March 24, 2010

Response of the Alliance for Safe Online Pharmacies ("ASOP") to the Request for Comments from United States Intellectual Property Enforcement Coordinator and the Office of Management and Budget, For the Coordination and Strategic Planning of the Federal Effort against Intellectual Property Infringement (Federal Register Notice of February 23, 2010)

INTRODUCTION

The Alliance for Safe Online Pharmacies ("ASOP") seeks to protect patient safety and ensure patient access to safe and legitimate online pharmacies in accordance with U.S. laws. ASOP's stakeholders include leading organizations representing pharmacists, pharmacies, pharmaceutical manufacturers, patients, and medication safety stakeholders who believe that patients deserve the right to enjoy the convenience of the Internet and access safe and legitimate websites to receive their medicines.

Despite the existence of many safe online pharmacies which do adhere to safety standards, the nature of the Internet has opened the door to thousands of illegal Internet sites posing as legitimate pharmacies but selling potentially unsafe, and often counterfeit, medicines. The result: patients are just one click away from purchasing alleged pharmaceutical products that could result in dangerous or even fatal outcomes.

In response to the request for written submissions for comment on the Intellectual Property Enforcement Coordinator's development of a Joint Strategic Plan for new intellectual property enforcement strategies for the Federal Government (the "Request"), ASOP submits the following research results and recommendations regarding the threat posed to the American public from the sale of counterfeit and other IP-infringing drugs conducted through the Internet.

This Response is divided into three parts, corresponding to those set forth in the Request:

- **PART I** describes the economic and safety threats posed by the sale of counterfeit pharmaceuticals through the Internet, and by related online IP violations.

- **PART II** provides specific recommendations to address the problem, focusing in particular on two areas in which we believe effective solutions can be implemented without overtaxing the resources of the federal government: search engine and domain name registrar practices.

- **PART III** provides responses to relevant "Supplemental Comment Topics" set forth in the Request, including a description of successful existing cooperative efforts by search engine operators and registrars to prevent online IP abuses, and recommendations for expanding such cooperation to materially improve these efforts.

I. THREAT POSED BY ONLINE PHARMACEUTICAL IP VIOLATIONS

The proliferation of counterfeit sales over the Internet is especially problematic in the area of prescription drugs. While U.S. consumers who use brick-and-mortar pharmacies can trust that their medicines are safe, as the pharmacy, pharmacist and pharmaceutical product are all subject to safety laws and standards, consumers who purchase prescription products online often do not enjoy the same protections.

Entering the brand name of a prescription drug or drug maker into a search engine does not guarantee that:

- websites listed in the search results (whether in the "natural" or "sponsored" results) offer only genuine products;
- the entity to which those websites are connected is authorized to sell pharmaceutical products in the U.S.; or
- the entity offers pharmaceuticals that are genuine and approved by the Food and Drug Administration ("FDA").

As FDA Commissioner Margaret Hamburg stated in connection with a government effort in 2009 to curb illegal online sales of medical products:

> Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, or unapproved products, or contain an inconsistent amount of the active ingredient. Taking these drugs can pose a danger to consumers.[1]

Sales of counterfeit drugs and other online pharmaceutical IP violations, often involving infringements of both trademarks and patents as well as violating laws governing the approval of medicines, create both economic threats and serious threats to the health and safety of American consumers.

A. The Economic Threat.

Increasingly in today's global marketplace, many sellers of counterfeit pharmaceuticals conduct their illicit activity almost entirely online – advertising and taking orders online, and arranging for direct shipment of the counterfeit goods from third party manufacturers to the customers. As a result, statutory remedies enacted prior to the explosion in Internet popularity are falling short.[2] When combined with the Internet's low barriers to entry,

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[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm (Nov. 19, 2009 FDA News Release).

[2] For example, those offering counterfeit goods via the Internet may have no storefront or other "brick-and-mortar" premises from which to seize goods pursuant to Section 34(d) of the Lanham Act, which was adopted in the 1980s to combat counterfeiting. *See* 15 U.S.C. § 1116(d). And, because the online sellers can use aliases and provide false identifying information to those hosting their websites, and may be

this has led to a proliferation of online sellers of counterfeit and otherwise illegal pharmaceuticals who are able to undercut the prices offered at traditional brick-and-mortar pharmacies and avoid the oversight of U.S. regulatory agencies by: (1) basing their operations on non-U.S. web servers, shipping and warehouse facilities; and (2) importing products from countries that do not respect the patent laws of the United States.[3] There are currently believed to be over 36,000 rogue online pharmacies operating via the Internet.[4]

Online sellers of counterfeits, like online sellers of genuine pharmaceutical products, can take steps to "optimize" or achieve higher search engine listings for their websites in the "natural" search results and (subject to evolving search engine rules) purchase an IP owner's trademark as a keyword to secure a listing in the "sponsored" results (discussed in more detail in **Part II-B** below). Online purchasers seeking to buy genuine pharmaceuticals – and intending to pay for genuine pharmaceuticals – may instead receive counterfeits. And it is easy for online sellers of counterfeit pharmaceuticals to deceive consumers. For example, Internet sellers can easily post pictures showing genuine products, but then ship counterfeits to those consumers once the sale is placed online.[5] This is in contrast to sales at brick-and-mortar pharmacies, where pharmaceutical products and pharmacists are subject to federal and state regulation and licensing requirements.

The result is a significant impact on the U.S. economy and tax revenues. It is estimated that ten percent (10%) of global pharmaceutical sales are of counterfeit drugs.[6] The World Health Organization estimates that "8% of the bulk drugs imported into the U.S. are counterfeit, unapproved, or substandard" and that "10% of global pharmaceutical commerce, or $21 billion, involves counterfeit drugs."[7] The online sale of

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located in countries where judgments from foreign courts are difficult to enforce, they may be difficult to trace and difficult to sue. *See also Perfect 10, Inc. v. Visa Int'l Serv. Ass'n*, 494 F.3d 788 (9th Cir. 2007) (payment service providers were not liable for unlawful online transactions consummated using their services even after being placed on notice of such transactions).

[3] *See, e.g.*, Sarah D. Scalet, "Auction Blocks," *CSO Magazine*, Aug. 2005, available at http://www.csoonline.com/read/080105/auction.html, (last visited March 16, 2010); CTV.ca News Staff, "Group smashes toys to 'crush' counterfeiting," CTV.ca, Oct. 25, 2007, available at http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20071025/crush_counterfeiting_071025?s_name=&no_ads, (last visited March 16, 2010).

[4] *See* http://www.legitscript.com/, which identifies 36,809 online pharmacies as of March 16, 2010 that do not meet the standards for certification from LegitScript.

[5] "Buying Authentic Products Online," Squidoo.com, available at http://www.squidoo.com/buyauthentic, (last visited March 16, 2010).

[6] Eoin Gleeson, "The Booming Trade in Fake Drugs," *MoneyWeek*, Feb. 13, 2009, available at http://www.moneyweek.com/news-and-charts/economics/the-booming-trade-in-fake-drugs-42209.aspx (last visited March 16, 2010); *see also* "Knock-offs catch on," *The Economist*, March 4, 2010, available at http://www.economist.com/business-finance/displaystory.cfm?story_id=15610089&source=hptextfeature (last visited March 23, 2010) (online sales of all counterfeit goods are estimated to comprise 5-7% of the more than $200 billion in annual online sales).

[7] Albert I. Wertheimer, et al, "Counterfeit Pharmaceuticals: Current Status and Future Projections," 43 J. Am. Pharm. Assoc. 710-8 (2003).

pharmaceuticals is largely unregulated and untaxed due to its multi-national reach and inherent illegality. With total pharmaceutical sales in 2008 expected to have reached nearly $1 trillion, it is clear how large of a potential problem counterfeit medications pose to the U.S. economy and tax revenues.[8]

B. The Health and Safety Threat.

IP violations in the prescription drug context create perhaps an even greater threat to the health and safety of Americans.[9]

The U.S. Food and Drug Administration ("FDA") has established an extensive submission and approval process to ensure that drugs purchased by U.S. consumers are safe and effective.[10] The shipment into the United States of drugs lacking FDA approval is a violation of U.S. law and FDA rules.[11] However, the FDA cannot and does not monitor every one of the countless foreign websites offering illegal versions of brand name drugs, including products that are counterfeit, unapproved and/or trademark- or patent-infringing – and lacks the resources to review every shipment into the U.S. As FDA Commissioner Hamburg recently explained, "It is simply not possible for FDA to inspect our way to safety."[12]

Online sales of unlawful pharmaceutical products pose a significant health and safety risk to U.S. consumers. Unless a website has been verified as adhering to standards required by the National Association of Boards of Pharmacy (NABP), consumers purchasing pharmaceuticals via the Internet currently have no way of knowing if the drugs they receive will contain the correct active ingredients, the correct amount of active ingredient in each dose, a completely different active ingredient, no active ingredient at all – or if the doses will contain toxic or hazardous materials. Problems associated with counterfeit drugs have been documented in countries around the globe. In Haiti, 100 fatal cases of kidney failure were attributed to patients who ingested cough syrup that had been made with antifreeze. In Niger, 60,000 to 80,000 children were treated with an inactive vaccine which may have led to 2,500 fatal infections that would have otherwise been prevented

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[8] Albert I Wertheimer, "Identifying and combating counterfeit drugs," 2008, Expert Rev. Clin. Pharmacol. 1(3), 333-336.

[9] *See, e.g.*, City of New York Office of Comptroller, William C. Thompson, Jr., Comptroller, "Bootleg Billions: The Impact of the Counterfeit Goods Trade on new York City," November 2004, available at http://www.comptroller.nyc.gov/bureaus/bud/04reports/Bootleg-Billions.pdf (last visited March 16, 2010).

[10] *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm (last visited February 6, 2008).

[11] *See* 21 U.S.C. § 331.

[12] Dr. Margaret Hamburg as Commissioner of Food and Drugs, Remarks at the Center for Strategic and International Studies (February 4, 2010) (transcript available at http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm (last visited March 23, 2010)).

by the vaccine.[13] In China, it is suspected that as many as 300,000 people per year die after taking substandard or fake medications.[14]

Selena Walrond of the United Kingdom died after ingesting unlicensed diet pills from a Chinese website. The diet pills, containing the pesticide dinitrophenol, had been banned in the United Kingdom since the late 1930s.[15] Marcia Ann Bergeron of British Columbia, Canada died with 15 times the normal level of aluminum in her liver after purchasing Zolpidem, a hypnotic drug not legally available in Canada, from an online pharmacy suspected of selling counterfeit drugs.[16]

Similar problems afflict U.S. patients. Reports include a U.S. patient in Illinois who fell into a coma after purchasing Xanax pills online that contained quadruple the usual dosage that would be prescribed by a doctor,[17] and another who died after purchasing counterfeit anti-depression drugs from an online pharmacy.[18] Tracy Taylor of Wichita, Kansas died after purchasing Soma, a pain medication, without a prescription and without consulting with a doctor, from an illegal online pharmacy based in Kansas.[19] Studies have found that counterfeit anti-HIV medications, cholesterol-lowering drugs and anti-arthritis medications have been sold in the U.S. containing cement, gypsum, sawdust, industrial solvents and yellow paint.[20]

In addition, there is a well-documented link between sales of counterfeits – including counterfeit drugs – and funding of terrorist activities. For example, some federal investigations, indictments or convictions have linked the counterfeiting of prescription drugs to Middle Eastern terrorist organizations.[21] Other reports have noted that some

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[13] Martijn ten Ham, "Health Risks of Counterfeit Pharmaceuticals," 26 (14) Drug Safety 991-997 (2003) and Roger Bate, "The Deadly World of Fake Drugs," Sept./Oct. 2008, *Foreign Policy*, pp. 56-65.

[14] *See* Steve Boggan, "Headache pills made of rat poison and Viagra made of chalk: We reveal the chilling truth about Internet drugs," April 27, 2009, *MailOnline*, http://www.dailymail.co.uk/health/article-1173735/After-deacons-daughter-killed-medicine-bought-online--chilling-truth-Internet-black-market-prescription-drugs.html (last visited March 16, 2010).

[15] *See* "Woman dies after buying banned slimming pills on the Internet," June 27, 2008, *MailOnline*, http://www.dailymail.co.uk/news/article-1029920/Woman-dies-buying-banned-slimming-pills-Internet.html (last visited March 16, 2010).

[16] *See* "Counterfeit pills bought online led to death, coroner confirms," July 6, 2007, *Victoria Times Colonist*, http://www.canada.com/victoriatimescolonist/news/story.html?id=05142ca2-9796-4868-bf42-76e939915fa5&k=29039 (last visited March 16, 2010).

[17] *See* Keith Epstein, "Online Extra: The Deadly Side Effects of Net Pharmacies," Dec. 18, 2006, *BusinessWeek*, available at http://www.businessweek.com/magazine/content/06_51/b4014070.htm (last visited March 16, 2010).

[18] *See* Angie Cannon, "Dicey Drugs from Abroad," June 18, 2001, *U.S. News & World Report.*

[19] *See* http://safemedicines.blogspot.com/, Weekly News Update, March 28, 2008 (last visited March 16, 2010).

[20] *See* Henry I. Miller, "Imported Drugs: Hidden Disasters," April 8, 2008, *New York Post.*

[21] *See, e.g.*, Ed White, "Detroit-area man guilty in cigarette scheme," *Chicago Tribune*, Jan. 12, 2009, http://archives.chicagotribune.com/2009/jan/12/news/chi-ap-mi-cigarettesmugglin (last visited March 23, 2010); Reuters, "Counterfeit goods are linked to terror groups," *International Herald Tribune*, Feb. 12,

counterfeit drug activity is facilitated by "Russian mafia" groups – more accurately described as organized crime networks mostly based in Russia and Eastern Europe – and Chinese triads, both of which often provide the Internet architecture and financial assistance or money laundering for illicit pharmaceutical operations.[22] Thus at least one potential future threat created by the prevalence of Internet pharmacies is that terrorists could set up rogue websites designed to sell poisonous fake drugs to unsuspecting Americans, or finance other terror-related activity through the illicit sale of counterfeit drugs. As FDA Commissioner Hamburg has recently stated, "we know that we are also vulnerable to potential attacks involving our food or drug supply by terrorists determined to do harm."[23]

II. SPECIFIC RECOMMENDATIONS

As set forth above, the problem of online sales of counterfeit drugs and related online IP violations with respect to prescription pharmaceuticals creates both economic threats and serious threats to the health and safety of American consumers. As described below, we believe that the problem can be combatted more effectively with the assistance of certain online "gate-keepers."

A. The Opportunity For Online Gate-Keepers to Help Combat The Problem.

The Internet presents special challenges to pharmaceutical IP owners trying to track down and stop sellers of counterfeit products, who often do not have physical storefronts or storage facilities from which illicit goods can be seized, and who operate in a virtual world in which it costs little to open new sales outlets or change identities.[24]

2007, available at http://www.iht.com/articles/2007/02/12/business/fake.php (last visited March 16, 2010).

[22] Wyatt Yankus, American Council on Science and Health, "Counterfeit Drugs: Coming to a Pharmacy Near You", August 2006. *See also* Graham Satchwell, *Sick Business: counterfeit medicines and organized crime* (London: Stockholm Network, 2004); *See also* INTERPOL media release, "INTERPOL warns of link between counterfeiting and terrorism. Cites evidence that terrorists fund operations from proceeds," July 16, 2003, available at http://www.interpol.int/Public/ICPO/PressReleases/PR2003/PR200319.asp (last visited March 16, 2010); Carratu International, Plc, "Rise in Counterfeit Market Linked to Terrorist Funding," June 26, 2002, available at http://www.pressbox.co.uk/Detailed/6073.html (last visited March 16, 2010) (counterfeiting proceeds linked to Al-Qaeda, the Irish Republican Army, ETA, the Mafia, Chinese Triad gangs, the Japanese Yakuza crime syndicates, Russian organized criminals and international illegal drug cartels); Revenues from counterfeiting are also reported to finance international crime syndicates that deal in money laundering, human trafficking, and child labor. Dana Thomas, "The Fake Trade," Harper's Bazaar, Jan. 2008, p.71; OECD, "The Economic Impact of Counterfeiting and Piracy – Executive Summary," available at http://www.oecd.org/dataoecd/13/12/38707619.pdf (last visited March 16, 2010) (OECD analysis indicates that criminal networks and organized crime thrive via counterfeiting and piracy activities).

[23] Dr. Margaret Hamburg as Commissioner of Food and Drugs, Remarks at the Center for Strategic and International Studies (February 4, 2010) (transcript available at http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm (last visited March 23, 2010)).

[24] Trademark owners also face obstacles trying to tackle this problem using traditional legal theories of trademark infringement and secondary liability that were largely developed in a pre-Internet world. *See, e.g., Perfect 10, Inc. v. Visa Int'l Serv. Ass'n*, No. C 04-00371 JW, 2005 WL 2007932, at *4-*5 (N.D.

On the other hand, illicit activity on the Internet is often easier to see than more traditional back alley and underground black markets, and there are a handful of convenient chokepoints at which illicit online drug commerce can be blocked electronically – without the cost of sending armed enforcement personnel to thousands of far-flung physical locations. Thus, with cooperation from those in position to block such transactions, there is hope that all stakeholders, including trademark and patent owners and health authorities, could make significant progress in combating online sales of counterfeits.

There are a number of "gate-keepers" involved in the process through which counterfeit and other illicit drugs are advertised, sold and distributed to consumers through the Internet. Each of these gate-keepers may profit from the activity, albeit often unwittingly. Registrars sell domain names to online illegal drug sellers who use them to deceptively attract consumers to the sellers' sites; search engine companies offer sellers the ability to advertise and consumers to link to the sellers' sites; Internet service providers ("ISPs") host the sellers' websites on computer servers; credit card companies and other payment service providers enable the sellers to consummate sales online; and shippers provide the infringing goods to the (often unsuspecting) consumers.

Each of these gate-keepers is potentially in a position to help deter the illegal activity, and we are supportive of a multi-pronged approach involving all of them. This Response focuses on two gate-keeping areas in which we believe effective solutions can be most efficiently and effectively implemented[25] without the need for additional legislation and without overtaxing the resources of the federal government: **search engine operators** and **domain name registrars**.[26]

We believe that, with the encouragement and assistance of the Intellectual Property Enforcement Coordinator, existing voluntary protocols can be uniformly adopted and extended by the relevant parties to significantly reduce the danger created by rogue pharmaceutical websites that abuse our nation's IP laws. ASOP has concluded that securing additional cooperation from search engine operators and domain name registrars – supplementing regimes that have already been voluntarily established with the cooperation of some of them, and regularizing the *ad hoc* assistance often provided to particular IP owners by these gate-keepers – would have a significant impact on the problem.

Cal. Aug. 12, 2005) (noting that "technological advances" and the "ever evolving Internet environment" can make application of current standards difficult).

[25] For example, the simple removal of a search engine link to a rogue Internet pharmacy could alleviate the need for the pharmaceutical trademark owner to take many additional and costly actions including tracking down the identities of those selling the goods (which is time-consuming and expensive, when it is even possible), instituting lawsuits against the sellers in a court with jurisdiction (also time-consuming and expensive, when feasible), prosecuting the cases to conclusion and enforcing any resulting judgments (also time-consuming, expensive, and not always possible).

[26] ASOP believes it is reasonable to expect such gate-keepers, who benefit from online commerce, to take some actions to assist in curbing the illegal sale of pharmaceuticals on the Internet, especially since they are in the best position to efficiently and effectively help stop the problem. Moreover, removal of rogue website listings from search results will presumably lead to a better experience for search engine users.

ASOP is sensitive to the challenges posed by placing any additional burdens on those like search engine operators and registrars that provide the structural underpinnings for the highly desirable online economy. ASOP also accepts that the primary burden for monitoring online sales by rogue Internet pharmacies may need to remain with others, such as affected pharmaceutical companies, and those involved with regulation of pharmacies and prescription pharmaceutical products in the U.S.[27] However, ASOP believes that the status quo is unacceptable and that new steps must be taken by those in the best position to protect the public from rogue Internet sellers of fake and illegal prescription drugs.

B. Search Engine Operators as Effective Gate-Keepers.

Most of the more than 200 million Internet users in the U.S.[28] rely on search engines to find websites offering what they are seeking.[29] Approximately 213 million searches are conducted on search engines in the U.S. each day.[30] Thus, if links to illegal online drug sellers did not appear in search engine results, counterfeit pharmaceutical sales would be significantly reduced.

Nearly all U.S. search engine traffic is handled by a small handful of search engines, with Google leading the way.[31] Although search engine methodologies differ, each search engine company provides two kinds of search results: "natural" search results (sometimes referred to as "organic" search results) that include links to websites

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[27] As described in **Part III-B** below, in November 2009, law enforcement agencies around the world completed a coordinated, weeklong, "International Internet Week of Action" to address the problem of online rogue pharmacies. In total, INTERPOL and the World Health Organization's (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT) coordinated efforts in 24 countries to target 751 websites "engaged in illegal activity including offering controlled or prescription only drugs." http://www.medicalnewstoday.com/articles/171689.php (last visited March 16, 2010). In the United States, the F.D.A. issued 22 warning letters to Web site operators and notified Internet service providers and domain name registrars that those sites were selling pharmaceutical products in violation of U.S. law. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm (last visited March 16, 2010).

[28] Internet World Stats – Usage and Population Statistics, http://www.Internetworldstats.com/stats2.htm (last visited March 16, 2010); Danny Sullivan, "Searches Per Day," Search Engine Watch, available at http://searchenginewatch.com/showPage.html?page=2156461 (last visited March 16, 2010).

[29] *See* Rank for Sales, Search Engine News Section, "Most Users Search to Find Web Sites and Information," http://news-01.rankforsales.com/news-br/001206-0804050746910314-sem-news.html (last visited March 16, 2010).

[30] *See* Danny Sullivan, "Searches Per Day," Search Engine Watch, available at http://search enginewatch.com/showPage.html?page=2156461 (last visited March 16, 2010).

[31] "Nielsen Reports February 2010 U.S. Search Rankings," http://blog.nielsen.com/nielsenwire/online_mobile/nielsen-reports-february-2010-u-s-search-rankings/ (last visited March 16, 2010) (February 2010 Nielsen/NetRatings figures showed 94.1% of the U.S. search engine traffic is handled by only four search engines, Google (65.2%), Yahoo! (14.1%), (Microsoft's MSN/Windows Live/Bing (12.5 %) and AOL (2.3%). *See also* Juan Carlos Perez, "Google crushes competitors in U.S. search market," http://www.itworld.com/AppDev/1634/060724googlesearch/ (last visited March 16, 2010).

"relevant" to the search identified by an algorithm,[32] and "sponsored" results (often placed above or to the right of the "natural" results), for which advertisers pay to have links to their websites appear. If a user enters a search that includes the advertiser's keyword – even in conjunction with other terms (e.g., "cheap [pharmaceutical trademark]"), a link to the advertiser's website may be included in the "sponsored links" section of the search results.

As described in **Part III-A** below, search engine operators have, to varying extents, implemented policies to curb advertising by rogue drug sellers through "sponsored links." These policies generally fall into two categories: (1) blocking links to online pharmacies not certified by an accreditation body, and (2) allowing notice and takedown of links to illegal online drug sellers. An example of the first category is Google's Pharmacy Policy,[33] which requires online pharmacies targeting customers in the United States to be accredited by the National Association of Boards of Pharmacy's VIPPS program.[34] Those not accredited are blocked from appearing in sponsored links. An example of the second category is Yahoo!'s False & Misleading Policy, which requires pharmaceutical IP owners to submit written complaints about rogue drug sellers advertising counterfeits and infringing drugs through sponsored links. Such "notice and takedown" policies generally permit the advertiser an opportunity to dispute the claim of IP infringement or other wrongdoing, to ensure that pharmaceutical IP owners are not overreaching[35] – similar to the protections afforded to accused online copyright infringers under the notice and take-down procedures in the Digital Millennium Copyright Act ("DMCA").[36]

ASOP applauds these policies to block and takedown links to illegal drug sellers in sponsored links, and sees them as an important step in the right direction. However, search engine operators have not always complied with requests to remove links to counterfeit drug sellers and other rogue internet pharmacies from the "natural" results – leaving the public vulnerable to potentially harmful non-FDA approved drugs.

It is believed that the primary rationale for the reluctance to block such listings is that it would affect the purity of the "natural" results upon which users rely. However, the

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[32] *See, e.g.*, "Technology Overview," http://www.google.com/corporate/tech.html (last visited March 16, 2010) ("We use more than 200 signals, including our patented PageRank™ algorithm, to examine the entire link structure of the web and determine which pages are most important. We then conduct hypertext-matching analysis to determine which pages are relevant to the specific search being conducted. By combining overall importance and query-specific relevance, we're able to put the most relevant and reliable results first.")

[33] *See*, http://adwords.google.com/support/aw/bin/answer.py?hl=en&answer=7463 (last visited March 23, 2010).

[34] For more information on VIPPS certifications, *see* http://vipps.nabp.net/verify.asp (last visited March 23, 2010).

[35] *See, e.g.*, http://searchmarketing.yahoo.com/legal/lsstrademarks.php (last visited March 16, 2010).

[36] *See* 17 U.S.C. § 512(c).

"natural" results are not truly pure in the first place. For example, search engines have routinely blocked and/or removed listings for a number of reasons, including:[37]

- To comply with U.S. restrictions on the advertising of gambling;[38]
- To comply with DMCA take-down notices regarding copyright infringements as required by search engine-specific provisions of the U.S. Copyright Act;[39]
- To prevent website owners from engaging in certain conduct designed to boost their search engine results ratings;[40] and
- To comply with French and German laws prohibiting the display and sale of Nazi memorabilia.[41]

ASOP respectfully submits that the danger created by the sale of fake and illegal prescription drugs poses at least as great a threat to public safety – and should be taken at least as seriously by search engine operators – as the above-listed grounds for removal

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[37] Until very recently, Google also filtered natural search results in China to comply with restrictions imposed by the Chinese government, which required "blacklisting" of certain search terms and filtering out many websites from search results – including those relating to independence movements in Taiwan and Tibet, promotion of democracy, and the Falun Gong religious movement – in exchange for permission to operate in that country. *See* Bruce Einhorn, "Search Engines Censured for Censorship," BusinessWeek online, August 10, 2006, http://www.businessweek.com/globalbiz/content/aug2006/gb20060810_220695.htm?_campaign_id=rss_null (last visited March 16, 2010); The SEO Blog, "Google Takes the Rap for the Tech Gang of 4," Apr. 10, 2006, http://www.stepforth.com/blog/2006/google-takes-the-rap-for-the-tech-gang-of-4/ (last visited March 16, 2010).

[38] *See* 31 U.S.C. §§ 5361-5367, "Unlawful Internet Gambling Enforcement Act." That Act requires financial institutions to "code" and "block" transactions from Internet casinos.

[39] 15 U.S.C. § 512(d); Declan McCullagh, "Google excluding controversial sites," cnet news.com, Oct. 24, 2002 (including complaints by the Church of Scientology concerning posting of its papers without authorization), http://news.com.com/Google+excluding+controversial+sites/2100-1023_3-963132.html (last visited March 16, 2010). *See also* Declan McCullagh, "Google pulls links to Kazaa imitator," cnet news.com, Sept. 3, 2003, http://news.com.com/2100-1032_3-5070227.html (last visited March 16, 2010) (Google removed links to eight sites distributing hacked version of Kazaa file-sharing software, and posted a notice stating: "In response to a complaint we received under the Digital Millennium Copyright Act, we have removed eight result(s) from this page. If you wish, you may read the DMCA complaint for these removed results").

[40] In 2004, Google and Yahoo disabled all links to adware maker WhenU when the search engine operators discovered that WhenU was engaging in "cloaking," a technique to boost its search engine results ratings, in violation of both companies' policies. Stephanie Olsen, "Search engines delete adware company," CNET News.com, May 13, 2004, http://news.com.com/2100-1024_3-5212479.html (last visited March 16, 2010).

[41] CNN.com, "Yahoo! loses Nazi auction case," Nov. 20, 2000, http://archives.cnn.com/2000/TECH/computing/11/20/france.yahoo.02/ (last visited March 16, 2010); Declan McCullagh, "Google excluding controversial sites," cnet news.com, Oct. 24, 2002, http://news.com.com/Google+excluding+controversial+sites/2100-1023_3-963132.html (last visited March 16, 2010). For example, Google.fr and Google.de filter out of results listings websites that are anti-Semitic, pro-Nazi, or affiliated with white supremacists. McCullagh, *supra*.

from "natural" search engine results.[42] And we are aware of no evidence indicating that removing listings for sites that sell counterfeit and illegal prescription drugs – the knowing sale of which is a criminal act under the laws of the United States and elsewhere – would be more difficult to implement than removing these other listings.

ASOP also notes that increased cooperation by these potential "gate-keepers" could be beneficial to the gate-keepers themselves. Search engines promise their users a selection system that provides links to "relevant" and "high-quality websites,"[43] and it would be difficult to argue that sites trafficking in counterfeit and illegal prescription drugs – which are by definition engaging in fraudulent, criminal and dangerous conduct – are "relevant" or "high-quality websites." Removal of illegal listings from search results will presumably lead to a better experience for search engine users. Thus, ASOP sees this as an opportunity to create a "win-win-win" situation for search engine operators, pharmaceutical IP owners, and the public, who will be protected from the unwitting purchase of potentially dangerous counterfeit drugs online.

Accordingly, ASOP suggests that appropriate government personnel seek to coordinate and assist efforts by pharmaceutical IP owners and those involved with the regulation of pharmacies and pharmaceutical products in the U.S. to (1) secure uniform search engine policies with respect to sponsored links, and (2) have search engine operators adopt take-down protocols with respect to links in "natural" search results.

C. Registrars as Effective Gate-Keepers.

The websites of rogue online drug sellers often use domain names that incorporate (or in the case of typo-squatting, misspell) pharmaceutical IP owners' product trademarks to attract consumers looking for genuine prescription drugs. In such circumstances, the trademark owner may be able to impede the online seller by recovering the domain name through an alternative dispute resolution procedure such as ICANN's Uniform Domain Name Dispute Resolution Policy ("UDRP"), or through a civil suit under the Anti-Cybersquatting Protection Act ("ACPA").[44]

However, there are serious limitations to such procedures. UDRP actions cost a minimum of $1,000 in filing fees (depending on the ADR provider, the number of domain names in dispute, and the number of arbitrators deciding the case) plus thousands more in attorney's fees to prepare the necessary filings, and the only remedy is obtaining

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[42] We also note that search engines enjoy Congressionally-mandated immunity by virtue of the Communications Decency Act for exercising "a publisher's traditional editorial functions -- such as deciding whether to publish, withdraw, postpone, or alter content," and therefore have full discretion to determine what results to include and not include. *Langdon v. Google, Inc.*, Civ. Action No. 06-319-JJF, 2007 U.S. Dist. LEXIS 11902, (D. Del. February 20, 2007).

[43] http://yhoo.client.shareholder.com/press/overview.cfm ("Yahoo!'s vision is to be the center of people's online lives by delivering personally relevant, meaningful Internet experiences.") (last visited March 16, 2010); http://www.google.com/intl/en/corporate/ ("We are constantly working to provide you with more relevant results so that you find what you're looking for faster.") (last visited March 16, 2010).

[44] The ACPA is codified in Section 43(d) of the U.S. Trademark (Lanham) Act, 15 U.S.C. § 1125(d)).

ownership of the domain name within several months of filing – there are no civil or criminal penalties for the illegal squatting and no recovery of attorney's fees or costs.[45] The ACPA provides for monetary remedies, but it requires institution of a civil court action and can therefore be far more expensive and time-consuming. It can also be difficult to secure and collect a judgment against cybersquatters based outside the U.S. Thus, the financial and time barriers to pursuing relief through these avenues are significant.

Registrars, the parties entrusted to assign domain names to those wishing to operate websites on the Internet, are in a position to provide a more efficient means of recourse by promptly preventing or suspending the posting of websites that use domain names sold by the registrars. The not-for-profit Internet Corporation for Assigned Names and Numbers (ICANN) grants a select number of registrars the privilege of leasing (for varying periods of time) domain names to website operators.[46] One of the policy and contractual requirements placed upon registrars by ICANN is that they must contractually prohibit domain name registrants from using the domain names for unlawful purposes.[47]

Registrars have the ability, and retain, under the terms of service with their customers, the right to disable websites that use the domain names they supply. And unlike ISPs that host websites, who are also in a position to disable access to rogue sites, there is a more limited number of registrars, and they must be accredited by ICANN to retain the privilege of maintaining their role. This places registrars in a good position to efficiently stop rogue Internet sellers of counterfeit pharmaceuticals, and provides justification for asking them to provide such cooperation – as opposed to letting them profit from unlawful conduct of domain name registrants that abuse the process to sell illegal prescription drugs.

As with search engine operators, we propose that pharmaceutical IP owners and those involved with regulation of pharmacies and pharmaceutical products in the U.S. be willing to continue monitoring domain name registrations (rather than impose pre-screening requirements on registrars) and to notify the registrars of rogue registrants (rather than requiring registrars to ferret out the rogues). And, as with search engine operators, there has already been some cooperation. Some registrars will remove access to a domain name and the website associated with it upon receipt of notification and evidence that it is being used for unlawful activity, and there are registrars that will actively assist brand owners by providing information about infringing registrants.[48]

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[45] An additional drawback to UDRP proceedings for the purposes of stopping counterfeiters is the strict requirements for successful UDRP actions, including the requirement that in addition to demonstrating trademark rights in the infringed name, the UDRP complainant must show that the registrant both registered the domain name in bad faith and has used the domain name in bad faith. Thus, UDRP actions have failed in cases addressing bad-faith use following a good-faith registration.

[46] *See* ICANN website at http://www.icann.org/en/about/ (last visited March 16, 2010).

[47] *See* Uniform Dispute Resolution Policy, Paragraph II, available at the ICANN website at http://www.icann.org/en/udrp/udrp-policy-24oct99.htm.

[48] Melbourne IT, for example, has offered a fee-based service called "Registrant Investigation Services" which provides brand owners with a report summarizing all relevant information on a registrant of a

Overall, however, compliance with ICANN policies and procedures relating to unlawful activity and intellectual property infringement is inconsistent, and varies by registrar.

Several registrars refuse to disable access to rogue online drug sellers absent a UDRP decision or court order, or provide other cooperation to pharmaceutical IP owners – again despite their own stated policies prohibiting infringing and unlawful conduct. Refusing to suspend domains clearly used in illegal activity, such as offering counterfeit or unapproved prescription drug products, or selling prescription drugs without requiring a prescription, puts the registrar in the position of knowingly facilitating and even profiting from criminal activity, and may result in potential vicarious or contributory liability. It also prevents the registrar from playing the role that ICANN, through its policies, envisions registrars should play in helping protect Internet users from websites engaged in intellectual property violations or unlawful activity, such as the sale of counterfeit drugs. Some registrars also exacerbate the problem by selling their customers "shielding" or "proxy" services that prevent the public listing of the domain name owner's identity and address, even though domain name registrants are required to provide the registrar with this information.

ASOP sees domain name registrars as potentially very helpful allies in the effort to shut down websites selling pharmaceuticals to U.S. patients in violation of U.S. intellectual property rights and health and safety laws. On the other hand, registrars that are given notice of infringing or unlawful websites but refuse to take action are not only ignoring their ICANN-imposed contractual requirements, they arguably become allies of illegal Internet drug sellers who facilitate the criminal and infringing activity.

Accordingly, ASOP suggests that appropriate government personnel seek to coordinate and assist efforts by pharmaceutical IP owners and those involved with the regulation of pharmacies and pharmaceutical products in the U.S. to secure cooperation by registrars to carry out their terms of service with their customers, and to take steps (including warnings and, for repeat violators, the disabling of websites) to cut the problem off at its source. To the extent registrars are concerned about customer complaints, this could be addressed through agreements in which monitoring parties are required to affirm and stand behind their representations as to the illegality of the rogue sites' conduct under U.S. law.

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particular domain name. *See* http://www.melbourneitdbs.com/online-brand-infringement/registrant-investigation-services.php (last visited March 16, 2010).

III. SUPPLEMENTAL COMMENT TOPICS

Below, as requested, are ASOP's comments with respect to relevant "supplemental" topics set forth in **Part III** of the Request.

A. Successful Agreements Among Stakeholders; Suggested Methods to Minimize Threat Posed by Infringing Goods, Limit Use of Internet to Disseminate Infringing Goods, and Reduce Threats to Public Health and Safety (e.g., Counterfeit Drugs).

(Supplemental Comment Topics 4, 13, 14, 17)

(i) Expand Development and Application of "Best Efforts" Protocols by IP Owners and Search Engines Concerning "Natural" Results.

As noted in **Part II-B** above, successful voluntary efforts have been made to help IP owners have sponsored links to rogue websites (e.g., sellers of counterfeit prescription drugs) removed from search engine listings. For example, an International Trademark Association ("INTA") working group that included trademark owners and search engine company representatives developed a set of "best practices" for securing search engine owners' cooperation based on trademark owners' submission of information deemed sufficient to justify the removal of the links.[49]

Indeed, some search engines now have online forms through which IP owners can submit their complaints about sponsored advertisers, provide links to the offending pages, and set forth the basis for the complaint all online. These complaint forms exist for general trademark violations with respect to sponsored links, as well as for violations of the search engine's particular policy with respect to the sale of counterfeit merchandise.[50] Although these procedures are not perfect (*see* Comment A(ii) below) and do not require responses within set timeframes as the DMCA does, we applaud these efforts by the search engines that are making them.

What is plainly needed now is the development of and voluntary compliance with similar "best efforts" guidelines or protocols for removing natural search engine results that link to websites offering counterfeit pharmaceuticals and engaging in other illegal conduct involving violation of pharmaceutical IP rights. As discussed in **Part II-B** above, we believe that the danger threatened by fake drug sellers is at least as significant as that threatened by copyright infringers, gambling sites, and others whose sites are regularly removed from the natural results of search engines. And our hope and belief is that, with government assistance, this can be achieved voluntarily.[51]

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[49] *See "Best Practices for Addressing the Sale of Counterfeits on the Internet,"* INTA Bulletin, Vol. 64, No. 16, Sept. 1, 2009.

[50] For general trademark complaints: https://services.google.com/inquiry/aw_tmcomplaint; for counterfeit complaints: http://services.google.com/inquiry/aw_counterfeit (sites last visited March 16, 2010).

[51] For example, Google does not offer a procedure for government agencies or brand owners to seek removal of a listing removed from the natural search results. Instead, such parties are instructed by Google to contact the "site's webmaster and request that the content is removed"; only once a brand

We believe that through cooperative efforts involving all concerned parties and, as necessary, appropriate government agencies, there can be further open exchange of ideas and solutions that would target counterfeiting and IP infringing drug abuses utilizing a search engine's natural and sponsored search results. Ultimately, whatever solution results from these efforts must include a method for blocking websites and links to websites suspected of selling or facilitating the sale of counterfeit or otherwise illegal medicines.

(ii) Expanded Cooperation of Search Engines and IP Owners on "Sponsored Links."

On February 9, 2010, Google announced a revision to the Google AdWords Pharmacy Policy in the United States and Canada. Under the new policy, only online pharmacy websites accredited by the U.S.-based National Association Boards of Pharmacy's VIPPS program are allowed to advertise in the U.S. using Google's AdWords keyword purchase program. Furthermore, pharmacies are now only allowed to target AdWords advertisements to users in the country in which they are accredited.[52] ASOP members have observed that this policy change has greatly reduced the number of sponsored link advertisements for brand name prescription drug products. We believe that all search engine operators should be encouraged to adopt similar measures.

In addition, ASOP encourages simplification of the process for submitting complaints to search engines such as Google, Yahoo! and Bing with respect to websites that sell counterfeit drugs or otherwise infringe pharmaceutical IP rights. In addition, we believe that it should be easier for aggrieved consumers to submit complaints, including by allowing anonymous submissions (to avoid discouraging reporting for fear of admitting to an illegal purchase of drugs online without a prescription), and by removing requirements that such consumers identify the IP owner and rights being violated – information to which a typical consumer may not have access.

(iii) Expand ICANN Protocol and Registrars' Assistance.

Consistent with the discussion in **Part II-C** above, we believe that domain name registrars should be encouraged to provide more consistent cooperation with IP owners, including by enforcing their own terms of service (e.g., content guidelines) to disable access to sites that infringe the IP rights of others and/or conduct unlawful activity, particularly when the illegal sale of prescription drugs are involved. Industry and government should work together to encourage all domain name registrars to explicitly prohibit the use of their services to facilitate the sale of prescription drugs in a way that

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owner and site's webmaster have resolved their dispute can either party contact Google to have any cached versions of the website removed that were stored by Google's computers prior to the change. *See* http://www.google.com/support/webmasters/bin/answer.py?hl=en&answer=164734 (last visited March 16, 2010). But it is virtually impossible to contact or even locate many of the operators of rogue online pharmacies, and they have no incentive to cooperate if contacted.

[52] *See* Dan Friedman, "Update to Pharmacy Policy in U.S. and Canada," Feb. 9, 2010, available at http://adwords.blogspot.com/2010/02/update-to-pharmacy-policy-in-us-and.html (last visited March 16, 2010).

violates drug and pharmacy regulations designed to protect the public against counterfeit medicines.[53]

B. Existing Effective Government Procedures/Policies and Existing Processes Involving Cooperation Between Stakeholders and Governments.

(Supplemental Comment Topics 2 & 3)

International Internet Week of Action, November 2009. The FDA's Office of Criminal Investigations, in conjunction with the Center for Drug Evaluation and Research and the Office of Regulatory Affair, Office of Enforcement, targeted over 100 websites (none for genuine U.S. or Canadian pharmacies) engaged in the illegal sale of unapproved or misbranded drugs to U.S. consumers. According to an FDA news release, the agency issued warnings to the website operators and gave notice to ISPs and domain name registrars, whose policies would permit blocking of the websites.[54]

During the week, OCI and FDA import specialists reportedly joined with Immigration and Customs Enforcement ("ICE"), Customs and Border Protection ("CBP"), the Drug Enforcement Administration ("DEA") and the U.S. Postal Inspection Service to target and interdict shipments of illegal drugs through certain International Mail Facilities and express courier hubs. Coordinated actions of this type produce significant efficiencies as they avoid the need for the numerous different pharmaceutical IP owners to take separate actions and they are able to exploit information and other resources not available to private companies.

We applaud this coordinated enforcement effort, especially the takedown of over 100 websites selling illegal medicines. As discussed elsewhere in this Response, this takedown effort should be expanded.

C. Suggestions for Information-Sharing Between Stakeholders and U.S. Agencies.

(Supplemental Comment Topic 5)

The National Center for Missing and Exploited Children ("NCMEC") Public-Private Partnership Model. NCMEC is a public-private group that, among other things, works to stop distribution of child pornography over the Internet using both public and private resources. NCMEC works with the Financial Coalition Against Child Pornography, whose members include the major payment service providers (American Express, MasterCard, Visa and PayPal), and search engine companies (Google, Yahoo!, Microsoft and AOL). The participation of government representatives provides the resources to

[53] Even without this explicit change to existing terms of service, if domain name registries, domain name registrars, Internet service providers and WhoIs privacy protection service providers were to exercise their discretion to terminate service to all individuals and companies that are found to be selling counterfeit or illegal pharmaceuticals, particularly upon receiving notice from interested rights owners, this would go a long way to curbing the explosive growth in online sales of counterfeit and illegal medicines.

[54] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm (Nov. 19, 2009 FDA News Release) (last visited March 16, 2010).

ferret out and address the abuses, and also provides NCMEC determinations with legitimacy that enables PSPs and others to confidently rely on its recommendations. The participation of private players also helps to fund that project.

We would encourage a similar initiative with respect to the online trade in fake and illegal prescription drugs. In addition, such a partnership might be able to adjudicate any disputes that arise in implementing best practices, such as determining when a site is engaged in unlawful activity requiring removal from search engine results or suspending a domain name to disable the site.

D. Suggestions on Public Education and Awareness Programs for Consumers.

(Supplemental Comment Topic 20)

Government agencies are engaged in education efforts to alert consumers about public health risks posed by illegal online drug sellers, but more action is needed.[55] ASOP encourages government agencies, including the FDA, CDC and DEA in coordination with the IPEC, as appropriate, to educate consumers about these risks. The public, including patients and health care providers, need to know that that not all medicine purchased online is sold by legitimate online pharmacies in accordance with U.S. laws. Medicine should not be a "buyer beware" transaction; too much is at stake.

Public-private partnerships could facilitate public education programs focusing on online pharmaceutical products. For example, as done in the past by the DEA, government agencies could partner with search engine providers so that "pop-up" public safety messages appear in response to a consumer's select keyword search, e.g. "cheap [trademarked drug name]." Such public-private partnerships could also arrange for patient safety-focused websites to always appear at the top of the select keyword search results (in the sponsored links section). ASOP also supports government-supported, sector-focused grassroots educational efforts, including targeted materials with data that health care providers, patient organizations, manufacturers and payors could share with their constituencies about how to access safe and legitimate medicine through online pharmacies.

Another method of increasing public awareness about how to avoid fake medicine when shopping online for pharmaceuticals is for the FDA to facilitate the use of an FDA icon that would link a patient to FDA-approved labeling for the particular medical product. These links could be required to be used by any FDA-regulated entity in its own communication and promotional activities, but may also be used voluntarily, according to certain FDA standards and guidelines, by entities not currently regulated by the FDA (such as by safe, legal online pharmacies). Legitimacy for non-regulated entities that are approved to use such an FDA icon would be enhanced, and patient safety would be improved by providing a quick and easy pathway to FDA-approved labeling. Risk of

[55] In late 2009, the FDA warned the public about fake H1N1 treatments where they found that "products represented online as Tamiflu (oseltamivir)" either contained no active ingredient or contained various levels of active ingredient, but were not approved for sale in the United States. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186861.htm (last visited March 17, 2010).

unauthorized use of such an icon could be reduced by technical measures and by increased penalties for counterfeiting that icon.[56]

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We thank the IPEC for allowing ASOP this opportunity to provide comments on the strategic plan to increase enforcement of U.S. intellectual property rights. Online drug sellers are not above the law, nor are they beyond the reach of the law. We look forward to working together with the IPEC to put in place a strategy and enforcement steps to ensure that is true.

[56] ASOP recommended this approach in comments to the FDA on the Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools, Docket No. FDA-2009-N-0441.