

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE THALOMID AND REVLIMID  
ANTITRUST LITIGATION**

**Civil Action No. 14-6997**

**OPINION**

**ARLEO, UNITED STATES DISTRICT JUDGE**

**THIS MATTER** is before the Court by way of Class Plaintiffs International Union of Bricklayers and Allied Craft Workers Local Health Fund (“IUB”), International Union of Operating Engineers Local 39 Health and Welfare Trust Fund (“Local 39”), The Detectives’ Endowment Association, Inc. (“DEA”), David Mitchell (“Mitchell”), City of Providence, and New England Carpenters Health Benefits Fund’s (“NEC” and, collectively, “Plaintiffs”) Motion for Class Certification and Appointment of Class Counsel. ECF No. 149. Defendant Celgene Corporation (“Defendant” or “Celgene”) opposes the motion. ECF No. 182.

To summarize, this motion seeks to certify a class of consumers and third parties that were allegedly overcharged because Defendant delayed entry of generic versions of its branded drugs onto the market. The crux of Defendant’s argument against certification is that the complicated purchasing relationships in the pharmaceutical industry render it impossible to either ascertain membership in the proposed classes or prove that common issues predominate. Plaintiffs contend that the obstacles to certification raised by Defendant are speculative and hypothetical and that there is abundant proof of class membership and common injury. Nevertheless, the Court agrees with Defendant that Plaintiffs have not, at this point, carried their burden with regard to

certification. The Court does not find that the concerns raised by Defendant are so pervasive as to render certification impossible, assuming Plaintiffs can address the issues discussed herein. Consequently, the Court will **DENY** the motion without prejudice to renew with appropriate supplementation.

## **I. BACKGROUND**

The Court discussed in detail the extensive factual allegations involved in this case when it denied Defendant's motion to dismiss. ECF Nos. 67, 68. In brief, this case involves claims that Celgene delayed the entry of generic versions of the drugs Thalomid and Revlimid—the generic names are thalidomide and lenalidomide, respectively—by listing and suing to enforce invalid patents, refusing to sell samples necessary to develop generics, and encouraging the FDA to reject generic applications based on sham safety concerns. Plaintiffs contend that these anticompetitive actions allowed Celgene to successfully monopolize the market for thalidomide based drugs for seven years, charge supracompetitive prices, and prevent the entry of generic manufacturers into the market. Plaintiffs further contend that these actions unjustly enriched Celgene by \$5.8 billion in profits.

As a result of Celgene's alleged behavior, Plaintiffs seek certification of three classes: (1) the "Antitrust/Consumer Protection Damages Class" under Federal Rule of Civil Procedure 23(b)(3), (2) the "Unjust Enrichment Damages Class" under Rule 23(b)(3), and (3) the "Injunction Class" under Rule 23(b)(2). Defendants oppose certification of all three classes, contending that (1) neither of the damages classes are ascertainable, that (2) Plaintiffs cannot demonstrate predominance, that (3) Plaintiff Mitchell does not satisfy the adequacy or typicality requirements of Rule 23(A), and (4) that the injunction class cannot be certified because the relief sought is primarily monetary.

### **A. Class Definition**

Plaintiffs seek certification of the following Classes:

The “Antitrust/Consumer Protection Damages Class” (under Rule 23(b)(3)):

All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after December 28, 2012, in California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, or Tennessee, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

The “Unjust Enrichment Damages Class” (under Rule 23(b)(3)):

All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after December 28, 2012, in California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, or Tennessee, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the “Unjust Enrichment Damages Class”).

The “Injunction Class” (under Rule 23(b)(2)):

All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after December 28, 2012, in the United States or its territories for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the “Injunction Class”).

Pl. Reply Br. in Support of Certification, ECF No. 210.

Excluded from the class are the following persons or entities:

- a. Defendant and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. Government entities, except for government-funded employee benefit plans;
- c. All persons or entities who purchased Revlimid or Thalomid for purposes of resale or directly from Defendant or their affiliates;
- d. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan’s reimbursement obligations to

its members);

e. “Single flat co-pay” consumers who purchased Revlimid or Thalomid only via a fixed dollar co-payment that does not vary on the basis of the purchased drug’s status as branded or generic (e.g., \$20 for both branded and generic drugs);

f. Pharmacy benefit managers;

g. Stop-loss insurers;<sup>1</sup>

h. The judges in this case and any members of their immediate families.

Id.

## **B. Expert Reports**

### **1. Luis Molina**

Plaintiffs submitted the expert report of Luis Molina, a professional in the pharmaceutical injury with experience in product launches of brand and generic drugs. Molina opined on whether Celgene prevented or delayed the entry of generic drugs that would have competed with Thalomid and Revlimid and on the timeframe in which generic equivalents to the drugs would have become available to classmembers. Report of Luis A. Molina (“Molina Rep.”) ¶11, ECF No. 150.16. He concluded that Celgene’s action prevented generic equivalents from entering the market, that, absent Celgene’s actions, a generic version of Thalomid would have been available beginning in November 2010, and that, absent Celgene’s conduct, a generic version of Revlimid would have been available by January 2011. Molina Rep. ¶ 12. Molina subsequently provided a Supplement to his report, wherein he predicted that generic Revlimid would have been available December 2012, rather than January 2011. ECF No. 169.

### **2. Dr. Leitzinger**

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<sup>1</sup> The exclusion for stop-loss insurers, along with pharmacy benefit managers, was not included in Plaintiffs’ original class definition; rather, it was proposed in Plaintiffs’ reply brief in support of their motion for class certification.

Plaintiffs also submitted the expert report of Dr. Jeffery J. Leitzinger in support of their motion for class certification. Expert Report of Jeffery J. Leitzinger (“Leitzinger Rep.”), ECF No. 150.17. Plaintiffs posit that Dr. Leitzinger’s methodology for measuring antitrust impact and aggregate damages demonstrate that the elements of Plaintiffs’ claims can be satisfied through proof at trial that is common to the class.

Dr. Leitzinger first opines that class members suffered common antitrust impact. He asserts that “the price benefits associated with . . . generic competition are predictable, substantial, and market-wide” and “[c]onduct that illegally delays, limits or altogether blocks that competition therefore would cause average prices paid by end-payors (members of the proposed Classes in this case) for Thalomid and Revlimid to be much higher than otherwise.” Id. ¶ 10. Dr. Leitzinger asserts that evidence common to the members of the Class shows that the “absence of generic alternatives . . . has likely caused 90 percent (or more) of the proposed Class members, collectively accounting for over 99 percent of the payments for these drugs within each Class, to incur at least some overcharge.” Id. The common evidence is comprised of “i) literature and prior studies . . . ; ii) forecasts prepared by Celgene, Mylan, and Watson . . . ; and iii) the actual experience of other orally administered cancer drugs and REMS drugs once generics entered the market.” Id. ¶ 16.

Dr. Leitzinger next opines that the classwide damages sought by Plaintiffs are “readily susceptible to formulaic calculation and do not require individualized analysis of Class members.” Id. ¶ 62. Dr. Leitzinger’s methodology for determining classwide damages involves analyzing the amounts charged to Plaintiffs for Revlimid and Thalomid and comparing it to the amounts Plaintiffs would have been charged in the but-for world—that is, the world absent the allegedly anticompetitive conduct in which there is generic competition. Id. ¶¶ 44-45. Dr. Leitzinger also considers the profits gained by Defendant during the period of delayed entry and compares them

to the profits Defendant would have realized in the but-for world. Id. ¶ 58. The difference between these two figures is Dr. Leitzinger’s measurement of Defendants’ unjust enrichment. Id. ¶ 61.

To arrive at his calculation of classwide damages, Dr. Leitzinger considered estimates of “[a]ctual sales and prices for Thalomid and Revlimid,” “[g]eneric penetration rates that would have occurred absent the exclusion,” “[g]eneric price discounts that would have resulted from generic entry and competition,” and “[i]ncremental profit rates on sales of the two brand drugs protected by the generic exclusion.” Id. ¶ 62. Dr. Leitzinger contends that these estimates can be determined without individualized inquiry. Id. Actual sales and prices “can be estimated from pharmacy-level electronic data and Celgene’s electronic transaction data.” Id. ¶ 63. Generic penetration rates can be derived, in part, from the “market outcomes associated with other orally administered cancer drugs that faced generic competition.” Id. Revenues and incremental profit margins can be estimated from Celgene’s financial records. And, finally, the overall calculation of damages “under both theories” is performed “through a set of computer programs and instructions applied to the data jointly and formulaically as to all Class members.” Id.

### **3. Dr. Hughes**

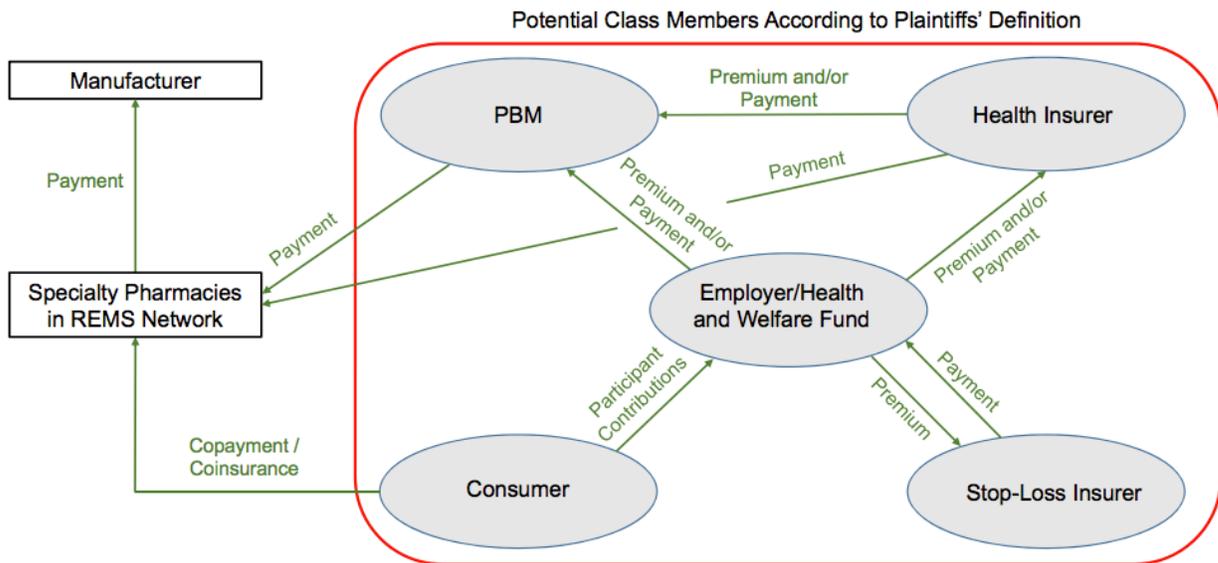
Defendants retained their own expert, Dr. James Hughes, who submitted an expert report regarding the obstacles to class-wide resolution. Expert Report of James W. Hughes (“Hughes Rep.”), ECF No. 182.4, Ex. 1. In sum, Dr. Hughes concludes that substantial individualized inquiry is necessary because of the significant variations throughout the pharmaceutical industry.

Dr. Hughes opines that “putative class membership, incidence of injury, and damages cannot be reliably determined on a class-wide basis using common proof.” Id. ¶ 46. He reasons that “for any given Thalomid® or Revlimid® transaction, there are a number of different individuals and entities involved who may have made a payment and may potentially claim

putative Class membership because of that payment”; yet, “determining the actual size of the payment made by each putative Class members and what the size of the payment would have been in Plaintiffs’ but-for world with generic versions on the market is a complicated task.” Id. In his view, it is complicated because it “requires disentangling a series of complex, changing, and idiosyncratic relationships between putative Class members and non-Class members.” Id. Consequently, “detailed individualized inquiry is the only way to determine reliably putative Class membership, incidence of injury, and damages.” Id.

To explain why the relationships among Class members and non-Class member are complicated, Dr. Hughes identifies the various entities involved in prescription drug markets. These include consumers, pharmacy benefits managers (“PBM”), insurers, and health and welfare plans. Dr. Hughes also describes the “payment flows” for prescription drugs, which includes uninsured and insured individuals as well as third party payors. Individuals who purchase drugs without health insurance pay for the entire cost of the drug, either directly to the manufacturer or indirectly through a wholesaler. Id. ¶ 15. Insured individuals, however, are part of a complex structure of payments. Third party payors (“TPPs”) will pay a portion of the price, typically leaving the insured with a co-pay. Id. ¶ 16. Dr. Hughes contends that determining who paid a portion of the price is varied and requires consideration of each individual contract between the TPPs. Id. ¶ 18. He provides the following chart to demonstrate the flow of payment.

### Payment Flows for Thalomid® or Revlimid® for an Insured Consumer



Hughes Rep., Ex. 1. Dr. Hughes goes on to discuss each of the entities described in the chart and their potential payments in detail.

A plan sponsor is an employer, a union, or another type of employee organization that makes health benefits available to its employees or members and their families. Hughes Rep. ¶ 19. Plan sponsors either enter into a fully insured contract or a self-insured contract, or a hybrid of the two. *Id.* ¶ 20. Under a fully insured contract, the sponsor pays premiums to a health insurer, which in turn covers certain health expenditures of the sponsor's insured members during the contract period. *Id.* ¶ 20. Plan sponsors with fully insured contract are excluded from the putative Classes because the plan sponsor does not directly bear any of the costs of drug prices. *Id.* Self-insured plans, on the other hand, involve a commercial insurer or a PBM administering the claims between a plan sponsor and a PBM or insurer at a contractually agreed price. *Id.* ¶ 21. When plan sponsors contract with health insurers or PBMs to manage their pharmacy benefit, the health insurer or PBM reimburses pharmacies at negotiated prices. *Id.* The health insurer or PBM then

may bill the plan sponsor for the prescription. Id. A plan sponsor may also use a hybrid of these two options. Id.

Plan sponsors can also contract with a stop-loss insurer to protect themselves against high healthcare expenditures of their members. Id. ¶ 22. Once an individual member's healthcare expenditures, or once all members' healthcare expenditures, exceed the aggregate stop-loss deductible, the plan sponsor notifies the stop-loss insurer who then starts reimbursing the plan sponsor for any covered healthcare expenditure in excess of the deductible. Id.

Health insurers themselves may also serve as TPPs in the prescription market. When a plan sponsor chooses to self-insure, it usually hires a health insurer to administer its health plan in an administrative services only ("ASO") capacity. Id. ¶ 30. The health insurer may bundle stop-loss insurance with its ASO contract. Id. The health insurer is paid an agreed price for each prescription or paid a flat rate. Id. When a plan sponsor chooses to have a fully insured contract with a health insurer, then the health insurer is responsible for all the covered healthcare expenditures, including drug expenditures, of the plan sponsor's insured members. Id. ¶ 31. The plan sponsor pays premiums, but it does not pay any specific medical or drug claim. Id. Many health insurers operate under an ASO contract in some instances and under a fully insured contract in other instances. Id. ¶ 32. Even when operating under a fully insured contract, health insurers may not be fully responsible for the pharmacy benefit, as they may also contract with a PBM and have a cost-sharing relationship with the PBM. Id. Finally, health insurers may also be involved in government-funded plans, such as Medicare Part D drug plans, and serve as plan sponsors. Id. ¶ 33.

Dr. Hughes also discusses PBMs at potential TPPs in the drug purchasing market. PBMs will often negotiate prices with retail pharmacies, charging insurers or plans more than they paid

for the drug to obtain profit. Id. ¶ 35. PBMs also negotiate rebates with manufacturers and will then pass some of that rebate on to insurers or plans. Id. Dr. Hughes opines that PBMs use a “variety of cost-sharing arrangements with health insurers and plan sponsors such as minimum discount guarantees, minimum rebate guarantees, and sharing of savings or costs relative to a specific target.” Id. ¶ 37. Consequently, “if the discounts and rebates [a PBM] receives from pharmacies and drug manufacturers are lower than the discounts and rebates it guaranteed to the plan sponsor or health insurer,” then “the PBM may share some of the drug cost.” Id. Additionally, “the PBM may also share some of the drug cost under a contract with a set target cost per insured member per month,” because, “if the cost per insured member is higher than expected, the PBM and the plan sponsor or health insurer split the excess payments.” Id. Finally, Dr. Hughes contends that, under a “capitation arrangement,” the PBM could bear the entire cost of a drug. Id.

Finally, consumers without prescription drug coverage “pay a price set by the entity dispensing the drug” and consumers with prescription drug coverage pay out-of-pocket up to the amount of their deductible and then pay either a fixed dollar amount, such as a co-pay, or a percentage of the total cost of the drug depending on their plan. Id. ¶ 39-40. These payments are affected by deductibles, annual benefit maximums, and out-of-pocket (“OOP”) maximums—a limit on the maximum amount that a consumer has to pay for prescription drugs during a benefit year. Id. ¶ 41. Consumer spending may also be affected by whether the consumer is a Medicare Part D beneficiary. Id. ¶ 42.

Out of these entities, Dr. Hughes opines that individualized inquiry is necessary to identify injured consumers and TPPs. First, with regard to consumers, Dr. Hughes asserts that there is no common method for identifying brand loyalists—those individuals who would have continued to use Thalomid or Revlimid even if generics were available. Id. ¶ 52 He also asserts that certain

consumers' annual drug expenditures would have remained the same, even if generics were available, if (1) the consumer would have reached his or OOP maximums even when purchasing a generic, if (2) generics were placed on the same formulary tier on the prescription drug plan resulting in equivalent payments, or if (3) a customer was eligible for Celgene's commercial copayment program, which reduced the amounts for Thalomid and Revlimid. Id. ¶¶ 53-58. Thus, with regard to consumers, Dr. Hughes concludes "[i]ndividualized inquiry is required to determine how many brand loyal customers there are and their identities" and to determine "how many additional consumers there are who may not be brand loyal and yet would still be uninjured." Hughes Rep. ¶ 58.

Dr. Hughes contends that similar individualized inquiry is necessary to determine whether TPPs suffered the alleged injury. First, he contends that plan sponsors with stop-loss insurance may not have suffered any injury so long as they would have exceeded their stop-loss deductible even in the but-for world. Id. ¶¶ 60-64. If they exceeded their deductible with or without generics, then the insurer would reimburse them for any amounts in excess of that deductible. Id. Dr. Hughes also contends that individualized inquiry is necessary to determine whether contractual rebates or formulary tiers eliminated injury to plan sponsors. Id. ¶¶ 65-69. Next, Dr. Hughes opines that individualized inquiry is necessary to determine whether PBMs were injured, and such inquiry requires consideration of myriad contracts between PBMs and other entities. Id. ¶¶ 70-74. Dr. Hughes reaches the same conclusion with regard to stop-loss insurers. Id. ¶¶ 75-77.

Turning to Dr. Leitzinger's classwide analysis of damages, Dr. Hughes opines that the Dr. Leitzinger's method is flawed because he cannot identify which individuals or entities made purchases in the damages jurisdictions and, therefore, cannot calculate the prescriptions that should be included in his damages estimate. Id. ¶ 90. Additionally, to the extent that Dr. Leitzinger

excluded PBMs from the Damages Classes, Dr. Hughes contends the damages estimates are inflated for the TPPs that remain in the putative Classes. Id. ¶ 97. This is because the excluded PBMs “may bear some or even the entire alleged overcharge” for Thalomid and Revlimid, and these damages are included in Dr. Leitzinger’s estimate despite the exclusion of the PBMs. Id. Finally, Dr. Hughes opines that Dr. Leitzinger has failed to accurately or reliably calculate federal reimbursement for Medicare on a classwide basis. Id. ¶¶ 102-107. Specifically, Dr. Hughes asserts that Dr. Leitzinger’s methodology is unreliable as to Medicare payments because it relies on incomplete third-party pharmacy data, because identifying whether Low Income Subsidy (“LIS”) Medicare payments requires individualized inquiry into the status of the covered consumers and their level of coverage, and because it fails to account for risk-sharing mechanisms provided by the federal government. Id.

#### **4. Dr. Leitzinger’s Rebuttal**

Plaintiffs provided Dr. Leitzinger’s rebuttal declaration in response to Dr. Hughes’ claims. Rebuttal Expert Report of Jeffery J. Leitzinger (“Leitzinger Reb.”), ECF No. 210.3. In his rebuttal, Dr. Leitzinger considers Dr. Hughes’ criticisms of his aggregate damages estimates and Dr. Hughes’ contentions regarding potentially uninjured class members.

First, Dr. Leitzinger addresses the contentions regarding the methodology for excluding federal Medicare reimbursements. Id. ¶¶ 7-19. Dr. Leitzinger contends that various payments and subsidies provided by the federal government are not directly related to purchases of Thalomid or Revlimid and do not constitute direct payments for either drug. Id. ¶¶ 10, 12. Next, Dr. Leitzinger opines that Dr. Hughes’ concerns regarding Low Income Subsidy Medicare payments are either irrelevant or already accounted for in his damages estimate. Id. ¶¶ 13-15. Finally, Dr. Leitzinger argues that the pharmacy data he relied on in making his determinations regarding Medicare

payments is representative of the overall experience for the two drugs and that Dr. Hughes has failed to provide any specific challenge to Dr. Leitzinger's list of Medicare plan names and types developed from the pharmacy data. Id. ¶ 19.

Next, Dr. Leitzinger considers the challenges to his methodology's ability to identify which entities and consumers purchased Thalomid or Revlimid in the damages jurisdictions and the contentions regarding PBMs. First, Dr. Leitzinger contends that his methodology results in reasonable estimates of overall Thalomid and Revlimid prescription volumes and that these estimates are borne out by other sources of information. Id. ¶¶ 20-28. Second, with regard to PBMs, Dr. Leitzinger asserts that PBMs do not cover any of the purchase price of Thalomid or Revlimid. Id. ¶¶ 29-33.

Turning to the question of uninjured class members, Dr. Leitzinger contends that Dr. Hughes' examples are either hypothetical and speculative, not included in the classes, very small in number, or previously identified in Dr. Leitzinger's report. Id. ¶ 36. In sum, he contends that none of the group resulted in overcharge estimates that are inflated. Id.

##### **5. W. Paul DeBree**

Finally, Plaintiffs submitted the expert declaration of W. Paul DeBree, an individual who has been involved in the PBM industry for more than twenty years and has expertise in "PBM contracting, payment flows, rebates, rebate contract billing, plan design, pharmacy network development and management, recordkeeping, and other services that PBMs perform for their customers." Expert Declaration of W. Paul DeBree ("DeBree Decl."), ECF No. 210.4. DeBree opined that the "identities of those who paid or reimbursed Thalomid and Revlimid are readily available and identifiable using existing prescription claim data" and that "PBMs do not pay some or all of the purchase for Thalomid and Revlimid – third partypayers and consumers do." Id. ¶ 6.

With regard to the identifies of class members, DeBree asserts that “patient/prescription electronic claim record sources,” “[p]harmacy records,” and “[c]laim processing records” will allow identification. Id. ¶ 35. And, with regard to payments to PBMs, DeBree contends that “[t]he retail price for Thalomid and Revlimid is paid solely by the TPP and its beneficiary,” that PBMs using an ASO model “are not themselves paying for drugs,” and that “Dr. Hughes’s statement [that PBMs pay for prescription drugs] is unsupported conjecture, and wrong.” Id. ¶ 40.

## II. LEGAL STANDARD

Every putative class action must satisfy the four requirements of Federal Rule of Civil Procedure 23(a): numerosity, commonality, typicality, and adequacy. City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc., 867 F.3d 434, 438 (3d Cir. 2017) (citations omitted). In addition to the Rule 23(a) requirements, a class action must be one of the types recognized by Rule 23(b). Boyle v. Progressive Specialty Ins. Co., No. 09-5515, 2018 WL 2770166, at \*4 (E.D. Pa. June 7, 2018). Here, Plaintiff has moved for certification under subsections (b)(2) and (b)(3).

The Rule 23 requirements are “not mere pleading standards;” rather, “[p]roper analysis under Rule 23 requires rigorous consideration of all the evidence and arguments offered by the parties.” In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 316, 321 (3d Cir.2008). A district court must “consider carefully all relevant evidence and make a definitive determination that the requirements of Rule 23 have been met before certifying a class.” Id. at 320. Additionally, “the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits . . . [and] [f]actual determinations necessary to make Rule 23 findings must be made by a preponderance of the evidence.” Id. at 307, 320. “Weighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands.” Id. at 323.

### **III. DISCUSSION**

#### **A. Rule 23(a) Requirements**

##### **1. Numerosity**

Rule 23(a)(1) requires that a class be “so numerous that joinder of all members is impracticable.” Hayes v. Wal-Mart Stores, Inc., 725 F.3d 349, 354, 356 (3d Cir. 2013) (quoting Fed. R. Civ. P. 23(a)(1)). Although numerosity is determined on a case-by-case basis, the Third Circuit has determined that “generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.” Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 595 (3d Cir. 2012) (quoting Stewart v. Abraham, 275 F.3d 220, 226-227 (3d Cir. 2001)). Numerosity is not an issue here. The proposed class consists of at least hundreds of persons and entities that paid for some or all the purchase price of Thalomid and Revlimid, as demonstrated by data obtained from subpoenas served on pharmacies. Leitzinger Rep. ¶ 46.

##### **2. Commonality**

Per Rule 23(a)(2)’s commonality requirement, the plaintiff must share a question of law or fact with the prospective class members. Commonality means “the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation.” Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 350 (2011) (emphasis in original) (citation omitted). “A putative class satisfies Rule 23(a)’s commonality requirement if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class.” In re Comty. Bank of N. Va. Mortg. Lending Practices Litig., 795 F.3d 380, 408-09 (3d Cir. 2015) (internal citation omitted). “Because the requirement may be satisfied by a single common issue, it is easily met.” Baby Neal v. Casey, 43 F.3d 48, 56 (3d Cir. 1994).

“As in other similar antitrust cases, ‘[e]ach class member’s claims depend on whether or not the defendants unlawfully engaged in anticompetitive behavior to limit the entry of generic competitors,’ which will require evidence common to the class.” Vista Healthplan, Inc. v. Cephalon, Inc., No. 06-1833, 2015 WL 3623005, at \*14 (E.D. Pa. June 10, 2015) (quoting In re Wellbutrin XL Antitrust Litigation, 282 F.R.D. 126 (E.D.Pa.2011) (citations omitted)). The commonality requirement is not disputed here, and it has been satisfied.

### **3. Typicality**

Rule 23(a)(3) requires that “the claims or defenses of the representative parties are typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). “The typicality inquiry is intended to assess whether the action can be efficiently maintained as a class and whether the named plaintiffs have incentives that align with those of absent class members so as to assure that the absentees’ interests will be fairly represented.” Baby Neal, 43 F.3d at 57 (citations omitted). Typicality exists “[i]f the representative’s claims and those of the absent class members arise from the same course of conduct and are based on the same legal theories . . . regardless of factual differences underlying the individual claims.” In re Wellbutrin XL, 282 F.R.D. at 138 (citing Baby Neal, 43 F.3d at 57-58).

The court must consider “whether the named plaintiff’s circumstances are markedly different or . . . the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based.” Hassine v. Jeffes, 846 F.3d 169, 177 (3d Cir. 1998) (quotation marks and citations omitted). “The typicality requirement is intended to preclude certification of those cases where the legal theories of the named plaintiffs potentially conflict with those of the absentees.” Georgine v. Amchem Prods., Inc., 83 F.3d 610, 631 (3d Cir. 1996) (citations omitted).

Defendant alleges that one of the six named Plaintiffs—David Mitchell—fails to satisfy the typicality requirement because he lacks standing to pursue either the damages claim or the claim for injunctive relief asserted in this action. Specifically, Defendant argues that Mitchell did not purchase Revlimid in a Damages Jurisdiction and that Mitchell has no likelihood of future injury that would give him standing to pursue injunctive relief. The Court disagrees.

With regard to the damages claim, “[c]ase law supports the position that [p]laintiffs suffered injury and have standing in states where they purchased a drug or reimbursed their members for purchase of a drug.” In re Flonase Antitrust Litig., 692 F. Supp. 2d 524, 533 (E.D. Pa. 2010) (citations omitted) (listing cases). Defendants contend that Mitchell lacks standing because he neither resided in D.C. nor purchased Revlimid at pharmacies located in D.C. Plaintiffs respond that Mitchell ordered Revlimid and provided his payment information from his office in D.C., thereby giving him standing.

It is not disputed that Mitchell ordered Revlimid over the phone in D.C. and paid for it using his credit or debit cards. Although the credit card bills were sent to his home in Maryland, the Court is satisfied that he nonetheless “purchased” the drug in D.C. See, e.g., Malin Int’l Ship Repair & Drydock, Inc. v. Oceanografia, S.A. de C.V., 817 F. 3d 241, 248 (5<sup>th</sup> Cir. 2016) (“‘Purchase’ means [t]he acquisition of an interest in real or personal property by sale...’ And a ‘sale’ may occur based on either an actual payment or a mere promise to make payment.”) (quoting Black’s Law Dictionary (10th Ed. 2014); Bourgeois v. Live Nation Entm’t, Inc., 3 F. Supp. 3d 423, 448 (D. Md. 2014) as corrected (Mar. 20, 2014) (“location” of online concert tick sales “may depend, inter alia, on the mechanics of the purchase process on the Ticketmaster website . . . the location from which the purchaser accessed the Ticketmaster website; the location at which the purchaser’s electronic funds were received; the location from which Ticketmaster

and/or the [theater] sent the tickets to the purchaser; the location at which the purchaser received the tickets; and, perhaps, the location of the event for which the ticket grants entry.”). As for the debit card purchases, Mitchell’s debit card was linked to a Flexible Spending Account provided by his employer in D.C. Given these facts, the Court is satisfied that Mitchell’s purchases of Revlimid give rise to standing to pursue damages claims under D.C. law.

Defendant also challenges Mitchell’s standing to pursue injunctive relief, contending that Mitchell has not demonstrated a likelihood of future injury because he no longer takes Thalomid or Revlimid. Again, the Court disagrees. To have standing to seek injunctive relief, a plaintiff must show: (1) that he is under imminent threat of suffering injury in fact ““that is concrete and particularized””; (2) “a causal connection between the injury and the conduct complained of”; and (3) “a likelihood that a favorable judicial decision will prevent or redress the injury.” ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 301 (3d Cir. 2012) (quoting Summers v. Earth Island Inst., 555 U.S. 488, 493 (2009)). The Third Circuit has repeatedly held that a plaintiff seeking an injunction must show that he is “likely to suffer future injury”; a mere “possibility” of future injury is insufficient. Id. (quoting City of Los Angeles v. Lyons, 461 U.S. 95, 111 (1983)).

Defendant asserts that Mitchell has never taken Thalomid and has not taken Revlimid since April 2016. ECF No. 182, Ex. 5. Consequently, Defendant contends that there is no likelihood of future injury. Plaintiffs respond with a declaration from Mitchell’s prescribing doctor, wherein he states “it is likely that we will treat Mr. Mitchell with Revlimid again in the future.” See Declaration of Kenneth Anderson, MD, Ex. 126, ECF No. 210.2. Given the fact that Mitchell has multiple myeloma, an incurable blood cancer that he will battle for the rest of his life, Plaintiffs have shown that Mitchell is likely to suffer future injury as a result of Defendant’s alleged conduct. Consequently, Mitchell has standing to pursue the claims for injunctive relief.

#### 4. Adequacy

Rule 23(a)(4) dictates that representative plaintiffs must “fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4). The “inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent.” Amchem, 521 U.S. at 625. The adequacy determination “depends on two factors: (a) the plaintiff’s attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class. In re Flonase, 284 F.R.D. at 218 (quoting New Directions Treatment Servs. v. City of Reading, 490 F.3d 293, 313 (3d Cir. 2007)).

Rule 23(g) governs the analysis as to Plaintiffs’ attorneys’ qualifications, experience, and ability to handle the proposed litigation. It provides that in appointing class counsel, the court must consider four factors:

- (i) the work counsel has done in identifying or investigating potential claims in the action;
- (ii) counsel’s experience in handling class actions, other complex litigation, and the types of claims asserted in the action;
- (iii) counsel’s knowledge of the applicable law; and
- (iv) the resources that counsel will commit to representing the class.

Cnty. Bank of N. Va., 622 F.3d at 292 (quoting Fed. R. Civ. P. 23(g)(1)(A)). Here, the Court is satisfied that Interim Co-Lead Counsel—the firms of Hausfeld LLP, Block & Leviton LLP, and Hach Rose Schirripa & Cheverie LLP, are qualified, experienced, and familiar with antitrust class action litigation. They have spent considerable time and resources on this litigation, including engaging in discovery and working with experts, and they have knowledge of substantive and class action law, as well as complex litigation rules, practice, and procedure.

With regard to the second factor, the Court is satisfied that all Plaintiffs share an interest in establishing Celgene's liability and in obtaining the largest monetary recovery possible. The basis of each class member's claim against Celgene is the alleged anticompetitive behavior resulting in higher payments for Thalomid and Revlimid than if Celgene had not blocked generic competition. The only argument raised by Defendants under this factor is that Plaintiff Mitchell lacks standing and therefore cannot serve as an adequate representative. The Court has already rejected this position. Given that the interests of the class members are aligned, the named Plaintiffs have satisfied the second part of the adequacy requirement.

### **B. Rule 23(b)(3) Damages Classes**

Under Rule 23(b)(3), certification is appropriate when: (i) common questions of law or fact predominate over questions affecting the individual class members only; and (ii) class treatment is superior to other available methods of adjudication. Fed. R. Civ. P. 23(b)(3); Boyle v. Progressive Specialty Ins. Co., No. 09-5515, 2018 WL 2770166, at \*4 (E.D. Pa. June 7, 2018). These requirements are called predominance and superiority. In addition to satisfying the predominance and superiority prongs, a "Rule 23(b)(3) class must . . . be 'currently and readily ascertainable based on objective criteria.'" City Select, 867 F.3d at 439 (quoting Marcus v. BMW of N. Am. LLC, 687 F.3d 583, 593 (3d Cir. 2012)).

#### **1. Predominance**

"In a class action brought under Rule 23(b)(3), common questions of law or fact must predominate over questions affecting only individual members and must be a significant part of the individual cases." Boyle, 2018 WL 2770166, at \*8. The predominance inquiry assesses whether the elements of the claims of the class can be proven at trial with "common, as opposed to individualized, evidence." Taha v. County of Bucks, 862 F.3d 292, 308 (3d Cir. 2017) (quoting

Hayes, 725 F.3d at 359). “Class certification is not appropriate if proof of the essential elements of the cause of action requires individual fact finding or application of different legal principles. Boyle, 2018 WL 2770166, at \*8 (citations omitted). “The evidence needed to prove each element of the plaintiff’s legal claim must be capable of common proof rather than individualized proof.” Id. (citing Marcus, 687 F.3d at 600). “To assess predominance, a court at the certification stage must examine each element of a legal claim ‘through the prism’ of Rule 23(b)(3). Marcus, 687 F.3d at 600 (quoting In re DVI, Inc. Sec. Litig., 639 F.3d 623, 630 (3d Cir.2011)). A court’s task is to predict how specific issues will play out at trial “in order to determine whether common or individual issues predominate in a given case.” Malack v. BDO Seidman, LLP, 617 F.3d 743, 746 (3d Cir. 2010) (quoting Hydrogen Peroxide, 552 F.3d at 311)).

A plaintiff need not provide his claims for purposes of the predominance inquiry; rather, he “need only show that he can establish the elements of his claim at trial by common, not individualized proof.” Boyle, 2018 WL 2770166, at \*8 (citing Sullivan v. DB Invs., Inc., 667 F.3d 273, 305 (3d. Cir. 2011). “Rule 23(b)(3) requires a showing that questions common to the class predominate, not that those questions will be answered, on the merits, in favor of the class.” Amgen, 568 U.S. at 459 (emphases omitted). “The merits underlying the cause of action need be considered only to the extent that they are ‘enmeshed’ with the certification inquiry.” Boyle, 2018 WL 2770166 (quoting Comcast Corp. v. Behrend, 569 U.S. 27, 34 (2013) (citations omitted)).

Defendant asserts that Plaintiffs have failed to satisfy their burden to show predominance for three reason: (i) Plaintiffs cannot prove injury on a class-wide basis because the class includes large numbers of uninjured person and entities; (ii) Plaintiffs’ proposed class-wide damages analysis inflates damages and cannot be corrected without individualized analysis; and (iii)

significant variations in the state laws governing Plaintiffs' unjust enrichment and consumer protection claims would render any class-wide trial impractical.

**i. Plaintiffs' Proof of Antitrust Impact**

Injury is an essential element of an antitrust claim. See, e.g., In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 164 (3d Cir. 2017) (“[t]o establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury”). To certify a class, “the putative class must first demonstrate economic loss—that is, the fact of damage—on a common basis.” Harnish v. Widener Univ. Sch. Of Law, 833 F.3d 298, 305-06 (3d Cir. 2016) (internal quotation marks omitted); see also In re Rail Freight Fuel Surcharge Antitrust Litig., 725 F.3d 244, 252 (D.C. Cir. 2013) (“plaintiffs must also show that they can prove, through common evidence, that all class members were in fact injured”). The same is true for Plaintiffs' state law unfair competition and unjust enrichment claims. See Gonzalez v. Corning, 317 F.R.D. 443, 517 (W.D. Pa. 2016) (denying certification of, inter alia, unjust enrichment claims where “plaintiffs failed to meet their burden to establish that injury can be proven by evidence that is common to the proposed [] class”).

Defendants contend that the predominance requirement is not satisfied here because there are large categories of uninjured class members that Plaintiffs have not identified and cannot identify without individualized inquiry. See, e.g., Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 190 (3d Cir. 2001) (affirming decision not to certify where “ascertaining which class members have sustained injury means individual issues predominate over common ones”). Plaintiffs respond that substantially all class members were injured. The Court agrees with Defendant.

Defendant relies on the report of Dr. Hughes, who described several categories of allegedly uninjured consumers, including: (1) brand loyal customers who would have bought branded

Revlimid or Thalomid even if a generic had been available, (2) consumers who purchased Revlimid or Thalomid after meeting an annual out-of-pocket maximum or deductible, (3) consumers who pay the same for a generic and a brand drug, and (4) consumers who obtain patient assistance. Dr. Hughes also identified categories of TPPs that would otherwise fall within the class definition but who were not injured such as, (1) plan sponsors with stop-loss insurance, (2) plan sponsors and PBMs who pay the same or less for a brand than a generic, and (3) plan sponsors with maximum plan limits.

The first category of allegedly uninjured class members is made up of brand loyalists—consumers that would purchase a brand product even if a generic alternative was available. Dr. Leitzinger asserted that up to 10 percent of consumer class members would purchase a brand product even if a generic were available, and he confirmed that he had not “done anything to try to identify which individual consumers members of these classes are in fact brand loyalists.” Leitzinger Dep. at 78:22-79:10; 79:12-79:25, ECF No. 182.4, Ex. 3. According to Defendant, the presence of brand loyalists is a significant barrier to class certification: “[W]hen every class member has the potential to be a brand loyalist, a person with a flat copay or a consumer who never paid out-of-pocket for their prescriptions, and the only way to identify persons who fall within those groups is individualized inquiry, individualized inquiries would predominate.” Vista Healthplan, Inc. v. Cephalon, Inc., No. 06-1833, 2015 WL 3623005, at \*19 (E.D. Pa. June 10, 2015). In the absence of a method for identifying which consumers would continue to take brand Thalomid or Revlimid and which would not, Defendant contends that certification is inappropriate.

Plaintiffs respond, first, that Dr. Leitzinger, while not individually identifying brand loyalists, already took them into consideration in determining that at least 90% of consumers were impacted by Celgene’s conduct, accounting for 99% of class period prescriptions. Leitzinger Rep.

¶¶ 36-37. Second, Plaintiffs argue that identification of individual brand loyalists is a question of damages allocation that is inappropriate for class certification. See Bogosian v. Gulf Oil Corp., 561 F.2d 434, 456 (3d Cir. 1977) (“it has been commonly recognized that the necessity for calculation of damages on an individual basis should not preclude class determination when the common issues which determine liability predominate”) (abrogated on other grounds). Plaintiffs cite to out-of-circuit cases for the proposition that consumers can, at the damages stage, “establish [their] injury through testimony . . . that, given the choice, he or she would have purchased the generic.” In re Nexium Antitrust Litig., 777 F.3d 9, 20 (1st Cir. 2015); In re Lidoderm Antitrust Litig., No. 14-2521, 2017 WL 679367, at \*17 (N.D. Cal. Feb. 21, 2017) (same); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-2503, 2017 WL 4621777, at \*16 n.16 (D. Mass. Oct. 16, 2017) (same).

None of the cases cited by Plaintiffs applied Third Circuit standards for class certification. As explained in Solodyn, “In Nexium III, the First Circuit explained that the putative class need not propose the specific mechanism to exclude uninjured consumers at the time of class certification, as long as a court is confident that such a mechanism does exist. . . .”<sup>2</sup> 2017 WL 4621777, at \*16. However, “[i]n Vista, the court specifically rejected the standards outlined in Nexium III, explaining that the Third Circuit imposes greater standards of proof at the time of class certification than does the First Circuit. . . . “ Id. Both Solodyn and Lidoderm followed the approach articulated in Nexium. This Court, however, is required to apply the “greater standards of proof” discussed in Vista Healthplan and, consequently, Plaintiffs’ inability to identify a non-individualized means of identifying brand loyalists weighs against certification. See, e.g., Vista

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<sup>2</sup> Both Solodyn and Lidoderm relied on the First Circuit’s holdings in Nexium, which—as discussed above—run contrary to the Third Circuit’s standards of proof at the time of class certification.

Healthplan, 2015 WL 3623005, at \*19; Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, No. CIV.A. 04-5898, 2010 WL 3855552, at \*25 (E.D. Pa. Sept. 30, 2010) (rejecting certification of end payor class in part because plaintiffs did not provide “a method for identifying which individual purchasers would remain brand loyal through analysis of common information” and therefore failed to demonstrate that common proof is available to show that supra-competitive prices passed through to purchasers of both branded and generic purchasers).

Furthermore, the First Circuit subsequently limited the reach of Nexium, bringing it into closer consistency with the Third Circuit’s standards for certification and undermining Plaintiffs’ reliance on it. In re Asacol Antitrust Litigation involved allegations that defendant delayed generic entry resulting in higher prices paid by some members of the putative class. The district court found that at least 10% of putative class members because they would have continued taking the brand drug even if a generic had been available earlier. ECF No. 247, Ex. A at 9. The district court certified the class, finding that the ten percent of brand loyalists was a de minimis number of uninjured members. Id. The district court further found sufficient a proposal by plaintiffs that class members be allowed to submit a claims form, along with data and documentation, to substantiate their membership in the class, which a claims administrator would review to determine class membership. Id. The First Circuit reversed, finding that a “‘claims administrator’s’ review of contested forms completed by consumers concerning an element of their claims would fail to be ‘protective of defendants’ Seventh Amendment and due process rights.’” Id. at 24-25 (quoting Nexium, 777 F.3d at 19). Because plaintiffs had not provided an appropriate common method for proving injury-in-fact, the First Circuit concluded that certification was inappropriate, as

individual inquiries regarding this issue would overwhelm common issues at trial.<sup>3</sup> Similarly, here, Plaintiff have not provided an appropriate common method of proving injury-in-fact given the presence of brand loyalists. Any renewed motion must enable this Court to offer a “reasonable and workable plan for how [the opportunity to press at trial genuine challenges to allegations of injury-in-fact] will be provided in a manner that is protective of the defendant’s constitutional rights and does not cause individual inquiries to overwhelm common issues.” Id. at 36.

Next, Defendants contend that consumers—and plans—who would have hit their out of pocket maximums even with a generic alternative are not injured. Defendants reason that Thalomid and Revlimid are expensive, that generic prices would not have been substantially lower, and that cancer patients, who likely have other high medical costs, are likely to reach their maximums regardless of the availability of generics given these expenses. Plaintiffs respond that if a consumer or a TPP paid more for brand Thalomid or Revlimid than it would have for their generic counterparts even one time, then it suffered antitrust injury. See Castro v. Sanofi Pasteur Inc., 134 F. Supp. 3d 820, 847 (D.N.J. 2015). Thus, it is “irrelevant to antitrust injury if that class member subsequently limited the damage it suffered from Celgene’s overcharge with contractual maximums.” Pl. Reply Br. at p. 18, ECF No. 210. Moreover, “even if the consumer would be

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<sup>3</sup> In reaching this conclusion, the First Circuit rejected argument that class certification was appropriate, regardless of whether a method for excluding brand loyalists was sufficient, because defendant “would only be found liable and forced to pay damages if the jury found that [its] actions unlawfully raised the price paid by consumers by a specified amount, and if the jury also determine the percentage of sales for which that price surcharge would not have been paid but for the illegal conduct.” Id. at 29. In other words, the “total aggregate damages award would therefore in theory net out all purchases by brand loyal consumers as a group.” Id. In rejecting this argument, the First Circuit explained that certifying a class containing a large percentage of uninjured members so long as the aggregate damages were reduced proportionally “would fly in the face of the core principle that class actions are the aggregation of individual claims, and do not create a class entity or re-apportion substantive claims.” Id. Plaintiffs here advance a similar argument, contending that question of brand loyalists is a question for damages allocation. For the same reasons articulated in Alcasol, the Court rejects this argument.

uninjured [due to a plan maximum], the third-party insurer who actually paid the costs would have been overcharged, and the aggregate damages award would remain the same, so there is no prejudice to Defendants at this time.” In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-02503, 2017 WL 4621777, at \*16 (D. Mass. Oct. 16, 2017).

The Court agrees with Plaintiffs that antitrust injury occurs on the first overcharge. While Plaintiffs expert acknowledged that six percent of consumers reached their out of pocket maximum on the first purchase, see Leitzinger Reb. ¶ 41, some patients within this group may not have reached their out of pocket limit if generics were available or may have reached their OOP limit as a result of other medical expenses after incurring the full overcharge for Thalomid and Revlimid, and thereby suffered injury. The Court finds that, at most, a de minimis number of consumers escaped injury as a result of out of pocket maximums.

Defendant also asserts that certain class members pay the same for a generic and a brand drug and, thus, suffered no injury. This situation would arise if a health plan included certain generic medication on the brand tier, meaning that consumers would have the same copayment for the generic version of those drugs as for the branded versions. Plaintiffs respond that such a situation is unlikely to occur and that it is purely hypothetical. Plaintiffs further respond that health plans generally benefit when consumers take generic drugs, so they create incentives to encourage consumer members to choose generics—including generic versions of cancer drugs—by placing them on less expensive tiers than brands. See, e.g., Ex. 121, 122, 123, ECF No. 150. Finally, Plaintiffs argue that, if a particular formulary required a consumer to pay a percentage of every drug’s price and capped the expenditure at a certain dollar amount, and that dollar amount was the same for both a generic and brand drug, then that consumer would fall under the flat co-pay exclusion. The Court rejects Defendants’ unfounded hypothetical and agrees with Plaintiffs.

Next, Defendant argues that Celgene offers patient assistance programs that reduce the amount that insured and uninsured patients are charged for Thalomid and Revlimid. The patient assistance “can cause consumers to pay less for the brand medication than they would have paid for the generic alternative,” so consumers receiving assistance “are not injured.” Def. Br. at 33, ECF No. 182; see also Ex. 11 (Plaintiff DEA explaining that it actively encourages its members to seek patient assistance); Ex. 33 (PBM confirming that “patient assistance will be pursued” for DEA members taking Revlimid). Plaintiffs contend that only a small number of overall consumers participated in the assistance program. See Leitzinger Reb. ¶ 46 (“With regard to Celgene’s copay assistance program more generally, only 9% of the Thalomid/Revlimid consumers receive some assistance from Celgene’s copay assistance program”). Moreover, participating consumers would still be injured, according to Dr. Leitzinger, if any of the following is true: (1) their co-pay for generics was less than \$100 before 2013; or (2) their co-pay for generics was less than \$25 during or after 2013; or (3) they received the maximum of \$10,000 in co-pay assistance before their last prescription was filled;<sup>4</sup> or (4) they otherwise did not qualify for or apply for the assistance program for any one prescription of Thalomid or Revlimid. As was the case with out of pocket maximums, the Court finds that, at most, a de minimis number of consumers escaped injury as a result of Celgene’s assistance program.

Turning to TPPs, Defendant argues that Plan Sponsors who pay the same or less for a brand than a generic as a result of the discount or rebate structures in their contracts with PBMs would not be injured. Defendant also argues that Plan Sponsors with stop-loss insurance, who would have hit their stop-loss deductibles even with a generic alternative, are not injured because they

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<sup>4</sup> Dr. Hughes agreed that a consumer would still suffer an injury after reaching the copay assistance maximum. Hughes Dep. at 180:21-181:15.

would have paid the same deductible amount. However, as Plaintiffs correctly argue, any amounts that such Plan Sponsors received in coverage or in the form of rebates is irrelevant to the question of impact. See Nexium, 777 F.3d at 28 (rejecting defendants’ argument that some class members were not injured because they “benefitted from rebates that reduced the actual class period price for branded Nexium”); In re Solodyn, 2017 WL 4621777, at \*18 (same). Thus, Plan Sponsors with stop-loss insurance or with a favorable discount or rebate structure suffered antitrust injury at the time they first paid for Thalomid or Revlimid, regardless of whether they eventually recouped all or part of their losses.

Ultimately, the Court finds that there are potentially uninjured class members remaining in the class—specifically, brand loyalists—and that identifying these members would require extensive individualized inquiry. Consequently, the Court will deny certification. See, e.g., Vista Healthplan, 2015 WL 3623005, at \*21. The Court will allow Plaintiffs another opportunity to address this issue and to propose a method of identifying potential brand loyalists without resorting to individualized inquiry.

#### **ii. Plaintiffs’ Proposed Class-wide Damages Calculation**

Defendant argues that Dr. Leitzinger’s model is fundamentally unreliable and does not accurately reflect the transactions that are attributable to Plaintiffs’ theory of class injury in three respects: (1) the model does not identify those purchases of Thalomid and Revlimid that occurred in the fourteen Damages Jurisdictions; (2) the model does not account for the role of PBMs; and (3) the model does not reliably estimate the amount of Medicare reimbursements. Plaintiffs respond that Dr. Leitzinger has adequately demonstrated that damages can be calculated on a class-wide basis.

“At the class certification stage, the plaintiffs are not required to prove damages by calculating specific damages figures for each member of the class, but rather they must show that a reliable method is available to prove damages on a class-wide basis.” In re Processed Egg Products, 312 F.R.D. 171, 202 (E.D. Pa. 2015). A class-wide damages model is invalid if it “identifies damages that are not the result of the wrong.” Comcast, 569 U.S. at 37; see also Franco v. Conn. Gen. Life Ins., 299 F.R.D. 417, 430 (D.N.J. 2014) (court must ensure that “proffered model measures only those damages attributable to the plaintiff’s theory of liability”), aff’d, 647 F. App’x 76 (3d Cir. 2016).

Defendant asserts that Dr. Leitzinger’s model is fundamentally unreliable, criticizing its reliance on averages and its failure to analyze or incorporate individualized differences. See Sheet Metal Workers, 2010 WL 3855552, at \*30 (finding certification unwarranted where the proposed model used averaged prices, thereby “glid[ing] over what may be important differences” in the “actual price paid by each purported class member.”) (internal quotation marks omitted). The Court disagrees. Dr. Leitzinger opined that his aggregate damages model, which is based on both extensive literature as well as Celgene’s own forecasts as described in the background of this opinion, illustrates that the price benefits associated with generic entry into the market “would have been shared broadly across patients (both with and without insurance) and third-party payors (including insurance plans, state and local government entities, and self-insured employers).” Leitzinger Rep. ¶¶ 34-36. The aggregate class-wide damages estimates have readily been accepted in other similar cases. See, e.g., In re Flonase Antitrust Litig., 284 F.R.D. 207, 226 (E.D. Pa. 2012); In re Cardizem CD Antitrust Litig., 200 F.R.D. 326, 351 (E.D. Mich. 2001).

Defendant goes on to specifically challenge several aspects of the classwide damages model. First, Defendant contends that the data relied on by Dr. Leitzinger does not reflect the

states in which the relevant purchasers were made, given that many patients using Thalomid and Revlimid travel great distances to receive their cancer treatment and many receive their prescriptions from out-of-state pharmacies. See Hughes Rep. ¶¶ 94-95. Dr. Hughes noted that, in the Revlimid claims data produced by Plaintiff DEA, “19 percent of the prescriptions were dispensed to consumers whose primary address was in a different state from the mailing address of their prescribing physician.” Id. ¶ 94. Based on these assertions, Defendant contends that the model does not reliably identify the purchases in the Damages Jurisdictions.

Plaintiffs provide Dr. Leitzinger’s rebuttal declaration, in which he contends that the relevant question is not “whether the . . . data allows [him] to properly determine patient locations for each prescription,” but rather “whether [the] data applied in the aggregate (that is, across all the health care plans in all of the Class states) results in reasonable estimates of overall Thalomid and Revlimid prescription volumes for the Classes.” Leitzinger Reb. ¶ 23. Dr. Leitzinger opines that the pharmacy data produced in this case—accounting for several hundred thousand prescriptions that have both patient and prescriber addresses—“show that the volume of Thalomid and Revlimid prescriptions used in the Class states during the damages period is within two-tenths of a percentage point of the volume prescribed in those states.” Id. ¶ 24. Dr. Leitzinger also performed robustness check on his estimates by “reviewing CDC data on diagnoses by state for myeloma and Non-Hodgkin Lymphoma (which are treated with Thalomid and Revlimid), and using census data based on age of population . . . and found his state-by-state damage estimates were robust.” Pl. Reply at 22; Leitzinger Reb. ¶¶ 26-28. Finally, Dr. Leitzinger used Celgene’s REMS database, which shows the number of Thalomid and Revlimid capsules purchased by each customer and each customer’s state of residence, to corroborate his estimates, finding that the Thalomid estimate essentially matched the REMS data percent and that the Revlimid estimate was

within five percentage points of the REMS data percent. Leitzinger Reb. ¶ 28. The Court finds that the damages model sufficiently estimates damages in the Damages Jurisdictions.

Defendant's second argument is that Dr. Leitzinger's model does not account for the role of PBMs, who Defendant alleges may bear part or all of the alleged overcharge. "To the extent Plaintiffs take the position that PBMs are not part of the Damages Classes, Dr. Leitzinger fails to identify and subtract costs borne by PBMs, which inflates his damages estimate for those payors who *are* class members." Def. Br. at 38 (emphasis in original). As discussed more fully elsewhere in this opinion, Defendant's underlying contention that PBMs may bear the price of Thalomid and Revlimid is unsupported and, therefore, the Court rejects this challenge to Dr. Leitzinger's model.

Finally, Defendant argues that Dr. Leitzinger uses unreliable data to exclude the federal government's Medicare payments and uses an unreliable method to ascertain Low Income Subsidy beneficiaries and to determine whether LIS beneficiaries are in the catastrophic coverage statute, two factors which allegedly impact the amount of the government's payments. Hughes Rep. ¶¶ 46, 104-05. "Dr. Leitzinger's failure to identify and exclude these non-class member payments weighs heavily against the reliability of his model to measure damages to purported class members." Def. Br. at 39. Having reviewed both Dr. Leitzinger's initial report and rebuttal declaration, the Court finds that his model adequately accounts for Medicare payments. See Leitzinger Reb. ¶¶ 7-19. The Court credits Dr. Leitzinger's analysis that any potential LIS issues on the overcharge analysis are de minimis and that the pharmacy data he relied on is representative of the overall experience for Thalomid and Revlimid. Id.

### **iii. Variations in State Law**

Plaintiffs' proposed classes include claimants under the laws of all fourteen Damages Jurisdictions, based on state antitrust and consumer protection statutes and common law unjust

enrichment. Defendant contends that there are significant differences among state laws that have led other courts to deny certification of similar proposed classes.

“In a motion for class certification, plaintiff bears the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification.” Lyon v. Caterpillar, Inc., 194 F.R.D. 206, 219 (E.D. Pa. 2000) (internal quotations marks omitted).

**a. Unjust Enrichment**

Defendant contends that there are significant variations in state unjust enrichment laws that preclude a finding of predominance. Defendant points to six differences regarding: (1) whether and how states recognize unjust enrichment as an independent cause of action, as opposed to requiring a separate underlying cause of action; (2) what conduct is required to prove a claim, including whether a plaintiff must prove inducement, solicitation, fraud, or inadequate consideration or compensation; (3) whether a relationship between the parties or a direct conferral of benefit is required; (4) whether a plaintiff must prove a defendant’s culpable state of mind; (5) the length of the statute of limitations period, and when the limitations period begins to run; and (6) whether an adequate remedy at law precludes an unjust enrichment claim. See App. A., ECF No. 182. Plaintiffs respond that all states’ unjust enrichment laws are virtually identical and that the differences identified by Defendant are either contradicted by superior precedent or overblown.

Plaintiffs assert the standard elements of unjust enrichment are: (1) benefit conferred by a plaintiff upon defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by defendant under circumstances where it would be unjust to do so without payment. See, e.g., In re Liquid Aluminum Sulfate Antitrust Litig., No. 16-2687, 2017 WL 3131977, at \*29 (D.N.J. July 20, 2017). With respect to the conduct required for proof of the claim, Plaintiffs

contend that “[u]njust enrichment is an equitable remedy, and thus by its very nature is a flexible doctrine.” In re. TFT-LCD (Flat Panel) Antitrust Litig., 2017 WL 4501223, at \*7 (N.D. Cal. Sept. 28, 2011) (“As a cause of action based in equity, ‘the requirements of proof of unjust enrichment are neither technical nor complicated.’”) (citing Restatement (Third), Restitution, § 1, cmt. a (noting the “inherent flexibility of the concept of unjust enrichment”). Plaintiffs also contend that their unjust enrichment claims here are well-suited for class treatment because the claims depend on common evidence of Defendant’s allegedly illegal behavior and the profits derived therefrom. Additionally, Plaintiffs provide a detailed overview of the various states’ unjust enrichment laws, including citations to relevant precedent.

After careful consideration, the Court is not convinced that any of the potential variations described by Defendant are so material as to prevent certification. As other courts have recognized, state claims of unjust enrichment “are universally recognized causes of action that are materially the same throughout the United States.” In re Terazosin Hydrochloride, 220 F.R.D. 672, 697 (S.D. Fla. 2004); see also Singer v. AT & T Corp., 185 F.R.D. 681, 692 (S.D. Fla. 1998) (citing Sollenbarger v. Mountain States Tel. & Tel. Co., 121 F.R.D. 417, 428 (D.N.M. 1988)). To the extent the variations identified by Defendant exist, they “do not significantly alter the central issue or the manner of proof.” In re Abbott Labs. Norvir Anti-Tr. Litig., No. 04-1511, 2007 WL 1689899, at \*9 (N.D. Cal. June 11, 2007). “Common to all class members . . . is whether Defendant unjustly acquired additional revenue or profits by virtue of an anti-competitive premium on the price of [the drug at issue].” Id. “The ‘idiosyncratic differences’ between state unjust enrichment laws ‘are not sufficiently substantive to predominate over the shared claims.’” Id. (citing Hanlon v. Chrysler Corp., 150 F.3d 1011, 1019 (9th Cir. 1998)). Based on Plaintiffs analysis of the states’ various unjust enrichment laws, their use in indirect purchaser actions, and the similarity between

unjust enrichment causes of action, the Court is satisfied that common questions predominate. Unlike the cases cited by Defendant where courts reached an opposite conclusion, the Court does not find that there is a need for inquiry into the equities of individual Plaintiffs. Moreover, to the extent there are variations in statutes of limitation or the preclusive effect of an adequate remedy at law, the Court finds that such differences can be accommodated without overcoming the efficacy of the class action.

**b. Unfair and Deceptive Trade Practices**

Defendant raises similar challenges to Plaintiffs' unfair and deceptive trade practices claims, contending that there are extensive variations among the relevant state laws that make them unsuitable for class treatment. Specifically, Defendant claims that jurisdictions vary regarding: (1) whether the law requires a showing of false or deceptive acts; (2) whether the conduct must be directed at consumers; (3) whether the defendant must act willfully or with intent to deceive; (4) whether the conduct must occur locally; (5) whether corporations, business entities, or third parties not directly involved in the alleged deceptive transaction can bring claims; (6) whether and to what extent a plaintiff must prove reliance on the alleged deceptive conduct; (7) the types of damages available; and (8) the length of the statute of limitations period and when it begins to run. See App. B., EXC No. 182.

Plaintiffs respond that common issues predominate and that any material variations can be handled via a special verdict form or by separating the purported differences into groups, both of which Plaintiffs allege are more efficient options than individual or state-wide class lawsuits. Further, to the extent there are variations among the relevant state laws, Plaintiffs contend that they do not predominate over the core elements of Plaintiffs' claims: "whether Celgene engaged in anticompetitive conduct; whether that conduct resulted in artificially inflated prices for Thalomid

and Revlimid; and the aggregate damages suffered by the Classes.” Pl. Reply at 29. The Court disagrees.

Defendant has identified substantial variations among the state laws. For example, Defendant identifies various definitions of protected consumers—a variation that is not accounted for in Plaintiffs’ analysis. See Def. App., ECF No. 182.2; see also In re Ford Motor Co. Ignition Switch Prod. Liab. Litig., 194 F.R.D. 484, 489 (D.N.J. 2000) (finding that there was not predominance of common legal issues because, in part, “some states have different definitions of the word ‘consumers.’”). Similarly, Defendant identifies differences related to standards for scienter and reliance under various states’ statutes. See Def. App., ECF No. 182.2; see also Mazza v. Am. Honda Motor Co., 666 F.3d 581, 591 (9th Cir. 2012) (finding material variations due to differing scienter and reliance requirements under consumer protection laws); see also Lyon, 194 F.R.D. at 219 (finding that “[s]tate consumer protection acts vary on a range of fundamental issues,” including on conduct that is actionable and level of scienter”). Additionally, Defendant demonstrates variations in the substantive preconditions to bringing a suit under various state consumer protection laws, which have likewise been found to defeat predominance. See S. States Police Benev. Ass’n, Inc. v. First Choice Armor & Equip., Inc., 241 F.R.D. 85, 93 (D. Mass. 2007). More generally, the Court is mindful of the fact that “[c]onsumer protection laws are a creature of the state in which they are fashioned. They may impose or not impose liability depending on policy choices made by state legislatures or, if legislators left a gap or ambiguity, by state supreme courts.” Id.

In sum, the Court finds that there are significant differences between the states’ consumer protection statutes and Plaintiffs’ causes of action. These distinctions “lessen the predominance of common legal issues” and “would demand significant attention from this Court, not the least of

which would be instructing the jury or juries consistent with the law of each relevant states.” In re Ford Motor Co. Ignition Switch Prod. Liab. Litig., 194 F.R.D. at 490. Plaintiffs fail to account for these variations in their analysis and, to the extent they seek to renew this motion, Plaintiffs must provide a more extensive analysis of the various consumer protection laws indicating that the variations described by Defendant would not raise an insuperable obstacle to certification.

## **2. Superiority**

Rule 23(b)(3) requires that a class action be “superior to other available methods for fairly and efficiently adjudicating the controversy” and provides a “non-exhaustive” list of factors to consider in determining superiority. Fed. R. Civ. P. 23(b)(3). These factors include the class members’ interest in individually controlling the prosecution of separate actions, the extent and nature of any similar litigation already commenced by class members, the desirability of concentrating the litigation in a particular forum, and the difficulties likely to be encountered in management of a class action. Fed. R. Civ. P. 23(b)(3); Cnty. Bank of N. Va., 795 F.3d at 409. “The superiority requirement asks a district court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication.” Cnty. Bank of N. Va., 795 F.3d at 409 (quotations omitted). “[S]imilar to the predominance requirement, the requirement of superiority ensures that resolution by class action will ‘achieve economies of time, effort, and expense, and promote . . . uniformity of decision without sacrificing procedural fairness or bringing about other undesirable results.’” Flonase, 294 F.R.D. at 234 (quoting Amchem, 521 U.S. at 615).

The superiority requirement is fulfilled here. In end payor class actions alleging generic entry, the “vast majority of district courts” have held that class action treatment is superior to other available methods of adjudication.” Flonase, 284 F.R.D. at 234; see also In re Cardizem CD

Antitrust Litig., 200 F.R.D. 326, 351 (E.D. Mich. 2001) (“Multiple lawsuits by the large number of class members allegedly injured by Defendants’ antitrust violations would be costly and inefficient.”) (citations omitted).

### **3. Ascertainability**

“A plaintiff seeking certification of a Rule 23(b)(3) class must prove by a preponderance of the evidence that the class is ascertainable.” Byrd v. Aaron's Inc., 784 F.3d 154, 163 (3d Cir. 2015). To demonstrate ascertainability, a plaintiff must show that “(1) the class is ‘defined with reference to objective criteria’; and (2) there is a ‘reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.’” Id. (quoting Carrera v. Bayer Corp., 727 F.3d 300, 306 (3d Cir. 2013)). Ascertainability should not be conflated with the predominance requirement. “Predominance focuses on whether the essential elements of the class claims can be proven at trial by ‘common, as opposed to individualized, evidence.’” Boyle v. Progressive Specialty Ins. Co., No. 09-5515, 2018 WL 2770166, at \*10 (E.D. Pa. June 7, 2018) (quoting Byrd, 784 F.3d at 164). Ascertainability, on the other hand, “focuses on whether the class members can be identified without resorting to ‘individualized fact finding.’” Id. (quoting Byrd, 784 F.3d at 163, 164). “In other words, predominance considers the evidence necessary to establish the claims while ascertainability considers the criteria and means necessary to identify class members.” Id. Ascertainability does not, however, require plaintiff to identify all class members at class certification; rather, “plaintiff need only show that ‘class members *can* be identified.” Byrd, 784 F.3d at 163 (quoting Hayes v. Wal-Mart Stores, Inc., 725 F.3d 349, 355 (3d Cir. 2013)) (emphasis in Byrd); see also City Select, 867 F.3d at 439. “[A] party cannot merely provide assurances to the district court that it will later meet Rule 23’s requirements.” Byrd, 784 F. 3d at 164. “Nor may a party ‘merely propose a method of ascertaining a class without any

evidentiary support that the method will be successful.” Id. (quoting Carrera, 727 F.3d at 306-07, 311).

The Third Circuit provides “three principal rationales for the ascertainability requirement.” In re Tropicana Orange Juice Mktg. & Sales Practices Litig., No. 11-07382, 2018 WL 497071, at \*8 (D.N.J. Jan. 22, 2018), reconsideration denied, No. 11-07382, 2018 WL 2357749 (D.N.J. May 24, 2018). “First, ‘ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of the class.’” City Select, 867 F.3d at 439 (quoting Carrera, 727 F.3d at 306 (3d Cir. 2013)). “Second, it ensures that a defendant’s rights are protected by the class action mechanism,’ [ ] and that ‘those persons who will be bound by the final judgment are clearly identifiable.” Id. (quoting Carrera, 727 F.3d at 306; Marcus, 687 F.3d at 593). “Finally, ‘it ensures that the parties can identify class members in a manner consistent with the efficiencies of a class action.’” Id. (quoting Carrera, 727 F.3d at 307).

**a. Third Circuit Ascertainability Precedent**

“An examination of the various factual circumstances in which [the Third Circuit has] analyzed the ascertainability standards help to demonstrates its contours.” City Select, 867 F.3d at 439. In Marcus, “plaintiff proposed a class of New Jersey purchasers of BMW vehicles equipped with ‘run-flat tires’ that had ‘gone flat and been replaced’ during the class period.” Id. (quoting Marcus, 687 F.3d at 592). However, the defendant “did not have access to the records of which vehicles were equipped with the defective tires,” the plaintiff “did not present a method of obtaining records from individual dealerships” to demonstrate whether the defective tires were replaced with regular tires, and plaintiff did not propose a method for ascertaining which purchasers’ tires had gone flat and been replaced, as required by the class definition. Id. (citations omitted). “Because plaintiff merely left the answer to each of these questions to ‘potential class members’ say so,” the Third

Circuit remanded for consideration of “the critical issue of whether defendants’ records can ascertain class members and, if not, whether there is a reliable, administratively feasible alternative.” Id. at 439-40 (quoting Marcus, 687 F.3d at 594).

In Hayes v. Wal-Mart Stores, Inc., the Third Circuit “considered claims brought by a putative class of New Jersey retail discount club customers who purchased goods with extended warranties.” Id. at 440 (citing Hayes, 725 F.3d at 352). “Plaintiff’s proposed class definition included all customers who purchased a ‘Service Plan to cover as-is products’ but excluded any customers whose ‘as-is product was covered by a full manufacturer’s warranty, was a last-one item, customers who obtained service on their product, and consumers who have previously been reimbursed for the cost of the Service Plan.’” Id. (quoting Hayes, 725 F.3d at 353). The Third Circuit determined that the class definition “required a number of separate factual inquiries to determine class membership: ‘(1) whether a Sam’s Club members purchased a Service Plan for an as-is item, (2) whether the as-is item was a “last one” item or otherwise came with a full manufacturer’s warranty, and (3) whether the member nonetheless received service on the as-is item or a refund of the cost of the Service Plan.’” Id. (quoting Hayes, 725 F.3d at 356). It remanded “so that plaintiff could propose reliable and administratively feasible methods of answering these questions without requiring ‘extensive and individualized fact-finding.’” Id. (quoting Hayes, 725 F.3d at 356).

Next, in Carrera, the “District Court certified a class composed of all purchasers of a particular over-the-counter diet supplement over several years in the state of Florida.” Id. (citing Carrera, 727 F.3d at 304). “Defendants in that case were the drug manufacturers, and thus did not have access to any retailers records that could have established which customers purchased the drug during the requisite time period.” Id. (citations omitted). “Plaintiff proposed using ‘retailer

records of online sales and sales made with store loyalty or rewards cards’ combined with affidavits from potential class members.” Id. (quoting Carrera, 727 F.3d at 304). “But plaintiff had not sought, nor obtained, the proposed records during class discovery.” Id. (citations omitted). The Third Circuit determined that further inquiry into the nature and extent of the available records was necessary and remanded. It “also noted that, even if the proposed records did exist, there was no evidence that a ‘single purchaser,’ let alone the whole class, could be identified using them.” Id. (quoting Carrera, 727 F.3d at 309).

Then, in Byrd, the Third Circuit “considered claims brought by people who leased computers with spyware that was installed and activated without their consent.” Id. (citing Byrd, 784 F.3d at 160). “This class definition included both the lessees and their household members.” Id. (citations omitted). “Defendants kept detailed records enabling identification of the lessees”—the lessees and owners amounted to 895 in total. Id. (citations omitted). The Third Circuit concluded that “identification of the household members was unlikely to pose ‘serious administrative burdens that are incongruous with the efficiencies expected in a class action.’” Id. (quoting Byrd, 784 F.3d at 170). The Third Circuit reasoned that “[a]ny forms used to indicate a household member’s status in the putative class must be reconciled with the 895 known class members or some additional public records.” Byrd, 784 F.3d at 171.

Finally, in City Select, plaintiffs “brought claims under the Telephone Consumer Protection Act against BMW who they alleged sent them unsolicited faxes through a database called ‘Creditsmarts.’” In re Domestic Drywall Antitrust Litig., No. 13 -2437, 2017 WL 3700999, at \*8 (E.D. Pa. Aug. 24, 2017). Plaintiff “sought to certify a class of ‘all auto dealerships that were included in the Creditsmarts database on or before December 27, 2012, with fax numbers identified in the database who were sent one or more telephone facsimile messages between November 20,

2012 and January 1, 2013, that advertised the commercial availability of property, goods or services offered by BMW Bank of North America.” Id. (quoting City Select, 867 F.3d at 437). The District Court denied certification, concluding that “even though [p]laintiff may be able to identify the potential universe of fax recipients, there is no objective way of determining which customers were actually sent the BMW fax.” City Select, 867 F.3d at 437. The Third Circuit remanded “because the court determined that the use of the Creditsmarts database, which included the entire potential universe of class members because it was part of the class definition, in addition to affidavits, could have been a reliable and administratively feasible method of determining class membership.” In re Domestic Drywall, 2017 WL 3700999, at \*8. The Third Circuit “emphasized that in that case, due to the limited universe of potential plaintiffs, two policy considerations that underpin the administrative feasibility requirements were not concerns: facilitating opt-outs and identifying persons bound by the final judgment.” Id.

**b. Is the class defined with reference to objective criteria?**

Plaintiffs contend that the proposed Classes are defined with reference to objective criteria. Any person or entity that paid some or all of the purchase price of thalidomide in any form after November 6, 2010 or lenalidomide in any form after January 29, 2011 for their personal consumption or the consumption of their members or subscribers is a member of the Classes (unless they fall within one of the named exclusions). See Lidoderm, 2017 WL 679367, at \*25 (similar class definition found to be based on sufficiently objective criteria). The Court agrees. Moreover, Defendant does not provide any specific challenge under this first prong of the ascertainability analysis.

**c. Is there an administratively feasible method for determining class membership?**

Defendant, does, however, contend that Plaintiffs have failed demonstrate a reliable and administratively feasible method for determining class membership. Specifically, Defendants contend that Plaintiffs have failed to provide sufficient information to identify (a) what entities or consumers are members of the class; (b) the flat copay consumers and fully insured health plans that are excluded; or (c) which entities or consumers have claims in the fourteen Damages Jurisdictions. Defendants also contend that Plaintiffs entirely ignore the role of PBMs and stop-loss insurers. Plaintiffs, relying heavily on City Select, respond that individual consumers may be identified using pre-existing documentation in combination with Defendant's REMS database. As for third-party payors, Plaintiffs contend that they possess substantial transaction data from pharmacies and that third-party payors can submit their own transaction data, in conjunction with documents showing they are not fully insured. Finally, Plaintiffs argue that PBMs and stop-loss insurers are not part of the Damages Classes and, consequently, need not be identified for purposes of the ascertainability analysis.

### **1. Individual Consumers**

Plaintiffs propose four methods for identifying consumer class members: (1) purchase receipts; (2) pharma prescription records; (3) insurer prescription records; and (4) Celgene's REMS database. Defendants argue that these methods are insufficient.

Celgene's REMS database contains the last name, date of birth, partial social security number, prescribing physician, and dispensing pharmacy for each patient, and the name and address of every pharmacy dispensing either drugs. Thus, this case resembles Byrd and City Select, insofar as all potential individual consumers are listed in Defendant's own database. See In re Domestic Drywall, 2017 WL 3700999, at \*10 (noting that, in both Byrd and City Select, the "possible universe of plaintiffs was defined with reference to a single database, and defendants

claimed that there was difficulty ascertaining who among those listed in the database qualified for class membership”). However, the inquiry as to the ascertainability of consumer class members does not end merely by noting the existence of the database. Plaintiffs must also demonstrate an administratively feasible method for excluding the single flat copay consumers, as required by the class definition.

Plaintiffs contend that application of the single flat copay exclusion can be determined through comparing consumer’s purchase receipts or prescription history with the description of the prescription drug benefits provided by a health benefit plan or insurer. To demonstrate that this method is administratively feasible, Plaintiffs rely on David Mitchell’s documentation. Defendant argues that this proposed method necessitates individualized inquiry, thereby rendering it infeasible on its face. Defendant further contends that, even if such an individualized inquiry is not per se infeasible, it is infeasible here because of the complicated nature of the analysis. The Court agrees.

According to Plaintiffs, identifying individuals with a flat copay is as simple as comparing the amount and date of a drug purchase on a purchase receipt or prescription history with the description of the prescription drug benefit provided by the individual’s health benefit plan or insurer. Indeed, federal law requires non-governmental employee benefit plans to give participants and their beneficiaries a “Summary Plan Description” (“SPD”). See 29 U.S.C. § 1022. Plaintiffs contend that every third party payor class representative provided its participants and beneficiaries with a summary document stating in plain English that brand and generic drugs are subject to different co-pay amounts. In support of this proposition, Plaintiffs provide a 2016 receipt for a drug purchase by David Mitchell and a copy of his SPD from 2016. See Ex. 97-99, ECF No. 150.

Defendant identifies several problems with the proposed methodology. First, Defendant provides evidence that the SPDs and plan benefit statements are often inaccurate or unavailable. For example, Defendant points to Plaintiff IUB, whose health plan is described in an SPD that has not been updated since it was issued in 1999. ECF No. 182, Ex. 6 at 114:25-115:24. Instead, notices about benefit changes have been sent to plan members over the last two decades. To identify what any particular benefit was in any particular year, one “would need to look at th[e] 1999 Summary Plan Description and also look at all of the subsequent notices” because there is “[n]o official document . . . that would summarize it all nice and neat.” *Id.* at 121:13-25. Defendant identifies similar issues with respect to Plaintiff NEC’s SPD. *See* Werner Dep. at 97:23-98:11, ECF No. 182.4, Ex. 2 (NEC has an SPD from 2005 that it did not update until 2016). Second, Defendant asserts that—even assuming accuracy and availability—the documents do not necessarily indicate whether consumers are excluded as uninjured flat copay consumers.

Plaintiffs do not directly rebut any of these assertions, citing to the documentation of David Mitchell for their assertion that excluded consumers are identifiable. However, Defendant contends that even Mitchell’s information is problematic. Specifically, Defendant argues that the information provided by Mitchell—a 2016 receipt and a 2016 brochure—fails to account for the entire period in which Mitchell took Revlimid, which began in 2010. Moreover, Mitchell testified that the 2016 enrollment brochure did not accurately reflect his copayment for Revlimid and that he needed to call the specialty pharmacy to determine his copay for any particular prescription. ECF No. 182, Ex. 5 at 80:23-81:3, 85:7-13; 102:10-104:7). In sum, Plaintiffs ask the Court to rely on the incomplete records of one consumer to find there is a feasible, reliable method for ascertaining the excluded members of the consumer class. However, Plaintiffs fail to rebut or account for the deficiencies in their proposed methodology, and the Court is not satisfied, at this

junction, that the proposed methodology will prove effective. Consequently, the Court agrees with Defendant that Plaintiffs have failed to present evidence of a reliable “mechanism for determining whether putative class members fall within the class definition,” insofar as it relates to individual consumers. Byrd, 784 F.3d at 163. On any renewed motion, Plaintiffs are directed to demonstrate that the excluded, flat co-pay members of the class can be identified using the proposed records. See Carrera, 727 F.3d at 309.

## **2. Third Party Payors**

Turning to TPPS, Plaintiffs contend that they have substantial transaction data from pharmacies that dispensed Thalomid and Revlimid during the class period—accounting for about half of all prescriptions—in which third-party payor purchasers are identified. Plaintiffs also argue that third-party payors can submit their own transaction data as proof of purchases, in conjunction with documents showing they are not fully insured. Defendant responds that the pharmacy data is incomplete and unavailable. The Court finds that the proposed method of identifying third party payors is administratively reliable and feasible.

Plaintiffs assert—without dispute—that every named Plaintiff maintains records of claims for its drug purchases, and insurance companies maintain claim records in the ordinary course of business. See, e.g., Ex. 90, 91, 92, ECF No. 150. In addition, Plaintiffs also have transaction data from 24 pharmacies that dispensed Thalomid and Revlimid during the Class Period, constituting about half of the total volume shipped by Celgene. Leitzinger Rep. ¶ 46. Plaintiffs contend that “[t]hese data usually contain a field identifying the TPP, which can be used to confirm a TPP’s purchase.” See, e.g., Ex. 93, 94, ECF No. 150.

Defendant highlights the fact that Plaintiffs have been able to gather only half of the transaction data from the pharmacies dispensing Thalomid and Revlimid, despite issuing

subpoenas over a year ago. Defendant contends that Plaintiffs' failure to obtain all relevant records "heightens the . . . concern that such pharmaceutical records may not be obtainable for use in the ascertainability inquiry." Wellbutrin, 308 F.R.D. at 150 (discussing plaintiffs' failure to obtain records despite service of subpoenas during discovery); accord Carrera, 727 F.3d at 308–09 (class unascertainable in part because plaintiffs had not obtained during class discovery the retail records that they proposed to use to show diet supplement purchases). Moreover, Defendant analogizes to Vista Healthplan, where the court determined that the class was unascertainable. There, plaintiffs provided the customer history of one named consumer plaintiff, which they had obtained from that consumer's pharmacy, and a "chart of claims data that . . . lists patients by number and identifies . . . the submitted cost of the prescription and the copayment paid by the consumer." 2015 WL 3623005, at \*9. The court determined that "[p]laintiffs have failed to present any evidence that they have developed a methodology for ascertaining the identities of class members, aside from simply assuring the court that records of . . . prescriptions exist. Nor have [p]laintiffs presented any evidence to demonstrate that it is possible to ascertain class members in an administratively feasible manner without highly individualized inquiry." Id. at \*13.

Vista Healthplan is not analogous here, with respect to TPP purchases. Unlike the plaintiffs there, Plaintiffs here provided evidence demonstrating that TPPs' own transaction data is useable as proof of purchases. Defendant does not rebut this showing. Consequently, the Court does not find that ascertaining the membership of TPPs is problematic for certification, even if Plaintiffs are unable to procure all of the relevant pharmacy records.

### **3. PBMs**

Defendant contends that PBMs are potential class members because they may have paid a portion of the price of Thalomid and Revlimid as a result of spread pricing arrangements or price

discount guarantees. Defendant further asserts that Plaintiff has not proposed any method, let alone an administratively feasible one, for ascertaining which PBMs bore a portion of the payments. Plaintiffs argue that PBMs do not pay any portion of the payments and, thus, are not class members, thus obviating the need for an ascertainability analysis. The Court agrees with Plaintiffs.

Defendant relies extensively on the court's decision in Wellbutrin to support their position that PBMS are both potential members of the class and that their potential membership is not readily ascertainable. 308 F.R.D. 134. In Wellbutrin, like here, plaintiffs "argue[d] that PBMs are not potential class members," and thus did "not need to show that [they] can ascertain which PBMs are class members and which are not." Id. at 148. The court disagreed, finding "PBMs are potential class members because they may have paid a portion of the retail purchase price . . . via so-called 'spread pricing arrangements' or 'price discount guarantees.'" Defendant contends that the same reasoning is fatal to the instant motion.

Defendant reasons that most sponsors, and all named Plaintiffs who are sponsors, use PBMs. Hughes Rep. ¶¶ 21, 48. Accordingly, each Thalomid and Revlimid claim paid by such a sponsor was paid to the pharmacy in the first instance by the PBM, which later would have sought reimbursement from the sponsor for the purchase price pursuant to the parties' contract. Defendant argues that, if the PBM paid more to the pharmacy than it received in reimbursement from the sponsor, it would be a class member, as it would have paid a portion of the price after accounting for payments by other entities. Defendant rightly contends that Plaintiffs have not identified which PBMs bore a portion of the payments for Thalomid and Revlimid. The same failing led the Wellbutrin court to find that "[t]here are thousands of PBMs and retail pharmacies; the [plaintiff] has not produced any evidence showing that it could synthesize records from these disparate

entities and use them to ascertain PBMs . . . in a reliable and administratively feasible manner.”  
308 F.R.D. at 150.

To remove any question of PBMs class membership, Plaintiffs propose excluding them from the class. While this solution would remove any potential ascertainability issues, it would potentially raise other concerns to the extent that PBMs do, in fact, bear responsibility for some or all of the purchase price of Thalomid and Revlimid. See In re Skelaxin, 299 F.R.D. at 575 (finding, in a similar delayed entry case, that excluding PBMs—or finding them excluded under the class definition—would create issues with plaintiffs’ impact and damages model because the model would “incorporate damages suffered by TPPs who are ostensibly excluded from the class” and that “such a model could be problematic” because the it would not measures those damages “attributable only to End Payors’ theory”) (emphasis in original). Thus, if the Court finds that PBMs potentially bear part or all of the cost of Thalomid and Revlimid, it would create issues either with ascertainability or, if PBMs are excluded, with the classwide damages model.

However, neither of these potential issues are relevant here, as the Court is not convinced that PBMs potentially bear any or part of the cost of Thalomid and Revlimid. First, Dr. Hughes has provided no evidence to support his opinion that PBMs may have paid pharmacies more for a drug than they received from the third-party payor. See Ex. 112, Hughes Dep. 246:22-247:15 (admitting that he had no citation to support his opinion). Dr. Hughes could not name an example of this happening. Id. at 81:23-83:17. The court in Lidoderm considered Dr. Hughes opinion that PBMs could potentially pay part of the price of a drug and concluded that, “[a]s with spread pricing, defendants identify a general, theoretical risk without substantiating the true impact (if any) of that risk.” 2017 WL 679367. Ultimately, the Lidoderm court found that “defendants criticize [plaintiff’s] model for its failure to exclude damages born by the PBMs that resulted from

the speculated failure of the PBMs to effectively negotiate rebates and set spread prices. However, . . . there is no evidence either of these scenarios actually occurred to PBMs” with respect to the product at issue. Id. at 25 (emphasis in original). There, as here, “[d]efendants’ speculation cannot defeat certification.”<sup>5</sup> Id.

#### **4. Purchases Falling Within the Relevant Jurisdictions’ Laws**

Defendant contends that, because the proposed Damages Classes are limited to persons or entities that purchased or paid for Thalomid or Revlimid in the fourteen Damages Jurisdictions, it is fundamental that Plaintiffs articulate a method to identify the purchases of Thalomid and Revlimid covered by the Damages jurisdictions while excluding other purchases. Defendant further contends that Plaintiffs have not, in fact, offered a method for determining which purchases fall within the jurisdictions at issue and, to make matters worse, they argue that Plaintiffs fail to apply a consistent criterion for deciding which state’s laws apply to a given purchase. Plaintiffs reply that the method for ascertaining whether a purchase was made in a Damages Jurisdiction is simple: did the purchaser pay for some or all the purchase price of Thalomid or Revlimid in a Damages Classes state? For consumers, Plaintiffs contend “a purchase occurs during the transaction with the pharmacy, which for Thalomid or Revlimid typically takes place over the telephone. So if consumers were in a Damages Class state when they made the purchase, then (as long as they do not pay a flat co-pay for all prescriptions) they are members of the Damages Classes.” Pl. Reply at 8; see In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 758 (E.D. Pa. 2014) (plaintiffs may sue under laws of states in which they reside or in which they purchased

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<sup>5</sup> Defendant provides a declaration from the CEO of IUB’s PBM, which states that the PBM may pay the pharmacy either more, less, or the same amount that it receives from the Sponsor. Again, the Court does not disagree that it is theoretically possible that a PBM end up paying part of the price of a prescription. Rather, the Court finds that this theoretical, unsubstantiated risk is not borne out by any evidence in the record.

drug). Health plans “can also be members of the Damages Classes if they themselves are located in one of the Damages Class states, as these health plans are paying for some or all . . . of the purchase price of Thalomid or Revlimid from the state in which they are located.” Pl. Reply at 9; see In re Flonase Antitrust Litig., 692 F. Supp. 2d 524, 533 (E.D. Pa. 2010) (finding plaintiff health and welfare plans had “standing to bring a claim under the laws of the states where they are located, and where they purchased Flonase or reimbursed their members for Flonase purchases”).

In sum, while the Court disagrees with most of Defendant’s contention regarding ascertainability, it nonetheless finds that Plaintiffs have failed to provide an administratively feasible method of determining class membership. In any renewed motion, Plaintiff must demonstrate that excluding flat co-pay consumers will not require extensive individualized inquiry and mini-trials.

### **C. Rule 23(b)(2) Injunction Class**

In addition to the Damages Classes, Plaintiffs also seek to certify an Injunction Class under Rule 23(b)(2). A class action is “maintainable under Rule 23(b)(2) when ‘the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.’” Barnes v. Am. Tobacco Co., 161 F.3d 127, 142 (3d Cir. 1998) (quoting Fed. R. Civ. P. 23(b)(2)). “Subsection (b)(2) class actions are ‘limited to those class actions seeking primarily injunctive or corresponding declaratory relief.’” Id. (quoting Fed. R. Civ. P. 23(b)(2) advisory committee’s note)).

Defendant raises one primary argument against certifying the Rule 23(b)(2) class—the relief sought by Plaintiffs is primarily monetary. See, e.g., In re Arthur Treacher’s Franchise Litig., 93 F.R.D. 590, 594 (E.D. Pa. 1982) (denying class certification because “the relief sought is

predominantly money damages”); Hall v. Burger King Corp., No. 89-0260, 1992 WL 372354, at \*11 (S.D. Fla. Oct. 26, 1992) (finding that, “where antitrust plaintiffs seek treble damages, certification under Rule 23(b)(2) is improper even if injunctive relief is sought as well”). Defendant notes several cases where Courts refused to certify 23(b)(2) classes “even where injunctive classes have been proposed alongside separate damages classes if the ‘primary intent’ driving the action ‘is to recovery damages for past purchases.’” Def. Br. at 50 (quoting In re Flash Memory Antitrust Litig., No. C 07-0086, 2010 WL 2332081, at \*7 (N.D. Cal. June 9, 2010); see also In re Processed Egg Prods. Antitrust Litig., 321 F.R.D. 555, 558 (E.D. Pa. 2017) (stating that “[a]ntitrust cases . . . at their core, revolve around money” and, consequently, “the very nature of antitrust claims does provide good cause for a court to examine a request for (b)(2) certification with some good faith skepticism”).

Plaintiffs contend that the relief sought is not primarily monetary here because a large portion of the proposed Injunction Class—namely, the members that are not in the Damages Jurisdictions—is not seeking money damages. See, e.g., In re OSB Antitrust Litigation, 2007 WL 2253425, at \*18 (“Although the classes are represented by the same named [p]laintiffs, they are not identical. The nationwide class potentially includes many members from states that do not permit damages actions. Thus, a significant portion of the nationwide class seeks injunctive relief only. In these circumstances, it is appropriate to certify two separate classes under Rule 23(b)(2) and 23(b)(3)”; Cohen v. Chicago Title Ins. Co., 242 F.R.D. 295, 301 (E.D. Pa. 2007) (rejecting argument that plaintiff sought primarily monetary damages and certifying Rule 23(b)(2) and (b)(3) classes, as “[a]ny remedy could include both money damages and enjoining the conduct”); Wilson v. County of Gloucester, 256 F.R.D. 479, 491–92 (D.N.J. 2009) (“certifying the equitable portion of this suit under (b)(2), and the damages portion under (b)(3), allows for the best of both worlds”).

The Court will not apply a brightline rule, as suggested by Defendant. Rather, the Court finds “that when a Rule 23(b)(2) class is proposed alongside Rule 23(b)(3) classes, the correct approach is to rigorously analyze whether the proposed class is appropriate.” In re Processed Egg Products, 312 F.R.D. at 166. The Court finds that Plaintiffs “have not met their burden of demonstrating that certification of the Rule 23(b)(2) class is appropriate.” Id. at 170. Plaintiffs have devoted only a fraction of their analysis to discussing the legal requirements of Rule 23(b)(2). One specific issue that must be addressed in any renewed motion is “the preclusive effect of an injunction-only class action on class members’ ability to bring subsequent damages claims.” See In re Skelaxin, 299 F.R.D. 555 (“Many courts have acknowledged the claim preclusive difficulties associated with injunction-only class actions”); see also In re Processed Egg Prod. Antitrust Litig., 312 F.R.D. 124, 171 (E.D. Pa. 2015). Because Plaintiffs have not sufficiently met their burden on this point, the Court will deny the motion in its entirety.

### **III. Conclusion**

Based on the foregoing, the Motion for Class Certification and Appointment of Class Counsel, ECF No. 149, is **DENIED** without prejudice. The parties are directed to meet with the Magistrate Judge regarding a renewed motion schedule.

/s Madeline Cox Arleo  
**Hon. Madeline Cox Arleo**  
**United States District Judge**