCheckerBlog*, December 4, 2014, by Gabriel Levitt, Vice President, PharmacyChecker.com see http://pharmacycheckerblog.com/visa-policies-curtail-consumer-access-to-safe-medicines-online-reminiscent-of-china-or-north-korea [Last accessed 1/19/2015]. Also see from the Canadian International Pharmacy Association, "Checks are Best When Ordering From CIPA Member Pharmacies," see http://www.cipa.com/news/checks-are-best-when-ordering-from-cipa-member-pharmacies/ [Last accessed 11/10/2014].

[47] Interpol on Operation Pangea: see http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea [Last accessed 9/22/14].

[48] *ibid*

[49] *ibid*

[50] Levitt, Gabriel, "Scare Tactics Over Foreign Drugs," March 24th, 2014, *New York Times*; see http://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html [Last accessed 10/21/2014]. Since cost is noted as the factor most likely to cause an American to skip filling a prescription, it follows that many consumers who rely on safe international online pharmacies will go without needed medications if that option is removed.

# Section 1127 of FDASIA Was Drafted By a Lobbyist for a Pharmaceutical Industry Funded Group

The GAO inquiry into online pharmacies mandated by FDASIA in its Section 1127 was drafted by a lobbyist in the employ of a government relations firm (FaegreBD Consulting) hired by the Alliance for Safe Online Pharmacies (ASOP), a group that is led by Eli Lilly, the National Association of Chain Drugstores and LegitScript. The executive director of ASOP is Libby Baney, who now runs a consulting firm called FWD Strategies International.[51] According to its website, FWD Strategies International "is not just a name; it is what we do – moving your vision forward." In marketing her firm, Ms. Baney notes that one of its services is drafting congressional legislation. As an example of draft legislation, she notes Section 1127 of FDASIA among others relating to online pharmacy.[52]

As evidenced above, it's not surprising that Section 1127 did not encourage the GAO to perform serious research and independent analysis about online pharmacy safety. Instead Section 1127 conspicuously calls for GAO to report on "laws, policies, and activities that would educate consumers about how to distinguish pharmacy Internet web sites that comply with Federal and State laws and established industry standards from those pharmacy Internet websites that do not comply with such laws and standards…" That language represents the "vision" of the founders and funders of ASOP, companies and people with a history[53] of working to curtail access by Americans to lower cost medication from safe international online pharmacies.[54]

# Industry Dominance of "Stakeholders" Consulted by GAO

Some pharmaceutical companies, including many members of the PhRMA, view foreign online pharmacies as a commercial threat because Americans are able to obtain medications at lower prices leading to lower profits.[55] The U.S. pharmacy industry views non-U.S. online pharmacies as unfair competition because the latter can charge lower prices.[56] Many of the groups identified by GAO as stakeholders are drug companies and U.S. pharmacies or groups that they fund, including the following groups:

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[51] Libby Baney is identified as a lobbyist for the Alliance for Safe Online Pharmacies in this lobbying disclosure report: http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=6B1B406C-D5C0-48C6-9484-B9FF3B372B1F&filingTypeID=51 [Last accessed 10/21/2014].

[52] *ibid*

[53] See supra note 50.

[54] Some of ASOP's funders seek extreme actions, such as "delisting," to achieve their goals. Eli Lilly recommends that search engines remove organic results so that Americans can no longer find online pharmacies that are not based in the U.S. See, testimony by Bruce Longbottom, JD, Eli Lilly, Statement to the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, February 27th, 2014, see http://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-Wstate-LongbottomB-20140227.pdf [Last accessed 10/24/2014]. View the actual testimony about delisting here.

[55] Hensley, Scott, "Drug Companies Cry 'Danger' Over Imports," September 22, 2003, *Wall Street Journal*; see http://online.wsj.com/articles/SB106418061476794700 [Last accessed 10/21/2014].

[56] Shepherd, Marv, Impact of Drug Importation on Community Pharmacy and Patient Care, *Journal of the American Pharmacists Association*, Vol. 47, No. 3, (May/June 2007) 319-327.

1. Alliance for Safe Online Pharmacies
2. International AntiCounterfeiting Coalition
3. National Association of Boards of Pharmacy Pharmacies
4. National Association of Chain Drug Stores
5. National Community Pharmacists Association
6. Partnership for Safe Medicines
7. Pharmaceutical Security Institute
8. PhRMA

Of the 35 stakeholder groups identified by GAO, at least 33% (13) are pharmaceutical companies or groups that receive funding by pharmaceutical companies or U.S. pharmacies. Another stakeholder is the Center for Safe Internet Pharmacies (CSIP), as are eight of its member companies. CSIP is a private consortium of businesses formed in response to pressure by the White House Office of the Intellectual Property Enforcement Coordinator,[57] which mostly operates as another voice and information clearinghouse for the other stakeholders listed.[58] Three associations representing U.S. pharmacy boards and pharmacies are listed above.

There are potentially unbiased stakeholders listed in GAO's report, but they are not included as sources of data in the GAO report. The only real consumer organization mentioned as a stakeholder is AARP, but nothing in the report demonstrates that they contributed data or their viewpoint was considered. AARP is on record as advocating the creation of an FDA list of approved Internet pharmacies dispensing prescription drugs from Canada and other countries,[59] as well as recommending PharmacyChecker.com and CIPA as information sources that help Americans find affordable medication from safe international pharmacies.[60]

An important source of data for the GAO is LegitScript. In 2010, LegitScript obtained a contract from the FDA for $2.6 million dollars to help FDA with Internet monitoring of online pharmacies.[61] In turn, with a number of pharmaceutical companies and the National Association of Chain Drug Stores (NACDS), LegitScript funds and is a steering member of the ASOP.[62] The GAO report informs us that CSIP contracts with a third party company to help identify rogue online pharmacies, but conspicuously doesn't mention that the contracted company is LegitScript.[63]

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[57] Supra note 43.
[58] *ibid*
[59] Prepared Statement of AARP, Statement to the Committee on Health, Education, Labor and Pensions, U.S. Senate, May 20th, 2004, S. Hrg. 108-470, see http://www.gpo.gov/fdsys/pkg/CHRG-108shrg93889/html/CHRG-108shrg93889.htm [Last accessed 10/24/2014].
[60] Hochadell, Maryanne, PharmD, BCPS, *The AARP Guide to Pills*, Sterling Publishing Company, 2006.
[61] Supra note 20.
[62] As disclosed on the website of Alliance for Safe Online pharmacies, see http://safeonlinerx.com/about-us/who-we-are/. Earlier versions of ASOP's website showed specifically that LegitScript, Eli Lilly, and the National Association of Chain Drugstores were funders and steering members of the group.
[63] The GAO report reads as follows: "CSIP contracts with a third-party company that proactively searches the Internet to identify rogue Internet pharmacies and disseminates this information to its members. Congress should inquire why GAO did not just identify LegitScript as the "3rd party".

As reviewed in detail below, the NABP, another critical source of data used in the GAO report, represents pharmacy boards. U.S. pharmacy boards, in turn, are staffed and led by U.S. pharmacy owners and executives. The conflicts of interest are clear in that about 50% of pharmacy board members own or work for a retail pharmacy[64]; a group of people that generally view international online pharmacies, and any kind of personal drug importation, as unfair competition.[65]

## History of Online Pharmacies

The Internet has facilitated a major proliferation of *mail-order pharmacy operations.* Mail-order pharmacies are not new; they have served Americans since the late 1800s.[66] Internet pharmacies, often referred to as "online pharmacies," can be defined as *websites that market and sell prescription medication over the Internet that is dispensed by mail-order*. When they began operating in the mid to late 1990s, online pharmacies quickly became a subject of concern for federal regulators and Congress due to dangerous and illicit practices.[67] The NABP created the Verified Internet Pharmacy Practice Sites (VIPPS) in 1999, a voluntary program open to domestic pharmacies to help consumers identify safe online pharmacies.

Drugstore.com, which launched its website in 1999, was considered a first-mover in the industry and an example of a safe online pharmacy without a bricks-and-mortar presence. It required a valid prescription and dispensed medication from a licensed pharmacy. By the beginning of the last decade, most major chain pharmacies were doing business online by taking new and refill prescription orders, and mailing them across the country. Drugstore.com and most but not all online pharmacies associated with major chain pharmacies and Pharmacy Benefit Management (PBM) companies became VIPPS-approved by 2003.

Around 2000, Canadian pharmacies began online marketing to reach American consumers, which provided Americans with access to low-priced drugs. Previously, personal drug importation from Canada was relegated to those living on border-states. This issue also gained public attention through media coverage of bus trips, which brought seniors up to Canada to buy medication and were sometimes sponsored by U.S. politicians supportive of reforming drug importation laws.[68] Canadian pharmacies later began partnering with licensed pharmacies in other countries, [69] such as Australia, New Zealand, and the UK, and later India and Turkey, as well as those in free trade zones. They did so in part to evade

[64] Unpublished Research by PharmacyChecker 2014. We compiled the names and positions of almost all pharmacy board members in the U.S. and found that 50% were working for and/or practicing in U.S. retail pharmacies.
[65] Supra note 56.
[66] C Horgan, B Goody, D Knapp and L Fitterman*, Health Affairs*, 9, no.3 (1990):66-74, The role of mail service pharmacies. See http://content.healthaffairs.org/content/9/3/66.full.pdf [Last accessed 9/23/14].
[67] Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight, GAO-01-69, October 2000. See http://www.gao.gov/assets/230/229781.pdf [Last accessed 9/23/2014].
[68] Pear, Robert, "For Price Break on Drugs, Congress Looks To Canada," *New York Times*, September 9th, 2001. See http://www.nytimes.com/2001/09/09/us/for-price-break-on-drugs-congress-looks-to-canada.html [Last accessed 9/23/2014].
[69] *PharmacyChecker.com*, "Four Canadian Pharmacies Sourcing Drugs from Outside Canada" (July 21, 2004), See http://www.pharmacychecker.com/news/news_072104.asp.

supply restrictions imposed by pharmaceutical companies against Canadian pharmacies, but also to take advantage of even lower drug prices found elsewhere[70] and to increase profits.

In 2002, PharmacyChecker.com began operations to verify both U.S. and foreign online pharmacies – as well as to compare drug prices for consumers seeking the lowest prices for their medications. CIPA was founded that same year. CIPA's vice president testified at a congressional hearing in 2003 entitled: "International Prescription Drug Parity: Are Americans Being Protected or Gouged?"[71] In 2004, the FDA recognized PharmacyChecker.com's efforts to help consumers find the lowest prices and directed people to www.pharmacychecker.com as part of media relations efforts to show that U.S. generic drug prices are lower in the U.S. than in Canada.[72]

While the Internet has enabled millions of Americans to find safe and lower cost medication from outside the U.S., it has also created a public health minefield where dangerous websites posing as safe pharmacies, U.S. and foreign, are accessed every day.[73] Such websites sell fake, adulterated and/or low quality medication, or genuine and safe prescription drugs but without requiring a prescription.[74] These rogue online pharmacies are a serious threat to patient safety and have caused sickness and death.[75]

While too many Americans today have online access to and buy from rogue foreign pharmacies, many are benefiting from safe foreign pharmacies.[76] Americans, including elected officials and public health regulators, know that low-priced and safe prescription medication can be found online internationally. For instance, former Health and Human Services Secretary Kathleen Sebelius adopted a personal drug importation program when she was Governor of Kansas that allowed consumers to find international pharmacies over the Internet.[77] The State of Maine recently updated its pharmacy licensure requirements to permit sales from pharmacies that are licensed in Australia, Canada, New Zealand and the United Kingdom, in effect abolishing state restrictions on personal drug imports from those countries.[78]

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[70] Agovino, Theresa, "Canadian Internet Pharmacies to Sell Medicines from Europe," Associated Press in *USA Today*, April 13, 2004. See http://usatoday30.usatoday.com/news/health/2004-04-13-netpharm_x.htm [Last accessed 9/23/2014].
[71] Supra note 15.
[72] "FDA: U.S. Generics Can Be a Better Bargain than Canadian Drugs," Associated Press in St. Petersburg Times Online. See http://www.sptimes.com/2004/01/18/news_pf/Worldandnation/FDA__US_generics_can_.shtml [Last accessed 9/23/2014].
[73] Mangan, Dan, "Patients Cross Borders for Online Deals on Medication, May 23, 2014, *CNBC*, see http://www.cnbc.com/id/101686424#. [Last accessed 11/22/14].
[74] *CBS This Morning*, "Inside the Dangers of Online Pharmacies," February 9, 2013, see http://www.cbsnews.com/news/inside-the-dangers-of-online-pharmacies/ [Last accessed 11/22/14].
[75] See section below "Patient Harm from Online Pharmcies."
[76] Supra note 18.
[77] "Full Text of Gov. Kathleen Sebelius News Release," *CJ Online*, November 30, 2004, see http://cjonline.com/stories/113004/kan_sebeliustext.shtml [Last accessed 9/23/2014].
[78] *PBS Newshour*, "Maine's Prescription for Drug Safety: Go Foreign," November 9 2013, see http://www.pbs.org/newshour/bb/health-july-dec13-mainerx_11-09/ [Last accessed 11/22/14].

## Why Do Americans Go Online for Medication?

High U.S. drug prices are one of the main reasons that Americans go online to buy medication. As stated previously, according to the CDC, about five million Americans buy medication internationally each year due to high domestic drug prices.[79] The CDC's figures and others identified below show that over the past 15 years, tens of millions of Americans have purchased medication from outside the U.S. using online pharmacies to save money or because they could not afford the prices at their local pharmacies. Fifty million Americans between the ages of 18 to 64 did not fill a prescription in 2012 due to cost, up from 29 million in 2001.[80] The data demonstrates that Americans need international online pharmacies due to a public health crisis of high domestic drug prices.[81]

There are other reasons Americans go online to buy medication besides cost. Online pharmacies offer convenience and anonymity. For some consumers with mobility problems or for those who live in rural locations, ordering online and receiving medication by mail can be very helpful. Others may feel embarrassed about their medical conditions, which are sometimes unintentionally disclosed at their local pharmacy counters,[82] preferring to order privately online.

Unfortunately, some Americans go online seeking medication without first obtaining a prescription from their healthcare providers. Many such people should not be judged. Americans who are uninsured may be unable to afford the medical care necessary to get a prescription and shop from online pharmacies that do not require one. Others just don't want the "hassle" of going to the doctor and getting a prescription. There are obvious and inherent dangers in taking certain medications without first consulting with a licensed prescriber. Additionally, online pharmacies, foreign and domestic, that do not require a prescription are more likely to sell falsified and substandard medication and not ship medication safely.[83]

Growing numbers of insured Americans in the coming years, a result of the Patient Protection and Affordable Care Act, will lead to a decline in medications ordered online without a prescription. However, many newly insured will find that their prescribed medications are not covered by their plans

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[79] Supra note 8.
[80] Supra note 5. .
[81] "Medication adherence: A call for action," *American Heart Journal,* September 1, 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].
[82] Walgreens Strategy Watch, "Study: Walgreens' New Pharmacy Model Increases Risks to Public Health, Patient Privacy and Medication Security," September 23, 2013. See http://walgreenstrategywatch.org/study-walgreens-new-pharmacy-model-increases-risks-to-public-health-patient-privacy-and-medication-security/ [Last accessed 9/23/2014]. For another source: Rudansky, Alex Kane, "Walgreens Accused Of Exposing Customer Health Data," October 24, 2013, *Information Week.* See http://www.informationweek.com/regulations/walgreens-accused-of-exposing-customer-health-data/d/d-id/1112057 [Last accessed 9/232014].
[83] Supra note 21.

and are too expensive to pay for out-of-pocket at a U.S. pharmacy.[84] For some, international online pharmacies are the only route to obtaining needed medication.[85]

Finally, some Americans looking to obtain prescription narcotics without a prescription turn to the Internet, but the prevalence of such purchases are a small part of America's prescription abuse problem.[86] Still, the most serious negative health consequences related to prescription drugs bought over the Internet are from controlled drugs purchased without a valid prescription. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which largely banned online prescribing for controlled substances, was named after 18 year-old Ryan Haight who purchased prescription narcotics from an online pharmacy based in Oklahoma without a valid prescription and died from an overdose.[87]

## Online Pharmacy: Illegal Doesn't Mean Unsafe

The GAO report misconstrues safety and legality in its analysis of Internet pharmacies. The report states: "By violating federal and state laws, rogue Internet pharmacies threaten the public health." For about fifteen years, often in violation of federal and state laws, millions of Americans have safely imported medication ordered online, pursuant to a valid prescription for their own use.[88] [89] As evidenced throughout this report, it's not the violation of federal or state laws that threaten the public health but the actions of rogue pharmacy operators who sell fake or otherwise dangerous medication, or real medication without requiring a prescription.

The facts about personal drug importation are as follows: 1) Through orders placed online, tens of millions of Americans have imported medication from licensed pharmacies that require a prescription over the past 15 years with no reported deaths or serious adverse effects; 2) the practice is technically illegal under most circumstances; 3) there is no evidence that shows personal drug importation of non-controlled medication where a prescription is required is inherently unsafe; 4) according to the FDA, no one has ever been prosecuted for importing small quantities of prescription drugs for personal use.[90]

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[84] Gotlieb MD, Scott, "No, You Can't Keep Your Drugs Either Under Obamacare," December 12, 2013, Forbes, see http://www.forbes.com/sites/scottgottlieb/2013/12/09/no-you-cant-keep-your-drugs-either-under-obamacare/ [Last accessed 11/6/2014].

[85] Supra note 18.

[86] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013. See http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf [Last accessed 9/19/2014].

[87] Flaherty, Mary Pat and Gilbert M. Gaul, "Experimentation Proves Deadly for One Teenager," *Washington Post*, October 21, 2003. See http://www.washingtonpost.com/wpdyn/content/article/2007/06/28/AR2007062801395.html [Last accessed 9/23/2014].

[88] *ibid*

[89] Supra note 25.

[90] "Should You Use an Overseas Pharmacy," *MoneyTalksNews.com*, 2/1/2013. An email written by Christopher Kelly, Center for Drug Evaluation and Research, FDA, states: "FDA is not aware of any actions taken against an individual resulting from their purchase of small quantities of unapproved drugs for personal use." http://www.moneytalksnews.com/2013/02/01/is-it-safe-to-use-an-overseas-pharmacy/, [Last accessed 12/17/2013].

If an American receives a drug ordered online that was dispensed and mailed properly from a licensed pharmacy, it makes no difference from a safety perspective whether the product came from a U.S. or foreign licensed pharmacy, as long as the drug has the right amount of the active ingredient, treats the condition as intended, and is administered in the manner intended by the physician who prescribed the drug. Like those sold in U.S. pharmacies, medications ordered from credentialed international online pharmacies are produced in factories employing Good Manufacturing Practices (GMP) and are distributed, stored, dispensed, and mailed properly. The drugs are the same as or foreign versions of those sold in U.S. pharmacies.

## Patient Harm from Online Pharmacies

Section 1127 requests that GAO report on "the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet Web sites." GAO did not do so. By "such pharmacy Internet Web sites," Section 1127 means online pharmacies that "act in violation of federal or state laws," which under most circumstances would encompass all international online pharmacies, due to drug importation and state pharmacy laws. There are zero incidents of reported deaths or even serious adverse reactions to date from prescription orders obtained from safe international online pharmacies. In contrast, rogue online pharmacies, especially domestic ones, have killed and sickened several people, though even with rogue online pharmacies there have been surprisingly few reported incidents of patient harm.

In a review of patient harm data spanning the years 2001-2012 published by ASOP there were no reports of an American being killed or sickened by medication ordered from an international online pharmacy that required a valid prescription.[91] According to ASOP's research, nine Americans who had purchased either counterfeit drugs or real drugs from websites that *did not require a valid prescription* were sickened or killed. Out of three imported orders, two people were sickened and one died. Six of the nine prescription orders were domestic; four led to death; one to permanent injury and one to temporary illness. Out of the five deaths attributed to online pharmacies between the years 2001 and 2012, four were linked to domestic purchases, three were due to ingesting controlled drugs, and in all instances prescriptions were either not required or issued to consumers who filled out online questionnaires, allegedly reviewed by a licensed prescriber.[92]

Even more striking are the lack of adverse reports of improperly dispensed prescription drugs from international online pharmacies. Between 44,000-98,000 Americans die each year from domestic medication errors[93], including thousands made in U.S. retail pharmacies.[94] Domestic medication errors are a problem that injure and kill Americans on a large scale, in contrast to online pharmacies, rouge or

[91] Supra note 31.
[92] *ibid*
[93] Gianutsos, Gerald, PhD, JD, "Identifying Factors That Cause Pharmacy Errors," December 1, 2009, *US Pharmacist*, see http://www.uspharmacist.com/continuing_education/ceviewtest/lessonid/105916/ [Last accessed 10/7/2014].
[94] Miller, Henry I., "Medication Mistakes Are a Tough Pill to Swallow," Forbes, February 16, 2011; see http://www.forbes.com/sites/henrymiller/2011/02/16/medication-mistakes-are-a-tough-pill-to-swallow/ [Last accessed 10/19/2014].

otherwise, but have received seemingly less critical attention than online pharmacies and personal drug importation from the NABP and NACDS.[95]

The greatest recent tragedies relating to Americans ingesting bad pharmaceuticals are related to the lawful supply chain, and not related to the Internet or personal drug importation. Eighty-one Americans died from tainted Heparin in 2007-2008, made by an American company with bad Chinese pharmaceutical ingredients.[96] Sixty-four Americans died and 751 were sickened from fungal meningitis contracted by U.S.-made tainted steroid injections sold by poorly regulated compounding pharmacies.[97]

## Research and Data about Online Pharmacy Safety

There are only two peer-reviewed studies of foreign and domestic online pharmacies that test drug and online pharmacy safety by comparing those that are members of online pharmacy credentialing programs with others. Their combined findings are published by the B.E Journal of Economic Analysis and Policy in an article called "In Whom We Trust: The Role of Certification Agencies In Online Drug Markets" ["BEJEAP Study"].[98] Its lead author is Roger Bate, an economist and expert on counterfeit drugs with the American Enterprise Institute. The studies strongly indicate that credentialed international online pharmacies are equally as safe as domestic ones: the results showed that they only sell genuine medication, as well as require valid prescriptions.

In the BEJEAP study, through 'mystery shopping' – meaning posing as a consumer making actual purchases from domestic and international online pharmacies – and testing the prescription drugs ordered using a Raman Spectrometer, the authors found that all *credentialed* U.S. and international online pharmacies sell genuine and safe medication and require prescriptions. In contrast, some *non-credentialed* sites sent counterfeit drugs and/or did not require a prescription. The credentialing programs tested were those operated by NABP, LegitScript, PharmacyChecker.com and the Canadian International Pharmacy Association (CIPA). The study classified U.S. online pharmacies with approval by NABP and/or LegitScript as tier 1 sites (8 online pharmacies); non-U.S. online pharmacies with approval by PharmacyChecker.com and/or CIPA as tier 2 sites (22 online pharmacies, all approved by PharmacyChecker.com; 12 of the 22 approved by CIPA); and non-credentialed online pharmacies as tier 3 sites (49 online pharmacies).

*Three hundred and seventy-eight orders of five medications were purchased from credentialed and non-credentialed online pharmacies. All medications ordered from credentialed online pharmacies, foreign and domestic, were genuine and dispensed pursuant to a valid prescription*. Many orders from non-

[95] Even worse, the NACDS defends chain pharmacy practices when confronted with the deadly problem of dispensing errors, asserting that pharmacies should not have to report errors to the government. See "Walgreens Told to Pay $25.8 Million Over Teen Pharmacy Tech's Error," ABC News, March 1, 2010, at http://abcnews.go.com/Blotter/walgreens-told-pay-285-mil-teen-pharmacy-techs/story?id=9977262&page=2 [Last accessed 10/7/2014].
[96] Harris, Gardiner, "U.S. Identified Tainted Heparin in Eleven Countries," April 22, 2008, *New York Times*, see http://www.nytimes.com/2008/04/22/health/policy/22fda.html?pagewanted=all&_r=0 [Last accessed 1/19/2015].
[97] U.S. Centers for Disease Control and Prevention, *Multistate Outbreak of Fungal Meningitis and Other Infections*, Updated October 23, 2013, see http://www.cdc.gov/hai/outbreaks/meningitis.html [Last accessed 1/19/2015].
[98] See supra note 21.

credentialed online pharmacies did not require a valid prescription; however, surprisingly, all products from non-credentialed sites were genuine, too, except Viagra, in which case 23% were not genuine and some contained dangerous ingredients.[99]

The 22 international online pharmacies (tier 2 websites) shown to operate safely in the BEJEAP study – those verified by PharmacyChecker.com – are designated as "unapproved" by LegitScript and "rogue" by NABP.[100] The authors of the BEJEAP study concluded: "If some foreign websites sell safe prescription drugs with substantial price discounts but American consumers are guided to buy from U.S. websites only, the FDA could potentially discourage price competition between U.S. and foreign pharmacies and therefore reduce drug affordability within the U.S."[101] A corollary conclusion is that by discouraging Americans never to use credentialed international online pharmacies, the FDA increases incidents of cost-related prescription non-adherence when U.S. pharmacy prices are the barrier to access.

The BEJEAP report's data was not mentioned in the GAO report and its lead author, Mr. Bate, was not consulted, despite his well-known expertise in this area. Mr. Bate published a book on counterfeit and substandard pharmaceuticals called "Phake: The Deadly World of Falsified and Substandard Medicines". He has consulted the FDA on drug safety, including directly with FDA Commissioner Margaret Hamburg and FDA is aware of Mr. Bate's online pharmacy research.[102]

The lead author of the GAO report participated with Mr. Bate in a series of expert panels organized by the Pew Charitable Trusts Drug Safety Project.[103] Mr. Bate articulated his findings about online pharmacies for the Pew project, specifically noting that pharmacy websites approved by NABP and PharmacyChecker.com, including foreign pharmacies sent only genuine medications.

Unlike GAO's recent report, the 2004 report by GAO also tested products and prescription requirements of online pharmacies. In "Internet Pharmacies: Some Pose Safety Risks for Consumers and are Unreliable in Their Business Practices," the GAO found that Canadian online pharmacies all required a prescription, included proper pharmacy labeling and sold genuine medication.[104] One of that report's authors was Marcia Crosse.[105]

In its 2013 report, the GAO appears to criticize state drug importation programs that, despite FDA warnings that "the agency could not ensure the safety of drugs not approved for sale in the United States," contributed "to a perception among U.S. consumers that they can readily save money and obtain safe prescription drugs by purchasing them from Canada." In this section the GAO seems to indicate that Americans are not able to obtain more affordable and safe medication from Canada when

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[99] *ibid*

[100] I know this because all 22 tier 2 sites were approved by PharmacyChecker.com during the mystery shopping of the researchers, and NABP routinely adds PharmacyChecker.com-approved online pharmacies to its Not Recommended list, as does LegitScript to its Unapproved List.

[101] *ibid*

[102] Verbal communication with FDA Commissioner Hamburg at the Partnership for Safe Medicines Interchange 2011 conference in which the author handed her a copy of Bate's report and she said she recently met with Roger Bate.

[103] Pew Health Group. *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*, See http://www.pewtrusts.org/~/media/Assets/2011/08/12/Pew_Heparin_Final_HR.pdf?la=en [Last accessed 10/19/2014].

[104] Supra note 25.

[105] *ibid*

GAO's own data from 2004, which was derived from mystery shopping and independent analysis, concludes that Americans can and do save money safely when purchasing medication online from Canada. Ironically, it's reasonable to assume that state drug importation programs were pursued in earnest based on findings similar to those of the earlier GAO report or even the actual GAO report itself.

In contrast to the aforementioned peer-reviewed studies and the earlier GAO report, other studies about purchasing medication from online pharmacies focus only on rogue websites, such as those selling prescription drugs without requiring valid prescriptions and/or that don't publish contact information. Not surprisingly, such studies conclude that rogue online pharmacies are dangerous. Those studies may help to understand and demonstrate the dangers presented by Internet drug sales, but do not help in determining which online pharmacies are safe and a clear benefit to consumers.

One such study is called "Internet-Ordered Viagra (Sildenafil Citrate) Is Rarely Genuine."[106] The study is financed and conducted by drug company Pfizer.[107] None of the websites Pfizer assessed required consumers to submit a valid prescription based on a physical exam (but two did require online or "remote" consultations, which is legal in some states). Not surprisingly, the *prescription requirement* assessment concluded that no websites required a valid prescription, meaning based on a physical exam. The costs per pill were between $3.28 and $33.00. The products were shipped from Hong Kong (11 sites), United States (6 sites), United Kingdom (2 sites), Canada (1 site), China (1 site), and India (1 site). Seventy-seven percent of the products received were counterfeit; 18% authentic; 5% foreign generics (generic version approved in another country) that are not approved in the U.S.

The Pfizer study concludes "Internet sites claiming to sell authentic Viagra shipped counterfeit medication 77% of the time; counterfeits usually came from non-U.S. addresses and had 30%-50% of the labeled API [active pharmaceutical ingredients] claim. Caution is warranted when purchasing Viagra via the Internet." While most of these sites were foreign-based, none were credentialed or required a prescription based on an in-person consultation with a licensed prescriber.[108] The incidence of counterfeits received in Pfizer's study appears very high, even compared to other studies that procure medications from non-credentialed online pharmacies.[109] This research, and other studies like it, shows there are many rogue online pharmacies that sell counterfeit Viagra, but it does not negate the existence of safe international online pharmacies.

## Prescription Drug Abuse; Controlled Drugs and the Internet

As reported above, the most severe reports of adverse health outcomes associated with the use of online pharmacies relate to orders placed on foreign and domestic rogue pharmacy websites that sell controlled drugs without a valid prescription. Safe and properly credentialed international online

[106] Campbell, N, JP Clark, VJ Stretcher, I. Goldstein, "Internet-Ordered Viagra (sildenafil citrate) is rarely genuine," PubMed.gov, U.S. National Library of Medicine, National Institutes of Health, August 27, 2012, see http://www.ncbi.nlm.nih.gov/pubmed/22925379 [Last accessed 10/19/2014].
[107] *ibid*
[108] *ibid*
[109] In the BEJEAP study [see supra note 21], for instance, 91% of medicines procured for *non-credentialed* sites, most considered rogue, were surprisingly, genuine.

pharmacies do not sell controlled drugs into the U.S. at all, even pursuant to a prescription,[110] and cannot be considered a cause of prescription drug abuse. To highlight this point, Senator Charles E. Schumer (D-NY) made the distinction clear in discussing a bill introduced in 2006 to combat rogue pharmacy sites selling prescription narcotics: "The bill is geared to domestic Internet pharmacies that sell drugs without a valid prescription, not international pharmacies that sell drugs at a low cost to individuals who have a valid prescription from their U.S. doctors."[111]

According to the DEA, the Internet is a very minor source of illegally distributed controlled prescription narcotics and it informed GAO authors that online pharmacies are a low agency priority. The DEA told GAO that the Ryan Haight Act was successful at deterring illegal sales of controlled drugs over the Internet. The GAO report appears to take issue with DEA's position by citing data from the DEA as evidence that the Internet is a big threat for illegal and dangerous sales of controlled drugs. GAO identified that DEA mystery shopped 10 Internet pharmacies that offered controlled drugs and was able to obtain them without a valid prescription in four out of 10 instances.[112] A selection of only 10 websites that offer to sell controlled drugs without a prescription shows the existence of a problem, but it is insufficient to determine the scope of that problem.

Meanwhile, the GAO report omits any mention of the main source of data on which DEA bases its view that the Internet is an exceedingly minor part of the prescription drug abuse problem. The source is the most extensive survey data relating to the nation's prescription abuse problem administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), a part of the Department of Health and Human Services. Its data shows that .2% of illegal prescription narcotic purchases are made online.[113] This is a decrease from .4% in 2010.[114]

This author agrees that the Internet remains a threat to people who might seek to obtain controlled drugs online without a valid prescription and the DEA and FDA should remain vigilant. However, future legislation that may address the sale of controlled prescription drugs over the Internet should conspicuously avoid provisions that may affect access to or delegitimize safe international online pharmacies.

## Fake Canadian Online Pharmacies

The GAO report correctly identifies the problem of rogue online pharmacies purporting to be Canadian, "when they are actually located elsewhere or selling drugs sourced from other countries." Many rogue

[110] PharmacyChecker.com Verification Program Guide and Standards, version 1.3, 2014, http://www.pharmacychecker.com/verification_program_guide_and_standards_1_3.pdf. See Program Standards for Physical Pharmacies #2. "If dispensing controlled substances within or into a U.S. state, the pharmacy must be registered with the United States Drug Enforcement Administration (DEA)."

[111] Senator Charles Schumer, press release "Schumer Pushes Bill to Crack Down on Illegal Online Pharmacies As New Report Reveals Rampant Prescription Drug Abuse by Teens," June 14, 2006, see http://www.schumer.senate.gov/new_website/record.cfm?id=259624 [Last accessed 10/192014].

[112] Supra note 1.

[113] Supra note 33.

[114] Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, *NSDUH Series H-41, HHS Publication No. (SMA) 11-4658*. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011.

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pharmacy sites include pictures of the Canadian flag, use the word Canada, publish logos and graphics associated with Canada, such as the maple leaf, and even display fake pharmacy licenses with photographs of a fake bricks-and-mortar location. Many such sites are not based in Canada. They are often based in Russia and Eastern European countries and sometimes have ties to organized crime.[115]

In contrast, there are credentialed international online pharmacies, based in Canada, that fill orders through pharmacies in other countries that are not fake Canadian online pharmacies. For example, the oldest and most safe Canadian online pharmacies are actually based in Canada and operate Canadian pharmacies. However, their prescription services have become more global over the past decade by forming prescription fulfillment arrangements with licensed pharmacies in many other countries.[116] Some Canadian pharmacies made these changes because pharmaceutical companies cut off their supplies in an attempt to stop their sales of lower priced medication to Americans.[117] The drug quality tests conducted in the BEJEAP study included prescription drugs ordered from credentialed Canadian online pharmacies that were filled by partner pharmacies in several countries, including Australia, India, New Zealand, Turkey and the United Kingdom.

As presented in this report, the safe international online pharmacies are relatively equal in safety to domestic pharmacies. The fact that the medications are dispensed from pharmacies in several countries does not show lack of safety. After all, the pharmaceuticals sold on U.S. pharmacy shelves are manufactured in about 150 countries.[118] When "American" medications are purchased from Walgreens, CVS, or other U.S. pharmacies, in-store or online, about 80% of the active pharmaceutical ingredients in those medications are foreign; about 40% of the finished medicine products are imported,[119] and about 34% of the medications come from India.[120]

## Are Most "Rogue" Online Pharmacies Really Foreign?

Potentially, the majority of rogue online pharmacies are domestic, yet the GAO report asserts that most rogue online pharmacies "operate from abroad." According to the NABP, of the over 10,181 sites that it calls "rogue":

- 23% have a physical address located outside of the U.S. (though most rogue sites do not post any address)
- 88% do not require a valid prescription
- 60% issue prescriptions per online consultation or questionnaire only
- 49% offer foreign or non-Food and Drug Administration (FDA-) approved drugs

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[115] Krebs, Brian, *Spam Nation*: *The Inside Story of Organized Cybercrime – From Global Epidemic To Your Front Door*, Sourcebooks, Inc., 2014.
[116] Agovino, Theresa, "Canadian Internet Pharmacies to Sell Medicines from Europe," August 13, 2004, Associated Press in *USA Today*: http://usatoday30.usatoday.com/news/health/2004-04-13-netpharm_x.htm [Last accessed 10/21/14].
[117] "Pfizer Cuts Drug Channel to 50 Canadian Pharmacies," August 6, 2003, *Bloomberg News*; see http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aCvq1haSII2E [Last accessed 10/21/2014].
[118] Autor, Deborah M, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, FDA, *Statement to the Committee on Health, Education, Labor and Pensions*; Hearing on "Securing the Pharmaceutical Supply Chain," September 14, 2011, see http://www.fda.gov/NewsEvents/Testimony/ucm271073.htm [Last accessed 10/19/2014].
[119] *ibid*
[120] The figure 33% is based on the following calculation: 86% of prescription medicines dispensed in the U.S. are generic; 40% of generics dispensed are imported from India.

- 16% do not have secure sites
- 41% have server locations in foreign countries
- 12% dispense controlled substances[121]

If 49% of rogue online pharmacies are offering foreign or non-FDA approved drugs then it appears that over half (51%) are selling FDA-approved drugs, which indicates they are based in the U.S. Forty-one percent have server locations in foreign countries, which indicates a clear majority locate their servers in the U.S. Overemphasizing the threat of foreign versus domestic online pharmacies can lead to a misappropriation of resources that does not best serve the public health. For example, as we've identified above, some online pharmacies sell safe and effective medications even when those medications, often due to their packaging, are not technically approved by the FDA. A clear cut example of a safe "foreign" online pharmacy is a licensed Canadian pharmacy selling medication online that requires a prescription from, and does not sell controlled drugs to, Americans. It is not a threat to the public health. In contrast, a U.S.-based website that only sells FDA-approved controlled drugs without requiring a valid prescription is very dangerous. As mentioned in this report, most reported deaths are attributed to online domestic pharmacies selling controlled drugs.

## How Many Americans Are Buying Medication Online from Dangerous Pharmacy Websites?

The GAO report is confusing, lacking clarity and analysis about the numbers of online pharmacy users, reflecting a lack of independent research or scrutiny of available data. GAO states:

> According to a recent survey conducted by the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, nearly one in four adult U.S. Internet consumers surveyed reported purchasing prescription drugs online. At the same time, nearly 30 percent said that they lacked confidence about how to safely purchase medicine online. This is a matter of grave concern as rogue Internet pharmacies may sell products that, among other things, have expired; been labeled, stored, or shipped improperly; and may even be counterfeits—unauthorized versions—of other drugs.[122]

GAO's description of the data presents a more threatening picture than what the FDA's survey actually shows. First, as the agency affirms, the FDA's estimate of Americans using online pharmacies is likely too high because its survey, "did not recruit randomly from the population at large, neither was it weighted to simulate representation from major demographics. As such, the findings from the survey cannot be generalized outside the population of *highly engaged Internet users*" (emphasis added).[123] So there are potentially far fewer Americans buying medication online than the survey suggests.

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[121] National Association of Boards of Pharmacy; "Buying Medicine Online – Internet Pharmacies and You," see http://www.nabp.net/programs/consumer-protection/buying-medicine-online [Last accessed 12-26-2013].
[122] Supra note 5.
[123] FDA Consumer Survey Highlights: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafe

Second, the GAO report omits a crucial finding of FDA's data: while 23% of American adults may have bought medication online, 83% of them buy medication from U.S. online pharmacies "associated with their health insurance."[124] These figures show that at a maximum 4% of Americans are purchasing from online pharmacies not associated with their health insurance. FDA draws the following conclusion: "Approximately 17% reported that they purchased from online pharmacies that were not associated with a local pharmacy or health insurance plan. This behavior may be risky because there are thousands of fake pharmacy websites on the Internet." FDA does not specify why these consumers may be at risk simply because they don't use online pharmacies associated with their health insurance or buy from a local pharmacy when purchasing online. For instance, does the FDA consider it "risky" when an American without health insurance buys from a credentialed U.S. online pharmacy? Such Americans could be buying from Costco.com, for instance, which has low generic drug prices. For those reasons, the number of Americans buying from websites that FDA views as risky may be far less than 4%.

**Some international online pharmacies may not be "risky" according to FDA's survey. FDA's data shows that more Americans import prescription drugs through online pharmacies (21%)[125] than Americans who may be putting themselves at risk (17%).[126]**

FDA asserts that we can't generalize the findings to the whole adult population beyond "highly engaged Internet users." They do not define "highly engaged Internet users," but it's not difficult to extrapolate an approximation of the real numbers of Americans who buy products online. One survey by the Pew Research Center's Internet and American Life Project estimated in 2010 that 52% of Americans have bought a product over the Internet.[127] Applying that percentage to FDA's data to the larger adult population the chart below shows how many Americans are likely buying medications online a) overall, b) legally, c) with risks and d) internationally.

| **Americans Who Buy Medication Online Do So…** | | | | |
|---|---|---|---|---|
| | A. Overall | B. Legally in the U.S | C. From sites that "may be risky" | D. from sites outside the U.S. |
| Percentage<br><br>FDA Survey Findings | NA<br><br>23% of respondents | 83%<br><br>(of the 23% who buy medication online) | 17%<br><br>(of the 23% who buy medication online) | 21%<br><br>(of the 23% who buy medication online) |
| Raw Adult Population Data | 55,248,300 | 45,856,089 | 9,392,211 | 11,602,143 |
| *Adjusted to general population* | *28,729,116* | *23,845,166* | *4,883,950 (2% of adult population)* | *6,033,114 (2.5% of adult population)* |

RxKnowYourOnlinePharmacy/ucm318497.htm: "FDA's Center for Drug Evaluation and Research (CDER) conducted a behavioral assessment survey to understand the knowledge, attitudes and practices associated with purchasing prescription medicine from online pharmacies in May 2012."

[124] *ibid*

[125] FDA Website, Consumer Updates, "Buying Medicines Online? Be Wary, FDA Says," see http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm321121.htm [Last accessed 10/21/2014].

[126] Supra note 123.

[127] Pew Internet and American Life Project, Online Product Research, September 29, 2010; see http://www.pewinternet.org/2010/09/29/online-product-research/ [Last accessed 10/21/2014].

The adjusted data shows 6,033,114 Americans buying medication online from outside the U.S. and 4,883,950 from websites that may be of risk to consumers. That leaves, according to the FDA, 1,149,164 Americans who buy foreign medication online from websites not identified by FDA as risky. Further clarification from the agency is needed to determine this overlap, which indicates that FDA may view certain international online pharmacies as safe, at a maximum, or at least "not risky" at a minimum.

After the noted statistical adjustments of FDA's data, its results are very similar to other much larger independent surveys. In a survey of 33,014 Americans, the CDC reports that about five million Americans buy medication from outside the U.S. due to cost.[128] This figure corresponds well with another survey conducted by Deloitte Center for Health Solutions, which found that 4% of adults *who take prescription medication*, about 5.3 million, purchased medication from outside the U.S.[129] Separately, a Consumer Reports survey estimates that 4.6 million Americans bought medication *online* from outside the country to save money.[130] These three reports all support an estimate of just under five million Americans buying medication online from international sources to *help them afford* prescription medication.

None of the surveys mentioned above show how many Americans are buying medication internationally from online pharmacies without a valid prescription. FDA's data that shows 1,149,164 Americans buy foreign medication online from websites that may not pose risks. That number probably represents a portion of those international prescription sales in which a prescription is known to be required. This number supports the claim by Canadian International Pharmacy Association (CIPA) that its membership serves over one million Americans each year, about ten million U.S patients since 2002.[131] Many, but not all, members of CIPA are also members of the PharmacyChecker.com Verification Program.

A small survey conducted by the Partnership at Drugfree.org –funded by ASOP – concluded that one out of every six American adults – 36 million – have bought medication online without a prescription.[132] The survey questions are not available to the public. It is known that the survey was conducted from November 7 to 10, 2010 by asking 1,015 adults something about online pharmacies. The figure of 36 million Americans must apply to medications purchased online without a prescription at some point in a person's life – *not on an annual basis*. The time horizon could be 15 years, about the time online pharmacies have existed. On an annual basis this is about 2.4 million Americans per year, which may be a reasonable estimate. While the adjusted FDA survey data shows 4,883,950 Americans ordered from online pharmacies *within the last twelve months* that may pose a risk to consumers, it is not clear how

[128] Supra note 8.
[129] Deloitte, 2011 Survey of Health Care Consumers in the United States, Key Findings, Strategic Implications, *Deloitte Center for Health Solutions*; see http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/US_CHS_2011ConsumerSurveyinUS_062111.pdf [Last accessed 10/21/14].
[130] "Best Buy Drugs Prescription Drug Tracking Poll 3," August 10, 2011, *Consumer Reports National Research Center*; see http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/2011-BBD-Rx-poll-public-release.pdf [Last accessed 10/21/2014].
[131] Canadian International Pharmacy Association, "CIPA Fights Rogue Internet Pharmacies Displaying CIPA Seal Without Authorization", October 15th, 2011, see http://www.cipa.com/news/cipa-fights-rogue-internet-pharmacies-displaying-cipa-seal-without-authorization/ [Last accessed 1/19/2015], and see http://www.cipa.com/about/ [Last accessed 10/21/2014].
[132] The Partnership at Drugfree.org, *Thirty-Six Million Americans Have Bought Medications Online Without a Doctor's Prescription* (Washington, D.C.: Dec. 14, 2010), See http://www.drugfree.org/newsroom/thirty-six-million-americans-have-bought-medications-online-without-a-doctor%E2%80%99s-prescription-2, [Last accessed 12-26-2013].

many of them did not require a valid prescription. Members of congress should request clarification from the Partnership at Drugfree.org and FDA on their data.

It is likely that the number of Americans buying medication online without a prescription increased through the 2000s, reaching three to four million people, but now has now started to decline. The explanation for this trajectory is that access to rogue online pharmacies proliferated in the mid-2000s but is now being curtailed due to public education and outreach by NABP, LegitScript, PharmacyCheceker.com, and CIPA, as well as media coverage and health organizations that warn Americans about dangerous pharmacy websites. Research also shows that Google's implementation of vigorous technical blocks of ads by rogue online pharmacies has diminished their visibility.[133]

The BEJEAP report provided the most extensive survey data about online pharmacy shoppers, explaining who is buying medication online, why they buy it online, and what steps they take to protect themselves.[134] The survey was done in conjunction with RxRights.org, a non-profit coalition of seniors' and consumer rights groups, private stakeholders, and approximately 82,000 consumers.[135] Using its newsletter list in 2011 (when it was smaller), RxRights.org asked 20,000 people to participate in the survey.[136] Two thousand nine hundred and seven (2,907) prescription drug purchasers responded to questions about online pharmacies. The final sample was reduced to 2,522 to control for sex, age, and income variables. Of the 2,522 American respondents, less than one percent used only U.S. online pharmacies, 73.8% used only foreign online pharmacies, and 29.94% use both. Of those who use foreign online pharmacies, 92.53% reported lower prices as the reason for doing so. The survey also asked how consumers find online pharmacies. The BEJEAP report states: "Conditional on shopping online, 53.93% use Internet search, 41.11% check with a credentialing agency such as PharmacyChecker.com, 22.62% use personal referrals, and only 12.95% look for the cheapest deal. Consistently, most online shoppers restrict themselves to one primary website, sometimes with supplements from other websites."[137]

The data and analysis above is helpful in understanding the demographics of people who buy medication online, but the findings cannot be generalized to the American population at large. An overwhelming percentage of these people are seeking out international online pharmacies because of high drug prices in America, not to obtain a prescription drug without a prescription. The survey also demonstrates that properly educated consumers who access online pharmacy verification programs successfully protect their health and finances when buying medication online internationally.

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[133] Chesnes, Matthew and Weijia (Daisy) Dai, and Ginger Zhe Jin, "Banning Foreign Pharmacies from Sponsored Search: The Online Consumer Response," April 16, 2014, *FTC Bureau of Economics*, Working Paper Series, Working Paper No. 321, Federal Trade Commission, Washington, DC; see http://www.ftc.gov/system/files/documents/reports/banning-foreign-pharmacies-sponsored-search-online-consumer-response/wp321.pdf [Last accessed 10/21/2014].
[134] Supra note 21.
[135] Communication with Lee Graczyk, head of RxRights.org, dated 10/23/2014.
[136] Supra note 21.
[137] *ibid*

## Laws Governing Online Pharmacies

### Federal laws and drug importation

The only federal law dedicated to regulating online pharmacies is the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which prohibits remote medical consultations (one where the patient is not examined physically by a licensed practitioner) over the Internet toward the prescribing of a controlled prescription drug, except where the provider obtains a special registration from the DEA for such purpose.[138] The law was necessary to deter online pharmacies and healthcare practitioners from prescribing controlled drugs without establishing a valid doctor-patient relationship and to enable successful prosecutions of those who do.

There is no corresponding online pharmacy law for non-controlled prescription medications. However, under the Food, Drug and Cosmetic Act (FDCA) certain medications can only be sold pursuant to a *valid prescription*.[139] States regulate pharmacy and medical practices, resulting in different and sometimes conflicting legal definitions of a valid prescription. In some states such as Hawaii and Utah, a prescription can be valid when based on a remote medication consultation.[140] In contrast, in states such as Indiana "…issuing a prescription, based solely on an on-line questionnaire or consultation is prohibited."[141]

Under federal law, the practice of buying prescription medication from online pharmacies is legal so long as orders are filled with FDA-approved medications pursuant to a valid prescription as defined under state law and dispensed from a licensed U.S. pharmacy. The challenges faced by regulators from foreign online pharmacies that do require a valid prescription and do not offer controlled drugs are related to drug importation and distribution, but not *online pharmacy laws*.

**Drug importation is not illegal**: It is legal but generally not for individuals buying medication for themselves. The political debate about drug importation has created a false dichotomy: those who favor legalizing drug importation and those who oppose it. Most active pharmaceutical ingredients found in local U.S. pharmacy prescription drugs were manufactured overseas. According to FDA Commissioner Margaret Hamburg, 80% of the active pharmaceutical ingredients used in prescription drugs sold in U.S. pharmacies are imported, as are 40% of the finished pharmaceutical products.[142]

There are no federal laws *specifically* banning personal drug importation, either through border crossings or by mail (ordered through online pharmacies).[143] While drug importation is legal, federal

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[138] 21 U.S.C. §§ 802(50)-(56), 829(e), 841(h) (amended by Pub. L. No. 110-425, 122 Stat. 4820 (2008)).

[139] See 21 U.S.C. § 353(b).

[140] Hawaii: See Hawaii Revised Statutes, Chapter 453 - http://www.capitol.hawaii.gov/hrscurrent/Vol10_Ch0436-0474/HRS0453/HRS_0453-.htm. Utah: See Utah Code Ann. ch. 58-83; Utah Admin. Code R156-83-306 - http://www.rules.utah.gov/publicat/code/r156/r156-83.htm.

[141] Federation of State Medical Boards, *Internet Prescribing Language, State-by-State Overview*, Updated February 16, 2012. See http://www.fsmb.org/pdf/InternetPrescribing-law&policylanguage.pdf [Last accessed 9/24/2014].

[142] Statement of FDA Commissioner Margaret Hamburg to the *Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies U.S. House of Representatives*, "President's Fiscal Year 2013 Budget Request for the FDA," February 29, 2012.

[143] Drug importation laws do not ban personal drug importation. Section 801 (d) (1) of the Food Drug and Cosmetic Act bans all importation of prescription drugs manufactured in the U.S. except by the manufacturer. Any drug manufactured in a foreign

laws regulate *who* can do the importing and *which* medications are acceptable. Under the FDCA, medications that are made in the United States and exported can only be reimported by the manufacturer.[144] Foreign-made drugs that are FDA-approved can be imported by wholesalers, retail pharmacies, hospitals, packagers, and, technically, individuals.[145] "FDA-approved" is a designation that is product specific, based on registered manufacturers, manufacturing plants, packagers, pharmaceutical ingredients, formulations, labeling, composition, appearance and color.[146] Essentially, foreign FDA-approved drugs are those manufactured, packaged and labelled for eventual sale in U.S. pharmacies. Those same drugs are packaged and labelled for different country markets as well.

Prescription drugs manufactured, packaged and labeled for eventual sale in Canadian or other foreign pharmacies generally will not meet all FDA regulations and are, therefore, considered **unapproved drugs** by the FDA.[147] When FDA reports that it has seized *unapproved* prescription drug imports for personal use at an international mail facility, those products can certainly be, and often are, legally manufactured, safe and effective medications.[148] In other words, the unapproved drug is a legitimate foreign version of a drug that is approved by the FDA, and often one made by the same manufacturer.

Foreign prescription drugs made in FDA-registered plants where the actual capsule, tablet, inhaler, patch, or other formulation is identical to those sold in U.S. pharmacies are usually considered **misbranded drugs** because the drugs are *labelled* and *packaged* differently. Even these identical products are subject to seizure by FDA when imported by Americans for personal use.

For example, the drug Lipitor was, for years, manufactured by its patent holder, Pfizer, in an FDA-registered facility in Ireland. The same Lipitor was exported for sale to the U.S. and Canadian markets, ending up in retail pharmacies in both countries. The Lipitor exported to the U.S. was packaged to meet FDA labelling guidelines, while the Lipitor exported to Canada was packaged to conform to the requirements of Health Canada's Therapeutic Products Division, Canada's FDA counterpart. Those Lipitor pills sold in Canadian pharmacies would be considered *misbranded* if brought into the U.S. and considered illegal if imported by Americans.

The FDA provides a contradictory position on why personal drug importation is "almost always unlawful." On the one hand, the illegality is due to FDA's lack of jurisdiction over medication sold in other countries; on the other hand it's due to the *potential* unsafety of the medication. The FDA's website states:

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FDA-approved manufacturing could be imported legally by an individual without violating federal law if the drug was packaged and labelled in accordance with FDA standards.

[144] 21 U.S.C. § 381(d)(1).

[145] U.S. Congressional Research Service. *Prescription Drug Importation and Internet Sales: A Legal Overview* (RL32191; January 8, 2004), by Jody Feder, Legislative Attorney, American Law Division, see http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl32191.pdf [Last accessed 9/24/2014].

[146] *ibid*

[147] *ibid*

[148] Girion, Lisa, "Seized Drugs Being Released," *LA Times*, March 1, 2006. See http://articles.latimes.com/2006/mar/01/business/fi-seize1 [Last accessed 9/24/2014].

> 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. For example, if a drug is approved by Health Canada (FDA's counterpart in Canada) but has not been approved by FDA, it is an unapproved drug in the United States and, therefore, illegal to import. FDA cannot ensure the safety and effectiveness of drugs that it has not approved.[149]

According to the FDA's language, the illegality (under most circumstances) of personal drug importation appears to be due to the fact that the agency cannot *ensure* the imported drug's safety and efficacy, not that the drug is unsafe and ineffective. The reasons given by the FDA have more to do with the unknowns of manufacturing, labeling and prescription requirement standards. However, many foreign pharmacies sell prescription medications ordered online that are manufactured, stored and distributed properly and only dispensed pursuant to a valid prescription. GAO's earlier research found that 100% of personal prescription drug imports ordered online from Canada met all aforementioned key safety considerations.[150]

If FDA's position is based on what it can and cannot "ensure" about the safety and efficacy of a drug, it assumes or implies that the agency can ensure the safety for pharmaceuticals sold legally in the U.S. Yet GAO research shows that the FDA may have never inspected thousands of manufacturing plants that legally export pharmaceuticals to the U.S. A Government Accountability Office report from 2010, based on FDA data, found "of the 3,765 foreign establishments in FDA's inventory for fiscal year 2009, there were 2,394 foreign establishments that may never have been inspected by FDA…This is an increase from the 2,133 foreign establishments that may never have been inspected in 2007."[151] Through user-fees paid by generic drug companies, FDASIA has increased FDA's ability to inspect more foreign establishments, which can *improve its ability to ensure* -- but not guarantee drug safety and efficacy – and keep track of those foreign establishments that export pharmaceuticals to the U.S.[152]

Prescription drugs sold from licensed pharmacies in the most regulated and advanced markets are just as safe as those sold in U.S. pharmacies.[153] Thus, medications sold in many foreign pharmacies are just as safe and effective as those sold in U.S. pharmacies whether or not they are "FDA-approved."

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[149] U.S. Food and Drug Administration's website: http://www.fda.gov/aboutFDA/Transparency/Basics/ucm194904.htm [Last accessed 9/29/2014].
[150] Supra note 25.
[151] *Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed*, GAO-10-961. (Washington, DC. Government Accountability Office, September 2010), see http://www.gao.gov/new.items/d10961.pdf (Last accessed November 13th, 2012).
[152] "FDA Favoring DUNS for Manufacturing Plant IDs in FDASIA," October 10, 2013, *ExpertBriefings.com*, see http://www.expertbriefings.com/news/fda-favoring-duns-for-manufacturing-plant-ids-in-fdasia/ [Last accessed November 25, 2014].
[153] Bate, Roger, *Phake: The Deadly World of Falsified and Substandard Medicines*, American Enterprise Institute for Public Policy Research, Washington, DC, Rowman and Littlefield Publishing Group, Lanham, MD, 2012. Also see Ram Kamath, PharmD, and Scott McKibben, *Report on Feasibility of Employee and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies*, Office Of Special Advocate For Prescription Drugs Illinois Department Of Central Management Services October 27, 2003: see

The safety of personal drug importation from online pharmacies includes foreign-approved generic versions, not just brand name drugs. For example, in 2004, FDA reported making undercover purchases of prescription drugs from a pharmacy in Canada. One of the products purchased was called APO-Gabapentin, a generic version of Neurontin, which treats postherpetic neuralgia and epileptic seizures. The FDA stated in a press release:

> Instead of Neurontin, FDA received unapproved drugs called APO-Gabapentin and Novo-Gabapentin. The unapproved drugs purchased through the defendants pose a public health threat because, as alleged in the complaint, FDA cannot assure the safety and efficacy of unapproved drugs.[154]

The FDA's claim is factually tenuous and misleading. FDA communicates that the drugs received were "unapproved" in the U.S. but doesn't mention that they are generic versions of Neurontin approved for sale in Canada. The medications do not pose a *public health threat* because "FDA cannot assure the safety and efficacy of unapproved drugs." The medications were not found to be counterfeit, stored improperly, incorrectly labelled, or substandard. Five months later APO-Gabapentin was approved for sale in U.S. pharmacies.[155]

Since many enforcement problems facing federal regulators in addressing online pharmacies are actually questions of drug importation law, not necessarily safety, it's important to recognize the adverse public health risks of curtailing safe personal drug importation in efforts to crackdown on rogue online pharmacies. The FDA's lack of jurisdiction over the safety of medications sold in Canada and other foreign pharmacies is not a public health basis for curtailing online access to those pharmacies, particularly if they are the only ones Americans can afford.

As the GAO report accurately identifies, federal regulators face obstacles to shutting down foreign online pharmacies operating abroad because they lack jurisdiction in foreign countries. The obstacles are even greater when such foreign online pharmacies are operating legally in their own countries and, more importantly, safely. For example, the FDA cannot shut down a licensed pharmacy in Canada or the United Kingdom that is legally (under Canadian or UK laws) selling prescription medication by mail-order to Americans.[156] While the Canadian government has not helped FDA shut down safe, licensed pharmacies that sell to Americans, it is very active in shutting down dangerous rogue online pharmacies.[157] This type of balanced enforcement, which shuts down and prosecutes dangerous online

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http://www.pharmacychecker.com/pdf/illinois%20report%20drug%20importation%20from%20canada.pdf [Last accessed 10/1/2014]. Also by Ram Kamath, PharmD, and Scott McKibben, *I-SaveRx Safe and Affordable Prescription Drugs – Australia and New Zealand: Recommended Expansion of the Illinois Personal Importation Program*. State of Illinois, see http://www.pharmacychecker.com/pdf/ram-kamath-au-nz-report.pdf [Last accessed 10/19/2014].

[154] U.S. Food and Drug Administration press release from 12/1/2004: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108381.htm [Last accessed 10/1/2014].

[155] U.S Food and Drug Administration Orange Book: See http://www.accessdata.fda.gov/scripts/Cder/ob/docs/obdetail.cfm?Appl_No=075360&TABLE1=OB_Rx [Last accessed 10/1/2014].

[156] For example, several pharmacies in Manitoba, Canada have a license designating them as an *international prescription service* or IPS. Under UK law a pharmacy can have a wholesale and retail license, which permits the export and international dispensing of prescription medication.

[157] Health Canada Press Release, October 4, 2012, "Operation PANGEA V - RCMP and INTERPOL Efforts Result in the Seizure of

pharmacy enterprises, but takes no action against licensed pharmacies in other countries operating safe international mail order pharmacies, should be viewed as the appropriate policy for federal regulators.

## Removing Criminality of (Decriminalizing) Personal Drug Importation

While the FDA has never prosecuted an individual for importing small quantities of prescription drugs for personal use, the law still subjects Americans to the possibility of criminal charges. Technically, an American could be sentenced to one year in prison for importing a foreign-made prescription medication for personal use. The second offense could result in a felony with a prison term up to three years, a $10,000 fine or both. Worse, an American can be sentenced to ten years in jail or fined $250,000 for knowingly *reimporting* a prescription drug for his or her own use.[158] A reimported drug is one made in the U.S., exported to another country and imported back into the U.S.

The criminal penalties for illegal drug importation were created for those who import prescription drugs for resale, not personal use. The relevant statute should be amended to remove criminal penalties for personal drug importation. In conjunction, Congress can create stronger criminal penalties to deter dangerous rogue online pharmacy operators.

FDA's personal drug importation guidance expressly allows the agency's personnel to use their discretion to permit prescription drugs for personal import that are not available for sale in the U.S.[159] Some have interpreted this policy as a greenlight for buying prescription drugs for personal use, in small quantities, at a lower cost from Canadian pharmacies, noting that no Americans have been prosecuted for this practice. However, FDA communicates that the policy only applies to drugs that are not available in the United States (in U.S. pharmacies) and usually those carried, not shipped.

Yet what is more relevant than its guidance about regulatory discretion is FDA's policy of non-enforcement against individuals for illegal personal drug importation, and the fact that about 99% of personal imports reach the consumers awaiting them. Most would agree that these practices have created a "yellow-light" for consumers.

So, unlike the majority of drugs personally imported by Americans, the ones that are in a sense "permitted" under the strictest interpretation of FDA's personal drug importation policy, ironically, are **not approved** for sale in the U.S. The purpose of this policy is to allow Americans treatments that are not available domestically. The same common sense and compassion should extend to medications that Americans can't afford here but can afford at foreign pharmacies, which is why personal drug importation should be decriminalized.

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3.75 Million Units of Potentially Life-threatening Medicines," see http://news.gc.ca/web/article-en.do?nid=698819 [Last accessed 10/1/2014].

[158] 21 U.S.C. § 333(a)(2). *Id.* at §§ 333(b)(1), 381(d)(1). *Id.* at § 332.

[159] Office of Regulatory Affairs, U.S. Food and Drug Administration, *Coverage of Personal Importations*, Regulatory Procedures Manual, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm [Last accessed 10/1/2014].

## State Pharmacy Laws, Regulations, and Conflicts of Interest

To sell prescription drugs in the U.S. a pharmacy must have a license from the state where it operates. Safe international online pharmacies can be viewed as violating state pharmacy laws because foreign pharmacies don't generally have U.S. state pharmacy licenses (with some exceptions mentioned below). Enforcement against foreign pharmacies is exceedingly difficult for state pharmacy boards because they have no authority over pharmacies in other countries and limited budgets.

There are exceptions where state legislatures and governors have expressly permitted personal drug importation. Interestingly, some states, such as Florida[160] and Nevada,[161] have granted licenses to Canadian pharmacies. More recently and influentially, in 2013, Maine's legislature voted to exempt licensed pharmacies in Australia, Canada, New Zealand, and the UK from having to obtain a Maine pharmacy license to dispense medications to Maine's residents.[162] While Maine does not have authority to regulate drug importation, through passage of state law LD 171 it chose to change its pharmacy statute to remove state restrictions on personal drug importation.[163]

Prior to the law's passage, throughout much of the last decade, the City of Portland and various companies in Maine contracted a Canadian company to provide international mail order pharmacy services to their employees.[164] During that time, about a decade, no one was reported hurt or sickened by these imported medicines.[165] Still, in 2012 those programs were shut down by Maine's attorney general at the behest of Maine's Board of Pharmacy, which argued that the foreign pharmacies were not licensed in Maine and therefore could not sell prescription drugs into Maine. By passing the personal drug importation law in 2013, Maine's legislature removed the statutory obstacle to the personal drug importation programs and they have resumed.

The FDA has taken no enforcement action to date against Maine, the City of Portland, or companies helping their employees import lower cost medication from foreign pharmacies. The Pharmaceutical Researchers and Manufacturers of America (PhRMA), the Maine Pharmacy Association and two Maine pharmacists, sued Maine to enjoin the personal drug importation programs and invalidate Maine's law.[166] The case is still pending. PhRMA was dropped from the lawsuit for lack of standing, however the

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[160] Adv Care Pharmacy, located in Toronto, once held an out-of-state Florida Board of Pharmacy license # PH19692. The pharmacy was informed that its Florida license would be closed without cause, see http://ww2.doh.state.fl.us/IRM00PRAES/PRASINDI.ASP?LicId=11979&ProfNBR=2205. The Florida Board of Pharmacy held that it made a mistake in issuing the license in the first place.

[161] The Nevada Pharmacy Board voted to issue out-of-state pharmacy licenses to Canadian pharmacies in 2006: See http://bop.nv.gov/uploadedFiles/bopnvgov/content/board/ALL/2006_Meetings/2006-03-01_02_MeetingDocs_BOP.pdf [Last accessed 10/2/2014].

[162] Maine Legis. Serv. Ch. 373 (S.P. 60) (L.D. 171); see http://www.mainelegislature.org/legis/statutes/32/title32sec13731.html [Last accessed 10/1/2014].

[163] Charles Ouellette et al., plaintiffs v. Janet Mills, et al. Civil 1:13-cv-00347-NT, filed May 5th, 2014: see http://www.med.uscourts.gov/Opinions/Torresen/2014/NT_05152014_1_13cv347_Ouellette_v_Mills.pdf [Last accessed 10/1/2014].

[164] "Maine's Prescription for Drug Savings: Go Foreign," *PBS NewsHour*, December 31st, 2013; see http://www.pbs.org/newshour/bb/health-july-dec13-drugs_12-31/ [Last accessed 10/1/2014].

[165] *ibid*

[166] Chidi, George, "Maine Sued by Big Pharma Because It Won't Stop Foreign Drug Imports," *Raw Story*, November 9, 2013: see http://www.rawstory.com/rs/2013/11/09/maine-sued-by-big-pharma-because-it-wont-stop-foreign-drug-imports/ [Last accessed 10/1/2014].

court granted standing to the Maine pharmacists for reasons related to commercial injury but not safety.[167] In its ruling the Maine court noted that plaintiffs did not show any harm done to Maine residents from their past purchase of foreign drugs.[168]

On behalf of state pharmacy boards, the National Association of Boards of Pharmacy (NABP) is the fulcrum for action regarding online pharmacies, and the organization was a critical source of information for the GAO report. The NABP has been active in tackling the issue of online pharmacies since the emergence of the industry. In 1999, NABP created its VIPPS program as a voluntary program to which online pharmacies can apply. Members are able to publish the VIPPS seal of approval, thereby identifying them as safe and lawful online pharmacies. From the program's inception, Canadian pharmacies that sold to Americans were not eligible for VIPPS certification.

As mentioned in this report, opposition to personal drug importation by U.S. pharmacies and their owners is explained by the threat of price competition from foreign pharmacies, as well as safety concerns about foreign drugs.[169] According to the National Association of Chain Drugstores (NACDS), U.S. pharmacies and pharmacists are commercially disadvantaged when Americans buy medication outside the country when they could do so locally.[170]

The NABP's website states that it is an "independent and impartial" organization, but its leadership, affiliations and funding sources cast serious doubt on that assertion. The NABP, like its member pharmacy boards, are governed by owners and executives of U.S. pharmacies. In this case, many pharmacy board regulators, those who own or work in U.S. pharmacies, have a financial incentive to prevent Americans from buying medication outside the U.S. For example, the NABP's current president has been an employee of the Walgreens Corporation since 1977.[171]

State pharmacy boards are often led by pharmacists and pharmacy owners. As business people, they are understandably concerned about price competition from lower priced foreign pharmacies. In 2013, over 50% of state pharmacy board members worked in or owned pharmacies.[172] U.S. pharmacy boards have been cited for serious conflicts of interest and for the dominance of leadership positions held by employees of the largest chain pharmacies, such as Walgreens, Rite Aid, CVS, and Walmart.[173] The largest pharmacy trade association, the National Association of Chain Drugstores (NACDS), has for over a

[167] Supra note 163.
[168] *ibid*
[169] Supra note 56.
[170] For well over a decade, U.S. pharmacies have lobbied against personal drug importation, such as through the National Association of Chain Drug Stores (NACDS). NACDS's government affairs VP asserted in congressional testimony: "Legitimate pharmacies in the U.S. lose business each time a consumer buys from a drug importer rather than visiting their local pharmacies," in a letter to John Morrall, Officer of Information and Regulatory Affairs, OMB, from S. Lawrence Kocot, Senior Vice President and General Counsel, NACDS, dated May 28th, 2002.
[171] As of October 1, 2014, Joseph L. Adams, a Walgreens employee, is the president of NABP.
[172] Supra note 64.
[173] McCoy, Kevin, "Chains' Ties Run Deep on Pharmacy Boards," *USA Today*, December 31, 2008; see http://usatoday30.usatoday.com/money/industries/health/2008-12-30-pharmacies-boards-mistakes-prescriptions_n.htm [Last accessed 10/1/2014].

decade opposed personal drug importation and its leadership has testified before Congress about unfair commercial competition from foreign pharmacies.[174] [175]

It's understandable that American pharmacists are frustrated by Americans accessing lower cost foreign pharmacies with which they can't compete. Price competition and even employment losses, however, do not obviate the ethical imperative of the U.S. pharmacy community and their business and trade associations to impartially assess online pharmacies, their safety and cost.

A decade ago, large chain pharmacies, such as CVS and Walgreens, voiced support for reforming drug importation laws to facilitate *wholesale* importation of foreign prescription drugs to bring down drug costs. [176] Thomas Ryan, the former CEO and Chairman of CVS, stated:

> While many in our industry believe that importation is a fundamentally flawed concept and oppose it without exception, I have come to a slightly different view… Millions of Americans already have opted to import drugs because they can't afford not to. We owe it to them to face this issue head on and not look the other way.[177]

Today, Mr. Ryan's position often goes ignored by U.S. pharmacy groups and their appointed leaders, but the need for drug importation legal reform has never been greater.[178] In contrast to personal drug importation, new wholesale drug importation regulations, as advocated by CVS and Walgreens a decade ago, would permit lower cost foreign-made prescription drugs into our formal supply chain. (These would be drugs sold in U.S. pharmacies, not purchased directly from foreign pharmacies, and a worthy policy goal, but laden with safety and economic considerations outside the scope of this analysis).

For well over a decade, the NABP has been very active in advocating against personal drug importation as a means to lower drug prices, both as currently practiced by individual Americans and through the reform of importation laws to formally legalize personal drug importation.[179] In a 2005 hearing before the Senate Health, Education, Labor and Pensions Committee, NABP Executive Director, Carmen Catizone testified: "If the illegal importation of drugs into the U.S. is allowed to continue unabated, the impact on patient safety will be devastating."[180] As demonstrated above, after ten years since Mr.

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[174] Supra note 170.

[175] "Senate Defeats Personal Importation Bill," *Drug Topics*, October 24, 2011, see http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/senate-defeats-personal-importation-bill?page=full [Last accessed 10/2/2014].

[176] Representative Rahm Emanuel (IL), "Emanuel Statement: Applaud CVS, Walgreens for Support of Prescription Drug Importation," May 6, 2004, Washington DC, see https://votesmart.org/public-statement/45467/emanuel-statement-applaud-cvs-walgreens-for-support-of-prescription-drug-importation#.VDP88OfD-FE [Last accessed 10/7/2014].

[177] "CVS Chairman: Legalize Prescription Drug Imports," Associated Press, in *USA Today*, May 5th, 2004. See http://usatoday30.usatoday.com/news/washington/2004-05-05-drug-importation_x.htm [Last accessed 10/7/2014].

[178] The need is greater because drug costs are increasingly a barrier to accessing medication at U.S. pharmacies. See supra note 5 for the relevant data from the Commonwealth Fund.

[179] National Association of Boards of Pharmacy, Press Release, "NABP Urges Enforcement of US Drug Laws; New Bill Supporting Drug Importation Threatens Patient Safety," February 27, 2003: see http://www.nabp.net/news/nabp-urges-enforcement-of-us-drug-laws-new-bill-supporting-drug-importation-threatens-patient-safety [Last accessed 10/7/2014].

[180] Catizone, Carmen, Statement to the *Committee on Health, Education, Labor and Pensions*; Hearing on "Examining the Realities of Safety and Security Regarding Drug Importation," February 16, 2005, see http://www.gpo.gov/fdsys/pkg/CHRG-109shrg98923/html/CHRG-109shrg98923.htm [Last accessed 10/7/2014].

Catizone's dire warning, the impact on patient safety has not been *devastating*. To the contrary, while problems persist due to rogue websites, the facts show that personal drug importation through safe international online pharmacies has helped millions of Americans afford needed medications, despite the illegality.

The NABP receives large amounts of funding by drug companies. Among its publicly known funders are Pfizer, Merck, and Eli Lilly[181] , and NABP's financial holdings include substantial stockholdings in drug companies, U.S. chain pharmacies and wholesalers. NABP's executive director earns about $680,000 in annual compensation,[182] – over 1000% above the average salary of executive directors of non-profits in America.[183]

Launched with a grant from Pfizer, NABP started the Internet Drug Outlet Identification Program to create a "Not Recommended" list of online pharmacies, all of which are considered "rogue".[184] NABP does not discern between a licensed Canadian pharmacy that sells to Americans online pursuant to a valid prescription and a rogue online pharmacy (such as one that sells prescription narcotics without requiring a prescription), but classifies them both as rogue.[185] In addition to funding the NABP, the largest pharmaceutical companies fund the NACDS, a practice that has received intense criticism from lawmakers due to lack of transparency and potential conflicts of interest.[186]

State laws usually preclude the sanctioned personal import of prescription medication. However, the current system in which regulators, pharmacies and their trade groups create programs, policies, and laws governing online pharmacies cannot be viewed as impartial for the reasons identified above.

## History of Google and Online Pharmacies: Learning the Right Lessons

The GAO report mentioned investigations and prosecutions of companies that provide services to online pharmacies, referred to as "gatekeepers," as another method of deterring rogue online pharmacies. The most well-known of these investigations led to Google's $500 million forfeiture in 2011, after the company signed a non-prosecution agreement (NPA) with the U.S. Department of Justice, which found

[181] Website of the National Association of Boards of Pharmacy: https://www.nabp.net/programs/pharmacy/pharmacy-and-nabp/coalition-support [Last accessed 10/7/2014].
[182] See NABP tax filing for 2010, 2011 form 990 and NABP tax filing for 2013.
[183] Pay Scale, Human Capital, Executive Director Salary Data: see http://www.payscale.com/research/US/Job=Executive_Director,_Non-Profit_Organization/Salary [Last accessed 10/7/2014].
[184] National Association of Boards of Pharmacy press release, "NABP Names 79 Internet Drug Outlets Operating in Conflict with Patient Safety and Pharmacy Practice Standards," see https://www.nabp.net/news/nabp-names-79-internet-drug-outlets-operating-in-conflict-with-patient-safety-and-pharmacy-practice-standards, [Last accessed 12/17/2013].
[185] "NABP Report Lumps Real and Rogue Pharmacies Together," *RxRights.org*, November 14th, 2014, see http://www.rxrights.org/nabp-report-lumps-real-and-rogue-pharmacies-together/ [Last accessed 10/7/2014]. Also, see the position of Peter Maybarduk, Public Citizen's Director of Access to Medicines Program: http://www.citizen.org/PC-to-ICANN-Do-not-let-big-Pharma-contro-internet-domains [Last accessed 10/7/2014].
[186] Letter from Senator Charles Grassley (IW), Ranking Member, Senate Judiciary Committee, to Steven C. Anderson, President and Chief Executive Officer of the National Association of Chain Drug Stores: see http://www.grassley.senate.gov/sites/default/files/about/upload/2011-05-04-CEG-Letter-to-National-Association-of-Chain-Drug-Stores.pdf [Last accessed 10/7/2014].

the company allowed certain kinds of dangerous online pharmacies to advertise.[187] The $500 million *forfeiture* – not a criminal fine or civil monetary penalty – was calculated by adding ad revenues and sales made by Google and, allegedly, "Canadian" online pharmacies, respectively, from the advertising and sale of *controlled* prescription drugs without a prescription (such as OxyContin, Vicodin, Valium, Adderall, and Xanax), but not advertisements by credentialed international online pharmacies for **non-controlled** prescription drugs, such a Abilify, Celebrex, Crestor, Lexapro, Lipitor, Plavix, Pradaxa, Seroquel, Singulair, Victoza, and Zoloft.

The GAO report did not mention that under the NPA Google agreed to ban all licensed non-U.S. pharmacies, including Canadian pharmacies that require a prescription and do not sell controlled drugs into the U.S., from advertising on Google's search marketing programs that target U.S. consumers. Roger Bate, lead author of the BEJEAP report, wrote in a separate article:

> What is most distressing about the Google agreement is that Google's earlier policy was actually optimal from a health standpoint. All domestic and foreign sites advertising on Google were supposed to be vetted by PharmacyChecker.com, an independent credentialing organization. My research team's sampling of drugs (published in the peer-reviewed literature) found that none of the sites approved by PharmacyChecker.com sold poor quality medicines even though they advertised lower prices than U.S. firms, and were all based overseas. But poor enforcement by Google led to advertising from web entities that were not credentialed by phamacychecker.com, some of which probably sold substandard and counterfeit medicines. Because of this poor oversight, officials concerned with promoting public health were right to challenge Google's weak enforcement of its policy.[188]

Reputable Canadian and other international online pharmacies, those that legitimately advertised on Google prior to its policy changes, remain banned from advertising on Google, as well as the other major search engines, due to government pressure, if not coercion.[189] Lawmakers should consider encouraging policies to reverse that ban.

## How to Shut Down Dangerous Rogue Online Pharmacies without Curtailing Online Access to Safe and Affordable Medication

Targeted and effective government enforcement, and private voluntary actions against rogue online pharmacies, need not interfere with the safe provision of low-cost medications from international online pharmacies. National and international actions conducted via annual campaigns entitled 'Operation Pangea' have successfully shut down and blocked thousands of rogue online pharmacies without

[187] Bate, Roger, "Google's Ad Freedom Wrongly Curtailed," September 28, 2011, *RealClearMarkets.com*, see http://www.realclearmarkets.com/articles/2011/09/28/googles_advertizing_freedom_is_curtailed_99281.html [Last accessed 10/19/2014].
[188] *ibid*
[189] *Ibid*

shutting down safe international online pharmacies.[190] In Pangea, FDA cooperates with Interpol and other criminal enforcement agencies by alerting Internet service providers, domain registrars, and other online gatekeepers (see discussion below on gatekeepers) about suspect websites. The agencies also conduct enhanced surveillance at international mail facilities, where prescription orders are seized, as well as initiate the seizure and take downs of rogue online pharmacies through court orders.[191]

The most thorough and legalistic takedown actions against rogue online pharmacies are by order of a court of competent jurisdiction. Such court orders are obtained and used by FDA's Office of Criminal Investigations. In Pangea VI, the FDA, in its public relations, focused on the takedowns of three rogue online pharmacies that were clearly fraudulent in pretending to be websites operated by popular U.S. chain pharmacies.[192]

**U.S. consumers attempting to go to the following three websites will view a screen that notifies them about the court order and seizure: http://www.canadianhealthandcaremall.com/, http://www.walgreens-store.com, http://www.c-v-s-pharmacy.com.**


Creating a rational but expedited system for obtaining court orders to shut down rogue online pharmacies will provide a pathway that respects due process of law, Internet freedom principles, and access to affordable medicine.

[190] U.S. Food and Drug Administration, press release, "FDA takes action to protect consumers from dangerous medicines sold by illegal online pharmacies, June 27th 2013; see http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358794.htm [Last accessed 10/21/2014].
[191] *Ibid*
[192] *Ibid*

As a federal contractor, LegitScript can (and may currently) serve a valuable investigative role for the FDA in its efforts to identify and monitor rogue online pharmacies and their activities, particularly because its classification system does not conflate safe international online pharmacies with rogue online pharmacies.

## Prioritize Online Pharmacy Enforcement Targets: Properly Defining "Rogue Online Pharmacy"

As explained above, the GAO report's use of the phrase "rogue Internet pharmacy" is at times inaccurate and wrongly identifies safe international online pharmacies as "rogue." Additionally, the GAO report inaccurately communicates that "The Food and Drug Administration Safety and Innovation Act enacted in 2012 required that we report on problems posed by 'rogue' Internet pharmacies."[193] There is no mention of the word "rogue" or the term "rogue Internet pharmacy" in FDASIA. The GAO report included the positions of, and research conducted by, the NABP and LegitScript, but misrepresents or misunderstands critical distinctions in how they classify online pharmacies. GAO's stakeholders, NABP and LegitScript, have conflicting classification systems when it comes to defining "rogue online pharmacies." For lawmakers and regulators to prioritize and identify the right targets for enforcement actions to protect the public health it is critical to properly define this phrase, as it's so commonly misapplied.

NABP's classification system does not accurately describe the scope of online drug sales because it groups safe international online pharmacies together with dangerous ones in a category called "rogue." As discussed above, the NABP designates any online pharmacy that is based outside the U.S. and sells to Americans as "rogue," regardless of its safety credentials. This misleading classification blurs the clearly distinguishable lines between dangerous rogue pharmacy practices and safe international online pharmacy services.

In contrast, LegitScript does distinguish between safe international online pharmacies and rogue online pharmacies. Like the NABP, LegitScript's program does not "approve" international online pharmacies that sell to consumers in the U.S., regardless of their credentials. However, safe international online pharmacies are *not* classified as "rogue" by LegitScript.com. Instead, safe international online pharmacies, such as those approved by PharmacyChecker.com, are generally categorized as "unapproved." While the "unapproved" designation may scare consumers who are seeking safe and affordable medication away from a safe online pharmacy, it does distinguish safe international online pharmacies from "rogue online pharmacies."

The GAO's report inaccurately describes LegitScript's classification terms, which may cause its readers to miss these critical distinctions. GAO writes that LegitScript classifies Internet pharmacies into one of four categories: "(1) legitimate, (2) not recommended, (3) rogue, (4) pending." LegitScript does not have a category called "not recommended," which is a category used by the NABP to mean "rogue." In fact LegitScript is explicit that "unapproved" online pharmacies are <u>not</u> rogue:

[193] See supra note 1.

> "Unapproved" Internet pharmacies are those for which LegitScript has verified some lack of compliance with LegitScript's international Internet pharmacy verification standards or applicable laws or regulations but that do not meet the definition of being 'rogue.' [194]

Further, a "lack of compliance" may have nothing to do with safety but could refer to technical violations of drug importation laws (i.e. personal drug importation from licensed pharmacies that require valid prescriptions). Under this classification system, a Canadian online pharmacy could meet the highest safety standards, and be safer than a U.S. pharmacy, and still be "unapproved" if it dispenses to consumers in the U.S.

The examples of rogue online pharmacies found in the GAO report explicitly demonstrate its failure to distinguish between safe and dangerous online pharmacies. In Figure 3, page 28, the GAO report shows a picture of the home page of an online pharmacy called CanadaDrugs.com. The GAO report reads: "Figure 3: Screenshot of a Rogue Internet Pharmacy Website That Received a Warning Letter from FDA in 2012 as Part of Operation Pangea". Unlike a rogue online pharmacy, CanadaDrugs.com meets very high standards of pharmacy practice and is approved in the PharmacyChecker.com Verification Program, a member of the Canadian International Pharmacy Association, two of the credentialing agencies cited by experts for using quality standards.[195] LegitScipt classifies CanadaDrugs.com as "unapproved" not "rogue".[196]

CanadaDrugs.com has operated a pharmacy in Canada selling medications internationally for almost 15 years. It is licensed by the Manitoba Pharmaceutical Association as an International Prescription Service.[197] CanadaDrugs.com has sold safe and effective medications to millions of consumers without any reported problems. It did not receive a warning letter from the FDA because it is a "rogue" site, but because the FDA decided to use its enforcement authority to cite CanadaDrugs.com for selling certain foreign, but legal and genuine, versions of medications to individuals in the U.S. that are considered unapproved and/or misbranded when personally imported.[198] FDA could have sent a similar warning letter to any safe online pharmacy based outside the U.S. that sells prescription medication into the U.S. The letter also warned CanadaDrugs.com that it was selling Domperidone, which is no longer approved in the U.S., but is approved in many other countries. CanadaDrugs.com removed that medication from its website.

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[194] LegitScript Internet Pharmacy Certification Standards. See https://www.legitscript.com/pharmacies/standards [Last accessed 10/7/2014].

[195] Safe international online pharmacies, such as ones approved in the PharmacyChecker.com Verification Program, fill orders with licensed pharmacies, require valid prescriptions, publish accurate mailing address and phone number, encrypt web pages on which personal and financial information is transmitted online, and do not share a customer's information with third parties. See http://www.pharmacychecker.com/sealprogram/choose.asp [Last accessed 10/7/2014].

[196] See http://www.legitscript.com/pharmacy/canadadrugs.com [last accessed 6/25/2014].

[197] Manitoba Pharmaceutical Association, License# 32195 International Prescription Service: see http://mpha.in1touch.org/company/roster/companyRosterView.html?companyRosterId=5 [Last accessed 10/7/2014].

[198] U.S. Food and Drug Administration Warning Letter to CanadaDrugs.com, 9/21/2012; see http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm321068.htm [Last accessed 11/13/2014]. http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm321068.htm.

It is likely that CanadaDrugs.com was wrongly labeled a "rogue" in the GAO report because its owner is a target of an FDA investigation over his alleged involvement -- through other companies he operated – in the wholesale importation of counterfeit Avastin that was given to patients in U.S. medical clinics.[199] Avastin was not sold by the website CanadaDrugs.com. Imported and domestically sold counterfeit medications are a serious threat to the public health, especially counterfeits of life-saving products. FDA resources are rightly and efficiently expended on criminal investigations to protect the U.S. drug supply from counterfeit drugs. However, the existence of wholesale businesses responsible for distributing the counterfeit Avastin does not mean that CanadaDrugs.com is not a safe international online pharmacy. Christopher Weaver of the Wall Street Journal wrote, "There is no indication that fake medicines were sold through the company's consumer-focused website, CanadaDrugs.com."[200]

The GAO report provides examples of two other sites, which appear to be actual "rogue" online pharmacies. AllMedsPharmacy.net advertised the sale of prescription drugs without a prescription. According to the FDA, the site was found selling counterfeit and misbranded drugs, as well as controlled substances to Americans.[201] Interestingly, the site is still operating and appears to have revised its policies to require a prescription.

The other "rogue" online pharmacy identified in the GAO report is called NewPharm.net. Its operators plead guilty to smuggling counterfeit and misbranded drugs into the U.S., including selling controlled substances, specifically Meridia, without a valid prescription. Unlike AllMedsPharmacy.net, NewPharm.net ostensibly required a prescription but it was one based on a "free doctor consultation" offered by the online pharmacy itself. In the investigation, federal agents purchased prescription medications without a valid prescription; the products often came from China or India, and the sellers intentionally hid the ingredients of the packaging. The GAO report noted, "Laboratory results of drug samples purchased by federal agents revealed that the drugs were not genuine versions of the approved drugs that they purported to be."[202] It's difficult to discern exactly what this means in terms of drug quality and safety but it indicates that the website's operators were committing fraud by fooling consumers into thinking they were buying a certain brand product when they were not. (The actual product may have been a genuine generic version from another country).

A cursory evaluation of CanadaDrugs.com by GAO should have led its authors to conclude that it was fundamentally different from the other two sites mentioned, due to its verifiable licensure, long history of pharmacy safety, and transparency. Indeed, CanadaDrugs.com could be used as a good example of why millions of Americans have benefited for many years from lower cost medications from other countries.

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[199] Weaver, Christopher, "FDA Warns of New Batch of Fake Cancer Drug," *Wall Street Journal*, February 6, 2013, see http://online.wsj.com/news/articles/SB10001424127887324900204578286483013578190?mg=reno64-wsj&url=http%3A%2F%2Fonline.wsj.com%2Farticle%2FSB10001424127887324900204578286483013578190.html [Last accessed 10/7/2014].
[200] *Ibid*
[201] See supra note 1.
[202] *Ibid*

A proper and practical definition of "rogue online pharmacy" is *a drug-selling website that intentionally sells fake, adulterated, or unlicensed medication; genuine and regulated medication that is not dispensed by a licensed pharmacist and/or pursuant to a valid prescription; or engages in fraud.* That definition focuses on the combined factors of public health protection, domestic legal compliance (where the products is dispensed from), and access to affordable medication. Under that definition, an online pharmacy is not a rogue if it meets all the criteria below:

- Requires a valid prescription
- Publishes verifiable and truthful contact information
- Fills orders through licensed pharmacies
- Sells regulated medications, produced under GMP
- Dispenses prescription orders via licensed pharmacists
- Takes reasonable measures to protect personal and financial information

In contrast, a "rogue online pharmacy" does one or more of the following:

- Doesn't require a prescription
- Doesn't publish verifiable or truthful contact information
- Doesn't fill orders through licensed pharmacies
- Doesn't sell regulated medications (this would encompass counterfeit drugs)
- Dispenses prescription orders via unqualified personnel
- Doesn't protect personal and financial information

Using the definition and guidance above, lawmakers and regulators have a clear roadmap to identify those online pharmacies operating domestically and abroad that endanger the public health and those that do not.

## The Online Gatekeepers

Search engines, domain registrars, credit card companies and payment processors have the ability to shut down or more significantly curtail access to dangerous rogue online pharmacies (or any company operating online) by prohibiting service to them. They are sometimes referred to as "Gatekeepers." Cooperation among such companies through CSIP, and in collaboration with government agencies, already curtails access to rogue online pharmacies by preventing them from advertising on search engines, suspending domain registrations by registrars, and preventing their use of merchant accounts so they can't offer customers credit card processing.[203] Unfortunately, such actions have already overreached to affect safe international online pharmacies. Safe international online pharmacies are banned from advertising on major search engines, as noted in the Google case, are having difficulty

[203] CSIP identifies its voluntary principles for refusing service to pharmacy websites: http://www.safemedsonline.org/wp-content/uploads/2014/03/CSIP-Principles-of-Participation.pdf. Under this policy, safe international online pharmacies are potentially subject to refusal of service.

finding credit card processing due to new online pharmacy restrictions by VISA,[204] and some have had their domains actually locked by registrars.[205]

### Search Engines

In February of 2010, Google banned non-U.S. pharmacies, including safe international online pharmacies, from advertising on its U.S. search marketing programs; began requiring NABP-approval to be a pharmacy advertiser;[206] and, just prior to its policy changes, implemented new technical solutions for blocking rogue online pharmacies.[207] Until that time, Google's policies allowed safe international online pharmacies approved by PharmacyChecker.com to advertise, but did too little to effectively block advertising by rogue online pharmacies, domestic or foreign, that were not approved by PharmacyChecker.com.[208] Google's ban on international online pharmacy advertisers "includes foreign sites selling safe drugs to patients with valid prescriptions."[209] The best policy for public health is to maintain the strict block on rogue online pharmacies but remove the ban against safe international online pharmacies.[210]

Some pharmaceutical companies are now calling for the removal of all non-U.S. online pharmacies from *organic* search results, arguing that banning online ads is not enough.[211] Eli Lilly is pushing for a policy of "delisting," a process whereby search engines such as Google and Bing would remove any non-U.S. online pharmacy from their search results viewed in the U.S.[212] Google attests that it will not censor its listings in this extreme manner except under court order. On its blog Google states: "It's not Google's place to determine what content should be censored - that responsibility belongs with the courts and the lawmakers."[213] Despite its claims, Google does build into its search algorithm a demotion signal targeting websites for which it has received a large number of Digital Millennium Communications Act (DMCA) take down requests[214] and it may do so for other such requests as well.

### Domain Registrars

For a website to operate it needs to work with a domain name registration service, such as those offered by GoDaddy, Register.com or EasyDNS. Putting pressure on registrars to disallow service to rogue online pharmacies is another method of pushing them out of business. LegitScript has used this

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[204] Supra note 46.
[205] In Fall 2014, I was informed that a safe international online pharmacy, which was not a member of the PharmacyChecker.com Verification Program, but apparently met similar standards, was shut down and locked by the U.S. registrar GoDaddy.
[206] Supra note 187.
[207] Non-prosecution agreement between Google, Inc. and the United States Attorney's Office for the District of Rhode Island, Department of Justice, August 19th, 2011: http://googlemonitor.com/wp-content/uploads/2011/05/Google%20Agreement.pdf.
[208] *Ibid,* also see supra note 174.
[209] Supra note 197.
[210] *ibid*
[211] Supra note 54. View a video of the testimony by Eli Lilly about delisting here.
[212] *ibid*
[213] Barea, Adam, Legal Director, Google, Inc., "Combatting Rogue Online Pharmacies," June 18, 2013, Google Public Policy Blog, see http://googlepublicpolicy.blogspot.com/2013/06/combating-rogue-online-pharmacies.html [Last accessed 10/29/2014].
[214] Gold, Matea and Tom Hamburger, "Google Faces New Pressure From States to Crack Down on Illegal Drug Sales," April 15th, 2014, *Washington Post*, see http://www.washingtonpost.com/politics/google-faces-new-pressure-from-states-to-crack-down-on-illegal-online-drug-sales/2014/04/15/6dfc61fa-be6d-11e3-b195-dd0c1174052c_story.html [Last accessed 10/29/2014].

mechanism to help shut down many rogue pharmacy sites.[215] Often, however, a rogue online pharmacy will just move to another registrar. To prevent that from happening registrars have the ability to "lock" domain names ("DNS locking") to actually prevent a website from moving to a different registrar, thereby putting that particular websites out of business.

In cases where pharmacy-related websites are clearly dangerous, DNS locking should be pursued. However, measured policies should prevent such aggressive enforcement without a court order in the case of safe international online pharmacies or those deemed "unapproved" by LegitScript but not "rogue." This enforcement discretion is justified for public health reasons, but also because private sector, voluntary actions -- in this case, those long sought by the pharmaceutical industry -- should not be the catalyst for ending access to safe international online pharmacies, which is their commercial goal. Governments should have to explicitly request such actions of registrars and ICANN when they believe the public health imperatives justify it.

Furthermore, in the absence of the measured protocols recommended above, unencumbered DNS locking would advantage rogue online pharmacies vs. safe international online pharmacies. The former are often fly-by-night websites, while the latter have often existed for a decade or more and aren't likely to return to the marketplace with another website. *It would be indefensible to shut down the safest international online pharmacies and leave tens of thousands of foreign rogue pharmacy websites to rush in to fill the void.*

In a letter from January of this year, the NABP alerted registrars that they should take down online pharmacies upon the request of NABP or LegitScript without a court order. NABP is careful to note "exceptions" that appear (but the letter is not explicit) to relate to LegitScript's online pharmacy classification of "unapproved" – safe international online pharmacies that fall outside of U.S. regulations. The letter reads:

> We confirm that LegitScript is well aware of where exceptions exist to these common global standards (e.g. where pharmacy licensure reciprocity exists as a matter of regulation) and Internet pharmacies falling under an exception are not designated as rogue and not included in rogue Internet pharmacy abuse notifications to Registrars. [216]

The NABP and LegitScript are within their rights to *notify* domain registrars about online pharmacy registrants, their practices, and legal considerations. However, domain registrars are only required to abide by requests of a court order to take down a registrant's website.

To date, NABP's and LegitScript's requests to domain registrars appear to target "rogue online pharmacies" as per LegitScript's – not NABP's – definition creating a de facto standard that forms the

[215] LegitScript, press release, "LegitScript Shuts Down 6,700 Rogue Internet Pharmacies," June 28, 2013; see http://www.prnewswire.com/news-releases/legitscript-shuts-down-6700-rogue-internet-pharmacies-213544321.html [Last accessed 11/13/14].

[216] Masnick, Mike, "Pharmacy Lobbyists Lie to Registrars If We Complain About a Site It Must Be Taken Down, No Questions Asked," January 10, 2014, *TechDirt*, see https://www.techdirt.com/articles/20140110/12140025836/pharmacy-lobbyists-lie-to-registrars-if-we-complain-about-site-it-must-be-taken-down-no-questions-asked.shtml [Last accessed 10/29/2014].

basis for appropriate guidance to domain registrars. A standard of legal compliance, as per LegitScript's terms, combined with exceptions for legally and safely operating online pharmacies, is the one that best serves the public health. *To meet this requirement, approval by either LegitScript or PharmacyChecker.com, should be sufficient for a domain registrar to permit and maintain service to an online pharmacy. One domain registration company called EasyDNS already has adopted this policy*.[217]

### The Role of the Internet Corporation for Assigned Names and Numbers (ICANN)

ICANN, an international non-profit organization, is responsible for managing core technical components of the Internet relating to domain names, Internet protocol numbers, and protocol port and parameter numbers. Under ICANNs Registrar Accreditation Agreement (RAA), registrars accept responsibility to disallow illegal activity among registrants (websites). NABP and LegitScript argue that one way of shutting down rogue online pharmacies is for ICANN is to more fully enforce its RAAs, whereby registrars must respond dutifully to notifications about illegal activity by shutting down domain names and locking them even without a court order.[218] The FDA is frustrated with ICANN for not doing more along these lines.[219] Again, there is a measured policy response for ICANN, which involves pressuring registrars to disallow service to sites that are truly "rogue online pharmacies" but not safe international online pharmacies.[220]

### Credit Card Companies/Payment Processors

Most online merchants, whether they sell books, computers, or drugs, take payments by credit card. Preventing them from offering credit card payment options is another method of curtailing the use of online pharmacies. It has become harder for online pharmacies to obtain merchant accounts to offer credit card payments unless they are credentialed by the NABP or LegitScript.[221] Many safe international online pharmacies are being refused service[222], which means that Americans who buy from these online pharmacies have difficulty making payments to them. Some Americans who use international online pharmacies now pay for their medications by personal check instead of using a credit card.[223]

Online pharmacy merchants are categorized as *high risk* operations by payment processing companies. Rogue online pharmacies have greater chargebacks, refund requests, and fraud complaints from consumers. In contrast, credit card processing for safe international online pharmacies has not been high risk, meaning their transactions are generally trouble free, as would be expected with a credentialed U.S. online pharmacy.

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[217] Masnick, Mike, "EasyDNS Tries to Balance Bogus Requests to Take down Legit Foreign Online Pharmacies Against Truly Rogue Pharmacies," August 26th, 2014, *TechDirt*, see https://www.techdirt.com/articles/20140824/07373128307/easydns-tries-to-balance-bogus-requests-to-take-down-legit-foreign-online-pharmacies-against-truly-rogue-pharmacies.shtml [Last accessed 10/29/2014].
[218] ibid
[219] Elder, Jeff, "ICANN, Regulators Clash Over Illegal Internet Drug Sales," October 27, 2014, *Wall Street Journal*, see http://online.wsj.com/articles/icann-regulators-clash-over-illegal-internet-drug-sales-1414463403.
[220] Supra note 217.
[221] Supra note 46.
[222] *ibid*
[223] *ibid*

Some non-U.S. payment processors are willing to work with safe international online pharmacies, but now charge very high transaction fees to justify the "risk." Rogue online pharmacies use fraud in order to obtain merchant accounts by pretending not to be an online pharmacy business, securing the account, and then offering medication for sale – a "bait and switch" operation. Therefore, private sector "voluntary actions" – ironically – lead to a situation where rogue online pharmacies may be able to acquire reasonable credit card processing terms while safer online pharmacies have far more difficulty.

### Transparency

The Center for Safe Internet Pharmacies (CSIP), working with LegitScript, and in concert with the Alliance for Safe Online Pharmacies, is the organizational vehicle for private sector actions against rogue and illegal online pharmacies. Due to the public health ramifications, CSIP should be transparent in its enforcement actions. It should correctly define for consumers, regulators, and the public health community, what pharmacy sites are "rogue" and are subject to private sector takedown efforts. CSIP should also take the following actions:

- Clearly state what recourse companies and people have if their businesses are shut down by actions taken by CSIP's members.
- Provide information on those sites that were shut down, and the reasons they were shut down based on applicable laws.
- Identify the precise public health risk of a website refused service or shut down.[224]

The Obama administration, as discussed below, was the catalyst for CSIPs creation. If the federal government is going to deputize private actors in carrying out law enforcement-type actions that affect the health of Americans, then it should compel transparency from those actors. Not only should CSIP communicate what they are doing to protect consumers from the dangers of rogue online pharmacies but, perhaps more importantly, if safe international online pharmacies are more directly targeted for takedown by CSIP in the future, then consumers who rely on those online pharmacies for obtaining medicine they cannot afford locally should know why CSIP ended their online access to safe and affordable medication.

## The Obama Administration's Role in Combatting Rogue Online Pharmacies and Their Conflation with Safe International Online Pharmacies

The GAO report briefly mentioned the efforts of the White House Office of the Intellectual Property Enforcement Coordinator (IPEC), through which the Obama administration has shaped policies and encouraged actions affecting online access to medication. In 2010, as part of its mission to combat intellectual property infringement on the Internet, IPEC requested that the private sector take "voluntary" actions against online pharmacies.[225] The result was the formation of CSIP.[226]

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[224] Supra note 43.
[225] McQuillen, William, "Google, Microsoft Join Obama to Combat Knockoff Drugs," December 14, 2010, Bloomberg News; see http://www.bloomberg.com/news/2010-12-14/google-microsoft-joining-to-help-combat-illegal-web-pharmacies.html [Last accessed 10/21/14].
[226] Supra note 43.

While CSIP does help combat rogue Internet pharmacies, it also acts to discourage Americans from accessing safe, affordable pharmacies outside the United States.[227] CSIP provides a database on its website for consumers to find "legitimate" online pharmacies, which is powered by LegitScript. When American consumers use this tool to look up an online pharmacy operating outside the U.S., they find that all safe international online pharmacies are "unapproved." The CSIP website is mostly a clearing house of information for pharmaceutical industry-funded or allied groups such as the Alliance for Safe Online Pharmacies, LegitScript, the National Association of Boards of Pharmacy (NABP), and the Partnership for Safe Medicines.

Congress is examining voluntary agreements in the private sector, ones recommended by the Obama administration, as a solution to copyright and other intellectual property right violations that occur on the Internet.[228] Some voluntary agreements, such as those exercised by CSIP, are being afforded considerable market power, as well as the ability to deter competition and innovation.[229] Consider the possibility that some executives with CSIP member companies may own other companies, such as GoodRx, a website that offers drug price comparisons among U.S. chain pharmacies, which are in turn commercially advantaged by CSIP's actions. GoodRx (a company which this author admires) competes for search engine traffic with online pharmacies, safe and rogue – and with PharmacyChecker.com. If its competitors are disadvantaged by CSIPs actions then GoodRx and its owners profit. To ensure CSIP's, and other similar voluntary private sector consortiums' powers are used properly, lawmakers should consider the appointment of an independent ombudsman to oversee these agreements. The ombudsman would analyze voluntary agreements, such as those affecting access to medication online, in order to make sure private sector actions aren't blocking Internet competition and are consistent with the Administration's other goals of due process, free speech, free trade and transparency.[230]

Through IPEC's activities, the conflation of rogue online pharmacies with safe international online pharmacies was strongly encouraged if not mandated by the Obama administration. IPEC is an executive office created by an act of Congress to protect intellectual property rights. It may be inappropriate for IPEC to work in tandem with drug companies and U.S. pharmacies in the formation of public health policies regarding the distribution of medicines, as doing so may give the appearance that protection of intellectual property rights and U.S. corporate interests, not the public health, are the driving force behind federal policies toward online pharmacies.

## Properly and Ethically Educating Consumers about Online Pharmacies

The GAO was tasked under Section 1127 to report on efforts to educate consumers about the dangers of buying drugs online. Educating consumers about the dangers of rogue online pharmacies is another important measure to protect the public health. The programs and outreach of FDA and several GAO

[227] *ibid*
[228] *ibid*
[229] *ibid*
[230] *ibid*

stakeholder entities created to educate consumers about online pharmacies are identified but not fully examined in the GAO report. In considering the benefits and risks of online pharmacies, the public health and interest are best served when consumers are provided the most accurate information on how to avoid rogue pharmacy websites and find safe and affordable medication on the Internet.

In warning them against rogue online pharmacies, the public education programs identified in the GAO report communicate the message that the only safe online pharmacy options are domestic ones. That message is inaccurate and inimical to public health imperatives. Independent studies, consumer testimonials, fifteen years of experience, and numerous state drug importation programs show that there are safe international options for obtaining affordable and safe medication. The GAO report appears to actually criticize the U.S. states that implemented programs to help their residents find affordable medication online from international pharmacies. It is here where GAO's analysis is perhaps most flawed:

> More recently, some state and local governments implemented programs that provided residents or employees and retirees with access to prescription drugs from Canadian Internet pharmacies. Despite FDA warnings to consumers that the agency could not ensure the safety of drugs not approved for sale in the United States that are purchased from other countries, the prevalence of such programs may have contributed to a perception among U.S. consumers that they can readily save money and obtain safe prescription drugs by purchasing them from Canada.[231]

Since U.S. consumers do readily save money and obtain prescription drugs by purchasing them from Canada and other countries,[232] the GAO's analysis is misguided. GAO's own research tested Canadian Internet pharmacies and found that they all sold genuine medication and required a prescription.[233]

As reported by GAO, through its "BeSafeRx" program, the FDA advises Americans about dangers associated with buying medication online, how to avoid rogue online pharmacies, and how to identify legitimate ones. The FDA's program overreaches by scaring Americans away from safe international online pharmacies. In an article published on ABC News' website, FDA Commissioner Margaret Hamburg is quoted as saying:

> If the price is bedrock cheap and it seems too good to be true, it probably is too good to be true. And if it is not located in the United States and it's offering to ship drugs worldwide, another red flag; don't go there.[234]

The drug prices at *safe international online pharmacies*, which are often much lower than domestic prices, are *true* and are sometimes the only affordable ones for Americans shopping online.[235] Since

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[231] Supra note 1.
[232] As evidenced throughout this report.
[233] Supra note 25.
[234] Avila, Jim and Serena Marshall, "FDA: Beware Buying Prescription Drugs Online," *ABC News*, Associated Press, September 28, 2012, http://abcnews.go.com/Health/fda-warns-consumers-dangers-buying-prescription-drugs-online/story?id=17352895&page=2 [Last accessed 10/30/2014].

prescription drug utilization is price elastic, meaning high drug costs are associated with Americans not taking prescribed medications,[236] consumers who are scared away from a lower cost international online pharmacy that sells genuine, safe and effective medication may unnecessarily go without their prescribed treatments. In effect, FDA's public education program, which warns Americans against buying from any non-U.S. online pharmacy, may exacerbate problems of prescription non-adherence and financial hardship.

The GAO report mentions NABP's application to the Internet Corporation for Assigned Names and Numbers (ICANN) to operate a registry, generic top-level domain (i.e., .com, .edu, .gov, etc) called .pharmacy. NABP plans to set global standards for any website selling medication; of a non-profit group that focuses on pharmacy-related issues; and providing information about medication for those wishing to obtain the .pharmacy gTLD. The .pharmacy application was funded by Eli Lilly, Gilead, Jansen Therapeutics, Merck and Pfizer.[237] NABP's standards exclude any international online pharmacy that sells into the U.S. from obtaining .pharmacy. Consumer advocates and public health activists, as well as Internet freedom activists, have protested NABP's application for .pharmacy.[238] Congress should eschew legislation that would codify this standard and also consider blocking funding to public education campaigns that would employ NABP's .pharmacy as a means to scare Americans away from every online pharmacy that does not end in .pharmacy.

## Conclusion

The GAO report conflates online pharmacies operating internationally that offer Americans a source of safe and affordable medication with dangerous pharmacy websites by referring to them both as "rogue". It omits empirical data and analyses about matters relating to Americans obtaining prescription drugs online that may lead lawmakers to make or allow the continuation of misguided public policies, or to encourage misguided voluntary actions by companies.

Due to the public health crisis of high drug prices, Americans have come to rely on safe international online pharmacies, such as CanadaDrugs.com, which GAO refers to as "rogue". Misleading information about online pharmacies encourages overreaching federal enforcement and private sector actions that endanger the public health by curtailing access to lower-cost, safe, prescribed medication.

Lawmakers should oppose legislation that would aggravate the public health crisis by curtailing access to safe international online pharmacies. In contrast, Congress should pass legislation to facilitate actions

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[235] Supra note 21. The peer-reviewed literature showing the safety of credentialed international online pharmacies is important but not necessary to prove that the prices listed on PharmacyChecker.com are for genuine medications are therefore **true**.
[236] Briesacher, Becky A. and Jerry H. Gurwitz, Stephen B. Soumerai, "Patients At-Risk for Cost-Related Medication Nonadherence: A Review of the Literature," *J Gen Intern Med*. 2007 June; 22(6): 864–871. Published online 2007 April 5. doi: 10.1007/s11606-007-0180-x.
[237] Funding sources transparently disclosed by NABP: http://www.dotpharmacy.net/about-us [Last accessed 10/30/2014].
[238] Masnick, Mike, "Big Pharma Firms Seeking Pharmacy Domain to Crowd Out Legitimate Foreign Pharmacies," May 17, 2013, *TechDirt*; see http://pharmacycheckerblog.com/opposition-grows-to-pharma-funded-application-by-nabp-for-pharmacy-to-icann [Last accessed 10/30/2014]. Also see, "Opposition Grows to Pharma-Funded Application by NABP for .Pharmacy to ICANN," see http://pharmacycheckerblog.com/opposition-grows-to-pharma-funded-application-by-nabp-for-pharmacy-to-icann [Last accessed 10/30/2014].

that shut down dangerous rogue pharmacy websites but explicitly prohibit funding for federal regulators to shut down safe international online pharmacies.

While the FDA has never prosecuted an individual for importing small quantities of prescription drugs for personal use, the law should not subject Americans to even the possibility of criminal or misdemeanor charges simply for buying medication for their own use and health protection. Criminal penalties were created for those who are illegally importing *and re-selling* prescription drugs, not individuals who are struggling to afford prescription medication. Technically, under current law, an American could be charged, prosecuted and put in jail for buying safe medication internationally for her or his own use. The relevant statutes should be amended to remove criminal penalties for personal drug importation.

Section 708 of FDASIA facilitates the destruction of safe, personally imported drugs. According to the FDA's proposed regulations, Section 708 is a public benefit to the extent that "illnesses and deaths are avoided because FDA destroyed a drug valued at $2,500 or less…that posed a public health risk." FDA fails to note the cost to the public health. Clearly, destroying prescription drug orders of safe and effective medication will threaten the public health because people won't receive the medications they ordered. Congress can pass legislation to clarify under what circumstances FDA and CBP should not refuse admission to personally imported medications.[239]

Coordinated, federal and global efforts that bring together law enforcement and private industry in annual campaigns called Operation Pangea have proven effective in shutting down tens of thousands of rogue online pharmacies.[240] Pangea's "Activities target the three principal components used by illegal websites to conduct their trade – the Internet Service Provider (ISP), payment systems and the delivery service."[241] Additionally, counterfeiters and those threatening the public health through online drug sales have been arrested and imprisoned.[242] Continuing such enforcement efforts, without overreaching to engulf safe international online pharmacies; developing public education campaigns that do not scare consumers away from safe international online pharmacies; and using all measures possible to lower drug prices in America will greatly reduce threats to the public health from rogue online pharmacies, while not endangering the public health by curtailing online access to safe and affordable medication.

**About PharmacyChecker.com**

PharmacyChecker.com (www.pharmacychecker.com) is the only independent company that verifies U.S. and international online pharmacies and compares prescription drug prices. Its verifications and price comparisons have been referenced by AARP Magazine, the New York Times, the Wall Street Journal, and

[239] For specific suggestions on how to best implement Section 708, see PharmacyChecker.com Public Comments on FDA's proposed regulations to implement Section 708 of the Food and Drug Administration Safety and Innovation Act (FDASIA), July 4th, 2014: http://www.pharmacychecker.com/pdf/public-comments-fda-section-708.pdf [Last accessed 11/13/14].

[240] See Operation Pangea information on Interpol's website: http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea [Last accessed 10/30/2014].

[241] *ibid*

[242] *ibid*

many others. Formed in 2002 when its founder, Tod Cooperman, M.D., saw that increasing numbers of Americans were looking on the Internet to save money on medication but did not have adequate information to protect their health. PharmacyChecker.com is a stakeholder in the online consumer-driven healthcare community, seeking an open Internet environment that promotes innovation and new business models, especially those that serve the public health.

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Mr. Levitt manages the online pharmacy verification program and listing programs, as well as web content and development. He is responsible for business development, and research. He is also a public advocate for prescription drug affordability in America, Internet freedom, and the United Nations. He has testified before Congress on issues relating to access to affordable medicines and Internet freedom, published an op-ed in the New York Times about online pharmacies and personal drug importation, and is the proud author of a chapter in an anthology about defeating the Stop Online Piracy Act (SOPA). Mr. Levitt is president of the United Nations Association Brooklyn Chapter and sits on the Brooklyn County Democratic Committee. Mr. Levitt received his Masters in International Relations from American University and a Bachelor's degree in International Relations and Political Science from Roger Williams University.

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