

PharmacyChecker.com, LLC 333 Mamaroneck Avenue White Plains, NY 10605 p: 718.554.3067 f: 718.715.1033

Testimony of Gabriel Levitt Vice President, PharmacyChecker.com (<u>www.pharmacychecker.com</u>)

House Judiciary Committee, Subcommittee on the Courts, Intellectual Property and the Internet Hearing on "The Role of Voluntary Agreements in the U.S. Intellectual Property System"

September 18th, 2 pm, 2141 Rayburn House Office Building

Chairman Goodlatte and Ranking Member Congressman Watt, thank you for inviting me here today.

I am Gabriel Levitt, the vice president of PharmacyChecker.com, which, for the past 10 years, has been helping Americans find affordable medication from safe online pharmacies by checking and verifying the credentials of these pharmacies and posting price comparisons.

We believe that voluntary agreements can be a useful tool in protecting Americans from counterfeit products, but they can also be misused in anti-competitive ways which scare and thwart Americans from accessing affordable medication. This leads to poor medication compliance with negative health consequences and also goes against the Administration's desire that voluntary agreements not be used to impede competition.<sup>i</sup> I will present recommendations which can keep this from happening.

Last year, fifty-million Americans ages 19-64 did not fill a prescription due to cost, up from 48 million in 2010, according to the Commonwealth Fund.<sup>ii</sup> We also know that nearly five million Americans have been buying their medication from outside the U.S. in order to get affordable prices, because the cost to buy brand-name medicine is often 80% lower in other countries than in the U.S. <sup>iii,iv</sup> Independent studies and over a decade of experience have demonstrated the safety of domestic and international online pharmacies approved in rigorous programs such PharmacyChecker's.<sup>v</sup>

A voluntary agreement of particular concern is one established by a group of Internet and credit card companies called the Center for Safe Internet Pharmacies, or CSIP. While CSIP has been effective at taking down some rogue pharmacies, it also acts to discourage Americans from accessing safe, affordable pharmacies outside the United States. CSIP uses a company called LegitScript to help it identify rogue sites for "take down" and to power an online tool for consumers to look up the status of an online pharmacy. Unfortunately, if you use this tool to look up any online pharmacy operating in any country other than the U.S., such as Canada, it will tell you that pharmacy is "unapproved," regardless of the fact that it may be licensed, require a prescription, and safely selling only genuine medication. The CSIP website has become a clearing house for information from pharmaceutical industry-funded groups such as The

Page 1 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

Partnership for Safe Medicines and the National Association of Boards of Pharmacy (NABP) with scare campaigns conflating all non-U.S. pharmacies with rogue pharmacies. In fact, any pharmacy outside the U.S. which sells to Americans is labeled by NABP as a rogue.

To keep voluntary agreements from misleading Americans, we ask that your committee make sure that CSIP does not discourage Americans from accessing safe and affordable medication online. In particular, we would urge that the basis for defining a "rogue pharmacy" include any of the following, but not simply whether or not it is licensed in the U.S.:

- Intentionally sells adulterated and/or counterfeit medication
- Sells prescription medication without requiring a prescription
- Engages in fraudulent and deceptive business practices
- Does not follow generally accepted safety standards of pharmacy practice
- Sells medication that is not regulated, i.e., not registered by a drug regulatory authority

We would also like to see CSIP and other institutions established under voluntary agreements be more transparent by providing the following information:

- clearly state what recourse companies and people have if their businesses are shut down by actions taken by CSIP;
- provide information on those sites that were shutdown, and the reasons they were shutdown based on applicable intellectual property laws; and
- identify the precise public health risk of a website.

Last, it is important to recognize that voluntary agreements are being afforded considerable market power. To ensure these powers are used properly, we recommend the appointment of an independent Ombudsman to oversee these agreements. The Ombudsman would analyze voluntary agreements 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, and transparency.<sup>vi</sup>

I have provided the Committee with a transcript of this presentation and included our public comments submission to the United States Patent and Trademark Office in **Exhibit A**.

Thank you for your time.

<sup>ii</sup> "The Commonwealth Fund 2012 Biennial Health Insurance Survey". *The Commonwealth Fund*. See <u>http://www.commonwealthfund.org/Publications/Fund-Reports/2013/Apr/Insuring-the-Future.aspx</u> (Last accessed 7/22/2013).

<sup>iii</sup> Cohen RA, Kirzinger WK, Gindi RM. Strategies used by adults to reduce their prescription drug costs. NCHS data brief, no 119. April 2013. Hyattsville, MD: National Center for Health Statistics. 2013. See <u>http://www.cdc.gov/nchs/data/databriefs/db119.pdf</u>. (Last accessed 7/22/2013).

<sup>iv</sup> See "Savings on Brand Name Drugs Rise to 85% Using Verified Online Pharmacies Outside the U.S., According to PharmacyChecker.com — Consumers Told How to Avoid Rogue Pharmacies <u>http://www.pharmacychecker.com/news/online\_pharmacy\_prescription\_savings\_2012.asp</u>.

<sup>v</sup> See Bate, Roger and Ginger Zhe Jin, Aparna Mathur. "Unveiling the Mystery of Online Pharmacies: An Audit Study. *The National Bureau of Economic Research*. March 2012. See <u>http://www.nber.org/papers/w17955</u>.
[Last accessed 8/10/2012]
<sup>vi</sup> Ibid.

<sup>&</sup>lt;sup>i</sup> See Request of the United States Patent and Trademark Office for Public Comments: Voluntary Best Practices Study. 78 FR 37210. https://www.federalregister.gov/articles/2013/06/20/2013-14702/request-of-the-united-states-patent-and-trade. mark-office-for-public-comments-voluntary-best [Last accessed online 9-17-2013].

Exhibit A



PharmacyChecker.com, LLC 333 Mamaroneck Avenue White Plains, NY 10605 p: 718.554.3067 f: 718.715.1033

August 20<sup>th</sup>, 2013

Teresa Stanek Rea Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office

RE: Request of the U.S. Patent and Trademark Office for Public Comments: **Voluntary Best Practices Study** 

Docket #*PTO-C-2013-0036* 

Gabriel Levitt, Vice President, PharmacyChecker.com, LLC

Founded in 2003, PharmacyChecker.com verifies online pharmacies, provides drug price comparisons among verified online pharmacies, and advocates for expanding access, online and off, to safe and affordable medication. Our main mission is to help Americans find the lowest prescription drug prices offered by safe online pharmacies or discount cards offered by U.S. pharmacy benefit managers. We are a stakeholder in the online business community seeking an open Internet environment that promotes innovation and new business models, especially those that serve the public health. Thus, the main focus herein is to examine the effectiveness of cooperative voluntary initiatives (CVIs) encouraged by the White House Office of the Intellectual Property Enforcement Coordinator (IPEC) as they relate to online pharmacies. The formation of the Center for Safe Internet Pharmacies (CSIP) is often noted as one of IPEC's achievements in encouraging and facilitating the development of CVIs to protect intellectual property on the Internet and its operation will be discussed accordingly.

Reducing intellectual property infringement (IPI) is the goal of IPEC, and CVIs are a part of its strategy to curtail IPI on the Internet. Generally, effectiveness of such efforts is defined by whether or not CVIs are actually reducing IPI. However, it's more complex when it comes to online prescription drug sales than for other types of Internet commerce. For instance, counterfeit handbags do not impact the public health, whereas counterfeit or real medication, which can kill or save lives, respectively, can have a great public health impact. That's why IPEC's main focus when it comes to online pharmacies appears to be protection of the public health, not IPI. The excerpt below, from a March 2011 IPEC document, exemplifies this public health focus:

"On December 14, 2010, White House Intellectual Property Enforcement Coordinator, Victoria Espinel, announced that GoDaddy, Google, Microsoft, Yahoo!, Network Solutions, Neustar, eNom, PayPal, MasterCard, Visa, and American Express have agreed to support an initiative which will start taking voluntary action against illegal Internet pharmacies.

Page 1 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

"This fall, Espinel challenged the private sector to voluntarily address the health and safety issues presented by rogue online pharmacies...These discussions culminated in a well-attended, cross-industry meeting at the White House on November 9<sup>th</sup>, 2010. At that meeting, GoDaddy and Google took the lead on proposing the formation of a private sector 501 (c)(3) non-profit organization dedicated to promoting information sharing, education, and more efficient law enforcement of rogue online internet pharmacies".<sup>i</sup>

From this excerpt it's clear that the basis for IPEC's "challenge" and the subsequent formation of CSIP was predicated on "health and safety issues." We believe that this is the proper focus for engaging the private sector to deter and shutdown online pharmacies that intentionally sell counterfeit, adulterated, or substandard medications, or sell real medications but without requiring a prescription. In addition to protecting the public health, violations of intellectual property rights will be curtailed by curtailing online sales of counterfeit drugs.

CVIs against online pharmacies should, at a minimum, *do no harm*, the philosophical foundation of medical ethics. Harm can be caused by CVIs that curtail or block online access by consumers to safe and affordable medication. In fact, any actions that block access to safe and affordable medication are harmful ones. The public health importance of incorporating this truism into metrics for effectiveness of CVIs dedicated to infringing online pharmacies merits a full explanation.

There is a vast and well documented crisis of prescription drug non-compliance in our country, and, according to a CVS/Caremark study the main cause is the cost of medication in the United States.<sup>ii</sup> Fifty-million Americans ages 19-64 did not fill a prescription due to cost in 2012, up from 48 million in 2010, according to the Commonwealth Fund.<sup>iii</sup> An analysis of a 2005 study by Kaiser, USA Today, and the Harvard University School of Public Health, found that approximately twenty-five million Americans became sicker from not taking their medications due to cost.<sup>iv</sup> The FDA estimates \$290 billion in added annual healthcare costs due to prescription non-compliance.<sup>v</sup>

Other documented adverse effects from prescription non-compliance include the death of 125,000 Americans who were not adhering to their prescribed heart medication.<sup>vi</sup> It's likely that hundreds of thousands more die each year from prescription non-compliance for other medications. The numbers above suggest that high drug prices are a major factor in these deaths.

Almost five million Americans personally import medication because of more affordable prices abroad.<sup>vii</sup> Over the past decade, tens of millions of prescriptions have been ordered online and filled internationally through which Americans have received safe and effective medication: the same medications sold in the United States but at a much lower price. Empirical studies and over a decade of experience show the high degree of safety of personally imported medication from properly credentialed online pharmacies. This remains an inconvenient truth for those who seek to curtail access to such safe online pharmacies. Countless Americans would have gone without needed medication if not for these international and online sources.

A study published in the National Bureau of Economic Research in 2012 called "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets" demonstrates the safety of properly credentialed online pharmacies. The study tracked 370 prescription orders placed with online pharmacies, *both foreign and domestic*. The population of online pharmacies included international and domestic ones credentialed by PharmacyChecker.com, international ones who are members of the Canadian International Pharmacy Association (CIPA), and domestic ones in the National

Page 2 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites and LegitScript.com programs. The study concluded that all credentialed online pharmacies, foreign and domestic, required a prescription and passed all drug authenticity tests. Of those drugs ordered from non-credentialed online pharmacies, 9% of products were fake or counterfeit medication, all of those for Viagra only.<sup>viii</sup>

The real health and safety *threat* stems from domestic and international prescription drug orders that are filled by *un-credentialed online pharmacies*, many of which are not safe.

# Thus, to maximize positive public health outcomes, CVIs should endeavor to encourage access to *all* safe online pharmacies for Americans, including international online pharmacies, while preventing access to dangerous online pharmacies.

From here we try to address the USPTO's questions in the "Supplementary Information" section:

#### 1. How should effectiveness of cooperative voluntary initiatives (CVIs) be defined?

Effectiveness is the degree to which CVIs can reduce and stop access to dangerous online pharmacies while encouraging access to safe online pharmacies, specifically those credentialed by PharmacyChecker.com, Canadian International Pharmacy Association, LegitScript.com and the NABP.

Dangerous and fraudulent online pharmacies are often referred to as "rogue online pharmacies." Unfortunately, the NABP, which represents U.S. pharmacy boards and pharmacists, defines any online pharmacy that is based outside the United States and sells to Americans as "rogue," regardless of its credentials. NABP publishes a "Not Recommended" list that includes fraudulent and dangerous online pharmacies but also includes some safe international online pharmacies approved in the PharmacyChecker.com Verification Program because they are not based in the U.S.<sup>ix</sup> We believe this conflates the problem of "real" rogue online pharmacies (which hurt consumers) with the practice of safe personal drug importation (which helps consumers). As a practical and ethical matter we believe IPEC should reject NABP's definition of "rogue online pharmacy."

LegitScript.com comes closer to the right classification system for "rogue online pharmacy," but it suffers from too much ambiguity and potential for overreach. Like the NABP, LegitScript.com's program does not allow for the approval of non-US, international, online pharmacies that sell to consumers in the United States. However, to its credit, 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." The "unapproved" designation is misleading, as it scares consumers who are seeking safe and affordable medication away from safe sources, but at least it distinguishes safe international online pharmacies from "rogue online pharmacies".

A reasonable definition of "rogue online pharmacy" is any website that:

Page 3 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

- 1) Sells prescription medication without requiring a prescription;
- 2) Engages in fraudulent and deceptive business practices;
- 3) Does not follow accepted safety standards of pharmacy practice;
- 4) Intentionally sells adulterated and counterfeit medication.

This definition would certainly describe most online pharmacies that are dangerous but not sweep into its ambit ones that are safe. CVIs are effective when they reduce the volume of, and access to, dangerous online pharmacies.

# 2. What type of data would be particularly useful for measuring effectiveness of voluntary initiatives aimed at reducing infringement and what would the data show?

The answer depends in part on how "infringement" is defined. In the case of online pharmacies "infringement" should be defined within the framework of IPEC's main goal of protecting the public health. By defining "infringement" as "the intentional sale of counterfeit or adulterated medication, or the sale of genuine and safe medication but without a prescription," CVIs would target not only the worst offenders, such as criminal networks known to sell counterfeit drugs, but the large majority of websites that the U.S. Food and Drug Administration (and the pharmaceutical industry) seek to put out of business and, in some cases, prosecute.

Useing the definition of "infringement" above, the data needed to measure effectiveness would show on a year-to-year basis the reduction in the number of infringing online pharmacies *caused by CVIs* – private sector *actions that led to the shutdown of a website that did not entail any corresponding government action*. It would also show if any non-infringing sites – safe online pharmacies – were inadvertently shutdown by CVIs.

Useful data could be obtained by working with companies, organizations and associations that currently verify online pharmacies, including our company, PharmacyChecker.com, as well as LegitScript, NABP, and CIPA. More data to determine how to classify an online pharmacy could be obtained by conducting mystery purchases from online pharmacies to show if they are rogue or not, such as by using the methods of the National Bureau of Economic Research study mentioned above.

A national survey on consumer purchases of prescription medication would also be helpful in determining the public safety and health ramifications of online pharmacies (good and bad). This would help identify the types of websites that help and hurt the public health. Considering the public health threat that federal authorities see from online pharmacies it should engage the U.S. Centers for Disease Control and Prevention (CDC) by asking CDC to include questions relating to online pharmacy purchases in their National Health Interview Survey. In its last such survey, the following questions were asked of 33,014 Americans ages 18 and over:

"DURING THE PAST 12 MONTHS, are any of the following true for you? ... You skipped

Page 4 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

medication doses to save money ...You took less medicine to save money ...You delayed filling a prescription to save money ...You asked your doctor for a lower cost medication to save money ...You bought prescription drugs from another country to save money ...You used alternative therapies to save money." vii

A survey to determine public health ramifications of online pharmacies could ask: "are any of the following true for you? You ordered medication from another country through an online pharmacy to save money. You ordered medication from a U.S. online pharmacy to save money. You ordered from an online pharmacy that required a prescription from your doctor. You ordered from an online pharmacy that issued you a prescription based on an online questionnaire. You ordered from an online pharmacy that did not require a prescription at all. You received the medication that you ordered. The medication you ordered online worked as you expected. The medication you ordered did not work as expected. You experienced negative health effects after taking the medication ordered online.

LegitScript.com's online pharmacy database already contains tens of thousands of websites identified as "rogue" that can be used as a baseline to measure progress. Encouragingly, its data shows that the number of "not legitimate" sites has decreased over the past year by 10,240 or 23.7%.

June 24, 2013	July 23, 2012
43,075 Internet pharmacies	32,835 are active Internet pharmacies
225 are legitimate (0.5%)	279 are legitimate (0.8%)
1,210 are potentially legitimate (2.8%)	1,512 are potentially legitimate (4.6%)
41,640 are not legitimate (96.7%)	31,204 are not legitimate (94.6%)
Source: LegitScript.com Home Page as viewed on June 24 <sup>th</sup> , 2013.	Source: LegitScript.com's home page on July 23 <sup>rd</sup> , 2012, as crawled by Alexa.com.

The question is how many of these were actually shut down by CVIs, rather than from government actions. The answer is simply those cases where a private company's action effectively shut down the rogue online pharmacy. Private company actions include refusal of service to rogue online pharmacies by payment processors, domain registrars, and search engines. A LegitScript press release claims that LegitScript has "dismantled over

Page 5 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

40,000 rogue Internet pharmacies since 2009."<sup>x</sup> Since LegitScript doesn't have legal authority to "dismantle" a company we believe that it has influenced domain registrars to end service to rogue online pharmacies: In other instances, LegitScript may identify for federal agencies those websites that ought to be seized by the government.

To determine what techniques are most effective, Center for Safe Internet Pharmacies, LegitScript.com, or both should enumerate the number of rogue online pharmacies shut down by the different private actions mentioned above.

To prevent inadvertently shutting down safe online pharmacies, and to better assist the Center for Safe Internet Pharmacies and the public, LegitScript.com should provide a breakdown of the number of sites that are classified as *not legitimate* by "rogue" and "unapproved," since the latter designation, as per the discussion above, usually refers to safe online pharmacies that require a prescription, follow the laws where they operate, and provide affordable medication to Americans.

Effectiveness should also be measured in line with the Obama Administration's goals that CVIs are "consistent with due process, free speech, privacy of users, and competition" while being as "transparent" as possible. CSIP should make public its protocols for action against infringing online pharmacies and the due process available to those websites targeted for takedown. When a website is shutdown through CVIs it should be informed of the legal basis for the action. CSIP's website, for example, should:

1) clearly state what recourse companies and people have if their businesses are shut down by actions taken by CSIP;

2) provide information on those sites that were shutdown, and the reasons they were shutdown;

3) identify the precise public health risk of a website; and

4) provide the legal basis for determining intellectual property infringement activities of those websites which are shut down, if there are any.

One of the Obama Administration's goals for CVIs is that they do not stifle competition. There's an inherent risk in "deputizing" private companies for law enforcement-type activities when such activities could curtail competition and business innovation. Thus, the degree to which CVIs curtail competition and business innovation, especially if such curtailment threatens the public health, must be factored in measuring effectiveness.

Online pharmacies are a relatively new business model for distributing medications and offer a good example to show how CVIs could stifle competition. Online pharmacies provide significant benefits to consumers in terms of cost and convenience. They make it easier for consumers to find companies in different states and countries that operate mail-order pharmacies, providing them more choices and lower prices. Their operations, which can greatly benefit consumers and the public health, challenge existing pharmacy business models. Entrenched business interests often seek to stifle new competition. For example,

on behalf of U.S. chain pharmacies, the National Association of Chain Drugstores has lobbied the government to stop Americans from buying lower cost medication from Canada and other countries for over a decade<sup>xi</sup>. For drug companies it's a commercial imperative to segment national markets by preventing them from parallel trade of pharmaceuticals, especially in protection of the U.S. market from which they derive the greatest profits. Furthermore, international drug price transparency serves to advantage consumers vis a vis drug companies as it gives rise to the former's advocacy for lower domestic drug prices. Like U.S. pharmacies, but for somewhat different reasons, the pharmaceutical industry lobbies the U.S. government to prevent Americans from buying lower cost medication from licensed Canadian or other international pharmacies for their personal use.<sup>xii</sup>

The discussion above is necessary because drug companies and U.S. pharmacies are lobbying the government to promote CVIs that stifle the development of international online pharmacies. In the case of the Center for Safe Internet Pharmacies, some of its member companies pay LegitScript.com to assist them in taking actions against online pharmacies. However, LegitScript.com is a steering committee member of the Alliance for Safe Online Pharmacies, a group that is funded by the NACDS and Eli Lilly:<sup>xiii</sup> both are engaged in lobbying Congress and federal agencies to stop Americans from personal drug importation. This interplay of private action to bring about CVIs will no doubt disadvantage consumers in areas other than online pharmacy.

To prevent CVIs from anticompetitive policies and actions, we recommend an **independent** ombudsman. For example, the CVI ombudsman would be someone with neither a financial interest nor alignment with pharmacy or pharmaceutical companies nor a federal or state regulator. The CVI Ombudsman will analyze CVIs to make sure private sector actions aren't blocking Internet competition and innovation. As part of his or her efforts the CVI Ombudsman would determine the negative effects to the public health of CVIs.

We understand that while the main goal of IPEC in combatting rogue online pharmacies is protecting the public health it's also concerned with online IPI. For the sake of effectiveness and transparency, IPEC should clearly, and with the greatest specificity, identify what practices by rogue or other online pharmacies constitute intellectual property violations. Only then can we measure how effectively CVIs are protecting intellectual property rights.

#### 3. If the data is not readily available, in what ways could it be obtained?

LegitScript's data is useful for measuring a reduction in the number of active rogue online pharmacies. As stated above, it should go one step further and show the number of "illegitimate" online pharmacies that are not rogue but classified as "unapproved" since many of those are safe and should not be subject to takedown actions by CVIs.

Please also refer to the recommendation above for the CDC to conduct a national survey of Americans who buy medication online.

## 4. Are there particular impediments to measuring effectiveness, at this time or in general, and if so, what are they?

There may be a lack of political will to actually determine the public health effects of online pharmacies because they are inconveniently positive. Indeed, millions of prescriptions have been safely filled internationally by Americans through online pharmacies, despite the fact that under most circumstances they may have broken the law or violated intellectual property rights. Keeping in mind the tens of millions of Americans who skip filling prescriptions due to cost, what are the public health effects if such access is blocked?

The dangers of rogue online pharmacies – "rogue" as defined by LegitScript.com – are very clear and compelling. Publicizing patient harm from such websites would 1) deter Americans from buying from them, and 2) clarify those sites that need to be shutdown to protect the public health.

5. What mechanisms should be employed to assist in measuring the effectiveness of voluntary initiatives?

As stated above, identifying the specific private actions taken under CVIs that led to the shutdown or dismantlement of rogue online pharmacies will be helpful. For example, out of the 40,000 rogue online pharmacies dismantled by LegitScript.com, it should be determined how many such takedowns occurred via domain registrars refusing service to rogue online pharmacies vs. payment processors refusing to service them.

## 6. Is there existing data regarding efficacy of particular practices, processes or methodologies for voluntary initiatives, and if so, what is it and what does it show?

The number of rogue online pharmacies has diminished, according to LegitScript.com, and many through CVIs. The processes include identifying rogue online pharmacies to domain registrars, payment processors and search engines and asking them to refuse service to such websites, effectively dismantling them.

http://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma\_Report\_Final.pdf [Last accessed 8/14/13].

<sup>ii</sup> "CVS Caremark Study Says Cost is Biggest Barrier to Prescription Adherence". 2012. CVS Caremark Cooperate: <u>http://www.cvscaremarkfyi.com/blogs/cvs-caremark-survey-says-cost-biggest-barrier-prescription-adherence</u>. (Last accessed 7/22/13).

<sup>iii</sup> "The Commonwealth Fund 2012 Biennial Health Insurance Survey". *The Commonwealth Fund*. See <u>http://www.commonwealthfund.org/Publications/Fund-Reports/2013/Apr/Insuring-the-Future.aspx</u> (Last accessed 7/22/2013).

<sup>iv</sup> "USA Today/Kaiser Family Foundation/ Harvard School of Public Health Care Costs Survey, 2005". *The Kaiser Family Foundation*. See <u>http://www.kff.org/newsmedia/upload/7371.pdf</u> (Last accessed 8/10/2012). Twenty percent of survey respondents reported not filling a prescription due to cost; and 54% of those said their condition got worse as a result. Extrapolated to the 2012 population of adults 18 and older, which is 234,564,071, the number is 25 million.

v U.S. Food and Drug Administration. 76 FR 12969. March 2011. <u>Campaign To Improve Poor Medication</u> <u>Adherence: https://www.federalregister.gov/articles/2011/03/09/2011-5287/campaign-to-improve-poor-medication-adherence-u18.</u> (Last accessed 8/10/12)

<sup>vi</sup> McCarthy, R. "The Price You Pay for the Drug Not Taken". *Business Health 1998*. See <u>http://findarticles.com/p/articles/mi\_m0903/is\_n10\_v16/ai\_n27541886/</u>. (Last accessed 8/10/2012)

<sup>vii</sup> Cohen RA, Kirzinger WK, Gindi RM. Strategies used by adults to reduce their prescription drug costs. NCHS data brief, no 119. April 2013. Hyattsville, MD: National Center for Health Statistics. 2013. See <u>http://www.cdc.gov/nchs/data/databriefs/db119.pdf</u>. (Last accessed 7/22/2013).

<sup>viii</sup> Bate, Roger and Ginger Zhe Jin, Aparna Mathur. "Unveiling the Mystery of Online Pharmacies: An Audit Study. *The National Bureau of Economic Research*. March 2012. See <u>http://www.nber.org/papers/w17955</u>. (Last accessed 8/10/2012)

<sup>ix</sup> National Association of Boards of Pharmacy publishes a list of "Not Recommended Sites" found here: http://www.nabp.net/programs/consumer-protection/buying-medicine-online/not-recommended-sites (Last accessed 8/12/2013). All sites on the list are defined as "rogue". The definition of "rogue" can be found here: http://www.nabp.net/programs/consumer-protection/buying-medicine-online/why-notrecommended/. Online pharmacies that are safe and approved by PharmacyChecker.com appear on this list alongside dangerous websites that intentionally sell counterfeit and adulterated medication and/or do not require a prescription.

x "LegitScript Shuts Down 6,700 Rogue Internet Pharmacies." LegitScript Press Release dated June 28<sup>th</sup>, 2013. See <u>http://online.wsj.com/article/PR-C0-20130628-909470.html</u> (Last accessed 8/12/2013)

<sup>xi</sup> Kocot, S. Lawrence, Senior Vice President and General Counsel, National Association of Chain Drug Stores. April 5<sup>th</sup>, 2004. Statement on Importation of Prescription Drugs Prepared for United States Department of Health and Human Services Task Force on Drug Importation. <u>http://archive.hhs.gov/importtaskforce/session2/presentations/NACD.pdf</u> [Last accessed 8/13/13].

Page 9 - Gabriel Levitt, Vice President, PharmacyChecker.com, LLC , Subcommittee on Courts, Intellectual Property and the Internet, September 18<sup>th</sup>, "Role of Voluntary Agreements in the U.S. Intellectual Property System."

<sup>&</sup>lt;sup>i</sup> "Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and Congress." Executive Office. Prepared by the Office of the Intellectual Property Enforcement Coordinator. March 2011, page 9. See

xii Ismail, M. Asif. "Drug Lobby Second to None: How the Pharmaceutical Industry Gets its Way in Washington." July 7th, 2005. <u>The Center for Public Integrity</u>. <u>http://www.publicintegrity.org/2005/07/07/5786/drug-lobby-second-none</u> [Last accessed 8/13/2013]. Also: Peter Baker. "Obama Was Pushed by Drug Industry, E-Mails Suggest." June 6, 2009. <u>New York Times</u>. <u>http://www.nytimes.com/2012/06/09/us/politics/e-mails-reveal-extent-of-obamas-deal-with-industry-on-</u>

health-care.html?pagewanted=all& r=0 (Last accessed 8/12/2013)

xiii See Alliance for Safe Online Pharmacies "Who We Are" web page: <u>http://safeonlinerx.com/about-us/who-we-are/</u> [Last accessed 8/14/2013].