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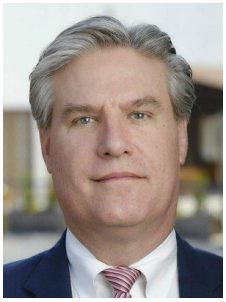
Finding Uninjured Consumers In Drug Antitrust Class Actions

By **George Korenko and Tram Nguyen** (May 16, 2022, 6:26 PM EDT)



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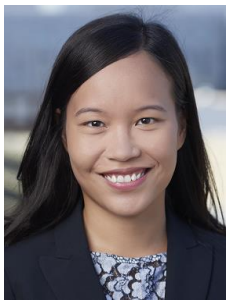


Tram Nguyen

In an amicus brief filed in March opposing an appeal from end payers seeking to certify a class of end purchasers of the cholesterol drug Niaspan in In re: Niaspan Antitrust Litigation, the Washington Legal Foundation stated that:

> Plaintiffs offered the District Court no workable way of identifying members of the class of end-payors they seek to represent from more than 20 million transactions. That is the end of this case.[1]

However, whether class members could be identified was not the only issue in the Niaspan case. The presence of uninjured groups of purported class members was also an issue cited by the U.S. District Court for the Eastern District of Pennsylvania in rejecting class certification.[2]

Specifically, the court viewed the use of averages as inappropriate when it hid "several groups of uninjured class members who cannot be easily identified."[3] This follows other recent pay-for-delay class actions where courts have ruled that a proposed end-purchaser class that includes more than a de minimis number of uninjured class members is a barrier to class certification.

For example, in In re: Asacol Antitrust Litigation, the U.S. Court of Appeals for the First Circuit in 2018 reversed a decision to grant class certification when approximately 10% of the proposed class were found to be uninjured — reflecting thousands of uninjured class members.[4]

In our experience, the presence of uninjured class members is more likely to be hidden in a pharmaceutical antitrust class action with a highly aggregated economic model that relies on the use of averages. In this article, we identify dimensions along which, over aggregation and averaging, likely lead to findings of uninjured class members.

Injury and Damages to Class Members

At the class certification stage in an antitrust case, a key question for the economic experts is whether the plaintiffs' economic model is capable of demonstrating that all, or nearly all, members of the proposed class were impacted by the alleged conduct, or if individual inquiry is required to assess antitrust impact.[5]

Put differently, to assess predominance, the question before the economist is: If all potential class members were to pursue litigation individually against the defendants, could they all use the same economic analysis to establish impact and damages?

The economic framework for demonstrating injury requires comparing the price paid in the world absent the alleged conduct — often called the "but-for" price — to the price actually paid. The amount of this difference is damages.

In a pay-for-delay end purchaser case, a customer is impacted if they paid a higher price for the pharmaceutical product than they would have if a generic product had been available. This requires each payor in the complex pharmaceutical supply chain to have incurred an overcharge, and passed at least a portion of that overcharge along until it reaches third-party payers, or TPPs, and end consumers.

Since the but-for price cannot be observed, an economic expert develops a model to estimate the price and quantity effects of earlier generic entry. The outputs of this model include estimates of the but-for prices and quantities of the branded and generic pharmaceutical products, had generic entry occurred at an earlier date.

In pay-for-delay cases, we often observe approaches to demonstrating antitrust impact and damages that are based on highly aggregated overcharge models. For example, a frequently applied approach seeks to show common impact by comparing a single average but-for price to a single average actual price.

Specifically, the expert calculates an average but-for price and an average actual price across all purchasers of all formulations of the branded and generic products, respectively. In some cases, we have even seen the prices of branded and generic products averaged together.

Using this approach, damages are calculated as the difference between the actual and but-for average prices, multiplied by the total unit volume. However, this aggregated approach makes certain critical assumptions that may be problematic when tested against the underlying disaggregated data.

In particular, an important implicit assumption in this approach is that all proposed class members each paid the same price for the products, and would also have done so in the but-for world.

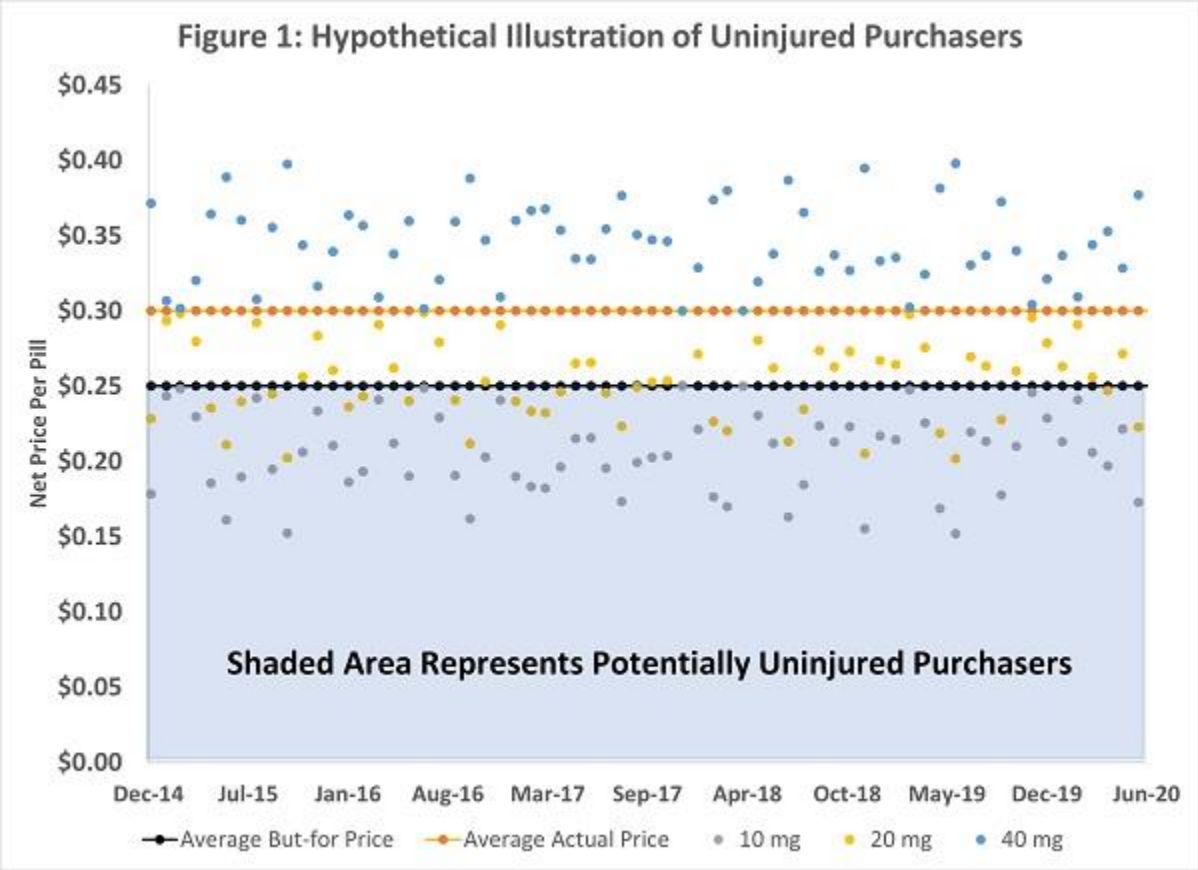
Flaws in Aggregate Economic Pricing Models

Aggregation of Products

A single average price across all products may mask differential amounts paid between branded and generic pharmaceutical products, or within the branded and generic categories. Studies in the economic literature show that branded products are typically, though not always, sold at a higher price than generic products — which means that an average of the two would likely be misleading.[6]

Similarly, an average price across formulations would fail to account for price differences for different strengths (e.g., 25 milligrams and 100 mg), formulations (e.g., oral solid or topical cream), and dosage forms (e.g., tablet or capsule). Each of these products may be sold at different prices, and a single average price can obscure the variation in pricing across products.

If this is the case, members of the proposed class that paid lower prices for their products may have paid less than the proposed average but-for price, suggesting that they are uninjured. Figure 1 illustrates how this can occur using a hypothetical comparison of the average actual and but-for price of products with different strengths with the actual individual prices paid.



As Figure 1 shows, all customers who made purchases in the shaded area — including all purchases of the 10 mg strength and many of the 20 mg strength — paid less than the average actual and but-for prices. Hence, these customers would be uninjured, according to the economic model.

Aggregation of Customers

A single average price also ignores the individualized negotiations that occur throughout the pharmaceutical supply chain. For example, manufacturers and their customers often conduct bilateral negotiations that can result in differential prices, rebates and discounts across the many types of proposed class members in direct purchaser cases, which include:

- Large wholesalers such as McKesson Corp., Cardinal Inc. and AmerisourceBergen Corp.;
- Retail pharmacies such as Walgreens Co., CVS Health Corp., Walmart Inc. or Rite Aid Corp.;
- Mail order pharmacies, such as Humana Inc. or Optum Rx Inc.;
- Group purchasing organizations that vary substantially in size; and

- Independent pharmacies that may purchase pharmaceutical products directly from the manufacturers, or through wholesalers or group purchasing organizations.

Given the bargaining power of some large direct purchasers, it is highly unlikely that all these types of entities would pay the same average price. Prices paid may be affected by negotiated terms and conditions, such as special off-invoice rebates and discounts for large purchases, pricing or discounting based on purchases of a portfolio of products, price protection terms, and rights of first refusal.

As a result, some direct purchasers may pay substantially lower than the average price, and others substantially higher. A single average price for the brand and/or generic across all direct purchasers will obscure these pricing differentials. Moreover, any entities that paid less than the average but-for price would be uninjured, similar to the results shown in Figure 1 above.

Aggregation and averaging can also be problematic when studying the purchases of TPPs and end consumers. TPPs fund different health plans with a variety of formularies that have different provisions for coverage and cost sharing with members. In our experience, these differences cannot be captured by a single average TPP payment amount.

Similarly, for end consumers, an aggregated model may average out-of-pocket prices paid by all consumers, despite differences in copayments, coinsurance payments and deductibles. This approach cannot account for the ubiquitous differences in pricing to insured consumers under different health plans, cash payers, or consumers that utilize coupons or discount programs.

For example, an analysis of prices paid by end consumers using coupons at purchase may show they paid lower out-of-pocket expenses compared to the aggregate average but-for price. When a model uses a price that is averaged across many types of end consumers, it cannot account for prices paid by coupon users and other consumers.

This was a key issue cited by the court in Niaspan:

> In sum, the Court is concerned that the class contains, at minimum, substantial numbers of uninjured consumer brand loyalists, coupon users, and flat co-payers. The Court is not satisfied that EPPs have a non-individualized means of identifying these uninjured class members in a way that protects defendants' constitutional rights.[7]

Competitive Factors That Overly Aggregated Models Fail to Capture

The pharmaceutical supply chain is complex, and prices paid by members of a proposed direct purchaser class may be influenced by downstream competitive conditions or lawful strategic behavior by manufacturers. Pharmacy benefit managers, or PBMs, play an important role for manufacturers, pharmacies and end payers:

- Manufacturers of branded products negotiate with PBMs for pricing and placement on formularies. The formulary, which lists the pharmaceutical products covered under a prescription drug plan, determines the tiers for branded and generic products and establishes their respective reimbursement levels.

- PBMs negotiate reimbursement rates with pharmacies, setting the amount the pharmacy will receive for a given pharmaceutical product. For generic products, reimbursement is often limited to a maximum amount that is negotiated between the PBM and pharmacy.

- TPPs and/or their PBMs may select different formularies that provide various levels of coverage and cost sharing arrangements for their members — i.e., end consumers.

The negotiations between manufacturers, PBMs, pharmacies and TPPs may influence the prices paid by TPPs.[8] For example, if the cost of a product is higher than a therapeutic alternative, the PBM or health plan may incentivize physicians and members to switch to the lower cost product.

In response, the manufacturer of the higher cost product may decide to offer rebates to lower the net price paid and encourage use of its product. This competitive dynamic could result in either a reduced overcharge or no overcharge for certain TPPs. However, data aggregated across TPPs would fail to capture these differences and the existence of uninjured TPPs.

Identifying Class Members and Uninjured Class Members

Courts have considered approaches for identifying class members and removing uninjured class members from proposed classes. In the Niaspan case, the court concluded that the plaintiffs' expert's proposed model did not demonstrate classwide injury, because it relied on averages that hid "several groups of uninjured class members who cannot be easily identified."[9]

These included "brand loyalists, coupon users, and flat co-payers" that the aggregated model could not identify and remove from the proposed class. In addition, the court found that class members could not be identified either — it was "concerned about the economic feasibility of obtaining such information and the ability of EPPs to identify class members in a reliable and administratively feasible manner."[10]

Conclusion

In pay-for-delay cases, experts may proffer economic models that oversimplify pricing in the industry. A thorough analysis of the specific competitive conditions for a given product may reveal important factors that cause differences in pricing — such as formulary placement, rebates and pricing pressure from competitive therapeutic substitutes.

These differences in net pricing across products, TPPs and end consumers can be demonstrated using more granular pricing data. Importantly, the use of aggregate average prices may not only hide uninjured class members, but also makes it difficult to identify and remove them from the proposed class.

As in the Niaspan case, these issues not only call into question the issue of identifying class members, but also whether the economic model has actually shown common impact.

George G. Korenko, Ph.D., is a partner and Tram Nguyen, Ph.D., is a principal consultant at Edgeworth Economics LLC.

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[1] Brief of Washington Legal Foundation as Amicus Curiae in Support of Defendants-Appellees, March 18, 2022, p. 2.

[2] In re: Niaspan Antitrust Litig., No. 13-MD-2460, 2020 WL 2933824 (E.D. Pa. June 2, 2020) ("Niaspan").

[3] Niaspan, p. 50. Also see George Korenko and Tram Nguyen, "Pay-For-Delay May Need More Evidence After 3rd Circ. Ruling," Law 360, July 21, 2020, discussing the Lamictal direct purchaser decision, where the vourt noted that "[A]verages may be acceptable where they do not mask individualized injury."

[4] In re: Asacol Antitrust Litig., 907 F.3d 42, 51 (1st Cir. Oct. 15, 2018). Courts in In re: Intuniv Antitrust Litig., No. 1:16-CV-12396, 2019 WL 3947262 (D. Mass. Aug. 21, 2019) ("Intuniv"), In re: Loestrin 24 Fe Antitrust Litig., 410 F. Supp. 3d 352, 404 (D.R.I. July 2, 2019), and In re: Thalomid and Revlimid Antitrust Litig., No. CV 14-6997, 2018 WL 6573118 (D.N.J. Oct. 30, 2018) have also ruled that uninjured class members were a barrier to class certification.

[5] See, for example, Intuniv and In re: Rail Freight Fuel Surcharge Antitrust Litig., 934 F.3d 619 (Aug. 30, 2019).

[6] See, for example, Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg and Oded Bizan, "Generic Competition in the US Pharmaceutical Industry," International Journal of the Economics of Business, Vol 13, No. 1, 2006, p. 18.

[7] Niaspan, p. 61.

[8] When dispensing a pharmaceutical product to a consumer, a pharmacy may receive a copayment or co-insurance payment from the consumer, and then seeks reimbursement from a PBM or health plan for the cost of the product and other applicable charges (e.g., dispensing fees). The terms of that reimbursement are negotiated in advance between the pharmacy and a PBM.

[9] Niaspan, p. 50.

[10] Niaspan, p. 31-2.