UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC,

Plaintiff,

vs.

National Association of Boards of Pharmacy, Alliance for Safe Online Pharmacies, Center for Safe Internet Pharmacies Ltd., LegitScript LLC, and Partnership for Safe Medicines, Inc.,

Defendants.

Civil Action No. 7:19-cv-07577-KMK

PLAINTIFF'S REPLY BRIEF TO DEFENDANT CENTER FOR SAFE INTERNET PHARMACIES LTD'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Judge Kenneth M. Karas Magistrate Judge Paul E. Davison

INTRODUCTION

CSIP of largely does dispute the substantive merits not PharmacyChecker.com's position or its request for a preliminary injunction. Instead, mostly quibbles with of the factual characterizations it some in PharmacyChecker.com's complaint and motion for preliminary injunction. It argues that it is a limited actor in this space, independent of the other named defendants, and one that has no control over its member organizations and does not maintain or even know about another other "blacklist" but for NABP's.

publicly available CSIP's Yet. materials, including "Principles of Participation"-which every CSIP member agrees to adhere to-make clear that CSIP's version of the facts in its opposition does not exactly reflect reality. See Principles, Ex. 1, filed with this reply. Instead, CSIP is a key actor in the concerted effort to suppress competition in the relevant markets and in the related prescription drug market and has close ties to the pharmaceutical industry and the other defendants named here. Further, CSIP does have authority to control its membership and to direct members to take certain actions, including participation in its online database and communications efforts. Finally, as referenced, CSIP maintains its own databases of online pharmacy-related websites that it has deemed unworthy.

Thus, PharmacyChecker.com's requested injunctive relief is appropriate. Courts have long recognized that parties can face antitrust liability for the acts of coconspirators, and injunctions can bind not only principals, but agents as well.

1

ARGUMENT

1. CSIP Is an Integral Player

Although CSIP downplays its own role in the coordinated efforts to curtail access to information about safe and affordable medicine online (and damage PharmacyChecker.com), CSIP has emerged as an active and integral player in the underlying conduct and closely tied to pharmaceutical interests. Indeed, CSIP's very origins make this clear.

CSIP was organized by pharmaceutical interests through efforts led by Eli Lilly, the Alliance for Safe Online Pharmacies (ASOP), and LegitScript. Indeed, ASOP does not simply have close ties to the pharmaceutical industry—it is the pharmaceutical industry. As a Lilly representative explained: "ASOP is the manner in which Lilly (and PhRMA as an observer) is working with other key stakeholders to compile data and collaborate to address the problem of online drug sellers/counterfeits, as we cannot do this as one company, or as PhRMA alone." The Lilly representative identified those "key stakeholders" to include NABP, LegitScript, and the Partnership for Safe Medicine—all co-conspirators named in Plaintiff's complaint. Tellingly, CSIP makes all efforts to avoid even mentioning ASOP in its brief, even though it has partnered with ASOP on extensive "consumer education" campaigns. *See* Ex. 1 at 8 ("In collaboration with our partner, Alliance for Safe Online Pharmacies (ASOP), CSIP supported consumer education campaigns . . . which generated a total of 41,265,758 social media impressions."). CSIP insists that it is independent of these efforts, but if it was truly independent, CSIP would have control over its own decisions of what is and is not a legitimate website. CSIP is under no obligation to follow its co-conspirators' "guidance," yet it—and its members—continue to do so. That guidance includes efforts to boycott PharmacyChecker.com.

Thus, CSIP's active participation in these efforts opens it up to antitrust liability and supports issuance of the requested injunctive relief. See Linens of Eur., Inc. v. Best Mfg., Inc., 2004 WL 2071689, at *13 (S.D.N.Y. Sept. 15, 2004) (recognizing that "knowingly associating" with the principal actor and "act[ing] at its behest to achieve the conspiracy's objective" can be sufficient to impose antitrust liability); see also SmithKline Beecham Corp. v. E. Applicators, Inc., 2002 WL 1197763, at *8 (E.D. Pa. May 24, 2002) ("If... parties agreed to collude in a manner that adversely affected competition within a relevant market, a non-competitor may be part of that conspiracy."); Ozdoba v. Verney Brunswick Mills, Inc., 152 F. Supp. 136, 138 (S.D.N.Y. 1946) ("[M]embers of an affiliated group may conspire illegally to restrain the interstate commerce of others and thereby subject themselves to the prohibitions of the anti-trust laws.").

2. CSIP Has Authority to Require Its Members to Take Affirmative Action

CSIP's primary gripe with PharmacyChecker.com's motion for injunctive relief relates to the request that CSIP be ordered to "require" its members to immediately reflect the changes in all applications of the blacklist. Instead, CSIP suggests that it should only be ordered to "request" that its members reflect any Court-directed changes. CSIP insists on this change by claiming it is in no position to require its members to do anything. Yet, CSIP's past practices and "Principles of Participation" belie this suggestion.

To begin, CSIP has the power to determine the requirements of its membership and has established other non-voluntary requirements, such as participation in data sharing and in communications campaigns. For example, as noted in CSIP's Principles, "CSIP members also have full access to a data-sharing tool . . . about suspected illegitimate online pharmacy websites" Principles at 14. However, CSIP members must agree to participate in this data-sharing tool, which includes "Adding URLs (and other relevant information) of suspected or confirmed illegitimate sites." *Id.* at 8.

Further, CSIP requires its members to agree to "[i]ntegration of communications campaigns via social media, press releases, and other forms through external communications channels." *Id.* These members "are committed to supporting [CSIP's] communications efforts" *Id.* at 15. Indeed, CSIP requires its members, including Google and Microsoft's Bing, to place, at their own expense, ads supplied by CSIP that read "It's not worth the risk" above search results for PharmacyChecker.com and related terms:

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Q	
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pharmacychecker	x Q
ALL NEWS SHOPPING	VIDEOS
Ad · www.verifybeforeyoubuy.org/	
Buy Prescription Drugs Online - Choose a Safe Pharmacy	
It's not worth the risk. Use our free search tool to check your online pharmacy.	
About CSIP	
Help Others Stay Safe	
PharmacyChecker.com - home	
PharmacyChecker.com	
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The ads also encourage viewers to "Use our free tool to check your online pharmacy" and directs the user to a search box "powered by" co-conspirator LegitScript on CSIP's VerifyBeforeYouBuy.com website.

In pursuing this argument CSIP cites case law stating that courts "cannot lawfully enjoin the world at large" when exercising their equitable powers under Rule 65. The point is a valid one, though not useful or relevant in the matter at hand. Plaintiff does not seek to enjoin the world at large; to the contrary, the relief sought is tailored to a handful of key actors in the conspiracy to injure PharmacyChecker.com, including CSIP. Rule 65 is clear: a preliminary injunction may bind "(A) the parties; (B) the parties' officers, agents, servants, employees, and attorneys; and (C) other persons *who are in active concert or participation* with anyone described in Rule 65(d)(2)(A) or (B)." Fed. R. Civ. P. 65(d)(2) (emphasis added). "This language gives force to injunctions and prevents parties from violating them by proxy." *Eli Lilly & Co. v. Gottstein*, 617 F.3d 186, 195 (2d Cir. 2010).

As CSIP itself concedes, courts in the Second Circuit "have found 'active concert' between non-parties and already-enjoined parties in cases where an enjoined party is substantially intertwined with a non-party, including the shared occupation of office space, payment of employee expenses between the non-party and enjoined party, considerable control by the enjoined party over the non-party's operations, and other substantial interconnections" In re Sledziejowski, 533 B.R. 408, 424 (Bankr. S.D.N.Y. 2015); see also New York by Vacco v. Operation Rescue Nat'l, 80 F.3d 64, 70 (2d Cir. 1996); Vuitton et Fils S.A. v. Carousel Handbags, 592 F.2d 126, 129 (2d Cir. 1979).

As discussed above, CSIP is certainly an active participant in these efforts, and it also requires its own members to actively participate as well. Thus, it is appropriate for this Court to enter injunctive relief that may impact them. Still, this concern is premature—and not CSIP's objection to raise.

CSIP relies extensively on *Doctor's Assocs. v. Reinert & Duree, P.C.*, 191 F.3d 297, 304 (2d Cir. 1999). But there, the Second Circuit expressly recognized that an "order forbidding the principal to do an act on her own would normally be understood to bar the principal's servants or agents from doing the act for the principal's benefit." *Id. Doctor's Associates* is distinguishable because it involved an injunction against an agent that was used to bind the principal. As with more associations and

organizations, CSIP acts as the principal with respect to its individual members, directing them to take certain actions. Accordingly, it is appropriate to enter injunctive relief that may bind CSIP and its agents.

3. CSIP Maintains Its Own Version or Versions of the "Blacklist"

Finally, CSIP complains about PharmacyChecker.com's request that the "Not Recommended Sites' blacklist and any similar list" be revised to remove PharmacyChecker.com and PharmacyCheckerBlog.com. Specifically, CSIP claims that it has never "proactively" used the NABP list, nor ever circulated or downloaded it. It also insists that it "does not maintain any other list or database similar to NABP's 'Not Recommended Sites' list." These suggestions are disingenuous, as publicly available information reflects.

To begin, CSIP concedes that it has provided the public URL for the list to its members, so CSIP's distinction is really without a difference. Moreover, CSIP's Principles of Participation state, "In July 2012, CSIP launched its data sharing portal, allowing our partner companies to share information anonymously about illegitimate online pharmacies and be more effective in identifying and taking action against their websites." Principles at 7. "CSIP members . . . have full access to [this] data-sharing tool . . . and each legitimacy designation is made available to CSIP members." *Id.* at 14. The Principles add:

In partnership with a third party vendor, which provides investigative and monitoring services related to illegitimate pharmacies, *CSIP provides an online pharmacy verification tool*. Consumers can enter a URL to see whether an online pharmacy is legitimate, find

7

patient-assistance programs for affordable medications, or report an illegitimate online pharmacy. *This tool is recognized by the National Association of Boards of Pharmacy (NABP) as adhering to its standards aside from the NABP's own VIPPS program*

Id. at 8 (emphases added). The "third party" referred to by CSIP is LegitScript, which powers CSIP's consumer portal and maintains CSIP's database. CSIP cannot seriously claim it does not have its own database / list simply because LegitScript maintains it on its behalf. These materials clearly suggest that CSIP not only utilizes NABP's blacklist but maintains its own list or database as well.¹

CONCLUSION

For the foregoing reasons, PharmacyChecker.com respectfully requests that

the Court grant its motion and enter a preliminary injunction against NABP and CSIP.

Respectfully submitted,

DATED: September 6, 2019

By:

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^{1.} CSIP's Executive Director Marjorie Clifton largely repeated these talking points in a statement to the Subcommittee on Courts, Intellectual Property and the Internet of the House of Representatives Judiciary Committee on September 18, 2013 <u>https://archive.org/stream/gov.gpo.fdsys.CHRG-113hhrg82846/CHRG-113hhrg82846 djvu.txt</u> at 319-20 (last visited Sept. 4, 2019).

CERTIFICATE OF SERVICE

I, Gabriela Hamilton, hereby certify that on this 6th day of September 2019, I caused a copy of Plaintiff's Reply Brief to Defendant Center for Safe Internet Pharmacies Ltd.'s Opposition to Plaintiff's Motion for Preliminary be served upon counsel of record via the Court's electronic filing system.

MILTON

1

EXHIBIT 1

Principles of Participation for Members



March 2014

Prepared by the Center for Safe Internet Pharmacies

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Table of Contents

- I. Executive Summary
- II. Background
- III. Objectives of Document
- IV. CSIP Mission and Goals
- V. CSIP Membership
- VI. Guiding Principles
 - 1. Advertising Service Providers
 - 2. Registries/Registrars
 - 3. Shipping Companies
 - 4. Payment System Operators
- VII. Policies and Methodologies for Addressing Illegitimate Online Pharmacies
 - 1. Be a Good Resource, through CSIP, to Other Organizations Seeking to Improve Practices Related to Addressing Illegitimate Online Pharmacies
 - 2. Information Sharing
 - 3. Collaboration with Partners to Raise Awareness and Protect the Public
- VIII. Conclusion

I. <u>Executive Summary</u>

The Center for Safe Internet Pharmacies (CSIP) is a nonprofit organization chartered in 2011 to allow Internet industry leaders to come together and continue their efforts to address the growing problem of consumer access to illegitimate pharmaceutical products on the Internet.

Over a dozen of the world's leading Internet and e-commerce companies have come together to form CSIP to focus on the promotion of safe online pharmacies through education and enforcement and the provision of a neutral forum for sharing information by and among private sector entities.

This document outlines our Principles of Participation for Internet intermediaries to address illegitimate online drug sellers as well as fundamentals of member involvement. It underscores the need for stakeholders to be willing to take voluntary actions that will enable all organizations involved to do more to make the Internet safer for patients.

II. <u>Background</u>

Illegitimate online drug sellers, sometimes called "rogue online pharmacies," threaten the health, lives, privacy and security of Internet consumers. These actors peddle counterfeit or otherwise illegitimate medications to unsuspecting consumers.¹ And they make millions of dollars doing it.

The threat will not go away on its own. Indeed, the confluence of four global trends – increasing use of the Internet, limited access to and convenience of seeing a doctor, rising consumer confidence in online shopping, and an aging population – portend an even bigger global market for illegitimate online drug sellers, exacerbating the already significant patient safety threat.

As the result of the threat posed by these rogue actors to consumers' trust and safety, and the part that the Internet commerce ecosystem plays in the activities of these illegitimate online sites, some companies – including search advertising providers, social media platforms, registrars, registries, and payment system operators – have responded by establishing compliance policies and voluntary enforcement programs aimed at combating the problem and minimizing the threat posed to Internet users by these bad actors².

As criminals become more sophisticated in how they promote and transact illegitimate online drug sales, it is clear that companies working collaboratively can attempt to frustrate these efforts, in partnership with others who help regulate the Internet ecosystem. Built on the desire of Internet intermediaries to voluntarily try to help protect e-commerce consumers from the health, privacy and security threats posed by illegitimate online drug sellers, CSIP was founded in 2011 as a non-profit with the mission to promote and encourage safe online pharmacies through education, enforcement, and information sharing. CSIP has taken key steps to combat illegitimate online pharmaceutical sites in a few short years, including working with partners to create video public service announcements on the dangers of illegitimate online drug sellers and establishing a secure portal for members to share information about identified suspect online pharmacy websites. As illegitimate pharmacy sites proliferate, CSIP will continue efforts to educate consumers about the dangers of illegitimate drugs and medicines and take actions, individually and collectively, to shut down online pharmacies.

Online service providers can play an important role in helping to better protect consumers by frustrating illegitimate online drug sellers' use of their platforms or services. For example, while Internet search engines do not control the content on third-party websites and are not able to remove websites from the Internet, they can still strive to prevent illegitimate pharmacy websites from advertising via their services. Domain name services providers, registries, and registrars can also suspend services and shut down illegitimate pharmacy sites once these sites have been identified as having illegitimate content.

We encourage CSIP member companies to develop and enforce policies that discourage or prevent websites that are principally dedicated to selling illegitimate prescription drug products. To this end, these Principles of Participation describe some model practices that companies may adopt to help CSIP achieve its goals.

¹ Toscano, P. "The Dangerous World of Counterfeit Prescription Drugs," USA Today. Web. 7 Oct. 2011 at <u>http://www.usatoday.com/money/industries/health/drugs/story/2011-10-09/cnbc-drugs/50690880/1</u>, ("The FDA confirmed that counterfeit versions of legitimate drugs, including Ambien, Xanax, Lexapro, and Ativan, are available for Americans to purchase online. Although counterfeit drug production was originally concerned with lifestyle medications treating non-life threatening conditions, the industry has expanded to produce nearly every type of medicine.") ² In 2010 Google, Yahoo and Bing changed their advertising policies to only allow certified online pharmacies² to participate in their search advertising programs.

We invite other companies and organizations to join CSIP in its work to create a safe online environment for the purchasing of prescription drugs.

III. Objectives of Document

CSIP has five primary objectives for this document:

- i. Provide information about CSIP's mission, goals, and membership;
- ii. Create a tool-kit to share with other online services providers and related companies;
- Actively encourage appropriate sharing of information about illegitimate online pharmacies, the methods being used to circumvent national and international drugs laws, and potential best practices to stop these methods;
- iv. Promote a national discussion about the rise in illegitimate online drug sellers, the dangers to consumers, and the role the private sector can play in curbing illegitimate online pharmacies; and
- v. Be a role model and resource to other private sector organizations and participants in discussions around safe online pharmacy practices.

IV. CSIP Mission and Goals

CSIP's mission is to promote and encourage safe online pharmacies through education, enforcement, and information sharing.

CSIP achieves its goals with three key actions:

- 1. Provide a neutral forum for sharing relevant information among members about illegitimate internet pharmacies identified on their respective systems;
- 2. Establish a publicly available list for consumers of known safe online pharmacy websites; and
- 3. Educate consumers about how to find safe medicine online through partnerships with government leaders, regulators, law enforcement, public health and consumer groups, and health care providers.

Information Sharing

In July 2012, CSIP launched its data sharing portal, allowing our partner companies to share information anonymously about illegitimate online pharmacies and be more effective in identifying and taking action against their websites. Through this collaboration, our member companies have taken action against millions of illegitimate pharmacy sites and related advertisements.

Additionally, in 2012 and 2013, CSIP took part in Operation Pangaea, an international day of education and action against illegitimate online pharmaceuticals. Participants include the FDA, INTERPOL, the World Customs Organization, Permanent Forum of International Pharmaceutical Crime, Heads of Medicines Agencies Working Group of Enforcement Officers, the Medicines and Healthcare products Regulatory Agency of the United Kingdom, the Irish Medicines Board, the London Metropolitan Police, the U.S. Department of Homeland Security, the Center for Safe Internet Pharmacies, and national health and law enforcement agencies from 100 other participating countries. Investigations conducted by the law enforcement, customs, and regulatory authorities involved resulted in civil and criminal charges, seizure of illegal produces, and removal of websites. CSIP member companies were notified about specific sites being targeted, evaluated those sites against member company terms of service and other policies, and took action against sites violating their policies. We also took

part in educational and messaging about the scope of illegitimate online pharmaceuticals. To learn more about the Operation, see the story <u>here</u>.

Separately, CSIP partners with the National Cyber-Forensics and Training Alliance (NCFTA). By way of background, the <u>FBI</u> established NCFTA in 1997 as a forward-looking organization to proactively address the issue of cyber crime, and it has become an international model for bringing together law enforcement, private industry, and academia to share information to stop emerging cyber threats and mitigate existing ones.

Create Safe List

In partnership with a third party vendor, which provides investigative and monitoring services related to illegitimate pharmacies, CSIP provides an online pharmacy verification tool. Consumers can enter a URL to see whether an online pharmacy is legitimate, find patient-assistance programs for affordable medications, or report an illegitimate online pharmacy. This tool is recognized by the National Association of Boards of Pharmacy (NABP) as adhering to its standards aside from the NABP's own VIPPS program.

Consumer Education

In collaboration with our partner, Alliance for Safe Online Pharmacies (ASOP), CSIP supported consumer education campaigns for the Food and Drug Administration (FDA)'s *BeSafeRX* and the Partnership for DrugFree.org's *Medicine Abuse Project*, which generated a total of 41,265,758 social media impressions. The *Medicine Abuse Project's* medication disposal, hosted by the DEA, collected over 244 metric tons of medications at 5,200 sites across the country.

In 2013, CSIP launched a public service announcement competition with Tongal[™], an innovative video production company. This was an opportunity to engage and educate a young adult audience and build our social media following. The winning video was titled 'ePharmony' and can be viewed on our <u>website</u>. Currently, CSIP partners with the Partnership for Safe Medicines to provide infographic materials educating consumers about the issue of illegal online pharmacies and offering advice and information on safe channels for purchasing medications. The campaign is being promoted through CSIP and its member companies.

V. <u>CSIP Membership</u>

CSIP members are proud to work as voluntary participants in promoting the mission of the organization. Currently, our board includes members from online advertising service providers, social media companies, payment system operators, payment processors, domain name services providers and shipping companies.

As part of the CSIP Board of Directors, partner organizations agree to the following guiding principles:

- 1. Annual membership fee to support CSIP operations
- 2. Attendance in monthly telephonic or in-person board meetings
- 3. Participation in the data-sharing tool³
 - Adding URLs (and other relevant information) of suspected or confirmed illegitimate sites
 - Adherence to strict confidentiality provisions
 - All action taken on illegitimate sites is voluntary and subject to individual company guidelines
- 4. Integration of communications campaigns via social media, press releases and other forums through external communications channels

³ Participation in the data-sharing tool as permitted subject to participants' respective policies and consistent with relevant law.

- 5. Willingness to speak publicly about CSIP in appropriate channels (internal and external)
- 6. In kind contribution of resources that benefit the mission of the organization, such as:
 - Communications support
 - Online advertising
 - Hosting board meetings or events
 - Staffing support
- 7. Only addressing human prescription medicines (HPMs) as defined by a legal prescription in the United States; and
- 8. Enforcing company terms and conditions that prohibit the sale and distribution of illegitimate drugs and medicines, suspending suspected rogue operators from participating in monetized member programs, and explaining to participants in those programs the penalties for such violations including the suspension and/or termination of online services.

VI. <u>Guiding Principles</u>

Our member companies offer a wide array of services. Members include advertising service providers, social media platforms, domain name services providers, shipping companies and payment system operators offer significantly different types of services to their customers. Accordingly, some of the suggestions offered in this document may apply differently depending upon the type of member company.

The following lists represent some of the voluntary practices, by sector, taken by our members against illegitimate online drug sellers. These serve not only as guidelines for CSIP members, but are also offered as a model for non-member global organizations operating in the relevant sectors.

1) Advertising Service Providers

Advertising Service Providers enable the placement of advertisements online. For example, Microsoft's Bing, Google and Yahoo (through Bing) are search advertising providers that enable advertisers to place advertisements on sites across the web.

Model practices for advertising service providers:

- Suspension and Termination
 - Prohibit engaging in illegal activity and require compliance with applicable law, and maintain a right to suspend and/or terminate services if these provisions are breached.
- Public Statements

Have a "zero tolerance" policy that prohibits illegitimate online pharmaceutical sites from utilizing advertising services. For example, Bing, Yahoo, Facebook and Google have published advertising policies that prohibit illegitimate online pharmacies from advertising on their platforms.⁴⁵⁶⁷

• Protections

Have controls in place regarding advertising by pharmacies. For example, require that online pharmacies (which advertise prescription drugs to customers in the United States) must be accredited

⁴ Bing's advertising policy can be found here: <u>http://advertise.bingads.microsoft.com/en-us/editorial-pharmacy-prescription-medicine-guidelines</u>

⁵ Google's advertising policy can be found here: <u>https://support.google.com/adwordspolicy/answer/176031?hl=en</u>.

⁶ Facebook's advertising policy can be found here: <u>https://www.facebook.com/ad_guidelines.php</u>

⁷ Yahoo's advertising policy can be found here: http://advertising.yahoo.com/ad-policies/index.htm.

by the National Association Boards of Pharmacy Verified Internet Pharmacy Practice Sites (VIPPS) program, and require advertisers to provide proof of accreditation prior to advertising.

• Enforcement Policies

Have an internal process in place to enforce advertising policies and remove or block known illegitimate online pharmaceutical sites. This process may also allow customers, users, or other interested parties to report suspected illegitimate sites for service provider review.

2) Registries/Registrars

Registries and registrars are involved in the provisioning and sale of domain names. From time to time, illegitimate online pharmacies register domain names and then develop websites on these domain names to try and create a distribution channel for pharmaceuticals in violation of federal and state laws. If given the proper notice information regarding these illegal activities, registrars and registries can take effective action to take down these websites and suspend the domain names from use.

Model practices for registries and registrars:

General Policies

Registrars and registries should acknowledge the ongoing problem of illegitimate online pharmacies and publicly support the work of CSIP and the Alliance for Safe Online Pharmacies (ASOP) and other organizations and companies involved in combating the use of domain names for the illegal distribution of drugs and medicines by illegitimate online pharmacies.

• Monitoring

Where permissible and consistent with company policies and procedures, registrars and registries should submit a list of domain names suspected of being used by illegitimate online pharmacies to online pharmacy verification provider to verify the legitimacy of the websites. After receiving written confirmation from a verification company that a domain name hosts a website that is used to market and distribute drugs and medicines in violation of applicable laws, registrars and registries should take prompt action to take down the illegitimate website.

• Suspension and Termination

Registrars and/or registries should immediately lock and suspend the domain names from use or resolution in the domain name system if a hosted website is determined to be operated by an illegitimate online pharmacy.

Public Statement

Registrars and registries should publish, on their respective websites, a "zero tolerance" statement or policy against illegitimate online pharmacies and include specific provisions in their registrations terms and conditions prohibiting the use of domain names for websites distributing illegitimate pharmaceuticals.

Reporting

Registrars and registries should also include contact information for an "Abuse Contact" on their website

so that users can report suspected illegitimate websites for further investigation by a online pharmacy verification provider.

3) Shipping Companies

Carriers seek to keep consumers safe and help stop the shipment of drugs by illegitimate online pharmacies.

Model practices for shipping companies:

General Policies

Require each shipper to comply with all laws and regulations governing the dispensing, shipment or tender of shipment of prescription pharmaceuticals.

• Training

Train delivery drivers, management, sales and marketing teams, security personnel, and other relevant employees and contractors how to spot red flags that may indicate potentially illegitimate online pharmacy shippers. Teach that red flags, especially in combination with pharmaceutical packaging, may indicate that the shipper is an illegitimate online pharmacy.

• Reporting

Accept reports, including anonymous reports, of potentially illegitimate online pharmacy shippers. Collect all information available regarding the shipper being reported, especially all websites associated with the shipper and the red flag(s) that led to the report being made.

• Investigating

Investigate any reports of potentially illegitimate online pharmacy shippers using the following steps and any additional steps as appropriate: (a) perform Internet or other research on the shipper, including reviewing lists maintained by NABP and other verification and monitoring services; (b) review the account's shipment history, volume, credit history, related accounts, and other relevant information about the shipper; (c) interview personnel familiar with the shipper and/or shipments; (d) consult with law enforcement.

• Termination

When a carrier determines that a shipper is violating federal, state, or local laws or regulations governing the dispensing, shipment or tender of shipment of prescription pharmaceuticals, the carrier should terminate the shipper's account and suspend all pickup, delivery, and other services. The carrier should also take appropriate steps to report the shipper to law enforcement.

4) Payment System Operators

Below are model practices for payment system operators to address the sale of illegitimate pharmaceuticals over the Internet. These voluntary practices are intended to supplement, not replace, policies that payment system operators already have in place and are not designed to replace any law enforcement actions.

• Policies and Procedures

Maintain policies and procedures reasonably designed to prevent unlawful Internet pharmacy merchants from transacting through the electronic payment system, which may include policies and procedures requiring transactions to be legal in both the buyer's and seller's jurisdictions.

• Proactive Internet Monitoring

Employ third party firms and/or proprietary technologies to proactively monitor the Internet for

merchants that attempt to process illegitimate Internet pharmacy transactions.

• Investigate and Remediate

Maintain risk management programs to identify illegitimate Internet pharmacy merchants in order to terminate or remediate offending merchants in a timely manner.

- Under a four party model⁸, the payment system operator would require the merchant's acquiring entity to investigate and subsequently terminate or remediate the offending merchant.
- Under a three party model⁹ (or the PayPal model) the payment system operator would investigate and subsequently terminate or remediate the offending merchant directly.

• Third Party Agent Oversight

Payment system participants, utilizing Third Party Agents to sign up merchants on their behalf, should conduct due diligence on their agents in order to ensure compliance with the payment system operator's policies and procedures regarding the sale of illegitimate pharmaceuticals.

• Stay Informed

Remain informed about legal and regulatory developments with respect to Internet pharmacy sales and adjust risk strategies as appropriate.

⁸In a four-party model, the payment system operator connects four parties in each transaction: card issuing banks, merchant acquiring banks or merchant acquirers, cardholders and merchants.

⁹ In a three-party model, the payment system operator interacts directly with merchants and consumers, in addition to processing transactions, issuing cards and signing up merchants.

VII. Policies and Methodologies for Addressing Illegitimate Online Pharmacies

1. Be a Resource, through CSIP, to Other Organizations Seeking to Improve Practices Related to Addressing Illegitimate Online Pharmacies

CSIP member companies are committed to the mission of good corporate citizenship by a) providing a model of collaborative and proactive engagement against illegitimate online pharmacies and b) being a resource to other organizations striving to minimize the presence of illegitimate online pharmacies on their platforms.

• Model of Collaboration

The fight against illegitimate online pharmacies can be effectively supported by the global community of Internet and e-commerce organizations; however, the efforts of only a few will be futile in completely eliminating the problem. Through coordinated action, information sharing and pooled resources, CSIP members have established a working model with a proven track record of success. It is our hope that the CSIP model will be supported worldwide for maximum impact.

• Resource to Other Organizations

CSIP members support educational efforts not only to consumers, but also to a larger community of Internet and e-commerce organizations. By participating in conferences, industry events, and global forums related to the topic of online pharmacies, CSIP members seek to educate and engage new partners in their efforts. Further, our member companies are committed to being resources to organizations that seek to better their internal policies and practices related to online pharmacies.

2. Information Sharing Among and Between Internet-Related Services Providers

CSIP members also have full access to a data-sharing tool that allows the voluntary sharing of information (consistent with applicable law) about suspected illegitimate online pharmacy websites among members. CSIP members can either query the portal to determine if any other CSIP member has submitted information about a suspected illegitimate Internet pharmacy website, or submit a new website to the database. CSIP has contracted with an Internet pharmacy monitoring and verification service to administer the portal.

Websites submitted to the database are matched against the third party vendor's pharmacy database, and each legitimacy designation is made available to CSIP members (e.g., whether the Internet pharmacy is "illegitimate" or "legitimate", or whether the website is selling dietary supplements or prescription medicines, etc). Websites not yet in the vendor's database are reviewed and classified, and the new classification is made visible to CSIP members along with, when requested, the basis for the classification.

3. Collaboration with Partners to Raise Awareness and Protect the Public

Consumer education is one of CSIP's ongoing priorities. Informed by consumer research, the organization and its partners develop annual communications plans aimed at increasing public awareness about the many issues related to illegitimate online pharmacies and medications purchased through illegal enterprises. The campaigns are designed to reach a variety of stakeholders through targeted channels. Our member companies are committed to supporting our communications efforts by using their online and social media platforms to increase visibility and distribution of our ads and materials. As an example, Microsoft and Google both sponsor search engine ads about CSIP (through Bing and Google Search), and Facebook profiles CSIP materials on their safety page. Such support is critical for outreach to consumers, and we invite other companies to join CSIP and support our efforts.

As part of our ongoing communications efforts, in 2012 CSIP partnered with the Alliance for Safe Online Pharmacies (ASOP) for the "Keep Meds Safe Video Project" via Tongal, a rich social media platform that facilitates video content by crowdsourcing creative work through collaborative contests. The purpose of this educational campaign was to create awareness of the dangers of online pharmacies through social media and public service announcement platforms.

The winning entry, "<u>ePharmony</u>" by Tongal participant FCR Creations, illustrates the dangers of purchasing from illegitimate online pharmacies through a humorous spoof of online dating. It premiered at the Transatlantic Strategic Summit on Internet Pharmacies in Brussels, Belgium in December 2012.

In 2012 and 2013, CSIP supported consumer education campaigns by the Food and Drug Administration (FDA)'s *BeSafeRX* and the Partnership for Drugfree.org's *Medicine Abuse Project*, which generated a total of 41,265,758 social media impressions. Additionally, CSIP partners with the Partnership for Safe Medicines to provide infographic materials about the issue of illegal online pharmacies and offering advice and information on safe channels for purchasing medications. Other trusted online links can be found on CSIP's website, under the <u>Resources</u> tab, to help guide consumers, medical community members, and others considering purchasing prescription drugs via the Internet.

In 2014, CSIP will launch an exciting research project with the Partnership for Drugfree.org. This project aims to identify gaps in current research related to consumer awareness of online pharmacies.

VIII. Conclusion

This working document, drafted by the Center for Safe Internet Pharmacies, is intended to be a resource for organizations wishing to join our call for good corporate citizenship to help protect consumers from the potential harms posed by illegitimate Internet pharmacies. Theses guidelines are intended to promote a safer and more responsible online environment, allowing only safe channels to sell and distribute drugs and medicines through the Internet. The participation of e-commerce and other online platforms will, we hope, substantially reduce the efficacy of predatory and illegitimate online pharmacies that endanger the public and profit international criminal networks.

We encourage any organization to reach out to us if they are interested in adopting the practices described in this document and to take a public stage on the issue. This problem cannot be solved alone, and the Center for Safe Internet Pharmacies seeks global collaboration.

CSIP members are proud of the successes of this voluntary initiative and are committed to continuing their work. If your company is interested in joining CSIP, or in supporting our cause as an ex-officio member, please contact us for more information.

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