

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 NATIONAL
ASSOCIATION OF BOARDS OF
PHARMACY'S OPPOSITION TO
PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION

Judge Kenneth M. Karas
Magistrate Judge Paul E. Davison

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NABP's focus on the importation issue is a red herring that distracts from the question before the Court. Although the parties have engaged in a longstanding dispute over the merits of personal importation, the Court need not choose a side in that argument in order to determine that PharmacyChecker.com is entitled to the relief it seeks. The question before the Court is about competition: Can the defendants lawfully combine to exclude a competitor from the two relevant markets—the market for pharmacy verification services and the market for comparative drug pricing information?

Vigilantism is not a defense to the Sherman Act, and in any case, PharmacyChecker.com does not import medicine—it provides consumers with valuable information that helps keep them safe and make informed purchasing decisions. It has effectively been excluded from these markets by the defendants and suffered irreparable harm, including reputational damage and loss of goodwill that NABP wholly overlooks. The motion-to-dismiss standard is irrelevant to this motion, which is supported by direct and circumstantial **evidence** of the conspiracy. And unlike the consumers in *In re Canadian Import Antitrust Litigation* whose higher prices were caused by government policies, PharmacyChecker.com's injuries were proximately caused by the defendants' anticompetitive conduct. PharmacyChecker.com has shown it is likely to succeed on the merits of its antitrust challenge to defendants' group boycott, that the boycott caused irreparable harm exactly of the type the anti-

trust laws were intended to prevent, that the balance of equities favors PharmacyChecker.com, and that an injunction is in the public interest. This Court should grant the motion and enter an injunction against NABP and CSIP.

ARGUMENT

I. THE INJUNCTION IS PROHIBITORY

Like most preliminary injunctions, the relief sought by PharmacyChecker.com is prohibitory because it seeks a return to the status quo as it existed prior to the conduct giving rise to the complaint. NABP's arguments to the contrary do not comport with the decisions of this circuit: an injunction is not mandatory simply because it requires an affirmative act to return to the status quo, and the status quo does not depend on the passage of time. Regardless, the mandatory/prohibitory distinction is not relevant in antitrust cases.

A "typical preliminary injunction is prohibitory and generally seeks only to maintain the status quo pending a trial on the merits," while a "mandatory injunction, in contrast, is said to alter the status quo by commanding some positive act." *Tom Doherty Assocs. v. Saban Entm't, Inc.*, 60 F.3d 27, 34 (2d Cir. 1995). The status quo is "the last actual, peaceable uncontested status which preceded the pending controversy." *Mastrio v. Sebelius*, 768 F.3d 116, 120 (2d Cir. 2014) (citations omitted). Preserving it "is not confined to ordering the parties to do nothing: it may require parties to take action." *Id.* at 120–21.

In *Mastrio*, the court considered whether an order granting a temporary restraining order requiring the government to reinstate the plaintiffs' health benefits

restored or altered the status quo. *Id.* It held that the order’s “effect was simply a return to the status quo.” *Id.* PharmacyChecker.com likewise seeks relief that returns the parties to the last peaceable status prior to the controversy giving rise to the motion: before PharmacyChecker.com was added to the blacklist. That it took months to result in irreparable harm does not change the analysis.

Regardless, the distinction between mandatory and prohibitory conduct is not relevant in the antitrust context. *California v. Am. Stores Co.*, 495 U.S. 271, 282 (1990) (“[T]he distinction between . . . prohibitory and mandatory relief is illusory in a case of this kind.”). In fact, the Clayton Act, 15 U.S.C. § 26, gives this Court broad power to fashion injunctive remedies aimed at preventing threatened harm to competition. *Am. Stores*, 495 U.S. at 284 (15 U.S.C. § 26 was enacted “not merely to provide private relief, but to serve as well the high purposes of enforcing the antitrust laws.”); *see also Perma Life Mufflers, Inc. v. Int’l Parts Corp.*, 392 U.S. 134, 138(1968) (rejecting requirements beyond those set by Congress because “private [antitrust suits] serve[] important public purposes”), *overruled on other grounds by Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752 (1984).

II. VENUE HERE IS PROPER

The appropriate vehicle to contest venue is a motion for improper venue under Federal Rule of Civil Procedure 12(b)(3), which NABP has not filed. Regardless, NABP transacts business in this district: it has accredited and continues to maintain accreditations for at least 89 pharmacies located in the Southern District of New York

on its own website, the listings for which it publicly posts on its VIPPS website. *See* 15 U.S.C. § 22; Decl. of Lisa Mittwol, Ex. 1. Thus, venue here is proper.

III. PHARMACYCHECKER.COM SHOWS IRREPARABLE HARM

1. PharmacyChecker.com’s Irreparable Harm Is from the Conspiracy, Not Merely NABP’s Overt Act

NABP attempts to put distance between PharmacyChecker.com’s irreparable harm and its act of placing PharmacyChecker.com on its blacklist, which occurred months earlier. But NABP’s overt act in December 2018 is not the appropriate benchmark. This is an antitrust conspiracy case; the question is whether the conspiracy caused PharmacyChecker.com irreparable harm—not whether NABP did, because a conspiracy does not accomplish its objective through one conspirator alone. *Cf. Pinkerton v. United States*, 328 U.S. 640, 646–47 (1946) (holding conspirators liable for all acts in furtherance of conspiracy). In fact, since the filing of this lawsuit, NABP has doubled down on its harm to PharmacyChecker.com: it has now ratcheted up its assertions on its Not Recommended Sites webpage, stating that “all sites” on the list are “unsafe.”¹ It also created new individual pages for each of PharmacyChecker.com and PharmacyCheckerBlog.com to further suppress its search-engine visibility. *See* Exs. A–B attached to the Declaration of Aaron Gott (“Gott Decl.”) filed with this reply.

PharmacyChecker.com could not have shown a threat of irreparable harm in late December 2018, as the full consequences of NABP’s conduct had not yet been

¹ *See* <https://safe.pharmacy/not-recommended-sites/> (last visited Sept. 6, 2019).

realized. Google updated its page rank algorithms implementing the updated blacklist in March 2019. Then, in July 2019, Bing began displaying the pop-up warning to scare consumers away from PharmacyChecker.com.² See Mot. at 6. It was after this latter date that a pattern emerged as crucial circumstantial evidence that forcefully rebuts the very denial that NABP now makes. See Opp’n at 25 (“these allegations deal with unilateral conduct wholly unconnected to any other defendant.”).

2. PharmacyChecker.com Is Threatened with Three Distinct Types of Irreparable Harm

The motion details three types of irreparable harm that PharmacyChecker.com faces: (1) a major disruption of its business, which relies on its visibility to consumers, *Saban Entm’t.*, 60 F.3d at 37 (threatened loss of business is irreparable harm); *Roso–Lino Beverage Distribs. v. Coca–Cola Bottling Co.*, 749 F.2d 124, 125-26 (2d Cir. 1984) (loss of “ongoing business representing many years of effort” is irreparable harm); (2) lost good will and customers, “neither of which could be rectified by monetary damages,” *Jacobson & Co. v. Armstrong Cork Co.*, 548 F.2d 438, 445 (2d Cir. 1977); and (3) reputational damage, particularly since July when Bing added a warning box to PharmacyChecker.com’s search results. NABP largely only addresses the first type, dissecting and downplaying individual facts such as how many customers PharmacyChecker.com has lost to date. NABP argues that a business who loses one-sixth of its

2. As of yesterday, Sept. 5, it appears that Bing removed many warnings relating to PharmacyChecker.com and PharmacyCheckerBlog.com. It continues to maintain warnings for other websites on the blacklist, suggesting that Bing did so in response to this lawsuit.

total customers does not face a major disruption. PharmacyChecker.com disagrees, but it is beside the point: PharmacyChecker.com has lost a substantial proportion of its customers and 70% of its revenue in just a couple of months—that indicates a *threat* of a major business disruption yet to come as the reality of defendants’ scheme sets in and PharmacyChecker.com’s customer base continues to drop.³ That is hardly speculative. Moreover, given the nature of the services that PharmacyChecker.com provides—verification and publication of information about safe online pharmacies—its credibility is especially vital to its success and any loss of reputation or goodwill is both catastrophic and unrecoverable.

IV. NABP’S HARM IS MINIMAL

NABP argues that it will be harmed if an injunction is issued, but it does not explain what that harm is. Elsewhere in the opposition, it references “direct costs on its operations” due to having to modify its list and notify third parties as well as unspecified “reputational damage.” Opp’n at 25. Even if the Court could ascertain those costs and the effect on NABP’s reputation from these vague references, those potential side effects pale in comparison to the irreparable harm PharmacyChecker.com will suffer, and that it has already begun suffering, at the hands of the defendants’ purposeful scheme. To the extent NABP will suffer reputational damage from having

3. As of this filing, PharmacyChecker.com has now lost a total of 8 pharmacies from its listing program since December 2018, the majority of which (6) were lost since March. No new pharmacies have entered the listing program in 2019, in contrast to 8 that joined in 2018. The total number has decreased from 31 at the end of 2018 to 23 at present. Aff. of Tod Cooperman, MD, ¶ 4.

to unwind its anticompetitive conduct, that is not an appropriate consideration for equitable balancing.

V. COMPETITION IS THE OVERRIDING PUBLIC INTEREST

NABP spends substantial effort attempting to convince the Court that international pharmacies are a risk to the public health, but these claims are devoid of any actual evidence that accredited safe international pharmacies pose any risk to public health. Indeed, reported data, including peer-reviewed research, show they are just as safe as U.S. pharmacies. *See, e.g.,* Gott Decl., Ex. C. Setting aside the broader questions about the safety of drug importation, NABP's position defies logic: the very mission of PharmacyChecker.com is to provide patients with information about purchasing medicines from verified **safe** sources online (both U.S. and international). Even Dr. Catizone, who now claims on behalf of NABP that PharmacyChecker.com is a risk to public health, previously admitted on the record that “clearly [PharmacyChecker.com] serve[s] a purpose, and they help consumers, and we serve a different purpose, or maybe just slightly different.” Gott Decl., Ex. D at 10. Thus, NABP's blacklist serves as a risk to public health, denying consumers valid and, indeed, critical prescription drug information.

NABP's argument is further belied by its own course of conduct—it previously added PharmacyChecker.com to its blacklist in 2010, only to reverse course and remove it when PharmacyChecker.com protested. Did NABP simply stand by and watch this supposed patient harm in the intervening eight years—evidence of which

it does not present—occur?

In any case, one public interest overrides all others in an antitrust case: the protection of competition. In fact, the Supreme Court has rejected arguments that enforcing the antitrust laws should take a back seat to safety as nothing more than a full-frontal assault on the national policy in favor of competition. “The Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services.” *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 695 (1978). To make “[e]xceptions to the Sherman Act for potentially dangerous goods and services would be tantamount to a repeal of the statute.” *Id.* It would be no different to deny a preliminary injunction on those same rejected public safety grounds. *See Am. Stores*, 495 U.S. at 283–84 (Clayton Act remedies in public interest); *Minn. Stores*, 495 U.S. at 283–84 (same); *Minn. Mining & Mfg. Co. v. N.J. Wood Finishing Co.*, 381 U.S. 311, 318 (1965) (“[P]rivate antitrust litigation is one of the surest weapons for effective enforcement of the antitrust laws.”).

VI. PHARMACYCHECKER.COM IS LIKELY TO SUCCEED

1. PharmacyChecker.com’s Injury Flows from Defendants, Not the Government

NABP relies entirely on an Eighth Circuit case, *In re Canadian Import Antitrust Litigation*, to contest PharmacyChecker.com’s antitrust standing. 470 F.3d 785 (8th Cir. 2006). That case involved a class of consumers who alleged they suffered an antitrust injury in the form of higher prices for prescription medicine as a result of a conspiracy by pharmaceutical manufacturers to suppress international pharmacy

competition. *Id.* at 791. That court found that the higher prices the consumers paid were not the result of the conspiracy but instead the result of federal government policies restricting the importation of prescription medicine. *Id.* In other words, the plaintiffs' injuries did not flow from the anticompetitive conduct—they flowed from the government policies. By contrast, PharmacyChecker.com's injuries did not result from government policies or government action. They resulted from the defendants' conspiracy. Indeed, they are exactly the desired consequence of the conspiracy: exclusion of PharmacyChecker.com as a competitor in the markets for pharmacy verification and price comparisons by effectively silencing its consumer-facing expression in markets where that expression is the very essence of the service provided.

NABP's proposition that personal importation is necessarily illegal under all circumstances is flatly incorrect—there are exceptions and numerous legitimate pathways to import medicine. *See* Compl., ¶¶ 48–52. Even if that were not the case, this private-party vigilantism is not somehow immunized from antitrust liability. *See Perma Life*, 392 U.S. at 140 (*in pari delicto* inapplicable to antitrust); *Pinto Trucking Serv., Inc. v. Motor Dispatch, Inc.*, 649 F.2d 530, 534 n.5 (7th Cir. 1981) (same).

2. PharmacyChecker.com Submits Evidence, Not Just Allegations, Proving Conspiracy

NABP argues that the injunction should be denied because the complaint fails to state a claim under Federal Rule of Civil Procedure 12(b)(6). But the pleading standard is wholly inapplicable to a motion for preliminary injunction. PharmacyChecker.com, in fact, must show evidence, and it submits that it met its burden of

showing a likelihood of success on the concerted action requirement by supplying both direct and circumstantial evidence of defendants' conspiracy before even having the benefit of discovery.

Even if this motion for preliminary injunction turned, even in part, on whether a complaint would survive a motion to dismiss, NABP's argument is misplaced for two reasons. First, it attempts to rebut those allegations with its own averments despite that, for purposes of Rule 12(b)(6), the Court must assume the truth of the allegations in the complaint and draw all reasonable inferences in favor of the plaintiff. Second, this is ***not*** a parallel conduct case like *Twombly*: PharmacyChecker.com pleads detailed facts that require no inferences to support a conclusion that the defendants consciously committed to a common scheme in violation of Sherman Act Section 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.

DATED: September 6, 2019

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Respectfully submitted,

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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 National Association of Boards of Pharmacy's Opposition to Plaintiff's Motion for Preliminary Injunction and the Declaration of Aaron Gott in Support of Plaintiff's Reply Brief to Defendant National Association of Boards of Pharmacy's Opposition to Plaintiff's Motion for Preliminary Injunction be served upon counsel of record via the Court's electronic filing system.



GABRIELA HAMILTON

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PharmacyChecker.com LLC,

Plaintiff,

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National Association of Boards of
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Pharmacies Ltd., LegitScript LLC, and
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Civil Action No. 7:19-cv-07577-KMK

DECLARATION OF AARON GOTT IN
SUPPORT OF PLAINTIFF'S REPLY
BRIEF TO DEFENDANT NATIONAL
ASSOCIATION OF BOARDS OF
PHARMACY'S OPPOSITION TO
PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION

Judge Kenneth M. Karas
Magistrate Judge Paul E. Davison

I, Aaron Gott, declare and state as follows:

1. I am an attorney admitted in the states of California and Minnesota. I am a Partner at the law firm of Bona Law PC which represents plaintiff PharmacyChecker.com LLC in this matter.

2. This declaration is made in support of Plaintiff's Reply to Defendant National Association of Boards of Pharmacy's Opposition to Motion for Preliminary Injunction.

3. Attached are true and correct copies of the following exhibits:

Exhibit A: "Buy Safely," <https://safe.pharmacy/buy-safely/?url=pharmacychecker.com>.

Exhibit B: "Buy Safely," <https://safe.pharmacy/buy-safely/?url=pharmacycheckerblog.com>.

Exhibit C: "Catch 22: Credentialed online pharmacies are so safe that peer review literature is no longer interested in results showing it" (July 18, 2017), <http://www.aei.org/publication/catch-22-credentialed-online-pharmacies-are-so-safe-that-peer-review-literature-is-no-longer-interested-in-results-showing-it/>.

Exhibit D: Michael McAuliff, "Keeping International Pharmacies Under a Cloud," Tarbell (May 2, 2018), <https://tarbell.org/2018/05/keeping-international-pharmacies-under-a-cloud/>.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 6th day of September 2019 at Minneapolis, Minnesota.

s/Aaron Gott
AARON GOTT

EXHIBIT A

Buy Safely

Purchase medication from legitimate websites online. Search for a site to see if it is safe or not recommended.

Check to see if a site is safe:

pharmacychecker	Search
-----------------	--------

pharmacychecker.com
is on our Not
Recommended List.
Click [here](#) for more
information.



Staying informed about safe ways to buy medication is essential. Although you may be able to find low-priced medication online, you want to make sure that the site is reputable before making a purchase.

Out of almost 12,000 websites reviewed by NABP, nearly 95 percent operate out of compliance with NABP patient safety and pharmacy practice standards, or applicable laws. The scope of the problem is expansive.

- 89 percent of illegal online pharmacies reviewed by NABP did not require a prescription for the sale of prescription-only medicine.
- There is a general lack of awareness about online pharmacies — less than 5 percent of consumers are aware of tools available to help them find safe online pharmacies, according to a [2017 Alliance for Safe Online Pharmacies survey](#).

Look for the .Pharmacy Domain

The .pharmacy domain at the end of a web address means the site has been verified as safe by NABP. Logos are not enough to signal safety on the internet anymore — the .pharmacy domain cannot be faked or forged. When purchasing medicine online, we recommend using pharmacies that have been accredited or verified by NABP.

Beyond the Screen



Risks of Buying from an Unverified Website

- Receiving medication that does not treat a serious medical condition as promised
- Receiving pills with dangerous fillers, such as drywall and rat poison
- Taking drugs laced with fentanyl, a substance up to 100 times stronger than morphine that can cause respiratory distress and death
- Buying drugs that have not been approved by the US Food and Drug Administration
- Falling victim to fraud and identity theft
- Exposing your computer to malware

Some illegal online pharmacies pretend to be based in Canada to give the illusion of more stringent regulation and safer drugs, but they may be based in countries without the regulatory safeguards found in the US and Canada. Historically, illegal online drug sellers advertised on social media and search engines. To combat this, many internet companies — including Google, Bing, Yahoo!, Twitter, and Snapchat — now require drug advertisements be from verified sites.

Not Recommended List

NABP's Not Recommended List (NRL) includes those websites that appear to be out of compliance with NABP patient safety and pharmacy practice standards, or applicable law. Websites on NABP's NRL commonly facilitate:

- the sale of prescription-only medicine without requiring a valid prescription;
- the sale of medicine that has not been approved or authorized for sale in the patient's jurisdiction;
- the practice of pharmacy without required licensure in all relevant jurisdictions.

Some websites on the NRL do not sell drugs directly. Instead, they refer patients to websites that operate in violation of NABP patient safety and pharmacy practice standards, or applicable law.

Using websites on the NRL to purchase drugs may put you or your loved ones at risk.

If you believe your website is mistakenly included on the NRL, email IDOI@nabp.pharmacy to request information about NABP's appeals process.

Found a suspicious website? Report it.

If a website you visited is suspicious, but is not currently listed on the NRL, report it below.

Name of the company or sponsor of the site (if known):

URL of the site: *

Date you found the site: *

How did you learn of the suspicious site? *

- ☐ Email
- ☐ Website referral
- ☐ Other

What was suspicious about the site? *

State where company is located (if known):

Your state of residence: *

Were you or someone you know harmed by the actions of the operators of the site? (Explain) *

May NABP or a regulatory agency contact you for more information or clarification (if necessary)? *

- ☐ Yes
☐ No

Submit

For those interested in applying for a .pharmacy domain, visit our [main website](#).

Stay Connected

Subscribe to our newsletter

email	Subscribe
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[Contact](#) | [Terms of Use](#)

The [NABP privacy policy](#) applies to all NABP websites, including safe.pharmacy.



EXHIBIT B

Buy Safely

Purchase medication from legitimate websites online. Search for a site to see if it is safe or not recommended.

Check to see if a site is safe:

pharmacycheckerblog.com	Search
-------------------------	--------

pharmacycheckerblog.com
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Your state of residence: *

Were you or someone you know harmed by the actions of the operators of the site? (Explain) *

May NABP or a regulatory agency contact you for more information or clarification (if necessary)? *

- ☐ Yes
☐ No

Submit

For those interested in applying for a .pharmacy domain, visit our [main website](#).

Stay Connected

Subscribe to our newsletter

email	Subscribe
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[Contact](#) | [Terms of Use](#)

The [NABP privacy policy](#) applies to all NABP websites, including safe.pharmacy.



EXHIBIT C



Roger Bate

July 18, 2017 9:13 am | *AEIdeas*

Catch 22: Credentialed online pharmacies are so safe that peer review literature is no longer interested in results showing it

Health Care, Health Policy



For nearly a decade I have been buying medicines online for several discrete studies. Seven different medications have been assessed. The first five — Celebrex, Lipitor, Nexium, Viagra, and Zoloft — were rigorously assessed and published in several peer review journals, notably those of the [Public Library of Science](#) and [Berkeley Electronic series](#).



Credentialed pharmacies sell good medicines, whether they come from the United States or overseas.
Via Twenty20.

Subsequently I sampled two generic products, atorvastatin and ciprofloxacin, posting a [short review](#) of the findings.

All in all 822 samples of medicines have been bought, and 26 (about 3%) failed quality tests (22 fake and four substandard). Of the 363 samples bought from non-US credentialed pharmacies, none was fake and only one was substandard. This should be compared with 128 samples from credentialed US pharmacies which had no fakes and also one substandard. All the fakes and remaining substandards (24) came from the 331 samples bought from non-credentialed sites.

These results lead me to conclude that credentialed pharmacies sell good medicines, whether they come from the United States or overseas. (The couple of substandard cipro samples came from approved producers from India, which is a problem whether you buy online or from a bricks and mortar establishment).

One of the reasons that the latter study was not published in the peer review literature is because the literature accepts that credentialed pharmacies sell good products (even if those pharmacies are based outside of US), and new publications would require either much larger sample sizes across myriad medicine types or demonstrable problems with quality for it to be worthy of publication. Editors I've spoken with see little point in repeat purchases and publication unless something newsworthy is found.

But I am told by insiders at the White House and the Food and Drug Administration that it is argued by the industry and its fellow travelers that my sample sizes are too small from too few medicines to be relied upon, and that danger still may lurk in credentialed foreign sites. With the current turmoil in health politics, advancing access through credentialed pharmacies is stalled.

Essentially, the medical and economic literature broadly accepts that credentialed pharmacies are safe, but politically this is irrelevant.

[CORRECTION: The original version of this post initially misstated the number of samples bought. It has since been corrected.]

Learn more: [Patients misled: Indian drugs of uncertain quality are replacing FDA approved products](http://www.aei.org/publication/patients-misled-indian-drugs-of-uncertain-quality-are-replacing-fda-approved-products/)
(<http://www.aei.org/publication/patients-misled-indian-drugs-of-uncertain-quality-are-replacing-fda-approved-products/>)
| [New study: Substandard atorvastatin and ciprofloxacin from web pharmacies](http://www.aei.org/publication/new-study-fda-web-pharmacies/)
(<http://www.aei.org/publication/new-study-fda-web-pharmacies/>) | [What the FDA can do to improve competition](http://www.aei.org/publication/what-the-fda-can-do-to-improve-competition/)
(<http://www.aei.org/publication/what-the-fda-can-do-to-improve-competition/>)

[Drug safety](#), [Drugs](#), [FDA](#), [Generic drugs](#), [Medicine](#), [Pharmacy](#)

EXHIBIT D

Keeping International Pharmacies Under a Cloud

The drug industry worked with the Obama administration to sow safety fears about cheaper medications from foreign sources.

By **Michael McAuliff**

Millions of Americans pinched by high drug prices turn to overseas Internet pharmacies each year. An array of groups funded by the pharmaceutical industry seeks to steer people away from the money-saving option, citing safety concerns that advocates say are largely unfounded.

For years, drug companies have opposed efforts to make it easier for Americans to import cheaper prescription drugs for personal use. Doing so is, in fact, illegal, though the U.S. government does not prosecute individual buyers using the medicines for personal use. The Food and Drug Administration maintains that drugs obtained from foreign sources can be dangerous.



What is striking is the extent to which the industry is winning the battle to limit the online marketplace, including legitimate international pharmacies, under the guise of promoting safety—and, as *Tarbell* has found, with government help.

According to documents obtained through the Freedom of Information Act and provided to *Tarbell*, much of the current constellation of online pharmacy watchdogs was created in 2009 and 2010 by the pharmaceutical industry and advanced, in part, through the White House.

The umbrella organization is called the Alliance for Safe Online Pharmacies, or ASOP. When the Obama administration launched a push to protect U.S. intellectual property in 2010, the group saw a chance to use the battle against counterfeit and copycat products not just to discourage fakes and patent-infringers, but to curtail all importation of drugs, including properly manufactured medicine coming from regulated pharmacies outside the U.S.

Produced by Joey Rettino

Though the organization only appears to have been semi-formally organized at that point, it was able to offer a detailed plan for how to curtail all foreign online drug sales. And it was an official at drug giant Eli Lilly who won the group an audience with officials with the White House Office of the U.S. Intellectual Property Enforcement Coordinator, which helps defend patent rights.

Email Trail

In a May 3, 2010, email seeking an introductory meeting with the office, a member of Lilly's government affairs office named Jeannie Salo explained the role of the group clearly—to go after online pharmacies on behalf of pharmaceutical firms and their lobbying organization, the Pharmaceutical Research and Manufacturers of America.

“As a reminder, 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,” wrote Salo, who is now the company's senior director of international corporate affairs.

Lilly's press office did not respond to email and phone requests from *Tarbell* asking about its role. PhRMA also did not respond to requests for comment for this story.

Other backers of the effort included self-appointed online pharmacy watchdog LegitScript, the National Association of Boards of Pharmacy, and the National Association of Chain Drug Stores, among others. Dues-paying members of ASOP now include the world's largest drug manufacturers, such as Johnson & Johnson, Gilead Sciences, and Merck & Co.

ASOP is run by Libby Baney, an attorney with Faegre Baker Daniels in Washington, D.C., where she is also a principal in its consulting branch. ASOP's address is the same as Faegre's, on K St. ASOP has paid the consulting firm \$675,000 since 2011, according to lobbying disclosures, most of which went to oppose Sen. Bernie Sanders' (I-Vt.) most recent bill to legalize personal prescription imports.

Emails show that after Lilly's Salo introduced ASOP to the White House and IPEC's senior adviser, Andrew Kline, Baney proceeded to set up a meeting in late June 2010. She and Salo were soon regularly corresponding with Kline, primarily to discuss ways to limit online pharmacies. Kline, who now teaches at American University, did not respond to emails asking about his interactions with industry groups to formulate the policy.

After another meeting in September in which ASOP pitched its agenda, the White House office made the industry representatives part of an effort to get Internet companies such as Google, domain name registrars, and credit card companies to do exactly what Big Pharma detailed in its March Blueprint—to implement a voluntary crackdown on online pharmacies that do not have licenses in the United States. The companies were sometimes dubbed “chokepoint” stakeholders in the email traffic since they could cut off electronic payments and shut down websites.

“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,” says the document.

That meeting happened Nov. 9, 2010. While it was focused on Internet and payment firms, one series of emails hints at how deeply the drug industry was pushing the agenda. Although Visa did not attend that

meeting, in the run up to it, the credit card firm apparently agreed to support the broader effort. That information came to the White House's IPEC via an email thread forwarded to Kline from drug companies with the subject line, "Visa agrees to join fight against illegal online sales of medicines."

At the November meeting itself—for which Salo, Baney, and Kline did extensive preparation—ASOP's positions were translated into a PowerPoint presentation for an opening segment designed to convince the Internet and payment companies not so much that intellectual property was at stake, but that online pharmacies are dangerous. Baney sent along the PowerPoint presentation and said she would bring 60 paper copies to hand out. The document also called for federal legislation to address the problem.

The agenda specified that the purpose of the meeting was merely to "encourage" voluntary private sector efforts, and specified that it was "not to have the participants act as a collective body in order to provide advice, opinions, or recommendations to government officials (i.e., the participants are not being asked to serve as a federal advisory committee)." Yet, a follow-up congratulatory email from one of the attendees who had been working on it with ASOP noted "there was some great agreement on the concept of the non-profit entity."

A New Non-Profit

The administration and the industry allies, it seems, were smitten with the idea of cajoling Internet firms and payment processors to get on board with Big Pharma's push against online pharmacies, even if the participants thought they were still just in the talking stage.

According to a story in *Politico Magazine*, those same companies were surprised to learn from a Dec. 14, 2010, news conference with Attorney General Eric Holder, the intellectual property coordinator Victoria Espinel, and Homeland Security Secretary Janet Napolitano that they had agreed to create something called the Center for Safe Internet Pharmacies.

“Prior to that news conference, the participants from those companies had a roundtable conference call to talk about it, but nobody went into that meeting planning to agree to form that group,” Gary Warner, the director of research in computer forensics at the University of Alabama at Birmingham, told *Politico*. “The people I spoke to who watched that announcement saying they’d agreed to form that group came out afterwards and were like, ‘We did?’”

It took more than a year and a half for the new CSIP to get off the drawing board, but in the end, it was what the drug industry wanted, closely matching the blueprint ASOP had offered earlier in the year. Domain registrars would help shutdown rogue pharmacy sites. Credit card companies would deny payments to online pharmacies that were not verified by LegitScript or were flagged by manufacturers.

Search engines would no longer run online pharmacy ads, including from legitimate overseas pharmacies. Google—which had already backed away from pharmacy ads while facing prosecution for running ads from rogue pharmacy sites—was a key part of the deal. This all would likely have been impossible, as Salo argued early on, had ASOP and drug companies not leveraged the White House’s intellectual property push.

The CSIP agreement has had a real impact, making it harder for overseas pharmacists to get paid, said Gabriel Levitt, a vice president and co-founder of PharmacyChecker.com, a New York-based business that verifies the credentials and practices of Internet-based pharmacies.

“Several of PharmacyChecker’s verified pharmacies prefer to take checks now because they can’t take credit cards,” Levitt said. “And it makes them look bad because they can’t offer Visa and MasterCard options to pay.”

The Canadian International Pharmacy Association, which credentials more than 60 international pharmacies, has seen a similar impact.

“We see ourselves as being collateral damage to a policy that they’ve created that is overall designed to stop the sale of narcotics, and controlled substances and prescription drugs without a prescription,

none of which we are involved with,” said CIPA’s general manager, Tim Smith.

A “Smokescreen”

To economist Roger Bate, who is affiliated with the conservative American Enterprise Institute, pharmaceutical manufacturers raise legitimate concerns about counterfeit drugs; he has written a book about it. But Bate says their insistence on lumping regulated overseas pharmacies in with rogue websites is primarily a smokescreen to protect profits.

“The prime reason is economic,” said Bate, who has also authored a number of peer-reviewed studies evaluating the quality and safety of prescription drugs bought online. He and his colleagues have purchased more than 450 drug samples from 75 different Internet sites, including rogue ones. What he found repeatedly is that sites verified by PharmacyChecker and CIPA provide medicine that is essentially the same as what they purchased from verified sites in the United States. Unverified rogue sites were less reliable. In all, Bate came up with nine bogus batches—all Viagra, all from non-credentialed operations.

The idea that regulated drugs from regulated pharmacies in other countries are just as safe as the same drugs in the United States seemed so obvious to Sen. Rand Paul (R-Ky.) last year at Alex Azar’s confirmation hearing to head the Department of Health and Human Services that he tore into the former Lilly executive when Azar refused to say whether those medicines were safe or not.

“What I want you to tell me is why the drugs are not safe in the European Union, and how you’d make it safe,” Paul said, picking Europe as one example and arguing that it would not be hard to create rules to ensure safe imports of those same drugs.

“Everybody just says, ‘It’s not safe,’ and so we never do it,” Paul added. “That’s BS, and the American people think it’s BS that you can’t buy drugs from Europe or from Canada or Mexico or other places.”

There are proponents like PharmacyChecker and CIPA that think they have an answer to the problem. Their model is to work only through international pharmacies that are strictly regulated in the countries where they do business, have actual brick-and-mortar locations, employ licensed pharmacists, and require a doctor's prescription. They say they are connecting Americans to suppliers who get the same regulated drugs from the same manufacturers that U.S. pharmacies do, but for a much lower cost.

“Our business is clearly a private-sector solution to the dearth of information available to patients who are buying medication online from Canada and other countries,” said PharmacyChecker's Levitt.

There have been legal cases involving pharmacies monitored by such groups, although the most prominent prosecution—focused on a site called CanadaDrugs.com—involves a wholesale operation catering to cancer doctors, not retail sales to individuals. A judge accepted a plea deal in the case in April, fining the company \$34 million. Both of the private watchdog sites say that the FDA has never found a dangerous drug that was provided to patients by any of their verified pharmacies.

“We're very careful about what gets dispensed, and I'm not familiar with there ever being an error or an instance of a patient not getting exactly what they had ordered,” said CIPA's Smith.

Industry-Funded Safety Groups



Credit: Joey Rettino | Tarbell

Creating and backing safety advocates like ASOP is a familiar route for the drug industry, which also gives lavishly to hundreds of patient advocacy groups.

For instance, the independent National Association of Boards of Pharmacy—which works extensively with the drug industry—runs an online effort similar to LegitScript that validates safe Internet pharmacies called the Verified Internet Pharmacy Practice Sites (VIPPS) program. It will only verify sites based in the United States, and it has recently required any business getting the verification to use a new “.pharmacy” domain name. According to archived records of NABP’s website, the effort to create that domain was heavily funded by pharmaceutical companies. Lilly, Merck and Pfizer all contributed a minimum of \$100,000. ASOP backed the campaign as well.

Carmen Catizone, the executive director of the NABP, acknowledged that the industry committed seed money needed to create the domain, but insisted his group is independent of the industry, which he said contributes “less than 0.1 percent” of his group’s daily operating budget.

His association's alignment with the pharmaceutical manufacturers' position on importation stems from the need to strictly follow federal law.

"Our interpretation, from the FDA directly and from some states, is it's illegal to import drugs from outside of the US into the US," Catizone said, adding that his organization takes a similar approach in shunning any sort of cannabis business, including in states that have legalized marijuana, because it's still illegal at the federal level.

If federal law changed, NAPB might not oppose import proponents such as PharmacyChecker and the Canadian International Pharmacy Association, he said.

"With PharmacyChecker and CIPA, NABP would love to work and cooperate with them," Catizone said. "It all depends upon that fine line of what's federal law. But clearly they serve a purpose, and they help consumers, and we serve a different purpose, or maybe just slightly different."

Another industry-backed safety group, the Partnership for Safe Medicines, was run for years by PhRMA executive Scott LaGanga, who is a senior vice president for the trade group. The association launched a major advertising campaign in 2017 aimed at derailing Bernie Sanders' proposed legislation to legalize personal importation of prescription drugs and the Partnership continues to run web ads against foreign-sourced medicines. LaGanga did not return a telephone call from *Tarbell* requesting comment.

The group lists a former high-ranking FBI agent named Tom Kubic, who runs another non-profit called the Pharmaceutical Security Institute, or Psi-inc, as treasurer on its most recent IRS forms. The two groups shared a suite at an address in Vienna, Va. for years. Psi-inc is funded by its membership, which its website says is made up of 33 pharmaceutical companies.

Last summer, the Partnership for Safe Medicines retained retired FBI Director Louis Freeh, Kubic's former boss, to investigate and write a report on the dangers of importing drugs. Freeh's work is now

regularly cited by the industry and in op-eds opposing importation, but its connection to pharmaceutical firms is not noted.

Kubic downplayed the interconnectedness of the groups and Big Pharma, saying he primarily viewed his relationship with the Partnership as a way to get important safety information out to various patient groups that are members. He recently left his position there, and the Partnership has moved out of Psi-inc.'s offices. He doesn't see much room to work with private groups whose intent is to evade U.S. law.

"The core question is, 'Is there a way to differentiate a rogue network offering medicines that are unapproved, that are counterfeit, that are stolen, that are diverted?'" Kubic asked. "How confident are you that one of the organizations that claim to be certifying the medicines are safe does in fact do that?"

The Partnership for Safe Medicines did not respond to *Tarbell's* request for interview by our deadline.

International drug importation advocates say there has been no attempt by drug-industry backed organization to look for safer methods of importing drugs, and perhaps ensure certification methods are sound. They feel the groups' only safety play is making it harder for people to step outside the pricing structure currently permitted in the United States.

Asked why people should accept ASOP's guidance, given its ties to Big Pharma, ASOP's Baney said the group's "advice is consistent with that of the U.S. Food and Drug Administration (U.S. FDA) and the National Association of Boards of Pharmacy (NABP), and is directed by leaders from U.S. Pharmacopeia, Purdue College of Pharmacy, RefillWise (a prescription discount program), LegitScript, along with dozens of other non-industry members."

She also pointed out that her board goes beyond drug companies, and that the group "represents the broad array of nonprofit, consumer, public health, provider, academic, and industry stakeholders who care about patient safety online."

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

DECLARATION OF LISA MITTWOL

Judge Kenneth M. Karas
Magistrate Judge Paul E. Davison

I, Lisa Mittwol, declare and state as follows:

1. I am a Senior Paralegal at the law firm of Bona Law PC which represents plaintiff PharmacyChecker.com LLC in this matter.

2. This declaration is made in support of Plaintiff's Reply Brief to Defendant National Association of Boards of Pharmacy's Opposition to Plaintiff's Motion for Preliminary Injunction.


3. Aaron Gott, a Partner at Bona Law PC, asked me to compile a list of pharmacies in the Southern District of New York that are accredited by the National Association of Boards of Pharmacy.

4. I compiled the chart by clicking on the url address, <https://nabp.pharmacy/programs/vipps/vipps-accredited-pharmacies-list/>. I then entered "New York" under the "State" drop-down menu. From there, I expanded the list of each individual pharmacy to see which of those pharmacies were in the Southern District and compiled a chart re: same.

5. Attached as Exhibit 1 is the chart I created of the pharmacies in the Southern District of New York. *See* Ex. 1.

6. I declare under penalty of perjury that the foregoing is true and correct.

Executed this 6th day of September, 2019 at Woodcliff Lake, New Jersey.



Lisa Mittwol

EXHIBIT 1

PHARMACIES IN THE S.D.N.Y. THAT ARE ACCREDITED BY NABP

<u>Pharmacy Name</u>	<u>Street Address</u>	<u>City, State and Zipcode</u>
Acaria Health Pharmacy 12, Inc.	5 Skyline Drive	Hawthorne, NY 10532
Costco Pharmacy - 241	1 Industrial Lane	New Rochelle, NY 10805
Costco Pharmacy - 305	50 Overlook Blvd.	Nanuet, NY 10954
Costco Pharmacy - 321	20 Stew Leonard Drive	Yonkers, NY 10710
Costco Pharmacy - 326	1 Westchester Avenue	Port Chester, NY 10573-4314
Costco Pharmacy - 1062	517 East 117th Street	New York, NY 10035
K Mart Pharmacy - 7749	1 Penn Plaza, 250 W. 34th Street	New York, NY 10119
K Mart Pharmacy - 7777	770 Broadway	New York, NY 10003
Meijer Pharmacy - 459	415 Crossways Park Drive, Suite A	Woodbury, NY 11797-2061
Community, A Walgreens - 16512	2462 Jerome Avenue	Bronx, NY 10467
Walgreens - 5074	55 Westchester Square	Bronx, NY 10461
Walgreens - 7627	3575 Boston Rd	Bronx, NY 10469
Walgreens - 10217	4401 White Plains Road	Bronx, NY 10470
Walgreens - 10411	406 E Fordham Road	Bronx, NY 10458
Walgreens - 10911	1031 Westchester Avenue	Bronx, NY 10459
Walgreens - 10989	2431 Boston Road	Bronx, NY 10467
Walgreens - 11172	1371 Metropolitan Avenue	Bronx, NY 10462
Walgreens - 11267	244 161st Street	Bronx, NY 10451
Walgreens - 11745	2817 3rd Avenue	Bronx, NY 10455
Walgreens - 12309	2504 Eastchester Road	Bronx, NY 10469
Walgreens - 12758	1820 Williamsbridge Road	Bronx, NY 10461
Walgreens - 12899	3085 E. Tremont Avenue	Bronx, NY 10461
Walgreens - 13120	1612 Westchester Avemie	Bronx, NY 10472
Walgreens - 17499	691 Co Op City Blvd., Unit L	Bronx, NY 10475
Walgreens - 17604	541 W. 235th Street	Bronx, NY 10463
Walgreens - 17665	3480 Jerome Avenue	Bronx, NY 10467
Walgreens - 17828	3901 White Plains Road	Bronx, NY 10466
Walgreens - 17926	4232 Baychester Avenue	Bronx, NY 10466
Walgreens - 18322	3012 3rd Avenue	Bronx, NY 10455
Walgreens - 19889	32 E. 170th Street	Bronx, NY 10452
Walgreens - 15212	411 King Street	Chappaqua, NY 10514
Walgreens - 19578	89 Brookside Avenue	Chester, NY 10918
Walgreens - 11291	11 Ashford Avenue	Dobbs Ferry, NY 10522
Walgreens - 9866	370 White Plains Road	Eastchester, NY 10709
Community, A Walgreens	19 Bradhurst Avenue, Suite L1	Hawthorne, NY 10532
Walgreens - 15104	1333 Boston Post Road	Larchmont, NY 10538
Walgreens - 18100	1 Fitzgerald Drive	Middletown, NY 10940
Walgreens - 19693	96 Dolson Avenue	Middletown, NY 10940
Walgreens - 12631	2084 State Road 208	Montgomery, NY 12543
Walgreens - 17736	381 Broadway	Monticello, NY 12701
Walgreens - 13468	31 Cavalry Drive	New City, NY 10956
Walgreens - 12067	416 Windsor Highway	New Windsor, NY 12553
Community, A Walgreens - 16463	29 West 116th Street	New York, NY 10026
Community, A Walgreens - 16547	3954 Broadway	New York, NY 10032
Walgreens - 10135	198 1st Avenue	New York, NY 10009
Walgreens - 10279	1000 2nd Avenue	New York, NY 10022

PHARMACIES IN THE S.D.N.Y. THAT ARE ACCREDITED BY NABP

<u>Pharmacy Name</u>	<u>Street Address</u>	<u>City, State and Zipcode</u>
Walgreens - 10417	1160 3rd Avenue	New York, NY 10065
Walgreens - 11871	545 Third Avenue	New York, NY 10016
Walgreens - 11962	1471 Broadway	New York, NY 10036
Walgreens - 1214	1328 2nd Avenue	New York, NY 10021
Walgreens - 12474	353 W. 57th Street	New York, NY 10019
Walgreens - 15948	525 E. 68th Street, Suite F	New York, NY 10065
Walgreens - 6159	145 4th Avenue	New York, NY 10003
Walgreens - 6160	350 5th Avenue	New York, NY 10118
Walgreens - 7675	33 E. 23rd Street	New York, NY 10010
Walgreens - 9735	20 Astor Place	New York, NY 10003
Walgreens Specialty Pharmacy	205 8th Avenue	New York, NY 10011
Walgreens - 10914	82 N. Plank Road	Newburgh, NY 12550
Walgreens - 13611	16 Route 59	Nyack, NY 10960
Walgreens - 12871	78 Croton Avenue	Ossining, NY 10562
Walgreens - 12760	1201 Main Street	Peekskill, NY 10566
Walgreens - 17494	2460 Route 52	Pine Bush, NY 12566
Walgreens - 7485	107 N. Main Street	Port Chester, NY 10573
Walgreens - 11961	704 Freedom Plains Road, Suite A1	Poughkeepsie, NY 12603
Walgreens - 122633	827 Dutchess Turnpike	Poughkeepsie, NY 12603
Walgreens - 7932	2024 South Road	Poughkeepsie, NY 12601
Walgreens - 12093	870 Central Park Avenue	Scarsdale, NY 10583
Walgreens - 13726	208 E. Rte. 59	Spring Valley, NY 10977
Walgreens - 10446	135 S. Liberty Drive	Stony Point, NY 10980
Walgreens - 4029	209 Rte. 59	Suffern, NY 10901
Walgreens - 16064	81 Rte. 303	Tappan, NY 10983
Walgreens - 2758	162 Wildey Street	Tarrytown, NY 10591
Walgreens - 10464	35 Kensico Road	Thornwood, NY 10594
Walgreens - 12158	1575 Route 9	Wappingers Falls, NY 12590
Community, A Walgreens - 20583	66 E. Post Road, 1st Floor	White Plains, NY 10601
Walgreens - 11593	210 Westchester Avenue	White Plains, NY 10601
Walgreens - 11593	6 Mclean Avenue	Yonkers, NY 10705
Walgreens - 11593	73 Market Street, Suite 178D	Yonkers, NY 10710
Walgreens - 11593	1046 Yonkers Avenue	Yonkers, NY 10704
Sam's Club - 6674	333 Saw Mill River Road	Elmsford, NY 10523
Sam's Club - 6356	56 W. Merritt Blvd.	Fishkill, NY 12524
Walmart Store - 1810	56 W. Merritt Blvd.	Fishkill, NY 12524
Sam's Club - 6423	300 N. Galleria Blvd.	Middletown, NY 10941
Walmart Store - 1959	470 Route 211 E.	Middletown, NY 10940
Walmart Store - 2531	3133 E. Main Street	Mohegan Lake, NY 10547
Walmart Store - 2637	288 Larkin Drive	Monroe, NY 10950
Walmart Store - 2547	41 Anawana Lake Road	Monticello, NY 12701
Walmart Store - 2104	1201 Route 300	Newburgh, NY 12550
Walmart Store - 2905	250 Route 59	Suffern, NY 10901

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.

7:19-cv-07577-KMK

**AFFIDAVIT OF TOD
COOPERMAN, MD IN SUPPORT
OF PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION**

I, Tod Cooperman, MD declare, and state as follows:

1. I am chief executive officer and founder of PharmacyChecker.com, the plaintiff in the above-captioned matter.

2. This affidavit is made in support of Plaintiff's Reply to NABP's Opposition to the Motion for Preliminary Injunction.

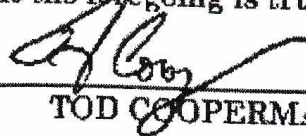
1. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would competently testify.

2. Since NABP placed PharmacyChecker.com on the blacklist in December 2018, PharmacyChecker.com has lost a total of 8 online pharmacies from its listing program and has gained no new ones.

3. Since Google's core update in mid-March 2019, PharmacyChecker.com has lost 6 online pharmacies from its listing program.

4. The total number of pharmacies has decreased from 31 at the end of 2018 to 23 currently.

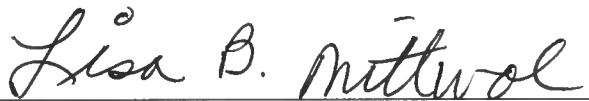
I declare under penalty of perjury that the foregoing is true and correct.



TOD COOPERMAN, MD

State of New York)
) ss
County of New York)

Subscribed to and sworn before me this 6th day of September, 2019 by Tod
Cooperman, MD



Lisa B. Mittwol, Notary Public
My commission expires: December 20, 2021

LISA B. MITTWOL
Notary Public, State of New York
No. 01MI6034982
Qualified in New York County
Commission Expires December 20, 2021