UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION (Indirect Purchasers)	* * * * * * * * * * *	Civil Action No. 1:16-cv-12396-ADB

MEMORANDUM AND ORDER

BURROUGHS, D.J.

This pay-for-delay case involves allegations that the Defendants settled patent litigation over the ADHD drug Intuniv on anticompetitive terms. The Indirect Purchaser Plaintiffs ("IPPs") are parents and caretakers who purchased Intuniv (the brand name for extended release guanfacine hydrochloride) or generic Intuniv[1] for a child's or ward's medical needs. They claim that the settlement agreement between brand Intuniv manufacturer Shire LLC and Shire U.S., Inc. (together, "Shire") and generic Intuniv manufacturer Actavis Holdco US Inc. and Actavis Elizabeth LLC (together, "Actavis" and collectively with Shire, "Defendants") improperly delayed competition for both brand Intuniv and generic Intuniv, thereby causing them to pay an inflated price for the drug. See generally [ECF No. 39 ("Consolidated Complaint" or "Consol. Compl.")]. The IPPs seek to represent two classes of consumers who were allegedly

[1] Although Intuniv is a brand name, the Court refers to its generic equivalent as generic Intuniv to avoid repetitive use of the phrase "extended release guanfacine hydrochloride."

overcharged for Intuniv because of Defendants' anticompetitive conduct: a nationwide class and a class of consumers from the twenty-six jurisdictions that have Illinois Brick repealer laws.[2]

Before the Court are the IPPs' motion for class certification [ECF No. 146], the IPPs' motion to exclude the opinions of Defendants' expert, Professor James W. Hughes ("Prof. Hughes") [ECF No. 175], and Defendants' motion to exclude the opinions of the IPPs' expert, Professor Meredith Rosenthal ("Prof. Rosenthal") [ECF No. 163]. For the reasons explained herein, the motions are **DENIED**.

I. BACKGROUND

This background presumes the truth of the allegations in the Consolidated Complaint. The Court's order on Defendants' motion to dismiss contains a more complete summary of the facts alleged. See Picone v. Shire PLC, No. 16-CV-12396-ADB, 2017 WL 4873506, at *1–3 (D. Mass. Oct. 20, 2017).

A. Patent Litigation and Anticompetitive Settlement

Shire manufactures and sells Intuniv, which is generally prescribed for young patients to treat ADHD. [Consol Compl. ¶¶ 1–2]. On September 2, 2009, the Food and Drug Administration ("FDA") approved Shire's New Drug Application ("NDA") for Intuniv pursuant to 21 U.S.C. § 355. [Id. ¶¶ 2, 4]. During the relevant time period, Shire held three patents that covered Intuniv (collectively, the "Intuniv Patents"). [Id. ¶¶ 45, 50]. According to the Consolidated Complaint, Wall Street analysts, generic pharmaceutical companies, and Shire itself considered the Intuniv Patents to be "weak." [Id. ¶ 51].

[2] Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977), holds that indirect purchasers of goods cannot recover damages under the federal antitrust laws for overcharges that were allegedly passed on to them by the direct purchaser of the goods, 431 U.S. at 730.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, a generic manufacturer may file an Abbreviated New Drug Application ("ANDA") to seek approval of a proposed generic version of a brand drug. See 21 U.S.C. § 355(j). Obtaining approval for an ANDA is easier than obtaining approval for an NDA. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 543 (1st Cir. 2016). In filing an ANDA to obtain approval for a generic drug, a generic manufacturer must certify that the generic does not infringe any of the patents that the brand company lists as covering the drug at issue. See 21 U.S.C. § 355(j)(2)(A)(vii). On December 29, 2009, Actavis became the first company to file an ANDA for a generic version of Intuniv. [Consol. Compl. ¶¶ 53–54].

The certification that Actavis filed with its ANDA constituted a constructive act of infringement, granting Shire standing to sue Actavis. See 35 U.S.C. § 271(e)(2)(A); In re Loestrin 24 Fe, 814 F.3d at 543. Shire then filed suit pursuant to 21 U.S.C.§ 355(j)(5)(B)(iii), which triggered an automatic 30-month stay of any FDA approval of Actavis' ANDA. [Consol. Compl. ¶ 58]; see In re Loestrin 24 Fe, 814 F.3d at 543. As the first filer of an ANDA, if successful in its bid for approval of its generic Intuniv, Actavis would have obtained "a 180-day period of exclusivity during which 'no other generic can compete with the brand-name drug.'" In re Loestrin 24 Fe, 814 F.3d at 543 (quoting FTC v. Actavis, 570 U.S. 136, 144 (2013)); see 21 U.S.C. § 355(j). A critical exception to that exclusivity is that the brand company can itself market an "authorized generic" during this 180-day, first-filer exclusivity period. See Sanofi-Aventis v. Apotex Inc., 659 F.3d 1171, 1175 (Fed. Cir. 2011). Shortly after Actavis filed its ANDA, several other companies including TWi Phamaceuticals, Inc. and Anchen

Pharmaceuticals, Inc. (together, "Twi/Anchen") filed their own ANDAs. [Consol. Compl. ¶¶ 56−57]. Shire initiated patent infringement litigations against each ANDA filer. [Id. ¶¶ 59].

The IPPs allege that Shire engineered a settlement with Twi/Anchen that would have allowed Twi/Anchen to release an authorized generic Intuniv if Actavis launched its own generic without settling the lawsuit brought by Shire. [Id. ¶¶ 77–78]. That settlement threatened Actavis with the prospect of competition during its valuable 180-day exclusivity period, which Actavis was eager to avoid. [Id. ¶ 79]. On April 25, 2013, Shire and Actavis settled Shire's claims in a manner that allegedly reduced the prospect of unwanted competition for both companies. See [id. ¶ 93]. The IPPs claim that the settlement effectively guaranteed Actavis a full 180-day exclusivity period during which it would face no authorized generic competition. [Id. ¶¶ 94–95]; see [ECF No. 148 at 6–10]. In exchange, Actavis agreed to delay its launch of generic Intuniv until December 1, 2014, thereby allowing Shire to enjoy monopoly profits for brand Intuniv in the interim. [Consol. Compl. ¶ 94]. The IPPs argue that this was sham litigation and that the anticompetitive settlement agreement caused them to pay artificially inflated prices for both brand and generic Intuniv. See [id. ¶¶ 9–12].

B. Procedural History

Plaintiffs initiated this action on November 23, 2016, [ECF No. 1], and filed their Consolidated Complaint on March 10, 2017, after this case was consolidated with two related actions, see [ECF No. 32; Consol. Compl.]. On November 1, 2018, the IPPs filed the instant motion for certification of the following two classes of indirect purchasers of Intuniv:

> **The Nationwide Consumer Class**: For the period beginning November 15, 2012, to the present: (A) all persons who purchased brand or generic Intuniv in the United States for personal or household use, and who paid the purchase price themselves; and (B) all persons covered by commercial health insurance who purchased brand Intuniv in the United States for personal or household use, and who paid some of the purchase price pursuant to a co-payment or co-insurance provision.

> **Illinois Brick Repealer Class:** For the period beginning November 15, 2012, to the present, all persons in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia, Wisconsin, and the District of Columbia: (A) who paid the purchase price themselves for brand or generic Intuniv in the United States for personal or household use; and (B) all persons covered by commercial health insurance who purchased brand Intuniv in the United States for personal or household use, and who paid some of the purchase price pursuant to a co-payment or co-insurance provision.

[ECF No. 146 at 1–2]. The proposed classes exclude third-party payers, direct purchasers of Intuniv, individuals who purchased the drug for resale, individuals who purchased Intuniv with a flat co-payment or so-called Cadillac insurance plan, government entities, Defendants and certain associated individuals, and judicial officers who preside over this case. [Id. at 2].

C. Uninjured Putative Class Members

The market and government systems through which pharmacies are paid for the medications they sell include an alphabet soup of entities and programs. See [Rosenthal Rep. ¶¶ 13–23, ECF No. 148-55; Hughes Rep. ¶¶ 17–28, ECF No. 162-1]. For the purposes of this Memorandum and Order, one need only understand the basics of how consumers' various out-of-pocket costs for medications like Intuniv are typically determined. While some consumers pay the entire cost for their prescription medications in cash, most purchases involve a third-party payer, such as an insurance company. [Rosenthal Rep. ¶ 16]. At the point of sale, most insured consumers pay either a co-payment (often a fixed dollar amount that varies depending on which "tier" a medication is in) or co-insurance (a percentage of the retail price of the drug). [Id.]. Insurance policies that have fixed co-payments often make generic drugs cheaper for consumers than brand drugs so that consumers have an incentive to choose the less expensive generic option, see [id. ¶¶ 16, 18], but the cost of a drug may vary due not only to a consumer's insurance plan, but also based on other individual-specific circumstances, see [Hughes Rep.

¶¶ 21–24].[3] For example, insurance plans frequently include an out-of-pocket maximum that caps medical expenses, including expenses for prescription drugs, and brand manufacturers including Shire often offer coupon programs that effectively lower consumers' co-payments for their medications. [Id.]. Therefore, although generic drugs are less expensive for most consumers at the point of sale, that is not true for all consumers in all circumstances.

Varying out-of-pocket consumer costs, consumer preferences, and drug availability cause a modest and generally declining fraction of brand consumers to continue to purchase brand medication even after a generic version of a drug enters the market. See, e.g., [Rosenthal Rep. ¶ 7]. These market complexities mean that, even assuming that Defendants entered into an anticompetitive settlement agreement, thousands of putative class members did not actually pay an overcharge because they would not have paid less for either brand or generic Intuniv absent that anticompetitive conduct. See [Hughes Rep. ¶ 14; Rosenthal Rebuttal Rep. ¶¶ 31–32, ECF No. 177-1].[4] More specifically, at least three groups of putative class members did not pay an overcharge. First, some number of "brand loyalists" would have continued to purchase brand Intuniv over a generic and were uninjured because the amount they paid for brand Intuniv would have been unaffected or increased by an earlier generic entry into the market. See [Hughes Rep. ¶¶ 14, 53–66; Rosenthal Rebuttal Rep. ¶ 32]. Second, Shire offered several co-payment coupons to eligible consumers, including $15 co-payment coupons. [Hughes Rep. ¶¶ 44–52]. Consumers

[3] Third-party payers and pharmacy benefit managers also provide pharmacies with incentives to fill prescriptions for a brand drug with a generic drug when one is available, and in most states such substitution is allowed or mandated. [Rosenthal Rep. ¶ 18, ECF No. 148-55].

[4] "But-for world" is a short-hand term for the world as it would exist but-for Defendants' anticompetitive conduct. Prof. Rosenthal contemplates four but-for world scenarios. The scenarios vary in when they assume generic Intuniv would have entered the market but-for the anticompetitive conduct and in the extent and timing of additional generic competition. See [Rosenthal Rep. ¶ 9].

who only made purchases of brand Intuniv with those $15 co-payment coupons and who could not have obtained generic Intuniv for an out-of-pocket expense less than $15 in the but-for world did not suffer any injury. See [id.; Rosenthal Rebuttal Rep. ¶ 38]. Third, some consumers likely purchased brand or generic Intuniv only after reaching out-of-pocket maximums under their insurance plans and therefore were not injured because they did not pay for Intuniv. See [Hughes Rep. ¶ 14; Rosenthal Rebuttal Rep. ¶ 39].

The parties' experts disagree on the likely number of uninjured class members. Under the but-for scenario on which the experts have focused their analysis, Defendants' expert, Prof. Hughes, initially estimated that 44,000 class members comprising 12.4% of the class did not incur an overcharge, including 8.0% who would not have paid an overcharge as a result of brand loyalty. [Hughes Rep. ¶¶ 14, 66]. Prof. Hughes later estimated, based on Prof. Rosenthal's analysis, that between 12.4% and 16.8% of class members were uninjured. [Hughes Sur-Rebuttal Rep. ¶ 25, ECF No. 203-2]. Conversely, the IPPs' expert, Prof. Rosenthal, contends that the number of brand loyalists who would not have incurred an overcharge is "closer to 2.8% than . . . 8%." [Rosenthal Rebuttal Rep. ¶ 32]. Prof. Rosenthal arrives at this estimate by examining brand loyalty in the actual world after generic Intuniv became available. [Id.]. She posits that 24,909 class members were uninjured based on her estimate of the number of consumers who were brand-loyal and paid only fixed co-payments after a generic became available. [Rosenthal Dep. 133:6–134:23, ECF No. 203-1]. Although Prof. Rosenthal asserts that Prof. Hughes' estimate of uninjured brand loyalists is too high, she acknowledges that her 2.8% estimate is too low because she calculated that figure by dividing her estimate of uninjured, brand-loyal class members by a denominator that includes non-class members. [Rosenthal Dep. 137:19–138:23]. Prof. Rosenthal further argues that Prof. Hughes' estimates vastly overstate the

number of uninjured coupon users and that the number of consumers who were uninjured because of out-of-pocket maximums was likely de minimis. [Rosenthal Rebuttal Rep. ¶¶ 38–39].

The Court cannot precisely determine the number of uninjured class members at this stage of the litigation, but after considering the experts' reports, it concludes that more than 25,000 nationwide putative class members never paid an overcharge and were therefore uninjured by Defendants' allegedly anticompetitive conduct. The Court arrives at this conservative figure based on Professors Rosenthal's estimate that 24,909 brand-loyal class members would not have been injured and because that figure does not fully account for uninjured coupon users or individuals who purchased Intuniv only after reaching their out-of-pocket maximums. See [Rosenthal Rebuttal Rep. ¶¶ 31–32]. The Court estimates that these uninjured, brand-loyal class members account for at least 8% of the class, which reflects Prof. Hughes initial estimate of the percentage of class members who would not have paid an overcharge as a result of brand loyalty and is the lowest percentage estimate that is not marred by a calculation error. See [Hughes Rep. ¶ 66].[5]

II. CLASS CERTIFICATION STANDARD

To obtain class certification under Federal Rule of Civil Procedure 23, a plaintiff must first satisfy the four requirements of Rule 23(a). They must demonstrate that:

> (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.

[5] Although the Court declines to offer a precise estimate of the number of putative class members who were uninjured due to reasons other than brand loyalty, it expects that those uninjured class members number in the thousands.

Fed. R. Civ. P. 23(a). These requirements "ensure[] that the named plaintiffs are appropriate representatives of the class whose claims they wish to litigate." Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 349 (2011). "The Rule's four requirements—numerosity, commonality, typicality, and adequate representation—'effectively limit the class claims to those fairly encompassed by the named plaintiffs claims.'" Id. (quoting Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 156 (1982)).

Because the Plaintiffs seek money damages, they must also satisfy Rule 23(b)(3)'s predominance and superiority requirements. See Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1053 (2016) (citing Comcast Corp. v. Behrend, 569 U.S. 27, 33 (2013)). Rule 23(b)(3) requires a showing that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). "In adding predominance and superiority to the qualification-for-certification list, the Advisory Committee sought to cover cases in which a class action would achieve economies of time, effort, and expense, and promote ... uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 615 (1997) (quotation marks omitted). The IPPs must show that "the fact of [an] antitrust violation and the fact of antitrust impact [can] be established through common proof." In re New Motor Vehicles Canadian Exp. Antitrust Litig., 522 F.3d 6, 20 (1st Cir. 2008).

In addition to the explicit requirements of Rule 23, there is also an implicit requirement that the proposed class be ascertainable. Donovan v. Philip Morris USA, Inc., 268 F.R.D. 1, 9 (D. Mass. 2010) ("While not explicitly mentioned in Rule 23, an implicit prerequisite to class

certification is that a 'class' exists—in other words, it must be 'administratively feasible for the court to determine whether a particular individual is a member.'" (quoting Kent v. SunAmerica Life Ins., 190 F.R.D. 271, 278 (D. Mass. 2000))); see also In re Nexium Antitrust Litig., 777 F.3d 9, 19 (1st Cir. 2015) ("[T]he definition of the class must be 'definite,' that is, the standards must allow the class members to be ascertainable."). A class is generally ascertainable where it is defined in terms of an "objective criterion." Matamoros v. Starbucks Corp., 699 F.3d 129, 139 (1st Cir. 2012).

"Rule 23 does not set forth a mere pleading standard. A party seeking class certification must affirmatively demonstrate his compliance with the Rule." Wal-Mart Stores, 564 U.S. at 350. The Court must engage in a "rigorous analysis," which may involve "prob[ing] behind the pleadings" in order to decide whether certification is appropriate. Id. (quoting Gen. Tel. Co. of Sw., 457 U.S. at 160).

III. MOTIONS TO EXCLUDE EXPERT OPINIONS

Federal Rule of Evidence 702 provides that a person who is qualified by knowledge, skill, experience, training, or education may testify in the form of an opinion 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. Trial judges are tasked with "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993). Before admitting expert testimony, district courts "must perform a gatekeeping function by preliminarily assessing 'whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology

properly can be applied to the facts in issue.'" Seahorse Marine Supplies, Inc. v. P.R. Sun Oil Co., 295 F.3d 68, 80 (1st Cir. 2002) (quoting Daubert, 509 U.S. at 592–93). "When a dispute exists between two experts both of whom use reliable methods, that dispute 'goes to the weight, not the admissibility, of the testimony.'" Koninklijke Philips N.V. v. Zoll Med. Corp., 256 F. Supp. 3d 50, 52 (D. Mass. 2017) (quoting Cummings v. Standard Register Co., 265 F.3d 56, 65 (1st Cir. 2001)).

Defendants move to exclude the opinions of Prof. Rosenthal, while the IPPs have moved to exclude the opinions of Prof. Hughes. Both sides argue that the other side's expert proffers opinions that are inadmissible pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

A. Motion to Exclude the Opinions of Prof. Rosenthal

Defendants move to exclude the opinions of Prof. Rosenthal because they claim that her model cannot show whether each putative class member actually suffered an injury from the alleged anticompetitive conduct and is therefore irrelevant to the key inquiry in this case. [ECF No. 164 at 10]. Defendants are correct that Prof. Rosenthal has not provided a model that can ascertain whether or when an individual class member would have switched to generic Intuniv had the allegedly anticompetitive conduct not occurred, and the IPPs do not assert that she has offered such an opinion. See [ECF 176 at 1 ("Prof. Rosenthal . . . is not proffered to opine on how to identify any one particular class member.")].[6]

[6] Prof. Rosenthal opines that she has "determined that economic proof can be used to demonstrate common impact of the alleged foreclosure on Class Members," but the Court does not understand this to be an opinion that every class member was in fact injured. [Rosenthal Rep. at 1].

Whatever effect the fact that Prof. Rosenthal has not offered a model to identify particular uninjured putative class members has on the Court's ability to certify the putative classes, it does not compel the Court to exclude her damages opinions under Federal Rule of Evidence 702 or Daubert, 509 U.S. 579. As a professor of health economics and policy at the Harvard T.H. Chan School of Public Health who has testified in numerous pharmaceutical cases and whose principal academic interests concern health economics and health policy, Prof. Rosenthal is unquestionably qualified to assist a trier of fact in assessing damages in this case. See [Rosenthal Rep. ¶¶ 1–4]. Here, she uses a yardstick method based on reliable data to estimate antitrust damages. [Id. at 1]; see also [Rosenthal Rebuttal Rep. ¶ 41]. Her methodology is consistent with models that have been accepted by courts in similar cases. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 181 (D. Mass. 2013) ("Prof. Rosenthal explains her methodology as a 'yardstick' approach, utilizing average measures, publicly available data, and a single 'benchmark' brand-name price to calculate aggregate overcharges."); see also Eleven Line, Inc. v. N. Tex. State Soccer Ass'n, 213 F.3d 198, 207 (5th Cir. 2000) ("[T]he two most common methods of quantifying antitrust damages are the 'before and after' and 'yardstick' measures of lost profits . . . ."). But see Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, No. 04-CV-5898, 2010 WL 3855552, at *30 (E.D. Pa. Sept. 30, 2010) (finding that class issues would not predominate where court was not persuaded that "the yardstick methodology Dr. Rosenthal proposes is commonly accepted in antitrust cases").

Defendants seemingly briefed the admissibility of Prof. Rosenthal's opinions as a way to provide the Court with seventeen additional pages as to why class certification should be denied, even if Prof. Rosenthal's opinions are accurate and relevant. The three of Defendants' twenty

pages of briefing that address perceived errors in Prof. Rosenthal's opinions raise issues that go to the weight rather than the admissibility of those opinions. See [ECF No. 194 at 7–9]. Defendants do not credibly argue that Prof. Rosenthal's model is not probative of the total damages suffered by the putative classes, and the Court therefore DENIES Defendants' motion to exclude her opinions [ECF No. 163].

B. Motion to Exclude the Opinions of Prof. Hughes

Not to be outdone in motion filing, the IPPs move to exclude the testimony of Prof. Hughes. Prof. Hughes is a professor of economics at Bates College and also has extensive experience testifying in prescription drug antitrust cases. See [Hughes Rep. ¶¶ 1–2 & nn.1–3]. As with Prof. Rosenthal, there is no doubt that Prof. Hughes is qualified to assist a trier of fact in assessing damages in this case.

Notwithstanding his qualifications, the IPPs advance two arguments as to why Prof. Hughes' opinions should be excluded. First, the IPPs contend that his assertion that putative class members who used coupons to purchase brand Intuniv and never paid an overcharge were uninjured is "novel" and "unmoored from legal precedent." [ECF No. 179 at 4–5]. Second, the IPPs argue that Prof. Hughes conflates the numbers of prescriptions with the number of consumers and uses an unreliable estimate of prescriptions per consumer to inflate the number of uninjured consumers. [Id. at 6–13]. The Court finds these arguments unavailing and concludes that Prof. Hughes has applied reliable principles and methods to data and facts that would be relevant to measuring damages in this case. As with Prof. Rosenthal, the perceived flaws in Prof. Hughes' methodology go to the weight rather than the admissibility of his opinions.

The IPPs argument that Prof. Hughes is mistaken when he claims that some portion of coupon users were uninjured is based upon the First Circuit's opinion in In re Nexium Antitrust

Litigation, 777 F.3d 9 (1st Cir. 2015). There, the First Circuit explained that "[p]aying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show—as a legal and factual matter—impact or fact of damage." Id. at 27. A consumer may claim to have suffered antitrust injury based on an overcharge "whether or not that injury is *later* offset." Id. (emphasis added). Consistent with Prof. Hughes' report, however, a habitual coupon user who always obtained the brand Intuniv at a cost of $15 and would have been unable to obtain generic Intuniv at a lower price never suffered an injury because he or she would not have paid less for Intuniv absent the allegedly anticompetitive conduct at issue. Prof. Hughes makes a reasonable adjustment in his calculations to account for the fact that not all coupon users always use coupons. See [Hughes Rep. ¶ 52].

The IPPs' second argument, that Prof. Hughes' opinions should be excluded based on his use of prescription-level data to estimate the number of uninjured consumers, is also unavailing. This argument too goes to the weight a trier of fact should afford Prof. Hughes' conclusions, not the reliability of his methods. Although prescriptions cannot function as a direct stand-in for consumers, see In re Nexium, 777 F.3d at 27–28 ("[T]here is no necessary relationship between the percentage of prescriptions and the percentage of consumers since a class member may fill one prescription with an overcharge and another with no overcharge."), Prof. Hughes' report demonstrates that there is a relationship between the number of Intuniv consumers and the number of Intuniv prescriptions such that the number of prescriptions may serve as a useful proxy for at least estimating numbers of consumers. See [Hughes Rep. ¶¶ 49–52, 62–66].[7]

[7] The parties' dispute over the correct estimate of prescriptions per consumer goes to a factual issue that informs an input for Prof. Hughes' model, not the reliability of the model itself or the validity of the data used. The Court therefore declines to strike Prof. Hughes' opinions due to his use of prescription-level data. Cf. In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D.

The Court therefore DENIES the IPPs' motion to exclude the opinions of Prof. Hughes [ECF No. 175].

IV. MOTION TO CERTIFY CLASS

The Court will not prolong this opinion with an application of the numerosity, commonality, typicality, and adequacy requirements of Federal Rule of Civil Procedure 23(a) because the parties' dispute centers on the predominance requirement of Rule 23(b)(3) and the Court finds that issue dispositive. The crux of the issue here is whether the IPPs have shown either that the number of uninjured class members is de minimis or have designed a reasonable and workable mechanism to allow Defendants to challenge class members' individual, purported injury while still ensuring that common issues of law and fact will predominate over those individual issues.

A court may certify a class with a "de minimis" number of uninjured individuals, at least where those class members may be "picked off in a manageable, individualized process at or before trial." In re Asacol, 907 F.3d at 53; see also In re Nexium, 777 F.3d at 30 ("What counts as a 'de minimis' deviation 'from a prescribed standard must, of course, be determined with reference to the purpose of the standard.' We thus define 'de minimis' in functional terms." (quoting Wis. Dep't of Revenue v. William Wrigley, Jr., Co., 505 U.S. 214, 232 (1992))). The First Circuit clarified in In re Asacol Antitrust Litigation, 907 F.3d 42 (1st Cir. 2018), that in pharmaceutical antitrust class actions brought by indirect purchasers, where the defendants reasonably contend that numerous class members were uninjured and individualized inquiries are relevant to that determination, the defendants are entitled to some "meaningful opportunity to

168, 177–179 (D. Mass. 2013) (holding that finding of facts at class certification stage was akin to "admitting opinions under Federal Rule of Evidence 702" and accepting several of Prof. Hughes' assertions).

contest whether an individual would have, in fact, purchased a generic drug had one been available," 907 F.3d at 53.[8]

The proposed class in In re Asacol included thousands of uninjured class members who accounted for approximately 10% of the class. Id. at 47, 53. The First Circuit rejected the argument that average measures of damages could "net out all purchases by brand loyal consumers as a group" and that payment of some damages to uninjured persons should be of no concern to the defendant. Id. at 55. The court reasoned that where "the aggregate damage amount is the sum of damages suffered by a number of individuals, such that proving that the defendant is not liable to a particular individual because that individual suffered no injury reduces the amount of the possible total damage," and where "determining whether any given individual was injured (and therefore has a claim) turns on an assessment of the individual facts," "the defendant must be offered the opportunity to challenge each class member's proof that the defendant is liable to that class member." Id.

In re Asacol dictates the outcome here. Although the Court cannot determine a precise number or percentage of uninjured class members at this stage of the litigation, based on the

[8] In re Asacol Antitrust Litigation, 907 F.3d 42 (1st Cir. 2018), held that a district court abused its discretion when it found that common issues predominated and certified a class even though thousands of class members had likely suffered no injury. That conclusion was based on an extrapolation of the Supreme Court's holding in Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338 (2011), that a "class cannot be certified on the premise that [a defendant] will not be entitled to litigate its statutory defenses to individual claims," 564 U.S. at 367; see In re Asacol 907 F.3d at 53. In the view of this Court, In re Asacol is likely a death knell for pharmaceutical, antitrust class actions brought by indirect purchasers. Given the myriad ways in which consumers could theoretically be uninjured, once a defendant asserts an intent to challenge each claim to have been affected by their conduct, it becomes nearly impossible for indirect purchasers to show that common issues will predominate under In re Asacol. Absent class certification, it is likely that most putative class members' claims will go unremedied. Thus, assuming that Defendants engaged in anticompetitive conduct, although In re Asacol eliminates the possibility that some consumers might obtain a recovery for damages they did not suffer, it also ensures that a much larger number of Intuniv consumers will receive no remedy for harm actually suffered.

experts' reports, the Court estimates that 25,000 brand loyalists, several thousand coupon-using class members, and some relatively de minimis number of class members who purchased Intuniv only after reaching their health insurance out-of-pocket maximum were not injured by the allegedly anticompetitive conduct at issue. See supra Part I.C; see also [Hughes Rep. ¶¶ 14, 52, 55, 62, 66; Rosenthal Rebuttal Rep. ¶ 32–39; Hughes Sur-Rebuttal Rep. ¶¶ 20–25, 28]. If the Court was to consider only putative class members from Illinois Brick repealer states, the number of uninjured class members would decline by roughly half but would still exceed 10,000. See [Hughes Rep. ¶ 13]. Uninjured consumers likely comprise at least 8% of each putative class, and perhaps considerably more. See supra Part I.C; see also [Hughes Rep. ¶ 14; Hughes Sur-Rebuttal Rep. ¶ 25]. Identifying uninjured consumers with any degree of confidence would require an assessment of individual-specific facts such as the consumer's insurance plan, any peculiar views about the equivalence of brand and generic Intuniv, their consumption habits when faced with similar choices between brand and generic drugs, their use of coupons, the timing of their purchases of Intuniv, and potentially other factors. See [Hughes Rep. ¶¶ 38–43].

The IPPs have not put forth a reasonable and workable plan to weed out uninjured class members. Defendants claim that they will challenge at trial whether particular class members were injured, [ECF No. 165 at 13, 17], and they must be afforded that opportunity in accordance with Asacol, see 907 F.3d at 53. Defendants' assertion of their intention to challenge individual class members' claims of injury distinguishes this case from In re Nexium, 777 F.3d 9, for the same reason that the First Circuit distinguished that case in In re Asacol, see 907 F.3d at 54 ("The need to identify [thousands of uninjured class members] will predominate and render an adjudication unmanageable absent evidence such as the unrebutted affidavits assumed in In re Nexium, or some other mechanism that can manageably remove uninjured persons from the class

in a manner that protects the parties' rights"). The IPPs argue that "issues pertaining to the allocation of those aggregated damages can[] and will be addressed at the claims administration stage," [ECF No. 178 at 12], but the case law that the IPPs cite in support of that argument predates In re Asacol, which precludes this approach, see In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-MD-02503, 2017 WL 4621777, at *11 (D. Mass. Oct. 16, 2017); In re Nexium (Esomeprazole), 297 F.R.D. at 183; In re Terazosin Hydrochloride, 220 F.R.D. 672, 699 (S.D. Fla. 2004).

Where the IPPs have failed to put forth a reasonable and workable plan to weed out the more than 10,000 uninjured class members in each putative class and Defendants intend to challenge any attestation that individual class members were injured, the IPPs have not shown that "questions of law or fact common to class members [will] predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). Compare In re Loestrin 24 Fe, No. 13-MD-2472-WES, 2019 WL 3214257, at *15 (D.R.I. July 2, 2019) (granting class certification where, unlike In re Asacol, it might have been "borne out through the evidence at trial that there are a couple uninjured members [in a] class" with forty-seven members), with In re Thalomid & Revlimid Antitrust Litig., No. 14-CV-6997, 2018 WL 6573118, at *13 (D.N.J. Oct. 30, 2018) (denying class certification where, as in In re Asacol, "plaintiff[s] have not provided an appropriate common method of proving injury-in-fact given the presence of brand loyalists"). The IPPs' motion for class certification [ECF No. 146] is therefore DENIED.

V. CONCLUSION

Accordingly, the motion for class certification [ECF No. 146] and the motions to exclude expert opinions [ECF Nos. 163, 175] are **DENIED**.

SO ORDERED.

August 21, 2019

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE