IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In Re: OPANA ER ANTITRUST LITIGATION	**Case No 14 C 10150** **MDL No. 2580**
This Document Relates to All Cases	**Judge Harry D. Leinenweber**

ORDER

The Court amends its June 4, 2021 order certifying class to include End Payor Plaintiff's proposed exclusions to the class definition. All other portions of the order remain intact.

STATEMENT

This is a class action antitrust and unjust enrichment suit against Defendants Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Penwest Pharmaceuticals Co. (collectively, "Endo") and Impax Laboratories, Inc. Plaintiffs allege that Endo and Impax settled a patent infringement lawsuit with terms that "restrain[ed] trade" in violation of the Sherman Act and other antitrust laws. 15. U.S.C. § 1; *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013).

I. BACKGROUND

The Court recounts briefly the facts relevant to this Order and incorporates fully the facts from its prior Order and Opinion. (*See generally* Mem. Op. and Order, Dkt. No. 725.) Endo, a drug

manufacturer, was the first and exclusive seller of an extended release oxymorphone drug product named Opana ER. The drug was protected by a patent that expired in 2008. Impax, another drug manufacturer, filed a 2007 application with the U.S. Food & Drug Administration to sell generic Opana ER as soon as the patent expired. Endo then publicly listed two additional patents. In response, Impax amended its application to the FDA and asserted that the newly listed patents were invalid. The FDA approved the application, and Endo filed a lawsuit to prevent Impax's sale of generic Opana ER.

On June 8, 2010, the parties settled the suit. The terms of agreement included concessions on both sides. Impax agreed to delay release of the generic Opana ER until January 2013. Endo agreed to (1) compensate Impax financially in the event there was an adverse change in demand during the two-and-a-half-year delay to market, (2) provide Impax with a license to sell generic Opana ER even if future patents were issued to Endo, and (3) forbear launching its own competing generic Opana ER. The parties also executed a side agreement on June 8, 2010, in which Endo provided Impax with $10 million for a non-opioid pharmaceutical joint venture. Defendants contend that the joint venture was unrelated to the oxymorphone dispute.

Both the side agreement and the settlement agreement ended up providing Impax with millions of dollars in direct transfers and monetary value. The primary reason for the large payments to Impax was that Endo did, in fact, change the market conditions prior to Impax's generic product release. First, Endo launched a reformulated Opana ER in February 2012. Concurrent with the reformulation, Endo announced it was discontinuing the original Opana ER market and ceased shipping the product by May 31, 2012, approximately six months before Impax's delayed start date. Original Opana ER prescriptions fell by 88% by the end of 2013. (Rosenthal Rep. ¶ 24, Mem. To Exclude, Ex. A, Dkt. No. 560-2.) Second, Endo was issued and separately acquired additional patents related to original Opana ER, which it successfully enforced against all generic producers of Opana ER except Impax. Per the agreement with Impax, Endo never launched its own competing product. In total, under the settlement agreement, Endo paid Impax approximately $102 million in market disparity revenue, and Impax is the only producer of generic Opana ER to this day.

According to Plaintiffs, the terms of the 2010 settlement agreement constitute an unlawful restraint on trade because Impax agreed to delay entering the market in return for a portion of Endo's monopolistic profits. The agreement with Impax purportedly allowed Endo to bridge the gap between the expiration of its

patents and the implementation of new strategies to maintain market share, such as acquiring more patents and launching a reformulated Opana ER. Plaintiffs allege that the agreement ultimately prevented competitive price decreases during the vulnerable interim. As alleged by Plaintiffs, Impax agreed to help Endo create an illegal monopoly in the short term in return for (1) $10 million of the "unrelated" side agreement, (2) $102 million dollars at generic product launch, and (3) a portion of the later acquired, legal monopoly on generic Opana ER revenue through the license agreement. Plaintiffs argue any of these payments could qualify as a 'reverse payment' as set forth in *Actavis*, 570 U.S. at 141. According to Defendants, the forgoing transfers of value from Endo to Impax were either unrelated to Impax's agreement to delay the production of its generic Opana ER or unproblematic under *Actavis*. On June 4, 2021, the Court denied Defendants' Motion for Summary Judgment.

At the same time as the summary judgment motion, the Court decided two Motions for class certification. One of those Motions is the subject of this amended order. The End Payor Plaintiffs moved to certify a class for entities at the "end" of the chain of sale. The proposed class included two broad groups: consumers who purchased Opana ER at the allegedly inflated price and third-party entities, such as insurers, who paid for part or all the consumers'

cost of the drug. To show a common injury among class members, End Payor Plaintiffs relied on the report of Dr. Meredith Rosenthal, a Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates. (Rosenthal Rep. ¶ 1.) In her report, Dr. Rosenthal provided an overview of the pharmaceutical drug market and her findings on injured putative class members.

A. Dr. Rosenthal's Expert Report

When an insured patient receives a prescription and then purchases the prescribed drug from a pharmacist, the cost is split between the insurance company and the patient as dictated by the medical insurance contract between the parties. Starting in the 1990s, prescription drug spending increased substantially. (*Id.* ¶ 38.) A more traditional insurance plan typically requires the patient pay a small, fixed cost regardless of the drug purchased. This type of cost allocation, however, incentivized drug companies to market the most expensive drugs at the direct actors involved, i.e., the doctor, the pharmacist, and the patient, and then receive the bulk of the payment from the insurance company or other third-party reimbursing entity. In response, insurance companies and other risk-bearing entities have adapted their prescription drug programs with counterincentives to lower their costs. (*Id.* ¶¶ 37-38.) Dr. Rosenthal provided three ways in which costs are mediated

down by insurance programs: tiered formularies, generic substitution programs, and coinsurance. (*Id.* ¶ 38.)

Tiered formularies provide the patient and prescribing physician with drug options on a price-sensitive scale. (*Id.* ¶ 39.) On the lowest tier, a patient may elect to purchase the generic version of a drug, the cheapest for the patient and the insurance company. (*Id.*) The middle tier offers brand-name drugs where the insurance company has negotiated with the drug company to receive a discount or rebate on the list price, and the patient pays a corresponding middling copayment. (*Id.*) On the most expensive tier, the remaining brand-name drugs are available at the highest copayment for the patient. (*Id.*) This induces patients and physicians to consider drug options on the lower tiers, but it also incentivizes drug companies to create rebates or other discount deals so that their drugs are more attractive to consumers from a cost perspective.

Generic substitution also decreases drug prices for insurance companies. Generic products are bioequivalent to their branded counterpart, and there is no difference in pharmacodynamic effect in patients. Pharmacists have varying amount of discretion, depending on local laws, to fill a prescription written out for a brand name drug with its generic, cheaper substitute. (*Id.* ¶ 41.) Insurance companies will reward pharmacists who fill a high

percentage of their prescriptions with a generic, regardless of how the prescription was written. (*Id.*) Some states mandate generic substitution; others require the pharmacist to request the permission from the prescribing physician. (*Id.*)

Finally, insurance companies induce lower costs on brand name drugs through coinsurance, in which the cost to the patient is a percent of the retail price of the drug rather than a fixed dollar amount. (*Id.* ¶ 39.) This induces patients, and by extension drug companies, to be more cost sensitive.

Dr. Rosenthal determined approximate overcharges by calculating the average price of branded Opana ER multiplied by the quantity of branded Opana ER purchased to achieve the total amount spent in the market. Dr. Rosenthal then did the same with generic Opana ER. (*Id.* ¶¶ 50–51.) Using these base figures and assuming that the purchased market remains constant, Dr. Rosenthal then calculated (1) overcharge damages to class members who would have switched to the generic given the opportunity ("early adopters"), (2) overcharge damages to members who would have continued to use branded Opana ER but would have paid less for it with the introduction of competition ("brand loyalists"), and (3) overcharge damages to those who purchased the generic but would have paid less for it with the introduction of competition ("post-2013 purchasers"). (*Id.* ¶ 52.) The Court notes that the terminology

of "adopters" and "loyalists" does not necessarily reflect the position of the consumers themselves. Early adopters, for example, may provide prescriptions written out for branded Opana ER but in a state that mandates generic substitution of branded drugs, and thus would have received generic product and the corresponding lower price.

In opposition, Defendants argued, among other things, that the End Payor Plaintiffs' class definition contained a great number of putative class members who could not have been harmed by Defendants' conduct. According to Defendants' brief, 51% percent of consumers "could not have incurred overcharges because they would have continued to pay the same (or more) for brand Opana ER even if generic Opana had been available prior to January 2013." (Opp. at 12, Dkt. No. 451.) In other words, Defendants believe over half of consumers are brand loyalists with insurance companies that did not use the competitive entrant to lower the cost to themselves and the consumer (or would have renegotiated to a more expensive position). Defendants also argued that there was a group of consumers "who paid a generic copay in the actual world and who would have paid the same generic copay in the but-for world." (*Id.* at 3.) These consumers would be post-2013 purchasers whose insurance plans were not affected by the entrance of a generic competitor. According to Defendants, these two categories combined

caused the uninjured class members to be "approximately 65% of consumers." (*Id.*) Defendants argued that it would be impossible to separate out these uninjured class members absent the examination of over 100,000 affidavits. (*Id.*)

B. Dr. Hughes' Expert Report

Defendants also incorporated a report from their expert, Dr. Hughes, who is a Professor of Economics at Bates College in Lewistown, Maine. (Hughes Rep. ¶ 1, Opp., Ex. A, Dkt. No. 451-1.) Dr. Hughes identified numerous complicating factors that could alter the numbers suggested by Dr. Rosenthal.

1. Brand Loyalists Who Were Not Injured

First, Dr. Hughes identified two subgroups of "brand loyalists" who would not have been injured: (1) brand loyalists that would have switched from branded Opana ER to reformulated Opana ER, estimated from 21% to 47% of all class members, and (2) brand loyalists that would have continued to purchase the branded Opana ER product, estimated from 2% to 4% of all class members. (*Id.* ¶¶ 82–92.) Dr. Hughes notes that the conversion of branded Opana ER to reformulated Opana ER is accounted for in Dr. Rosenthal's model, but that "does not address the flaw in her approach, and her failure to identify and remove uninjured brand-loyal consumers." (*Id.* ¶ 88.) In an effort to identify this subset of consumers, Dr. Hughes analyzes what share of consumers were brand loyal to reformulated Opana ER after 2013, and extrapolates

this percentage to the pre-2013, brand loyalist data set. (*Id.* ¶ 89.) Based on this analysis, Dr. Hughes estimates that 47% of consumers would have been brand loyal, even in the presence of a generic Opana ER option. (*Id.* ¶ 90.) Dr. Hughes then uses "the available literature and projections in this case" to assert that Dr. Rosenthal's analysis of those brand loyal to branded Opana ER was off by 1.2%. (*Id.* ¶ 92.)

2. Consumers Who Purchased Generic Oxymorphone ER and Paid a Copay

Dr. Hughes identifies a subgroup of the post-2013 purchasers who paid a generic copay. Dr. Hughes states that the consumer copay for generic oxymorphone ER would have been the same even if the retail price would have been lower, and thus the consumers would not have been uninjured, because only the insurance companies could have paid more. (*Id.* ¶ 93.) He estimates this number at 14% of all class members. (*Id.* ¶ 94.)

3. Consumers Switching to Generic with No Cost Benefit

Next, Dr. Hughes identifies consumers whose copay for generic Opana ER was the same for branded Opana ER or reformulated Opana ER. Dr. Hughes acknowledges that Dr. Rosenthal excluded the more traditional, single-tier plans but states that some multi-tier formularies should have also been excluded. To support this statement, Dr. Hughes analyzes data from 2012 to 2014 to find that an additional 16% of the multi-tier formularies placed generic

oxymorphone ER on the same or less preferred tier as branded Opana ER and reformulated Opana ER. (*Id.* ¶ 97.) Dr. Hughes alleges these consumers are likely to be uninjured as a result of this analysis.

4. Consumers Who Pay Nothing for Opana ER

Dr. Hughes identifies a subgroup of consumers who have insurance contracts that limit the patients' drug purchasing copays. After the patient reaches that limit, the patient does not have to pay anything further for the drugs purchased for the remainder of the insurance year. Dr. Hughes estimates that approximately 4% of consumers paid nothing for their opioid prescription for some portion of the year. (*Id.* ¶¶ 99–101.)

5. Consumers Who Relied on Coupons

Dr. Hughes identifies a subgroup of brand loyalists who used coupons to purchase branded Opana ER and compares that discounted price with the prices that actual consumers paid for generic extended release oxymorphone. (*Id.* ¶ 103.) Dr. Hughes identifies 15% of consumers who would have paid higher amounts of money for generic oxymorphone, had they chosen to purchase that product in the real world. (*Id.*)

6. Consumers Who Would Have Switched to Other Opioids

Finally, Dr. Hughes challenges Dr. Rosenthal's assumption that the market remained relatively stable and hypothesizes that some persons may have switched to a different branded opioid with the introduction of a generic Opana ER product. (*Id.* ¶ 105.)

C. Amended Class Definition

In reply to Dr. Hughes report, the End Payor Plaintiffs amended the Antitrust/Consumer Class and Unjust Enrichment Subclasses to exclude the following:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Opana ER for purposes of resale or directly from Defendants or their affiliates;

d. Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

e. Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

f. Any consumer who purchased only Endo's branded version of Opana ER after the AB-rated generic version became available in January 2013;

g. Consumers with copay insurance plans that purchased only generic versions of Opana ER;

h. Pharmacy Benefit Managers ("PBMs");

i. All Counsel of Record; and

j. The Court, Court personnel and any member of their immediate families.

(Rosenthal Rebuttal ¶ 6, Reply, Ex A, Dkt. No. 469-1.) The End Payor Plaintiffs note that most of Dr. Hughes' calculations to exclude class members used real world data to predict uninjured class members. These numbers, by definition, do not and cannot capture the change in price that occurs with the introduction of competition. In contrast, Dr. Rosenthal used generally accepted economic methods to arrive at her conclusions on market effects, including the effects on the structure of insurance program multi-tier formularies, coupons, coinsurance, and automatic generic substitution. For example, Dr. Rosenthal reviewed Dr. Hughes' estimates regarding the probable penetration of the market and found an 11.8% conversion rate, which predicted the number of brand loyalists, *i.e.*, uninjured class members, at 7.1%. Assuming that the competition lowered branded prices, this percentage of uninjured members would be even smaller percentage of End Payor Plaintiffs' defined class.

II. DISCUSSION

On June 4, 2021, the Court certified the End Payor Plaintiffs' class of "all payors who purchased or reimbursed at least a portion of the branded or generic versions of Opana ER from April 1, 2011 until the still-in-dispute end of the injurious conduct." (Order at 2, Dkt. No. 726.) The Court found Dr. Hughes methodology to be unreliable and unable to predict accurately whether there are

uninjured class members. The Court reasoned that, because the settlement agreement prevented Impax's product from being concurrently available as the branded Opana ER, all the class members had been deprived of the opportunity of choice, as well as the opportunity for market forces to depress the price of both drugs. The Court found that all plaintiffs could potentially prove their injury and that it was premature for individualized inquiries.

After the issuance of the Court's order, Impax requested leave to appeal. The Seventh Circuit granted the appeal and held that the Court overlooked some of Impax's arguments regarding uninjured class members. The Seventh Circuit reviewed two specific subgroups of members: first, members whose insurance plans charged "the same flat copay for both generic and non-generic drugs," or "flat copay" members, and second, members who started taking generic oxymorphone ER only after the generic had been introduced and whose plans charged the same amount regardless of the price or type of generic drug on the market, or "generic-only copay" members. (Order at 2, Dkt. No. 734.) The Seventh Circuit held these members "could not have been harmed" by the allegedly illegal conduct. (*Id.* (quoting *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 824 (7th Cir. 2012).)

The Seventh Circuit remanded the case to consider "(1) whether the copay groups are large enough to be a barrier to certification, and (2) whether to adopt plaintiffs' proposed amended class definition excluding those groups." (*Id.*) The Court first considers the copay groups identified by the Seventh Circuit as barriers to class certification, and then reviews the plaintiffs' amended definition.

A. Flat Copay Groups

There are two types of "flat copay" members discussed in the expert reports and briefing. First, there are flat copay members who have the more traditional insurance coverage where every drug, regardless of generic or branded status, requires the patient to contribute the same nominal copay. The probability that these insurance contracts would be affected by a single drug price is so remote that the patients subject to these contracts should have been initially excluded from the class. In fact, Dr. Rosenthal excluded them in her original calculations, and End Payor Plaintiffs did not intend to include these class members in their definition. Because they were excluded from the initial calculations, neither Dr. Rosenthal nor Dr. Hughes discuss these class members in their reports. As a result, the Court has not been provided any figures on which class members in the original

definition might be a part of this group. The Court considers these parties to be excluded from the definition.

Second, there are "flat copay" class members whose insurance programs use multi-tier formularies but are still considered "flat" because the programs have generic Opana ER and reformulated Opana ER on the same tier, or even have reformulated Opana ER on a lower tier than generic Opana ER in the actual world. In his report, Dr. Hughes challenges the inclusion of these class members and calculates that these members make up 14% of the class.

The Court discounts Dr. Hughes' expert opinion because Dr. Hughes considers what the multi-tier formularies ranked reformulated Opana ER and generic Opana ER in 2014 and then extrapolates this data backwards into 2010 through 2012. There is no evidence to suggest that, with the introduction of competition, the same multi-tier formularies would have existed in the but-for world. Because of this faulty assumption, the Court cannot rely on Dr. Hughes' analysis. Dr. Rosenthal's estimate of plans where this would be the case in the but-for world finds the number to be much smaller at 0.5% of all insurance plans. (Rosenthal Rebuttal ¶ 104.) As a result, the Court finds that this is a negligible percentage of the class members and does not find it to be a barrier to class certification. *See*, e.g., *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 826 (7th Cir. 2012) ("[A] 2.4 percent

decrease in the size of the class is certainly not significant enough to justify denial of certification.")

B. Post-2013 Generic Purchasers

The Court also considers a subgroup of the post-2013 purchasers who began taking generic oxymorphone ER after branded Opana ER was off the market and whose insurance copays were not affected by any lingering price inflation. Dr. Hughes estimates that 14% of class members fall within that definition. Dr. Rosenthal agrees with Dr. Hughes objection as to the consumer members of the class. As a result, Dr. Rosenthal proposed excluding the consumers from the class. Due to the heavily documented nature of prescription products, Dr. Rosenthal asserts it would not be difficult to exclude these class members by cutting off new generic purchasers after the 2013 cutoff date.

While the Seventh Circuit limited this Court's review to those consumers who were not affected by lingering price inflation, the expert reports filed in association with the class certification motion do not attempt to differentiate between insurance copays which were and were not affected by price inflation. Instead, Dr. Rosenthal and Dr. Hughes both agree that all insured consumers who only began purchasing Opana ER after 2013 and only purchased generic Opana ER should be excluded from the class definition. The Court concurs in this conclusion.

C. Amended Definition

Because the Court finds that (1) the first group identified by the Seventh Circuit was not intended to be included in the class definition, and (2) the second group is large enough to garner concerns about the viability of class members, the Court adopts the proposed amended class definition, which excludes these class members under Subsections (e) "Flat co-payers," and (g) "Consumers with copay insurance plans that purchased only generic versions generic versions of Opana ER." (Rosenthal Rebuttal ¶ 6.)

The Court also reviews the other subsections of the proposed list of exceptions. End Payor Plaintiffs propose to exclude persons otherwise involved in this lawsuit in Subsections (a), (b), (c), (h), (i), (j), which the Court finds acceptable. (*Id.*) Substantively, End Payor Plaintiffs also propose to exclude Subsection (d), "Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligation to its members)", and Subsection (f) "[a]ny consumer who purchased only Endo's branded version of Opana ER after the AB-rated generic version became available in January 2013." (*Id.*)

The Court's finds that Subsection (d) is arguably already excluded from the class as defined because an insurance entity who purchased its own insurance would no longer be an End Payor, defines as "all payors who purchased or reimbursed" in the class

definition. Nevertheless, the Court finds the exclusion to be acceptable for the purposes of clarity.

Although branded Opana ER was removed from the market six months prior to the sale of generic Opana ER, there is a very small percentage of consumers who continued to purchase the product, presumably from retailers who hadn't fully sold their supply, estimated 1% of the class by Dr. Hughes. (Hughes Report ¶ 19.) Subsection (g) excludes these consumers from class members. Although negligible, the Court accepts this exclusion.

For these reasons, the Court amends its June 4, 2021 Order and certifies End Payor Plaintiffs' proposed amended class definition. All other portions of the Order remain intact.

Harry D. Leinenweber, Judge
United States District Court

Dated: 8/11/2021