

EXHIBIT 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT**

IN RE AGGRENEX ANTITRUST LITIGATION

C.A. No. 3:14-MD-2516 (SRU)

This Document Relates to:

ALL DIRECT PURCHASER ACTIONS

DECLARATION OF JEFFREY LEITZINGER, PH.D.

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September 5, 2017

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I. Introduction

1. I am an economist and President of Econ One Research, Inc., an economic research and consulting firm with offices in half a dozen cities around the country. I have master's and doctoral degrees in economics from UCLA and a bachelor's degree in economics from Santa Clara University. My doctoral work concentrated on the field within economics known as industrial organization, which involves among other things the study of markets, competition, antitrust, and other forms of regulation.
2. During the past 35 years of my professional career, industrial organization has remained the principal focus of much of my work. I have worked on numerous projects relating to antitrust economics, including analyzing issues involving market power, market definition, and the competitive effects of firm behavior. I also have frequently assessed damages resulting from alleged anticompetitive conduct and have substantial experience in the calculation of damages in class action litigation. Additionally, I have significant experience with economic issues related to class certification in antitrust contexts.
3. I have testified as an expert economist in State and Federal courts, and before a number of regulatory commissions. I previously submitted three declarations in this case.¹ A more detailed summary of my training, past experience, and prior testimony is shown in Exhibit 1.
4. I have been continuously involved in research regarding the pharmaceutical industry for more than ten years now. I am familiar with the economic and academic literature on the subject of generic drug competition and impaired generic drug competition. I also have specific and extensive experience making economic assessments of the effects of AB-rated² generic drug competition in pharmaceutical

¹ See Declaration of Jeffrey J. Leitzinger, Ph.D., dated September, 21 2015 (“Declaration”); Declaration of Jeffrey J. Leitzinger, Ph.D. Regarding Relevant Market and Market Power, dated September 26, 2016; Declaration of Jeffrey J. Leitzinger, Ph.D., Regarding Overcharges on Generic Purchases, dated August 3, 2017.

² “AB-rated” is a term the United States Food and Drug Administration (“FDA”) uses to classify a generic drug product that has been found to be therapeutically equivalent to its branded counterpart. An AB-rated generic drug may be freely substituted for its branded counterpart at the pharmacy level without the prescribing physician’s permission in most or all states. The FDA lists such substitutable drugs in its “Orange

markets. I previously have analyzed anticompetitive effects, impact and class-wide overcharge issues, monopoly power, as well as issues relating to the post-settlement allocation of aggregate overcharges to individual class members, in a number of antitrust cases that involve allegations very similar to this case--i.e., class actions involving direct purchasers of brand-name drugs who were overcharged as a result of impaired generic drug competition. Exhibit 1 lists these engagements. Direct purchaser classes were certified for litigation and/or settlement purposes in a number of these prior cases.³

5. Econ One is being compensated for the time I spend on this matter at my normal and customary rate of \$800 per hour. Econ One also is being compensated for the time spent by my research staff on this project at their normal and customary hourly rates.

II. Assignment, Materials Reviewed and Summary of Conclusions

6. Miami-Luken, Inc., Rochester Drug Co-Operative, Inc., American Sales Company, LLC, and Cesar Castillo, Inc. (collectively “Plaintiffs” or “Class Plaintiffs”) filed a complaint⁴ on behalf of themselves and a proposed class of direct purchasers of the

Book,” the formal title of which is *Approved Drug Products With Therapeutic Equivalence Evaluations*. “Therapeutically equivalent” is a technical term for products that meet certain criteria including safety and efficacy, “pharmaceutical equivalence,” “bioequivalence,” and labeling and manufacturing standards. The definitions of therapeutic equivalence, pharmaceutical equivalence, and bioequivalence are listed in Sections 1.2 and 1.7 of the FDA’s Orange Book. The FDA Orange Book can be found at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

³ *In re Lidoderm Antitrust Litigation*, No. 14-md-2521 (N.D. Cal.); *In re Wellbutrin XL Antitrust Litigation*, No. 08-2431 (E.D. Pa.); *In re Relafen Antitrust Litigation*, Master File No. 01-12239-WGY (D. Mass.); *In re Tricor Direct Purchaser Antitrust Litigation*, C.A. No. 05-340 KAJ (D. Del.); *Meijer, Inc. et al. v. Warner Chilcott Holdings III, Ltd., et al.*, No. 05 Civ. 2195 CKK (D.D.C.) (involving the drug Ovcon 35); *In re Nifedipine Antitrust Litigation*, (D.D.C.); *In re K-Dur Antitrust Litigation*, (D.N.J.); *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis, et al.* (S.D.N.Y.) (involving the drug Arava); and *In re Flonase Direct Purchaser Antitrust Litigation*, Master File No. 2:08-cv-03149 (E.D. Pa.). I also have offered testimony (either by deposition or declaration or both) regarding aggregate overcharge damages suffered by classes of direct purchasers in numerous cases including those listed above as well as: *In re Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich.); *In re Buspirone Patent & Antitrust Litigation*, MDL No. 1413 (S.D.N.Y.); *In re Remeron Direct Purchaser Antitrust Litigation*, No. 03-CV-0085 (D.N.J.); *North Shore Hematology-Oncology Associates, P.C. v. Bristol-Myers Squibb Co.*, (D.D.C.) (involving the drug Platinol); *In re Terazosin Hydrochloride Antitrust Litigation*, MDL No. 1317 (S.D. Fla.); and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, MDL No. 1383 (E.D.N.Y.).

⁴ “Consolidated Amended Class Action Complaint,” *In re Aggrenox Antitrust Litigation*, June 16, 2014

drug Aggrenox or generic Aggrenox (the “Class”).⁵ The Defendants in this case are Boehringer Ingelheim Pharma GmbH & Co. KG (“BIPKG”), Boehringer Ingelheim International GmbH (“BI”), and Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), (collectively “Boehringer”), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited, Barr Pharmaceuticals Inc., (n/k/a Barr Pharmaceuticals, LLC), Barr Laboratories Inc., Duramed Pharmaceuticals Inc. (n/k/a Teva Women’s Health Inc.), and Duramed Pharmaceuticals Sales Corp. (n/k/a/ Teva Sales and Marketing, Inc.) (“Teva”) (collectively “Defendants”). Aggrenox is the brand name for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid which is used to “lower the risk of stroke in people who have had a ‘mini-stroke’ [] or stroke due to a blood clot”.⁶

7. Based upon the settlement Class definition, transaction data showing sales to direct purchasers, and instructions from counsel regarding the status of certain entities, I have identified 36 Class members (including named plaintiffs and assignees--see Exhibit 2). Exhibit 3 shows the geographic dispersion of these Class members.
8. Class Plaintiffs allege, among other things, that Boehringer entered into unlawful exclusion or “reverse payment” agreements, whereby Boehringer paid Barr not to

(“Complaint”).

⁵ The Class is defined in the Settlement Agreement as:

All persons or entities in the United States and its territories and possessions including the Commonwealth of Puerto Rico who directly purchased branded Aggrenox in any form from any of the Defendants from December 1, 2009 through June 30, 2015 (the “Class Period”), or their assignees (the “Class”). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities. Also excluded from the Class are CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P. and Albertson's LLC and their officers, directors, management and employees, predecessors, subsidiaries and affiliates who have brought individual claims as direct purchasers or assignees of direct purchasers to the extent they have valid assignments as more fully described in paragraph 10 [of the Settlement Agreement] (“Retailer Plaintiffs”).

Generic only purchasers are not included in the settlement Class. I have not identified circumstances in this case that would give rise to overcharges on generic purchases.

⁶ <https://www.aggrenox.com/>.

market generic versions of Aggrenox until July 2015.⁷ Class Plaintiffs allege that, as a result of the unlawful acts, Class members incurred overcharges in their purchases of Aggrenox.⁸

9. I have been asked to undertake several tasks in connection with Plaintiffs' motion for certification of a settlement class in connection with a proposed settlement between Plaintiffs and the Class and Defendants, assuming that but for the alleged unlawful conduct, generic competition for Aggrenox would have begun earlier. First, I have been asked to form an opinion about the impact of Defendants' alleged conduct on the prices Class members paid for Aggrenox. Second, I have been asked to analyze whether proof of widespread antitrust injury (i.e., the payment of at least some overcharge) among members of the Class can be accomplished in this case with evidence that is predominantly common and class-wide. Third, I have been asked whether the aggregate amount of overcharges incurred by the proposed Class can be calculated in this case on a class-wide, formulaic basis.
10. In performing this assignment, my staff and I collectively have reviewed the Complaint, various documents produced in discovery, sales data produced by the Defendants and publicly available data.
11. I have concluded that:
 - a. The price benefits associated with AB-rated generic competition are predictable, substantial, and market-wide. AB-rated generic versions of a drug are typically sold at a small fraction of the price for the branded product. Once AB-rated generic entry occurs, those generics largely displace the branded product within the prescription base for the drug. As a result, AB-rated generic competition greatly reduces the average price that wholesalers and other buyers pay manufacturers in order to meet prescription demand.
 - b. Conduct that delays AB-rated generic competition therefore causes average prices for the drug at issue to be higher than they would otherwise be, resulting in overcharges to the entities (here, members of

⁷ Complaint, ¶¶ 6-7, 58-60.

⁸ Complaint, ¶¶ 17.

the Class) that purchase the drug. I conclude there is economic evidence common to the proposed Class that is sufficient to prove the existence of this form of antitrust injury as to all or nearly all Class members, assuming that but for Defendants' allegedly unlawful conduct, generic competition would have begun earlier.

- c. The calculation of aggregate overcharges for the Class in this case is readily susceptible to formulaic analysis and will not require individualized inquiry as to each Class member. In the discussion below, I describe the common nature of the data that can be used to calculate aggregate Class overcharges caused by Defendants' allegedly unlawful conduct and the formulaic nature of that calculation.

III. Patents and Regulatory Protection in the Pharmaceutical Industry

12. The pharmaceutical industry is oriented, to a great extent, around the development and monetization of intellectual property. Manufacturers of branded pharmaceuticals devote resources to the development of new drugs. The incentive for this effort is the substantial profit that often derives from commercial success.⁹ One of the main reasons for these profits is the legal protection from competition that newly developed drugs enjoy (at least, for some period in time.) This protection comes in multiple forms. Often, developers of new products are able to acquire patents covering the compound itself, the manufacturing process, the formulation of the compound, or the compound's application.¹⁰ Also, the FDA is not permitted to accept an application for a generic version of a new drug until five years after the approval of that drug.¹¹

⁹ Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998 (hereafter, "CBO Study"), p. 3.

¹⁰ Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002 (hereafter, "FTC Study"), p. 41.

¹¹ FTC Study, p. A-35, fn 33; 21 USC § 355(j)(5)(F)(ii); CBO Study, pp. xiv, 41. Since a company seeking to market a generic product cannot file its Abbreviated New Drug Application ("ANDA") until 5 years after FDA approval of the originator drug, the *de facto* period of exclusivity runs until the generic applicant gets final FDA approval and comes to market, a process which is by no means immediate. As such, the ANDA process itself creates substantial barriers to entry protecting branded pharmaceutical products. Moreover, where there is a patent, the mandatory exclusivity (prior to the time an ANDA filing can be accepted)

13. These legal protections only apply for limited periods of time. Patents expire within twenty years of filing.¹² And, by its own terms, the FDA limits on accepting applications for generic versions only last five years. In addition, Congress passed the Hatch-Waxman Act (“Hatch-Waxman”) to “make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962” and “to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval.”¹³ Under Hatch-Waxman, would-be generic competitors can conduct clinical tests prior to patent expiration without incurring liability for patent infringement.¹⁴ Finally, having successfully tested their products, generic manufacturers are allowed to bring them to market under an abbreviated application process (“Abbreviated New Drug Application” or “ANDA”).¹⁵
14. Patents that, according to the developer, apply to their drugs are listed in the FDA’s Orange Book.¹⁶ These filings are made available to generic manufacturers. At the time of its ANDA filing, a generic manufacturer must declare its position with respect to the patents listed in the Orange Book for the reference drug. One possibility in that regard is that the generic company certifies that its product would

becomes four years if the generic applicant files what is known as a Paragraph IV Certification with its ANDA, challenging the validity or applicability of the patent. 21 USC § 355(j)(5)(F)(ii).

¹² “General Information Concerning Patents,” available at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

¹³ H.R. Rep. 98-857 (I), 1984 U.S.C.C.A.N. 2647.

¹⁴ CBO Study, p. 3; *Mylan Pharmaceuticals, Inc. v. Tommy G. Thompson, et al.*, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (hereafter, “*Mylan Pharms*”).

¹⁵ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (“*Actavis*”), p. 2228 (“once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an [ANDA] specifying that the generic has the ‘same active ingredients as,’ and is ‘biologically equivalent’ to, the already-approved brand-name drug.”). See also, 21 U.S.C. § 355(j). Manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). *Actavis*, p. 2228 (“a drug manufacturer, wishing to market a new prescription drug, must submit a New Drug Application to the federal Food and Drug Administration (FDA)”).

¹⁶ *Actavis*, p. 2228 (“[The Hatch-Waxman Act] requires the pioneer brand-name manufacturer to list in its New Drug Application the ‘number and the expiration date’ of any relevant patent.”); *FTC Study*, p. 5; *Mylan Pharms.*, p. 1326.

not infringe the listed patents or that those patents are invalid or unenforceable. This certification is referred to as a “Paragraph IV” ANDA filing.¹⁷ Once the generic company provides notice to the brand company of its Paragraph IV filing, the brand company--should it dispute the certification--has 45 days to commence infringement litigation in order to trigger an automatic stay of FDA approval of the generic for up to 30 months.¹⁸

15. Under Hatch-Waxman, the first company to file a Paragraph IV application (the “first-filer”) is entitled to a 180 days of marketing exclusivity.¹⁹ During this 180-day exclusivity period, the first filer is protected against competition from other ANDA filers. The exclusivity period can be very valuable to a generic manufacturer.²⁰ Also, when a generic product meets FDA standards for safety and efficacy, the FDA gives the product an “AB” rating. This rating is the FDA’s assurance to physicians, pharmacists, and patients that the product will have the same therapeutic effects, safety, and efficacy as the brand.
16. In effect, generics sit inside many of the barriers described above. They also have the benefit of reviewing claimed patents and the freedom to test their product without fear of infringement claims. Finally, they have the FDA’s endorsement regarding the therapeutic equivalence of their products. As a result, the generic purchase decision is largely about prices and prescription costs.
17. This is where competition takes over. Once an AB-rated generic is allowed to enter the market, their lower prices, state laws and regulations, managed care policies, and pharmacy incentives together induce rapid and substantial substitution in place of the branded version when it comes to filling prescriptions.²¹ In the end, the costs

¹⁷ *Actavis*, p. 2228.

¹⁸ FTC Study, p. ii; Federal Trade Commission, “Authorized Generics: An Interim Report,” June 2009, (hereafter “2009 FTC Study”), p. 2.

¹⁹ *Actavis*, pp. 2228-2229. See also, Federal Trade Commission, “Authorized Generic Drugs: Short-Term Effects and Long-Term Impact,” August 2011 (“2011 FTC Study”).

²⁰ *Actavis*, p. 2229 (“...this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars.’”). See also, Grabowski, et al., “Recent trends in brand-name and generic drug competition,” *Journal of Medical Economics*, 2013, at p. 2.

²¹ Hughes, Moore, and Snyder also note that branded manufacturers “decide to cede the bulk of the market

associated with supplying the prescription base associated with the brand drug fall substantially and rapidly. As a result, since the passage of Hatch-Waxman, generics have been a powerful engine for consumer benefits.²²

18. Consequently, conduct that delays or limits generic competition (as alleged in this case) creates significant consumer harm. By keeping generics out of the market, a brand company prevents substantial sales losses, with no need to lower prices, and, in that way, artificially extends the period of competitive protection contemplated by the legal and regulatory framework. As a result, the cost of supplying the prescription base, and ultimately the costs borne by consumers, are greatly increased.

IV. Background

19. This case involves Aggrenox, a brand-name anti-platelet combination drug product sold in the United States by Boehringer.²³ The FDA approved Aggrenox – a medication combining extended-release dipyridamole and acetylsalicylic acid – in 1999.²⁴ Boehringer owns U.S. Patent No. 6,015,577 (the “577 patent”) which was issued in January 2000 by the United States Patent and Trademark Office and then

to generics and retain the relatively small brand loyal segment.” (Hughes, J., M. Moore and E. Snyder, “Napsterizing’ Pharmaceuticals: Access, Innovation, and Consumer Welfare,” NBER Working Paper No. 9229, 2002.) However, brand companies frequently launch their own “authorized generics” to compete directly with other generics on price, as discussed below.

²² The powerful effects of generic competition are described in the following sources, among others: U.S. Congress, Office of Technology Assessment, “Pharmaceutical R&D: Costs, Risks and Rewards” (1993) OTA-H-522, Washington D.C.: U.S. Government Printing Office (available at <http://www.fas.org/ota/reports/9336.pdf>), pp. 83, 87, 89 fn.17, 243; CBO Study, pp. ix, xii-xiii, 8-9, 13, 27-35; “Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,” An FTC Staff Study, January 2010 (hereafter “2010 FTC Study”). The CBO study notes that “after a drug’s patent expires, generic copies quickly gain a large share of its market” and estimates that generics saved drug consumers between \$8 billion and \$10 billion in 1994 alone. Another study by the FDA found that drug costs per day could fall by 14 to 16 percent if patients use generics instead of branded drugs. Additionally, according to the FDA, patients who could fully meet their medical needs with generics could reduce their daily drug costs by 52 percent. “Savings from Generic Drugs Purchased at Retail Pharmacies,” available at <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134205.htm>.

²³ Complaint ¶¶ 1, 100.

²⁴ https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20884_AGGRENOX_APPROV.PDF. See also, Complaint ¶¶ 1, 53.

listed in the Food and Drug Administration's "Orange Book" as covering Aggrenox.²⁵

20. In 2007, Barr filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Aggrenox.²⁶ In connection with its application Barr filed a Paragraph IV certification, in which it certified that its generic product would not infringe any valid claim of the '577 patent and that the patent was otherwise invalid.²⁷ Boehringer filed suit against Barr on July 11, 2007, alleging infringement of the '577 patent.²⁸
21. According to the complaint, on August 11, 2008, Boehringer entered into an agreement with Barr under which Boehringer agreed to pay Barr, and in exchange Barr pledged to drop its challenge to the '577 patent and to delay coming to market with a less expensive generic version of Aggrenox until July 1, 2015.²⁹ According to Plaintiffs the payments were made under the guise of various services and arrangements.³⁰
22. According to Plaintiffs, generic Aggrenox would have been available as early as December 1, 2009 but for Defendants' conduct.³¹ Instead, no generic Aggrenox was available until Roxane entered with a generic version of Aggrenox in June 2015 and Barr (now owned by Teva³²) entered in July 2015.³³

²⁵ Complaint ¶ 54.

²⁶ https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/078804s000ltr.pdf. See also, Complaint ¶ 55.

²⁷ Complaint ¶ 56.

²⁸ Complaint ¶ 56.

²⁹ Complaint ¶¶ 58-60.

³⁰ Complaint ¶¶ 6-13, 58-82.

³¹ Complaint ¶ 89 ("But for the continuing illegal agreements between Barr and Boehringer[...] Barr would have begun selling a less expensive AB-rated generic version of Aggrenox on or after November 30, 2009").

³² Subsequent to the settlement agreement, Teva Pharmaceutical Industries, Ltd. ("Teva") acquired Barr. Teva Completes Acquisition of Barr (in December 2008), *available at* <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1554791&highlight>.

V. Antitrust Injury

23. I have concluded that there is evidence in this case which is common to members of the Class (as opposed to being individualized to its members) that, assuming that but for Defendants' allegedly unlawful conduct, generic competition would have begun earlier, would show that all or nearly all Class members suffered antitrust injury in the form of overcharges. In particular, this evidence would show that, more likely than not, each Class member paid at least some overcharge. This evidence is comprised of i) literature and prior studies showing that generic competition rapidly converts the vast majority--often upwards of 90 percent--of the affected prescription base to generics which carry prices that are substantially below those charged by the brand and that prices fall further as the number of generic competitors increases; ii) forecasts prepared by Defendants regarding the prospect of generic competition for Aggrenox which similarly reflect high expected generic substitution rates and lower generic prices; and iii) the price declines experienced for generic Aggrenox in the time period after generics actually entered the market;³⁴ and (iv) the direct purchasers' role in the distribution chain.

A. Economic Literature Pertaining to the Effects of Generic Competition

24. There is an extensive literature concerning the competitive effects of AB-rated generic entry.³⁵ The principal conclusions of that literature are that AB-rated generic products: 1) enter the market at substantially lower prices than their branded counterparts; and 2) capture a significant share of the combined product (brand and AB-rated generic) unit sales. To pick just a couple of representative examples, a 2009 FTC Study found generics captured between approximately 72 and 85 percent of

³³ Roxane and Teva manufacturer data.

³⁴ These outcomes are born out in my own prior experience with a number of drugs. Before coming to my work in this case, I studied the effects of AB-rated generic entry on pricing for Cardizem, Buspar, Relafen, Remeron, Ovcon, Tricor, Wellbutrin XL, Provigil, and Lidoderm (among others). In each case, generic competition substantially reduced the acquisition costs of the drug.

³⁵ See, for example, the references listed in Saha, A., H. Grabowski, H. Birnbaum, P. Greenberg and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, n. 1, v. 13 (February 2006), pp. 15-38 ("Saha, et al. (2006)").

sales in the first six months.³⁶ A 2010 FTC Study concludes that one year following initial entry, generics on average accounted for 90 percent of the corresponding prescription base.³⁷

25. The literature also devotes much attention to the price benefits associated with generics. Lichtenberg and Duflos found that when generic competitors entered the market, prices declined by approximately 60 percent.³⁸ A study by Saha, et al. (2006), investigated 40 drugs that experienced generic entry between July 1992 and January 1998.³⁹ They reported that generic prices averaged 76 percent of the brand price one month after generic entry and 54 percent of the brand price one year. A 2010 FTC Study states, “in a mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug price.”⁴⁰ As these results would suggest, the price benefits generally associated with generic competition have been increasing over

³⁶ 2009 FTC Study. See also Grabowski, H., M. Kyle, R. Mortimer, G. Long and N. Kirson, “Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act,” *Health Affairs*, Vol. 30, no. 11, 2011 (noting that brand drugs facing first generic entry in 2007-2008 retained 15 percent of the volume a year after generic entry). This is consistent with industry experience. PharmaCare, a pharmacy benefit manager wholly-owned by CVS, shifted nearly 95 percent of its Zocor patients to generics during the first month of their availability. (CVS Caremark Press Release, “PharmaCare’s Aggressive Outreach Successfully Shifts 95% of its Zocor Market Share to Generic Simvastatin in One Month, Generating Significant Savings for Clients,” August 17, 2006). Another pharmacy benefit manager, Medco, observed that generic dispensing rates for Allegra were nearly 90 percent within 30 days of the generic becoming available. (Medco Press Release, “New Analysis: Recent Generic Blockbusters Show Huge Gains; Consumer Adoption Rates Accelerate,” January 18, 2006 (“Medco Press Release”). Medco also claims that through its mail-order pharmacies, it “regularly achieves a near-95 percent substitution rate within the first week for new generic chronic-care medications.” (Medco Press Release). Such rapid generic penetration has led the president of generic manufacturer Par Pharmaceuticals to observe that “[o]vernight, quite literally, the branded [drug] companies are losing their entire franchise,” as a result of generic entry. (Sandra Levy, “Why Authorized Generics Are Making a Comeback,” *Drug Topics*, November 3, 2003).

³⁷ 2010 FTC Study, p. 8.

³⁸ Lichtenberg, F. and G. Duflos, “Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public,” *Medical Progress Report*, Center for Medical Progress at the Manhattan Institute, No. 11, October 2009, p. 5.

³⁹ Saha, et al., (2006).

⁴⁰ 2010 FTC Study, p. 8.

time.⁴¹ The literature also shows that the pricing benefits created by generic competition increase with the number of competitors.⁴²

26. Often the price reductions associated with generic entry also occur with respect to the brand itself. According to a CBO Study, “[a] statistical analysis of pharmaceutical prices shows that purchasers tend to obtain higher discounts from manufacturers on brand-name drugs when generic substitutes are available....”⁴³ The CBO Study concluded that when two or more generic manufacturers were competing with a brand, discounts off the brand price were 10 to 17 percent greater.⁴⁴
27. The literature also notes a growing tendency among brand manufacturers to engage in direct price competition with generic manufacturers through “authorized generics.”⁴⁵ As one study notes, “...pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”⁴⁶ A study by Berndt, et al. involving three drugs for which there were authorized generics found that, “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”⁴⁷ An FTC study published in 2011 found that, during the 180-day exclusivity period, wholesale generic prices were 7-14 percent lower when there was competition from

⁴¹ Berndt, E. and M. Aitken, “Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation,” *International Journal of the Economics of Business*, Vol. 18, No. 2, July 2011.

⁴² See for example, Saha, et al., (2006) and Wiggins and Maness, “Price Competition in Pharmaceuticals: The Case of Anti-Infectives,” *Economic Inquiry*, 2004.

⁴³ CBO Study, p. 24. Unlike some of the earlier literature, which focused just on list prices, the CBO Study used data including discounts from brand list prices.

⁴⁴ CBO Study, p. 29.

⁴⁵ When faced with AB-rated generic entry, branded pharmaceutical companies often release their own generic--known as an authorized generic--in order to compete with AB-rated generics on price without compromising the pricing for the brand version.

⁴⁶ Hassett, K. A. and R. J. Shapiro, “The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals,” *Sonecon*, May 2007, p. 3.

⁴⁷ Berndt, E., R. Mortimer, A. Bhattacharjya, A. Parece and E. Tuttle, “Authorized Generic Drugs, Price Competition, and Consumers’ Welfare,” *Health Affairs*, v. 26, n. 3, May/June 2007, p. 796.

an authorized generic.⁴⁸ An IMS Consulting study found that generic prices were 16 percent lower when there was authorized generic in the market.⁴⁹

B. The Manufacturers' Internal Generic Penetration Models and Forecasts

28. The likely effects of unimpaired generic competition (but for the conduct alleged by Plaintiffs) were analyzed by Defendants. They generated detailed models and forecasts of brand and generic Aggrenox pricing and sales in a world with generic competition. Those forecasts show the same market-wide competitive benefits described in the literature--generic Aggrenox would be priced at a substantial discount relative to branded Aggrenox; generic Aggrenox would substantially displace brand Aggrenox within the Aggrenox prescription base; and prices for generic Aggrenox prices would be lower with more generic Aggrenox competitors.⁵⁰

C. Actual Aggrenox Experience

29. I have reviewed IMS data for Aggrenox and for generic Aggrenox. These data bear out the general patterns described in the literature and the forecasts prepared by Defendants (as noted above). Prior to generic entry, the only source of 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid was branded Aggrenox, with purchasers paying an average price that was approximately 5 percent below the Aggrenox wholesale acquisition cost ("WAC"). The prices paid by direct purchasers for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid declined immediately and substantially once generic competition commenced. During the first two quarters following generic entry, generic Aggrenox was used to fill nearly 75 percent of the total 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid prescription volume. The prices paid for those generics were 44 percent below the brand WAC.

⁴⁸ Federal Trade Commission, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," August 2011 (hereafter "FTC 2011 Study"), pp. ii, 33, 46, 48. See also, 2009 FTC Study, pp. 9-11.

⁴⁹ IMS Consulting, "Report to PhRMA, Assessment of Authorized Generics in the U.S.," Spring 2006.

⁵⁰ See, e.g., BI-Aggrenox-00897731 (forecast prepared by Boehringer); BI-Aggrenox-01001939 (forecast prepared by Boehringer); BARR.AGG.023890 (forecast prepared by Barr); BARR.AGG.024065 (forecast prepared by Barr).

D. Common Injury Across the Direct Purchaser Class

30. Insofar as Defendants illegally delayed generic competition, this conduct forced Class members to continue paying inflated prices for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid needed to supply Aggrenox prescriptions. These inflated prices reflected the absence of substitution to much cheaper generics. In that way, the challenged conduct gave rise to overcharges. The likelihood each Class member purchasing Aggrenox during the generic delay period incurred at least some part of this overcharge therefore corresponds to the likelihood that, but for the delay in generic competition, some of the Aggrenox volumes it purchased would have been replaced with generics.
31. In my opinion, this likelihood is extremely high--approaching 100 percent. Class members are nearly all wholesalers or retailers supplying product to broad cross-sections of the patient community. Recognizing that something close to 90⁵¹ percent of all Aggrenox prescriptions would have converted to generics in the but-for world, the likelihood that at least some of each Class member's Aggrenox purchases would have been shifted to lower-priced generics but for the delay is very high.⁵² There is no reason to suppose that any Class member (in its capacity as either a wholesaler or a retailer) exclusively served that small fraction of the prescription base that would not have taken advantage of the enhanced generic competition in the but-for world.
32. Based on these considerations, the only plausible inference and my opinion is that, assuming illegal delay in generic competition, all (or nearly all) Class members paid inflated prices for (at least some of) the Aggrenox they purchased during the delay.⁵³

VI. Class-Wide Analysis of Overcharges

33. In my past work, I have analyzed aggregate overcharges associated with delayed generic entry for direct purchaser classes involving the branded products Cardizem,

⁵¹ 75 percent of the branded Aggrenox volume converted to generic Aggrenox in the first six months after generic entry.

⁵² 90 percent as to one prescription, 99 percent for two prescriptions and 99.9 percent for three prescriptions (assuming independence in the probability that each prescriptions would be converted).

⁵³ Having now been involved in dozens of pharmaceutical cases involving generic competition, I have yet to observe anything more than isolated exceptions to this common pattern.


Buspar, Relafen, Remeron, Ovcon, Tricor, Wellbutrin XL, Lidoderm, and Provigil (among others). In all of these cases, I have been able to measure the aggregate overcharge using a class-wide formulaic approach that did not require individual class member analyses. Often, the aggregate overcharge analysis I performed in these cases served as the basis for the court's review and approval of class-wide settlements. My review of the facts in this case reveals nothing to indicate that overcharges will not be similarly susceptible to Class-wide aggregate measurement using evidence that is common to the Class as a whole rather than individual to its members.

34. Overcharges arise from the difference between the prices that Class members actually paid for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid and the prices they would have paid had generic competition not been delayed. Actual prices, purchase volumes can be calculated using manufacturer transaction data. But-for prices and but-for generic substitution patterns must be estimated. As in my past work, the method I would employ for that purpose is the “before/after” method-- i.e., I would use the actual experience following generic entry to model outcomes that would have existed beforehand but for the delay.⁵⁴ In that regard, this “after” period is particularly useful for this purpose because it reflects the same competitors, the same product, and (essentially) the same customers that would have made up the 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid market in the but-for world.
35. As just described, I would model but-for prices for generic Aggrenox by backcasting actual prices following generic entry in June 2015 to the earlier entry date. I would use the pricing outcomes from that period to model outcomes that would have occurred in the but-for world. That is to say, I would use actual generic price discounts relative to brand WAC and essentially shift that experience back to the

⁵⁴ The use of post-conduct (“after”) experience as a benchmark for but-for performance is a widely recognized and utilized method for measuring antitrust damages. See, e.g., ABA Section of Antitrust Law, *Antitrust Law Developments*, 6th edition, 2007, pp. 840-841 (“Several different methodologies have been developed for proving damages. The ‘before and after’ theory compares a plaintiff’s...prices it paid during the period of violation with...prices paid prior to the beginning of the violation period or after its termination.”) (footnotes omitted).

appropriate time in the but-for world. I would set the but-for brand Aggrenox price equal to the actual brand Aggrenox price.

36. But-for quarterly generic substitution rates (generic sales relative to total 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid volume) can be estimated by backcasting the generic substitution rates that occurred after generic entry. I would then combine the but-for mix of generic and brand sales over the course of the overcharge period with the but-for brand and generic prices (calculated as described above) to obtain a but-for average molecule price.
37. With estimates of but-for prices in hand, I would then calculate aggregate Class-wide overcharges by multiplying the differences over time (for as long as such differences would have persisted) between the average price the Class actually paid for 200 mg extended-release dipyridamole/25 mg acetylsalicylic acid (both brand and generic) and the average price the Class would have paid but for the challenged conduct by the corresponding volume of actual purchases. This formulaic approach to Class-wide overcharges does not require individualized analysis of overcharges for each Class member.
- The calculation of actual prices and quantities purchased by the Class will be based upon computerized data. No investigation into Class member records or collection of data from individual Class members is needed.
 - This calculation incorporates single market-wide estimates for generic penetration, generic prices and brand prices in the but-for world. It is not necessary to examine but-for prices or purchase patterns as to individual Class members.
 - The overcharges will be calculated from the brand and generic Aggrenox data jointly and formulaically for all Class members using computer programs.



Jeffrey J. Leitzinger, Ph.D.
September 5, 2017



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EDUCATION

Ph.D., Economics, University of California, Los Angeles
M.A., Economics, University of California, Los Angeles
B.S., Economics, Santa Clara University

WORK EXPERIENCE

Econ One Research, Inc., President, July 1997 to date
Founded *Econ One Research, Inc.*, 1997

Micronomics, Inc., President and CEO, 1994-1997
Micronomics, Inc., Executive Vice President, 1988-1994
Cofounded *Micronomics, Inc.*, 1988

National Economic Research Associates, Inc. 1980-1988
(Last position was Senior Vice President and member of the Board of Directors)

California State University, Northridge, Lecturer, 1979-1980

AREAS OF EXPERTISE

Has offered expert testimony regarding:

- Competition economics
- Commercial damages
- Econometrics and statistics
- Intellectual property
- Valuation

INVITED PRESENTATIONS

Some Implications of Tyson for Econometric Models in Class Action Antitrust Cases, *American Bar Association*, 65th Antitrust Law Spring Meeting, March 2017.

Where Are We on Class Certification? Examples from Health Care and Pharmaceutical Cases, *ABA Section of Antitrust Law, Health Care and Pharmaceuticals and Civil Practice and Procedure and Trial Practice Committees*, March 2016.

Corporations & Cartels: Should You Be a Plaintiff?, *American Bar Association*, 62nd Antitrust Law Spring Meeting, March 2014.

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Class Certification and Calculation of Damages, *American Bar Association*, Section of Antitrust Law and *International Bar Association*, 8th International Cartel Workshop, February 2010.

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Antitrust Injury and the Predominance Requirement in Antitrust Class Actions, *American Bar Association*, Houston Chapter, April 2007.

Class Certification Discussion and Demonstration, *American Bar Association*, Section of Antitrust Law, The Antitrust Litigation Course, October 2005.

What Can an Economist Say About the Presence of Conspiracy?, *American Bar Association*, Antitrust Law, The Antitrust Litigation Course, October 2003.

Lessons from Gas Deregulation, *International Association for Energy Economics*, Houston Chapter, December 2002.

A Retrospective Look at Wholesale Gas Industry Restructuring, *Center for Research in Regulated Industries*, 20th Annual Conference of the Advanced Workshop in Regulation and Competition, May 2001.

The Economic Analysis of Intellectual Property Damages, *American Conference Institute*, 6th National Advanced Forum, January 2001.

Law and Economics of Predatory Pricing Under Federal and State Law, *Golden State Antitrust and Unfair Competition Law Institute*, 8th Annual Meeting, October 2000.

INVITED PRESENTATIONS (cont'd.)

Non-Price Predation--Some New Thinking About Exclusionary Behavior, *Houston Bar Association*, Antitrust and Trade Regulation Section, October 2000.

After the Guilty Plea: Does the Defendant Pay the Price in the Civil Damage Action, *American Bar Association*, Section of Antitrust Law, 48th Annual Spring Meeting, April 2000.

Economics of Restructuring in Gas Distribution, *Center for Research in Regulated Industries*, 12th Annual Western Conference, July 1999.

A Basic Speed Law for the Information Superhighway, *California State Bar Association*, December 1998.

Innovation in Regulation, *Center for Research in Regulated Industries*, 11th Annual Western Conference, July/September 1998.

Electric Industry Deregulation: What Does the Future Hold?, *Los Angeles Headquarters Association*, November 1996.

Why Deregulate Electric Utilities?, *National Association of Regulatory Utility Commissioners*, November 1995.

Restructuring U.S. Power Markets: What Can the Gas Industry's Experience Tell Us?, *National Association of Regulatory Utility Commissioners*, July 1995.

Natural Gas Restructuring: Lessons for Electric Utilities and Regulators, *International Association for Energy Economics*, May 1995.

Techniques in the Direct and Cross-Examination of Economic, Financial, and Damage Experts, *The Antitrust and Trade Regulation Law Section of the State Bar of California and The Los Angeles County Bar Association*, 2nd Annual Golden State Antitrust and Trade Regulation Institute, October 1994.

Demonstration: Deposition of Expert Witnesses and Using Legal Technology, *National Association of Attorneys General*, 1994 Antitrust Training Seminar, September 1994.

Direct and Cross Examination of Financial, Economic, and Damage Experts, *The State Bar of California, Antitrust and Trade Regulation Law Section*, May 1994.

Price Premiums in Gas Purchase Contracts, *International Association for Energy Economics*, October 1992.

Valuing Water Supply Reliability, *Western Economic Association*, Natural Resources Section, July 1992.

INVITED PRESENTATIONS (cont'd.)

Transportation Services After Order 636: "Back to the Future" for Natural Gas, Seminar sponsored by Jones, Day, Reavis & Pogue, May 1992.

The Cost of an Unreliable Water Supply for Southern California, Forum presented by Micronomics, Inc., May 1991.

Market Definition: It's Time for Some "New Learning", *Los Angeles County Bar Association*, Antitrust and Corporate Law Section, December 1989.

Market Definition in Antitrust Cases: Some New Thinking, *Oregon State Bar*, Antitrust Law Section, March 1987.

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REGULATORY SUBMISSIONS

In the Matter of the Application of Southern California Gas Company Regarding Year Six (1999-2000) Under its Experimental Gas Cost Incentive Mechanism and Related Gas Supply Matters; A.00-06-023, Public Utilities Commission of the State of California, November 2001.

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In the Matter of the Application of Sadlerochit Pipeline Company for a Certificate of Public Convenience and Necessity; Docket No. P-96-4, Alaska Public Utilities Commission, May 1996.

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Transcontinental Gas Pipe Line Corporation; Docket No. RS 92-86-000 (Affidavit regarding Transco's Proposed IPS Service), Federal Energy Regulatory Commission, June 1992.

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In the Matter of Natural Gas Pipeline Company of America; Docket No. CP89-1281 (Gas Inventory Charge Proposal), Federal Energy Regulatory Commission, January 1990.

In the Matter of United Gas Pipeline Company, UniSouth, Cypress Pipeline Company; Docket No. CP89-2114-000 (Proposed Certificate of Storage Abandonment by United Gas Pipeline Company), Federal Energy Regulatory Commission, December 1989.

In the Matter of Tennessee Gas Pipeline Company; Docket No. CP89-470 (Gas Inventory Charge Proposal), Federal Energy Regulatory Commission, July 1989.

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Trans-Alaska Pipeline System: Docket Nos. OR 78-1-014 and OR 78-1-016 (Phase 1 Remand), Federal Energy Regulatory Commission, October 1983.

Dr. Jeffrey Leitzinger
 September 2013 – August 2017

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date	On Behalf Of
1. <u>In Re: Wellbutrin XL Antitrust Litigation</u>	U.S. District Court, Eastern District of Pennsylvania	Case No. 2:08-CV-2431	Deposition Hearing Deposition Deposition	March 2010 April 2011 November 2011 November 2014	Plaintiff Plaintiff Plaintiff Plaintiff
2. <u>King Drug Company of Florence, Inc., et al. v. Cephalon, Inc., et al.</u>	U.S. District Court, Eastern District of Pennsylvania	No. 06-CV-1797-MSG	Deposition Deposition Deposition	August 2011 February 2014 July 2014	Plaintiff Plaintiff Plaintiff
3. <u>In Re: Wholesale Grocery Products Antitrust Litigation</u>	U.S. District Court, District of Minnesota	Civil Action No. 09-md-02090-ADM/AJB, 09-md-02090-ADM/TNL	Deposition Hearing Deposition Deposition	December 2011 May 2012 April 2016 March 2017	Plaintiff Plaintiff Plaintiff Plaintiff
4. <u>In Re: AndroGel Antitrust Litigation</u>	U.S. District Court, Northern District of Georgia	Case No. 1:09-MD-2084-TWT	Deposition Deposition Deposition	July 2012 October 2016 July 2017	Plaintiff Plaintiff Plaintiff
5. <u>Astrazeneca AB, Aktiebolaget Hässle, KBI-E Inc., KBI Inc., and Astrazeneca, LP v. Apotex Corp., Apotex Inc. and Torpharm, Inc.</u>	U.S. District Court, Southern District of New York	Civil Action No. 01-CIV-9351 (BSJ)	Deposition Trial	August 2013 November 2013	Defendant Defendant
6. <u>In re: Prograf Antitrust Litigation</u>	U.S. District Court, District of Massachusetts	Case No. 1:11-cv-10344-RWZ	Deposition	November 2013	Plaintiff

Dr. Jeffrey Leitzinger
 September 2013 – August 2017

Proceeding	Court/Commission/Agency	Docket or File	Deposition/Trial/Hearing	Date	On Behalf Of
7. <u>The Shane Group, Inc., et al., v. Blue Cross Blue Shield of Michigan</u>	U.S. District Court, Eastern District of Michigan, Southern Division	No. 2:10-cv-14360-DPH-MKM	Deposition	December 2013	Plaintiff
8. <u>Adriana M. Castro, M.D., P.A. and Sugartown Pediatrics, LLC, et al. v. Sanofi Pasteur, Inc.</u>	U.S. District Court, District of New Jersey	Action No. #11-CV-07178-JLL	Deposition	September 2014	Plaintiff
9. <u>FiTeq Inc. v. Venture Corporation, LTD., and Cebelian Holding PTE, LTD.</u>	U.S. District Court, Northern District of California, San Jose Division	Case No.: C 13-01946 BLF	Deposition	January 2015	Plaintiff
10. <u>Louisiana Wholesale Drug Co., Inc., et al., v. Schering-Plough Corporation; Upsher-Smith Laboratories; and American Home Products Corporation</u>	U.S. District Court, District of New Jersey	MDL No. 1419	Deposition	May 2015	Plaintiff
11. <u>In Re: Rail Freight Surcharge Antitrust Litigation</u>	U.S. District Court, District of Columbia	Case No. 1:07-MC-00489	Deposition Hearing	June 2015 September 2016	Plaintiff Plaintiff
12. <u>In Re: Lidoderm Antitrust Litigation</u>	U.S. District Court, Northern District of California	No. 14-MD-02521-WHO	Deposition Deposition Deposition	July 2016 November 2016 June 2017	Plaintiff Plaintiff Plaintiff
13. <u>Social Ranger, LLC v. Facebook, Inc.</u>	U.S. District Court, District of Delaware	C.A. No. 14-1525-LPS	Deposition	March 2017	Plaintiff

Dr. Jeffrey Leitzinger
 September 2013 – August 2017

Proceeding	Court/Commission/Agency	Docket or File	Deposition/ Trial/Hearing	Date	On Behalf Of
14. <u>UFCW & Employers Benefit Trust, et al., v. Sutter Health, et al.</u>	Superior Court of California, County of San Francisco	No. CGC 14-538451	Deposition Deposition	March 2017 June 2017	Plaintiff Plaintiff
15. <u>Merced Irrigation District v. Barclay's Bank, PLC</u>	U.S. District Court, Southern District of New York	No. 1:15-cv-04878-VM-GWG	Deposition	March 2017	Plaintiff
16. <u>In re: Celebrex (Celecoxib) Antitrust Litigation</u>	U.S. District Court, Eastern District of Virginia, Norfolk Division	Civil Action No. 14-cv-00361	Deposition Hearing	April 2017 June 2017	Plaintiff Plaintiff
17. <u>Sourceone Dental Inc. v. Patterson Companies, et al.</u>	U.S. District Court, Eastern District of New York	Case No. 15-cv-05440	Deposition	July 2017	Plaintiff
18. <u>In Re Solodyn (Minocycline Hydrochloride) Antitrust Litigation</u>	U.S. District Court, District of Massachusetts	MDL No. 14-md-2503-DJC	Deposition	August 2017	Plaintiff

Exhibit 2 List of Class Members

Class Member

1. American Sales
2. Amerisource Bergen
3. ANDA Inc
4. Bellco
5. Burlington Drug
6. Capital Wholesale
7. Cardinal Health
8. Cesar Castillo Inc
9. Dakota Drug
10. Discount Drug Mart
11. DMS Pharmaceutical
12. Drogueria Betances
13. Drogueria Central
14. Drugs Unlimited
15. Express Scripts
16. FMC Distributors
17. Frank W Kerr
18. H. D. Smith Wholesale
19. Harvard Drug
20. Integrated Commercialization Solutions
21. JM Blanco
22. Kaiser
23. King Drug Company of Florence
24. Kinray
25. Louisiana Wholesale
26. McKesson
27. Miami Luken
28. Morris & Dickson
29. North Carolina Mutual Wholesale Drug
30. PBA Health
31. Prescription Supply
32. R & S Northeast
33. RDC
34. Smith Drug
35. Valley Wholesale Drug
36. Value Drug

Note: American Sales is a Class member by assignment.
Source: Manufacturer data.

Exhibit 3 Class Member Locations

