IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUSTLITIGATION

MDL 2724

16-MD-2724

HON. CYNTHIA M. RUFE

IN RE: LEVOTHYROXINE CASES

16-LV-27240

THIS DOCUMENT RELATES TO:

ALL DIRECT PURCHASER ACTIONS

16-LV-27241

Civil Action No.

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated

Plaintiffs,

v.

LANNETT COMPANY, INC., MYLAN PHARMACEUTICALS INC., SANDOZ, INC., and NOVARTIS AG,

Jury Trial Demanded

Defendants.

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("Plaintiff"), brings this Class Action Complaint on behalf of itself and on behalf of a Class of direct purchasers (hereinafter referred to as "Class Members") who purchased generic Levothyroxine products from Defendants Lannett Company, Inc., Mylan Pharmaceuticals, Inc., Sandoz, Inc., and Novartis AG, during the period from June 3, 2014 to the present ("Class Period").

- 2. Plaintiff seeks to recover damages incurred by itself and the Class due to Defendants' and co-conspirators' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an overarching scheme to eliminate competition in the market for generic Levothyroxine and to artificially inflate prices through unlawful agreements.
- 3. As a result of Defendants' anticompetitive scheme, Plaintiff and Class Members paid more for generic Levothyroxine than they otherwise would have paid in the absence of Defendants' unlawful conduct. As set forth below, Defendants' scheme violates the federal antitrust laws and, in particular, Section 1 of the Sherman Act, 15 U.S.C. § 1 ("Sherman Act").
- 4. Plaintiff makes the allegations herein based on personal knowledge of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

- 5. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to foreclose competition in the market for generic Levothyroxine in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for the generic Levothyroxine.
- 6. Plaintiff, on behalf of itself and the proposed Class, seeks redress for the overcharge damages sustained as a result of Defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for generic Levothyroxine.
- 7. Plaintiff's allegations made on behalf of itself and Class Members are based on information made public by Defendants Lannett and Mylan and from government investigations

of alleged unlawful conduct in the generic drug market. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began an in-depth investigation of alleged criminal conduct in the generic drug industry. As a result of the DOJ's investigation, grand jury subpoenas were issued to Defendants Lannett, Mylan and Sandoz.

- 8. Generic Levothyroxine is not the only drug at issue in the DOJ's ongoing investigation.
- 9. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing. The NCPA's news release states,

Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

"Over the last six months I have heard from so many of our members across the U.S. who have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate," NCPA CEO B. Douglas Hoey, RPh, MBA wrote in a letter to the panels' respective leaders, Chairman Tom Harkin (D-Iowa) and Ranking Member Lamar Alexander (R-Tenn.) and Chairman Fred Upton (R-Mich.) and Ranking Member Henry Waxman (D-Calif.).

- 10. NCPA's survey of community pharmacists found the following:
 - 77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price.

¹ News release available at http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

- 86% of pharmacists said it took the pharmacy benefit manager (PBM) or other third-party payer between two and six months to update its reimbursement rate (but not retroactively).
- Patients may be referred to other pharmacies because the community pharmacy could not absorb losses of \$40, \$60, \$100 or more per prescription filled, due to inadequate and/or outdated reimbursement rates.
- 84% of pharmacists said the unsustainable losses per prescription are having a "very significant" impact on their ability to remain in business to continue serving patients.
- 11. In December 2016, the DOJ filed the first criminal indictments to result from the ongoing investigation of the generic drug industry. On December 12 and December 13, 2016, the DOJ filed separate two-count felony indictments in the U.S. District Court for the Eastern District of Pennsylvania against two former executives of Defendant Heritage Pharmaceuticals, Inc. for conspiring to allocate customers and fix the prices of two other generic drugs, doxycycline hyclate and glyburide.
- 12. State Attorneys General are also conducting an ongoing investigation of the generic drug industry. On December 15, 2016, Connecticut Attorney General George Jepsen, along with the Attorney Generals of nineteen other states, filed suit in the U.S. District Court for the District of Connecticut against Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Heritage Pharmaceuticals, Inc., Mayne Pharma (USA), Inc., Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc., for price-fixing of doxycycline hyclate delayed release and glyburide ("the AG Complaint").³ The AG Complaint states claims under Section 1 of the Sherman Act,

² See U.S. v. Glazer, 2:16-cr-00506-RBS (E.D. Pa.) and U.S. v. Malek, 2:16-cr-00508-RBS (E.D. Pa.).

³ See Connecticut et al. v. Aurobindo Pharma USA, Inc. et al, 3:16-cv-02056-VLB (D. Conn.). The plaintiff states include Connecticut, Delaware, Florida, Hawaii, Idaho, Iowa, Kansas,

- 15 U.S. C. § 1, and notes that, "the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time."
- 13. Plaintiff reserves the right to amend its complaint to include additional parties and claims related to the pricing of other generic drugs as new information from the government investigation becomes public.

III. JURISDICTION AND VENUE

- 14. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).
- 15. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22 and 28 U.S.C. § 1391(b) and (c) because during the Class Period, the Defendants transacted business in the United States, including in this District.
- 16. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic Levothyroxine in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.
- 17. This Court has personal jurisdiction over each Defendant because, inter alia, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic Levothyroxine throughout the United States, including in this District; (c) had and maintained substantial contacts with the United

Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, North Dakota, Ohio, Pennsylvania, Virginia, and Washington.

States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic Levothyroxine that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. THE PARTIES

A. PLAINTIFF

18. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH directly purchased generic Levothyroxine from one or more Defendants during the Class Period. For example, KPH's purchased generic Levothyroxine products from Defendant Mylan. As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for generic Levothyroxine and was injured by the illegal conduct alleged herein.

B. DEFENDANTS

- 19. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation with its principal place of business at 9000 State Rd., Philadelphia, PA 19036. During the Class Period, Lannett sold Levothyroxine in this District and throughout the United States.
- 20. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. During the Class Period, Mylan sold Levothyroxine in this District and throughout the United States. Mylan maintains an office in this District at 405 Lexington Avenue, NY, NY 10174.

- 21. Defendant Sandoz, Inc., is a Colorado corporation with its principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz, Inc. is a wholly-owned subsidiary of Defendant Novartis AG. During the Class Period, Sandoz, Inc. sold Levothyroxine in this District and throughout the United States. Sandoz, Inc. manufactures products at locations in Hicksville and Melville, New York. Defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz, Inc. is the U.S. affiliate of Sandoz International GmbH ("Sandoz International"), a German company with its principal place of business in Holzkirchen, Germany. Sandoz, Inc. distributes drugs developed and manufactured by Sandoz International. Sandoz Inc. and Sandoz International operate as the generic pharmaceuticals division of Novartis AG, a pharmaceutical corporation based in Switzerland. During the Class Period, Sandoz marketed and sold generic Levothyroxine to purchasers in this District and throughout the United States.
- 22. Defendant Novartis AG ("Novartis"), is a Swiss multinational pharmaceutical company based in Basel, Switzerland. During the Class Period, through Sandoz, Inc., Novartis sold Levothyroxine to customers in this District and other locations in the United States. Sandoz, Inc. and Novartis are referred to collectively herein as "Sandoz."
- 23. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs.

V. UNIDENTIFIED CO-CONSPIRATORS

24. Various other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged

herein, and have aided, abetted and performed acts and made statements in furtherance of the conspiracy.

- 25. The true names and capacities, whether individual, corporate, associate, or representative, are unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.
- 26. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful monopolization as described herein.
- 27. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

28. Generic drugs typically provide consumers with a lower-cost alternative to brand name drugs while providing the same treatment. Specifically,

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.⁴

⁴ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G

- 29. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."⁵
- 30. Generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)).
- 31. Economic literature in the healthcare market has demonstrated that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand name drug rapidly loses sales, as much as 80% or more by the end of the first year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among

⁵ *Id*.

the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates as more generic options are available to purchasers.⁶

- 32. Generic competition usually enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and/or (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.
- Abbreviated New Drug Application ("ANDA") with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The filing is called "abbreviated" because the ANDA sponsor references data submitted in the approval of the Reference Listed Drug ("RLD") (the brand name drug). "By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart." An ANDA sponsor is generally not required to include clinical trial data to establish the safety and efficacy of the drug. Instead, a generic drug company must show that its generic product is "bioequivalent" to the name brand drug, 8 i.e., the generic product and the brand RLD have the same (i) active ingredient, (ii) maximum amount of drug in the blood at a given time, (iii) total amount of drug in the blood over time, (iv) strength, dosage, dosage form, (v) expected safety and efficacy, and (vi) FDA approval of manufacturing facilities. Upon the FDA's determination that

⁶ See, e.g., Ernst R. Berndt, et al., Authorized Generic Drugs, Price Competition, And Consumers' Welfare, Health Affairs 26, no. 3 (2007):790-799.

⁷ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD.

⁸ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#A.

bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

34. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code ("TE Code"). ⁹ An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations. ¹⁰

B. Consolidation in the Generic Drug Industry

- 35. Since 2005, consolidations in the generic drug industry have affected control of product supply and pricing for consumers.
- 36. For example, Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation for \$7.4 billion in 2006; Barr Laboratories for \$7.4 billion in 2008; Ratiopharm, Germany's second largest generic drug producer, for \$5 billion in 2010, and agreed to acquire Allergan Generics in 2015 for \$40.5 billion. Watson Pharmaceuticals acquired Andrx Corporation in 2006 for \$1.9 billion; Daiichi Sankyo acquired a majority stake in Ranbaxy in 2008; and Endo Pharmaceuticals acquired Qualitest for \$1.2 billion in 2010.
- 37. In July 2012, Sandoz acquired Fougera Pharmaceuticals Inc. for \$1.5 billion. In November 2015, Lannett acquired Kremers Urban Pharmaceuticals Inc. (KU), the U.S. specialty generic pharmaceuticals subsidiary of global biopharmaceuticals company UCB S.A. for \$1.23 billion. In June 2015, Lannett acquired privately held, Silarx Pharmaceuticals, Inc., a manufacturer and marketer of generic pharmaceutical products.

⁹ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#T.

¹⁰ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.

38. Consolidation in the generic drug industry has led to higher prices for consumers and the combining or discontinuation of generic product lines, which contributed to reducing price competition. Mergers within the generic drug industry were a reaction, in part, to the consolidation of distributors. Generic manufacturers then had leverage to charge higher prices if distributors were unable to negotiate lower prices with other generic manufacturers offering therapeutically equivalent drugs.

C. Opportunities for Collusion

- 39. The DOJ is reportedly examining trade associations where Defendants allegedly have opportunities to communicate and collude, such as the Generic Pharmaceutical Association's ("GPhA"). According to an intelligence report from the *Policy and Regulatory Report* ("PaRR"), a source that was given inside information by someone with knowledge of the government's generic pricing investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."
- 40. The GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance. ¹²

http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

¹² In February 2017, the GPhA changed its name to the Association for Accessible Medicines ("AAM"). See Russell Redman, New name for Generic Pharmaceutical Association, CHAIN DRUG REVIEW (Feb. 14, 2017), available at http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/.

- 41. Defendant Sandoz has a representative on GPhA's 2016 Board of Directors. An executive of Mylan N.V. was the 2016 GPhA Chair of the Board of Directors.
- 42. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."¹³
- 43. Generic drug manufacturers attend meetings and various industry trade shows throughout the year, including those hosted by the GPhA, National Association of Chain Drug Stores, Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.¹⁴
- 44. At these meetings and trade shows, generic drug manufacturers have opportunities to discuss and share competitively sensitive information, such as pricing, upcoming bids, and customer contracts.¹⁵
- 45. Many of these conferences and trade shows also include organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors.
- 46. High-level executives of generic drug manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic drug prices were increasing

¹³ http://www.gphaonline.org/about/membership.

¹⁴ See AG Complaint at ¶ 50.

¹⁵ *Id.* at ¶ 51.

exponentially, at least thirteen (13) high-ranking male executives of various generic drug manufacturers met at a steakhouse in Bridgewater, New Jersey. 16

- 47. Female sales representatives for generic drug manufacturers regularly hold meetings and dinners for "Girls Night Out" ("GNO") and Women in the Industry events, where competitively sensitive information is discussed.¹⁷ For example, GNOs were held at the ECRM conference in February 2015, in Baltimore in May 2015, and at the NACDS conference in August 2015.¹⁸
- 48. Many generic drug manufacturers, including two of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, providing them with more opportunities to meet and collude.

D. Generic Levothyroxine Market and Pricing Information

- 49. Levothyroxine, first made in 1927, is a medication used to treat thyroid hormone deficiency and is a manufactured form of thyroxine, a thyroid hormone. Levothryroxine is one of the most widely-prescribed drugs in the U.S. Levothryroxine is classified by the FDA as a Narrow Therapeutic Index drug, which means that even small differences in dosing may cause adverse patient reactions.
- 50. Before November 2013, the price of Levothyroxine was stable. Beginning in November 2013, Defendants caused prices for Levothyroxine products to increase significantly. The price increases were the result of Defendants' agreement to increase pricing and restrain

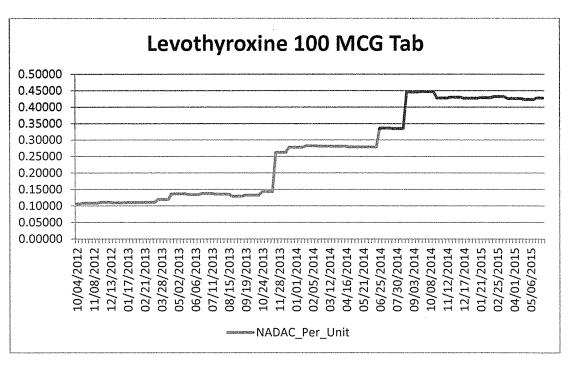
¹⁶ *Id.* at ¶ 55.

¹⁷ *Id.* at ¶ 57.

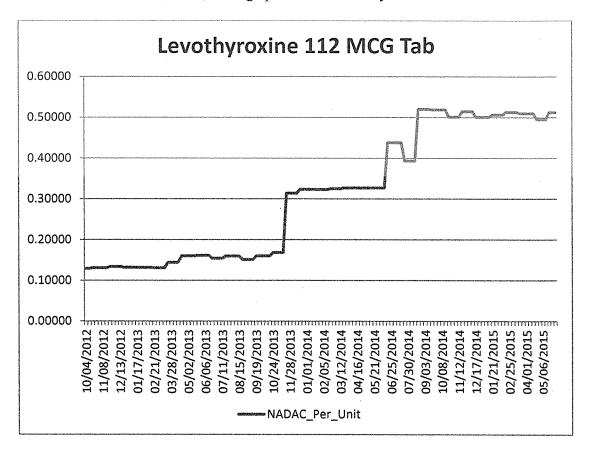
¹⁸ *Id.* at ¶ 60.

competition. Defendants met at least one or more times prior to implementing their price increases, including at GPhA events.

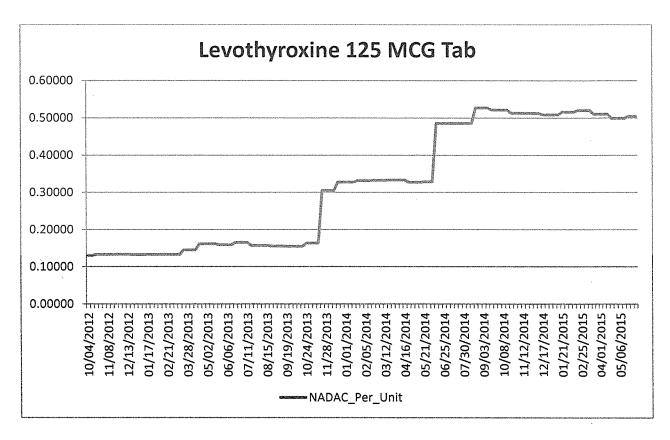
- 51. Defendants each attended the GPhA Fall Technical Conference in Bethesda, Maryland on October 28-30, 2013, and the GPhA annual meeting in Orlando, Florida on February 19, 20 and 21, 2014.
- 52. These meetings provided Defendants with opportunities to collude, along with Defendants' other contacts. On information and belief, Defendants agreed to increase pricing for Levothyroxine at these meetings.
- 53. Shortly after the October 2013 meeting, the average prices for Levothyroxine began to sharply increase. In November 2013 alone, according to NADAC data, each of the twelve available dosage units of Levothyroxine nearly doubled in price. In total, Levothyroxine tablets increased by the following amounts during the Class Period:
 - a. Levothyroxine 100 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 212%.



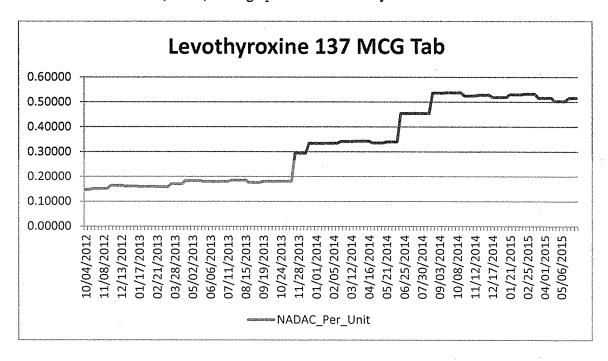
b. Levothyroxine 112 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 208%.



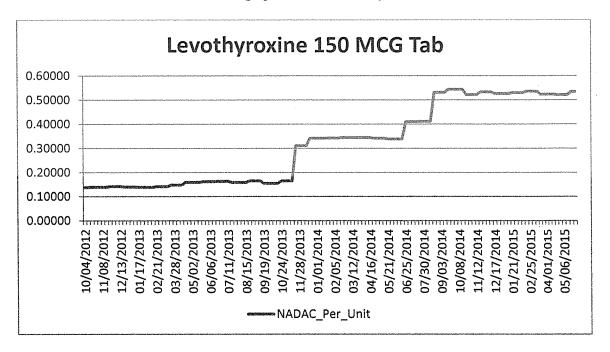
c. Levothyroxine 125 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 219%.



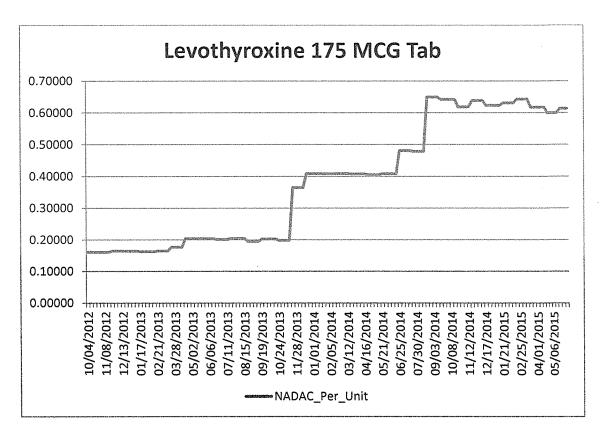
d. Levothyroxine 137 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 197%.



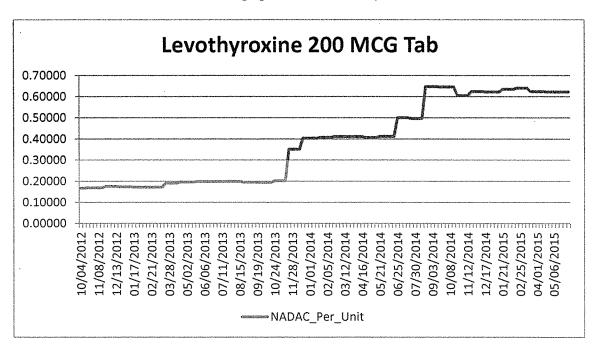
e. Levothyroxine 150 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 231%.



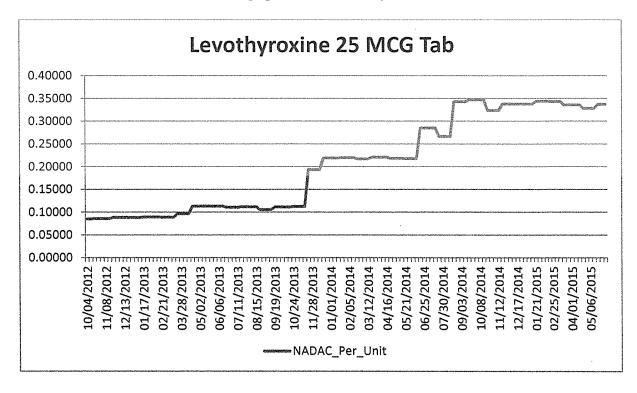
f. Levothyroxine 175 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 224%.



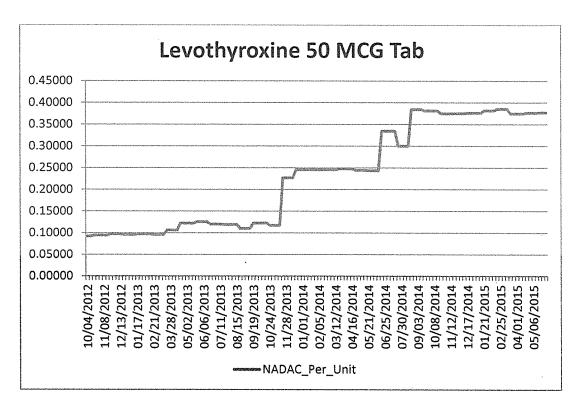
g. Levothyroxine 200 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 220%.



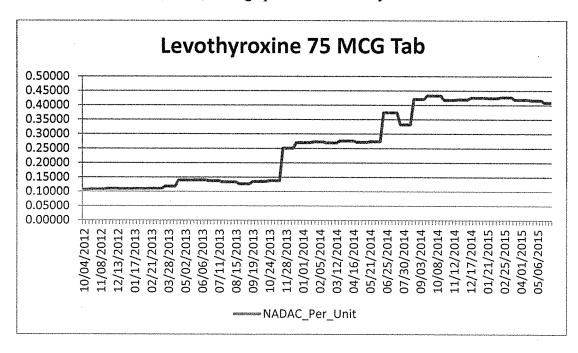
h. **Levothyroxine 25 MCG Tablets**: Between November 14, 2013 and October 15, 2014, average prices increased by 208%.



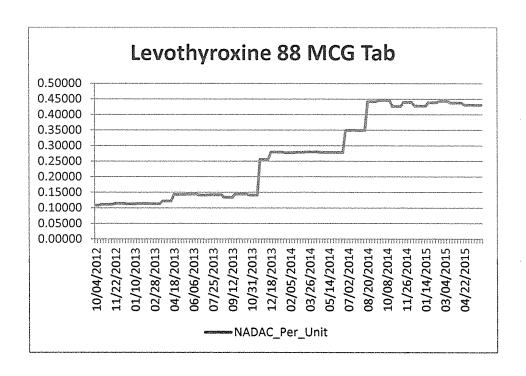
i. Levothyroxine 50 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 225%.



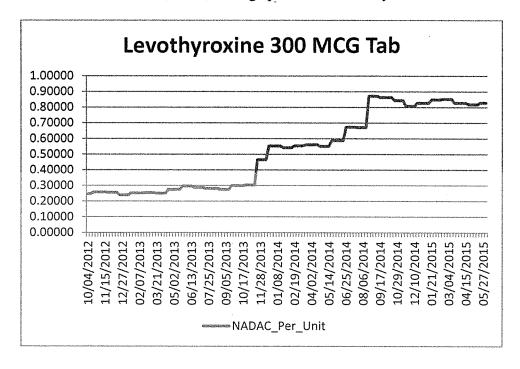
. Levothyroxine 75 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 214%.



k. Levothyroxine 88 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 216%.



 Levothyroxine 300 MCG Tablets: Between November 14, 2013 and October 15, 2014, average prices increased by 185%.



- 54. There were no reasonable justifications for this abrupt shift in pricing, as Defendants' price increases were not necessitated by increased manufacturing costs, or research and development costs. Likewise, there were no shortages of Levothyroxine in the United States.
- 55. Federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons for the shortage, and the expected duration of the shortage. No supply disruption was reported by Defendants with respect to Levothyroxine during the Class Period.
- 56. Consumers have suffered harm due to the supracompetitive prices of Levothyroxine. As noted in letters from members of Congress to generic drug manufacturers as part of a wide investigation into unexplained increases in generic drug prices:

This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients.

57. Supracompetitive generic drug prices also have a detrimental impact on direct purchasers of the drugs:

One factor that squeezed retailers' profit margins was the generic price inflation that roiled the pharmacy market, beginning in 2013 and extending through 2014 into 2015. The sharp price hikes — particularly for single-source generics — increased pressure on pharmacy retailers, who were caught between rising acquisition costs and limits on how much they could raise their own prices at the pharmacy counter. Compounding the squeeze: the frequent failure of MAC (maximum allowable cost)- and AMP (average manufacturer price)- based drug pricing models — and the payers that base their pharmacy reimbursements on

them — to keep pace with the inflationary price spiral for some generics in their reimbursements to pharmacies for the medicines dispensed to their members. 19

58. Similarly, a 2015 white paper published by Elsevier Clinical Solutions noted:

High generic drug prices have had an adverse effect on almost everyone in the pharmaceutical supply chain. Consumers face higher co-pays and prices and health plans are dealing with higher drug spend. Physicians are finding the need to prescribe alternative drug therapies while dealing with angry patients. In some cases, consumers are declining their medications due to increased prices. Many pharmacies are receiving inadequate reimbursements and can lose money when drugs must be purchased at rapidly rising prices but reimbursed at lower predetermined rates.²⁰

- 59. Levothyroxine was a major driver of revenue and profit for Defendants, meaning that their price-fixing scheme had the power to dramatically improve the companies' bottom lines. For example, an October 2013 Roth Capital Partners analyst report noted that "[t]he single largest revenue contributor for Lannett is the levothyroxine franchise, which is currently in an environment with limited generic competition." The price-fixing scheme resulted in increased profits for Lannett. For example, in Lannett's Q2 2014 Earnings Call on February 6, 2014 (just three months after the first sharp price increase), CFO Martin P. Galvan cited Levothyroxine as one of two "key products that are...driving our gross margin from a price increase perspective."
- 60. For Mylan, a much larger company than Lannett, Levothyroxine represented one of the company's top ten generic drugs by revenue throughout the Class Period. According to analyst estimates published by Susquehanna Financial Group, LLLP, Mylan's North America revenues from Levothyroxine sales increased from \$88.7 million in 2012, to \$150 million in 2013, to \$200 million in 2014, to \$300 million in 2015, with \$280 million projected for 2016.

Drug Store News, "Generic Drug Report 2016," available at https://www.drugstorenews.com/sites/drugstorenews.Com/files/GenericReport 2016.pdf.

²⁰ "The Impact of Rising Generic Drug Prices on the U.S. Drug Supply Chain," at pp. 1-2, available at http://www.ncpa.co/pdf/elsevier_wp_genericdrug.pdf.

- 61. In Mylan's Q2 2015 Earnings Call on August 6, 2015, John D. Sheehan, Mylan's Executive VP, Chief Financial & Accounting Officer cited "increased margins on existing [generic] products in North America," and noted "positive pricing in the North America," even as Mylan increased "mid-single-digit price declines in Europe... and low-single-digit price in the rest of world."
 - 62. Currently, the price of Levothyroxine continues to be supracompetitive.
- 63. At all times during the class period, there were at least three or more separate manufacturers of generic Levothyroxine. The active ingredient for the drug product, Levothyroxine sodium, has eight approved holders of active Drug Master Files ("DMF").²¹
- 64. Drug shortage reports for the time period do not list Levothyroxine as being in short supply.²²
- 65. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as shown in the tables, absent anticompetitive conduct.
- 66. There was no commercial justification for the Levothyroxine price hikes. As generic manufacturers, Defendants did not incur the same costs, such as research and development, as brand drug manufacturers in bringing their generic Levothyroxine products to

A Drug Master File, or DMF, is a regulatory document that contains the complete information for an active pharmaceutical ingredient (or API or drug substance), or a finished dosage form (the complete drug product, such as a tablet). The DMF contains information on the drug manufacture, stability, purity, chemistry, packaging and the good manufacturing practices that were used in the processes to make the product that is the subject of the DMF.

²² See FDA Drug Shortages website, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm#P; American Society of Health-System Pharmacists, http://www.ashp.org/shortages.

market. Further, the increased costs were not associated with any related increase in manufacturing costs or supply disruptions.

E. Government Investigations of Generic Drug Industry

- 67. As noted above, defendants' conduct in generic pharmaceutical pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as state government investigations.
- 68. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to fourteen pharmaceutical manufacturers, including defendants Lannett and Mylan, seeking information relating to the escalating prices of generic pharmaceuticals (the "October Letters").
 - 69. The October Letter to Mylan, for example, states,

This dramatic increase in generic prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays..."

70. The October Letters were accompanied by a press release by Senator Sanders and Congressman Cummings, which stated,

"We are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to lifethreatening illnesses," Sanders, chairman of a Senate health care subcommittee,

²³ See Letter from Senator Sanders and Representative Cummings to Heather Bresch, CEO, Mylan, Inc., October 2, 2014, available at https://www.sanders.senate.gov/download/letter-to-mrs-bresch-ceo-mylan-inc?inline=file.

and Cummings, ranking member of the House oversight committee, wrote in letters to 14 pharmaceutical companies.

. . .

Cummings and Sanders cited a survey that found pharmacies across the country "have seen huge upswings in generic drug prices that are hurting patients" and having a "very significant" impact on pharmacists' ability to continue serving patients. The study for the National Community Pharmacists Association also found some patients refused to fill needed prescriptions because of rising prices.

"It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs. Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We've got to get to the bottom of these enormous price increases," Sanders said.

"When you see how much the prices of these drugs have increased just over the past year, it's staggering, and we want to know why," said Cummings. "I am very pleased that Chairman Sanders has joined me in this bicameral investigation because in some cases these outrageous price hikes are preventing patients from getting the drugs they need."²⁴

- 71. The U.S. Senate HELP Committee held a Senate Hearing on November 20, 2014 (Why Are Some Generic Drugs Skyrocketing in Price?). Lannett's CEO, Bedrosian, was invited to testify but did not attend the hearing.²⁵
- 72. During the Senate Hearing on generic pharmaceutical prices, pharmacist Rob Frankil testified on November 20, 2014 that, "it was extremely concerning when about a year

²⁴ Press release, Congress Investigating Why Generic Drug Prices are Skyrocketing, Oct. 2, 2014, available at http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

²⁵ U.S. Senator Bernie Sanders Press Release, *Drugmakers Mum on Huge Price* Hikes (Nov. 20, 2014), *available at* http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs."²⁶

- 73. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter to the Office of the Inspector General ("OIG") of the Department of Health and Human Services asking that the OIG "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs." The OIG responded to the request on April 13, 2015 and stated that it planned to review quarterly average manufacturer prices ["AMPs"] for the top 200 generic drugs from 2005 through 2014, and would "determine the extent to which the quarterly AMPs exceeded the specified inflation factor." The OIG concluded that escalating generic drug prices have cost taxpayers \$1.4 billion in overpayment by Medicaid. In a 2015 budget deal by Congress, legislation requires generic drug manufacturers to pay back the Medicaid program when their prices rise faster than inflation. Later in 2015, Senator Sanders and Representative Cummings proposed comprehensive legislation to address prescription drugs prices.
- 74. Subsequent congressional hearings concerning the dramatic rise of generic pharmaceutical prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, the Director of the Drug

²⁶ Testimony of Rob Frankil, U.S. Senate Hearing, *Why Are Some Generic Drugs Skyrocketing in Price?* (Nov. 20, 2014), *available at* http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

²⁷ http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

²⁸ http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

²⁹ Office of the Inspector General, Average Manufacture Prices increased faster than Inflation for Many Generic Drugs, December 2015, available at https://oig.hhs.gov/oas/reports/region6/61500030.pdf.

Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."

- 75. The DOJ is conducting an ongoing investigation into generic drug pricing. Several leading generic drug manufacturers have been subpoenaed for information, documents and testimony relating to "communication or correspondence with any competitor in the sale of generic prescription medications." Grand jury subpoenas have been issued to, among other generic pharmaceutical companies, Lannett, Lannett's Vice-President of Sales and Marketing, Mylan, and Sandoz. Upon information and belief, Lannett's Vice-President of Sales and Marketing is Kevin Smith.
- 76. In July 2014, Lannett reported that it and "at least one of its competitors" received a subpoena and interrogatories from the Connecticut Attorney General's Office concerning its investigation into the pricing of another generic drug, digoxin. According to Lannett's 2014 Annual Report, the Connecticut Attorney General was "investigating whether anyone engaged in any activities that resulted in (a) fixing, maintaining or controlling prices of digoxin or (b) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law."
- 77. Lannett's 10-Q report dated February 6, 2015, discloses that on November 3, 2014, "the Senior Vice-President of Sales and Marketing was served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations

³⁰ See Impax Laboratories, Inc., Form 8-K, November 3, 2014.

of the Sherman Act," and that on December 5, 2014, "[t]he Company was served with a grand jury subpoena related to the federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products."

- 78. Lannett similarly disclosed in its annual report for fiscal year ending June 30, 2015, that it was served with a grand jury subpoena for documents relating to communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.
- 79. Lannett also reported that "Levothyroxine Sodium and Digoxin collectively accounted for 50% of our net sales in fiscal year 2015."
- 80. Mylan N.V., parent company to Mylan Pharmaceuticals, Inc., reported on February 16, 2016 in its 10-K that, "[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company's generic products and communications with competitors about such products." On October 7, 2016, Defendant Mylan disclosed that the DOJ subpoenaed a Mylan subsidiary, a senior executive, and other employees about alleged price fixing and that the DOJ had executed multiple search warrants. The DOJ sought additional information relating to the marketing, pricing and sale of generic drugs, documents relating to generic pharmaceutical products and pricing, and communications with competitors and others regarding the sale of generic pharmaceutical products.

- 81. Defendant Sandoz received a DOJ subpoena in March 2016 relating to the industry-wide investigation into generic drug pricing.
- 82. The fact that grand jury subpoenas were served on defendants is indicative that they have potentially violated antitrust law. According to the DOJ's *Antitrust Division Manual*, "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." If a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]." The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." Then, "[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."
- 83. As discussed above, the first indictments to result from the DOJ's investigation of the generic drug industry were filed in the Eastern District of Pennsylvania in December 2016 against former executives of Heritage Pharmaceuticals, Inc., Jeffrey A. Glazer and Jason T.

³¹ See Antitrust Division Manual, Chapter III, Section F.1 at III-82 (Apr. 2015), available at https://www.justice.gov/atr/division-manual.

³² *Id*.

³³ *Id.* at III-83.

³⁴ *Id*.

Malek. Glazer and Malek pleaded guilty to violating Section 1 of the Sherman Act in January 2017.

- 84. Further, as a result of the Connecticut Attorney General's two-year investigation of the generic drug industry, the AG Complaint was filed in December 2016 and provides additional details on anticompetitive conduct in certain generic drug markets. According to the AG Complaint, "[i]n July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that investigation, which is still ongoing, uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States."
- 85. One of the targets of the DOJ investigation has reportedly applied for leniency. This is significant because the applicant must admit to participation in a criminal antitrust violation. As the DOJ notes on its web site:
 - 5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?

Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.³⁶

³⁵ See AG Complaint at ¶ 1.

³⁶ Frequently Asked Questions Regarding the Antitrust Division's Leniency Program, Dept. of Justice (last visited Jan. 24, 2017), *available at* http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program

- 86. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials."³⁷
- 87. DOJ and state government investigations of Defendants' alleged price-fixing conduct in the generic pharmaceutical industry continue.

F. Order Denying Motion to Dismiss in Propranolol Antitrust Litigation

- 88. In another generic drug price-fixing case, *In re: Propranolol Antitrust Litigation*, the U.S. District Court for the Southern District of New York entered an Opinion and Order on April 6, 2017 denying a motion to dismiss direct purchasers' consolidated amended complaint. *See In re Propranolol Antitrust Litig.*, No. 16-cv-9901, -- F.3d --, 2017 WL 1287515 (S.D.N.Y. Apr. 6, 2017) (Rakoff, J.) ("Propranolol Order"). Plaintiffs in the *Propanolol* case alleged a conspiracy among generic manufacturers to manipulate the market for generic propranolol, with facts similar to those alleged herein for the generic Levothyroxine market. Defendant Mylan is also named as a defendant in the *Propanolol* case.
- 89. In denying the defendants' motion to dismiss, Judge Rakoff found that *Propranolol* plaintiffs pled a plausible price-fixing conspiracy and that plaintiffs alleged market specific factors suggesting that defendants had an incentive to manipulate prices. *See* Propranolol Order at 11, 13, 24. Judge Rakoff noted that Plaintiffs' pleadings "set forth in detail a regulatory regime that has historically pushed the price of Propranolol downwards and

³⁷ *Id*.

³⁸ The *Propranolol* defendants are Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Par Pharmaceutical, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceutical, Inc., and Upsher-Smith Laboratories, Inc.

gradually reduced defendants' profits, thereby giving them a common motive to conspire." *Id.* at 13. Further, Judge Rakoff found that plaintiffs' pleadings "allege a pattern of price fixing spanning several years and no clear mechanism through which the defendants could legitimately and consistently monitor each other's pricing activity." *Id.* at 15-16.

- 90. The *Propranolol* plaintiffs alleged the presence of four plus factors to plausibly establish that the defendants conspired to fix prices of Propranolol capsules and tablets in 2013 and 2015: "(1) defendants had a motive to increase prices because they operate in an oligopolistic market characterized by falling prices; (2) the price increases were against defendants' self-interest because in a competitive market, defendants should have tried to undercut each other's prices to increase their market share; (3) defendants frequently communicated at trade association meetings; and (4) there are ongoing state and federal investigations for price manipulation of generic drugs, including Propranolol." *Id.* at 10-11, 24.
 - 91. As alleged herein, the same plus factors exist in the market for Levothyroxine.
- 92. Judge Rakoff rejected defendants' explanations for Propranolol price increases. For example, "plaintiffs plausibly allege that because the FDA did not report a shortage of Propranolol capsules following Mylan's exit, there was no 'shift' in the total supply of Propranolol that would rationally increase prices." *Id.* at 17. In addition, "while it is true that defendants' price increases did not always align on a monthly basis, defendants consistently raised prices on a bi-monthly and quarterly basis, which is consistent with an illegal agreement." *Id.* (emphasis in original). Similar price increases for Levothyroxine are shown in this complaint. *See infra*.

G. In re: Generic Pharmaceuticals Pricing Antitrust Litigation

- 93. On April 6, 2017, the U.S. Judicial Panel on Multidistrict Litigation entered a Transfer Order granting Rochester Drug Cooperative, Inc.'s motion to transfer ten generic drug price-fixing actions to the Eastern District of Pennsylvania for inclusion in *In re: Generic Digoxin and Doxycycline Antitrust Litigation*, MDL No. 2724 (E.D. Pa.). The MDL was renamed *In re: Generic Pharmaceuticals Pricing Antitrust Litigation* and now includes price-fixing allegations for eighteen generic drugs: (1) Doxycycline, (2) Digoxin, (3) Albuterol, (4) Clomipramine, (5) Desonide, (6) Pravastatin, (7) Divalproex, (8) Benazepril HCTZ, (9) Levothyroxine, (10) Propranolol, (11) Baclofen, (12) Glyburide, (13) Ursodiol, (14) Amitriptyline, (15) Lidocaine/Prilocaine, (16) Clobetasol, (17) Fluocinonide, and (18) Econazole.
- 94. This case has been filed as a related case to *In re Generic Pharmaceuticals*Pricing Antitrust Litigation, MDL No. 2724.

VII. THE LEVOTHYROXINE MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

- 95. The factors necessary to show that a market is susceptible to collusion are present in this case:
 - (1) **High Degree of Industry Concentration** As discussed above, a small number of competitors control a significant market share for generic Levothyroxine, following consolidation in the industry. A concentrated market is more susceptible to collusion and other anticompetitive practices. The Levothyroxine market is highly concentrated and is dominated primarily by only three companies. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.
 - (2) **Barriers to Entry** Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. For example, while ANDAs are generally approved faster than NDAs, they may still take longer than a year to obtain approval and a majority of ANDAs are rejected. Barriers to entry increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supra-competitive prices. As the dominant players in the Levothyroxine market, Defendants were able to fix, raise, and

- maintain their prices for Levothyroxine without competitive threats from rival generic drug manufacturers.
- (3) **Demand Inelasticity** Generic Levothyroxine is necessary treatment for millions of patients. If a price change triggers a smaller proportionate change in quantity of the drug demanded, then the demand for the drug is said to be inelastic. If demand is inelastic, price increases result in limited declines in quantity sold or consumed in the market. For a cartel to profit from supracompetitive prices, demand must be inelastic at competitive prices such that cartel members are able to raise prices without triggering a decline in demand that would make a concerted price increase unprofitable. Demand for Levotyhroxine is highly inelastic because it is a unique product for which there is no reasonable substitute. Levothyroxine is a necessary treatment for millions of patients for which no substitutes are available. Levothyroxine is thus particularly susceptible to collusive price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.
- (4) Lack of Substitutes Patients are often unable to substitute other medications for generic Levothyroxine. Levothyroxine is often the only effective medicine for patients with thyroid hormone deficiency.
- (5) **High Degree of Interchangeability** Levothyroxine is a commodity product. Defendants' generic Levothyroxine products are interchangeable as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. Thus, generic Levothyroxine is standardized across suppliers and is highly interchangeable from one Defendant to the next. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, all Defendants had to raise prices for the cartel to work. Indeed, it was against a Defendant's individual economic interest to raise prices since the other Defendants could have priced below that Defendant's price and taken substantial market share.
- (6) Opportunities for Contact and Communication Among Competitors Defendants are members of the trade association GPhA, and attend other industry events and meetings, which provides opportunities to communicate. Defendants' representatives regularly attended meetings of GPhA, including the October 2013 meeting and meetings of other trade associations during the Class Period. Indeed, the DOJ is reportedly analyzing trade associations like GPhA as a potential avenue for facilitating collusion between different generic drug manufacturers as part of its years-long investigation into anticompetitive pricing activities among them.
- 96. Defendants' dominant market power has allowed them to substantially foreclose the market to rival competition, thereby impairing competition, maintaining and enhancing

market power, and enabling Defendants to charge Plaintiff and the Class Members inflated prices above competitive levels for generic Levothyroxine.

- 97. Levothyroxine is a commodity product. Therefore, absent a cartel, if any manufacturer increased the price of Levothyroxine, it would be expected that its competitors would not increase the price but would seek to sell more Levothyroxine to the first manufacturer's customers. Accordingly, it would not be in any manufacturer's unilateral self-interest to increase the price of the Levothyroxine it sold unless it had an agreement with the other manufacturers that they would do the same.
- 98. During the Class Period, there was no significant increase in the costs of making Levothyroxine and no significant increase in demand. Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Levothyroxine. Such price increases in a commodity product for which there were no significant increases in costs or demand would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

VIII. CLASS ACTION ALLEGATIONS

99. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf of a class defined as follows:

All persons or entities that directly purchased generic Levothyroxine: from Defendants in the United States and its territories and possessions at any time during the period November 21, 2013 through the present (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

100. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds of Class Members, geographically dispersed throughout the

United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by Defendants

- 101. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.
- 102. Plaintiff will fairly and adequately protect and represent the interests of the Class.

 The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.
- 103. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.
- 104. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.
- 105. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, include, but are not limited to, the following:
 - (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of Levothyroxine in the United States;
 - (b) The duration and extent of the alleged contract, combination, or conspiracy:

- (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
- (d) The effect of the contract, combination, or conspiracy on the prices of Levothyroxine in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for Levothyroxine;
- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and
- (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 106. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.
- 107. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. INTERSTATE TRADE AND COMMERCE

- 108. Defendants are the leading manufacturers and suppliers of Levothyroxine sold in the United States.
- 109. Levothyroxine is produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

- 110. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Levothyroxine throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.
- 111. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.
- 112. Defendants' and their co-conspirators' conduct, including the marketing and sale of Levothyroxine, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.
- 113. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Levothyroxine within the United States.
- 114. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Levothyroxine, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Levothyroxine prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

X. DEFENDANTS' ANTITRUST VIOLATIONS

- 115. Defendants' combination and conspiracy had the following anticompetitive effects in the market for generic Levothyroxine:
 - (a) Competition in the market for generic Levothyroxine has been reduced;
 - (b) Prices for generic Levothyroxine have increased and have not followed the typical pricing patterns of generic drugs over time; and

- (c) U.S. purchasers have been deprived of the benefit of price competition in the market for generic Levothyroxine.
- 116. During the Class Period, Plaintiff and Class Members directly purchased generic Levothyroxine from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for generic Levothyroxine than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.
- 117. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.
- 118. Defendants' misconduct reduced competition in the generic Levothyroxine market, reduced choice for purchasers, and caused injury to purchasers.
- 119. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic Levothyroxine.

XI. CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

- 120. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.
- 121. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

- 122. Defendants' anticompetitive acts were intentional, were directed at the sales of Levothyroxine in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Levothyroxine prices throughout the United States.
- 123. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:
 - a. Prices charged to, and paid by, Plaintiff for Levothyroxine were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
 - b. Plaintiff was deprived of the benefits of free, open, and unrestricted competition in the sale of Levothyroxine in the United States market; and
 - c. Competition in establishing the prices paid for Levothyroxine was unlawfully restrained, suppressed, or eliminated.
- 124. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.
- 125. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of generic Levothyroxine in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.
- 126. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.
- 127. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic Levothyroxine, as described herein.

- 128. Defendants' and their co-conspirators' anticompetitive activities directly and proximately caused injury to Plaintiff in the United States. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff paid artificially inflated prices for Levothyroxine.
- 129. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic Levothyroxine than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.
- 130. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

- A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;
- B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of the violations;
- C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;
- D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the complaint in this action;

- F. The costs of this suit, including reasonable attorney fees; and
- G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: June 6, 2017

Dianne M. Nast

NastLaw LLC

1101 Market Street

Suite 2801

Philadelphia, Pennsylvania 19107

Telephone: (215) 923-9300 Facsimile: (215) 923-9302 Email: dnast@nastlaw.com

Michael L. Roberts ROBERTS LAW FIRM, P.A. 20 Rahling Circle Little Rock, AR 72223

Telephone: (501) 821-5575 Facsimile: (501) 821-4474

Email: mikeroberts@robertslawfirm.us

RECEIPT# ____ AMOUNT ____ APPLYING IFP ____ JUDGE ____ MAG. JUDGE _____

FOR OFFICE USE ONLY

Case 217-cv-02554-CMR Document 1-1 Filed 06/06/17 Page 2 of 4

UNITED STATES DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be assignment to appropriate calendar.	
Address of Plaintiff: 520 East Main Street, Gouverneur,	NY 13642
Address of Defendant: See attached sheet	
Place of Accident, Incident or Transaction: nationwide	
(Use Reverse Side For A	dditional Space)
Does this civil action involve a nongovernmental corporate party with any parent corporation at (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. X 1(a))	/
Does this case involve multidistrict litigation possibilities? RELATED CASE, IF ANY: Case Number: 16-MD-2724 Judge Cynthia M. Rufe 16-LV-2724, 16-LV-27241 Civil cases are deemed related when yes is answered to any of the following questions:	Date Terminated:
1. Is this case related to property included in an earlier numbered suit pending or within one year. 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior staction in this court?	Yes□ No☒ uit pending or within one year previously terminated
B. Does this case involve the validity or infringement of a patent already in suit or any earlier not terminated action in this court? B. Is this case a second or successive habeas corpus, social security appeal, or pro se civil right.	Yes□ No [[
	Yes□ NoX
CIVIL: (Place 🗸 in ONE CATEGORY ONLY)	
A. Federal Question Cases:	B. Diversity Jurisdiction Cases:
1. Indemnity Contract, Marine Contract, and All Other Contracts	1. □ Insurance Contract and Other Contracts
≥ □ FELA	2. Airplane Personal Injury
3. □ Jones Act-Personal Injury	3. □ Assault, Defamation
4. Antitrust	4. □ Marine Personal Injury
5/ Patent	5. Motor Vehicle Personal Injury
6. D Labor-Management Relations	6. □ Other Personal Injury (Please specify)
7. 🗆 🗗 ivil Rights	7. Products Liability
8. Habeas Corpus	8. Products Liability — Asbestos
9. □ Securities Act(s) Cases	9. □ All other Diversity Cases
10. □ Social Security Review Cases	(Please specify)
11. □ All other Federal Question Cases (Please specify)	
	tegory)
\$ 150,000.00 exclusive of interest and costs; Relief other than monetary damages is souther	

\$550,000.00 exclusive of interest and concern Rule of Relief other than monetary dama		PA 24424	ine sum or
DATE: 6//6/201/	Attorney-at-Law	PA 24424 Attorney I.D.#	
I certify that, to my knowledge, the we except as noted above.	rithin case is not related to any case now pending or within or		_ 2017
• , •	rithin case is not related to any case now pending or within or Attomey-at-Law	Le year previously terminated action in this court JUN - 6 Attorney I.D.#	



Attachment to Designation Form

Addresses of Defendants

Lannett Company, Inc. 9000 State Rd. Philadelphia, PA 19036

Mylan Pharmaceuticals, Inc. 781 Chestnut Ridge Road Morgantown, West Virginia 26505

Sandoz, Inc. 100 College Road West Princeton, NY 08540

Novartis AG Forum 1 Novartis Campus CH-4056 Basel Switzerland



IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Telephone	FAX Numl	per	E-Mail Address	
215-923-9300	215-923-93	02	dnast@nastlaw.com	
Date	Attorney-at	-law	Attorney for	
5/6/2017	Mari	uh. Na	Maintiff	
(f) Standard Management -	- Cases that do not	fall into any one	of the other tracks.	$\langle \langle \rangle$
(e) Special Management – commonly referred to a the court. (See reverse management cases.)	s complex and that	need special or in	ntense management by	(x)
 d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. 			()	
c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2.				()
 Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. 				()
(a) Habeas Corpus – Cases	brought under 28	U.S.C. § 2241 thr	rough § 2255.	()
SELECT ONE OF THE F	OLLOWING CA	SE MANAGEM	ENT TRACKS:	
In accordance with the Civplaintiff shall complete a Cifiling the complaint and servide of this form.) In the designation, that defendant	ase Management To a copy on all deferent that a defend shall, with its first arties, a Case Management To a control of the con	Track Designation endants. (See § 1: dant does not ago appearance, subnagement Track De	ction Plan of this court, counse Form in all civil cases at the tir 03 of the plan set forth on the re- ree with the plaintiff regarding nit to the clerk of court and serves esignation Form specifying the	ne of verse said ve on
Lannett Company, I et al.	110.,	:	NO.	
- V.		: :		
KPH Healthcare Ser d/b/a Kinney Drugs	•	:	CIVIL ACTION	2

(Civ. 660) 10/02