UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PHARMACYCHECKER.COM,

Plaintiff,

v.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, *et al.*,

Defendants.

No. 19-CV-7577 (KMK)

OPINION & ORDER

Appearances:

Aaron R. Gott, Esq.
James F. Lerner, Esq.
Matthew R. Riley, Esq.
Bona Law PC
Minneapolis, MN, New York, NY, and La Jolla, CA
Counsel for Plaintiff/Counter-Defendant

Erik T. Koons, Esq.
Jana I. Seidl, Esq.
Baker Botts LLP
Washington, DC
Counsel for Defendant/Counter-Plaintiff National Association of Boards of Pharmacy

Brian E. Casey, Esq.
Barnes & Thornburg LLP
Washington, DC
Counsel for Defendant/Counter-Plaintiff National Association of Boards of Pharmacy

Leslie E. John, Esq.
Justin W. Lamson, Esq.
Elizabeth P. Weissert, Esq.
James A. Mitchell, Esq.
Ballard Spahr LLP
Philadelphia, PA, and New York, NY
Counsel for Defendant Partnership for Safe Medicines, Inc.

Rachel J. Adcox, Esq.
Melanie Kiser, Esq.

Denise Plunkett, Esq.
Jeny Maier, Esq.
Axinn Veltrop & Harkrider LLP
Washington, DC and New York, NY
Counsel for Defendant Alliance for Safe Online Pharmacies

Barry Werdin, Esq.
Nicholas G. O. Veliky, Esq.
Joshua M. Herman, Esq.
Herrick, Feinstein LLP
New York, NY
Counsel for Defendant Center for Safe Internet Pharmacies Ltd.

KENNETH M. KARAS, United States District Judge:

PharmacyChecker.com ("PCC" or "Plaintiff") brings this Action against the National Association of Boards of Pharmacy ("NABP"), Alliance for Safe Online Pharmacies ("ASOP"), Center for Safe Internet Pharmacies Ltd. ("CSIP"), and Partnership for Safe Medicines ("PSM"; collectively, "Defendants") alleging that Defendants unlawfully conspired to restrain trade in violation of § 1 of the Sherman Act, 15 U.S.C. § 1, and that NABP falsely advertised or promoted in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125. (*See generally* Am. Compl. (Dkt. No. 82).)[1] Before the Court are four motions: (1) Defendants' Joint Motion for Summary Judgment on Plaintiff's Sherman Act § 1 claim, (*see* Not. of Mot. ("SJ Not. of Mot.") (Dkt. No. 263)); (2) Plaintiff's Motion to Strike Portions of Defendants' Submissions in Support of Defendants' Motion for Summary Judgment, (*see* Pl.'s Mot. to Strike Portions of Def.'s Submissions ("Mot. to Strike") (Dkt. No. 273)); (3) Defendants' Joint Motion to Strike Portions of the Declaration of Gabriel Levitt (*see* Defs.' Pre-Motion Letter to Strike ("Levitt Decl. PML") (Dkt. No. 280)); and (4) Defendants' Joint Motion to Exclude the Expert Testimony of Benjamin

[1] PCC also originally brought claims against LegitScript LLC. (*See* Am. Compl.) However, PCC's claims against LegitScript LLC were severed and transferred to the U.S. District Court for the District of Oregon. (*See* Dkt. No. 219.)

England, Esq., (*see* Not. of Mot. ("Daubert Not. of Mot.") (Dkt. No. 260)). For the following reasons, Defendants' Joint Motion for Summary Judgment on Plaintiff's Sherman Act § 1 claim is granted, Plaintiff's Motion to Strike is denied, Defendants' Motion to Strike is denied, and Defendants' Joint Motion to Exclude Expert Testimony is granted in part and denied in part.

I. Background

A. The Parties' Motions to Strike

To start, the Court must address the Parties' motions to strike, which ask this Court to strike portions of both Plaintiff's and Defendants' submissions related to Defendants' motion for summary judgment. (*See generally* Mot. to Strike; Levitt Decl. PML; Defs Mem. of Law in Supp. of Mot. ("Defs.' Mot. to Strike") (Dkt. No. 288).) "Because 'a decision on the motion to strike may affect [the movant's] ability to prevail on summary judgment,' it is appropriate to consider a motion to strike prior to a motion for summary judgment." *Pugliese v. Verizon N.Y. Inc.*, No. 05-CV-4005, 2008 WL 2882092, at *5 (S.D.N.Y. July 9, 2008) (alterations in original) (quoting *Gucci Am., Inc. v. Ashley Reed Trading, Inc.*, No. 00-CV-6041, 2003 WL 22327162, at *2 (S.D.N.Y. Oct.10, 2003)); *see also Pearlstein v. BlackBerry Ltd.*, No. 13-CV-7060, 2022 WL 19792, at *7 (S.D.N.Y. Jan. 3, 2022) ("[I]f [the] defendants' motion to strike is denied, there are numerous genuine issues of material fact that would preclude summary judgment in their favor."). Specifically, "[b]ecause the purpose of summary judgment is to weed out cases in which there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law, it is appropriate for district courts to decide questions regarding the admissibility of evidence on summary judgment,' where the Court must exercise this 'gatekeeper' role." *Congregation Rabbinical Coll. of Tartikov, Inc. v. Vill. of Pomona*, 138 F. Supp. 3d 352, 398 (S.D.N.Y. 2015) (quoting *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997)).

In its Memorandum of Law, Plaintiff argues that certain exhibits and statements "should be stricken and/or disregarded because they violate the Federal Rules of Evidence, are false, and/or blatantly misrepresent the evidence." (Mot. to Strike 1.) Specifically, Plaintiff argues that several of Defendants' statements pursuant to Local Rule 56.1 "rely[] on quoted deposition questions masquerading as testimony." (*Id.*) Plaintiff also argues that several exhibits are not properly authenticated, contain inadmissible hearsay, and lack foundation. (*Id.* at 8.)

In their Memorandum of Law, Defendants argue that Plaintiff offered "rebuttal-type expert witness testimony" in a declaration by PCC's President Gabriel Levitt accompanying Plaintiff's 56.1 reply. (Defs.' Mot. to Strike 2.) Specifically, Defendants request that the Court strike nine statements from the Levitt declaration for lack of foundation based on Mr. Levitt's expertise, as well as for "conclusory opinions" that "contradict the findings of Defendants' SEO expert without evidentiary support." (*Id.* at 2–5.)

For the reasons stated below, Plaintiff's Motion to Strike and Defendants' Motion to Strike are both denied.

1. Applicable Law

Under Local Rule 56.1, motions for summary judgment must be supported by "a separate, short[,] and concise statement, in numbered paragraphs, of the material facts as to which the moving party contends there is no genuine issue to be tried" and, for each paragraph, a "citation to evidence which would be admissible." Local Rules of the United States District Courts for the Southern and Eastern District of New York, Rule 56.1(a) & (d) ("Local Rule 56.1"). "The purpose of Local Rule 56.1 is to streamline the consideration of summary judgment motions by freeing district courts from the need to hunt through voluminous records without guidance from the parties." *Mayaguez S.A. v. Citibank, N.A.*, No. 16-CV-6788, 2022 WL 901627, at *8 (S.D.N.Y. Mar. 25, 2022) (quoting *Holtz v. Rockefeller & Co.*, 258 F.3d 62, 74 (2d

Cir. 2001). Accordingly, a Rule 56.1 statement "is not itself a vehicle for making factual assertions that are otherwise unsupported in the record." *Holtz*, 258 F.3d at 74.

However, "[m]otions to strike are generally disfavored and will not be granted unless the matter asserted clearly has no bearing on the issue in dispute." *Pearlstein*, 2022 WL 19792, at *7 (quoting *Kehr ex rel. Kehr v. Yamaha Motor Corp., U.S.A.*, 596 F. Supp. 2d 821, 829 (S.D.N.Y. 2008)). "A party seeking to strike a Rule 56.1 statement bears a heavy burden . . . ." *Christians of Cal., Inc. v. Clive Christian N.Y., LLP*, No. 13-CV-275, 2014 WL 3407108, at *2 (S.D.N.Y. July 7, 2014) (quotation marks and citation omitted). Accordingly, "courts in this Circuit frequently deny motions to strike paragraphs in Rule 56.1 statements, and [instead] simply disregard any improper assertions." *Ross Univ. Sch. Of Med., Ltd. v. Brooklyn-Queens Health Care, Inc.*, No. 09-CV-1410, 2012 WL 6091570, at *6 (E.D.N.Y. Dec. 7, 2012) (collecting cases), *report and recommendation adopted in relevant part*, 2013 WL 1334271 (E.D.N.Y. Mar. 28, 2013); *see also In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-CV-7488, 2017 WL 6606629, at *1 (S.D.N.Y. Dec. 20, 2017) (disregarding improper legal argument in 56.1 statement).

For that reason, "[w]here . . . the record does not support the assertions in a Local 56.1 statement, those assertions [are] disregarded and the record reviewed independently." *Holtz*, 358 F.3d at 74; *see also Baity v. Kralik*, 51 F. Supp. 3d 414, 419 (S.D.N.Y. 2014) (finding statements "lack[ing] citations to admissible evidence" to violate Local Rule 56.1 and Federal Rule of Civil Procedure 56). Similarly, the Court can also disregard legal conclusions or unsubstantiated opinions in a Local Rule 56.1 statement. *See Am Gen. Life Ins. Co. v. Diana Spira 2005 Irrevocable Life Ins. Trust*, No. 08-CV-6843, 2014 WL 6694502, at *1 (S.D.N.Y. Nov. 25, 2014) ("The Court grants [the plaintiff's] motion [to strike] as to argumentative statements in the [56.1

statement] and as to purported factual statements which are unsupported by any citation to record evidence."); *Epstein v. Kemper Ins. Cos.*, 210 F. Supp. 2d 308, 314 (S.D.N.Y. 2002) ("Statements in an affidavit or Rule 56.1 statement are inappropriate if they are not based on personal knowledge, contain inadmissible hearsay, are conclusory or argumentative, or do not cite to supporting evidence."); *Simmons v. Woodycrest Ctr. for Human Dev., Inc.*, No. 10-CV-5193, 2011 WL 855942, at *1 n.1 (S.D.N.Y. Mar. 9, 2011) (disregarding portions of the defendants' Rule 56.1 statement consisting of legal conclusions or "gross distortions of the summary judgment record"). Importantly, Courts have "broad discretion to determine whether to overlook a party's failure to comply with local court rules." *Holtz*, 258 F.3d at 73.

2. Plaintiff's Motion to Strike

In contravention of this Court's Individual Rules, Plaintiff filed an unauthorized motion asking the Court to strike, in whole or in part, over a quarter of Defendants' statements pursuant to Rule 56.1 and related exhibits: 37 statements and 24 exhibits to be exact. (*See generally* Mot. to Strike.) Plaintiff proffers several overlapping reasons for striking each statement and exhibit, including alleging that Defendants improperly insert legal argument, disputing the factual accuracy of several of Defendants' statements based on quoted material in associated exhibits, as well as questioning the admissibility of exhibits for lack of foundation, authentication, and hearsay concerns. (*Id.*)

In opposition, Defendants categorize Plaintiff's objections as "(i) arguments about how to interpret the evidence provided by Defendants, and (ii) arguments regarding the admissibility of the evidence." (Defs.' Joint Opp. to Mot. to Strike ("Defs Mot. to Strike Opp.") 4 (Dkt. No. 292).) As to the interpretation arguments, Defendants argue that the Court may "draw its conclusions from the documents and depositions submitted, not [a party's] characterization [sic] of [them]," and should deny the formal motion to strike. (*Id.* (quoting *Pharm., Inc. v. Am.*

Pharm. Partners, Inc., No. 05-CV-776, 2007 WL 2728898, at *1 (E.D.N.Y. Sept. 14, 2007)).) As to the admissibility arguments, Defendants broadly disagree, and state that they have satisfied their responsibility at this stage of litigation. (*Id*. at 4–5.)

Regarding Plaintiff's argument that Defendants' statements are replete with legal conclusions and contain factual errors, the Court is well equipped to "disregard" these assertions and review the record independently. *Holtz*, 358 F.3d at 74; *see also Baity*, 51 F.Supp.3d at 419 (finding statements "lack[ing] citations to admissible evidence" to violate Local Rule 56.1 and Federal Rule of Civil Procedure 56); *Simmons*, 2011 WL 855942, at *1 n.1 (disregarding portions of the defendants' Rule 56.1 statement consisting of legal conclusions or "gross distortions of the summary judgment record"). The Court therefore declines to make piecemeal rulings on the relevance of each statement, although it will, as a matter of course, decline to rely upon disputed or otherwise inaccurate assertions.

As to the statements that Plaintiff alleges rely on inadmissible evidence, this Court will exercise its broad discretion and "simply ignore . . . those paragraphs lacking factual support or citing to inadmissible evidence." *Mayaguez S.A.*, 2022 WL 901627, at *8 (alterations and quotation marks omitted) (citing *Emanuel v. Griffin*, No. 13-CV-1806, 2015 WL 1379007, at *2 (S.D.N.Y. Mar. 25, 2015)); *see also Sauerhaft v. Bd. of Educ. of Hastings-on-Hudson Union Free Sch. Dist.*, No. 05-CV-9087, 2009 WL 1576467, at *8 (S.D.N.Y. June 2, 2009) ("[N]othing in the rules or the case law requires a court to strike any portion of a Rule 56(e) affidavit that is not properly supported." (alteration, quotation marks, and citation omitted)). The Court "declines Defendant[s'] invitation to analyze [exhibits] line-by-line to determine which parts comport with the local rules and Fed. R. Civ. P. 56(e) and which do not. The better course of action is to admit" the exhibits and consider only the portions that are admissible. *Miller v.*

Batesville Casket Co., No. 02-CV-5612, 2007 WL 2120371, at *5 (E.D.N.Y. July 23, 2007), *vacated on other grounds*, 312 Fed. App'x 404 (2d Cir. 2009) (summary order); *see also Mayaguez S.A.*, 2022 WL 901627, at *8; *Sauerhaft*, 2009 WL 1576467 at *8 ("A court may decline to conduct a line-by-line analysis and instead simply disregard the allegations that are not properly supported.").

Plaintiff also lodges a blanket objection at scores of exhibits, stating that the exhibits lack authentication and foundation. (*See, e.g.*, Mot. To Strike 8 (listing objections to "other exhibits").) Evidence is authenticated if its proponent provides sufficient evidence to demonstrate that it "is what the proponent claims it is." Fed. R. Evid. 901(a). "A district court 'has broad discretion in determining whether an item of evidence has been properly authenticated.'" *Hallett v. Stuart Dean Co.*, 517 F. Supp. 3d 260, 268 (S.D.N.Y. 2021) (quoting *United States v. Dhinsa*, 243 F.3d 635, 658 (2d Cir. 2001)). As Defendants point out, (*See* Defs. Mot. to Strike Opp. 5), the majority of these exhibits "were produced [by Plaintiff to Defendants] in this litigation, and [Plaintiff] offers no specific reason to doubt any document's authenticity." *Hallett*, 517 F. Supp. 3d at 268; *see also John Paul Mitchell Sys. v. Quality King Distribs., Inc.*, 106 F. Supp. 2d 462, 472 (S.D.N.Y. 2000) ("[T]he act of production implicitly authenticate[s] [a] document[].") . To the extent that Plaintiff's authentication and foundation objections rest upon documents Plaintiff itself produced, the Court will overrule this objection for the purposes of summary judgment. *Comm. Data Servers Inc. v. IBM*, 262 F. Supp. 2d 50, 58 n.3, 60 (S.D.N.Y. 2003) ("There is sufficient evidence of their authenticity for the court to consider these documents on this motion for summary judgment."). For other objections related to authentication or foundation, the Court will address the objections as needed throughout the Court's analysis.

As such, the Court will not "expend judicial resources addressing each of the [exhibits and associated statements] that [Plaintiff] identifies in its motion to determine whether it should be stricken." *Mayaguez S.A.*, 2022 WL 901627, at *8 (alteration omitted). Instead, this Court will, as it is required to do, carefully review and disregard inadmissible or unsupported material. *Id*. To the extent that Defendants' Rule 56.1 Statement cites inadmissible material, or does not provide supporting citations to the record, this Court will disregard it in resolving Defendants' motion for summary judgment.

3. Defendants' Motion to Strike

Defendants argue that "[i]nstead of retaining one or more experts" to rebut Defendants' proffered experts, "Plaintiff has instead attempted a run-around by including what is clearly on its face rebuttal-type expert witness testimony from a lay witness," namely Gabriel Levitt. (Levitt Decl. PML 1.) Specifically, Defendants allege that the relevant statements in the Levitt Declaration "either reference selected portions from the opinions and detailed computations of Defendants' experts, and attempt to refute or twist them to favor Plaintiff, or offer conclusory opinions . . . without evidentiary support." (*Id*. at 2 (citations omitted).) In opposition, Plaintiff argues that the testimony represents "an objective recitation of factual information rather than opinion[,]" and that the statements were otherwise admissible as lay opinion under Federal Rules of Evidence 701. (Pl.'s Opp. to Mot. ("Pl.'s Strike Opp.") 1 (Dkt. No. 299).)

For reasons similar to Plaintiff's motion to strike, this Court denies Defendants' motion to strike as well. This Court will exercise its broad discretion and "simply ignore . . . those paragraphs lacking factual support or citing to inadmissible evidence." *Mayaguez S.A.*, 2022 WL 901627, at *8 (citing *Emanuel*, 2015 WL 1379007, at *2); *see also Sauerhaft*, 2009 WL 1576467, at *8 (explaining that "nothing in the rules or the case law requires a court to strike any portion of a Rule 56(e) affidavit that is not properly supported" and that "[a] court may decline to

conduct a line-by-line analysis and instead simply disregard the allegations that are not properly supported." (alterations, quotation marks, and citations omitted)). To the extent that the Levitt Declaration cites inadmissible material, or does not provide supporting citations to the record, this Court will disregard it in resolving the instant motion for summary judgment.[2]

B. Factual Background

The following facts are taken from the Parties' statements pursuant to Local Civil Rule 56.1, specifically Defendants' 56.1 Statement, (Defs.' Mem. in Supp. of Joint Mot. for Summ. J. Ex. 1 ("Defs.' 56.1") (Dkt. No. 264-1)), Plaintiff's Response to Defendants' 56.1 Statement, (Pls.' Resp. to Defs.' 56.1 Statement ("Pl.'s Resp. 56.1") (Dkt. No. 269-1)), Defendants' Reply to Plaintiff's 56.1 Statement, (Defs.' Reply to Pl.'s 56.1 ("Defs.'56.1 Reply") (Dkt. No. 281-1)), and the admissible evidence submitted by the Parties.[3] The facts are recounted "in the light most

[2] Defendants also lodge several objections to Levitt's "analysis and computations based on numbers derived from the expert report[s]" of Defendants' experts, specifically arguing that this practice is improper expert testimony. (Defs.' Mot. to Strike 2–3 (quotation marks omitted).) It is true that an affidavit may not contain expert testimony unless the affiant has first been designated an expert under Fed. R. Civ. P. 26(a)(2). In this case, no such designation was made. However, Levitt's testimony is more properly understood as testimony by a lay witness "result[ing] from a process of reasoning familiar in everyday life,"—namely, basic arithmetic—instead of expert testimony which "results from a process of reasoning which can be mastered only by specialists in the field." Fed. R. Evid. 701, advisory committee's notes to 2000 amends.; *see also United States v. Rigas*, 490 F.3d 208, 224 (2d Cir. 2007) (ruling that a witness provided permissible lay testimony under Rule 701 "because he merely did the math" (quotation marks omitted)); *Bryant v. Farmers Ins. Exch.*, 432 F.3d 1114, 1124 (10th Cir. 2005) (finding that "the mere calculation of an average of 103 numbers is not the sort of statistical determination which requires" special knowledge). Accordingly, the Court will consider the mathematical calculations contained in Mr. Levitt's declaration.

[3] While "Local Civil Rule 56.1 does not provide for a 'reply' in further support of a Rule 56.1 statement of undisputed facts," it also "does not prohibit such replies." *Cap. Rec., LLC v. Vimeo, LLC*, No. 09-CV-10101, 2018 WL 4659475, at *1 (S.D.N.Y. Sept. 7, 2018). The Court will consider Defendants' reply to the extent that it responds to new facts raised by Plaintiffs in their response, including Plaintiff's additional statements of undisputed facts and any new evidence introduced in Plaintiff's response. *See Roth v. Cheesecake Factory Rests., Inc.*, No. 19-CV-6570, 2021 WL 1103505, at *2 (S.D.N.Y. Feb. 5, 2021) (considering only facts asserted in response to new facts raised in the non-movant's response), *report and recommendation*

favorable to" Plaintiff, the non-movant. *Wandering Dago, Inc. v. Destito*, 879 F.3d 20, 30 (2d Cir. 2018) (quotation marks omitted).

1. Overview of Plaintiff PCC's Website

The Parties agree that PCC itself "is not a pharmacy and does not sell, dispense, or distribute drugs." (Pl.'s Resp. 56.1 ¶ 96; Defs.' 56.1 Reply ¶ 96.)[4] However, the Parties dispute the ultimate mission of PCC, specifically whether PCC is targeting its marketing toward U.S. consumers. (*See* Defs.' 56.1 ¶¶ 38–50; Pl.'s Resp. 56.1 ¶¶ 38–50.) Defendants assert that "PCC's mission is to help U.S. consumers find and purchase lower-cost medicine from pharmacies outside the U.S." (Defs.' 56.1 ¶ 38.) Plaintiff asserts that PCC's mission is to "ensure that consumers are properly informed about purchasing safe and affordable medication online to meet their individual health needs" and "to help consumers afford medication they need." (Pl.'s Resp. 56.1 ¶ 38.) Defendants argue that "PCC solicits American consumers to use PharmacyChecker.com to find and import drugs from international pharmacies to save money."

adopted, No. 19-CV-6570, 2021 WL 912416 (S.D.N.Y. Mar. 10, 2021); *Cunningham v. Cornell Univ.*, No. 16-CV-6525, 2019 WL 4735876, at *1 n.3 (S.D.N.Y. Sept. 27, 2019) ("The Court will not consider . . . [the] [d]efendants' [r]eply except to the extent it responds to new facts in [the] [p]laintiffs' [c]ounterstatement."); *Pape v. Dircksen & Talleyrand Inc.*, No. 16-CV-5377, 2019 WL 1435882, at *3 (E.D.N.Y. Feb. 1, 2019) (declining "to consider the Reply Rule 56.1 Statement, except to the extent it responded to [] new facts"), *report and recommendation adopted*, No. 16-CV-5377, 2019 WL 1441125 (E.D.N.Y. Mar. 31, 2019).

[4] Defendants dispute this clause only insofar as it "implies that [PCC] does not assist in or enable the sale and distribution of drugs to consumers." (Defs.' 56.1 Reply ¶ 96.) This dispute does not substantively undermine the factual allegation, and accordingly, the Court deems this fact admitted. *See Arch Specialty Ins. Co. v. TDL Restoration, Inc.*, No. 18-CV-6712, 2021 WL 1225447, at *1 n.1 (S.D.N.Y. Mar. 31, 2021) (collecting cases) ("Where the Parties identify disputed facts but with semantic objections only or by asserting irrelevant facts, [the Court will not consider] these purported disputes, which do not actually challenge the factual substance described in the relevant paragraphs, . . . as creating disputes of fact.").

(Defs.' 56.1 ¶ 39.)[5] Plaintiff argues that PCC "encourages visitors worldwide to use information on its website." (Pl.'s Resp. 56.1 ¶ 39.) Finally, Defendants claim that PCC "targets U.S. consumers with the 'title tags' of its web pages—around 70% of the site's pages have 'US' or 'U.S.' in their title tags." (Defs.' 56.1 ¶ 41.) Plaintiff counters that the HTML meta tags "reflect information [P]laintiff tracks so that [PCC] users have an accurate idea of what to expect on [P]laintiff's website." (Pl.'s Resp. 56.1 ¶ 41.) Regardless, the Parties agree that "PCC's 'forte' is 'international online pharmacies' prices[,]'" (Defs.' 56.1 ¶ 44; Pl.'s Resp. 56.1 ¶ 44), and that "PCC has described itself as a 'maverick' for recommending foreign pharmacy websites and providing 'information to consumers about safe international pharmacies that sell to consumers in the United States[,]'" (Defs.' 56.1 ¶ 50; Pl.'s Resp. 56.1 ¶ 50).

When a user navigates to PCC's website, the homepage allows users to search for a prescription drug name in search of "prescription savings you can trust." (Defs.' 56.1 ¶ 45; Pl.'s Resp. 56.1 ¶ 45.) The page states that there are "Verified International and Canadian online

[5] Plaintiff lodges evidentiary objections to Defendants Exhibits 40 and 41 which are used to support statement 39. (*See* Pl.'s Resp. 56.1 ¶ 39; Mot. To Strike 8.) As to Exhibit 41, Plaintiff appears to mistakenly believe that this is a draft email rather than a blog post. (*See* Pl.'s Resp. 56.1 ¶ 39.) As to both exhibits, Plaintiff argues that these exhibits are not authenticated, lack foundation, and are inadmissible hearsay. (Pl.'s Resp. 56.1 ¶ 39; Mot. To Strike 8.)

First, as the documents were produced by Plaintiff during discovery, the Court overrules the authentication and foundation objection. *See Hallett*, 517 F. Supp. 3d at 268 (overruling authentication objections because the exhibits "were produced [by Plaintiff to Defendants] in this litigation, and [Plaintiff] offers no specific reason to doubt any document's authenticity"). In addition, while both statements are hearsay being offered for the truth of the matter asserted (i.e. that "PCC solicits American consumers to use [PCC] to find and import drugs from international pharmacies to save money"), both statements fall firmly within the hearsay exception as admissions by a party-opponent. *See* Fed. R. Evid. 801(d)(2). Exhibit 40 is a pamphlet created by PCC, presumably to provide to consumers to "empower[] patients to afford medication." (Defs.' Mem. of Law in Supp. of Mot. Ex. 40 (Dkt. No. 264-41).) Exhibit 41 is a blog post from PCC's own website, quoting PCC's CEO Tod Cooperman. (Defs.' Mem. of Law in Supp. of Mot. Ex. 41 (Dkt. No. 264-42).) As such, the Court will consider these exhibits at summary judgment.

pharmacy options" as well as "[f]ree U.S. pharmacy coupons." (Defs.' 56.1 ¶ 45; Pl.'s Resp. 56.1 ¶ 45.) PCC also states that users can "[c]ompare drug prices and save up to 90%." (Defs.' 56.1 ¶ 45; Pl.'s Resp. 56.1 ¶ 45.) In addition, at the top of PCC's homepage, a user can click on two relevant links, one taking the user to a page about "Accredited Online Pharmacies," and another about "Prescription Savings." (*See* Defs.' 56.1 ¶ 45; Pl.'s Resp. 56.1 ¶ 45.)

On the "Accredited Online Pharmacies" page, the "web page listing . . . is titled 'Accredited Canadian and International Online Pharmacies.'" (Defs.' 56.1 ¶ 46; Pl.'s Resp. 56.1 ¶ 46.) Here, PCC describes the company's purpose as "helping patients across the world find the lowest prescription medication costs from licensed pharmacies in Canada and other countries." (*See* Defs.' 56.1 ¶ 46; Pl.'s Resp. 56.1 ¶ 46.)[6] PCC also lists several countries with pharmacies that are accredited through "the PharmacyChecker Verification Program[,]" including "Canada, Australia, India, Mauritius, New Zealand, Turkey, the UK, and the United States." (Defs.' 56.1 ¶ 46; Pl.'s Resp. 56.1 ¶ 46; Defs.' Mem. of Law in Supp. of Mot. Ex. 48 at 1.)

On the starting page for "Prescription Savings," PCC "compares U.S. prices to Canadian and International prices and shows the percentage savings available" to users interested in purchasing certain drugs from "trusted international mail order online pharmacies, including licensed Canadian pharmacies and local U.S. pharmacies." (Defs.' 56.1 ¶ 47; Pl.'s Resp. 56.1 ¶ 47.)[7] The page includes a comparison chart that lists a drug name, followed by the price of the

[6] The Court notes that the excerpted portion of PCC's website included in the body of Defendants' 56.1 statement differs from the attached Exhibit 48. (*Compare* Defs.' 56.1 ¶ 46 *with* Defs.' Mem. of Law in Supp. of Mot. Ex. 48 (Dkt. No. 264-49).) Specifically, Exhibit 48 excludes the first paragraph quoted in the excerpt in Defendants' 56.1. However, Plaintiff does not dispute the excerpt in ¶ 46, and the Court deems this fact admitted.

[7] Plaintiff disputes Defendants' assertion that these prices are specifically targeted to "Americans who import drugs from foreign pharmacies rather than buying those drugs locally in the U.S.," because there is "no admissible evidence that the prices are 'for Americans who

drug in the United States, Canada, and internationally. (Defs.' 56.1 ¶ 47; Pl.'s Resp. 56.1 ¶ 47.) All prices are listed on the website in U.S. dollars. (Defs.' 56.1 ¶ 42; Pl.'s Resp. 56.1 ¶ 42.)[8]

When a user searches for a specific drug price comparison, PCC will first state the lowest price found for the drug at the top of the page. (Defs.' 56.1 ¶ 16 (screenshot stating "[t]he lowest price on PharmacyChecker.com for Januvia . . . is $0.60 per tablet for 84 tablets at PharmacyChecker-accredited online pharmacies"); Pl.'s Resp. 56.1 ¶ 16 (same); *see also* Defs.' 56.1 ¶ 52.)[9] PCC then shows a chart of "Pharmacy Savings Option[s]" with international price comparisons, "including direct links to the online pharmacy pages where the consumer can order the drug." (Defs.' 56.1 ¶¶ 16, 52; Pl.'s Resp. 56.1 ¶¶ 16, 52.) Each listing also states which country the drug will ship from. (Defs.' 56.1 ¶ 16 (stating that Sunshine Pharmacy will "[s]hip[] [w]orldwide from Canada"); Pl.'s Resp. 56.1 ¶ 16 (same).)

Though the Parties dispute the timing, this chart is at least in part sorted by a "bidding system," where PCC "displays accredited pharmacies on its website in order of the highest

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import drugs.'" (*See* Pl.'s Resp. 56.1 ¶ 47.) However, as Plaintiff does not appear to dispute the actual text of the webpage and excerpted exhibit, the Court deems the relevant undisputed facts admitted.

[8] Plaintiff appears to have mistakenly stated that the relevant portion of this statement is disputed. As excerpted by the Court, Defendants stated that PCC "lists prices for prescription drugs in U.S. dollars and no other currency." (Defs.' 56.1 ¶ 42.) Plaintiff asserts that this statement is disputed, but then notes that "Plaintiff does list prices for prescription drugs in U.S. dollars," citing the same evidence as Defendants. (*See* Pl.'s Resp. 56.1 ¶ 42.) Plaintiff continues, seemingly explaining why PCC lists prices in U.S. dollars, but not disputing the fact that prices are indeed listed in a single currency. (*Id.*) As such, the Court deems this relevant fact admitted.

[9] Plaintiff's objection to Defendants' statement 52 is purely semantic: the screenshot as provided would be seen by a U.S. consumer, as stated by Defendant. Accordingly, the Court deems this fact admitted. *See Arch Specialty Ins. Co.*, 2021 WL 1225447, at *1 n.1.

bidder." (Defs.' 56.1 ¶¶ 16–17; Pl.'s Resp. 56.1 ¶¶ 16–17.)[10] "On instruction from an accredited pharmacy customer, PCC increases or decreases bids, and adds, removes, and adjusts daily budgets for total click through fees that a pharmacy is to be charged before being removed from the site for the remainder of the day once the daily budget is hit." (Defs.' 56.1 ¶ 20; Pl.'s Resp. 56.1 ¶ 20.) "At times, PCC advises its accredited pharmacies on how to test bid amounts to get to the top of the list displayed on PCC"s website." (Defs.' 56.1 ¶ 21; Pl.'s Resp. 56.1 ¶ 21.) This bidding system "is not disclosed to consumers using its website." (Defs.' 56.1 ¶ 19; Pl.'s Resp. 56.1 ¶ 19.)

Finally, "PCC's website has been published in English since 2003." (Defs.' 56.1 ¶ 43; Pl.'s Resp. 56.1 ¶ 43.) "When PCC launched a Spanish version of the website in 2016, PCC focused on the value of this for Spanish speakers in the U.S., noting that '38% of Hispanics living in the U.S. speak mainly Spanish.' The press release announcing the Spanish version quoted PCC CEO Tod Cooperman as saying 'No one living in the U.S. should have to forgo filling a prescription because of high drug prices, especially when lower prices on the same drugs are available to informed consumers. We are pleased to extend our information to the Spanish-speaking community.'" (Defs.' 56.1 ¶ 43; Pl.'s Resp. 56.1 ¶ 43.)

2. PCC's Pricing Model

From January 2015 through August 2021, the majority of PCC's revenue came from three sources: approximately [redacted] came from cost-per-click fees "that PCC charges its accredited pharmacies for sending consumers to those accredited pharmacies' websites"; [redacted] came from fees pharmacies pay to participate in PCC's Verification Program; and [redacted] came from fees

[10] Again, Plaintiff's objection to Defendants' characterization of a "bidding system" is purely semantic and immaterial to this Court. The Court acknowledges Plaintiff's evidentiary objection to Exhibit 11, but admits this statement of fact based on the other supporting Exhibits not in dispute by the Parties.

verified pharmacies pay to be listed on PCC's website. (Defs.' 56.1 ¶¶ 8–9; Pl.'s Resp. 56.1 ¶¶ 8–9.)[11] As to the verification program, approximately [redacted] of the fees paid to PCC were paid by foreign pharmacies. (Defs.' 56.1 ¶¶ 8, 22; Pl.'s Resp. 56.1 ¶¶ 8, 22.) As to the listing program, the Parties dispute nearly every aspect of the program's makeup, including how many U.S. pharmacies have participated in the listing program both currently and historically. (Defs.' 56.1 ¶¶ 24–25; Pl.'s Resp. 56.1 ¶¶ 24–25.) However, the Parties agree that "PCC's other revenue streams, including application fees received from online pharmacies, revenue from discount cards, Medicare drug plans, advertising, and e-book, provide less than [redacted] of its total revenues." (Defs.' 56.1 ¶ 10; Pl.'s Resp. 56.1 ¶ 10.)

At all times relevant to this litigation, the majority of PCC's accredited pharmacies were based outside of the United States. (Defs.' 56.1 ¶ 27; Pl.'s Resp. 56.1 ¶ 27.) In fact, during this period, between [redacted] and [redacted] of PCC's total revenue and "over [redacted] of its click-through revenue . . . came from PCC-accredited foreign pharmacies." (Defs.' 56.1 ¶ 22; Pl.'s Resp. 56.1 ¶ 22.) U.S. consumers in particular "generat[ed] [redacted] of click-through fees paid to the company" during this period. (Defs.' 56.1 ¶ 40; Pl.'s Resp. 56.1 ¶ 40.)[12] In addition, [redacted] different pharmacy websites received paid clicks from PCC. (*See* Defs.' 56.1 ¶¶ 29–30, 35 (comparing clicks for pharmacy websites during the relevant period); Pl.'s Resp. 56.1 ¶¶ 29–30,

[11] Plaintiff disputes the characterization of this evidence, but does not dispute its factual basis. As such, the Court deems this fact admitted. *See Arch Specialty Ins. Co.*, 2021 WL 1225447, at *1 n.1.

[12] Again, Plaintiff disputes the characterization of this evidence, but does not dispute its factual basis. Instead, Plaintiff introduces yet another metric it argues the Court should use to understand how cost-per-click fees factor into PCC's revenue, based on calculations by PCC CEO Gabriel Levitt. (*See* Pl.'s Resp. 56.1 ¶ 40.) The Court will address this characterization as needed while applying the law to the facts. As such, the Court deems this fact admitted. *See Arch Specialty Ins. Co.*, 2021 WL 1225447, at *1 n.1.

35 (same).) "The '[redacted]' of users who visit [PCC] click-through to pharmacies [redacted]" (Defs.' 56.1 ¶ 31; Pl.'s Resp. 56.1 ¶ 31.) However, the Parties dispute the relevance of this data as it pertains to U.S. consumers, disagreeing primarily about how much of the click-through fees from U.S. consumers were billed to these foreign websites. (*See* Defs.' 56.1 ¶¶ 32–34; Pl.'s Resp. 56.1 ¶¶ 32–34.) The Parties agree, however, that "[a]t least [redacted] websites that received clicks between January 2015 and August 2021 were foreign. Those [redacted] foreign websites accounted for [redacted] of the click fees ([redacted]) and [redacted] of clicks ([redacted])." (Defs.' 56.1 ¶ 29; Pl.'s Resp. 56.1 ¶ 29.) "Only [redacted] [websites] are U.S. sites, accounting for [redacted] of the click fees ([redacted]) and [redacted] of total clicks ([redacted])." (Defs.' 56.1 ¶ 30; Pl.'s Resp. 56.1 ¶ 30.)

3. PCC Consumer Support Materials and Services

PCC maintains a "Consumer Support page" which lists several frequently asked questions and associated answers. (*See* Defs.' 56.1 ¶ 48; Pl.'s Resp. 56.1 ¶ 48.)[13] First, the page states that "PharmacyChecker is the only free, independent company that verifies the safety of Canadian and other international online pharmacies. We then compare their drug prices to U.S. discounts so you get the best deal." (Defs.' 56.1 ¶ 48; Pl.'s Resp. 56.1 ¶ 48.) Next, the page asks several questions, excerpted as relevant below:

> *How much can Americans save by purchasing their prescription drugs online?*
>
> U.S. consumers could pay up to 90% less than what they pay at a local pharmacy—savings like this has meant thousands of dollars a year for users of PharmacyChecker price comparisons. Cost is the difference between patients adhering to their prescribed medication and having to go without it. Americans are

[13] Plaintiff disputes this statement because it is "overly broad" and "not supported by admissible evidence" that the page is "focused on Americans buying drugs from abroad." (Pl.'s Resp. 56.1 ¶ 48.) However, Plaintiff does not dispute the actual statements listed on the consumer support page, including the accuracy of the answers excerpted in Defendants' 56.1 or related Exhibit 6. (*Id.*) As such, the Court deems the relevant facts as excerpted by the Court admitted.

forced to make tough decisions: Do I pay my bills? Or should I skip my meds this week? This is unacceptable. Everyone deserves the opportunity and choice to purchase more affordable medication from licensed pharmacies, whether domestic or international.

How fast is international prescription delivery?

Be advised that medication ordered from outside the U.S. can normally take 2-3 weeks to arrive. If ordering medication from India, it can take even longer. If you need your medication quickly, then you should consult your local pharmacy for immediate supply, and then you may want to purchase more internationally for future use. We publish a pharmacy profile for each accredited pharmacy in the PharmacyChecker Verification Program to provide consumers with specific details, such as particular shipping locations, shipping costs, and payment methods accepted by the pharmacy.

Is it safe to order medication online from a pharmacy outside the U.S.?

Yes, as long as you buy from the safest international online pharmacies. With a valid prescription for the medication ordered, dispensed from a licensed pharmacy that is verified in the PharmacyChecker Verification Program, it is exceedingly safe. Peer-reviewed studies based on testing of prescription medication and online pharmacy practices, strongly demonstrate the safety of ordering medications from an international online pharmacy approved in the PharmacyChecker Verification Program. It is important to note, risks do exist when ordering medication from an unverified international online pharmacy, particularly one that does not require a prescription. [. . .]

[Unknown Question]?

[. . .] Online pharmacies based outside the U.S. are not "rogue" by definition. Licensed and legitimate pharmacies in Canada and other countries sell safe and effective medications internationally, including to consumers in the U.S. Some regulatory bodies, including the Food and Drug Administration (FDA), refer to such pharmacies as "illegal" or "fake" but such distinctions can mislead consumers and impede their access to affordable, safe and effective medication that they cannot obtain locally due to high U.S. drug prices. Pharmacies in some countries are equally as safe if not safer than those in the U.S. [. . .][14]

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[14] Plaintiff argues that Defendants' Rule 56.1 statement, which excerpts this question and answer, should be stricken in its entirety because "it is not supported by admissible evidence and is legal conclusion couched as fact." (Pl.'s Resp. 56.1 ¶ 3.) As discussed, this Court will only rely on admissible evidence and disregard improper statements or legal conclusions.

Here, Plaintiff offers no substantive evidentiary objection to Defendants' Exhibit 6, which is relevant to the quoted statement. Instead, Plaintiff argues that the Exhibit does not support Defendants' statement that "buying medications internationally is federally prohibited"

> *Is it legal to order prescription drugs online?*
>
> There is no law against ordering medication online. As a resident of the U.S., it's entirely legal to order medication online that is mailed directly from a state-licensed pharmacy. International drug importation is another story: Technically, in the U.S., under most circumstances, it is prohibited to import medication that you order *internationally* online. However, it is important to know that people in the U.S. are not prosecuted for doing so, as long as the medication imported is for your own use and not for resale. [. . .]
>
> *What if my medication gets stuck at Customs?*
>
> While the law allows the FDA and U.S. Customs and Border Patrol to detain and refuse international prescription orders arriving through the mail, less than one percent of medication orders are actually stopped, at least for orders where a prescription is required. If that happens, you will receive a letter from the FDA that your drug order was detained or refused. You are allowed to challenge the FDA's decision and try and have it released. [. . .]

(*See* Defs.' 56.1 ¶ 48; Pl.'s Resp. 56.1 ¶ 48; Defs.' Mem. Ex. 6 (Dkt. No. 264-7).)

On the Consumer Support page, PCC maintains a customer complaint form. (Defs.' 56.1 ¶ 61; Pl.'s Resp. 56.1 ¶ 61.) The complaint form states:

> We're sorry if a PharmacyChecker accredited online pharmacy has let you down. Below, you have the opportunity to file a complaint with us about the pharmacy. For us to process your complaint, you must authorize us to contact the company on your behalf. Please describe the problem you had with the pharmacy, and we will do our best to resolve the issue.

(Defs.' 56.1 ¶ 61; Pl.'s Resp. 56.1 ¶ 61.) "Under 'Desired Action,' the form allows the consumer to choose between the options of a full refund, a partial refund, send replacement product, or other." (Defs.' 56.1 ¶ 61; Pl.'s Resp. 56.1 ¶ 61.) While the Parties do not dispute that PCC has assisted U.S. consumers with issues that arose from their purchases from foreign pharmacies, the

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because the cited excerpt concerns pharmacies operating internationally, rather than the legality of importation. (Pl.'s Resp. 56.1 ¶ 3.) While the provided Exhibit appears to be cut off, Plaintiff again does not appear to dispute the statement that is actually quoted. (*Id.*) As such, the Court deems the relevant fact as excerpted by the Court admitted.

Parties do dispute the extent to which PCC intervened and the frequency of these types of requests. (Defs.' 56.1 ¶¶ 57, 59–60, 62–64; Pl.'s Resp. 56.1 ¶¶ 57, 59–60, 62–64.) For example, the Parties agree that PCC has assisted at least one consumer with obtaining a refund from an accredited pharmacy for unfulfilled purchases. (Defs.' 56.1 ¶ 62; Pl.'s Resp. 56.1 ¶ 62.) The Parties also agree that PCC has responded and assisted some consumers who receive incorrect or unmarked medication and has followed up and worked with accredited pharmacies on consumers' behalf regarding issues with orders. (Defs.' 56.1 ¶¶ 63–64; Pl.'s Resp. 56.1 ¶¶ 63–64.)

C. Procedural History[15]

PCC filed its initial Complaint on August 13, 2019. (*See* Compl. (Dkt. No. 1).) After the Court's denial of PCC's Motion for a Preliminary Injunction, (*see* Dkt. No. 73), PCC filed its Amended Complaint on October 21, 2019, (*see* Am. Compl.). On November 6, 2019, NABP, PSM, and LegitScript filed pre-motion letters in anticipation of moving to dismiss PCC's Amended Complaint. (*See* Dkt. Nos. 85, 86, 87.) After receiving responses from PCC, (*see* Dkt. Nos. 89, 90, 91), the Court held a pre-motion conference and set a briefing schedule, (*see* Dkt. (minute entry for Feb. 6, 2020); Dkt. No. 94).

On March 13, 2020, Defendants filed a Joint Motion To Dismiss PCC's Amended Complaint. (*See* Not. of Joint Mot. (Dkt. No. 97); Defs.' Mem. of Law in Supp. of Joint Mot. (Dkt. No. 100); Decl. of Erik T. Koons in Supp. of Joint Mot. (Dkt. No. 102); Decl. of Marjorie Clifton in Supp. of Joint Mot. (Dkt. No. 103).) On the same day, PSM, ASOP, and LegitScript filed individual Motions To Dismiss PCC's Amended Complaint. (*See* PSM's Not. of Mot.

[15] The procedural history of this case is lengthy and complex, involving a higher-than-average number of motions, which have often been briefed simultaneously. (*See generally* Dkt.) The Court herein recounts only the procedural history relevant to the instant Motion.

(Dkt. No. 97); PSM's Mem. of Law in Supp. of Mot. (Dkt. No. 98); Decl. of Leslie E. John in Supp. of PSM's Mot. (Dkt. No. 99); ASOP's Not. of Mot. (Dkt. No. 104); ASOP's Mem. of Law in Supp. of Mot. (Dkt. No. 105); LegitScript's Not. of Mot. (Dkt. No. 106); Decl. of Rachel J. Adcox in Supp. of LegitScript's Mot. (Dkt. No. 107); Decl. of John Horton in Supp. of LegitScript's Mot. (Dkt. No. 108); LegitScript's Mem. of Law in Supp. of Mot. (Dkt. No. 109).) On April 17, 2020, PCC filed responses to all four motions to dismiss. (*See* PCC's Mem. of Law in Opp'n to Joint Mot. (Dkt. No. 113); PCC's Mem. of Law in Opp'n to PSM's Mot. (Dkt. No. 111); PCC's Mem. of Law in Opp'n to ASOP's Mot. (Dkt. No. 110); PCC's Mem. of Law in Opp'n to LegitScript's Mot. (Dkt. No. 109).) On May 15, 2020, Defendants jointly filed their Reply and PSM, ASOP, and LegitScript each filed individual Replies. (*See* Defs.' Reply Mem. of Law in Supp. of Joint Mot. (Dkt. No. 116); PSM's Reply Mem. of Law in Supp. of Mot. (Dkt. No. 115); ASOP's Reply Mem. of Law in Supp. of Mot. (Dkt. No. 118); LegitScript's Reply Mem. of Law in Supp. of Mot. (Dkt. No. 117).) The Court held oral argument on all four motions on November 10, 2020, (*see* Dkt. (minute entry for Nov. 10, 2020)), and on March 30, 2021, the Court granted LegitScript's Motion To Dismiss, denied Defendants' Joint Motion To Dismiss, denied ASOP's Motion To Dismiss, and granted in part and denied in part PSM's Motion To Dismiss, (*see* Dkt. No. 129).[16]

On May 11, 2021, ASOP and PSM each filed Answers to PCC's Amended Complaint, (*see* ASOP's Answer (Dkt. No. 147); PSM's Answer (Dkt. No. 150)), and NABP filed both an

[16] By virtue of the Court's granting of LegitScript's Motion To Dismiss, PCC's claims against LegitScript were later severed and transferred to the U.S. District Court for the District of Oregon. *See supra* Note 1.

Answer and Counterclaims, (*see* NABP's Answer & Counterclaims (Dkt. No. 148).). CSIP filed its Answer on May 25, 2021. (*See* CSIP's Answer (Dkt. No. 157).)

On April 14, 2022, Defendants filed a pre-motion letter in anticipation of moving to exclude Plaintiff's expert testimony of Benjamin England, Esq. (*See* Dkt. No. 235.) On the same day, Defendants also filed a pre-motion letter in anticipation of a joint motion for summary judgment. (*See* Dkt. No. 233.) After receiving a response on both letters from PCC, (*see* Dkt. Nos. 238–39), the Court held a pre-motion conference and set a briefing schedule, (*see* Dkt. (minute entry for May 9, 2022); Dkt. No. 251).

On June 22, 2022, Defendants filed a joint motion to exclude the expert testimony. (*See* Daubert Not. of Mot.; Defs.' Mem. of Law in Supp. of Mot. ("Defs.' Daubert Mem.") (Dkt. No. 261).) PCC filed its Opposition on July 20, 2022. (*See* PCC's Mem. of Law in Opp'n to Mot. ("PCC's Daubert Mem.") (Dkt. No. 268); Decl. of James Lerner in Supp. of Pl.'s Opp. to Mot. ("Lerner Decl.") (Dkt. No. 268-1).) Defendants filed their Reply on August 5, 2022. (*See* Defs.' Reply Mem. of Law in Supp. of Mot. ("Defs.' Daubert Reply") (Dkt. No. 278).)

On June 22, 2022, Defendants also filed a joint motion for summary judgment. (*See* SJ Not. of Mot.; Defs.' Mem. of Law in Supp. of Mot. ("Defs.' SJ Mem.") (Dkt. No. 264); Defs.' 56.1.) PCC filed its Opposition on July 20, 2022. (*See* PCC's Mem. of Law in Opp'n to Mot. ("PCC's SJ Mem.") (Dkt. No. 269); Decl. of Gabriel Levitt in Opp. of Mot. ("Levitt Decl.") (Dkt. No. 271).) Defendants filed their Reply on August 5, 2022. (*See* Defs.' Reply Mem. of Law in Supp. of Mot. ("Def.'s SJ Reply") (Dkt. No. 281).)

On July 20, 2022, PCC filed a motion to strike portions of Defendants' submissions in support of Defendants' Motion for Summary Judgment. (*See* Mot. to Strike.) Defendants filed their Opposition on August 17, 2022. (*See* Defs Mot. to Strike Opp; Decl. of Melanie M. Kiser

in Supp. of Defs.' Opp. to Mot. to Strike (Dkt. No. 292-1).) PCC filed its Reply on August 24, 2022. (*See* Pl.'s Reply Mem. of Law in Supp. of Mot. (Dkt. No. 302).)

On August 5, 2022, Defendants filed a pre-motion letter requesting leave to file a motion to strike certain paragraphs of the Declaration of Gabriel Levitt. (*See* Levitt Decl. PML.) In lieu of a pre-motion conference, the Court set a briefing schedule. (Dkt. No. 284.) On August 15, 2022, Defendants filed a memorandum of law in support of their Motion. (*See* Defs.' Mot. to Strike.) Plaintiff filed its Opposition on August 22, 2022. (Pl.'s Strike Opp.)

Finally, on February 16, 2023, Defendants filed a notice of supplemental authority in support of Defendants joint motions for summary judgment and motion to exclude testimony. (*See* Dkt. No. 337.) Plaintiff filed a response on February 24, 2023. (*See* Dkt. No. 342.)

II. Discussion

A. Standard of Review

Summary judgment is appropriate where the movant shows that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Psihoyos v. John Wiley & Sons, Inc.*, 748 F.3d 120, 123–24 (2d Cir. 2014) (same). "In deciding whether to award summary judgment, the [C]ourt must construe the record evidence in the light most favorable to the non-moving party and draw all reasonable inferences in its favor." *Torcivia*, 17 F.4th at 354; *see also Horror Inc. v. Miller*, 15 F.4th 232, 240 (2d Cir. 2021) (same). "It is the movant's burden to show that no genuine factual dispute exists." *Vt. Teddy Bear Co. v. 1-800 Beargram Co.*, 373 F.3d 241, 244 (2d Cir. 2004); *see also Red Pocket, Inc. v. Interactive Commc'ns Int'l, Inc.*, No. 17-CV-5670, 2020 WL 838279, at *4 (S.D.N.Y. Feb. 20, 2020) (same).

"However, when the burden of proof at trial would fall on the non[-]moving party, it ordinarily is sufficient for the movant to point to a lack of evidence to go to the trier of fact on an

essential element of the non[-]movant's claim," in which case "the non[-]moving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment." *CILP Assocs., L.P. v. Pricewaterhouse Coopers LLP*, 735 F.3d 114, 123 (2d Cir. 2013) (alteration and quotation marks omitted). Further, "[t]o survive a [summary judgment] motion . . . , [a non-movant] need[s] to create more than a 'metaphysical' possibility that his allegations were correct; he need[s] to 'come forward with specific facts showing that there is a genuine issue for trial,'" *Wrobel v. Cnty. of Erie*, 692 F.3d 22, 30 (2d Cir. 2012) (emphasis omitted) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)), "and cannot rely on the mere allegations or denials contained in the pleadings," *Guardian Life Ins. Co. v. Gilmore*, 45 F. Supp. 3d 310, 322 (S.D.N.Y. 2014) (quotation marks omitted); *see also Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009) ("When a motion for summary judgment is properly supported by documents or other evidentiary materials, the party opposing summary judgment may not merely rest on the allegations or denials of his pleading."). And, "[w]hen opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment." *Scott v. Harris*, 550 U.S. 372, 380 (2007).

"On a motion for summary judgment, a fact is material if it might affect the outcome of the suit under the governing law." *Royal Crown Day Care LLC v. Dep't of Health & Mental Hygiene*, 746 F.3d 538, 544 (2d Cir. 2014) (quotation marks omitted). At this stage, "[t]he role of the court is not to resolve disputed issues of fact but to assess whether there are any factual issues to be tried." *Brod v. Omya*, 653 F.3d 156, 164 (2d Cir. 2011) (quotation marks omitted). Thus, a court's goal should be "to isolate and dispose of factually unsupported claims." *Geneva*

Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 495 (2d Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986)).

When ruling on a motion for summary judgment, a district court should consider only evidence that would be admissible at trial. *See Nora Beverages, Inc. v. Perrier Grp. Of Am., Inc.,* 164 F.3d 736, 746 (2d Cir. 1998). "[W]here a party relies on affidavits . . . to establish facts, the statements 'must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant . . . is competent to testify on the matters stated.'" *DiStiso v. Cook*, 691 F.3d 226, 230 (2d Cir. 2012) (quoting Fed. R. Civ. P. 56(c)(4)); *see also Sellers v. M.C. Floor Crafters, Inc.*, 842 F.2d 639, 643 (2d Cir. 1988) ("Rule 56 requires a motion for summary judgment to be supported with affidavits based on personal knowledge . . . ."); *Baity*, 51 F. Supp. 3d at 419 (disregarding "statements not based on [the] [p]laintiff's personal knowledge"); *Flaherty v. Filardi*, No. 03-CV-2167, 2007 WL 163112, at *5 (S.D.N.Y. Jan. 24, 2007) ("The test for admissibility is whether a reasonable trier of fact could believe the witness had personal knowledge." (quotation marks omitted)).

B. Analysis

On March 30, 2021, this Court denied Defendants' Motion To Dismiss, holding that Plaintiff's Amended Complaint "[did] not establish that Plaintiff's enterprise is completely illegal or geared toward illegality." *PharmacyChecker.com LLC v. Nat'l Ass'n of Bd. of Pharm.*, 530 F. Supp. 3d 301, 330 (S.D.N.Y. 2021). However, the Court noted that "[a]t summary judgment, Plaintiff will no longer be sheltered by the vagueness of its" complaint, stating that "[i]f discovery supports Defendants' claim that the primary purpose of Plaintiff's business is to facilitate unlawful importation, [Defendants] may advance the same argument at that juncture." *Id*. at 330–31 (citation, alterations, and quotation marks omitted). In the instant Motion,

Defendants do just that: moving for summary judgment on the very limited issue of illegality. (*See generally* Defs.' SJ Mem.)

In support of their motion for summary judgment, Defendants argue that (1) personal importation of prescription drugs from foreign online pharmacies is unambiguously illegal, (*see id*. at 11–15), (2) almost all of PCC's revenue is derived from accredited international online pharmacies that sell to U.S. consumers, (*see id*. at 15–19), and (3) that PCC's "primary mission" is to facilitate U.S. consumers' unlawful importation of foreign pharmaceuticals, (*see id*. at 19–27). The Court will address each argument in turn.

1. Applicable Law

Section 4 of the Clayton Act provides for a private right of action and treble damages to "[a]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws." 15 U.S.C. § 15(a). However, the Supreme Court has recognized that "Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534 (1983) (quotation marks omitted). As such, the right to seek treble damages for federal antitrust violations has "developed limiting contours . . . embodied in the concept of 'antitrust standing'." *Gatt Commc'ns v. PMC Assocs., L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (quoting *Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408, 436–38 (2d Cir. 2005)).

The Second Circuit has explained that "[t]o establish antitrust standing, 'a plaintiff must show (1) antitrust injury, which is injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful, and (2) that he is a proper plaintiff in light of the four efficient enforcer factors.'" *Schwab Short-Term Bond Mkt. Fund v. Lloyds Banking Grp. PLC*, 22 F.4th 103, 115 (2d Cir. 2021) (quoting *In re DDAVP Direct*

Purchaser Antitrust Litig., 585 F.3d 677, 688 (2d Cir. 2009) (quotation marks omitted)). Importantly, "[t]he fact that private plaintiffs have been injured by acts that violate the antitrust laws is not enough to confer standing to sue." *Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408, 438 (2d Cir. 2005). "[R]ather, the issue is whether that harm is an 'injury of the type the antitrust laws were intended to prevent.'" *In re Aluminum Warehousing Antitrust Litig.*, 95 F. Supp. 3d 419, 440 (S.D.N.Y. 2015) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

While legality is not formally an element of the antitrust inquiry, several courts around the country have found that a plaintiff cannot suffer an antitrust injury if its asserted harm is based in illegal conduct. This principle was established in *Maltz v. Sax*, 134 F.2d 2 (2d Cir. 1943), where the court held that the plaintiff could not recover because "the damages claimed were for an injury to something which the laws did not recognize as a legal right"; namely, gambling. *Id*. at 5. The *Maltz* court explained: "[The] [p]laintiff has no legal right in a business, the conduct of which was gambling, for which he may obtain protection either in an action at law, or by a suit in equity. He had no legal rights to protect. Therefore [the] defendants could not invade them." *Id*.

In ruling on Defendants' Motion To Dismiss, this Court surveyed opinions of courts across the country that issued similar opinions at various stages of litigation, finding that each case supports the principle of assessing the legality of an enterprise during an antirust standing inquiry. *PharmacyChecker.com LLC*, 530 F. Supp. 3d at 328–31. From these cases, the Court adopted the following principle: "where the plaintiff's enterprise is completely or almost

completely illegal, or completely or almost completely geared toward facilitating illegality, that plaintiff cannot plead an antitrust injury." *Id*. at 329–30.[17]

2. Application

a. Expert Testimony

As an initial matter, the Court will address Defendants' putative motion to disqualify Plaintiff's proffered expert witness. (*See generally* Daubert Not. of Mot.; Defs.' Daubert Mem.)

[17] PCC argues that this Court applied the wrong antitrust standing standard by introducing illegality, stating that "a federal court may not decline to enforce [§] 1 of the Sherman Act on the purported basis that a plaintiff's business is completely or almost completely geared toward facilitating unlawful conduct by others." (PCC's SJ Mem. 8–16 (quotation marks omitted).) Defendants in reply reiterate the "ample law supporting [the Court'] holding" and argue that PCC waived any alternative standing argument at this time. (Defs.' SJ Reply 3–6.) The Court agrees with Defendants for the reasons stated below.

Contrary to PCC's assertion that "this marks [P]laintiff's first opportunity to litigate the appropriate standard for determining standing," (*see* PCC's SJ Mem. 11), PCC has had ample opportunity to argue the "proper" standard. Of course, the Court did not create this standard out of thin air, despite PCC's assertion that the Court adopted this standard "without briefing." (*Id*. at 12.) In fact, the Parties briefed antitrust standing *extensively* at the motion to dismiss stage, and PCC raises very similar arguments here as it did at the motion to dismiss. (*Compare id*. at 8–15 *with* Pl.'s Opp. to Defs.' Joint Mot. to Dismiss 8–16 (Dkt. No. 114).) Moreover, as Defendants point out, this Court again revisited this issue in relation to Defendants' motion for Phase One discovery as well as Defendants' objection to the Magistrate Judge's order on expert disclosure sequencing. (*See* Dkt. Nos. 163, 194, 195.) At each stage of the litigation, this Court has reiterated the law of the case as it relates to antitrust standing.

"The law-of-the-case doctrine generally provides that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Musacchio v. United States*, 577 U.S. 237, 244–45 (2016) (citations and quotation marks omitted); *see also Bergerson v. N.Y. State Off. of Mental Health, Cent. N.Y. Psychiatric Ctr.*, 652 F.3d 277, 288 (2d Cir. 2011) (noting that "there is a strong presumption against amendment of prior orders" (citation omitted)); *Bellezza v. Holland*, No. 09-CV-8434, 2011 WL 2848141, at *3 (S.D.N.Y. July 12, 2011) (explaining that reconsideration is appropriate only where there are "cogent or compelling reasons not to [follow the earlier decision], such as an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice" (citation and quotation marks omitted)).

PCC fails to introduce any "cogent or compelling reasons" counselling this Court to reconsider the rule of law for this case, instead choosing to relitigate old arguments under the guise of PCC's "first opportunity to litigate" antitrust standing. As such, this Court will continue to adjudicate the issue of antitrust standing under the same standard delineated in deciding the motions to dismiss.

In opposing Defendants' Motion for Summary Judgment, Plaintiff relies on the expert testimony of Benjamin England, Esq. ("England"). (*See generally* PCC's SJ Mem.) England is the founding member and CEO of a "[f]ood [and] [d]rug [c]onsulting [p]ractice and FDA/USDA/Customs and Trade focused law firm . . . providing regulatory consulting and representation of clients" before various federal and state regulatory agencies. (Defs.' Daubert Mem. Ex. 1 ("England CV") (Dkt. No. 261-1).) Plaintiff retained England to "review case files, deposition testimony[,] and marketing materials for [PCC] to opine upon the operation and the interpretation and implementation of the Personal Importation Policy (PIP)" of the FDA. (Defs.' Daubert Mem. Ex. 3 ("England Report") at 6 (Dkt. No. 261-3).) Defendants argue that England's testimony "provides impermissible and incorrect legal conclusions" as well as "speculation" that is not helpful to the Court to assess the legality of Plaintiff's business. (Defs.' Dabuert Mem. 1.) The Court will address each argument to the extent necessary to decide the instant Motion.

At the summary judgment stage, a court can "decide questions regarding the admissibility of evidence, including expert opinion evidence[.]" *Gjini v. U.S.*, No. 16-CV-3707, 2019 WL 498350, at *13 (S.D.N.Y. Feb. 8, 2019) (alteration in original) (quoting *Bah v. Nordson Corp.*, No. 00-CV-9060, 2005 WL 1813023, at *6 (S.D.N.Y. Aug. 1, 2005)). "If a proffer of expert testimony is excluded as inadmissible pursuant to [Federal Rule of Evidence] 702, the court must make the summary judgment determination on a record that does not include that evidence." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 68 (S.D.N.Y. 2001). Rule 702 of the Federal Rules of Evidence provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based

> on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Although it is the role of the jury to determine the credibility of an expert witness, it is the role of the trial court to serve as a "gatekeep[er]" to ensure that the expert testimony is reliable and relevant before it is presented to the jury. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (finding that the trial judge's gatekeeping obligation applies to all expert testimony); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993) (holding that the district court must ensure that a witness is qualified as an expert and "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand").

"[T]he proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied." *I.M. v. United States*, 362 F. Supp. 3d 161, 191 (S.D.N.Y. 2019) (alteration in original) (quoting *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)); *see also LVL XII Brands, Inc. v. Louis Vuitton Malletier S.A.*, 209 F. Supp. 3d 612, 635 (S.D.N.Y. 2016) (same). "[T]he trial judge has broad discretion in the matter of the admission or exclusion of expert evidence[.]" *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962); *see also Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC*, 571 F.3d 206, 213 (2d Cir. 2009) ("The decision to admit expert testimony is left to the broad discretion of the trial judge and will be overturned only when manifestly erroneous.").

The Court must first address "the threshold question of whether a wItness is qualified as an expert by knowledge, skill, experience, training, or education to render his or her opinions." *Nimely v. City of N.Y.*, 414 F.3d 381, 396 n.11 (2d Cir. 2005) (quotation marks and citation omitted). In doing this, the Court asks "whether the proffered expert has the educational

background or training in a relevant field . . . by looking at the totality of the witness's background." *Arista Recs. LLC v. Lime Grp. LLC*, No. 06-CV-5936, 2011 WL 1674796, at *2 (S.D.N.Y. May 2, 2011) (citations and quotation marks omitted). Then, the Court must "compare the area in which the witness has superior knowledge, education, experience, or skill with the subject matter of the proffered testimony" to "ensure that the expert will actually be testifying on issues or subject matters within his or her area of expertise." *Id*. (alteration, citations, and quotation marks omitted). Courts in the Second Circuit liberally construe the expert qualifications requirement, and generally will not exclude expert testimony provided "the expert has educational and experiential qualifications in a general field closely related to the subject matter in question[.]" *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 559 (S.D.N.Y. 2004) ("The Second Circuit has taken a liberal view of the qualification requirements of Rule 702, at least to the extent that a lack of formal training does not necessarily disqualify an expert from testifying if he or she has equivalent relevant practical experience.").

Here, England has a Bachelor's degree in Biological Sciences from the University of Maryland and a law degree from the University of Miami School of Law. (*See* England CV 3–4.) Of significance, England spent approximately 14 years working for the FDA in several different capacities, including as: (1) a senior special agent charged with "[e]nforc[ing] [f]ood, [d]rug[,] and [c]osmetic [l]aws"; (2) as a "consumer safety officer/compliance officer" who "[a]pplied [f]ederal [f]ood, [d]rug[,] and [c]osmetic [l]aws . . . and directed civil and regulatory investigations related to the fraudulent importation of FDA regulated commodities"; and (3) as regulatory counsel to the Associate Commissioner for Regulatory Affairs "advising on matters related to FDA enforcement, imports, bioterrorism, and product safety; law, regulation, and

policy development, [as well as] agency-wide implementation of international trade issues for FDA-regulated products and jurisdiction." (*Id*. at 3.) Since leaving the FDA, England has spent almost 20 years in private practice counseling clients on similar regulatory issues, including the requirements of FDA, USDA, and US Customs law. (*Id*. at 2–3.) Given England's almost 35 years of experience directly related to the issues at hand in this case, the Court concludes that he has the educational credentials, experience, and training to qualify as an expert in FDA policy and practice.

However, this does not end the Court's inquiry into the permissibility of England's expert testimony. Defendants argue that "[t]he Court should exclude England's first three opinions about the federal laws and accompanying regulatory framework governing prescription drug importation because they state legal conclusions." (Defs.' Daubert Mem. 1.) Specifically, Defendants argue that England impermissibly "opines as to the federal laws and regulations" in his first three opinions, and the Court should exclude this testimony because "they state ultimate legal conclusions at the heart of Defendants' . . . motion for summary judgment and thus usurp the Court's role as arbiter of law." (*Id*. at 4–5.) In the alternative, Defendants argue that the Court "should exclude these opinions because they are simply incorrect." (*Id.* at 5.)

An expert's role, under Federal Rule of Evidence 702(a), is to assist the trier of fact in "understand[ing] the evidence" or "determin[ing] a fact in issue," not to dictate either the facts or the law to the jury. Fed. R. Evid. 702(a); *see also Scentsational Technologies, LLC v. Pepsi, Inc.*, No. 13-CV-8645, 2018 WL 1889763, at *3 (S.D.N.Y. Apr. 18, 2018) ("[E]xpert testimony may not usurp the province of the judge to instruct on the law, or of the jury to make factual determinations."). "Thus, while 'an opinion is not objectionable just because it embraces an ultimate issue,' the Second Circuit 'is in accord with other circuits in requiring exclusion of

expert testimony that expresses a legal conclusion.'" *Joint Stock Co. Channel One Russ. Worldwide v. Infomir LLC*, No. 16-CV-1318, 2021 WL 4810266, at *14 (S.D.N.Y. Sept. 30, 2021) (memorandum and order) (citations omitted) (quoting Fed. R. Evid. 704(a); then quoting *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992) (collecting cases)); *see also United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991) ("[A]lthough an expert may opine on an issue of fact within the jury's province, he may not give testimony stating ultimate legal conclusions based on those facts."). "[T]he general rule is that an expert may not testify as to what the law is, because such testimony would impinge on the trial court's function." *In re Air Disaster at Lockerbie Scot. on Dec. 21, 1988*, 37 F.3d 804, 826–27 (2d Cir. 1994), *overruled on unrelated grounds by Zicherman v. Korean Air Lines Co. Ltd.*, 516 U.S. 217 (1996). "Whereas an expert may be uniquely qualified by experience to assist the trier of fact, he is not qualified to compete with the judge in the function of instructing the jury [on the law]." *Hygh*, 961 F.2d at 364.

England offered four opinions in his expert report, three of which are relevant to this portion of the inquiry. (England Report 6.) Specifically, England stated the following opinions:

1. Drugs that comply with FDA's labeling and approval requirements can be and are legally imported whether commercially or by individuals for their own personal use and FDA lacks the power to prevent such importations.

2. Drugs that comply with FDA's approval requirements except for labeling or packaging differences may be imported under FDA's drug labeling exemptions, whether they are imported commercially or by individuals for their own personal use.

3. FDA was mandated by Congress to establish clear guidance to consumers explaining when FDA would permit the importation of drugs that might otherwise be refused admission if imported commercially and FDA's Personal Importation Policy is that guidance.

(*Id.*; *see also* Defs.' Daubert Mem. 3.) While Plaintiff argues that "Mr. England is not being proffered to testify whether plaintiff's enterprise is completely or almost completely geared

toward facilitating illegality," (PCC's Daubert Mem. 5 (quotation marks omitted)), it is clear to the Court that, at least with respect to these three opinions, England is doing exactly that. To decide whether PCC is "facilitating illegality," this Court must determine the purely legal question of whether personal importation is permissible under U.S. law. Each of the opinions England has proffered is an attempt to "testify as to what the law is," by offering England's view of the meaning of these statutes based on his experience as a lawyer under the guise of expert advice. *In re Air Disaster at Lockerbie Scot. on Dec. 21, 1988*, 37 F.3d at 826–87 (stating that this type of testimony would "impinge on the trial court's function" by "implicitly provid[ing] a legal standard to the jury").

In response, Plaintiff asserts that "in cases involving a specialized industry or complex regulatory scheme . . . courts routinely allow experts to interpret regulatory requirements and procedures because 'a lay jury cannot be expected to understand the complex regulatory framework that informs' the legality of the actor's conduct." (PCC's Daubert Mem. 8–13 (citing *In re Fosamax Prods. Liab. Litig. ("Fosamax")*, 645 F. Supp. 2d 164 (S.D.N.Y. 2009).) However, *Fosamax* as cited by Plaintiff is distinguishable for several reasons.

In *Fosamax*, the court permitted an expert witness to testify "about general FDA regulatory requirements and procedures" and "offering an opinion as to [the company's] compliance therewith." *Fosamax*, 645 F. Supp. 2d at 191. However, in deciding to allow this expert's testimony, the court cited the expert's "voluminous report of 143 pages" which was divided into four sections applying the duties and obligations of the FDA to the drug at issue. *Id.* at 189. Specifically, the court noted that the sections "then extensively summarize or quote the record evidence that provides the bases for her opinions." *Id.*

In comparison, England's report totals a mere 14 pages, including five pages describing his qualifications. (*See* England Report 2–6.) Moreover, England spends an additional four pages describing his interpretation of federal statutes and implementing regulations, followed by three pages of his view of the personal importation program without any citations to support his assertions. (*See id*. at 11–13.) For example, England states that the personal importation program was "[i]nitially established as travel policy[] in the 1970s" and the "FDA began permitting individuals who traveled abroad for medical treatment to return with personal use quantities of drugs even though the drugs were unapproved new drugs and misbranded." (*Id*. at 11.) England does not appear to base this fact and others throughout the report on his time at the FDA, as he was not employed at the FDA in the 1970s. (*See generally* England CV.) And despite Plaintiff's assertions that England's report is grounded on publicly available materials, (*see* PCC's Daubert Mem. 4), England offers several conclusory statements without any support. (*See, e.g.,* England Report 14 ("Clearly there are drugs that can be imported legally, ipso facto, under the PIP or relevant law and regulations."); *id.* ("Therefore, any [PCC] accredited (and licensed) pharmacy that ships to the U.S. a drug that is from an approved source, the fact that the labeling does not conform to the FDCA requirements for adequate directions for use does not make the drug misbranded if it is dispensed by the pharmacy pursuant to a valid prescription. The valid prescription (and other factors described in the FDA regulation) bring the drug within a drug labeling exemption and so the personal importation of the drug by the patient is legal.").) To borrow from language in *Fosamax*, "[s]ome opinions in [England's] report are too conclusory . . . to be admitted." *Fosamax*, 645 F. Supp. 2d at 191.

The other cases Plaintiff cites in support of this principle are similarly unavailing. For example, the court in *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152

(S.D.N.Y. 2018) specifically admitted expert testimony about a complex statutory scheme because the expert did *not* provide "legal conclusions" or "opine on whether [the defendants] violated the Act, but simply explain[ed] the mechanics of drug approval." *Id*. at 184 (quotation marks and citation omitted). England's testimony in contrast attempts to directly state what the law is as it relates to personal pharmaceutical importation. (*See, e.g.,* England Report 6 ("Drugs that comply with FDA's labeling and approval requirements *can be and are legally imported* whether commercially or by individuals for their own personal use . . . ." (emphasis added)).) Plaintiff's other cases fare no better as they acknowledge the limits of an expert's opinions about the law. *See, e.g., In re Suboxone Antitrust Litig.*, No. 16-CV-5073, 2020 WL 6887885, at *40 (E.D. Pa. Nov. 24, 2020) (excluding an expert's testimony on regulations related to citizen petitions because "her opinion is, at its core, a pure legal conclusion as to whether the [petition at issue] had merit," thus "usurp[ing] the jury's role in applying the law to the facts"); *Am. Home Assur. Co. v. Merck & Co.*, 462 F. Supp. 2d. 435, 448 (S.D.N.Y. 2006) (allowing expert testimony on FDA regulations but excluding other expert testimony that "clearly impinges upon the province of the [c]ourt, in so far as he essentially proffers his own version of contractual interpretation").

At bottom, England is not providing the Court with an extensive interpretation of a complex regulatory scheme, as was the case in *Fosamax* and similar cases. Instead, England is using his first three opinions to dictate what the law is for personal importation of prescription

drugs. For these reasons, the Court grants Defendants' Motion to exclude England's testimony as to the first three opinions listed in the expert report.[18, 19]

Defendants also challenge England's fourth opinion, arguing that the opinion should be excluded because it is (1) "irrelevant to the critical issue of whether Plaintiff facilitates" personal importation, (2) "constitutes unreliable speculation about the intent or motivation of a party," and (3) lacks foundation. (Defs.' Daubert Mem. 16 (emphasis omitted).) For the reasons stated below, the Court disagrees.

"In determining whether an expert's opinion should be excluded as unreliable, 'the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the

[18] In the alternative, Defendants also argue that the Court "should exclude these opinions because they are simply incorrect." (Defs.' Daubert Mem. at 5.) However, the Second Circuit has held multiple times that the focus of the *Daubert* inquiry is the *relevance* of an expert's testimony, not its "correctness." *See In re Pfizer Inc. Secs. Litig.*, 819 F.3d 642, 661 (2d Cir. 2016) (declining to weigh in as to whether "[p]laintiffs' [expert's] theory is either legally or factually sustainable" because "*Daubert* and Rule 702 merely authorize the court to ensure that the expert's testimony both rests on a reliable foundation and is relevant to the task at hand" (quotation marks and citation omitted)); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266–67 (2d Cir. 2002) ("In undertaking this flexible inquiry, the district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions.").

[19] To be clear, however, England's testimony would not have created a genuine issue of material fact sufficient to withstand summary judgment. Though the Court has determined England's opinions here to be impermissible legal opinions, taken most charitably, this testimony would represent "specialized knowledge" that could "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). In other words, England's opinions here are not "facts" themselves, but are instead additional context for the Court's ultimate legal conclusion on the statutory scheme for personal importation of pharmaceutical drugs. As such, England's opinions on the statutory scheme would not be dispositive or dictate what the law must be in this inquiry, as this is strictly the province of the Court. *See, e.g., In re Suboxone Antitrust Litig.*, 2020 WL 6887885, at *40 (excluding an expert's testimony because "her opinion is, at its core, a pure legal conclusion as to whether the [petition at issue] had merit," thus "usurp[ing] the jury's role in applying the law to the facts").

facts and methods to the case at hand.'" *Houser v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 470, 475 (W.D.N.Y. 2017) (quoting *Amorgianos*, 303 F.3d at 267). Neither "*Daubert* [n]or the Federal Rules of Evidence require[ ] a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Nimely*, 414 F.3d at 396 (italics omitted) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos*, 303 F.3d at 266.

> As relevant to the instant inquiry, England's fourth opinion reads as follows:
>
> > PharmacyChecker.com does not buy, sell, distribute, dispense or process orders for drugs and its requirements for pharmacy participation in the accreditation program are clearly consistent with FDA's Personal Importation Policy and designed to ensure participating pharmacies conform to the FDA policy as mandated by Congress.

(England Report 6.) Defendants argue that England's opinion is "irrelevant to the key issue of antitrust injury," counseling the Court to exclude the evidence on this ground. (Defs.' Daubert Mem. 16–17.)[20] However, while this Court has an essential gate-keeper role in determining the admissibility of expert testimony, the standards for inclusion of expert testimony are quite permissive for qualified experts—and rightfully so. England's testimony here has a "valid . . . connection to the pertinent inquiry," which is the relevant "precondition to admissibility." *Kumho Tire Co.*, 526 U.S. at 149 (quotation marks and citation omitted). Moreover, it is the role

[20] Defendants also argue that "whether Plaintiff itself buys, sells[,] or dispenses orders is a question of fact which is not an appropriate subject for expert testimony." (Defs.' Daubert Mem. 16 n.5.) However, and as Plaintiff points out in opposition, Defendants have lodged no dispute to this fact and thus the Court deems it admitted for the purpose of summary judgment. (*See* PCC's Daubert Mem. 19–20; Pl.'s Resp. 56.1 ¶ 96; Defs.' 56.1 Reply ¶ 96.)

of the Court at summary judgment to assess admissible evidence to determine whether it is "sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment." *CILP Assocs., L.P.*, 735 F.3d at 123 (quotation marks and citation omitted). While the Court declines to determine whether England's fourth opinion is material at this time, the Court will—as it must—rigorously review the record and expert evidence provided in determining whether to grant summary judgment. To put it simply: whether the Defendants find this evidence "irrelevant" is irrelevant to the Court at this time. The Court will determine the weight to give this expert testimony in deciding summary judgment.

Defendants also argue that England's opinion that PCC's verification program is "purportedly designed to ensure compliance with FDA policy" is "unfounded speculation about the intent of Plaintiff. (Defs.' Daubert Mem. 17–18.) Plaintiff argues that England "is not being proffered to testify as to the institutional intent or motive of [P]laintiff when it created its accreditation program," but instead represents England's "interpretation of the written language of the program." (PCC's Daubert Mem. 20–21.) While this is a much closer question, the Court agrees with Plaintiff.

The Parties argue about the import of *Town of Halfmoon v. Gen. Electric Co.*, No. 09-CV-228, 2016 WL 866343 (N.D.N.Y. Mar. 3, 2016). (*See* PCC's Daubert Mem. 20–21; Defs.' Daubert Reply 9.) In *Halfmoon*, the defendant gave notice that it would call an expert to address whether certain "response costs were necessary and consistent" with federal regulations that were a prerequisite to recovery under the relevant statute. 2016 WL 866343, at *15 (quotation marks omitted). The plaintiff challenged the expert's testimony on several grounds, including that the opinions "impermissibly rest[ed] on conclusions about the motivations and intent of [the plaintiff's] decision-makers." *Id*. at *16 (quotation marks omitted). The *Halfmoon* court

disagreed, noting that the expert's report did not "rest on any effort to read [the plaintiff's] institutional mind," but was instead "based on a review of the paper trail" created by a town official and "an examination of whether or not any documentary evidence produced in discovery substantiates [the plaintiff's] claim." *Id*. Here, while Defendants are correct that England did not review a "paper trail or documentary evidence" as the expert did in *Halfmoon*, this does not mean that England's expert opinion rests on motivations and intent. Instead, England relies on a thorough review of PCC's website, a 30(b)(6) deposition and its associated exhibits discussing PCC's verification program, and his expertise as a compliance officer to provide his view of compliance with laws and regulations. (*See* PCC's Daubert Mem. Ex. 2 (Dkt. No. 268-3).) Moreover, the *Halfmoon* court acknowledged that "the distinction between fact and legal conclusions is extremely fine," and "the mere fact that an expert's opinion is based on criteria delineated by the applicable law does not transmogrify it into a legal conclusion." *Halfmoon*, 2016 WL 866343, at *16 (alteration, quotation marks, and citation omitted).

Defendants also cite to *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004), for the same principle. However, the proposed testimony in *Rezulin* differed in ways that supported its exclusion. In *Rezulin*, the expert's proposed testimony "merely repeated facts or other opinions stated by other potential witnesses or in documents produced in discovery," including speculating about "what the FDA might have done with different information." 309 F. Supp. 2d at 546. In addition, the expert drew several inferences from documents produced in discovery, making comments such as the expert "knows for sure" that a pharmaceutical company took the drug off the market "for safety reasons because the chairman of the company allegedly wrote this in a letter." *Id*. at 546–47 (quotation marks omitted). The expert repeatedly made such claims and speculative inferences about intent, with the plaintiffs conceding that the expert

was describing "the facts and conditions from which the jury could infer [the] defendant's motivation in stifling research." *Id*. at 547 & n.45. Here, England's testimony does not come close to the improprieties at issue in *Rezulin*. And to the extent that the Court believes that the testimony does begin to veer that way, "the Court will exercise its supervisory authority . . . to ensure that neither [the expert's] testimony nor the testimony of any other expert for that matter, usurps the role of the trial judge . . . as to the applicable law or . . . applying that law to the facts before it." *Halfmoon*, 2016 WL 866343, at *17 (citation and quotation marks omitted).

Finally, as to Defendants' claim that the England opinion lacks "reasonable foundation," (*see* Defs.' Daubert Mem. 18), the Court disagrees for the same reasons stated above. To the extent that Defendants argue that England's lack of foundation is amplified by discrepancies between exhibits from discovery, testimony, and England's opinions, "factors which make evidence less than conclusive affect only weight, not admissibility." *United States v. Schultz*, 333 F.3d 393, 416 (2d Cir. 2003) (citation and quotation marks omitted); *see also United States v. Mustafa*, 753 F. App'x 22, 36 (2d Cir. 2018) (summary order) (citing *Schultz*).

Accordingly, the Court grants Defendants' Motion to Exclude England's testimony as to England's first three opinions, and denies Defendants' Motion to Exclude as to the final opinion.

b. Federal Standards for Illegality

Defendants first argue that they are entitled to summary judgment on the legal question as to whether the personal importation of prescription drugs from foreign online pharmacies is illegal. Specifically, Defendants argue that federal law "unambiguously" makes the personal importation of prescription drugs illegal, citing to the comprehensive scheme of federal laws and to decisions from courts outside of this District and Circuit who have found as such. (*See* Defs.' SJ Mem. 11–15.)

The importation of prescription drugs is governed by the Federal Food, Drug, and Cosmetic Act ("FFDCA"). In relevant part, the FFDCA prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded[,]" as well any introduction into interstate commerce of any new drug that is not manufactured pursuant to FDA approval. 21 U.S.C. § 331(a), (d); *see also* 21 U.S.C. § 355(a).

The Eighth Circuit has noted that:

> [t]he United States Food and Drug Administration ("FDA") repeatedly has expressed the view that virtually all importation of drugs into the United States by individual consumers violates the FFDCA, because the drugs are not approved in accordance with 21 U.S.C. § 355, are not labeled as required by 21 U.S.C. § 352, or are dispensed without a valid prescription in contravention of 21 U.S.C. § 353(b)(1).

In re Canadian Import Antitrust Litg. ("Canadian Import"), 470 F.3d 785, 788–89 (8th Cir. 2006); *see also Pharm. Rsch. & Mfrs. of Am. v. Dep't of Health & Human Servs.*, No. 10-CV-3402, 2023 WL 1795644, at *1–2 (D.D.C. Feb. 6, 2023) (analyzing *Canadian Import*). These laws overlap by design, "work[ing] in conjunction with the other statutory standards and FDA regulations to create a system that excludes noncompliant and potentially unsafe pharmaceuticals. *Canadian Import*, 470 F.3d at 790. For example, the FFDCA describes in various sections what drugs are "adulterated" or "misbranded." Drugs are considered misbranded in a variety of circumstances, including lacking information required by statute, *see* 21 U.S.C. § 352, if they are labeled in a language other than English, *see* 21 C.F.R. § 201.15(c), or are dispensed without a valid prescription, *see* 21 U.S.C. § 353(b)(1). In addition, the FFDCA expressly prohibits knowingly importing or reimporting drugs, subject to limited exceptions. 21 U.S.C. § 333(b)(1)(A).

Importantly, foreign pharmaceuticals—manufactured and distributed abroad and later imported into the United States—are "unapproved" drugs within the meaning of 21 U.S.C. § 355. *See Pharm. Rsch. & Mfrs. of Am.*, 2023 WL 1795644, at *1 (stating that "the domestic drug supply chain is strictly monitored"); *Canadian Import*, 470 F.3d at 789; *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 473 (D. Vt. 2005) ("Any drug, even a foreign version of an FDA approved drug, will be an unapproved drug unless it meets all United States packaging, labeling and dosage requirements."); *Personal Importation*, Food & Drug Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation ("If a drug is approved for use in another country but is an unapproved new drug in the U.S. it is illegal to import."); *United States v. Rx Depot Inc.*, 290 F. Supp. 2d 1238, 1245 (N.D. Okla. 2003) (finding that the defendants violated the FFDCA "each time" they introduce an unapproved Canadian drug in violation of 21 U.S.C. § 355). As the Eighth Circuit has summarized:

> [d]rugs that are manufactured and distributed [outside of the United States] are not approved pursuant to [the FDA's approval process]. Because foreign labeling differs from domestic labeling, approval granted to a particular product to be distributed in the United States does not constitute approval of another drug—even one with the same chemical composition—to be distributed [internationally] with different labeling, and then imported into the United States.

Canadian Import, 470 3d. at 780–90.

While Plaintiff is correct that there are various exceptions to and exemptions from these laws, (*see, e.g.*, PCC's SJ Mem. 22 (citing labeling exemptions listed under 21 C.F.R. § 201.100)), these exemptions do not negate the bright-line rule of illegality. The FDA defines personal importation as "a product not for further sale or distribution into U.S. commerce . . . carried in baggage or shipped by a courier or international mail." *Personal Importation*, Food & Drug Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation. The FDA further notes that "[i]n most circumstances, it is illegal

for individuals to import drugs . . . into the U.S. for personal use because these products purchased from other countries have not been approved by the FDA for use and sale in the U.S. *Id*. The FDA emphasizes the importance of this scheme, stating that it "cannot ensure the safety and effectiveness of the medicine purchased over the Internet from foreign sources. . . . For these reasons, the FDA recommends only obtaining medicines from legal sources in the U.S." *Id*. The FDA continues to provide information regarding situations for which personal importation of a prescription drug "might be allowed": (1) the drug "is for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means"; (2) "[t]here is no known commercialization or promotion of the product to persons residing in the U.S."; (3) the product "does not represent an unreasonable risk"; (4) the consumer "affirms in writing that the product is for personal use"; and (5) the quantity is "generally not more than a three month supply" and the consumer must "[p]rovide the name and address of the doctor licensed in the U.S. responsible for . . . treatment with the product, or [p]rovide evidence that the product is for the continuation of a treatment begun in a foreign country." *Id*. Notably, however, the FDA does not specifically state whether personal importation would indeed be allowed under these circumstances, just that it "might" be allowed. *Id*.

However, there are two clear statutory exceptions to this bright-line rule. First, the Secretary of Health and Human Services ("HHS" or "the Secretary") may authorize importation for emergency use. 21 U.S.C. § 381(d)(2). Second, importation may be permitted under section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108–173, 117 Stat. 2066 (2003) (the "MMA"). *See* 21 U.S.C. § 384. In 2003, Congress passed the MMA which provided the Secretary with various authorities to relax enforcement of

prescription drug importation penalties. *See id*. For example, the Secretary is given the authority to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." *Id*. at §384(b). In addition, "[t]he Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug . . . under such conditions as the Secretary determines to be appropriate." *Id*. § 384 (j)(2)(A). Specifically, the Secretary may grant a waiver to permit personal importation of a prescription drug under with the following conditions: the drug is (1) "imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply"; (2) "accompanied by a copy of a valid prescription"; (3) "is imported from Canada, from a seller registered with the Secretary"; (4) "is a prescription drug approved by the Secretary"; (5) "is in the form of a final finished dosage that was manufactured in an establishment registered under [the FFDCA]"; and (6) "is imported under such other conditions as the Secretary determines to be necessary to ensure public safety." *Id*. § 384(j)(3).

The Parties strongly disagree about whether this exception and related guidance (the "Personal Importation Policy") is indeed operative and relevant to PCC's business, and whether it governs the personal importation of prescription drugs from foreign pharmacies. (*See generally* Defs.' SJ Mem.; PCC's SJ Mem.) Specifically, the Parties disagree as to (1) whether the Secretary must certify any use of the personal importation plan under § 384(j); and, if so, (2) whether the Secretary has in fact ever invoked the Personal Importation Policy for importation from foreign pharmacies.

To both questions, Defendants argue that the Secretary has "never implemented this section to allow for personal importation," citing another section of the statute that notes that "[t]his section shall become effective only if the Secretary certifies to the Congress that the

implementation of this section will pose no additional risk to the public's health and safety; and result in a significant reduction in the cost of covered products to the American consumer." (Defs.' SJ Mem. 13). *See also* 21 U.S.C. § 384(l)(1). Plaintiff disagrees with Defendants' assertion that the Secretary must make this certification prior to invoking § 384(j), arguing that the "program" referenced in the relevant clause refers to the "wholesale importation program under subsection (b), not (j)." (PCC's SJ Mem. 25–26.) However, based on basic principles of statutory interpretation, it is clear that where the certification provision states that "this section shall become effective" only if preconditions occur, the statute intends for the entire section (i.e., § 384) to be affected, rather than just particular subsections (i.e., § 384(b)). Moreover, Plaintiff's interpretation of the statute has been roundly rejected by other courts, and this Court finds no compelling reason to disagree.

For example, in *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005), the court called Plaintiff's proposed reading of the statute "highly implausible," finding that the "only sensible way to read the statute is to assume that Congress intended the certification provision to apply to the whole of [§] 384." *Id*. at 474–75 ("The certification provision clearly states that 'this section shall become effective' only if the Secretary certifies. Thus, the Court begins with a very strong presumption that Congress meant 'section' when it wrote 'section.'" (citations omitted)). Other courts have agreed, citing the court's reasoning in *Leavitt*. *See Canadian Import*, 470 F. 3d at 790 ("In 2000 and 2003, Congress enacted amendments to the FFDCA that would permit limited importation of certain prescription drugs from Canada by pharmacists, wholesalers, or individuals, 21 U.S.C. § 384(b), (j), but only if the Secretary of Health and Human Services first certifies[.]"); *Montgomery Cnty. v. Leavitt*, 445 F. Supp. 2d 505, 510–11 (D. Md. 2006) (citing *Leavitt* to support the proposition that "it is clear that Congress intended the certification

provision to apply to both subsection (b) and to the individual waiver provision of subsection (j)"); *cf. Pharm. Rsch. & Mfrs. of Am.*, 2023 WL 1795644, at *2 (describing the Secretary's certification as a "precondition" to promulgating regulations to import prescription drugs from Canada).

Given this authority, this Court concludes that the Secretary has never invoked § 384(j) to put the Personal Importation Policy into effect. In July 2019, HHS and the FDA announced the "Safe Importation Action Plan," which proposed two pathways "to allow the safe importation of certain drugs originally intended for foreign markets" to provide "safe, lower cost drugs to consumers." Dept. of Health & Human Servs. & U.S. Food & Drug Admin., Safe Importation Action Plan (2019), https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf. In December 2019, the FDA issued a Notice of Proposed Rulemaking pursuant to the Safe Importation Action Plan, outlining the steps that the federal government intended to take for the importation of drugs. *See* Importation of Prescription Drugs, 84 Fed. Reg. 70796 (proposed Dec. 23, 2019). In the proposed rule, the FDA was careful to underscore that it was "not proposing to implement the personal importation provisions [in § 384(j)] through this rulemaking." *Id*. at 70800. The FDA went on to explain:

> The internet provides consumers with instant access to information and services, including prescription medications. Medications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers.
>
> While there are pharmacy websites that operate legally and offer convenience, privacy, and safeguards for purchasing medicines, there are many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States. These rogue online pharmacies are often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States. [. . .] Consumers go to these websites believing they are buying

> safe and effective medications, but often they are being deceived and put at risk by individuals who put financial gain above patient safety.
>
> [. . .]
>
> Given these risks, and other concerns . . ., the proposed rule, if finalized, would not implement personal importation provisions under [§ 384(j)].

Id. In the final rule promulgated in October 2020, the FDA addressed several comments that "ask[ed] FDA to expand the proposed rule to . . . allow personal importation of certain prescription drugs." Importation of Prescription Drugs, 85 Fed. Reg. 62094, 62097 (Oct. 1. 2020) (to be codified at 21 C.F.R. pts. 1, 251). Here, the FDA again reiterated that it was "not implementing the personal importation provisions . . . through this rulemaking." *Id*.

Despite this, Plaintiff continues to argue that there is significant daylight between federal law's prohibition on personal importation and the practical reality of importation, claiming that "there is no prohibition on introducing FDA-approved drugs, provided other requirements are met." (PCC's SJ Mem. 21.) In making this argument, Plaintiff appears to conflate the FDA website guidance on personal importation with the requirements of § 384, arguing that the existence of the Personal Importation Policy is, by design, evidence that there are some exceptions to the prohibition on personal importation that would make the conduct not per se illegal. (*Id*. at 21–28.)[21] Defendants largely rely on *Canadian Import* to argue that "personal

[21] In particular, Plaintiff cites *Cook v. Food & Drug Admin.*, 733 F.3d 1 (D.C. Cir. 2013) for several propositions, including that the FDA has discretion as to how it implements personal importation. (PCC's SJ Mem. 22–23.) Specifically, Plaintiff states that the FDA has pointed to § 384(j) "[a]s evidence that the Congress is aware of and agrees" that "it can 'allow the importation of drugs that are clearly for personal use.'" (*Id*. (citing *Cook*, 733 F.3d at 10 (quotation marks omitted)).)

However, the D.C. Circuit plainly disagreed with Plaintiff in the same paragraph, agreeing instead with the statutory interpretation outlined by this Court. *Cook*, 733 F.3d at 10. The D.C. Circuit stated that "[t]he FDA . . . conveniently overlooks the very next subsection, which effectuates the statute by authorizing the Secretary to grant individual waivers to import prescription drugs. [ ] Congress would have no reason to grant the FDA explicit waiver

importation of prescription drugs from foreign on[]line pharmacies is unambiguously illegal." (Defs.' SJ Mem. 11.)

As explained above, the Eighth Circuit in *Canadian Import* noted that the FDA "repeatedly has expressed the view that virtually all importation of drugs into the United States by individual consumers violates the FFDCA." 470 F.3d at 788–79; *see also Pharm. Rsch. & Mfrs. of Am.*, 2023 WL 1795644, at *2 ("The statutory drug-importation scheme has thus lain dormant for most of its history, and importing drugs from Canada or elsewhere has remained effectively illegal."). The *Canadian Import* court also found that this was a "congressional plan to create a closed system designed to guarantee safe and effective drugs for consumers in the United States." *Canadian Import*, 470 F.3d at 790 (quotation marks and citation omitted). While foreign drugs may be "similar in substance" to those manufactured in the United States, foreign drugs may also have "chemical compositions that are not yet approved by the FDA" and may not be "manufactured in accordance with FDA rules[ ] or . . . transported or stored in a manner that is deemed safe by the FDA." *Id*. Specifically, this "closed system ensures that approved prescription drugs are subject to FDA oversight and are continuously under the custody of a U.S. manufacturer or authorized distributor" which makes the drugs safe, consistent, and predictable for the American consumer. *Id*. (quotation marks and citation omitted).

Plaintiff attempts to limit *Canadian Import* by arguing that the case "considered only a class of U.S. plaintiffs who, as alleged, purchased certain drugs in the United States also sold in Canada with different labeling," but "'the Canadian prescription drugs at issue [were] not labeled in conformity with federal law' and were therefore illegal to import under the provisions the

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authority if, as the FDA argues, the agency was already authorized not to enforce [the personal importation of drugs]." *Id*. (citations omitted).

class invoked." (PCC's SJ Mem. 23 (citing *Canadian Import*, 470 F.3d at 788–89).) In the alternative, Plaintiff argues that "many drugs sold in Canada ae FDA-approved drugs" and *Canadian Import* only applies to the small, mislabeled class of drugs at issue in the opinion. (*Id*.) However, and as noted in *Canadian Import*, the "fundamental[]" issue regarding the mislabeled drugs in the case "illustrates why . . . Canadian drugs are 'unapproved' drugs'" under federal law—foreign manufactured and distributed drugs are not approved according to the existing statutory framework. *Canadian Import*, 470 F.3d at 789–790.

This Court finds the Eighth Circuit's reasoning is particularly persuasive given its discussion of the MMA. Specifically, the Eighth Circuit reasoned that it was under this "closed system" backdrop that Congress created a "special procedure for authorizing importation of prescription drugs from Canada," ultimately supported the conclusion that federal law does not permit personal importation. *See id*. at 790–91. "While it is true that no federal statute by its express terms bans importation of prescriptions drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system . . ., Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384." *Id*.

As such, and as relevant to the instant Motion, the Court finds that personal importation of prescription drugs is illegal under current federal law. Plaintiff argues in the alternative that its verification and accreditation system "filters out unlawful importations with requirements consistent with lawful importation." (*See* PCC's SJ Mem. 26–28.) Plaintiff cites provisions in its "Verification Program Accreditation Standards and Guide," which largely correlate with the FDA's personal importation guidance on its website. (*See id*. at 27 (listing the requirements); Pl.'s Mem. in Opp. Ex. 27 (Dkt. No. 270-28).) *See also Personal Importation*, Food & Drug

Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation. However, PCC does not establish that its accreditation program even follows all of the listed guidance. *Compare Personal Importation*, Food & Drug Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation (requiring that the product "is for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means" and does not represent an "unreasonable risk") *with* (PCC's SJ Mem. 27). Moreover, the Court emphasizes the fragility of this argument, as evidenced by the language the FDA itself uses to describe personal importation. *See Personal Importation*, Food & Drug Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation (providing "information regarding situations for which [personal importation of unapproved drugs] *might* be allowed" (emphasis added)). In addition, to the extent Plaintiff argues that its accreditation guidelines comport with the MMA, Plaintiff has quite the mountain to climb. Section 384(j) not only has not been invoked by the Secretary, but even if it had been invoked, the potential provisions only apply to Canada, not all international personal importation. *Id*. As such, Plaintiff's arguments are unpersuasive.

c. PCC's Revenue Share from International Pharmacies

Defendants next argue that "PCC's financial records firmly establish that its enterprise is almost completely geared toward facilitating illegal importation of drugs," because the "overwhelming majority of PCC's revenue comes from consumers clicking on the links that allow them to directly connect to, and unlawfully purchase drugs from, foreign pharmacies." (Defs.' SJ Mem. 15 (quotation marks omitted).) Specifically, Defendants argue that "[redacted] of PCC's total revenue comes from PCC's foreign online pharmacies for aspects of its business . . . that enable [those pharmacies] to make illegal prescription drug sales to consumers." (*Id.*)

The Court agrees that revenue is highly probative in determining whether summary judgment should be granted to Defendants because it is indicative of how much of Plaintiff's business is derived from illegality or facilitating illegality. In denying Defendants' Motion To Dismiss, this Court provided a non-exhaustive list of examples as to factors that may indicate "illegality" at summary judgment. *See PharmacyChecker.com*, 530 F. Supp. 3d at 330–331. For example, the Court found that Plaintiff's Amended Complaint "alleges that its business consists of presumably legal activities, including accrediting U.S. online pharmacies, and providing price comparisons for U.S. online pharmacies." *Id*. at 330 (citations omitted). The Court also noted that the Amended Complaint "does not allege that all or almost all of Plaintiff's business relates to these foreign pharmacies," nor did admissions at oral argument "concern the presumably legal aspects of Plaintiff's business." *Id*. In a later discovery order, this Court stated that the Amended Complaint "made no claims regarding the share of [PCC's] business related to the sales of prescription drugs from foreign pharmacies to U.S. consumers[.]" (Order 3 (Dkt. No. 167).) However, as Plaintiff is no longer "sheltered by the vagueness of its [amended complaint]," Plaintiff now faces the tall task of showing that the "primary purpose" of its business is not "to facilitate unlawful importation." *PharmacyChecker.com*, 530 F. Supp. 3d at 330–331.

Based on this background and the Court's finding here that personal importation of prescription drugs is illegal under current federal law, it follows that the overall breakdown of PCC's revenue is crucial: PCC's enterprise is necessarily "completely or almost completely illegal, or completely or almost completely geared toward facilitating illegality" if the majority of its revenue stems from facilitating the purchase of foreign drugs by U.S. consumers.

The Parties do not dispute that between [redacted] of PCC's total revenue from January 2015 to August 2021 is attributable to online pharmacies located outside of the United States. (Defs.' 56.1 ¶ 22; Pl.'s Resp. 56.1 ¶ 22; *see also* Defs.' Mem. Ex. 16 ("Farrar Report"), at ¶¶ 16, 38, 41 (Dkt. 264–17).) This Court underscores that it is not illegal for a U.S. business to receive some or even almost all of its revenue share from foreign entities. It is, however, illegal if this revenue stems from illegal activity (i.e., facilitating the purchase of foreign drugs the importation of which is prohibited by federal law). To make this determination, the Court must assess the sources of this revenue, and whether each of these sources facilitate illegal importation.

During the relevant period, the vast majority of PCC's revenue came from three sources: approximately [redacted] came from cost-per-click fees "that PCC charges its accredited pharmacies for sending consumers to those accredited pharmacies' websites"; [redacted] came from fees pharmacies pay to participate in PCC's Verification Program; and [redacted] came from fees verified pharmacies pay to be listed on PCC's website. (Defs.' 56.1 ¶¶ 8–9; Pl.'s Resp. 56.1 ¶¶ 8–9; *see also* Farrar Report at ¶ 14.) "PCC's other revenue streams, including application fees received from online pharmacies, revenue from discount cards, Medicare drug plans, advertising, and e-book, provide less than [redacted] of its total revenues." (Defs.' 56.1 ¶ 10; Pl.'s Resp. 56.1 ¶ 10; *see also* Farrar Report at ¶ 14.) Most relevant to this inquiry is an analysis of PCC's "cost-per-click" fees, otherwise described as "click-fees." Defendants' expert described this type of monetization for PCC, stating that "[a]ccredited [w]eb [s]ite[s] . . . pay[] a fee each time a consumer clicks on a link in [PCC] pointing to the[ir] website." (Defs.' Mem. Ex. 19 ("Kent Am. Report") at ¶ 24 (Dkt. No. 264-20).) These click-fees are "a very common form of payment for traffic on the Internet," according to Defendants' expert. (*Id.*)

Click-fees are also the key metric in analyzing PCC's revenue because they show (1) whether U.S. consumers are clicking on predominantly foreign pharmacies; and (2) whether these clicks represent the majority of Plaintiff's revenue. Importantly, the Parties agree that "[a]t least [redacted] websites that received clicks between January 2015 and August 2021 were foreign[,]" which accounted for "[redacted] of the click fees ([redacted]) and [redacted] of clicks ([redacted])[.]" (Defs.' 56.1 ¶ 29; Pl.'s Resp. 56.1 ¶ 29; *see also* Kent Am. Report ¶¶ 39–40.) "Only [redacted] [websites that received clicks] are U.S. sites, accounting for [redacted] of the click fees ([redacted]) and [redacted] of total clicks ([redacted])." (Defs.' 56.1 ¶ 30; Pl.'s Resp. 56.1 ¶ 30; *see also* Kent Am. Report ¶ 40.) As such, the vast majority of users who visit PCC end up clicking through to pharmacies outside of the U.S. (*See* Defs.' 56.1 ¶ 31; Pl.'s Resp. 56.1 ¶ 31.)

As it relates to U.S. consumers, the Parties agree that U.S. consumers "generat[ed] [redacted] of click-through fees paid to the company" during this period. (Defs.' 56.1 ¶ 40; Pl.'s Resp. 56.1 ¶ 40; *see also* Kent Am. Report ¶¶ 56–58 ("I found that clicks by US visitors on the [PCC] site were responsible for most of [PCC's] revenues.").) Put another way, within the almost [redacted] share of PCC's total revenue represented by U.S. consumers, those consumers were searching for prescription drugs from online pharmacies by clicking on links to accredited websites [redacted] of the time. This percentage is particularly stark when looking at the click percentages for users in other countries: the next largest share comes from [redacted] users who generate [redacted] of PCC's click fees, followed by users from the [redacted] who generate [redacted] of click fees. (Kent Am. Report ¶ 57.)

At bottom, the only material dispute between the Parties is how the Court should interpret the [redacted] of click-through fees. Defendants contend that the Court should rely on calculations from their expert, Mr. Peter Kent ("Kent"), who found that "[a]bout [redacted] of the click fees for

clicks from U.S. consumers were billed to foreign PCC-accredited websites." (Defs.' 56.1 ¶ 32; *see also* Kent Am. Report ¶¶ 16, 62 ("About [redacted] of the click fees for clicks from US consumers were paid by non-US Accredited Web Sites.").) In other words, Defendants calculate that [redacted] of the [redacted] of PCC's total revenue derived from U.S. consumers results from fees for U.S. consumers clicks to foreign websites. On the other hand, Plaintiff asks the Court to rely on a different figure, calculated based upon Defendants' expert testimony, which found that [redacted] of PCC's *total revenue* is from fees generated by U.S. consumers clicking to foreign online pharmacies. (*See* Pl.'s Resp. 56.1 ¶¶ 32–33; Levitt Decl. ¶ 45.)

It is clear to the Court, however, that no matter how one slices this pie, click fees from U.S. consumers to foreign pharmacies represents the largest share of PCC's revenue. Indeed, as outlined above, there is no source of revenue that could come even close to the costs per clicks generated by U.S. consumers. "The almost total magnitude of this illegal conduct by [Plaintiff] makes their miniscule conduct that may be legal, insignificant . . . ." *Pearl Music Co., Inc. v. Recording Indus. Ass'n of Am., Inc.*, 460 F. Supp. 1060, 1068 (C.D. Cal. 1978); *see also id.* (comparing the facts of the case to *Memorex Corp. v. IBM Corp.*, 555 F.2d 1379 (9th Cir. 1977) where the business was "engaged in wrongful or illegal conduct only in part of its sizeable enterprise"). And, most importantly for purposes of deciding Defendants' summary judgment motion, there is no genuine dispute of material fact as to the data that underlie these two calculations because, if PCC were to lose the click fees from U.S. consumer clicks to foreign websites under either calculation, PCC's business would likely cease to exist.

While not dispositive on its own, this finding is bolstered by PCC's statements on its website as well as PCC's actions toward U.S. consumers who request PCC's support for issues with their transactions. As Defendants explain: "PCC's primary mission is to facilitate U.S.

consumers' unlawful importation of foreign pharmaceuticals," because (1) the company "exists to facilitate the purchase of foreign drugs by American consumers"; (2) "PCC actively 'intervenes' in U.S. consumers' purchase transactions with PCC accredited foreign pharmacies"; and (3) "PCC is well aware of the illegality of the personal importation it facilitates and from which it profits." (Defs.' SJ Mem. 19–27.) While the Court recognizes the dispute between the Parties about the true "mission" of PCC, (*see* Defs.' 56.1 ¶¶ 38–50; Pl.'s Resp. 56.1 ¶¶ 38–50), there are several uncontroverted and undisputed facts bolstering Defendants' remaining assertions.

To start, when a user navigates to the "Prescription Savings" page on PCC's website, PCC states that it "compares U.S. prices to Canadian and International prices and shows the percentage savings available" to users interested in purchasing certain drugs from "trusted international mail order online pharmacies, including licensed Canadian pharmacies and local U.S. pharmacies." (Defs.' 56.1 ¶ 47; Pl.'s Resp. 56.1 ¶ 47.)[22] As users search for prescription drugs, all prices are listed in U.S. dollars, without regard to the location of the pharmacy or the location of the potential consumer. (*See* Defs.' 56.1 ¶ 42; Pl.'s Resp. 56.1 ¶ 42.)

In addition, PCC and its executives have made several statements—many of which are still available on PCC's website—indicating that the company is, at a minimum, aware of an effort to contravene the American pharmaceutical statutory scheme, and at most, aware of the illegality of personal importation that PCC offers to facilitate. For example, when announcing

[22] The Court notes that Plaintiff disputes that these prices are specifically targeted to "Americans who import drugs from foreign pharmacies rather than buying those drugs locally in the U.S.," because there is "no admissible evidence that the prices are 'for Americans who import drugs.'" (*See* Pl.'s Resp. 56.1 ¶ 47.) However, as discussed in the factual background, Plaintiff does not dispute the text of the page itself. (*See* Defs.' 56.1 ¶ 47; Pl.'s Resp. 56.1 ¶ 47.)

the Spanish version of its website, CEO Tod Cooperman was quoted in the press release stating "No one living in the U.S. should have to forgo filling a prescription because of high drug prices, especially when lower prices on the same drugs are available to informed consumers." (Defs.' 56.1 ¶ 43; Pl.'s Resp. 56.1 ¶ 43.) In its press release, PCC also focused on the value of a Spanish language website for U.S. consumers, "noting that 38% of Hispanics living in the U.S. speak mainly Spanish." (Defs.' 56.1 ¶ 43; Pl.'s Resp. 56.1 ¶ 43 (quotation marks omitted).) In addition, PCC openly touts its work helping all consumers "get the best deal" on its Consumer Support page, while simultaneously providing advice specifically to U.S. consumers. (*See* Defs.' Mem. Ex. 6; Defs.' 56.1 ¶ 48; Pl.'s Resp. 56.1 ¶ 48.) PCC lists at least seven "frequently asked questions" on its Consumer Support page, providing consumers with information on a variety of topics, including "[h]ow much can Americans save by purchasing their prescription drugs online" and how "fast" international prescription delivery can be for consumers. (*See* Defs.' Mem. Ex. 6; Defs.' 56.1 ¶ 48; Pl.'s Resp. 56.1 ¶ 48.) In response, PCC states that "U.S. consumers could pay up to 90% less than what they pay at a local pharmacy" and that "[e]veryone deserves the opportunity and choice to purchase more affordable medication from licensed pharmacies, *whether domestic or international*." (*See* Defs.' Mem. Ex. 6 (emphasis added).) PCC "advise[s] [consumers] that medication ordered from outside the U.S. can normally take 2-3 weeks to arrive[,]" and tells consumers to purchase from a local pharmacy "for immediate supply" and later "purchase more internationally for future use." (*Id*.)

Even more probative, however, are PCC's statements regarding its interpretation of federal law on personal importation, as well as various statements about the safety of prescription drugs from foreign pharmacies. In response to a question about the legality of ordering prescription drugs online, PCC describes the prohibition of "[i]nternational drug

importation" as a technicality, stating: "Technically, in the U.S., under most circumstances, it is prohibited to import medication that you order *internationally* online." (*Id*. (emphasis in original).) PCC continues by opining on FDA's enforcement discretion, telling its U.S. consumers that "it is important to know that people in the U.S. are not prosecuted for [importing medication], as long as the medication imported is for your own use and not for resale." (*Id*.) In response to another question about international shipping, PCC states that "the law allows the FDA and U.S. Customs and Border Patrol to detain and refuse international prescription orders[,]" but counsels that "less than one percent of medication orders are actually stopped, at least for orders where a prescription is required." (*Id*.) With these statements, PCC is attempting to downplay the potential illegality by citing unsubstantiated statistics about the FDA's interception of imported foreign prescription drugs. Of course, several cases cited within this Opinion agree with this Court's analysis: to the extent that there is statutorily authorized enforcement discretion for the FDA, HHS, or the FDA, these agencies have not officially invoked that discretion to allow personal importation. *See, e.g.*, *Cook*, 733 F.3d at 9–10 (disagreeing with FDA's various arguments for discretion in drug importation); *Canadian Import*, 470 F.3d at 789–91 (describing a "comprehensive regulatory system" where "Congress has effectively precluded importation of these drugs absent . . . special authorization").

Moreover, PCC answers at least two frequently asked questions by directly contradicting FDA guidance about the safety of prescription medications from foreign pharmacies, enticing U.S. consumers to purchase from foreign pharmacies despite the carefully controlled congressional scheme designed to keep consumers safe. In response to a question describing possible dangerous pharmacies, PCC states that "[o]nline pharmacies based outside the U.S. are

not 'rogue' by definition." (*See* Defs.' Mem. Ex. 6.) However, PCC does not stop there, explaining that:

> [s]ome regulatory bodies, including the [FDA], refer to such pharmacies as "illegal" or "fake" but such distinctions can mislead consumers and impede their access to affordable, safe and effective medication that they cannot obtain locally due to high U.S. drug prices. Pharmacies in some countries are equally as safe if not safer than those in the U.S. [. . .]

(*Id*.) This is in direct contravention of FDA guidance that PCC cites throughout its briefing arguing that personal importation is not always illegal. *See Personal Importation*, Food & Drug Admin. (last updated January 10, 2023), https://www.fda.gov/industry/import-basics/personal-importation (recommending that consumers "only obtain[] medicines from legal sources in the U.S." because the FDA "cannot ensure the safety and effectiveness of the medicine purchased over the Internet from foreign sources"); Importation of Prescription Drugs, 84 Fed. Reg. 70796 (proposed Dec. 23, 2019) (describing"rouge online pharmacies . . . run by sophisticated criminal networks," but also stating that "[g]iven these risks, *and other concerns*[,]" the proposed rule would not implement personal importation provisions (emphasis added)). Of course, in offering this assessment, PCC also holds itself out as a source for "exceedingly safe" medication "from a pharmacy outside the U.S." to U.S. consumers, despite apparently knowing—and attempting to discount—the exact risks that the FDA and federal laws are designed to prevent. (Defs.' Mem. Ex. 6; *see also id*. (reminding consumers that "risks do exist when ordering medication from an unverified international online pharmacy," unlike the pharmacies accredited by PCC's verification program).)

Finally, it is important to note that PCC does not stop by providing this information on its website. In fact, when consumers reach out to PCC with complaints of all varieties, it is undisputed that members of PCC's support team endeavor to assist. (*See* Defs.' 56.1 ¶¶ 57, 59–

60, 62–64; Pl.'s Resp. 56.1 ¶¶ 57, 59–60, 62–64.) These complaints vary, including issues with "address delivery details, obtain[ing] refunds for orders of prescription drugs, and follow[ing] up on order errors." (*See* Defs.' 56.1 ¶ 60.)[23] In addition, PCC advertises its ability to "contact the company" or "intervene" on a consumer's behalf. (*See* Defs.' 56.1 ¶ 61 ("For us to process your complaint, you must authorize us to contact the company on your behalf."); Pl.'s Resp. 56.1 ¶ 61 (same); Defs.' SJ Mem. Ex. 64 (Dkt. No. 264-65) ("If you would like us to assist you with a customer complaint we can intervene on your behalf.").)

Specifically, exhibits offered by Defendants establish that PCC has intervened on behalf of U.S. consumers with foreign pharmacies with issues related to their order. For example, PCC helped at least two U.S. consumers with relatively mundane requests: (1) ascertaining an order confirmation for a customer without a working email address for a prescription drug purchased from a Canadian pharmacy, (*see* Defs.' SJ Mem. Ex. 71 (Dkt. No. 264-72) (mailing the prescription drug to Los Angeles); Kent Am. Report ¶ 39 (listing QualityPrescriptionDrugs.com

[23] Plaintiff lodges a slew of objections to statement 60 and its supporting exhibits, almost all of which are unavailing to this Court. (*See* Pl.'s Resp. 56.1 ¶ 60.) Plaintiff argues that statement 60 should be stricken because it is "irrelevant" and "unsupported by admissible evidence." (*Id.*) The Court disagrees with Plaintiff's assessment of relevance for reasons discussed below. *See infra* ("[W]hile not dispositive, these emails are relevant in that they are consistent with the other evidence that reveals the mission and purpose of Plaintiff's business.").

The other objections are equally unpersuasive. First, the Court disagrees with Plaintiff's objection as it relates to Exhibits 75, 76, 77, and 78 as unauthenticated, as these exhibits were produced by Plaintiff to Defendants and Plaintiff "offers no specific reason to doubt any document's authenticity." *Hallett*, 517 F. Supp. 3d at 268; *John Paul Mitchell Sys*, 106 F. Supp. 2d at 472 ("[T]he act of production implicitly authenticate[s] [a] document[]."). Second, the Court will disregard Exhibits 28, 74, and 79 for the purposes of this analysis, given Plaintiff's evidentiary objections, but this does not change the analysis. (*See* Pl.'s Resp. 56.1 ¶ 60.) There are several other Exhibits that Defendants rely upon to substantiate this statement, to which Plaintiff has not lodged objections. (*See id.* (citing no objections to Exhibits 5, 10, 64, 73, and 80).)

as based in Canada)); and (2) assisting a customer with credit card processing issues (*see* Defs.' SJ Mem. Ex. 73 (Dkt. No. 264-74) (identifying a customer with an American phone number)).

More poignantly, PCC intervened on behalf of two U.S. customers who received incorrect or unmarked medication, potentially dangerous issues which are exactly the type of issues federal law is designed to prevent. (*See* Defs.' 56.1 ¶ 64; Pl.'s Resp. 56.1 ¶ 64.) In one email, a customer received a prescription order from pharmacies in Delhi, India that contained "no imprint to identify or verify their validity as a generic" drug. (Defs.' SJ Mem. Ex. 81 (Dkt. No. 264-82).) The customer expressed particular frustration with PCC because that customer "placed great reliance on [PCC's] association to oversee standards and compliance[,]" underscoring federal law that "[p]rescription pills without imprints are considered invalid in the US." (*Id.*) In this email chain, PCC's President Gabriel Levitt personally forwarded this email to two employees, recognizing that the pills could "be non-compliant" and urging the employees to "draft a response and plan of action" for his review. (*Id.*) Presumably after receiving a question through PCC's customer complaint form, (*see* Defs.' 56.1 ¶ 61; Pl.'s Resp. 56.1 ¶ 61), PCC sent a U.S. consumer an email advising the customer that "[m]edications approved for sale in other countries often have different packaging, labeling[,] and can also have different inactive ingredients and appearances than those approved for sale in the U.S.[,]" (Defs.' SJ Mem. Ex. 82 (Dkt. No. 264-83)). The customer responded to PCC with further information about their purchase from a Canadian pharmacy, where the customer received an order of prescription drugs "without any markings on the capsules" and were "not the same size" as the expected drug. (*Id.*) Plaintiff argues that these exhibits are largely "irrelevant and overly broad based on the cited evidence showing a total of [two] consumer complaints." (Pl.'s Resp. 56.1 ¶ 64.) However,

while not dispositive, these emails are relevant in that they are consistent with the other evidence that reveals the mission and purpose of Plaintiff's business.

Simply put, PCC cannot have it both ways. PCC cannot both lodge repeated objections to its mission and purpose throughout its briefing, arguing that its business is "encourag[ing] visitors worldwide," (*see* Defs.' 56.1 ¶¶ 38–50; Pl.'s Resp. 56.1 ¶¶ 38–50), while also instructing U.S. consumers *specifically* about ways to get around the "technicalities" of federal law. And as discussed, PCC's actions are not surprising, as U.S. consumers' clicks through to foreign pharmacies are what sustain PCC's business.

PCC's only remining argument attacks the sufficiency of Defendants' submissions, arguing that Defendants "rel[ied] on impermissible inferences" because they failed to "connect[] a click to a transaction and a transaction to an unlawful importation." (PCC's SJ Mem. 19–20.)[24]

[24] Plaintiff also argues that Defendants cannot prove as a matter of law that PCC is "almost completely geared toward facilitating illegality" because Defendants' "statistics do not account for their anticompetitive conduct's effect on [P]laintiff's enterprise." (PCC's SJ Mem. 28–30.) To support this argument, Plaintiff cites one email produced in discovery between PCC and a Kentucky-based pharmacy, alleging that the pharmacy withdrew its accreditation with PCC because of this pharmacy's potential concerns with their Verified Internet Pharmacy Practice ("VIPPS") certification, which was provided by NABP. (*See* Pl.'s Resp. 56.1 ¶¶ 9, 11, 24–25; Pl.'s Resp. 56.1 Ex. 22 (Dkt. No. 269-14).) Defendants argue that "PCC's claim rests on hearsay and speculation," noting that PCC "points to two employee declarations (both of whom Defendants deposed and PCC could have cross-noticed) and an unauthenticated email, all containing, at least double hearsay." (Defs.' SJ Reply 13–15.) For the reasons stated below, the Court agrees with Defendants.

As to the hearsay allegations, while the Court does not agree that this testimony and associated exhibit is unauthenticated, the email and associated testimony does include inadmissible hearsay. Exhibit 22 is an email that was produced in discovery by PCC and attested to by Mr. Levitt in a declaration, which is sufficient for authentication purposes at summary judgment. *John Paul Mitchell Sys*, 106 F. Supp. 2d at 472 ("[T]he act of production implicitly authenticate[s] [a] document[]."). However, PCC attempts to use this email to prove the truth of the matter asserted (i.e. that NABP "threatened to strip" a U.S. pharmacy's VIPPS accreditation) through an out-of-court statement from a non-party to the litigation, who learned from another unidentified source that working with PCC "is considered a violation." (*See* PCC's SJ Mem. 29; Pl.'s Resp. 56.1 Ex. 22.) There is no evidence or testimony indicating that this U.S. pharmacy representative was unavailable to testify to this email, nor do any other hearsay exceptions apply.

PCC describes this as a "necessary assumption[]" in the Court's analysis as to whether Plaintiff's enterprise is completely or almost completely geared toward facilitating illegality. (*Id*. at 20.) However, and as Defendants rightfully point out, this is not the standard. On its face, to "facilitate" illegal action does not require actual proof of purchases. "Facilitating" an offense means that a party "make[s] [the offense] easier" or "help[s] [to] bring [it] about." *Facilitate*, Merriam-Webster, https://www.merriam-webster.com/dictionary/facilitate#legalDictionary (last visited Dec. 2, 2022). This is not just a dictionary definition: courts within and outside the Second Circuit have also used this definition of facilitation in other areas of the law. *See, e.g.*, *United States v. Wyly*, 193 F.3d 289, 302 (5th Cir. 1999) (finding property used to facilitate money laundering was "forfeitable[] because of its substantial nexus to the crime" as it was

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Fed. R. Evid. 803, 804. And this Court finds no compelling reason to admit this statement under the residual hearsay exception, given that Plaintiff failed to provide any evidence to "corroborat[e] the statement." Fed. R. Evid. 807.

Plaintiff attempts to excuse this conduct by stating that PCC "does not know the full extent of [D]efendants' conduct . . . [because] [i]t has not been permitted to take that discovery." (PCC's SJ Mem. 29.) Presumably, PCC is arguing (without stating) that this Court precluded it from taking this discovery. However, PCC is incorrect. The Court adopted a phased discovery schedule, starting discovery with a focus on "whether Plaintiff's enterprise is completely or almost completely geared toward facilitating illegality." (*See* Dkt. No. 167.) As this Court has stated *repeatedly*, "[i]t is a threshold requirement that Plaintiff's enterprise not be completely or almost completely geared toward facilitating illegality" because it is essential to the antitrust injury. (Order at 2 (Dkt. No. 167); *see also* Order at 6 (Dkt. No. 220) (finding that "illegality is not an affirmative defense, but rather negates an element of Plaintiff's prima facie case").) In Phase One, Plaintiff bore "the burden of proving that its business is legal." (Order at 6 (Dkt. No. 220).) And as the nonmovant here at summary judgment, if Plaintiff "fail[s] to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof[," the movant is "entitled to a judgment as a matter of law." *Celotex*, 477 U.S. at 323. Plaintiff was well within its rights to seek affirmative discovery on this issue. Instead, PCC chose not to and rested on an inconsistent statement.

Without this inadmissible evidence, Plaintiff is asking this Court to "rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment," which it is well-established is improper in the Second Circuit. *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (quoting *Fletcher v. Atex, Inc.*, 68 F.3d 1451, 1456 (2d Cir. 1995)). This Court declines Plaintiff's invitation.

"indispensable" to the conspiracy at issue); *United States v. Sabhnani*, 566 F. Supp. 2d 148, 152 (E.D.N.Y. 2008) ("Facilitation occurs when the property makes the prohibited conduct less difficult or more or less free from obstruction or hinderance." (citing *Wyly*, 193 F.3d at 302)); *United States v. Schlesinger*, 396 F. Supp. 2d 267, 272 (E.D.N.Y. 2005) (establishing that the property at issue was "integral to the fraud perpetrated by the Defendants" and "facilitated" the offense). Here, it is clear that PCC "makes easier" the illegal conduct at issue: PCC directs U.S. consumers to foreign pharmacies where they can purchase prescription medication in violation of federal law. In fact, PCC has described this facilitation as its mission "to help consumers afford medication they need." (Pl.'s Resp. 56.1 ¶ 38.)

As such, Defendants have met their burden to prove that PCC's enterprise is "completely or almost completely geared towards facilitating illegality." *PharmacyChecker.com*, 530 F. Supp. 3d at 329–30. Plaintiff accordingly does not have standing to maintain its claim pursuant to § 1 of the Sherman Act. *Id.* (describing the principle and finding that, if true, "[P]laintiff cannot plead an antitrust injury"); *Pearl Music Co.*, 460 F. Supp. at 1068 (finding that plaintiffs lacked "the standing or capacity to maintain [an] anti-trust action" because the plaintiffs "engaged in a business which is, by its very nature, entirely illegal"). Therefore, the Court grants Defendants' Motion for Summary Judgment on Plaintiff's Sherman Act § 1 claim, and Defendants ASOP, CSIP, and PSM are dismissed from this case.

III. Conclusion

For the foregoing reasons, Defendants' Joint Motion for Summary Judgment on Plaintiff's Sherman Act § 1 claim is granted, Plaintiff's Motion to Strike is denied, Defendants' Motion to Strike is denied, and Defendants' Joint Motion to Exclude Expert testimony is granted in part and denied in part. The Clerk of Court is respectfully requested to file this Opinion under seal, restricted to the Parties and the Court, and to terminate the pending motions at Dkt. Nos. 260, 263, and 273. The Court will hold a status conference on May 1, 2023 at 2:00 PM.[25]

SO ORDERED.

Dated: March 28, 2023
White Plains, New York

KENNETH M. KARAS
United States District Judge

[25] Because unredacted versions of these Motions and accompanying Memorandum were filed under seal, the Parties may have two weeks from the date of this Opinion & Order (the "Opinion") to propose redactions to the Opinion before it is issued publicly.