NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Case No. 2:17-cv-00699 (BRM) (RLS) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before the Court is Plaintiffs' Motion for Class Certification pursuant to Federal Rule of Civil Procedure 23. (ECF Nos. 574, 575.) Defendants Novo Nordisk, Inc. ("Novo Nordisk"), Sanofi-Aventis U.S. LLC ("Sanofi"), and Eli Lilly and Company ("Eli Lilly")[1] (collectively, "Defendants") filed an opposition (ECF No. 576), Plaintiffs filed a reply (ECF No. 577), Defendants filed a sur-reply (ECF No. 587), and Plaintiffs filed a response to Defendants' sur-reply as part of an omnibus filing (ECF No. 597). Plaintiffs later filed a supplemental brief in further support of their Motion for Class Certification. (ECF No. 707.) Plaintiffs also filed a letter with a notice of supplemental authority—*In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, Civ. A. No. 19-2875, 2023 WL 1818922 (D.N.J. Feb. 8, 2023) (ECF No. 606), to which Defendants filed a letter in response (ECF No. 607), and Plaintiffs filed a letter in reply to Defendant's response (ECF No. 609). Defendants also separately filed a letter with an additional notice of supplemental authority—*In re Niaspan Antitrust Litig.*, 67 F.4th 118 (3d Cir. 2023). (ECF

[1] On May 26, 2023, Plaintiffs filed a Motion for Preliminary Approval of Class Action Settlement between Plaintiffs and Defendant Eli Lilly. (ECF No. 639.) This motion is *sub judice*, pending adjudication of various subsequently filed motions to intervene and object to this motion, which were referred to The Honorable Joseph A. Dickson, U.S.M.J. (ret.), appointed as mediator in this action. (*See* ECF No. 644; *see also* No. 23-md-03080, ECF No. 19 (Case Management Order #2 in related insulin pricing multi-district litigation) at 2.)

No. 635.)

Also before the Court is Defendants' Motion to Exclude the Expert Testimony of Plaintiffs' expert Meredith Rosenthal, Ph.D. (the "*Daubert* Motion"). (ECF Nos. 593, 594.) Plaintiffs filed an opposition (ECF No. 595), Defendants filed a reply (ECF No. 596), and Plaintiffs filed a sur-reply as part of an omnibus filing (ECF No. 597). Having reviewed the parties' voluminous submissions filed in connection with the two motions, and having held oral argument on November 28, 2023, for the reasons set forth below and for good cause having been shown, Plaintiffs' Motion for Class Certification is **DENIED**, and Defendants' *Daubert* Motion is **GRANTED IN PART and DENIED IN PART**.

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TABLE OF CONTENTS

I. BACKGROUND[2]

A. Factual Background

This action arises out of Plaintiffs' challenge to Defendants' allegedly unfair and unconscionable pricing scheme for their analog insulin products. (*See generally* ECF No. 411 (Third Amended Class Action Complaint).) Plaintiffs are analog insulin consumers who filed the Third Amended Class Action Complaint ("TAC") on behalf of themselves and all others similarly situated, *i.e.*:

> All individual persons in the United States and its territories who paid any portion of the purchase price for a prescription of Apidra, Basaglar, Fiasp, Humalog, Lantus, Levemir, Novolog, Tresiba, and/or Toujeo at a price calculated by reference to a list price, AWP (Average Wholesale Price), or WAC (Wholesale Acquisition Price) for purposes other than resale.

(ECF No. 411 ¶ 322; *see also id.* ¶¶ 25–185.) Defendants are manufacturers who manufacture and sell prescription medications, including analog insulin products.[3] (*Id.* ¶¶ 186–88.) Defendants set the Wholesale Acquisition Cost ("WAC"[4]), also known as the list price, for their prescription

[2] The factual and procedural backgrounds of this matter are well known to the parties and were previously recounted by the Court in its Opinion granting in part and denying in part Defendants' Motion to Dismiss the First Amended Complaint (ECF No. 252); the Court's Opinion granting in part and denying in part Defendants' Motion to Dismiss the Second Amended Complaint (ECF No. 304); and the Court's Opinion granting in part and denying in part Defendants' Motion to Dismiss the Third Amended Complaint (ECF No. 505). Therefore, the Court includes only the facts and procedural background relevant to the present motions.

[3] Defendant Eli Lilly is incorporated in Indiana with its principal place of business in Indiana. (ECF No. 411 ¶ 186.) Defendants Novo Nordisk and Sanofi are both incorporated in Delaware with their principal places of business in New Jersey. (*Id.* ¶¶ 187–88.) Defendant Eli Lilly manufactures the analog insulin products Humalog and Basaglar; Defendant Novo Nordisk manufactures the analog insulin products Fiasp, Novolog, Levemir, and Tresiba; and Defendant Sanofi manufactures the analog insulin products Apidra, Lantus, and Toujeo. (*Id.* ¶¶ 186–88.)

[4] "WAC" is defined as "Wholesale Acquisition *Price*" in Plaintiffs' filings (*e.g.*, ECF No. 411 ¶¶ 202, 322; ECF No. 575 at 58) and as "Wholesale Acquisition *Cost*" in Defendants' filings (*e.g.*, ECF No. 576 at 16). The Court understands Wholesale Acquisition Price and Wholesale

drugs, including analog insulin products. (*See id.* ¶ 205; ECF No. 576-2, Ex. 1 (Expert Report of Laurence C. Baker, Ph.D. ("Baker Rpt.")) ¶ 27.) WAC is defined as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price[.]" 42 U.S.C. § 1395w-3a(c)(6)(B) (2021). The WAC, or list price, serves as the reference point from which pharmacy benefit managers ("PBMs"[5]) and drug manufacturers negotiate rebates. (*Id.* ¶ 207.) WAC is related to, but not the same as, Average Wholesale Price ("AWP").[6] (*See id.* ¶¶ 202, 206.)

Acquisition Cost to be referring to the same thing—the list price Defendants set for their analog insulin products.

[5] As stated in Plaintiffs' TAC: "PBMs effectuate the drug transactions between health insurers, pharmacies, and drug manufacturers" and "[t]hey negotiate directly with drug manufacturers on behalf of health insurers to determine the prices those insurers pay for the manufacturers' drugs." (ECF No. 411 ¶ 4.) "Drug manufacturers and PBMs negotiate these price discounts in the form of 'rebates': drug manufacturers refund PBMs a portion of their drugs' prices (the rebate)" and "PBMs then pass on a portion of those rebates to their health insurer clients." (*Id.*) Three PBMs—CVS Health, Express Scripts, and OptumRx—"together cover over 80% of the insured market[.]" (*Id.*) "When two or more branded medicines fall into the same therapeutic category and have similar effectiveness and safety profiles (as is the case with the analog insulins), a PBM is in the position to sometimes exclude, or place in a non-preferred position, one of the medications in favor of another." (*Id.* ¶ 5.) Thus, "the large PBMs can push significant portions of the market toward or away from the [D]efendants' products." (*Id.*)

[6] *See In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83, 87 (D. Mass. 2008) (noting "AWP" or Average Wholesale Price refers to the average price that wholesalers charge to providers like doctors and pharmacies, which may not reflect the "true" average price charged by wholesalers); ECF No. 575 at 19 ("AWP is WAC plus 20% due to a court order settling two nationwide class-actions." (citing Rosenthal Rpt. ¶ 29) (other citations omitted)); ECF No. 576 at 16 n.3 ("Some—but not all—PBMs, insurers, and pharmacies also use a figure called the Average Wholesale Price ('AWP'). AWP is generally calculated by increasing WAC by a fixed percentage—often, but not always, 20%." (citing Baker Rpt. ¶¶ 30–32)); Baker Rpt. ¶¶ 30–31 ("Defendant insulin manufacturers do not determine AWP and do not publish AWP; instead, AWP is calculated and published by commercial pricing compendia, like IBM Micromedex Red Book and Medi-span, using manufacturers' WAC. As applicable to this case, AWP for the analog insulin has generally, but not always, been calculated as 1.2 × WAC. AWP has been used as a benchmark by insurance payers to determine how much to reimburse and pay for a given drug. As commonly used today, AWP is not a measurement of actual average wholesale prices. In fact, some pricing compendia have discontinued publishing AWP." (footnotes omitted)).

Branded prescription drugs in the United States move through a complex distribution chain where drug manufacturers typically sell their products to wholesalers at a negotiated price, who in turn sell the products to various providers including hospitals, clinics, and retail pharmacies, who then in turn distribute the products to patients who are prescribed those products. (*Id.* ¶¶ 193–97, 200.) Downstream charges generally flow from the manufacturer to the wholesaler, from the wholesaler to the retailer (or mail order), and from the "retailer (or mail order) to the health benefit providers (in the form of ingredient cost reimbursement and dispensing fees) and [to] consumers (in the form of coinsurance, copayment, deductible payment, and/or cash)." (*Id.* ¶ 198.) Upstream charges, however, flow from PBMs and/or health benefit providers back to the manufacturers. (*Id.* ¶ 199.) "[U]pstream charges are price discounts the defendant drug manufacturers offer PBMs and their health insurer clients in the form of 'rebates'" and "typically occur well after the point-of-sale transactions." (*Id.*)

This industry is unique because the way patients pay for prescription drugs vastly differs from the way wholesalers, PBMs, and health insurers pay for those same products. (*Id.* ¶ 203.) The prices for the products distributed in this chain differ for each participating entity—"different actors pay different prices for the same drugs." (*Id.* ¶ 202.) Manufacturers do not sell medications directly to the consumers, and as such, they do not set the price the consumer pays for any particular medication, but they do set the list price (the WAC) for their products, and consumers usually pay for prescription drugs based on those list prices. (*See id.* ¶¶ 200–08.) Patients typically pay in one of a few ways based on the manufacturer's list price. (*Id.* ¶ 203.) First, for insured patients who have coinsurance, they pay a pre-set percentage of the point-of-sale purchase price. (*Id.*) Second, for insured patients who have deductibles, they pay a portion of the point-of-sale purchase price. (*Id.*) Insured patients may also pay a fixed or tiered co-pay for prescription

medications. (*Id.*) Third, for uninsured patients, also known as cash-paying patients, they typically pay a usual and customary ("U&C") price.[7] (*Id.*)

Health insurers cover all or a portion of their insured customers' medication costs, submitting payments to pharmacies on behalf of their members, and their reimbursement amounts depend on whether and where the medication falls on their PBMs' formularies—*i.e.*, the ranked list of drugs an insurance plan will cover. (*Id.* ¶¶ 195, 207.) Formularies have different tiers that affect the prices insured consumers pay. (*See id.*) "When a drug is excluded from formulary or placed in a non-preferred position, health insurers using that formulary will make their plan beneficiaries shoulder a greater percentage or all of the disadvantaged product's cost." (*Id.* ¶ 5.) Insurance plans include different cost-sharing and coverage terms. (*See id*. ¶¶ 201, 214–21, 223–29.) The deductible is the amount a consumer must spend before the insurer begins sharing in those costs. (*Id*. ¶¶ 214, 225.) Insured consumers pay their insurer monthly premiums that are often based in part on the deductible level. (*See id*. ¶¶ 213–14.) In addition to their deductibles, insured consumers may also make co-payments or coinsurance payments for their healthcare costs.

[7] *See* ECF No. 575 at 20 ("Specifically, an insured patient with coinsurance or deductible requirements pays for analog insulin based on the lesser of her pharmacy's usual and customary price (U&C) or the reimbursement rate her pharmacy negotiated with her insurer (or, more commonly, the insurer's PBM). Both the U&C price and the negotiated reimbursement rate are tied to AWP. U&C is either pegged directly to AWP or otherwise set based on AWP. And the negotiated reimbursement rate for the analog insulins is AWP minus a fixed percentage. . . . Cash purchasers pay U&C, which, again, is tied to WAC or AWP." (citations omitted)); ECF No. 576 at 19–20 ("One type of pharmacy cash price is the Usual & Customary ('U&C') price. Medicare defines a pharmacy's U&C price as the lowest price at which a pharmacy has made a drug 'widely and consistently available' to the public. Like cash prices generally, U&C prices often do not correlate with WACs. That is because U&C prices are affected by factors other than list prices, such as competition between local pharmacies. Thus, U&C prices can vary substantially even within a single pharmacy chain. Regardless, 'very few customers actually pay the full usual and customary price,' because of discounts and affordability programs." (citations omitted)); Baker Rpt. ¶¶ 36–39 (discussing U&C prices).

(*Id.* ¶ 223.) After reaching the deductible, an insured consumer may have to pay a co-payment at a fixed dollar amount or coinsurance at a fixed percentage amount for healthcare costs including medications being purchased. (*Id*. ¶ 223–25.) Also, "[p]lans that cover prescription drugs right away, not requiring patients to reach deductibles first, usually require copayments or coinsurance contributions for every drug purchase." (*Id.* ¶ 225.)

"A copayment is a fixed or tiered fee that an individual must pay for a healthcare service at the time of care; for example, when she picks up a prescription." (*Id.*) "Copayment rates vary depending on the drug; usually drugs in preferred formulary positions have lower copays, and drugs in disfavored formulary positions require larger copays." (*Id*.) Coinsurance is "a fixed percentage of the cost of the healthcare service provided." (*Id.* ¶ 224.) Coinsurance percentages can similarly vary, "with lower coinsurance rates for preferred drugs and higher coinsurance rates for disfavored drugs." (*Id.*) When insured patients purchase a prescription medication from a pharmacy, their insurer pays a portion of the purchase price "based on the price its PBM negotiated for that medication (the net price)" and the patient also usually pays a portion of the purchase price out-of-pocket for that medication. (*Id.* ¶¶ 195, 201.)

Drug manufacturers may offer rebates to an insurer's PBM to gain formulary access for their prescription drugs. (*Id.* ¶¶ 8, 207.) PBMs then independently decide whether to pass along rebates to the health insurer. (*Id.* at ¶¶ 4, 234; Baker Rpt. ¶ 59; *id.*, Ex. 2 (Expert Report of Sean Nicholson, Ph.D. ("Nicholson Rpt.")) ¶ 28.) PBMs may retain a portion of the rebate before passing the remainder of the cost on to the health insurer. (ECF No. 411 ¶¶ 2, 4, 364; Baker Rpt. ¶ 59.) Some health insurers who receive those rebate savings can then choose to pass along some or all of those savings to their customers. (ECF No. 411 ¶¶ 214–21, 223–29; Baker Rpt. ¶ 60.) Depending on the insurer, these savings may come in the form of lower plan premiums or reduced

cost-sharing obligations on consumers for prescription drugs.[8] (*See id.*) For example, an insurer may take rebates into account in determining a consumer's coinsurance obligations. (*Id.* ¶ 86.) Other insurers who receive manufacturer rebates may choose not to pass on the rebate savings to their consumers. (*Id.*)

Here, Plaintiffs allege Defendants engaged in an unfair and unconscionable pricing scheme by artificially inflating the list prices for their analog insulin products so they could offer "secret rebates" to certain PBMs in exchange for preferred formulary placement, which Plaintiffs contend caused them and the putative class members to overpay for Defendants' analog insulin products. (ECF No. 411 ¶¶ 1–3, 8; ECF No. 575 at 1, 4, 54–55.) Plaintiffs contend Defendants artificially inflated the list prices for their analog insulin products to compete for preferred positions on the PBMs' drug formularies[9] by offering increased rebates to PBMs. (*Id.*) Plaintiffs claim they and the putative class members suffered harm because they had to overpay for Defendants' analog insulin products, paying "based on a fraudulently inflated list price." (ECF No. 411 ¶¶ 3, 8, 13; ECF No. 575 at 3, 18–24.) Plaintiffs assert Defendants published their list prices "while concealing their net prices, [which] has deceived the plaintiffs into believing that the list prices on which their out-of-pocket payments are based are reasonable and fair approximations of the actual cost of their analog insulins." (ECF No. 411 ¶ 14.) Plaintiffs premise this pricing scheme on Defendants' alleged unfair

[8] In 2020, one insurer disclosed to its plan members that for any rebate-eligible drug they purchase, the plan members will receive most of the estimated value of the rebates which will reduce their contribution to the cost of the drug. (Baker Rpt. ¶ 60.) Another insurer requires all rebates to be passed on to consumers enrolled in its fully insured plans. (*Id.*)

[9] Health insurers rely on PBMs to set and manage their drug formularies—the list of prescription drugs for which an insurance plan offers insurance benefits. (Rosenthal Rpt. ¶ 26.) Because analog insulins are interchangeable within their therapeutic classes, PBMs can restrict formularies to cover only one analog insulin for each class, thereby forcing manufacturers to compete for formulary placement. (*Id.* ¶¶ 46–47.)

and unconscionable practice of publicly reporting one price for their analog insulins while offering a far lower price—the net price—to certain PBMs, by virtue of offering them significant rebates.[10] (*Id.* ¶¶ 2, 234–41.)

According to Plaintiffs, Defendants' allegedly unfair and unconscionable scheme of competing for formulary access of the largest PBMs by unjustifiably raising the list prices for their analog insulin products so they could offer these middlemen bloated rebates—so-called "spreads" between list prices and net prices—began (for most analog insulins) sometime between 2014 and 2015, when Defendants' list prices began trending in a different direction from the net prices they were offering to the PBMs and insurers. (ECF No. 575 at 2, 8, 16–17.) "Net prices" refers to the prices PBMs negotiate and pay for Defendants' products after subtracting from the list prices the rebate amounts Defendants issued to them in order to gain formulary placement. (ECF No. 411 ¶¶ 2, 4, 7–8.) Net prices may fluctuate as they necessarily depend on a particular PBM's negotiations with Defendants. (*See id.*) Plaintiffs contend their proposed classes are based on the monetary losses they suffered in overpaying for their analog insulin products as a result of Defendants' allegedly unfair and unconscionable pricing scheme. (*Id*. ¶¶ 3, 12–14, 19–20.) Plaintiffs further allege whatever negotiations or transactions may or may not have taken place between manufacturers and wholesalers or between wholesalers and pharmacies did not impact the prices consumers paid. (*Id.* ¶ 439.)

[10] However, Plaintiffs and Defendants both generally agree that paying rebates to PBMs in the pharmaceutical industry is legal. (*See* ECF No. 576 at 2; ECF No. 577 at 1, 39–40; *see also* ECF No. 411 ¶ 6 ("When used correctly, rebates can significantly lower consumers' costs. In theory, drug manufacturers might offer PBMs discounts or rebates that lower the manufacturers' *net* selling prices while their list prices remain constant. Such rebates would serve as a legitimate basis to confer formulary status to the least costly medication. The legitimate use of discounts and rebates that actually reduce consumer costs is not at issue in this case.").)

Plaintiffs state PBM rebates are part of an industry scheme to inflate the price of analog insulin products, whereby the largest PBMs use their leverage to set formularies. (ECF No. 411 ¶¶ 2, 364, 392.) If a drug is excluded from the formularies, consumers may be required to pay a larger share of the cost, or even the full cost; accordingly, using formularies gives PBMs wide latitude to extract rebates from manufacturers. (*Id*. ¶¶ 2, 207, 239, 277.) Plaintiffs argue Defendants offer PBMs higher spreads in exchange for preferred positions on their drug formularies, rather than lower their list prices for their prescription drugs. (*Id*.) Plaintiffs contend Defendants' allegedly "fraudulent conduct in artificially inflating the list prices of the analog insulins" has "directly and proximately caused the plaintiffs and members of the class to be injured[,]" and Plaintiffs assert they "have overpaid many hundreds of millions of dollars" based on these artificial list prices. (*Id.* ¶¶ 306, 377.)

B. Procedural History

On April 20, 2021, Plaintiffs filed their Third Amended Class Action Complaint ("TAC"). (ECF No. 411.) On June 11, 2021, Defendants filed a Partial Motion to Dismiss the TAC. (ECF No. 422.) Plaintiffs filed an opposition (ECF No. 455), and Defendants filed a reply (ECF No. 468). On December 17, 2021, the Court granted in part and denied in part Defendants' Motion to Dismiss the TAC. (ECF No. 505.) The Court also directed the parties to provide a joint submission to the Court "with an agreed upon list as to which claims fail as to certain Defendants where no Plaintiff from the respective state purchased that Defendant's products" (ECF No. 505 at 34–35), which the parties did on February 1, 2022 (ECF Nos. 508, 508-1[11]).

[11] Relevant to Plaintiffs' Motion for Class Certification, Plaintiffs represented in this filing to the Court that they are not asserting claims against Sanofi under the Kansas Consumer Protection Act because no plaintiff is alleged to have purchased Sanofi's product in Kansas. (*See* ECF No. 508 (Feb. 1, 2022 Letter from the Parties to the Court submitted in response to the Court's Dec. 17, 2021 Order (ECF No. 506)) (attaching a chart (ECF No. 508-1) "showing which claims have been

On September 20, 2022, Plaintiffs filed a Motion for Class Certification. (ECF Nos. 574, 575.) Defendants filed an opposition (ECF No. 576), Plaintiffs filed a reply (ECF No. 577), Defendants filed a sur-reply[12] (ECF No. 587), and Plaintiffs filed a response to Defendants' sur-reply as part of an omnibus response (ECF No. 597). On February 9, 2023, Plaintiffs filed a letter with a notice of supplemental authority—*In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, Civ. A. No. 19-2875, 2023 WL 1818922 (D.N.J. Feb. 8, 2023)—in further support of their Motion for Class Certification (ECF No. 606), to which Defendants filed a letter in response (ECF No. 607), and Plaintiffs filed a letter in reply to Defendant's response (ECF No. 609). On May 9, 2023, Defendants separately filed a letter with an additional notice of supplemental authority—*In re Niaspan Antitrust Litig.*, 67 F.4th 118 (3d Cir. 2023)—in further support of its opposition to Plaintiffs' Motion for Class Certification. (ECF No. 635.)

On November 30, 2022, Defendants filed a Motion to Exclude the Expert Testimony of

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dismissed, withdrawn, or are not asserted against a particular defendant because no plaintiff is alleged to have purchased the defendant's product in a given state"); ECF No. 508-1 at 7 (indicating there are no plaintiff claims against Sanofi under the Kansas Consumer Protection Act); *see also* ECF No. 411 ¶¶ 724–31 (noting the count (Count Twenty-Seven) alleging a violation of the Kansas Consumer Protection Act is against *Novo Nordisk*).) Based on this filing, the Court understands Plaintiffs are not currently asserting any claims against Sanofi under the Kansas Consumer Protection Act.

[12] On October 28, 2022, Defendants filed a letter attaching a sur-reply in support of their opposition to Plaintiffs' Motion for Class Certification and requesting that the Court consider their sur-reply "to respond to new arguments that Plaintiffs advanced for the first time in their reply brief in support of their motion for class certification." (ECF No. 587 at 1.) On November 3, 2022, Plaintiffs filed a letter in response stating if the Court permitted Defendants to file their sur-reply, then it should also permit Plaintiffs to submit an omnibus sur-reply in response to both Defendants' sur-reply and Defendants' *Daubert* Motion. (ECF No. 588.) Plaintiffs stated they did not oppose Defendants' request to file a sur-reply so long as they could file a sur-reply in response to Defendants' sur-reply, and they represented that after meeting and conferring, Defendants consented to Plaintiffs' request. (ECF No. 588 at 1.) On November 4, 2022, the Court granted Defendants' request to file a sur-reply and Plaintiffs' request to file an omnibus sur-reply in response. (ECF No. 589.)

Plaintiffs' expert Meredith Rosenthal, Ph.D. ("Dr. Rosenthal") (the "*Daubert* Motion"). (ECF No. 593.) Plaintiffs filed an opposition (ECF No. 595), Defendants filed a reply (ECF No. 596), and Plaintiffs filed a sur-reply as part of an omnibus response (ECF No. 597).

On November 28, 2023, the Court held oral argument[13] on both Plaintiffs' Motion for Class Certification and Defendants' *Daubert* Motion. (ECF No. 713 (Sealed Tr. of Nov. 28, 2023 Oral Arg.).) The Court addresses both Motions in turn.

II. DEFENDANTS' *DAUBERT* MOTION

Defendants move to exclude the testimony of Plaintiffs' expert Meredith Rosenthal, Ph.D., a Professor of Health Economics and Policy at Harvard University's School of Public Health ("Dr. Rosenthal"). (ECF Nos. 593, 594.) Plaintiffs retained Dr. Rosenthal to opine on the following:

> (1) describe in economic terms the [alleged] list-price increase scheme orchestrated by the defendants, (2) assess how this scheme benefited the defendants and other major actors in the pharmaceutical supply chain while imposing costs on consumers, (3) evaluate the economic impact of this scheme on class members, (4) apply statistical methods to determine the date or dates when the injury to class members began, and (5) calculate damages.

(ECF No. 575-2 (Decl. of Meredith Rosenthal, Ph.D. in Supp. of Class Cert. ("Rosenthal Rpt.")) ¶ 1.) Among other things, Dr. Rosenthal opines that Defendants' alleged "list-price increase scheme" consisted of Defendants choosing to increase rather than decrease list prices for their analog insulin products to gain market share, and in doing so, undermined price competition and instead competed on rebates unobserved by, and unavailable to, consumers. (*Id.* ¶ 2.) Dr. Rosenthal asserts "[t]his led to a growing spread between the list prices, most of which increased faster than

[13] Oral argument was originally scheduled for February 9, 2023, and was rescheduled twice before being canceled on March 29, 2023, after the parties informed the Court about Plaintiffs' settlement with Eli Lilly. (*See* ECF Nos. 603, 605, 617, 619, 626.) Following the formation of the Insulin Pricing MDL (MDL No. 3080), oral argument was re-scheduled to November 28, 2023. (*See* ECF No. 705.)

they had before the class period, and net prices (prices net of rebates), which increased much less, or even decreased." (*Id.* ¶¶ 2, 45–58.) Dr. Rosenthal proffers that all, or virtually all, the proposed class members overpaid for Defendants' analog insulin products based on the "extremely high" list prices Defendants set for those products. (*Id.* ¶¶ 2, 79–97.) Dr. Rosenthal states Defendants' allegedly illegal price increases directly led to proposed class members having to overpay for Defendants' analog insulin products. (*Id.* ¶ 2.) Dr. Rosenthal concludes the estimated damages for the Proposed Nationwide Classes total $512.9 million for Novo Nordisk and $518 million for Sanofi, and the estimated damages for the Proposed Multi-State Classes and the other proposed state-specific classes total $160.7 million for Eli Lilly, $237.5 million for Novo Nordisk, and $206.9 million for Sanofi. (*Id.*)

In forming her opinions and reaching her conclusions, Dr. Rosenthal relied on a statistical "trend break" test to determine "when the trend in the ratio of net and list prices is statistically significantly different over two separate time periods." (*Id.* ¶ 114.) She asserts that for each of Defendants' analog insulin products, "this test finds a trend break representing the point when the ratio between net and list price increases faster than it had in the past." (*Id.*) Dr. Rosenthal determined "this trend break is the point when the challenged conduct affects prices." (*Id.*) Dr. Rosenthal labels the period before the trend break as the "pre-period," or the period before the challenged conduct affects prices, and she labels the period after the trend break as the "post-period," or the period after the challenged conduct affects prices. (*Id.*) Dr. Rosenthal relies on the trend break test and uses the trend break to determine when the alleged injury to the putative class members began (*i.e.*, the class periods). (*Id.* ¶¶ 1, 77, 114–17.) In other words, Dr. Rosenthal opines the trend breaks for each of Defendants' analog insulin products indicate the respective

start dates for the proposed class period for each of those products within each of Plaintiffs' twelve proposed classes. (*Id.*)

Dr. Rosenthal also contends "[l]ist prices are the basis of the price for virtually all retail pharmaceutical transactions" and accordingly the prices the putative class members pay for Defendants' analog insulin prices are based on Defendants' list prices for those products. (*Id.* ¶¶ 84–97.) To determine damages, Dr. Rosenthal created a but-for world where the trend breaks never occurred for any of Defendants' analog insulin products; she did this "by taking the average ratio of the AWP to the net price in the four quarters prior to the post-period" and then applying that ratio "to the net price in the post-period" to determine "an alternative AWP price that would have prevailed in the post-period, but for the challenged conduct." (*Id.* ¶ 118.) In Dr. Rosenthal's but-for world, the but-for AWP "constructs a scenario in which the gains from competition are shared with patients" and patients' "out-of-pocket payments rise and fall together with the net price." (*Id.*) Dr. Rosenthal uses this but-for AWP to calculate but-for out-of-pocket costs. (*Id.* ¶ 119.) According to Dr. Rosenthal, the damages are the difference between actual out-of-pocket costs and the but-for out-of-pocket costs "summed up across the universe of class transactions." (*Id.*; *see also id.* ¶¶ 120–39.)

Dr. Rosenthal argues she can calculate damages on a class-wide basis using common evidence for the following putative class members: (1) uninsured, "cash-paying consumers who paid based on list price"; (2) "insured consumers (either by commercial insurance or Medicare Part D plans) who paid coinsurance (*i.e.*, a specified percentage of the pharmacy reimbursement)"; and (3) "insured consumers (again, either by commercial insurance or Medicare Part D plans) who paid all or part of the price of the drug with a deductible payment." (*Id.* ¶¶ 83, 110–39; *see also id.* ¶¶ 98–109 (describing how putative class members were allegedly injured).) Dr. Rosenthal

excludes the following from Plaintiffs' proposed classes: (1) "purchases in which the consumer paid a co-pay (*i.e.*, a flat dollar amount that is the same regardless of the price of the drug)" because that consumer's payment "would have been the same even if the total retail price had been lower" and therefore was "not calculated by reference to a list price" (*id.* ¶ 80); (2) "transactions in which the consumer used a co-pay coupon" (*id.* ¶ 81); (3) "transactions reimbursed by Medicaid" (*id.* ¶ 82); and (4) transactions "where the consumer paid nothing" (*id.*).

Defendants argue Dr. Rosenthal's opinions are inadmissible under FRE 702 and *Daubert* and should be excluded because her apparent novel[14] methodology is not reliable—it cannot reliably identify whether Defendants' pricing for analog insulin is "unfair" or "unconscionable" and likewise cannot reliably measure injury or damages for putative class members. (ECF No. 594 at 1–4; *see also id.* at 13–31.) Defendants further contend Dr. Rosenthal's methodology: (1) "lacks any 'objective and verifiable indicia of reliability[,]" (2) does not reliably measure any "unfair or unconscionable" conduct, (3) does not reliably measure either injury or damages for proposed class

[14] Defendants state Dr. Rosenthal's methodology in this case "by her own admission has never been used before and no court has ever approved[.]" (ECF No. 594 at 1–2.) Defendants claim Dr. Rosenthal "is not using any recognized economic approach to detecting supposedly 'unfair' or 'unconscionable' pricing, or any settled principle for measuring damages from allegedly illegal pricing under state consumer protection laws[,]" and that she "invented" this methodology for this case, which methodology "rests solely on her say-so that prices after a certain statistical inflection point are 'unlawful.'" (*Id.* at 2; *see also id.* at 8 ("Here, 'there is simply too great an analytical gap between the data' that Prof. Rosenthal analyzed to find purported statistical 'trend breaks,' and 'the opinion proffered' that these changes in trends equate to unfair or unconscionable pricing—a methodology no court has ever accepted before." (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *id.* at 8–13; ECF No. 596 at 2 ("Without disputing Defendants' showing that a trend break test is not a 'recognized economic approach to detecting supposedly "unfair" or 'unconscionable' pricing', Plaintiffs mischaracterize this argument as a claim that trend break tests cannot be used for any purpose. But the relevant question under Daubert is whether the expert's method is 'reliably applied' to this case. Plaintiffs never answer this question. No established liability theory or economic doctrine holds that a trend break establishes if price-setting conduct is 'fair' or 'unfair.' The only link between those concepts is Prof. Rosenthal's say-so." (citations omitted)).)

members, (4) "does not correspond in any meaningful way to the prices that consumers actually pay[,]" (5) does not attempt to measure whether Defendants caused any injury, and (6) "does not, and cannot, reliably measure damages for any putative class member." (*Id.* at 1–4.) Defendants maintain Plaintiffs cannot point to any evidence showing Defendants' behavior, decision, or conduct through which their prices for their analog insulin products allegedly changed from lawful to unlawful and instead rely on Dr. Rosenthal "to draw that line for them." (*Id.* at 1.) Defendants assert Dr. Rosenthal, like Plaintiffs, does not use any specific price, price increase, rebate increase, or rebate percentage to determine what is "fair" versus "unfair" pricing; rather, she "employs an improvised methodology of comparing ratios 'to decide [] the specific start date' on which the alleged 'unfair' and 'unconscionable' conduct 'began' as to each Defendant's insulin products and then estimate class-wide damages." (*Id.*)

In opposition, Plaintiffs argue the structural break test Dr. Rosenthal uses in her opinion is a "widely accepted method" to detect the point at which some trend over time changes in a significant way. (ECF No. 595 at 9–20.) Plaintiffs contend courts have allowed experts in class actions in antitrust cases to rely on structural break analyses "as evidence of the class period, damages, or causation[,]" which Plaintiffs state is the same purpose Dr. Rosenthal offers here, (even though this is not an antitrust case)—she uses the structural break test to determine when the effects of the alleged conduct occurred; she does not opine on the legal question of whether Defendants' conduct was fair. (*Id.* at 9–17.) In other words, Dr. Rosenthal's methodology "analyzes *the effects of conduct*, not the conduct itself." (*Id.* at 15; *see also* ECF No. 577 at 38–39 ("The structural break (or trend break) analysis does not attempt to determine the unfairness or lawfulness of defendants' actions. The jury will decide that. What the structural break test does is determine the class period. Several courts have upheld the test for this purpose. . . . Plainly,

something changed about the way in which defendants price insulin. . . . The structural break test simply measures with scientific precision when that change occurred. The jury may then investigate what the defendants did to cause that trend break and can decide the lawfulness of that conduct from there.").) Further, Plaintiffs assert Defendants misrepresent the results of Dr. Rosenthal's trend break analysis, but even assuming their interpretation is true, this goes to the weight, not the admissibility, of Dr. Rosenthal's testimony. (ECF No. 595 at 17–21.)

Plaintiffs also submit Defendants do not challenge Dr. Rosenthal's methods employed in her damages model but instead claim they can prove her model as unreliable by identifying "flaws" or "mistakes" in her results and/or by showing her model yields "nonsensical," "arbitrary," or "inconsistent" results. (*Id*. at 21–25.) But Plaintiffs state, even assuming this is true, their claim is based on "unfair *practices*, not unfair prices" and therefore, "class membership does not depend on the patient having paid some threshold *amount*; it depends on whether the patient paid *a price inflated by defendants' conduct*." (*Id.* at 22.) In other words, Plaintiffs concede it is possible two people paid nearly identical sums for the same insulin but one of them falls into one of Plaintiffs' proposed classes and the other does not, because their membership in a class is based on Defendants' conduct with respect to those members, not the member's actual payment. (*See id.*) According to Plaintiffs, this is "an expected consequence where injury flows from the unlawful conduct, and not the other way around." (*Id.* at 23.) Lastly, Plaintiffs submit Defendants had sole control over the list prices of their analog insulin products, which Plaintiffs claim "confirms that only they could cause the injuries relevant here[,]" and therefore Dr. Rosenthal's damages model does not need to account for alternative causes related to putative class members' overpayment of those products. (*Id.* at 3, 26–28.) Plaintiffs also contend Dr. Rosenthal's model can accurately measure damages—the alleged overpayments putative class members paid for Defendants' analog

insulin products—because Defendants' list price has a direct effect on pharmacy prices. (*Id.* at 26 (citing Rosenthal Rpt. ¶ 123).)

In reply, Defendants contend: (1) trend breaks cannot reliably measure "unfair" or "unconscionable" pricing; (2) Dr. Rosenthal's trend break analysis cannot reliably determine when Defendants' conduct allegedly became unfair or unconscionable; (3) Plaintiffs cannot defend Dr. Rosenthal's "arbitrary methodological choices or the nonsensical results her method generates"; and (4) Dr. Rosenthal fails to reliably measure causation and injury. (ECF No. 596 at 2–15.) Defendants argue Dr. Rosenthal's trend break analysis is Plaintiffs' "sole evidence to delineate lawful and unlawful pricing: a break, they claim, "demarcates the 'pre-period'—***when the defendants' behavior was not unlawful***—from the 'post-period'—***when defendants' behavior was unlawful***." (*Id.* at 1 (quoting ECF No. 575 at 74).) Defendants contend "no court or objective independent source has *ever* endorsed using a trend break for such a purpose[,]" and that "[n]o established liability theory or economic doctrine holds that a trend break establishes if price-setting conduct is 'fair' or 'unfair'"—Dr. Rosenthal's opinion is the only link between those concepts. (*Id.* at 1–2.)

Defendants also assert (1) Plaintiffs do not respond to their argument "that there was 'no empirical foundation' for the claim that 'faster' increases in spreads between prices cause prices to become 'unfair' or 'unconscionable' under any objective standard or case law"; (2) Plaintiffs "cannot identify any expert who has used a trend break analysis for that purpose"; (3) Dr. Rosenthal herself "admits she has never used this method in her nearly two dozen expert engagements"; and (4) one of Defendants' experts, Professor Laurentius Marais, stated he "has never seen 'a structural break model like Dr. Rosenthal's model here used to detect and measure the effect of allegedly unfair and unconscionable pricing.'" (*Id.* at 4 (citing Rosenthal Dep. at

269:11-269:18; Marais Rpt. ¶¶ 1, 12).) Defendants also state Plaintiffs do not address Defendants' contention that Dr. Rosenthal's method "lacks any relationship to the amounts consumers pay, Plaintiffs' allegations, or the evidence" and that Plaintiffs do not dispute the nonsensical results her method generates (*e.g.*, "under her model, the *same* cost to a consumer can be fair one month but unfair the next"; "a *higher* consumer cost can be fair while a *lower* cost can be unfair"; "*identical* alleged conduct corresponds to 'trend breaks' *years* apart"; and "a product whose price '*follows*' another product's price has an 'unfair' cost a year *before* the product it follows"). (*Id.* at 1.)

Defendants also argue Dr. Rosenthal's failed attempts to accurately estimate even one proposed class member's injury shows the unreliability of her method for proving class-wide impact. (*Id.* at 2, 14–15.) Defendants further contend Dr. Rosenthal fails to account for alternative causes of injury despite admitting "the prices consumers pay for Defendants' products 'depend greatly' on alternative causes like 'consumer's plan terms'—never mind the countless decisions by insurers and PBMs 'that affect how much patients pay.'" (*Id.* at 13–14 (citations omitted).)

In their sur-reply, Plaintiffs contend Defendants "still fail[] to grapple with Dr. Rosenthal's damages model" and reiterate Defendants' *Daubert* motion should be denied. (ECF No. 597 at 24–25.) Plaintiffs claim Defendants attempt to frame Dr. Rosenthal's damages model as unreliable based on "a single data entry error" but argue this does not undermine "the wealth of data inputs Dr. Rosenthal would rely on to calculate damages for a certified class." (*Id.* at 24 (citing ECF No. 596 at 14–15).) Plaintiffs do not substantively address Defendants' other arguments in support of their *Daubert* motion.

A. Legal Standard

The Third Circuit has held that Federal Rule of Evidence 702 ("FRE 702") and *Daubert v.*

Merrell Dow Pharms., Inc., 509 U.S. 579 (1993) apply at the class certification stage. *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015) (holding "a plaintiff cannot rely on challenged expert testimony, when critical to class certification, to demonstrate conformity with Rule 23 unless the plaintiff also demonstrates, and the trial court finds, that the expert testimony satisfies the standard set out in *Daubert*"). FRE 702 governs the admissibility of expert testimony. *Daubert*, 509 U.S. at 588. FRE 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. FRE 702 "embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit."[15] *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80 (3d Cir. 2017) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). Pursuant to *Daubert*, "district courts perform a gatekeeping function to ensure that expert testimony meets the requirements of [FRE] 702." *Karlo*, 849 F.3d at 80. District courts, in exercising their gatekeeping function, "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *In re Paulsboro Derailment Cases*, 746 F. App'x 94, 98 (3d Cir. 2018) (quoting *Daubert*, 509 U.S. at 589). This gatekeeping function

[15] Of these three elements required for the admissibility of expert testimony, Defendants appear to only be contesting the reliability element with respect to Dr. Rosenthal's expert testimony, so the Court only addresses this element here.

"extends beyond scientific testimony to 'testimony based on "technical" and "other specialized" knowledge.'" *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 415 (E.D. Pa. 2015) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999)). "The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research." *De La Cruz v. Virgin Islands Water & Power Auth.*, 597 F. App'x 83, 91 (3d Cir. 2014) (quoting *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *as amended*, 199 F.3d 158 (3d Cir. 2000)). "Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology." *Id.* In other words, courts look to "whether the expert's testimony is supported by 'good grounds.'" *Karlo*, 849 F.3d at 81 (citations omitted). The party offering the expert's testimony bears the burden of establishing admissibility by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

The standard for reliability is "not that high." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994). For an expert's testimony to be reliable under FRE 702, "the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quotations and citations omitted). In determining whether a proposed expert's testimony is reliable, courts must consider the following factors:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subjected to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the

> methodology; and (8) the non-judicial uses to which the method has been put.

Oddi v. Ford Motor Co., 234 F.3d 136, 145 (3d Cir. 2000) (quoting *In re Paoli R.R.*, 35 F.3d at 742 & n.8). "[T]he reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia*." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999).

"[A] model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to that theory." *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013). At the class certification stage, while damages calculations need not be exact, "any model supporting a 'plaintiff's damages case must be consistent with its liability case[.]'" *Id.* (citations omitted). "The first step in a damages study is the translation of the *legal theory of the harmful event* into an analysis of the economic impact *of that event*." *Id*. at 38 (citation omitted).

B. Decision

The trend break test, also known as the structural break test, is a statistical test used to detect a point in time when a particular variable increases or decreases at a rate significantly different than it had in the past. *See, e.g.*, *In re Broiler Chicken Antitrust Litig.*, Civ. A. No. 16-8637, 2022 WL 1720468, at *9 (N.D. Ill. May 27, 2022). As such, the use of a trend break test to determine a point in time when some trend changed in a significant way is not unreliable. For example, in *In re Broiler Chicken Antitrust Litigation*, the court noted plaintiffs' expert did not state anywhere "that his structural break test is intended to identify a *cause* of the decrease in the rate of production." *In re Broiler Chicken Antitrust Litig.*, 2022 WL 1720468, at *9. Rather, the court said the structural break test "is simply intended to confirm whether the readily apparent decrease is truly statistically significant, such that it makes sense to investigate its cause in the first place[;]" it "is not intended to identify causes, collusive or otherwise." *Id.* The court also noted the

expert thoroughly considered alternative causes in his regression analysis, which made up the second part of his analysis, "[s]o, the fact that [the expert] did not consider non-collusive causes at that point in his analysis is not a reason to find his method unreliable." *Id.*

Similarly, in *In re Namenda Direct Purchaser Antitrust Litigation*, the defendants complained that the expert's "structural break test fail[ed] because it [did] not isolate the cause of the February 2014 break." 331 F. Supp. 3d 152, 178 (S.D.N.Y. 2018). However, the expert testified the structural break test was not designed to do so and "that '[the test] is not able to tease out where the source of the structural break comes from by itself[;]'" rather, "[o]ne has to implement it because one believes that there is some event which leads to a structural break." *Id.* In other words, the expert's "test demonstrate[d] that there was a 'structural break' in February 2014, which happened to be the date when the hard switch was announced." *Id.* The *Namenda* court stated "[c]orrelation does not prove causation, but the coincidence in timing between the announcement and the structural break shown by the data is some evidence of causation in support of Plaintiffs' theory." *Id.* The court noted that "[p]erhaps other things were happening in the market in February 2014, and [defendants] may go into them to undercut [the expert's] data" but "[f]or the purposes of *Daubert*, [the expert's] analysis passes muster." *Id.* at 178–79. At most, the court concluded the defendants' arguments concerning the expert's assumptions in his analysis "go to its weight, not [the] admissibility of that testimony." *Id.* at 179 (citation omitted).

Here, Dr. Rosenthal relies on the statistical trend break test, or structural break test, to (1) define the class periods for each of Defendants' analog insulin products within each of Plaintiffs' twelve proposed classes (*i.e.*, indicating when the alleged injury to the putative class members began) and (2) calculate aggregate damages based on Plaintiffs' and the putative class members' alleged overpayments for Defendants' analog insulin products. In other words, Dr. Rosenthal uses

the trend break test to identify when the effects of the alleged conduct occurred in order to support Plaintiffs' theory that that trend break is when Defendants' conduct allegedly began causing injury to the putative class members. But Dr. Rosenthal does not use the trend break test to measure any specific conduct or event or whether Defendants' conduct was unfair or unconscionable and when that conduct became unfair or unconscionable. Indeed, Dr. Rosenthal does not identify any strategy or decision by Defendants that began the allegedly unlawful conduct and likewise does not opine on *when* specifically Defendants allegedly began the unlawful conduct. Rather, as in *In re Broiler Chicken Antitrust Litigation*, her methodology simply shows something happened at a particular point of time for each of Defendants' analog insulin products at issue—a so-called trend break where the ratio between the list prices and the net prices for those products increased faster than it had previously.

Dr. Rosenthal's opinion based on her trend break analysis does not establish (1) whether Defendants' conduct caused the trend break, (2) whether Defendants' conduct constitutes "unfair practices" or was unconscionable, (3) when Defendants' conduct allegedly became unfair or unconscionable, or (4) whether Defendants' conduct caused injury to the putative class members; rather, these are legal questions for the fact finder and on which Plaintiffs bear the burden of proof. Dr. Rosenthal's method simply helps identify for the fact finder when the supposed trend breaks occurred with a reasonable degree of scientific precision. *See Comcast*, 569 U.S. at 35; *see also In re Broiler Chicken Antitrust Litig.*, 2022 WL 1720468, at *9 ("[T]he structural break test is not intended to identify causes, collusive or otherwise."); *Int'l Union of Operating Engineers Loc. No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007) (stating "[t]o the extent that plaintiff intends to rely on a single expert to establish a price effect in place of a demonstration of an ascertainable loss or in place of proof of a causal nexus between defendant's acts and the

claimed damages, however, plaintiff's proofs would fail" as "[t]hat proof theory would indeed be the equivalent of fraud on the market, a theory we have not extended to [NJ]CFA claims"). Plaintiffs themselves admit Dr. Rosenthal uses the trend break test to determine when the *effects* of the alleged conduct occurred (*i.e.*, the trend break), *not* the conduct itself, and that Dr. Rosenthal does not opine on the legal question of whether Defendants' conduct was unfair or unconscionable under the applicable state law (the jury will decide this).[16] (*See* ECF No. 595 at 13–17; ECF No. 577 at 38–39.)

It is possible that other variables, or a combination of variables, caused the significant divergence between the list prices and net prices for Defendants' analog insulin products or that Defendants' conduct did not in fact cause harm to Plaintiffs. However, this fact does not render as unreliable. Dr. Rosenthal's methodology of relying on a trend break test to determine when the trend in the ratio of net prices and list prices became "statistically significantly different." Additionally, Dr. Rosenthal's model appears consistent with Plaintiffs' liability case. *See Comcast*, 569 U.S. at 35 (citations omitted).

At the class certification stage, the Court need not determine whether Dr. Rosenthal's opinion is correct and/or what facts and assumptions are or were appropriate for her to include in her model. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("[T]he test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his

[16] Defendants argue Plaintiffs solely rely on Dr. Rosenthal's opinion regarding when the effects of the alleged conduct occurred (*i.e.*, the trend breaks) for each of Defendants' analog insulin products to argue these trend breaks are when Defendants' conduct allegedly became unlawful, *i.e.*, unfair or unconscionable, with respect to each of their insulin products, and that this alleged conduct caused Plaintiffs and the putative class members harm. These are legal arguments Plaintiffs will have to prove but, in their words, are *not* Dr. Rosenthal's testimony; therefore, the Court need not address this for purposes of deciding Defendants' *Daubert* Motion.

methodology."). Rather, the Court must simply determine whether her testimony is reliable. *See In re Paoli R.R.*, 35 F.3d at 744 ("The evidentiary requirement of reliability is lower than the merits standard of correctness. *Daubert* states that a judge should find an expert opinion reliable under Rule 702 if it is based on 'good grounds,' *i.e.*, if it is based on the methods and procedures of science. A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect. As *Daubert* indicates, '[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate.' The grounds for the expert's opinion merely have to be good, they do not have to be perfect." (alterations and citations omitted)).

Mindful that the standard for reliability is "not that high," *In re Paoli R.R.*, 35 F.3d at 745, the Court finds Dr. Rosenthal's methodology to be sufficiently reliable to survive Defendants' *Daubert* challenge at the class certification stage because it is based on the scientific trend break method. *See Calhoun*, 350 F.3d at 321; *cf. Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, Civ. A. No. 04-5898, 2010 WL 3855552, at *30 (E.D. Pa. Sept. 30, 2010) ("The plaintiffs contend, and [defendant] disputes, that Dr. Rosenthal's yardsticks provide a common method capable of showing damages across the class. The court does not need to resolve this issue, having already decided certification is inappropriate[.] . . . That being said, I believe the plaintiffs' methodology is insufficient because the calculations were made using *average* prices. This evidence says nothing about the actual price paid by each purported class member. Average prices falter as a method for proving class-wide injury, because 'averaging "by definition glides over what may be important differences."'" (citation omitted)).

Therefore, Defendants' Motion to Exclude the Expert Testimony of Dr. Meredith Rosenthal (ECF No. 593) is **GRANTED IN PART and DENIED IN PART**. To the extent

Plaintiffs intend to rely on Dr. Rosenthal's testimony to establish whether Defendants' conduct in setting list prices for their analog insulin products was unfair or unconscionable under the applicable state law, Defendants' *Daubert* Motion is **GRANTED** because Dr. Rosenthal's methodology is not reliable in determining this question of law. The parties have not cited, and the Court has not otherwise found, any case where the trend break test was used to establish whether price-setting conduct is unfair or unconscionable. Defendants' *Daubert* Motion is otherwise **DENIED**.

III. PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Plaintiffs seek to certify a total of fifteen classes under Federal Rule of Civil Procedure 23 ("Rule 23")—specifically under Rule 23(a), Rule 23(b)(2), and Rule 23(b)(3). (ECF Nos. 574, 575.) Plaintiffs first seek to certify two nationwide classes—one against Novo Nordisk and the second against Sanofi—for alleged unconscionable acts under the New Jersey Consumer Fraud Act ("NJCFA") (the "Proposed Novo Nordisk Nationwide Class" and the "Proposed Sanofi Nationwide Class"; collectively, the "Proposed Nationwide Classes"). (ECF No. 574 at 2–3; ECF No. 575 at 41–79.) Separately, Plaintiffs also seek to certify thirteen state-specific classes for alleged "unfair" acts under various state consumer protection laws prohibiting unfair or unconscionable conduct, as follows: (1) three multi-state classes—each comprised of sixteen state consumer protection statutes[17] (all of which Plaintiffs assert apply the Federal Trade Commission

[17] Plaintiffs assert the claims for these classes are brought under the following sixteen state statutes: (1) Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 *et seq*.; (2) Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42–110a *et seq.*; (3) Delaware Consumer Fraud Act, Del. Code Tit. 6, § 2511 *et seq*.; (4) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq*.; (5) Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 *et seq*.; (6) Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-1 *et seq*.; (7) Iowa Private Right of Action for Consumer Frauds Act, Iowa Code §§ 714H.1 *et seq*.; (8) Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. § 51:1401 *et seq*.; (9) Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 205-A *et seq*.; (10) Maryland

("FTC") three-part "substantial injury" test for unfairness to determine whether an act is "unfair")—one against each of the three Defendants for alleged "unfair" acts (the "Proposed Novo Nordisk Multi-State Class," the "Proposed Sanofi Multi-State Class," and the "Proposed Eli Lilly Multi-State Class"; collectively, the "Proposed Multi-State Classes"); (2) three New Jersey-specific classes—one against each of the three Defendants—for alleged "unconscionable" acts under the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq*. (the "Proposed Novo Nordisk New Jersey Class," the "Proposed Sanofi New Jersey Class," and the "Proposed Eli Lilly New Jersey Class"; collectively, the "Proposed New Jersey Classes"[18]); (3) three Texas-specific classes—one against each of the three Defendants—for alleged "unconscionable" acts under the Texas Deceptive Trade Practices Consumer Protection Act, Tex. Bus. & Com. Code § 17.41 *et seq*. (the "Proposed Novo Nordisk Texas Class," the "Proposed Sanofi Texas Class," and the "Proposed Eli Lilly Texas Class"; collectively, the "Proposed Texas Classes"); (4) two Kansas-specific classes—one against Novo Nordisk and one against Sanofi—for alleged "unconscionable" acts under the Kansas Consumer Protection Act, Kan. Stat. § 50-623 *et seq*. (the "Proposed Novo Nordisk Kansas Class" and the "Proposed Sanofi Kansas Class"; collectively, the "Proposed

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Consumer Protection Act, Md. Code Ann., Com. Law § 13-301 *et seq*.; (11) Massachusetts Consumer Protection Act, Mass. Gen. Laws Ch. 93A, § 1 *et seq*.; (12) North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 *et seq*.; (13) North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15-01 *et seq*.; (14) Oklahoma Consumer Protection Act, Okla. Stat. Tit. 15, § 751 *et seq*.; (15) South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10 *et seq*.; and (16) Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-104, 47-18-101 *et seq*. (ECF No. 574 at 3–4 n.1; *see also* ECF No. 411 ¶¶ 645–80, 696–723, 732–63, 822–37, 847–57, 874–90 (Counts 18 (Colorado), 19 (Connecticut), 20 (Delaware), 21 (Florida), 24 (Illinois), 25 (Indiana), 26 (Iowa), 28 (Louisiana), 29 (Maine), 30 (Maryland), 31 (Massachusetts), 40 (North Carolina), 41 (North Dakota), 43 (Oklahoma), 46 (South Carolina), and 47 (Tennessee).)

[18] To avoid potential duplication, the Court assumes for purposes of this Opinion that Plaintiffs intend for the Proposed Novo Nordisk New Jersey Class and the Proposed Sanofi New Jersey Class to be sub-classes of the Proposed Nationwide Classes since both of these proposed sets of classes are based on claims asserted under the NJCFA.

Kansas Classes"); and (5) two Utah-specific classes—one against Novo Nordisk and one against Sanofi—for alleged "unconscionable" acts under the Utah Consumer Sale Practices Act, Utah Admin. Code § 13-11-1 *et seq.* (the "Proposed Novo Nordisk Utah Class" and the "Proposed Sanofi Utah Class"; collectively, the "Proposed Utah Classes"). (ECF No. 574 at 3–14; ECF No. 575 at 79–99.)

Plaintiffs assert their proposed classes "include only those cash, coinsurance, deductible, or Medicare Part D patients who paid *based on WAC or AWP*." (ECF No. 575 at 19.) Plaintiffs exclude the following from all of their proposed classes: (1) "purchases where a manufacturer coupon was applied" (ECF No. 574 at 14); (2) "purchases (or receipt of) insulin through a Medicaid program" (*id.*); (3) "each [D]efendant and any entity in which it has a controlling interest, and their legal representatives, officers, directors, assignees, and successors" (*id.* at 14–15); and (4) "any co-conspirators and their officers, directors, management, employees, subsidiaries, and affiliates." (*id.* at 15; *see also* ECF No. 575 at 19–20, 64 ("The method for ascertaining class members will exclude those who did not pay for their prescribed analog insulins based on the defendants' list prices. . . . The plaintiffs will obtain [] information, which will allow Dr. Rosenthal and claims administrators to identify every single analog insulin purchase made with a coupon so that it can be excluded from the class." (footnotes omitted)).)

At oral argument, Plaintiffs represented that Eli Lilly is not part of their Motion for Class Certification (ECF No. 713 at 11), presumably because of the pending Motion for Preliminary Approval of a Class Action Settlement with Eli Lilly (*see* ECF No. 639). Therefore, the Court assumes for purposes of this Opinion that Plaintiffs are *not* seeking to certify their three proposed classes against Eli Lilly—the Proposed Eli Lilly Multi-State Class, the Proposed Eli Lilly New Jersey Class, and the Proposed Eli Lilly Texas Class—and accordingly **DENIES WITHOUT**

PREJUDICE Plaintiffs' motion to certify these three classes. The Court addresses Plaintiffs' request to certify the remaining twelve proposed classes not involving Eli Lilly.

A. Legal Standard

A class action under Federal Rule of Civil Procedure 23 ("Rule 23") is "an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores v. Dukes*, 564 U.S. 338, 348 (2011) (citing *Califano v. Yamasaki*, 442 U.S. 682, 700–01 (1979)). "To invoke this exception, every putative class action must satisfy the requirements of Rule 23(a) and the requirements of either Rule 23(b)(1), (2), or (3)." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 590 (3d Cir. 2012). A party seeking class certification must first demonstrate the proposed class satisfies the four requirements of Rule 23(a):

> (1) the class is so numerous that joinder of all members is impracticable;
>
> (2) there are questions of law or fact common to the class;
>
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
>
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). These four requirements are customarily referred to as: (1) numerosity, (2) commonality, (3) typicality, and (4) adequate representation, respectively. *Dukes*, 564 U.S. at 349. In addition to satisfying these four Rule 23(a) requirements, a party seeking class certification must also show that the requirements of Rule 23(b)(1), 23(b)(2), or 23(b)(3) are met. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997).

Under Rule 23(b)(2), a class action may be maintained if "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P.

23(b)(2). The Third Circuit has regularly held certification pursuant to Rule 23(b)(2) requires cohesiveness of class claims among the class members. *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 142 (3d Cir. 1998). The Third Circuit articulated the following two reasons for the cohesiveness requirement. *Id.* at 143. "First, unnamed members with valid individual claims are bound by the action without the opportunity to withdraw and may be prejudiced by a negative judgment in the class action." *Id.* Second, "the suit could become unmanageable and little value would be gained in proceeding as a class action . . . if significant individual issues were to arise consistently." *Id.* In other words, "the court must ensure that significant individual issues do not pervade the entire action because it would be unjust to bind absent class members to a negative decision where the class representative['s] claims present different individual issues than the claims of the absent members present." *Id.* Therefore, Rule 23(b)(2) is not appropriate where "significant individual liability or defense issues . . . would require separate hearings for each class member in order to establish defendants' liability." *Santiago v. City of Philadelphia*, 72 F.R.D. 619, 627 (E.D. Pa. 1976).

Under Rule 23(b)(3), a class action may be maintained if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). These requirements are known as "predominance" and "superiority," respectively. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 310 (3d Cir. 2008), *as amended* (Jan. 16, 2009). The issues pertinent to these findings include:

> (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
> (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
> (D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). Superiority "asks the court 'to balance, in terms of fairness and efficiency, the merits of a class action against those of "alternative available methods" of adjudication.'" *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283, 316 (3d Cir. 1998) (quoting *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 632 (3d Cir. 1996)). "Predominance 'tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation,' a standard 'far more demanding' than the commonality requirement of Rule 23(a)[.]" *In re Prudential*, 148 F.3d at 310–11 (quoting *Amchem*, 521 U.S. at 623–24). The Third Circuit has held that for proposed classes under Rule 23(b)(3), there is an "implicit requirement that class members be ascertainable," meaning a plaintiff's proposed class must be "currently and readily ascertainable based on objective criteria." *In re Niaspan*, 67 F.4th at 129–30, 133 (quoting *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 477 (3d Cir. 2020)).

"Class 'certification is proper only if the trial court is satisfied, after a rigorous analysis' that all of the necessary Rule 23 requirements have been fulfilled." *Ferreras v. Am. Airlines, Inc.*, 946 F.3d 178, 183 (3d Cir. 2019) (quoting *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350-51 (2011)). "The party seeking certification bears the burden of establishing each element of Rule 23 by a preponderance of the evidence." *Marcus*, 687 F.3d at 591 (citing *In re Hydrogen Peroxide*, 552 F.3d at 307). The Third Circuit has set forth "three key aspects of class certification procedure." *In re Hydrogen Peroxide*, 552 F.3d at 307. First, the court's decision to certify a class requires factual determinations in support of each Rule 23 requirement by a preponderance of the evidence, "not merely a 'threshold showing' by a party." *Id.* "Second, the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits—

including disputes touching on elements of the cause of action." *Id.* Lastly, "the court's obligation to consider all relevant evidence and arguments extends to expert testimony, whether offered by a party seeking class certification or by a party opposing it." *Id.* "An overlap between a class certification requirement and the merits of a claim is no reason to decline to resolve relevant disputes when necessary to determine whether a class certification requirement is met." *Id.* at 316. To determine whether the Rule 23 class certification requirements are satisfied, the Third Circuit has stated that district courts may "delve beyond the pleadings" where appropriate, and their certification analysis may include a "preliminary inquiry into the merits." *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 306 (3d Cir. 2011) (quoting *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 167 (3d Cir. 2001), *as amended* (Oct. 16, 2001)). However, "plaintiffs need not actually establish the validity of claims at the [class] certification stage." *Sullivan*, 667 F.3d at 306. "[T]rial courts 'must engage in a rigorous analysis and find each of Rule 23[]'s requirements met by a preponderance of the evidence before granting certification[,]" even if this "involves judging credibility, weighing evidence, or deciding issues that overlap with the merits of a plaintiff's claims." *In re Niaspan*, 67 F.4th at 130 (quoting *Harnish v. Widener Univ. Sch. of Law*, 304 (3d Cir. 2016)).

B. Decision[19]

The Court first addresses below whether Plaintiffs' twelve proposed classes[20] satisfy the

[19] The Court has jurisdiction over Plaintiffs' Motion for Class Certification under the Class Action Fairness Act of 2005 ("CAFA"). *See* 28 U.S.C. § 1332(d). CAFA confers jurisdiction on federal district courts over certain class actions where the following requirements are met: (1) the amount in controversy exceeds $5,000,000, as aggregated across all individual claims; (2) the citizenship of at least one plaintiff differs from that of any defendant, *i.e.*, there is minimal diversity; and (3) the class consists of at least 100 members. *See* 28 U.S.C. § 1332(d).

[20] This refers to Plaintiffs' twelve proposed classes not involving Eli Lilly—*i.e.*, the Proposed Nationwide Classes, the Proposed Novo Nordisk Multi-State Class, the Proposed Sanofi Multi-State Class, the Proposed Novo Nordisk New Jersey Class, the Proposed Sanofi New Jersey Class,

ascertainability requirement for class actions and then analyzes whether each of Plaintiffs' twelve proposed classes meets the requirements under Rule 23(a), Rule 23(b)(2), and Rule 23(b)(3). For purposes of this class certification analysis, the Court assumes Plaintiffs' allegations as true.

i. Ascertainability

The Third Circuit has held that for proposed classes under Rule 23(b)(3), there is an "implicit requirement that class members be ascertainable," meaning a plaintiff's proposed class must be "currently and readily ascertainable based on objective criteria." *In re Niaspan*, 67 F.4th at 129–30, 133 (quoting *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 477 (3d Cir. 2020)). "Ascertainability functions as a necessary prerequisite (or implicit requirement) because it allows a trial court effectively to evaluate the explicit requirements of Rule 23." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 162 (3d Cir. 2015), *as amended* (Apr. 28, 2015). "In other words, the independent ascertainability inquiry ensures that a proposed class will actually function as a class." *Id.* To satisfy this ascertainability requirement, "[p]laintiffs 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.'" *In re Niaspan*, 67 F.4th at 130 (alteration in original) (quoting *Hargrove*, 974 F.3d at 469–70). "A plaintiff must propose a classification method with evidentiary support to meet the ascertainability requirement." *In re Niaspan*, 67 F.4th at 130. In demonstrating ascertainability, plaintiffs do not have to be able to identify all potential class members at the class certification stage; rather, they "need only show that 'class members can be identified.'" *Id.* (quoting *Byrd*, 784 F.3d at 163). "If class members are

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the Proposed Novo Nordisk Texas Class, the Proposed Sanofi Texas Class, the Proposed Kansas Classes, and the Proposed Utah Classes. (ECF No. 575 at 41, 79–80; *see also* ECF No. 574 at 2–14.)

impossible to identify without extensive and individualized fact-finding or 'mini-trials,' then a class action is inappropriate." *Marcus*, 687 F.3d at 593. The burden is on the plaintiff to show "by a preponderance of the evidence that there is a reliable and administratively feasible method for ascertaining the class." *Hayes*, 725 F.3d at 356.

Here, Plaintiffs claim all their proposed classes meet both prongs of the ascertainability test because: (1) they are defined with reference to objective criteria—namely, data that can show whether the individual paid any portion of the purchase price for one or more of Defendants' analog insulin products at issue in this case "at a price calculated by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale"; and (2) there is a reliable and administratively feasible mechanism for determining whether class members fall within the definitions of each of their proposed classes—namely, by using a combination of electronically stored records of certain PBMs, retail pharmacies, insurers, and drug coupon administrators to identify putative class members during the various applicable proposed class periods. (ECF No. 575 at 5–6, 57–68, 87.) Plaintiffs argue these electronically stored records can identify the putative class members who "purchased the relevant insulins in the class period[s] at a price calculated by reference to a list price." (*Id.* at 60–61.) Plaintiffs also submit there is no requirement stating they must use a single, centralized source of data to identify putative class members (ECF No. 577 at 47), and the wealth of detailed PBM and pharmacy transactional data can be used to exclude any transactions that fall outside the definitions of their twelve proposed classes (*id.* at 44–48). Plaintiffs contend they can use transactional data to remove consumers who received manufacturer coupons (which they exclude from their proposed classes), but state consumers who used pharmacy coupons need not be removed because pharmacy programs do not shield consumers from the inflated list prices. (*Id.* at 49–50.) Plaintiffs also assert

their proposed classes are ascertainable, regardless of whether factors other than the list price affected the purchase price, because the proposed classes include transactions where any portion of the purchase price is set by reference to the list prices. (*Id.* at 52–53.)

However, Defendants contend none of Plaintiffs' proposed classes are ascertainable because they are "complex" and "reflect arbitrary exclusions," and Plaintiffs fail to present an administratively feasible method for identifying those who belong in their various putative classes. (ECF No. 576 at 73–75.) Defendants further assert there is no single dataset identifying all insulin purchases fitting the definitions of Plaintiffs' proposed classes, and speculation of uncollected data to potentially identify class members is insufficient to demonstrate ascertainability. (*Id.* at 75–76.) More specifically, Defendants argue Plaintiffs have failed to show they have an administratively feasible or reliable method for identifying insured and uninsured consumers who fit Plaintiffs' class definitions, no administratively feasible means for establishing that each insured and uninsured consumer paid a price set "by reference to the list price," and no reliable method for excluding insured consumers who fall outside Plaintiffs' class definitions. (*Id.* at 76–86.) Rather, Defendants state Plaintiffs "instead try to cobble together 'samples' of PBM and pharmacy data that reflect *some* insulin purchases during the class period[s]" but which "records lack essential information needed to identify putative class members[.]" (*Id.* at 75.)

Defendants note Plaintiffs' proposed method of identifying proposed uninsured class members is based on a combination of electronic records from (1) certain PBMs, (2) certain insurers, (3) certain retail pharmacies, and (4) drug coupon administrators. (*Id.* at 76 (citing ECF No. 575 at 5).) But Defendants argue three of these four sets of records cannot identify uninsured consumers; Defendants state the data from PBMs and insurers can only identify *insured* consumers, not *uninsured* consumers, and drug coupon administrator records can only be used to

exclude certain transactions, not identify potential class members, whether insured or uninsured. (ECF No. 576 at 76–77 (citing Baker Rpt. ¶ 130; Rosenthal Rpt. ¶¶ 105, 109).) Defendants contend Plaintiffs are thus left with relying solely on pharmacy records to identify uninsured consumers, but assert the sample of pharmacy records data Plaintiffs have collected only covers a subset of the relevant period[21] (not the entirety of Plaintiffs' proposed class periods) and cannot reliably identify uninsured purchasers; Defendants further argue "Plaintiffs have no workable plan to obtain records from the tens of thousands of pharmacies in the country to identify '*all* uninsured consumers' during the class period[s], as their class definition[s] require[]." (ECF No. 576 at 77–79.[22]) Additionally, Defendants state the evidence on which Plaintiffs rely—*i.e.*, "(1) statements from pharmacy representatives; (2) the claim that uninsured consumers always 'pay pharmacies' U&C price[s]'; and (3) Prof. Rosenthal's analysis that cash prices are '*nearly perfectly correlated* to the defendants' WACs'"—all undermine Plaintiffs' position. (*Id.* at 78–79 (alterations in original) (citing ECF No. 575 at 20–23; Rosenthal Rpt. ¶ 99).) Indeed, Defendants

[21] *See* ECF No. 575 at 62 ("Most [but not all] of these PBMs have produced data starting in January 2014—which is the start date of the earliest class period—and there is no dispute they have such data stretching from 2014 to the present." (citing Rosenthal Rpt. ¶ 132 n.155 [redacted]

[22] *See also* ECF No. 713 at 70–72 (Defense counsel asserting at oral argument that while Plaintiffs' counsel stated they can identify uninsured customers based on pharmacy records from [redacted], three of these four have a field for cash payers but "for [redacted], sure they have a field for it but they don't have any data. The field isn't populated in the data that the [P]laintiffs have been able to obtain from those pharmacies. [redacted] doesn't even have a field for cash transactions. And the fourth [redacted] . . . There are 66,000 pharmacies . . . . It's going to be [] harder to get data for the smaller ones, but even for the big ones they rely on they don't have the data that they need.").

state evidence including testimony from pharmacy representatives shows that "cash prices are *not* uniformly calculated 'by reference to a list price[,]'" not all uninsured consumers pay a pharmacy's U&C price (which Plaintiffs contend is calculated by reference to Defendants' list price), and Dr. "Rosenthal's own data refutes Plaintiffs' assertions that cash prices are 'pegged directly' or 'tied to' list prices." (ECF No. 576 at 79–80.[23]) Defendants also contend Plaintiffs' overbroad class definitions fail to exclude consumers who received one or more forms of financial assistance and therefore suffered no injury. (*Id.* at 86–89.[24]) Defendants submit "[c]onsumer affordability

[23] *See* ECF No. 576 at 79–80 ("For example, [redacted]." Thompson Decl. ¶ 10 (emphasis added). [redacted]' Dudley Dep. 146:6-15. In fact, Plaintiffs' own expert *agreed* that pharmacies use different definitions and 'multiple factors' to calculate cash prices. Wine Dep. 165:9–20, 244:4–17 (Ex. 29). . . . [redacted] Burke Decl. ¶ 9. [redacted] Shinton Decl. ¶ 19 (Pls.' Ex. 14). [redacted]. Baker Rpt. ¶ 136. . . . The below figure from Prof. Rosenthal's report, for example, shows that average prices paid by uninsured consumers in North Dakota during the putative class period for Lantus (which, according to Professional Rosenthal's theory, began in Q2 2014) fluctuated wildly, even when WAC was flat[.]").

[24] *See* ECF No. 576 at 88 ("Even if Plaintiffs *could* reliably identify coupon purchases, there are many other forms of financial assistance (apart from Defendants' affordability offerings) that cap or eliminate consumers' out-of-pocket costs:

- Medicare patients are eligible to receive 'predictable copays for select insulins (no more than $35 per prescription for the month's supply) in the deductible, initial coverage, and coverage gap phases.' CMS, *Part D Senior Savings Model*, available at https://tinyurl.com/PartDcopays (Ex. 60).
- Some states (including New Jersey, New York, Wisconsin, and Massachusetts) offer drug discount programs. Baker Rpt. ¶¶ 118-20.
- Some pharmacies (including [redacted]) offer drug discount coupons. *Id.* ¶ 122.
- Non-profit organizations like the Patient Assistance Network Foundation offer billions of dollars in financial assistance. *Id.* ¶ 121.

An insured or uninsured consumer who receives any of these forms of assistance does not pay a cost 'calculated by reference to list price,' and so would need to be excluded. But because consumers under some of these programs are reimbursed *after* they pay a pharmacy (*id.* ¶ 194), they cannot be identified in PBM or pharmacy data. The same problem exists with insured

initiatives, such as manufacturer co-pay coupons, typically cap the consumer's out-of-pocket cost" (meaning the consumer's costs do not vary when the list price changes), and "[c]onsequently, consumers who participated in such programs cannot have paid a price 'by reference to' the list price." (*Id.* at 86 (citing Baker Rpt. ¶ 166).)

Additionally, Defendants point to other gaps in the data on which Plaintiffs intend to rely to identify putative class members. For example, they assert "[t]he data from [redacted] (ECF No. 576 at 84 (citing Baker Rpt. ¶¶ 173, 198, 269).) Defendants also assert that Dr. Rosenthal proposes a workaround—"treating all 'claims where the member payment is not a whole number payment amount' (*e.g.*, $25.50) as co-insurance payments (keeping them in the class), while treating all 'whole number' amounts (*e.g.*, $25.00) as co-pays (excluding them from the class)[,]" but Defendants say this proposal does not work because "co-pays can be *non*-whole dollar amounts" and Dr. "Rosenthal would be *including* consumers Plaintiffs meant to *exclude* from the class." (ECF No. 576 at 84 (citing Rosenthal Rpt. ¶¶ 120, 126 & n.150; Baker Rpt. ¶ 196 (identifying co-pays of, *e.g.*, $18.15, $37.27, and $39.93)).) Defendants submit the only way to accurately distinguish co-insurance from co-pays for purposes of determining who would be included in Plaintiffs' proposed classes "is by reviewing each person's insurance plan." (ECF No. 576 at 84.)

Though this is a close call, the Court concludes Plaintiffs' proposed classes are sufficiently ascertainable. Plaintiffs' proposed classes include "coinsurance, deductible, Medicare Part D and cash [*i.e.*, uninsured] patients" who "paid any portion of the purchase price for a prescription of" Defendants' analog insulin products "at a price calculated by reference to a list price, AWP

consumers who benefited from rebates, including through lower plan costs. As Plaintiffs pled, the 'use of discounts and rebates that actually reduce consumer costs is not at issue in this case.' TAC ¶ 6. But Plaintiffs have no way to account for programs that provide such benefits[.]").

(Average Wholesale Price), and/or WAC (Wholesale Acquisition [Cost]) for purposes other than resale" during certain specified time periods that vary depending on the analog insulin product being referenced. (ECF No. 575 at 3–4, 19, 57–58; *see also* ECF No. 574.) To show their proposed classes are ascertainable, Plaintiffs must show their proposed classes are defined with reference to objective criteria and that they have a reliable and administratively feasible mechanism for determining whether putative class members fall within their various class definitions.

Here, Plaintiffs have proposed using a combination of records from certain PBMs, retail pharmacies, insurers, and drug coupon administrators to identify putative class members—*i.e.*, cash, coinsurance, deductible, and Medicare Part D patients who paid any portion of the purchase price of one or more of Defendants' analog insulin products at a price calculated by reference to list price (or AWP or WAC). Plaintiffs claim Dr. Rosenthal can, using the PBM data, "identify which insured individuals purchased the analog insulins at a price calculated by reference to list price and were therefore injured." (ECF No. 575 at 62 (citing Rosenthal Rpt. ¶ 132).) Plaintiffs assert they can also use the retail pharmacy data to ascertain uninsured consumers and "the exact amount" consumers paid for their analog insulin, as well as to determine which consumers paid coinsurance or co-pays and "which consumer[s] paid with reference to list price." (*Id.* at 63 (citing Rosenthal Rpt. ¶¶ 132 & n.155, Part VII.D; Ex. 6 ¶¶ 6, 10–11, 14, 21.).) Plaintiffs obtained declarations from several PBMs confirming the data they maintain can be used to separate ineligible members who paid fixed co-pays from eligible members who paid coinsurance—the former being excluded from Plaintiffs' proposed classes and the latter falling within Plaintiffs' proposed classes. (*Id.* at 62–63 (citing Ex. 7 ¶ 9 [redacted]); Ex. 8 ¶¶ 6-7 [redacted]); Ex. 9 ¶ 6 [redacted]); Ex. 10 ¶ 5 ([redacted])).) Plaintiffs also submit a declaration from an insurer claims data firm representing that claims data can be used to identify analog insulin purchases

made during the deductible period of a consumer's benefits plan, as well as analog insulin purchases made with coinsurance. (*Id.* at 64–65 (citing Ex. 5 ¶¶ 7, 10–13).) Moreover, Plaintiffs indicate they are in the process of obtaining records from two third-party vendors that administer all of Defendants' coupon programs and that this data will permit Dr. Rosenthal and claims administrators "to identify every single analog insulin purchase made with a coupon so that it can be excluded from the class." (*Id.* at 64 (citing Rosenthal Rpt. ¶¶ 109, 135; Ex. 6 ¶ 14; Ex. 5 ¶ 14).)

To the extent Defendants claim Plaintiffs have yet to identify all putative class members, Plaintiffs are not required to identify every class member at the class certification stage. *See Hargrove*, 974 F.3d at 480 (explaining plaintiffs "do not have to prove at this stage that each proposed class member was indeed [a member of the proposed class], but only that the members can be identified"). Additionally, to the extent Defendants contend Plaintiffs' proposed classes are not ascertainable because there is no single dataset of all insulin purchases (ECF No. 576 at 75), Defendants do not cite any authority supporting the proposition that only a single, centralized source of data can be relied upon to identify class members. Rather, Plaintiffs are required to show their "purported method for ascertaining class members is reliable and administratively feasible, and permits a defendant to challenge the evidence used to prove class membership." *Carrera*, 727 F.3d at 308. Plaintiffs have done so by utilizing a combination of data sources to identify eligible consumers and exclude ineligible consumers in accordance with the definitions of their proposed classes. *See Afzal v. BMW of N. Am., LLC*, Civ. A. No. 15-8009, 2020 WL 2786926, at *8 (D.N.J. May 29, 2020) (finding plaintiffs "can use a combination of records, such as those from the defendant as well as public records" to satisfy ascertainability). Plaintiffs propose an administratively feasible method to identify class members using evidentiary support including data sets produced by PBMs, insurers, retail pharmacies, and coupon administrators as well as

declarations from claims administrators with experience in distributing damages based on the produced data sets, and industry experts culling and interpreting this data. *See City Select Auto Sales, Inc. v. BMW Bank of N. Am., Inc.*, 867 F.3d 434, 441 (3d Cir. 2017) ("Affidavits, in combination with records or other reliable and administratively feasible means, can meet the ascertainability standard."). As such, Plaintiffs' proposed method permits Defendants to challenge the evidence used to prove class membership. *See Carrera*, 727 F.3d at 307 ("Ascertainability provides due process by requiring that a defendant be able to test the reliability of the evidence submitted to prove class membership.").

Therefore, the Court finds Plaintiffs' proposed classes satisfy the ascertainability requirement.

ii. Rule 23(a) Inquiry

Plaintiffs argue the Court should certify all twelve of their proposed classes because they all satisfy each of the four Rule 23(a) requirements—numerosity, commonality, typicality, and adequate representation. (ECF No. 575 at 2.) Specifically, Plaintiffs assert each of their twelve proposed classes: (1) meet Rule 23(a)'s numerosity requirement because "around seven million Americans take the analog insulins at issue in this lawsuit"; (2) meet Rule 23(a)'s commonality requirement "because common issues of law and fact regarding defendants' liability abound"; (3) meet Rule 23(a)'s typicality requirement because the class representatives' claims "mirror those of all class members" in that they are based on Defendants' alleged "unconscionable and unfair conduct and the [purported] resulting financial losses"; and (4) meet Rule 23(a)'s adequate representation requirement because the proposed "class representatives have shown dogged commitment to their representation of the classes over the past five years" in that "they have sat

for depositions, gathered extensive medical documentation, and demonstrated no conflicts with the classes." (*Id.*)

Defendants contend Plaintiffs have failed to adequately meet their burden to satisfy the four Rule 23(a) requirements for their proposed classes because: (1) "Plaintiffs cannot identify common questions whose answers would drive resolution of this litigation" in that Plaintiffs' proposed questions would not generate common answers; (2) "even if any classes could be certified (they cannot), insured proposed class representatives are not typical of uninsured consumers—whose costs are not based on formularies and rebates—meaning that classes with only *insured* class representatives cannot represent *uninsured* consumers" because "there is a fundamental difference in the 'individual factual circumstances' underlying putative class members' claims, depending on whether each individual is insured or uninsured"; and (3) "under this Court's prior rulings, no proposed class representative can adequately represent individuals who purchased *different* analog insulin products, further circumscribing any classes." (ECF No. 576 at 92–98.)

The Court addresses each of Rule 23(a)'s four requirements—numerosity, commonality, typicality, and adequate representation—in turn.

a. Numerosity

Plaintiffs argue they satisfy Rule 23(a)'s numerosity requirement for each of their twelve proposed classes. (ECF No. 575 at 2, 50–51, 87–88 (citations omitted).) To satisfy Rule 23(a)'s numerosity requirement, "a plaintiff must show by a preponderance of the evidence that 'the class is so numerous that joinder of all members is impracticable.'" *Zangara v. Zager Fuchs, P.C.*, Civ. A. No. 17-06755, 2019 WL 6310056, at *2 (D.N.J. Nov. 25, 2019) (quoting Fed. R. Civ. P. 23(a)(1)). "No minimum number of plaintiffs is required to maintain a suit as a class action, but

generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the [numerosity requirement] of Rule 23(a) has been met." *Stewart v. Abraham*, 275 F.3d 220, 226–27 (3d Cir. 2001) (citation omitted). However, a plaintiff must present evidence for the court to make a factual determination on whether the numerosity requirement is met. *See Marcus*, 687 F.3d at 595. When plaintiffs attempt to certify both nationwide classes and state-specific subclasses, as Plaintiffs seek here, "evidence that is sufficient to establish numerosity with respect to the nationwide class[es] is not necessarily sufficient to establish numerosity with respect to the state-specific subclass[es]." *Id.* Plaintiffs cannot "simply rely on the nationwide presence of [a defendant] to satisfy the numerosity requirement without [state]-specific evidence." *Id.*

Here, Plaintiffs assert Rule 23(a)'s numerosity requirement for all of their proposed classes is met because there are thirty-nine named class representatives and around seven million Americans who take analog insulin every day. (ECF No. 575 at 50–51 (citing William Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 Diabetes Care 1299 (2018); Flory Rpt. ¶¶ 57, 59).) Plaintiffs do not specify how numerosity is met for each of their twelve proposed classes individually, but presumably this requirement is met for each of Plaintiffs' proposed classes, and joinder of this number of plaintiffs would be impracticable. Defendants do not appear to contest numerosity for Plaintiffs' proposed classes (*see* ECF Nos. 576, 587), and at oral argument, conceded numerosity is not an issue (*see* ECF No. 713 at 35).

Therefore, the Court finds Plaintiffs have satisfied Rule 23(a)'s numerosity requirement for their twelve proposed classes.

b. Commonality

Plaintiffs likewise contend they satisfy Rule 23(a)'s commonality requirement for each of

their twelve proposed classes. (ECF No. 575 at 2, 51–54, 87–88.) Commonality under Rule 23(a) requires there to be "questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). "The threshold for establishing commonality is straightforward: 'The commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class.'" *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 596–97 (3d Cir. 2009) (quoting *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994)). Indeed, as the Third Circuit recognized, "[i]t is well established that only one question of law or fact in common is necessary to satisfy the commonality requirement, despite the use of the plural 'questions' in the language of Rule 23(a)(2)." *In re Schering Plough*, 589 F.3d at 597 n.10 (citations omitted). There is a low threshold for satisfying Rule 23(a)'s commonality requirement. *Newton*, 259 F.3d at 183. "The bar for establishing commonality is 'not high' and is 'easily met.'" *In re Pharmacy Benefit Managers Antitrust Litig.*, Civ. A. No. 03-04730, 2017 WL 275398, at *23 (E.D. Pa. Jan. 18, 2017) (first quoting *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 397 (3d Cir. 2015), and then quoting *Reyes*, 802 F.3d at 486); *see also In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (citations omitted) (noting the "threshold of commonality is not high"). However, a bald assertion that all putative class members suffered a violation of the same law is generally insufficient to satisfy the commonality requirement. *See, e.g.*, *Dukes*, 564 U.S. at 349–50 ("Commonality requires the plaintiff to demonstrate that the class members 'have suffered the same injury' . . . [but t]his does not mean merely that they have all suffered a violation of the same provision of law. Title VII, for example, can be violated in many ways—by intentional discrimination, or by hiring and promotion criteria that result in disparate impact, and by the use of these practices on the part of many different superiors in a single company. Quite obviously, the mere claim by employees of the same company that they have suffered a Title VII injury, or

even a disparate-impact Title VII injury, gives no cause to believe that all their claims can productively be litigated at once. Their claims must depend upon a common contention—for example, the assertion of discriminatory bias on the part of the same supervisor. That common contention, moreover, must be of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." (citations omitted)). *Cf. Griffin v. Zager*, Civ. A. No. 16-1234, 2017 WL 3872401, at *4–5 (D.N.J. Sept. 1, 2017) (finding commonality where the court determined that "[f]actually, [the plaintiff] and all class members would have to prove that [defendant] sent out [a] letter" and "the common legal question underlying [the plaintiff's] and class members' claims is whether [defendant] violated the [Fair Debt Collection Practices Act] by, among other things, falsely representing or implying its letter was a communication from an attorney" and that the defendant's conduct in sending out this letter containing false representations "was common as to all of the class members"); *A & L Indus., Inc. v. P. Cipollini, Inc.*, Civ. A. No. 12-07598, 2013 WL 5503303, at *2 (D.N.J. Oct. 2, 2013) (finding Rule 23(a)'s commonality prong met where "[e]ach of the class members' claims hinge[d] on the common contention that Defendant engaged B2B to send the exact same illegal facsimile to each potential class member, in violation of the [Telephone Consumer Protection Act,]" finding "that a determination as to the legality of that single fax will resolve in one stroke *the* issue 'central to the validity of each one of the claims'").

Rule 23(a)'s commonality requirement also does not require all putative class members to have identical claims, *see Hassine v. Jeffes*, 846 F.2d 169, 176–77 (3d Cir. 1988), and "factual differences among the claims of the putative class members do not defeat certification[,]" *Baby Neal*, 43 F.3d at 56. Rather, to satisfy commonality, what matters "is not the raising of common

'questions'—even in droves—but rather, the capacity of a class-wide proceeding to generate common *answers* apt to drive the resolution of the litigation." *Ferreras v. Am. Airlines, Inc.*, 946 F.3d 178, 185 (3d Cir. 2019) (emphasis added) (quoting *Wal-Mart*, 564 U.S. at 350). "Even where individual facts and circumstances do become important to the resolution, class treatment is not precluded." *Baby Neal*, 43 F.3d at 57. But dissimilarities within the proposed class "have the potential to impede the generation of common answers." *Ferreras*, 946 F.3d at 185 (quoting *Wal-Mart*, 564 U.S. at 350). The Rule 23(a) commonality and Rule 23(b) predominance requirements are "closely linked[,]" but the "predominance requirement is 'far more demanding than the commonality requirement[.]'" *Ferreras*, 946 F.3d at 185 (quoting *In re Hydrogen Peroxide*, 552 F.3d at 311).

Here, Plaintiffs argue Rule 23(a)'s commonality requirement is satisfied for each of their twelve proposed classes because they share common questions of law and fact that will yield common answers across the proposed classes. (ECF No. 575 at 2, 51–54, 87–88.) Plaintiffs contend the common questions of law and fact that would generate common answers for their Proposed Nationwide Classes include but are not limited to the following:

> (i) Whether the [D]efendants engaged in unfair and/or unconscionable conduct;
> (ii) Whether the [D]efendants controlled and inflated the list price (WAC) of their analog insulins;
> (iii) Whether the [D]efendants knew that the class members paid based on the list price (WAC) Novo [Nordisk] and Sanofi set;
> (iv) Whether the [D]efendants knew that the increased cost of analog insulin harmed the class members;
> (v) Whether the class members could reasonably avoid purchase of the analog insulins they were prescribed;
> (vi) Whether the [D]efendants took advantage of the class members' lack of capacity to forgo purchases of their analog insulins;

(vii) Whether the [D]efendants competed with one another through rebates to PBMs and insurers rather than reductions to list prices;
(viii) Whether the [D]efendants copied their competitors' price increases such that all rapid and long-acting insulins were infected by the scheme;
(ix) Whether the [D]efendants have lacked honesty regarding the justifications and driving forces behind their list price increases;
(x) Whether the [D]efendants are liable to plaintiffs and the class members for damages flowing from their alleged misconduct.

(ECF No. 575 at 52–53.[25])

In opposition, Defendants assert Plaintiffs fail to meet Rule 23(a)'s commonality requirement because their proposed common questions of law and fact will not generate common answers, and even if they did, those answers would not drive the resolution of the litigation. (ECF No. 576 at 92–94.) Defendants argue some of Plaintiffs' proposed questions—*e.g.*, "Whether the [D]efendants engaged in unfair and/or unconscionable conduct"—"parrot generic legal allegations, which is 'not sufficient to establish commonality.'" (ECF No. 576 at 93 (citing *Greco v. Grewal*, Civ. A. No. 19-19145, 2020 WL 5793709, at *5 (D.N.J. Sept. 29, 2020)).) Defendants state other of Plaintiffs' common questions will not advance the litigation because, for example, "[t]here is no dispute that Defendants set list prices for their insulins and 'competed with one another through rebates,' among other factors." (ECF No. 576 at 94 (quoting ECF No. 575 at 52–53).)

In reply, Plaintiffs contend "[t]he central question in this case asks not whether some threshold monetary amount to buy insulin is unfair, but whether the [D]efendants' conduct in

[25] As Defendants note (ECF No. 576 at 92–93), Plaintiffs' list of common questions of law and fact here differ from the "[q]uestions of law and fact common to the class" they listed in the TAC (*see* ECF No. 411 ¶ 332).

setting benchmark insulin list prices was unfair[,]" and this question "necessarily drives common answers." (ECF No. 577 at 57–58.) In other words, Plaintiffs suggest common questions to all potential members of each of their proposed classes include whether Defendants' alleged conduct in setting artificially inflated prices for their analog insulin products was unfair or unconscionable, depending on what Defendants did and knew and when,[26] and whether Defendants are liable to Plaintiffs and the putative class members for damages flowing from this alleged conduct. (*See id.*) Plaintiffs further claim the alleged harm every proposed class member suffered—overpaying for Defendants' analog insulin products—follows directly from Defendants' alleged conduct because the retail prices are based on Defendants' list prices for those products. (*Id.* at 58.)

By setting the list prices for their analog insulin products, Defendants effectively set the initial input from which all downstream prices flow. All proposed class members purchased an analog insulin product and allegedly paid a price based on Defendants' purportedly artificially inflated list price for that product. Accordingly, all proposed class members allegedly suffered the same injury because they all allegedly overpaid for their prescribed insulin based on Defendants' purported scheme to artificially inflate the list prices for those products. *See Dukes*, 564 U.S. at 349–50 (citation omitted) ("Commonality requires the plaintiff to demonstrate that the class members have suffered the same injury."). This is not to say all putative class members actually suffered an injury. As the Third Circuit has stated, meeting Rule 23(a)'s commonality requirement

[26] Defendants state Plaintiffs rely on Dr. Rosenthal to determine when Defendants' alleged unfair pricing schemes began. (ECF No. 576 at 23 (citing ECF No. 575 at 1, 4; Rosenthal Dep. at 190:8–190:20).) But Dr. Rosenthal admits her analysis is (1) "not based on 'when' Defendants 'were making decisions about rebates'" (ECF No. 576 at 23 (citing Rosenthal Dep. at 198:2–198:21)) and (2) "not about an amount per [insulin] pen paid at a particular transaction," and "[t]he individual transaction cost is not what's being deemed unconscionable" (*id.* at 24 (alteration in original) (citing Rosenthal Dep. 248:25–249:8, 252:15–252:22)).

is "easy enough." *In re Nat'l Football League Players Concussion Inj. Litig.*, 821 F.3d 410, 427 (3d Cir. 2016), *as amended* (May 2, 2016). For example, courts in this Circuit have "acknowledged commonality to be present even when not all members of the plaintiff class suffered an actual injury, when class members did not have identical claims, and, most dramatically, when some members' claims were arguably not even viable." *Id.* (quoting *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 397 (3d Cir. 2015)). In reaching those conclusions, courts have explained "the focus of the commonality inquiry is not on the strength of each class member's claims but instead 'on whether the defendant's conduct was common as to all of the class members.'" *In re Cmty. Bank of N. Va.*, 795 F.3d at 397 (quoting *Sullivan*, 667 F.3d at 305–07).

Here, Plaintiffs and the proposed class members for each of Plaintiffs' twelve proposed classes all allegedly suffered the same injury—overpaying for Defendants' analog insulin products—and all share at least one common question of law or fact, including whether Defendants' alleged conduct in setting the list prices for their analog insulin products was unconscionable and what Defendants did and knew in relation to setting these list prices, which would generate answers common to the class.[27] *See In re Pharm. Indus. Average Wholesale Price*

[27] To the extent Defendants rely on *Greco v. Grewal*, the Court finds Defendants' reliance is misplaced. In *Greco*, the court found the plaintiffs failed to sufficiently raise a common question "because the [d]efendants' conduct would be materially different as to each plaintiff." Civ. A. No. 19-19145, 2020 WL 5793709, at *7 (D.N.J. Sept. 29, 2020). Unlike in *Greco*, Defendants' allegedly unfair conduct of inflating list prices of analog insulin products would be materially the same as to each putative class member, even though individualized issues related to causation and damages may remain. *Cf. Eastman v. First Data Corp.*, 292 F.R.D. 181, 189–90 (D.N.J. 2013) (finding a lack of commonality and denying motion for class certification in a case where plaintiffs argued defendant's lease program was unconscionable because "it hid[] the true market value of the equipment being financed[,]" stating "the unconscionability inquiry will require determining the value to each individual merchant—an inquiry which cannot be determined with common evidence" and that plaintiffs did not propose "a method by which unconscionability could be determined with common evidence" (alterations in original) (citations and footnote omitted)).

Litig., 252 F.R.D. 83, 103 (D. Mass. 2008) (finding commonality and listing common factual issues as including "whether the AWPs and wholesale list prices for the subject drugs are false"; "whether such misrepresentations were knowing and intentional; whether the reporting of the prices was 'unfair'; and whether these misrepresentations caused plaintiffs harm during the class period").

Therefore, the Court finds Plaintiffs have satisfied Rule 23(a)'s commonality requirement for their twelve proposed classes because each proposed class shares at least one common question of law or fact.

c. Typicality

Plaintiffs also argue they satisfy Rule 23(a)'s typicality requirement for each of their twelve proposed classes. (ECF No. 575 at 2, 54–55, 87–88.) Typicality requires the class representative's claims be typical of the claims of the class. Fed. R. Civ. P. 23(a)(3). "The concepts of commonality and typicality are broadly defined and tend to merge, because they focus on similar aspects of the alleged claims." *Newton*, 259 F.3d at 182 (citation omitted). "Both criteria seek to assure that the action can be practically and efficiently maintained and that the interests of the absentees will be fairly and adequately represented." *Baby Neal*, 43 F.3d at 56. Like commonality, typicality is a "low threshold" to satisfy. *Newton*, 259 F.3d at 183. But unlike commonality, "[t]he 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). The typicality requirement can be satisfied where "'there is a strong similarity of legal theories' or where the claim arises from the same practice or course of conduct." *Newton*, 259 F.3d at 184 (citations omitted). "If the claims of the named plaintiffs and putative class members involve

the same conduct by the defendant, typicality is established regardless of factual differences." *Id.* at 183–84 (citations and footnote omitted).

The Third Circuit articulated a three-prong analysis in assessing Rule 23(a)'s typicality requirement, consisting of three distinct, yet related, concerns:

> (1) the claims of the class representative must be generally the same as those of the class in terms of both (a) the legal theory advanced and (b) the factual circumstances underlying that theory;
>
> (2) the class representative must not be subject to a defense that is both inapplicable to many members of the class and likely to become a major focus of the litigation; and
>
> (3) the interests and incentives of the representative must be sufficiently aligned with those of the class.

Marcus, 687 F.3d at 598 (quoting *In re Schering Plough Corp.*, 589 F.3d at 599). In other words, the named plaintiffs must be sufficiently similar to the rest of the proposed class "in terms of their legal claims, factual circumstances, and stake in the litigation." *In re Schering Plough Corp.*, 589 F.3d at 597. Typicality acts as a bar to class certification when "the legal theories of the named plaintiffs potentially conflict with those of the absentees." *Georgine*, 83 F.3d at 631; *Newton*, 259 F.3d at 183. Moreover, "[i]t is well established that a proposed class representative is not 'typical' under Rule 23(a)(3) if 'the representative is subject to a unique defense that is likely to become a major focus of the litigation.'" *In re Schering Plough*, 589 F.3d at 598 (quoting *Beck v. Maximus, Inc.*, 457 F.3d 291, 301 (3d Cir. 2006)). If a class representative has a unique defense, "the representative's interests might not be aligned with those of the class, and the representative might devote time and effort to the defense at the expense of issues that are common and controlling for the class." *Beck*, 457 F.3d at 297. However, plaintiffs can satisfy the typicality requirement if their claims "arise from the same event or practice or course of conduct that gives rise to the claims of

the class members, and are based on the same legal theory." *Brosious v. Child.'s Place Retail Stores*, 189 F.R.D. 138, 146 (D.N.J. 1999) (alterations and citations omitted).

Here, Plaintiffs contend the class representatives' claims are typical of the claims of the putative class members of each of their twelve proposed classes because they arise from the same allegedly wrongful conduct of Defendants and are based on the same legal theory, *i.e.*, the Defendants' allegedly unlawful pricing scheme to artificially inflate the list prices of their analog insulin products "to compete for formulary access through rebates[,]" which Plaintiffs assert "was unfair and unconscionable and caused the [proposed] class[es] and representatives to overpay for insulin." (ECF No. 575 at 54–55.)

In opposition, Defendants contend Plaintiffs fail to establish the typicality requirement because "there is a fundamental difference in the 'individual factual circumstances' underlying putative class members' claims, depending on whether each individual is insured or uninsured" in that "formularies and rebates apply only to purchases by *insured* consumers[,]" but "[u]ninsured consumers' transactions do not involve rebates, formularies, or PBMs." (ECF No. 576 at 94–95.) For example, Defendants assert Plaintiffs' "liability theory plays out entirely differently for uninsured individuals" in that "[i]f a manufacturer increases both its list *and* net prices for insured transactions by 20% (such that the ratio remains unchanged), the uninsured would be unharmed according to Prof. Rosenthal—even if they paid *more* out of pocket[,]" but "[c]onversely, if the list price remains flat while the average rebate for *insured* consumers increases, then the *uninsured* would experience *no change* in out-of-pocket-costs—but would still be injured under Plaintiffs' theory." (*Id.* at 96 (citations omitted).) Defendants state therefore that the insured proposed class representatives are not typical of the uninsured proposed class members and "classes with no

uninsured proposed representatives certainly cannot include uninsured members." (ECF No. 576 at 96.[28])

In reply, Plaintiffs submit the class representatives satisfy the typicality requirement for both insured and uninsured proposed class members because all of them can trace their injuries to the same unlawful practices—Defendants' alleged unlawful conduct. (ECF No. 577 at 60.) Plaintiffs further assert "[e]ach class representative here seeks to represent only class members who purchased insulin products in the same state from the same [D]efendant as that representative's purchases" and that "neither Dr. Rosenthal's methodology for determining damages nor the plaintiffs' theory of unfairness and unconscionability differs as to the analog insulin products at issue." (*Id.* at 61.)

Plaintiffs allege Defendants engaged in unfair and unconscionable conduct by raising the list prices of their analog insulin products in order to provide PBMs with larger "secret" rebates to gain formulary access at the expense of the putative class members who allegedly paid based on those inflated list prices. Defendants maintain the insured class representatives are not typical of the uninsured class members because there is a fundamental difference in the individual factual circumstances underlying the putative class members' claims depending on whether the individual is insured or uninsured. However, the difference in insurance status among class members does not defeat typicality because the legal theory and claims asserted by Plaintiffs—*i.e.*, Defendants' alleged artificial inflation of list prices for their analog insulin products was purportedly unfair and unconscionable, purportedly causing the proposed class members to overpay for these products—

[28] Defendants note Plaintiffs lack uninsured class representatives "in, at least, Illinois, Iowa, Maine, Massachusetts, New Jersey, and North Dakota" for Novo Nordisk and similarly lack uninsured class representatives "in, at least, Colorado, Connecticut, Delaware, Florida, Iowa, Massachusetts, New Jersey, North Carolina, and Texas" for Sanofi. (ECF No. 576 at 96 n.26.)

are the same among the putative class members, regardless of whether they are insured or uninsured. *See Newton*, 259 F.3d at 183–84 ("If the claims of the named plaintiffs and putative class members involve the same conduct by the defendant, typicality is established regardless of factual differences." (citations and footnote omitted)); *Marcus*, 687 F.3d at 598 ("If a plaintiff's claim arises from the same event, practice or course of conduct that gives rises to the claims of the class members, factual differences will not render that claim atypical if it is based on the same legal theory as the claims of the class."). Regardless of whether an individual class member is insured or uninsured, Plaintiffs' and the putative class members' claims arise from the same alleged conduct by Defendants. Therefore, the Court concludes factual differences between insured versus uninsured putative class members do not render Plaintiffs' claims atypical.

Moreover, to the extent putative class members suffered harm by overpaying for Defendants' analog insulin products, whether they were insured or uninsured, they can trace their injuries to the same alleged unlawful practice engaged in by Defendants. *See Boley v. Universal Health Servs.*, 36 F.4th 124, 134 (3d Cir. 2022) (finding typicality satisfied where each class member could "trace his or her injury to the same [alleged unlawful] practice"); *Baby Neal*, 43 F.3d at 58 ("Where an action challenges a policy or practice, the named plaintiffs suffering one specific injury from the practice can represent a class suffering other injuries, so long as all the injuries are shown to result from the practice."). Indeed, Plaintiffs' alleged cause of injury for each putative class member for each of their proposed classes all stem from Defendants' purported conduct of artificially inflating the list prices for their analog insulin products. To the extent Defendants contend the alleged harm differs between insured and uninsured proposed class members, these differences do not preclude a finding of typicality. *See Boley*, 36 F.4th at 134 (finding factual "differences relate[d] to degree of injury and level of recovery" will generally not

preclude a finding of typicality "[s]o long as the alleged cause of the injury remains the same" (citation omitted)); *In re Prudential*, 148 F.3d at 311 ("'[E]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories' or where the claim arises from the same practice or course of conduct." (alteration in original) (citation omitted)).

Therefore, the Court finds Plaintiffs satisfy Rule 23(a)'s typicality requirement for their twelve proposed classes.

d. Adequate Representation

Plaintiffs also argue they satisfy Rule 23(a)'s adequate representation requirement. (ECF No. 575 at 2, 55–57, 87–88.) Adequate representation requires the representatives of a class to "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "Rule 23(a)'s adequacy of representation requirement 'serves to uncover conflicts of interest between named parties and the class they seek to represent.'" *In re Pet Food Prods. Liab. Litig.*, 629 F.3d 333, 343 (3d Cir. 2010) (quoting *Amchem*, 521 U.S. at 625). The class representatives "must be part of the class and possess the same interest and suffer the same injury as the class members." *Id.* (quoting *Amchem*, 521 U.S. at 625–26). "A conflict must be 'fundamental' to violate Rule 23(a)(4)." *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 184 (3d Cir. 2012) (citations omitted). "A conflict is fundamental where it touches 'the specific issues in controversy.'" *Id.* (citation omitted). "A conflict that is unduly speculative, however, is generally not fundamental." *Id.* "Adequate representation 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." *Laurens v. Volvo Car USA, LLC*, Civ. A. No. 18-08798, 2020 WL 10223641, at *10 (D.N.J. Dec. 8, 2020) (quoting *Wetzel v. Liberty Mut. Ins. Co.*, 508 F.2d

239, 247 (3d Cir. 1975)). "[T]he linchpin of the adequacy requirement is the alignment of interests and incentives between the representative plaintiffs and the rest of the class." *Dewey*, 681 F.3d at183. Class representatives are "adequate" if their interests do not conflict with those of the putative class members. *See In re Prudential*, 148 F.3d at 312. "[T]he adequacy requirement assures that counsel possesses adequate experience, will vigorously prosecute the action, and will act at arm's length from the defendant." *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 389 (3d Cir. 2015) (citation omitted). "Adequacy functions as a 'catch-all requirement' that 'tend[s] to merge with the commonality and typicality criteria of Rule 23(a).'" *Laurens*, 2020 WL 10223641, at *10 (quoting *Newton*, 259 F.3d at 185).

Here, Plaintiffs contend they satisfy Rule 23(a)'s adequate representation requirement for their Proposed Nationwide Classes because the proposed class representatives "will fairly and adequately protect and represent the interests of the [proposed] classes[,]" and share coincident, not antagonistic, interests with the proposed class members. (ECF No. 575 at 56–57, 88.) Plaintiffs also assert proposed "[c]lass counsel are experienced in the prosecution of class action litigation and have extensive experience with class action litigation involving pharmaceutical products and drug pricing." (*Id.* at 56.)

In opposition, Defendants argue Plaintiffs fail to satisfy the adequate representation requirement because no proposed class representative can adequately represent individuals who purchased a different analog insulin product(s) in a different state(s) than those the class representatives purchased, noting the Court has already ruled Plaintiffs lack standing to pursue state law claims for insulin products they did not purchase in a particular state. (ECF No. 576 at 96–97 (citing *In re Insulin Pricing Litig.*, Civ. A. No. 17-00699, 2019 WL 643709, at *17 (D.N.J. Feb. 15, 2019).) Defendants contend "Plaintiffs expressly assert that Defendants' conduct was *not*

uniform across products, and became unlawful for different products on different dates depending on the specific relationship between each product's list and net prices, the named plaintiffs cannot be adequate representatives as to products that they did not purchase[,]" and therefore, "[a]ny certified class would thus need to exclude products that the relevant state's class representative did not purchase." (ECF No. 576 at 97–98 (citing App., Table 1, which lists the products not purchased by any class representative in each relevant state).)

In reply, Plaintiffs maintain Rule 23(a)'s adequacy requirement is satisfied because "[e]ach class representative here seeks to represent only class members who purchased insulin products in the same state from the same defendant as that representative's purchases." (ECF No. 577 at 61.) Indeed, Plaintiffs admit they are *not* seeking to represent class members who purchased insulin products from different Defendants or in different states than the representative. Plaintiffs further argue "neither Dr. Rosenthal's methodology for determining damages nor the plaintiffs' theory of unfairness and unconscionability differs as to the analog insulin products at issue[,]" and that "the class periods for the various drugs differ only because the methodology and legal theories of unfairness and unconscionability remain *consistent* across them." (*Id.*)

Although Defendants contend "the named [P]laintiffs cannot be adequate representatives as to products that they did not purchase" (ECF No. 576 at 97), Plaintiffs allege the same unlawful conduct across all analog insulin products purchased, and therefore, no fundamental conflict exists between members who purchased different analog insulin products. *See Georgine*, 83 F.3d at 630 (stating the adequacy of representation inquiry considers whether "the interests of the named plaintiffs [are] sufficiently aligned with those of the absentees"); *Hassine*, 846 F.2d at 179 ("The inquiry that a court should make regarding the adequacy of representation requisite of Rule 23(a)(4) is to determine that the putative named plaintiff has the ability and the incentive to

represent the claims of the class vigorously[.]"). Because Defendants allegedly engaged in the same unlawful conduct with respect to all analog insulin products, the proposed class representatives' interests do not conflict with those of the putative class members for each of Plaintiffs' twelve proposed classes.

Therefore, the Court finds Plaintiffs satisfy Rule 23(a)'s adequate representation requirement for their twelve proposed classes.

iii. Rule 23(b) Inquiry

Because the Court concludes Plaintiffs satisfy the four threshold requirements of Rule 23(a), the Court now turns to analyzing whether Plaintiffs also satisfy the requirements for class certification under Rule 23(b)(2) and Rule 23(b)(3) for each of their twelve proposed classes. The Court addresses the requirements under each of these Rule 23(b) sections in turn.[29]

a. Rule 23(b)(2) Inquiry

Under Rule 23(b)(2), the Court must find "the party opposing the class has acted or refused to act on the grounds that generally apply to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2). The Supreme Court has held the "key to the (b)(2) class is 'the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.'" *Dukes*, 564 U.S. at 360 (citation omitted). In other words, certifying a Rule 23(b)(2) class "applies only when a single injunction or declaratory judgment would provide relief to each member of the class." *Id.* Therefore, "[c]laims for individualized relief may not be certified under 23(b)(2), nor

[29] Because Plaintiffs only seek to certify classes under Rule 23(b)(2) and Rule 23(b)(3) and do not seek to certify any classes under Rule 23(b)(1) (*see* ECF Nos. 574, 575), the Court does not analyze the requirements under Rule 23(b)(1).

may claims for monetary relief that are 'not incidental to the injunctive or declaratory relief.'" *Lipstein v. UnitedHealth Grp.*, 296 F.R.D. 279, 291 (D.N.J. 2013) (quoting *Dukes*, 564 U.S. at 360). "Plaintiffs' sought injunction must be more specific than merely requiring that Defendants follow the law." *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 124, 170 (E.D. Pa. 2015) (citations omitted).

In addition, under Rule 23(b)(2), a plaintiff must show the class claims are cohesive among the putative class members. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 263–64 (3d Cir. 2011). Cohesiveness is a primary requirement because, in a Rule 23(b)(2) action, "unnamed members are bound by the action without the opportunity to opt out." *Barnes*, 161 F.3d at 142–43. "For a court to find a class cohesive, it must find that the 'class's claims are common ones and that adjudication of the case will not devolve into consideration of myriad individual issues.'" *In re Processed Egg Prods.*, 312 F.R.D. at 169 (quoting Newberg on Class Actions § 4:34). "'[D]isparate factual circumstances of class members' may prevent a class from being cohesive and, therefore, make the class unable to be certified under Rule 23(b)(2)." *Gates*, 655 F.3d at 264 (quoting *Carter v. Butz*, 479 F.2d 1084, 1089 (3d Cir. 1973)). Accordingly, the Third Circuit "has held that district courts have the discretion to deny certification under [Rule 23](b)(2) when a given case presents 'disparate factual circumstances,' or a prevalence of individualized issues." *In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, Civ. A. No. 03-04558, 2012 WL 379944, at *38 (D.N.J. Feb. 6, 2012) (quoting *Barnes*, 161 F.3d at 143). "Indeed, a [Rule 23](b)(2) class may require more cohesiveness than a [Rule 23](b)(3) class." *Gates*, 655 F.3d at 264 (footnote omitted) (quoting *Barnes*, 161 F.3d at 142).

Here, Plaintiffs argue certifying their twelve proposed classes under Rule 23(b)(2) is appropriate because without certification, Defendants can continue to subject consumers to alleged

unconscionable pricing. (ECF No. 575 at 77–79, 98.) However, Defendants contend Plaintiffs' cursory[30] request to certify injunctive classes under Rule 23(b)(2) fails because Plaintiffs do not specify the injunctive relief they seek, Plaintiffs' proposed classes are not sufficiently cohesive, and the majority of the proposed class members do not face future harm. (ECF No. 576 at 98–100.) Defendants further assert "*any* injunctive relief would require the Court to become the nation's insulin price regulator, tasked with determining what prices are 'fair'—apparently in perpetuity." (*Id.* at 98.) Defendants also state "Plaintiffs make no attempt to account for developments in Defendants' pricing practices in recent years." (*Id.* at 99 (emphasis omitted).) Defendants claim they "have broadened their affordability offerings to provide relief for patients struggling to afford insulin, with the vast majority of insulins now available for less than $50 and many consumers paying nothing[,]" and Defendants argue "[t]hese changes moot any request for injunctive relief." (*Id.* at 99–100 (emphasis and citations omitted).)

In reply, Plaintiffs clarify: (1) they are seeking to enjoin Defendants "from continuing to report artificially inflated list prices that do not approximate their true net prices to [PBMs] CVS, Express Scripts, and OptumRx" (ECF No. 577 at 61 (citing ECF No. 411 ¶ 269)) and this would not "require the Court to become the nation's insulin price regulator" because "the Court isn't asked to specify the prices at which insulin must be sold, but instead is asked to require the [D]efendants to price their insulin within the boundaries of state consumer protection laws" (*id.* at 61–62 (citations omitted)); (2) their proposed classes are sufficiently cohesive because Defendants set the list prices which affect the prices all of them paid for Defendants' analog insulin products

[30] Defendants note Plaintiffs "spare only about two pages of their 100-page brief for this request, and never actually try to explain how they satisfy Rule 23(b)(2)." (ECF No. 576 at 98 (citing ECF No. 575 at 77–79, 98).)

(*id.* at 62–63); and (3) future harm exists because Defendants do not claim they stopped the allegedly unlawful conduct at issue and Defendants' affordability programs "only apply to a sliver of the [proposed] class[es]." (*Id.* at 63.)

In their sur-reply, Defendants argue Plaintiffs "belatedly try to flesh out" their Rule 23(b)(2) request in their reply after treating it in a cursory manner in their opening brief. (ECF No. 587-1 at 2; *see also id.* at 19–23.) Defendants contend Plaintiffs' injunctive relief proposal violates Federal Rule of Civil Procedure 65(d)'s requirements[31] and "would compel Defendants to violate federal law governing the reporting of list prices." (*Id.*) Defendants also assert Plaintiffs "confirm they can neither show the required cohesiveness among the millions of differently situated putative class members, nor account for the substantial changes in Defendants' pricing practices and affordability offerings over time and in recent years." (*Id.*) Specifically, Defendants: (1) reiterate that Plaintiffs have not specified the injunctive relief they seek (*id.* at 20); (2) Plaintiffs have not shown how their proposed injunctive relief would satisfy the requirements of Rule 65(d) and "[p]utting aside that the concept of 'true net prices' has no nexus to Plaintiffs' 'trend break' method or any other aspect of Plaintiffs' reformulated unfairness or unconscionability claim," Plaintiffs' "vague formulation does nothing to enable the Court to 'at least conceive of an injunction that would satisfy [the] requirements' of Federal Rule of Civil Procedure 65(d)" (*id.* (citations omitted)); and (3) Plaintiffs do not state how the Court "*could* enjoin Defendants from reporting 'list prices that do not approximate their true net prices' without violating federal law—twice over" (*id.*). Defendants state federal law prohibits pharmaceutical manufacturers from reporting list

[31] Federal Rule of Civil Procedure 65(d) provides "[e]very order granting an injunction and every restraining order must: (A) state the reasons why it issued; (B) state its terms specifically; and (C) describe in reasonable detail--and not by referring to the complaint or other document--the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1).

prices that approximate net prices, and therefore, Plaintiffs are asking the Court to issue an injunction that would require Defendants to violate federal law. (*Id.* at 20–21 (citing 42 U.S.C. § 1395w-3a(c)(6)(B)).) Further, Defendants submit Plaintiffs' request for injunctive relief under Rule 23(b)(2) would also violate the Dormant Commerce Clause because "enforcing the boundaries of *some* consumer-protection laws would necessarily mean determining the WAC prices that Defendants can set for their insulins in *all* states (since Defendants necessarily set a single list price for each drug, consistent with federal law)." (*Id.* at 21 (citation omitted).)

Additionally, Defendants argue Plaintiffs' contention that their proposed classes are sufficiently cohesive because Defendants' list prices affect the prices all proposed class members paid "ignores the myriad factors that determine *how* point-of-sale prices are determined for any particular individual"—*e.g.*, "whether an individual had insurance (and the terms of any such coverage), the degree to which PBM rebates benefited the consumer, how the individual's pharmacy calculated the price he paid, whether the individual was eligible for one of Defendants' affordability offerings, [etc.]" (*Id.* at 22.) Defendants contend these consumer-specific considerations prevent finding the cohesiveness needed for Rule 23(b)(2). (*Id.*) Defendants further note Plaintiffs do not dispute that Defendants' analog insulin products are generally available for under $50 or free for many consumers, and despite Plaintiffs' claim that this only applies to a "sliver" of their proposed classes, Defendants assert the analysis of their expert, Dr. Baker, shows this is not true. (*Id.* (citing Baker Rpt. ¶ 107 & Ex. 4).) For example, Defendants state that, in 2018, "coupon redemptions through Defendants' financial-assistance initiatives accounted for more than one-third of the analog insulin claims for uninsured and commercially insured patients recorded in the data used by [Dr.] Rosenthal." (*Id.* at 22–23 (citing Baker Rpt. ¶ 107).)

In response, Plaintiffs argue: (1) "courts routinely hold that plaintiffs need not satisfy [Rule 65's] requirements at the class certification stage" and whether the Court can enter an injunction as they request "is a merits question"; (2) whether their requested relief would violate the Dormant Commerce Clause "is a merits issue" and, in any event, they are not requesting the Court to regulate the prices of insulin; rather they are requesting the Court enjoin Defendants from "inflating list prices as a means of providing inflated rebates"; (3) their proposed Rule 23(b)(2) classes are sufficiently cohesive and Defendants do not respond to Plaintiffs' assertion that their list prices affect the prices all consumer paid; and (4) Defendants' financial assistance programs do not render their Rule 23(b)(2) classes moot. (ECF No. 590 at 21–24 (citations omitted).) Tellingly, Plaintiffs do not address Defendants' argument that their requested injunctive relief would require Defendants to violate federal law.

Here, the Court finds none of Plaintiffs' proposed classes are sufficiently cohesive to be certified under Rule 23(b)(2) and are therefore not suitable for Rule 23(b)(2) relief. Plaintiffs' unconscionability and unfairness claims raise a host of individualized issues subject to various standards of review that could yield different results concerning the legality of Defendants' pricing practices related to their analog insulin products. *See Santiago*, 72 F.R.D. at 627 (finding Rule 23(b)(2) is not appropriate where "significant individual liability or defense issues . . . would require separate hearings for each class member in order to establish defendants' liability"). This includes whether each putative class member shared in the rebate savings, the variations among state consumer protection laws, the variations among health plans, and the different insurers and affiliated PBMs of each class member. *See In re Domestic Drywall Antitrust Litig.*, Civ. A. No. 13-md-02437, 2017 WL 3700999, at *16 (E.D. Pa. Aug. 24, 2017) ("[T]he same issues that prevented certification [of damages classes], in particular the differences in factual circumstances

between class members, also prevent a finding of cohesiveness. The factual circumstances among indirect purchasers vary widely. . . . It would be unfair to saddle some indirect purchasers who may have an easier time proving causation than others with a binding negative judgment, without the opportunity to 'opt out.'"). Many of these individualized issues create disparate factual circumstances among class members, and therefore fail to satisfy Rule 23(b)(2)'s cohesiveness requirement. *See, e.g.*, *In re Managerial, Pro. & Tech. Emps.*, Civ. A. No. 02-02924, 2006 WL 38937, at *6 (D.N.J. Jan. 5, 2006) (declining to certify class under Rule 23(b)(2) where the court found plaintiffs' proposed class was not cohesive and "raise[d] a number of individualized issues"). Additionally, the Court does not see—and Plaintiffs do not explain—how it would be able to enjoin Defendants as Plaintiffs request without causing Defendants to violate federal law. (*See* ECF No. 577 at 61–63; ECF No. 587-1 at 20–21; ECF No. 590 at 21–24; 42 U.S.C. § 1395w-3a(c)(6)(B) ("The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price*, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.").)

Therefore, Plaintiffs' motion to certify each of their twelve proposed classes under Rule 23(b)(2) is **DENIED**.

b. Rule 23(b)(3) Inquiry

Rule 23(b)(3) provides a class action may be maintained if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). These requirements are known

as "predominance" and "superiority," respectively. *In re Hydrogen Peroxide*, 552 F.3d at 310. "Predominance 'tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation,' a standard 'far more demanding' than the commonality requirement of Rule 23(a)[.]" *Id.* at 310–11 (quoting *Amchem*, 521 U.S. at 623–24). Superiority "asks the court 'to balance, in terms of fairness and efficiency, the merits of a class action against those of "alternative available methods" of adjudication.'" *In re Prudential*, 148 F.3d at 316 (quoting *Georgine*, 83 F.3d at 632).

"The predominance inquiry 'asks whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues.'" *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (citation omitted). "An individual question is one where 'members of a proposed class will need to present evidence that varies from member to member,' while a common question is one where 'the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Tyson Foods*, 577 U.S. at 453 (alteration in original) (citation omitted). "When 'one or more of the central issues in the action are common to the class and can be said to predominate," a class can be certified under Rule 23(b)(3) "even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members." *Id.*

"To establish predominance, Plaintiffs must show that a group trial of [the] action will not devolve into a series of mini trials concerning causation or injury." *Neale v. Volvo Cars of N. Am., LLC*, Civ. A. No. 10-04407, 2021 WL 3013009, at *9 (D.N.J. July 15, 2021). If, on the other hand, "proof of the essential elements of the cause of action requires individual treatment," then predominance is defeated, and a class should not be certified. *See Newton*, 259 F.3d at 172.

Therefore, the predominance inquiry depends upon the merits of a plaintiff's claims, because the "nature of the evidence that will suffice to resolve a question determines whether the question is common or individual." *In re Hydrogen Peroxide*, 552 F.3d at 311 (citations omitted).

"[A] district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." *Id.* (citation omitted). For example, in *Lewis v. Ford Motor Company*, the court noted that to prove a violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, "a plaintiff must [] show that as a result of the defendant's fraudulent or deceptive conduct, he or she suffered an 'ascertainable loss of money or property.'" 263 F.R.D. 252, 263 (W.D. Pa. 2009). The *Lewis* court ultimately denied plaintiffs' motion for class certification (for a count alleging a violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law) where the court found plaintiffs "failed to establish by a preponderance of the evidence commonality and predominance of common over individual issues" because "each class member would have to show not only justifiable reliance but also loss as a result of that reliance, aspects subject to individual, rather than common questions of law or fact" and "such lack of commonality" rendered the case "unsuitable for class treatment." *Id.* at 264, 268.

In determining whether common questions predominate, courts have focused on defendants' alleged liability. *See Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 456 (3d Cir. 1977); *Smith v. Suprema Specialties, Inc*., Civ. A. No. 02-168, 2007 WL 1217980, at *9 (D.N.J. Apr. 23, 2007) (citations omitted) ("The focus of the predominance inquiry is on liability, not damages."). Practically, this means "a district court must look first to the elements of the plaintiffs' underlying claims and then, 'through the prism' of Rule 23, undertake a 'rigorous assessment of the available evidence and the method or methods by which [the] plaintiffs propose to use the evidence to prove'

those elements." *Reinig v. RBS Citizens, N.A.*, 912 F.3d 115, 128 (3d Cir. 2018) (quoting *Marcus*, 687 F.3d at 600). "[T]he predominance requirement is met only if the district court is convinced that 'the essential elements of the claims brought by a putative class are 'capable of proof at trial through evidence that is common to the class rather than individual to its members.'" *Id.* at 127–28 (quoting *Gonzalez v. Corning*, 885 F.3d 186, 195 (3d Cir. 2018)).

Here, Plaintiffs seek to certify twelve classes under Rule 23(b)(3), excluding the classes involving Eli Lilly—the two Proposed Nationwide Classes, the two Proposed Multi-State Classes, the two Proposed New Jersey Classes, the two Proposed Texas Classes, the two Proposed Kansas Classes, and the two Proposed Utah Classes. (*See* ECF No. 574; ECF No. 575 at 68–77, 88–98.) Plaintiffs assert if the Court certifies all twelve proposed classes, a jury need only consider three legal standards: (1) "unconscionability" under New Jersey law; (2) a three-part FTC test for "unfair" acts that Plaintiffs contend applies to the laws of sixteen states; and (3) "unconscionability" under Texas law. (ECF No. 575 at 6.) Plaintiffs state the claims for the two Proposed Kansas Classes and the two Proposed Utah Classes are explicitly reserved for the Court to decide so those classes would not need to be presented to a jury. (*Id*. at 80.)

Plaintiffs argue each of their twelve proposed classes should be certified under Rule 23(b)(3) because "[c]ommon questions of law and fact predominate" and "a class action is superior to other available methods." (ECF No. 575 at 41–50, 69–77, 88–98.) Plaintiffs also contend that "[c]ommon evidence will establish that [Defendants] engaged in unconscionable conduct as to all class members under the NJCFA[,]" and "[c]lass-wide evidence will demonstrate impact and injury for all nationwide class members." (*Id.* at 69–76.) Plaintiffs assert they will be able to prove impact and calculate aggregate damages through common evidence showing Plaintiffs and the proposed class members overpaid for analog insulin products due to Defendants' alleged unfair

and unconscionable conduct. (*Id.* at 73–76.) Specifically, Plaintiffs state they will litigate every nationwide class member's claim using the same documents, data, and witnesses and, using Defendants' documents, will prove that Defendants understood that the coinsurance, deductible, and cash payments for their analog insulin products were tied to list price. (*Id.* at 71.) To do this, Plaintiffs submit they will rely on Dr. Rosenthal's analysis comparing Defendants' list prices to certain pharmaceutical industry data on retail pharmacy prices of Defendants' analog insulins and applying "the Pearson correlation coefficient—a statistical test—to measure the linear correlation between the two prices[,]" which Plaintiffs claim shows that the prices the proposed class members paid "are *nearly perfectly correlated*" to Defendants' list prices. (*Id.* at 72 (citations omitted).) Plaintiffs state they will also rely on data produced by non-party insurer [redacted] which Dr. Rosenthal analyzed and determined that "[redacted]" (*Id.* at 72–73 (citing Rosenthal Rpt. ¶ 96, Figs. 32–36).)

Regarding superiority, Plaintiffs argue a class action is superior because (1) the proposed class members cannot afford to prosecute separate actions, and without class certification, litigating this case would be cost-prohibitive; (2) this is the only case challenging Defendants' alleged conduct; and (3) they will litigate the proposed class members' claims with common evidence. (*Id.* at 76–77 (citations omitted).)

Moreover, Plaintiffs submit the claims of their Proposed Nationwide Classes "do not require proof of deception, turning on individual circumstances[,]" but rather "the unlawful conduct at issue is two centralized pricing schemes (one for Novo and one for Sanofi) that harmed all class members in the exact same way—by increasing their payments for analog insulin (only the amount of damages vary)" and that "[p]roof of liability will focus entirely on the [D]efendants'

actions." (ECF No. 575 at 70–71 (citations omitted).[32]) Plaintiffs also assert they will establish damages through common evidence, stating Dr. Rosenthal "will use Xponent data and [D]efendants' data to calculate what the price of the at-issue insulins would have been absent the [D]efendants' unfair conduct" and will use this to "calculate aggregate damages." (*Id.* at 53 (footnotes omitted).) Plaintiffs also claim common issues predominate for their proposed multi-state classes. (*Id.* at 90–93.) Plaintiffs state they "will prove, with common damages evidence, that each member of [their proposed] multi-state classes suffered 'substantial injury[,]'" "that those substantial injuries were not reasonably avoidable[,]" and that the "injuries are not outweighed by any benefit to consumers or competition." (*Id.* at 91–93.) Plaintiffs likewise argue common issues predominate for their proposed single-state classes and that "individualized evidence will not be required to establish liability and aggregate damages." (*Id.* at 94–95.)

In opposition, Defendants argue Plaintiffs do not satisfy Rule 23(b)(3)'s requirements because Plaintiffs fail to show predominance of common questions, and even if Plaintiffs could show this action involves a single common question, "individualized issues overwhelm any conceivable common ones." (ECF No. 576 at 27–29; *see also id.* at 29–73.) Defendants further contend: (1) the unconscionability and unfairness standards of the states in Plaintiffs' proposed classes "require highly fact-intensive inquiries that routinely result in courts denying class certification for lack of predominance"; (2) Plaintiffs' Proposed Nationwide Classes fail under Rule 23(b)(3) because "the NJCFA cannot apply to all consumers who bought [Defendants']

[32] *See also* ECF No. 575 at 71 ("For example, whether Novo [Nordisk] and Sanofi knew that the class members paid based on list price will not turn on Novo[Nordisk's] and Sanofi's knowledge as to a particular individual purchaser; instead, the plaintiffs will prove—through the [D]efendants' documents—that Novo [Nordisk] and Sanofi understood that coinsurance, deductible, and cash payments for analog insulin are tied to list price. Every nationwide class member's claim will be litigated with the exact same documents, witnesses, and data.").

products nationwide"; (3) Plaintiffs' Proposed Multi-State Classes likewise fail under Rule 23(b)(3) because of "the many material differences among the sixteen states' consumer-protection laws"; (4) "Plaintiffs' abandonment of their fraud theory means they can no longer establish 'ascertainable loss' as required by New Jersey's and other states' laws"; and (5) "Plaintiffs' novel, untested damages model fails the predominance requirement under *Comcast* because it does not reliably measure any unlawful conduct or classwide injury." (*Id.* at 27–29.)

Defendants assert proof of the essential elements of Plaintiffs' cause of action requires individual treatment, regardless of whether their claim is for "unconscionability" under the laws of New Jersey, Texas, Kansas, and Utah or for "unfairness" under sixteen other states' consumer protection statutes. (*Id.* at 29 (citing cases).) Defendants submit the relevant question in this action "is not whether any consumer must *take* analog insulin, but what the consumer *paid* for analog insulin and why[,]" and that "[a]ssessing the factors that impact consumers' costs entails individualized inquiries across millions of consumers, in different states, who used different products at different times." (*Id.* at 30 (citing *In re Domestic Drywall*, 2017 WL 3700999, at *15).) For example, Defendants state some of the individualized inquiries include: (1) whether each proposed class member's alleged injury was "reasonably avoidable"; (2) whether each proposed class member could limit their out-of-pocket costs using Defendants' affordability offerings and/or other forms of financial assistance; (3) whether proposed class members could have chosen a different insurance plan (*e.g.*, one with a co-pay rather than coinsurance), which "requires different assessments at different times"; (4) whether rebates were passed to proposed class members at the point of sale; (5) whether proposed class members suffered sufficient injury under the applicable state laws; and (6) whether proposed class members can prove that Defendants' conduct and not the conduct of insurers, PBMs, pharmacies, or other non-parties caused their alleged injuries. (ECF

No. 576 at 27–37.)

The Court addresses each of Plaintiffs' proposed classes under Rule 23(b)(3) in turn.

1. Proposed Nationwide Classes and Proposed Novo Nordisk and Sanofi New Jersey Classes

Plaintiffs argue the Proposed Nationwide Classes, the Proposed Novo Nordisk New Jersey Class, and the Proposed Sanofi New Jersey Class should all be certified under Rule 23(b)(3) for claims brought under the NJCFA because Defendants' conduct in allegedly artificially inflating the list prices for their analog insulin products was "unconscionable" as that term is used in the NJCFA, common issues predominate, and a class action is superior to other methods. (ECF No. 575 at 41–50.)

Plaintiffs state New Jersey adopted the Restatement (Second) Conflict of Laws' "most-significant-relationship test in sections 146, 145, and 6 for deciding the choice of substantive law in tort cases involving more than one state." (ECF No. 575 at 43 (quoting *McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207, 219 (N.J. 2017)).) Plaintiffs assert New Jersey applies the "most significant relationship" test to determine which state's substantive law applies, and even assuming a conflict exists between the consumer fraud laws of New Jersey and other states, the NJCFA should govern nationwide as to Plaintiffs' "unconscionable" acts claim because three of the four factors relevant to the choice-of-law analysis favor applying New Jersey law. (ECF No. 575 at 42–50; *see also id.* at 44 ("'Viewed through the [Second Restatement's] section 6 prism, the state with the strongest section 145 contacts will have the most significant relationship to the parties or issues, and thus its law will be applied.' Section 145(2) states that contacts to be considered include: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicil, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered.").)

Plaintiffs claim New Jersey's substantive law—*i.e.*, the NJCFA—should apply nationwide because under the analysis of the applicable factors in the § 145 choice-of-law analysis, New Jersey is (1) the place where the conduct allegedly causing injury occurred; (2) Defendants Novo Nordisk and Sanofi are companies who have their headquarters in New Jersey; and (3) "'the place where the relationship, if any, between the parties is centered' is New Jersey" because Defendants' "allegedly unconscionable conduct occurred solely within New Jersey"; only the proposed class members' monetary losses occurred in other states. (*Id.* at 44–48[33]; *see also* ECF No. 713 at 46 (Plaintiffs' counsel stating "Section 145 [of the] Restatement (Second) [of Conflict of Laws] applies to general tort claims, our unconscionability claim here, guided by the principles of Section 6.").)

In opposition, Defendants assert Plaintiffs' Proposed Nationwide Classes and Proposed Novo Nordisk and Sanofi New Jersey Classes fail under Rule 23(b)(3) because (1) individualized questions predominate over any common questions; (2) "the NJCFA cannot apply to all consumers who bought [Defendants'] products nationwide"; and (3) "Plaintiffs' abandonment of their fraud theory[34] means they can no longer establish 'ascertainable loss' as required by New Jersey's and

[33] Plaintiffs claim the Restatement (Second) Conflict of Laws § 146 "does not apply, because this is not 'an action for a personal injury'" (ECF No. 575 at 44 (quoting Restatement (Second) of Conflict of Laws § 146 (1971))), nor does Restatement (Second) Conflict of Laws § 148 apply, "because Plaintiffs do not claim that they and the Class members 'suffered pecuniary harm on account of [their] reliance on the defendant[s'] false representations'" (*id.* (alterations in original) (quoting Restatement (Second) of Conflict of Laws § 148 (1971))).

[34] *Compare* ECF No. 411 ¶¶ 567–68, 570 ("Novo Nordisk and Sanofi engaged in deceptive business practices prohibited by the NJCFA, including artificially inflating the publicly reported list prices of their analog insulins; misrepresenting, affirmatively and/or through omission, that their list prices were reasonable approximations of the true prices of these medicines; concealing and/or misrepresenting the net prices of their analog insulins; concealing and/or misrepresenting the existence and amount of the list-to-net price spreads for their analog insulins; and engaging in other unconscionable, false, misleading or deceptive acts or practices in the conduct of trade or commerce. In violation of the NJCFA, these acts and omissions constitute 'unconscionable

other states' laws." (ECF No. 576 at 27–29, 59–62.) Defendants argue "New Jersey courts stress that unconscionability is 'fact-specific and applied on a case-by-case basis'" and courts have rejected attempts to challenge broad pricing practices under the NJCFA's unconscionability provision. (*Id.* at 38–39 (quoting *Judge v. Blackfin Yacht Corp.*, 815 A.2d 537, 541 (N.J. Super. Ct. App. Div. 2003)).) Defendants further contend the NJCFA cannot apply nationwide to

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commercial practice[s], deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission in connection with the sale' and pricing of their analog insulins. . . . By failing to disclose the net prices they offered to PBMs and by actively concealing this pricing deceit, Novo Nordisk, and Sanofi engaged in unfair and deceptive business practices in violation of the NJCFA. In the course of Novo Nordisk's and Sanofi's business, they willfully failed to disclose and actively concealed their misrepresentations regarding list prices." (citing N.J. Stat. Ann. § 56:8-2)), *with* ECF No. 575 at 44 n.174 ("Plaintiffs do not claim that they and the Class members 'suffered pecuniary harm on account of [their] reliance on the defendant[s'] false representations.'" (alterations in original) (citations omitted)); *see also* ECF No. 577 at 37–38 ("[T]he plaintiffs' 'ascertainable loss' theory here is based on the defendants' unfair and unconscionable conduct, not fraud on the market caused by misrepresentations. . . . [T]he plaintiffs do not contend that the defendants defrauded the market but instead that the defendants set unfairly inflated list prices, knowing that certain consumers—the class here—would pay those inflated prices."); ECF No. 713 at 50 (Plaintiffs' counsel asserting at oral argument: "Fraud on the market. . . . We have nothing remotely of the sort here. We haven't argued an efficient market. We haven't argued fraud on the market. Our damage theory, our ascertainable loss is derived from what they did here to set the list price which directly impacted each and every one of our plaintiffs."); ECF No. 576 at 72 ("[Dr. Rosenthal] concedes that she has not attempted to 'measure injury caused by alleged misrepresentations.' Nor has she estimated damages by measuring the value of any insulin 'promised' and 'received'; any consumer 'expectations about insulin pricing'; or the 'true' 'pro-rata share of the net prices of' insulin in the absence of any supposed misrepresentation." (quoting Rosenthal Dep. 273:17-274:25, and then quoting *In re Insulin Pricing*, 2019 WL 643709, at *15–16)); ECF No. 577 at 43–44 (Plaintiffs not disputing Defendants' argument that Dr. Rosenthal did not measure injury caused by alleged misrepresentations but rather contending this argument is irrelevant because "[Dr. Rosenthal's] analysis validly rests on unfair and unconscionable conduct" as in *D'Agostino v. Maldonado*, 216 N.J. 168 (2013)); ECF No. 713 at 43 (Defendants' counsel stating Plaintiffs "abandoned their fraud theory and it's doomed the class certification decision because . . . they're not alleging any misrepresentation and they're not alleging a loss as a result of an alleged misrepresentation." (to which Plaintiffs did not dispute or even address)); *but see* ECF No. 590 at 17 ("But the plaintiffs raise fraudulent concealment in response to the defendants' limitations defense, not as a theory of liability. . . . The plaintiffs do not seek class certification for misrepresentations. But that does not constitute waiver of responding to a statute of limitations defense.").

Plaintiffs' proposed classes under the applicable conflict-of-laws analysis, and Plaintiffs' Proposed Nationwide Classes cannot be certified because this would require applying the differing consumer protection laws of every state. (*Id.* at 41–42.) Instead, Defendants submit the applicable factors for the conflict-of-laws analysis favor applying the home state laws of each plaintiff and proposed class members over applying the NJCFA nationwide. (*Id.* at 42–46.) Defendants appear to agree that the Restatement (Second) of Conflict of Laws § 145 applies but argue the Court must also analyze the principles in § 6,[35] which Plaintiffs do not address. (*Id.* at 41–42.)

In reply, Plaintiffs reiterate the applicable factors under the choice-of-law analysis favor applying the NJCFA nationwide here, reasoning "[a]pplication of a single law provides the best (and most efficient) opportunity for consumers to recover nationwide" and would "further[] New Jersey's goal of deterring corporate misconduct in its state." (ECF No. 577 at 14–19 (citations omitted).) Plaintiffs also contend the main cases Defendants rely on with respect to the conflict-of-laws analysis predate *In re Accutane Litigation*, 194 A.3d 503 (N.J. 2018), "where the New Jersey Supreme Court held that the judicial interests of certainty, predictability and ease in applying the law are paramount in a complex case such as this." (ECF No. 577 at 16; ECF No. 713 at 31; *id.* at 29–30 (Plaintiffs' counsel asserting "*Accutane* is the guiding case by the Supreme Court in New Jersey on choice of law" and "in *Accutane*, the New Jersey Supreme Court applied New Jersey law even though every one of those plaintiffs bought the drug somewhere else, a pharmacy [] prescribed the drug somewhere else, and allegedly sustained an injury somewhere

[35] This Court has stated the Restatement (Second) of Conflict of Laws § 6 principles are: "(1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." *Bond v. Johnson & Johnson*, Civ. A. No. 21-05333, 2021 WL 6050178, at *4 (D.N.J. Dec. 21, 2021).

else").)

Plaintiffs also argue they and the putative class members suffered an ascertainable loss under the NJCFA based on a benefit-of-the-bargain theory. (ECF No. 577 at 36, 42–44.) Plaintiffs do not appear to contest Defendants' claim that they abandoned their fraud theory—indeed, Plaintiffs state they are not asserting misrepresentation or a fraud-on-the-market theory (*see supra* n.34)—but Plaintiffs contend their benefit-of-the-bargain theory does not require that they suffer an ascertainable loss as a result of deception, and instead it is sufficient if they have suffered an ascertainable loss as a result of an "unconscionable" act, which they state they have. (ECF No. 577 at 36, 42–44; ECF No. 590 at 21 ("fraud is not required to demonstrate ascertainable losses").) Specifically, Plaintiffs allege Defendants set artificially inflated list prices for their analog insulin products knowing the proposed class members would pay based on those inflated prices, and therefore Plaintiffs assert "they were '*unfairly* deprived of the benefit of the bargain' as they paid more than their pro-rata share of the net prices of the subject insulin." (ECF No. 577 at 37–38, 42 (citations omitted).) In support of their argument on this point, Plaintiffs cite to *Pollard v. AEG Live, LLC*, where the court found the plaintiffs sufficiently alleged an ascertainable loss under the NJCFA where the plaintiff alleged she overpaid for concert tickets because the defendant "wrongfully manipulated the market for tickets to the concerts by withholding an amount of tickets in excess of the amount permitted by [N.J. Stat. Ann. § 56:8-35:1 (since repealed)] and thus drove up the ticket price by reducing the supply available to the general public." (ECF No. 577 at 37–38; ECF No. 590 at 20–21; *Pollard v. AEG Live, LLC*, Civ. A. No. 14-1155, 2014 WL 4637017, at *6 (D.N.J. Sept. 16, 2014).)

In their sur-reply, Defendants reiterate that, as this Court previously stated, a "benefit-of-the-bargain theory requires that the consumer be misled into buying a product that is ultimately

worth less than the product that was promised[.]" (ECF No. 587-1 at 18–19 (citing *In re Insulin Pricing*, 2019 WL 643709, at *15–16).) Defendants state Plaintiffs "cannot cite a *single* case—from any of the twenty states for which they seek certification—where a court certified a class based on a theory of alleged unfair or unconscionable pricing or price-setting conduct." (*Id.* at 1.) Defendants also assert *Pollard* is distinguishable because the plaintiff's claims in that case "were not for 'unconscionable commercial practices'; [rather,] they concerned a separate statutory provision on ticket sales[,]" which statutory provision is not at issue here. (*Id.* at 19 (citing *Pollard*, 2014 WL 4637017, at *6).)

Regarding the choice-of-law inquiry, "[a] federal court sitting in diversity applies the choice-of-law rules of the forum state—here, New Jersey—to determine the controlling law." *Maniscalco v. Brother Int'l (USA) Corp.*, 709 F.3d 202, 206 (3d Cir. 2013) (citations omitted). "New Jersey has adopted the 'most significant relationship' test set forth in the Restatement (Second) of Conflict of Laws[,]" which is a two-part test. *Id.* First, a court must determine whether "an actual conflict exists between the laws of the potential forums." *Id.* The New Jersey Supreme Court specified this step is "done by examining the substance of the potentially applicable laws to determine whether 'there is distinction' between them." *P.V. ex rel. T.V. v. Camp Jaycee*, 962 A.2d 453, 460 (N.J. 2008) (citation omitted). If no conflict exists, "there is no choice-of-law issue to be resolved." *Id.* However, if a conflict exists, the court then proceeds to the second part of the test and "determine[s] which jurisdiction has the 'most significant relationship' to the claim." *Maniscalco*, 709 F.3d at 207 (quoting *Camp Jaycee*, 962 A.2d at 460). In other words, "the Court determines 'which state has the most meaningful connections with and interests in the transaction and the parties.'" *Spence-Parker v. Del. River & Bay Auth.*, 616 F. Supp. 2d 509, 523 (D.N.J. 2009) (quoting *NL Indus., Inc. v. Comm. Ins. Co.*, 65 F.3d 314, 319 (3d Cir. 1995)); *see also In re*

Accutane Litig., 194 A.3d at 519 ("In *Camp Jaycee*, we adopted the *Restatement*'s most-significant-relationship test set forth in sections 146, 145, and 6 as the paradigm for deciding 'which state's substantive law applies in personal injury cases involving more than one state." (citing *Camp Jaycee*, 962 A.2d at 459–65)); Restatement (Second) Conflict of Laws §§ 6, 145, 146 (2023).

Here, the Court does not reach the more detailed conflict-of-laws analysis because even assuming there is no conflict or that the factors in that analysis favor applying the NJCFA nationwide, the Court finds Plaintiffs do not satisfy Rule 23(b)(3)'s predominance requirement for either their Proposed Nationwide Classes or Proposed Novo Nordisk and Sanofi New Jersey Classes, as further explained below.[36]

The NJCFA prohibits unlawful practices, which it defines as:

> The act, use or employment by any person of any commercial practice that is unconscionable or abusive, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby[.]

N.J. Stat. Ann. § 56:8-2. The NJCFA defines "person" as including "any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trustent thereof[.]" N.J. Stat. Ann. § 56:8-1(d).

A plaintiff asserting an NJCFA claim must show proof of the following: "(1) unlawful

[36] However, the Court notes it is not aware of any federal court in this Circuit who has certified a nationwide class applying the NJCFA nationwide under the "most significant relationship" test.

conduct; (2) an ascertainable loss; and (3) a causal relationship between the defendants' unlawful conduct and the plaintiff's ascertainable loss." *Neale v. Volvo Cars of N. Am., LLC*, Civ. A. No. 10-4407, 2021 WL 3013009, at *9 (D.N.J. July 15, 2021) (quoting *Int'l Union*, 929 A.2d at 1086). Therefore, "[t]o state a claim under the NJCFA, a plaintiff must allege that the defendant engaged in an unlawful practice that caused an ascertainable loss to the plaintiff." *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (citing *Cox v. Sears Roebuck & Co.*, 647 A.2d 454, 462–65 (N.J. 1994)).

Regarding the first prong (proving unlawful conduct), the NJCFA proscribes three general categories of unlawful practices: "(1) affirmative acts, (2) knowing omissions, and (3) regulation violations." *Bianchi v. Lazy Days R.V. Ctr., Inc.*, Civ. A. No. 06-1979, 2007 WL 1959268, at *4 (D.N.J. July 5, 2007) (citations omitted). Unconscionable commercial practices are categorized as "affirmative acts" under the NJCFA, and therefore "do not require a showing of 'intent to deceive' or 'knowledge of the falsity of the representation.'" *Katz v. Live Nation, Inc.*, Civ. A. No. 09-3740, 2010 WL 2539686, at *5 (D.N.J. June 17, 2010) (quoting *Busse v. Homebank LLC*, Civ. A. No. 07–3495, 2009 WL 424278, at *9 (D.N.J. Feb.18, 2009)); *Cottrell v. Alcon Labs.*, 874 F.3d 154, 166 (3d Cir. 2017) (finding the NJCFA "prohibit[s] business practices that are unfair and unconscionable"). The NJCFA "does not define 'unconscionable commercial practice.'" *Ciser v. Nestle Waters N. Am., Inc.*, 596 F. App'x 157, 160 (3d Cir. 2015). Also, "[t]here is no precise formulation for an 'unconscionable' act [under the NJCFA] that satisfies the statutory standard for an unlawful practice." *D'Agostino v. Maldonado*, 78 A.3d 527, 537 (N.J. 2013). Rather, "[t]he New Jersey Supreme Court has instructed courts to 'pour content' into the term on a case-by-case basis." *Ciser*, 596 F. App'x at 160–61 (quoting *Kugler v. Romain*, 279 A.2d 640, 651 (N.J. 1971)). "The word 'unconscionable' must be interpreted liberally so as to effectuate the public purpose of

the [NJ]CFA." *Assocs. Home Equity Servs., Inc. v. Troup*, 778 A.2d 529, 543 (N.J. Super. Ct. App. Div. 2001) (citing *Kugler*, 279 A.2d at 651). However, "[t]hough an unconscionable commercial practice 'is an amorphous concept obviously designed to establish a broad business ethic,' the term is not without limits" and "[t]he standard of conduct that the term 'unconscionable' implies is lack of 'good faith, honesty in fact and observance of fair dealing.'" *Id*. at 161 (quoting *Cox v. Sears Roebuck & Co.*, 647 A.2d 454, 462 (N.J. 1994)). "Most importantly, the New Jersey Supreme Court has instructed that '[t]he capacity to mislead is the prime ingredient of all types of consumer fraud.'" *Id.* (quoting *Fenwick v. Kay Am. Jeep, Inc.*, 371 A.2d 13 (N.J. 1977)). Whether conduct is unfair for purposes of the NJCFA is a question for the jury. *Slack v. Suburban Propane Partners, L.P.*, Civ. A. No. 10-02548, 2010 WL 3810870, at *5 (D.N.J. Sept. 21, 2010) (alteration in original) (citing *Hassler v. Sovereign Bank,* 374 F. App'x 341, 344 (3d Cir. 2010)).

Regarding the second prong (proving an ascertainable loss), an "ascertainable loss" can be "either [an] out-of-pocket loss or a demonstration of loss in value . . . that is quantifiable or measurable." *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792–93 (N.J. 2005); *see also Hemy v. Perdue Farms, Inc.*, Civ. A. No. 11-00888, 2011 WL 6002463, at *18 (D.N.J. Nov. 30, 2011) ("To plead ascertainable loss under the NJCFA, a plaintiff must allege loss that is 'quantifiable or otherwise measurable.'" (quoting *Thiedemann*, 872 A.2d at 792)). "Put differently, a plaintiff is not required to show monetary loss, but only that he purchased something and received 'less than what was promised.'" *Marcus*, 687 F.3d at 606 (quoting *Union Ink Co., Inc. v. AT&T Corp.*, 801 A.2d 361, 379 (N.J. Super. Ct. App. Div. 2002)). "[W]hat New Jersey Courts require for [a] loss to be 'ascertainable' is for the consumer to quantify the difference in value between the promised product and the actual product received." *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 99 (D.N.J. 2011). Therefore, "[a] plaintiff arguing that he suffered an ascertainable loss

must provide 'evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss'" and "[s]uch a loss must be 'quantifiable or measurable' under New Jersey law." *DiCuio v. Brother Int'l Corp.*, 653 F. App'x 109, 112 (3d Cir. 2016) (quoting *Thiedemann*, 872 A.2d at 792–93). "When an unconscionable commercial practice has caused the plaintiff to lose money or other property, that loss can satisfy [] the 'ascertainable loss' element of the [NJCFA] claim[.]" *D'Agostino*, 78 A.3d at 542.

"[T]o have standing under the [NJCFA] a private party must plead a claim of ascertainable loss that is capable of surviving a motion for summary judgment." *Dabush v. Mercedes-Benz USA, LLC*, 874 A.2d 1110, 1116 (N.J. Super. Ct. App. Div. 2005) (quoting *Weinberg v. Sprint Corp.*, 801 A.2d 281, 283 (N.J. 2002)). "In that connection, [p]laintiffs' allegations must provide 'enough specificity as to give the defendant notice of possible damages.'" *Hemy*, 2011 WL 6002463, at *18 (citation omitted). For example, "when a merchant violates the [NJCFA] by delivering defective goods and then refusing to provide conforming goods, a customer's ascertainable loss is the replacement value of those goods." *Furst v. Einstein Moomjy, Inc.*, 860 A.2d 435, 440 (2004). *Cf. Int'l Union*, 929 A.2d at 1088 (concluding "to the extent that plaintiff seeks to prove only that the price charged for [defendant's product] was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail"); *see also Dugan v. TGI Fridays, Inc.*, 171 A.3d 620, 641–42 (N.J. 2017) ("[The plaintiffs'] proposed price-inflation theory does not establish ascertainable loss and causation in this [NJ]CFA class action case. Individual plaintiffs may be able to establish ascertainable loss and causation by showing that they would not have purchased the [products] or would have spent less money on them had they been informed of their cost. The [] plaintiffs cannot establish ascertainable loss and causation, however,

by demonstrating that [the products'] prices were higher than they would have been had [defendants] listed [their] prices . . . . A 'fair' or 'reasonable' price . . . is no substitute for proof of the actual claimants' ascertainable loss and causation. Plaintiffs' price-inflation theory does not globally establish those elements of the [NJ]CFA for the vast and varied class of [individuals] for which the [] plaintiffs seek certification.").

"The New Jersey Supreme Court has repeatedly and explicitly endorsed a benefit-of-the-bargain theory under the [NJCFA] that requires nothing more than that the consumer was *misled* into buying a product that was ultimately worth less to the consumer than the product he was promised." *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 99 (D.N.J. 2011) (emphasis added) (citations omitted). A plaintiff alleging a benefit-of-the-bargain theory under the NJCFA "states a claim if he or she alleges (1) a reasonable belief about the product *induced by a misrepresentation*; and (2) that the difference in value between the product promised and the one received can be reasonably quantified." *See id.* (emphasis added); *see also Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 300 (D.N.J. 2009) ("When pleading a benefit-of-the-bargain loss, the plaintiff must allege 'the difference between the [product] she received and the [product] as represented at purchase.'" (alterations in original) (quoting *Romano v. Galaxy Toyota*, 945 A.2d 49, 57 (N.J. Super. Ct. App. Div. 2008)). Simply "[a]lleging a 'failure to receive the benefit of the bargain' does not satisfy the 'ascertainable loss' requirement[.]" *Parker v. Howmedica Osteonics Corp.*, Civ. A. No. 07-02400, 2008 WL 141628, at *3 (D.N.J. Jan. 14, 2008) (alteration and citation omitted)). Rather, a "plaintiff must suffer a definite, certain and measurable loss, rather than one that is merely theoretical." *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009).

Regarding the third and final prong (proving a causal relationship between the defendants' unlawful conduct and the plaintiffs' ascertainable loss), the NJCFA requires that, "in order to

recover *any* damages, a plaintiff must show that she has suffered an ascertainable loss *as a result of* the defendant's unlawful commercial practice." *Cannon v. Cherry Hill Toyota, Inc.*, 161 F. Supp. 2d 362, 373 (D.N.J. 2001) (citing N.J. Stat. Ann. § 56:8-19). In other words, the NJCFA "requires a consumer to prove that [his or her] loss is attributable to the conduct that the [NJ]CFA seeks to punish by including a limitation expressed as a causal link." *Bosland*, 964 A.2d at 748; *see also Meshinsky v. Nichols Yacht Sales, Inc.*, 541 A.2d 1063, 1067 (N.J. 1988) ("[A] plaintiff must establish 'the extent of any ascertainable loss, particularly proximate to a misrepresentation or unlawful act of the defendant condemned by the [NJCFA].'" (quoting *Ramanadham v. N.J. Mfrs. Co.*, 455 A.2d 1134, 1136 (N.J. Super. Ct. App. Div. 1982))). "[U]nlike common law fraud, the NJCFA does not require proof of reliance." *Marcus*, 687 F.3d at 606 (citing *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 366 (1997)). But "the alleged unlawful practice must be a proximate cause of the plaintiff's ascertainable loss." *Marcus*, 687 F.3d at 606. Plaintiffs must show "an ascertainable loss of moneys or property, real or personal," proximately caused by the defendant's allegedly unlawful conduct. *Dabush*, 874 A.2d at 1116.

"[T]he [NJCFA] does not provide for recovery of statutory damages where a plaintiff cannot show actual harm." *Id.* (citation omitted). "While the Attorney General does not have to prove that the victim was damaged by the unlawful conduct in order to recover any damages, a private plaintiff must demonstrate 'an ascertainable loss of moneys or property, real or personal," as a result of the defendant's unlawful conduct." *Id.* (citation omitted). Simply showing a violation of the NJCFA "is insufficient to entitle a private citizen to damages under the [NJCFA]." *Dabush*, 874 A.2d at 1116. "While obstacles to calculating damages may not preclude class certification, the putative class must first demonstrate economic loss on a common basis." *Newton*, 259 F.3d at 189.

Here, with Plaintiffs' apparent abandonment of their fraud theory for liability, Plaintiffs have not sufficiently alleged a benefit-of-the-bargain theory and likewise have not shown they and the putative class members have suffered an ascertainable loss under the NJCFA. At the motion-to-dismiss stage, in considering whether Plaintiffs adequately pled an ascertainable loss under the NJCFA, the Court found Plaintiffs' Complaint failed to plead an "out-of-pocket-loss" theory because it never alleged Defendants' analog insulin products were "essentially worthless." *In re Insulin Pricing*, 2019 WL 643709, at *15 (citation omitted). However, the Court found Plaintiffs adequately pled ascertainable loss under a "benefit-of-the-bargain" theory because Plaintiffs "alleged that they were misled as to the difference between the benchmark prices and the 'true prices' of the medications" and "that Defendants intentionally and knowingly misrepresented material facts and thereby 'inflated' the price of analog insulin to the detriment of the consumers, who 'pay for analog insulin based on the medicines' *benchmark* price.'" *Id.* at *16. Based on these allegations, the Court found Plaintiffs sufficiently alleged they "were 'unfairly deprived of the benefit of the bargain' as they paid more than their pro-rata share of the net prices of the subject insulin." *Id.*[37]

[37] In its opinion for Defendants' Motion to Dismiss the First Amended Complaint ("FAC"), the Court also found, based on Third Circuit precedent, that the heightened pleading standard and specificity requirement set forth in Federal Rule of Civil Procedure 9(b) applies to Plaintiffs' NJCFA claim. *In re Insulin Pricing*, Civ. A. No. 17-00699, 2019 WL 643709, at *14 (D.N.J. Feb. 15, 2019). *See also Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 606 (D.N.J. 2016) ("The claims under the NJCFA and the ACFA are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b), which requires particularized pleading for the conduct underlying fraud claims." (citing cases)). The Rule 9(b) standard requires the pleading to "state what the misrepresentation was, what was purchased, when the conduct complained of occurred, by whom the misrepresentation was made, and how the conduct led plaintiff to sustain an ascertainable loss." *In re Insulin Pricing*, 2019 WL 643709, at *14. The Court found Plaintiffs sufficiently alleged "the necessary, specific allegations to withstand Defendants' Motion to Dismiss" because they alleged "misrepresentation in that Defendants warranted that the artificially inflated publicly reported benchmark prices of Novolog, Levemir, Apidra, Lantus, and Toujeo were the reasonable approximations of the true cost." *Id.* Additionally, the Court concluded Plaintiffs alleged that they

But at the class certification stage, Plaintiffs seemingly clarify their theory is not one based on fraud or misrepresentation but rather is based on alleged unfair and unconscionable conduct, which they submit is sufficient to show an ascertainable loss under the NJCFA because they claim they do not need to show any deception or fraud to bring this claim. (ECF No. 575 at 70 ("The claims of the nationwide classes do not require proof of deception, turning on individual circumstances."); ECF No. 577 at 42 ("Benefit-of-the-bargain damages do not require the plaintiffs to suffer an ascertainable loss as a result of deception; it suffices that plaintiffs suffered an ascertainable loss as a result of an unconscionable act.").) Essentially Plaintiffs' theory now is that Defendants' alleged conduct in setting artificially inflated list prices for their analog insulin products was an unconscionable commercial practice constituting unfair conduct under the NJCFA, which purportedly caused injuries to the putative class members by causing them to overpay for those products. Plaintiffs understandably may not want to focus on fraud or misrepresentation because courts generally seem hesitant to certify classes involving allegations of fraud, misrepresentation, or deception, as those often turn on individual circumstances. *E.g.*, *Kelley v. Microsoft Corp.*, 251 F.R.D. 544, 557 (W.D. Wash. 2008) ("Many courts have denied class certification where plaintiffs alleged a deception-based theory of consumer fraud." (citing cases)); *Webster v. LLR, Inc.*, Civ. A. No. 17-00225, 2018 WL 10230741, at *9 (W.D. Pa. Aug. 20, 2018) ("[W]hen district courts have faced the problem of nationwide classes which seek to apply state consumer protection laws, those courts have refused to certify a class." (citing cases)). But abandoning their fraud theory at the class certification stage does not allow them to adequately show an ascertainable loss for purposes of certifying a class action based on an alleged violation

"purchased the subject drugs, provide[d] allegations concerning when the conduct occurred, and assert[ed] that the conduct led Plaintiffs to suffer a loss." *Id.*

of the NJCFA.

While New Jersey courts have stated the NJCFA does not require proof of reliance, *Marcus*, 687 F.3d at 606 (citation omitted), and that unconscionable commercial practices as "affirmative acts" under the NJCFA "do not require a showing of 'intent to deceive' or 'knowledge of the falsity of the representation[,]'" *Katz*, 2010 WL 2539686, at *5 (citation omitted), New Jersey courts have also held that a plaintiff alleging a benefit-of-the-bargain theory under the NJCFA must allege "(1) a reasonable belief about the product *induced by a misrepresentation*; and (2) that the difference in value between the product promised and the one received can be reasonably quantified." *Smajlaj*, 782 F. Supp. 2d at 99. With Plaintiffs' apparent abandonment of their fraud theory with respect to Defendants' liability, they do not sufficiently allege a benefit-of-the-bargain theory under the NJCFA and therefore do not sufficiently allege an ascertainable loss under the NJCFA. Simply alleging a benefit-of-the-bargain loss or an unconscionable commercial practice is insufficient to show Plaintiffs have suffered a "a definite, certain and measurable loss, rather than one that is merely theoretical." *See Bosland*, 964 A.2d at 749; *Int'l Union*, 929 A.2d at 1088 (concluding "to the extent that plaintiff seeks to prove only that the price charged for [defendant's product] was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail"); *see also Dugan*, 171 A.3d at 641–42 ("[The plaintiffs'] proposed price-inflation theory does not establish ascertainable loss and causation in this [NJ]CFA class action case."). Plaintiffs have not sufficiently shown they failed to receive the benefit of the bargain as they have not alleged that they had "a reasonable belief about the product *induced by a misrepresentation*"—and in fact they have asserted the opposite, that their ascertainable loss theory is *not* based on misrepresentation (*see supra* n.34))—or that they were misled into buying insulin

that was worth less than was promised. Therefore, Plaintiffs have "failed to propose a cognizable theory of damages that is sufficiently supported by class-wide evidence." *See Harnish*, 833 F.3d at 313; *cf. Dugan*, 171 A.3d at 641–42 (concluding the plaintiffs' price-inflation theory did not establish ascertainable loss and causation under the NJCFA).

In *Harnish v. Widener University School of Law*, the plaintiffs' theory of damages was a price inflation theory where plaintiffs alleged that the defendant's "alleged misrepresentations inflated its tuition prices above what they should have been, and all [putative class members] suffered damages when they paid the extra, 'inflated' tuition amount." Civ. A. No. 12-00608, 2015 WL 4064647, at *6 (D.N.J. July 1, 2015). The *Harnish* court noted the plaintiffs "intend[ed] to prove damages on a classwide basis by using an expert statistical analysis to quantify the alleged tuition inflation" but found this "unacceptable" because the plaintiff's "method of proving classwide damages relies on a 'fraud on the market' theory which New Jersey courts have rejected outside the federal securities fraud context." *Id.* at *6–7. The *Harnish* court concluded the plaintiff failed to show that the damages elements of his NJCFA claims could be established by common proof, and hence, his proposed class could not be certified under Rule 23(b)(3). *Id.* at *8. The court found the plaintiff did not satisfy Rule 23's predominance requirement because "individual questions predominate over common questions regarding the loss each proposed class member sustained." *Id.* at *6–7.

The Third Circuit affirmed the *Harnish* court's decision, stating "[t]he state courts, like the District Court in this case, have emphasized that recognizing 'price inflation' as a 'cause' of 'ascertainable loss' is essentially the same as extending the fraud-on-the-market presumption to all consumer-fraud cases"; "[t]he practical effect of both [fraud-on-the-market and 'price inflation'] theories is indeed the same, and . . . the state courts have refused to recognize either [a

fraud-on-the-market or a 'price inflation'] theory outside the federal securities fraud context." *Harnish*, 833 F.3d at 312–13. The Third Circuit concluded the plaintiffs "therefore failed to propose a cognizable theory of damages that is sufficiently supported by class-wide evidence." *Id.* at 313. *See also Dugan*, 171 A.3d at 626 (stating "[NJ]CFA class action jurisprudence rejects 'price-inflation' theories . . . as incompatible with the [NJ]CFA's terms" and concluding based on this jurisprudence, plaintiffs alleging a price inflation theory "have not established predominance with respect to their [NJ]CFA claims").

Similarly, here Plaintiffs do not have a cognizable theory of damages that is sufficiently supported by class-wide evidence. *See Harnish*, 833 F.3d at 313. Plaintiffs allege a price inflation theory—that Defendants' engaged in unlawful conduct, a purportedly unconscionable pricing scheme, by artificially inflating the list prices for their analog insulin products so they could offer rebates to certain PBMs in exchange for preferred formulary placement, which allegedly caused Plaintiffs to suffer an ascertainable loss in that they overpaid for Defendants' analog insulin products and accordingly were unfairly deprived of the benefit-of-the-bargain because they paid more than their pro-rata share of the net prices of those products. However, merely "[a]lleging a 'failure to receive the benefit of the bargain' does not satisfy the 'ascertainable loss' requirement." *Parker*, 2008 WL 141628, at *3. Rather, a "plaintiff must suffer a definite, certain and measurable loss, rather than one that is merely theoretical." *Bosland*, 964 A.2d at 749.

Even assuming, *arguendo*, Plaintiffs sufficiently alleged an ascertainable loss under the NJCFA, the Court finds Plaintiffs fail to satisfy Rule 23(b)(3)'s predominance requirement because individual questions predominate over any common ones that may exist and the Court is not convinced the essential elements of the putative class members' NJCFA claims are capable of proof at trial through evidence that is common to the class rather than individual to its members.

In particular, proof of the essential elements of Plaintiffs' NJCFA claim (including whether each putative class member suffered an ascertainable loss and whether Defendants' alleged conduct caused that loss) would require multiple fact-specific individualized inquiries and evidence individual to its members, which would likely "devolve into a series of mini trials concerning causation or injury[,]" which defeats predominance. *See Neale*, 2021 WL 3013009, at *9. Determining Defendants' liability under the NJCFA would require delving into evidence individual to each putative class member and their respective factual circumstances—whether they were insured; the terms and policies of their insurance coverage, if any; whether they benefited from any of the rebates passed down through the PBMs and/or insurers; etc. *Cf. Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, Civ. A. No. 04-5898, 2010 WL 3855552, at *31 (E.D. Pa. Sept. 30, 2010) (denying class certification in an antitrust case, finding "that proof of antitrust impact and damages resulting from [the defendant's] allegedly anti-competitive conduct will require evidence individual to class members" and concluding that "plaintiffs failed to meet their burden of showing that common questions of law of fact predominated over any questions affecting individual members").

Plaintiffs are premising their alleged injury on being unfairly deprived of the benefit-of-the-bargain because they and the putative class members purportedly paid more for Defendants' analog insulin products than their pro-rata share of the net prices of those products because of Defendants' alleged unlawful pricing scheme. (ECF No. 577 at 42.) But multiple individualized inquiries will be required to determine injury, causation, and damages for Plaintiffs' alleged claims under the NJCFA, overwhelming any common issues. Like in *Dugan v. TGI Fridays*, "Plaintiffs' price-inflation theory does not globally establish those elements of the [NJ]CFA for the vast and varied class of [individuals] for which the [] plaintiffs seek certification." *See Dugan*, 171 A.3d at

641–42. Plaintiffs have not sufficiently shown economic loss, *i.e.*, the fact of damage—here, ascertainable loss and a causal relationship, "core elements of liability under the NJCFA"—on a common basis or that this can be proven with common evidence. *See Harnish*, 833 F.3d at 306 (citation and quotations omitted) ("While obstacles to calculating damages may not preclude class certification, the putative class must first demonstrate economic loss—that is, the fact of damage—on a common basis.").

In particular, causation will not be uniform across putative class members because whether each consumer paid more than their pro-rata share of the net prices for Defendants' analog insulin products and what caused this alleged overpayment will vary depending upon each putative class member's individual circumstances, *e.g.*, (1) whether the class member was insured or had the opportunity to be insured at any point during Plaintiffs' proposed class periods; (2) if the class member was insured, the terms of their insurance coverage and what was their reason(s) for choosing that insurance coverage; (3) whether the class member had options for alternative insurance coverage at any point during Plaintiffs' proposed class periods; and (4) what amount(s), if any, the class member paid for which of Defendants' analog insulin products and how the class member's pharmacy calculated the transaction price. To make these fact-specific determinations, various individualized inquiries, essentially "a series of mini trials" on liability, would be required to determine whether each putative class member in fact suffered an ascertainable loss under the NJCFA, and if so, whether Defendants' alleged conduct caused that class member's loss. Therefore, this cannot be determined with common evidence and instead will require evidence individual to each putative class member.

Individualized inquiries will also be required to determine whether and how putative class members benefited from the rebates. Some PBMs pass along rebates to insurers, and insurers who

receive those rebate savings can choose to pass along some or all (or none) of those savings to their customers. Some insurers choose to pass along rebate savings to consumers, while others do not. Some consumers may therefore benefit from those rebate savings through lower premiums and/or lower deductibles and/or by having set copays rather than coinsurance. Other consumers may benefit from those rebates through point-of-sale rebate programs aimed at helping to offset out-of-pocket spending. Still other consumers may not benefit from those rebates at all. Therefore, determining Defendants' liability under the NJCFA will not be the same among putative class members because some insured class members may have benefitted from all or some of the rebate savings from the PBMs and insurers. Whether they benefitted depends on the specific policy (or policies) of each putative class member's particular insurer at any given time during the Plaintiffs' proposed class periods, which would require individualized fact-specific inquiries and evidence. In other words, whether an insured putative class member benefits from these rebates that make up the difference between the list price and the net price, and if so by how much, will vary depending on individualized issues concerning that putative class member's insurer(s), insurance plan(s), and affiliated PBM(s), which can all change over time.

Additional individualized inquiries would be needed to determine (1) whether the price each putative class member paid for each of Defendants' analog insulin product at issue was based on list price at all relevant times within Plaintiffs' proposed class periods; (2) whether the pharmacies charged the U&C price for every one of Defendants' analog insulin product at issue, for each putative class member, every time, and if not, how else they calculated the transaction price; (3) whether each putative class member used or could have used manufacturer coupons or other forms of financial assistance in purchasing Defendants' analog insulin product; (4) whether an uninsured putative class member could have been insured and chose not to for whatever reason;

and (5) whether insured putative class members could have changed insurance plans with different coverage terms and options at any time during the proposed class periods.

Considering the breadth of Plaintiffs' twelve proposed classes and the numerous individualized inquiries that will be required to decide the factual and legal questions in this action (*e.g.*, whether Defendants' conduct was unfair or unconscionable, and if so, when their conduct supposedly became unfair and unconscionable, whether each putative class member suffered an ascertainable loss, and if so, whether Defendants' conduct proximately caused the class members' losses), the Court finds common legal and factual questions do not predominate over individualized issues. *See Sanders v. Johnson & Johnson, Inc.*, Civ. A. No. 03-02663, 2006 WL 1541033, at *5–6 (D.N.J. June 2, 2006). Therefore, the Court concludes Plaintiffs fail to satisfy Rule 23(b)(3)'s predominance requirement because of the various fact-specific, individualized inquiries that would be required for Plaintiffs to prove the essential elements of their NJCFA claim, which cannot be determined with common evidence or without "mini trials" but rather would require individualized treatment, and which overwhelm any common issues, making class certification unsuitable for Plaintiffs' proposed classes. *See Tyson*, 577 U.S. at 453 (finding "[a]n individual question is one where 'members of a proposed class will need to present evidence that varies from member to member,' while a common question is one where 'the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof" (alteration in original) (citation omitted)).

Because the Court is not convinced that the essential elements of the putative class members' NJCFA claims are "capable of proof at trial through evidence that is common to the class rather than individual to its members," the Court concludes the predominance requirement is not met, and therefore certification under Rule 23(b)(3) is inappropriate as to Plaintiffs'

Nationwide Classes and Plaintiffs' Novo Nordisk and Sanofi Classes. *See Reinig*, 912 F.3d at 127–28 (quoting *Gonzalez v. Corning*, 885 F.3d 186, 195 (3d Cir. 2018)).

Additionally, to the extent Plaintiffs argue the Court should certify the Proposed Nationwide Classes and the Proposed Novo Nordisk and Sanofi New Jersey Classes for the same reasons as the courts who granted class certification in the *Valsartan* and *James v. Global Tel*Link Corporation* cases, the Court finds those cases are distinguishable from this action. *See Valsartan*, 2023 WL 1818922; *James v. Global Tel*Link Corp.*, Civ. A. No. 13-4989, 2018 WL 3727371 (D.N.J. Aug. 6, 2018).

Valsartan was a products liability case where it was uncontested that the defendants' products were contaminated and for which products the plaintiffs were attempting to recover the full purchase price paid. Based on the parties' factual and legal arguments, the *Valsartan* court found it was "incontrovertible . . . that the contamination resulted from defendants' non-compliance of cGMPs at some level[,]" and concluded "[s]ince defendants' conduct in making contaminated VCDs and in putting these into the U.S. drug supply chain, which plaintiffs paid for, is incontrovertible, that singular fact grounds all of plaintiffs' claims." *Valsartan*, 2023 WL 1818922, at *14. Based on this incontrovertible fact, the *Valsartan* court stated the plaintiffs had "common facts upon which to base their economic loss claims and which are 'capable of proof at trial through evidence that is common to the class rather than individual to its members, and which dominate each putative class member's claims." *Id.*

In contrast, this is not a products liability case involving contaminated products; Plaintiffs here allege an unfair pricing scheme purportedly resulting in overpayment, which Plaintiffs contend is unconscionable conduct and which Plaintiffs are seeking to recover *any portion* of the purchase price allegedly overpaid, not necessarily the full price. The *Valsartan* plaintiffs asserted

defendants' products "were worthless because, had the contamination [of defendants' products] been publicly known, [they] would not have been sold, *i.e.*, were not merchantable" and therefore they sought "as their economic loss the full cost of their payments for their insured's [products] over the relevant period." *Valsartan*, 2023 WL 1818922, at *20. Here, however, Plaintiffs are not alleging any such contamination or that Defendants' insulin products were "worthless." Rather, Plaintiffs allege they and the putative class members paid more than their pro-rata share for Defendants' insulin products.

The *James* case is likewise distinguishable. *James* involved alleged overcharges for calls made by inmates at New Jersey prisons and jails at fees "many times greater" than the costs of providing the inmate calling services. *James*, 2018 WL 3727371, at *2. The *James* plaintiffs alleged a violation of the NJCFA for "charging unconscionable rates and fees" and a violation of the Takings Clause of the Fifth Amendment and sought to certify a class action based on those two alleged violations—a class consisting of all persons who were incarcerated in New Jersey and made calls using the inmate calling services during the class period (or persons who funded those calls for the inmates). *Id.* at *3–4, *10. The court noted plaintiffs' expert "assume[d] a reasonable calling rate of 5-cents-per-minute, based on his extensive experience in the telecommunications industry" and on Global Tel*Link charging "roughly 5 cents per-minute for all calls[,]" but defendants "allegedly charged between 40 cents and $1.00 per minute during the class period." *Id.* at *7–8. Therefore, the court found there was "no concrete evidence that such costs varied so substantially as to make some fees unconscionable and others not." *Id.* at *7. In other words, whether the alleged overcharge was 35 cents per minute or 95 cents per minute or anywhere in between, that did not matter because any of those would be unconscionable. *See id.* Also, *James* was not a nationwide class action case.

In *James*, the court certified a class based on claims brought under one state statute (the NJCFA) and the Takings Clause of the Fifth Amendment, and the class was limited to New Jersey inmates who made calls or individuals who funded those calls. In contrast, Plaintiffs here propose certifying two separate *nationwide* classes in addition to multiple *multi-state* and state-specific classes involving a number of different state consumer protection statutes, with numerous putative class members across multiple states, some insured and some uninsured, who made purchases of different insulin products with different prices at different places and at various different times. In *James*, the parties put forth evidence showing concrete numbers (*i.e.*, the cost of the calls was 5 cents per minute, yet defendants were charging between 40 cents and $1.00 per minute, which overcharges were allegedly unconscionable) and based on this, the court found plaintiffs' expert could calculate damages owed to the class "even if he ha[d] not yet perfected that calculation." *James v. Glob. Tel*Link Corp.*, Civ. A. No. 13-4989, 2018 WL 3727371, at *2, *8 (D.N.J. Aug. 6, 2018).

In contrast, here, Plaintiffs are not alleging that charging a specific dollar amount or percentage (*e.g.*, $50 or 30%) for Defendants' insulin products is unconscionable; rather, Plaintiffs are alleging that Defendants' conduct in setting artificially inflated list prices for their analog insulin products and paying rebates to PBMs and other middlemen at the expense of the consumers is what is unconscionable. Put another way, Plaintiffs are not alleging, for example, that anything over $50 for one of Defendants' analog insulin products is unconscionable; instead, Plaintiffs' theory is based on putative class members who paid *any portion of the purchase price* for Defendants' analog insulin products based on reference to Defendants' list price.[38]

[38] *See also* ECF No. 713 at 77 (counsel for Defendants stating at oral argument: "[Plaintiffs] are clinging to the idea that if they can establish that a list price is unconscionable on some abstract theory but then everybody that pays even the tiniest fraction of that list price, if you paid one

Therefore, Plaintiffs' motion to certify the Proposed Nationwide Classes,[39] the Proposed Novo Nordisk New Jersey Class, and the Proposed Sanofi New Jersey Class under Rule 23(b)(3) is **DENIED**.[40]

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percent of list, plaintiffs would say, well, that's unconscionable even though the actual amounts might be very small. At the same time if you're paying a lot but you're not paying a percentage of list price, plaintiffs aren't here to help. They're defining them out of a class, so you still have the same problem with some people that have suffered that are going to have a very hard time getting relief.").

[39] Additionally, as Defendants note in their opposition, the Court previously ruled Plaintiffs lack standing to pursue state law claims for Defendants' insulin products that they did not purchase in a particular state. (ECF No. 576 at 96–97 (citing *In re Insulin Pricing*, 2019 WL 643709, at *17).) Therefore, because Plaintiffs do not claim their proposed class representatives reside and/or purchased one or more of Defendants' analog insulin products in every US state, the Court denies Plaintiffs' motion to certify their Proposed Nationwide Classes on this additional basis. *See In re Insulin Pricing*, 2019 WL 643709, at *17 ("Consistent with *Neale* [*v. Volvo Cars of N. Am., LLC*, 794 F.3d 353 (3d Cir. 2015)], district courts within the Third Circuit and throughout the nation have held that named plaintiffs in a class action 'lack standing to bring claims on behalf of putative classes under the laws of states where no named plaintiff is located and where no named plaintiff purchased the product at issue.' Indeed, the Complaint includes seventeen counts in which no named plaintiff resides in such state, nor is there any allegation of injury in such state. This runs afoul of the Supreme Court's holding in *DaimlerChrysler*, as well as the rules promulgated by courts of this Circuit." (quoting *In re: Niaspan Antitrust Litig.*, Civ. A. No. 13-md-02460, 2015 WL 8150588, at *3 (E.D. Pa. Dec. 8, 2015))).

[40] Because the Court denies Plaintiffs' motion to certify their proposed classes under Rule 23(b)(3), it does not address the separate issue of whether Plaintiffs' class periods for each of their proposed classes—which extend "through the date on which the class is certified" (*see* ECF No. 574)—is appropriate. *See In re Domestic Drywall*, 2017 WL 3700999, at *10 ("[Indirect Purchaser Plaintiffs ('IPPs')] include in their definition of a class member anyone who is an 'end user' of drywall 'to the present time.' This open-ended timeframe is not warranted here, and further complicates ascertainability. This is not a case of an alleged 'continuing violation' which may allow damages to be awarded for a time period after the complaint was filed. Indeed, very few cases have facts which qualify for damages 'up to the present time.' . . . It was the responsibility of counsel for IPP to limit the class in an ascertainable way, and by including the open-ended timeframe in the definition, IPPs have provided an additional reason to find that the class is not ascertainable. The Court concludes that IPPs have not met their burden to show that their proposed class is ascertainable."). The Court also notes Plaintiffs have not analyzed any potential effects any or all of the following may have on their putative classes as currently proposed: (1) President Biden's Inflation Reduction Act; (2) Novo Nordisk's MyInsulinRx program for its analog insulin products, which became effective on September 13, 2023; and (3) Sanofi's price changes and cap for certain of its analog insulin products, which became effective on January 1, 2024.

2. Proposed Novo Nordisk and Sanofi Multi-State Classes

Plaintiffs argue both the Proposed Novo Nordisk Multi-State Class and the Proposed Sanofi Multi-State Class should be certified under Rule 23(b)(3) for claims brought under the consumer protection statutes of sixteen states (*see supra* n.17) because: (1) all sixteen states prohibit unfair or unconscionable practices and variations in these states' laws do not defeat commonality or predominance; (2) common issues predominate because all sixteen states apply the same three-part FTC test for determining whether an act or practice is "unfair"; and (3) they will prove impact and damages using class-wide, common evidence. (ECF No. 575 at 80–86, 88–98.) Plaintiffs argue the three-part FTC test for determining whether an act or practice is unfair requires showing that the challenged conduct: (1) caused a substantial injury, (2) that is not reasonably avoidable by consumers, and (3) is not outweighed by the benefits to consumers or competition. (*Id.* at 7, 80 (citation omitted).) Plaintiffs contend certifying their Proposed Multi-State Classes under Rule 23(b)(3) is appropriate because they will use common evidence to establish Defendants' conduct in setting the list prices for their analog insulin products was "unfair" under this three-part test, which Plaintiffs allege caused all putative class members to suffer monetary losses. (*Id.* at 88–97.) Plaintiffs maintain this showing will not require any individualized evidence because they can calculate the alleged overcharges using common evidence and "[i]ndividual reliance is not required for claims of unconscionable and unfair acts under the laws of the [] states at issue." (*Id.* at 95–98.)

In opposition, Defendants contend certification of Plaintiffs' Proposed Novo Nordisk and Sanofi Multi-State Classes is not appropriate because variations among the unfairness and unconscionability standards of the sixteen states' consumer protection statutes require highly individualized and fact-intensive inquiries that overwhelm any common issues and defeat

predominance.[41] (ECF No. 576 at 29–37, 48–58.) First, Defendants argue even assuming putative class members were injured, the Court would have to engage in individualized inquiries to determine whether the injury was "reasonably avoidable," which "requires analyzing each person's decision-making and options for avoiding the cost she paid" for Defendants' analog insulin product at any given time during Plaintiffs' proposed class periods—*e.g.*, whether the consumers used, or could have used one of Defendants' affordability offerings or manufacturer coupons, or whether the consumers otherwise limited, or could have limited, their out-of-pocket costs by using other forms of assistance programs offered by *other* entities, such as insurers, pharmacies, and state government agencies." (*Id.* at 31–32 (citations omitted).) In support, Defendants cite evidence showing some named Plaintiffs used Defendants' affordability offerings and others chose not to. (*Id.* at 31 (citations omitted).) Additionally, Defendants argue each putative class member has a distinctive set of insurance options, which "are not set in stone; they can change any time a consumer (or family member) changes jobs, insurance plans, or insurers[,]" and "[t]hus, a consumer's ability to avoid higher costs requires different assessments at different times." (*Id.* at 32 (citing Baker Rpt. ¶ 102).) Defendants assert since some putative class members "'could—and did—purchase' alternative products, depending on their particular circumstances," this undermines their claim that all class members "had no meaningful opportunity to avoid paying the higher retail price, and thus, whether or not a class member could have avoided the defendants'

[41] Defendants also note: (1) certain states (including Louisiana, North Carolina, Iowa, and Maryland) "have developed their own jurisprudence on what makes conduct unfair"; (2) other states (including Massachusetts) "impose more specific requirements on what qualifies as 'unfair' conduct"; and (3) the law is not settled in all sixteen states—"Plaintiffs recognize that *no court* has decided what standard applies in Colorado and Indiana, which lack codified definitions of unfairness. Likewise, no North Dakota court has applied that state's unfairness provision since its adoption." (ECF No. 576 at 52–53 (citing ECF No. 575 at 85–86 & n.329).)

conduct is an individualized question of fact." (ECF No. 576 at 33–34 (quoting *Siegel v. Shell Oil Co.*, 612 F.3d 932, 936 (7th Cir. 2010)).).

Second, Defendants also submit Plaintiffs cannot show through common proof that each putative class member suffered a substantial injury, stating the individual amount consumers paid for Defendants' analog insulin products—their alleged injury—is person-specific. (*Id.* at 34.) Additionally, Defendants contend "rebates may have lowered a consumer's costs in ways not reflected in the transaction price" because "the insulin may have been on a more favorable formulary tier (meaning the consumer paid a lower price) because rebates were paid"; (2) "the insurer may have used the rebate to lower premiums or deductibles" for the consumer; or (3) "the insurer may have passed along the rebate to the consumer at the point of sale." (*Id.* (citing Baker Rpt. ¶¶ 57–60, 224; Anthem Cert. at 69).) Defendants state these individualized issues cannot be proven using common evidence. (*Id.* (citation omitted).)

Third, Defendants assert Plaintiffs also cannot establish causation on a class-wide basis by simply alleging they suffered a loss because of Defendants' conduct. (*Id.* at 34.) Rather, Defendants argue Plaintiffs "must prove that *Defendants' conduct*—not the conduct of PBMs, insurers, pharmacies, or any other third party—caused each putative class member's allegedly 'excessive' costs" and this "requires a case-by-case inquiry." (*Id.* at 34–35 (citing ECF No. 575 at 47).)

Fourth, Defendants contend that analyzing whether Defendants' conduct was "outweighed by the benefits to consumers or competition" is likewise overrun by individual questions that Plaintiffs do not explain how they would address with common proof. (ECF No. 576 at 36.) Defendants submit Plaintiffs do not have any class-wide means to assess the benefits of rebates and their expert Dr. Rosenthal conceded 'consumers differentially benefit from rebates or the lack

of them.'" (*Id.* at 36–37 (citing Rosenthal Dep. at 223:11–223:16).) Defendants also state that, because they "offered different rebates for different products, different PBMs, and different formularies, the benefits to consumers from this rebate competition will necessarily vary." (*Id.* at 36 (citing Baker Rpt. ¶¶ 234–35).) In contrast to the AWP wholesale price litigation involving misrepresentation-based claims that manufacturers reported fictitious and artificial AWPs, Plaintiffs seem to no longer be alleging fraud or misrepresentation (*see supra* n.34) and "do not dispute that Defendants' list prices are what they claim to be: the prices Defendants charge wholesalers, exclusive of rebates and discounts, as defined by federal law." (*Id.* (citations omitted).)

Fifth, and finally, Defendants argue the sixteen states in Plaintiffs' Proposed Novo Nordisk and Sanofi Multi-State Classes do not apply the "exact same" unfairness standard. Even assuming they did, Plaintiffs do not address the variations in the other elements (*e.g.*, scienter, causation, and statutes of limitations) of the consumer protection statutes of those states. (ECF No. 576 at 53–54.)

In reply, Plaintiffs (1) maintain common issues predominate as to whether Plaintiffs and the putative class members could reasonably avoid the harm because "where the basis for all retail prices (WAC) is the same everywhere, the consumer couldn't have avoided it as a matter of fact"; (2) contend Defendants' arguments "present common issues on the merits under an objective, reasonable person standard" because "[a] jury may decide using common proof whether it's reasonable to expect the average consumer to avoid an [alleged] overcharge by altering their physician's prescribed treatment, buying different insurance, or scouring the market for discounts only available to the select few"; (3) reiterate the three-part "substantial injury" test for unfairness applies under the laws of the sixteen states at issue; (4) state Defendants misread the case law in asserting "many states have developed their own jurisprudence on what makes conduct unfair";

(5) assert the Defendants err in asserting the Court cannot decide whether the three-part FTC test applies in Colorado, Indiana, and North Dakota, arguing that, "[w]hile no higher court in these states has explicitly outlined a test for unfair conduct, that fact does not bar certification because: ([a]) it's a common issue of law as to what test should apply; and ([b]) there are reasons to suggest each state would apply the three-part FTC test"; and (6) argue the other state law elements and state-specific issues Defendants identified do not preclude certification under Rule 23(3)(b). (ECF No. 577 at 3–11, 21–32 (citations omitted).)

In their sur-reply, Defendants contend, among other things, Plaintiffs' reply introduces a "new argument that all sixteen state laws in the putative multi-state classes turn on a singular assessment of what is 'reasonably avoidable' under an 'objective reasonable person standard'" but submit this is not the test and Plaintiffs do not cite any cases from any of the sixteen states supporting that proposition. (ECF No. 587-1 at 8 (citations omitted).)

In their response to Defendants' sur-reply, Plaintiffs assert class-wide evidence shows Defendants "proffered means of avoiding overpayment were unreasonable for all class members" and maintain they can prove substantial injury and causation with class-wide evidence and that this evidence will show the substantial injuries suffered are not outweighed by any countervailing benefits. (ECF No. 590 at 4–19.) Plaintiffs also assert Defendants' purported benefits of rebates are "speculative" and "indirect" and constitute payments by collateral sources. (*Id.* at 8–13.) Further, Plaintiffs claim even assuming these rebates are relevant, "whether their collateral benefits to class members factually mitigate the grossly inflated prices that class members pay . . . is an affirmative defense." (*Id.* at 9.)

For many of the same reasons the Court denies certification of Plaintiffs' Proposed Nationwide Classes and Proposed New Jersey Classes, the Court likewise concludes certification

of Plaintiffs' Proposed Multi-State Classes is inappropriate because individual questions predominate over any common ones that may exist and the Court is not convinced the essential elements of the putative class members' claims brought under the consumer protection laws of sixteen states are capable of proof at trial through evidence that is common to the class rather than individual to its members, as discussed more fully below.

The FTC Act defines the term "unfair or deceptive acts or practices" as including such acts "that (i) cause or are likely to cause reasonably foreseeable injury within the United States; or (ii) involve material conduct occurring within the United States." 15 U.S.C. § 45(a)(4)(A). However, the FTC Act also states the FTC "shall have no authority . . . to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." *Id.* § 45(n). In other words, "the FTC Act defines 'unfair acts or practices' as those that 'cause[ ] or [are] likely to cause substantial injury to consumers which [are] not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.'" *F.T.C. v. Wyndham Worldwide Corp.*, 10 F. Supp. 3d 602, 613 (D.N.J. 2014), *aff'd*, 799 F.3d 236 (3d Cir. 2015) (quoting 15 U.S.C. § 45(n)).

Here, Plaintiffs maintain they can prove Defendants are liable for alleged "unfair" acts under the sixteen states' consumer fraud laws by using common evidence to show that each putative class members suffered (1) a substantial injury, (2) that was not reasonably avoidable, and (3) was not outweighed by benefits to consumers or competition. However, setting aside potential issues with the differences in the sixteen different states' consumer fraud laws themselves, and assuming for purposes of this Opinion that each of these sixteen states would apply the FTC's

three-part test, the Court finds that, as with Plaintiffs' NJCFA claims, determining Defendants' liability under this test would similarly require multiple fact-specific, individualized inquiries and evidence individual to each putative class member. The Court is not convinced that common evidence can be used to prove whether each putative class member suffered a substantial injury that was not reasonably avoidable and that was not outweighed by countervailing benefits, as well as whether Defendants' alleged conduct caused or was likely to cause this alleged substantial injury.

For example, individualized inquiries would be required to determine (1) whether each putative class member benefitted from any rebates that may have been passed down from PBMs and/or insurers, and (2) whether putative class members used (or chose not to use for whatever reason) prescription assistance plans, manufacturer coupons, pharmacy coupons, and/or other form(s) of financial assistance, both of which are relevant to whether each putative class member suffered a substantial injury that was not reasonably avoidable. *See, e.g.*, *Siegel*, 612 F.3d at 936 ("[W]hether or not a class member could have avoided the defendants' conduct is an individualized question of fact."); *Porsche Cars N. Am., Inc. v. Diamond*, 140 So.3d 1090, 1099 (Fla. Dist. Ct. App. 2014) (explaining "[c]onsumers may act to avoid injury before it occurs if they have reason to anticipate the impending harm and the means to avoid it, or they may seek to mitigate the damage afterward if they are aware of potential avenues toward that end" (quoting *In re Orkin Exterminating Co.*, 108 F.T.C. 263 (1986), *aff'd*, 849 F.2d 1354 (11th Cir. 1988))). When Defendants issue rebates to PBMs for formulary placement for their analog insulin products, the PBMs independently decide whether to pass along those rebate savings along to the insurers. In turn, the insurers then likewise independently decide whether to pass along all or a portion of those rebate savings to their insured consumers, *e.g.*, in the form of lower plan premiums or reduced

cost-sharing obligations for prescription drugs. Some putative class members may have benefitted from these downstream rebate savings making up the so-called spread between the list price and the net price that Plaintiffs assert constitutes evidence of an unfair and unconscionable pricing scheme. Some insurers pass along these rebate savings and others do not.

Further, the cost an insured consumer pays for an analog insulin product will vary depending on whether his or her PBM placed the product in a more favorable formulary tier because of the rebates issued by Defendants. Not all insured consumers within each of Plaintiffs' proposed classes have the same insurance plan (*e.g.*, insurance plans and terms vary in their coverages, deductible amounts, coinsurance percentages, etc.) or the same PBM, and not all PBMs maintain the same formularies. A consumer who purchased a Defendant's analog insulin product where his or her insurer's PBM places that product in a higher formulary tier would pay less than another consumer with a different insurer with a different PBM that places the same analog insulin product in a lower formulary tier. Accordingly, if a PBM placed an analog insulin product on a more favorable formulary tier because of the rebates they received from Defendants, the consumer would pay a lower fixed percentage for the product than another consumer whose PBM placed the product on a less favorable formulary tier and accordingly would benefit from that rebate. Both consumers could fall within the definitions of Plaintiffs' proposed classes while raising fact-intensive, individualized questions concerning their alleged injury and the alleged unfairness of Defendants' conduct. For these reasons, Plaintiffs' argument that PBMs and insurers are not relevant in assessing Defendants' liability is unpersuasive. Defendants' conduct cannot be determined to be unfair or unlawful unless their conduct "causes or is likely to cause *substantial injury . . . which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits*." *See* 15 U.S.C. § 45(n) (emphasis added). And determining Defendants'

liability under this test—*i.e.*, whether Defendants' conduct caused or was likely to cause substantial injury to the putative class members that was not reasonably avoidable and was not outweighed by countervailing benefits—cannot be determined without delving into multiple individualized inquiries and evidence individual to each putative class member. These individualized inquiries overwhelm any common ones and defeat predominance.

While Plaintiffs contend all class members belong to a captive market because they can only choose between Defendants' products, which are all subject to the same scheme, and therefore, common issues predominate (ECF No. 577 at 3–6), this misconstrues the specific inquiry required by Rule 23(b)(3). "[T]he [Rule 23(b)(3)] predominance requirement is met only if the district court is convinced that 'the essential elements of the claims brought by a putative class are 'capable of proof at trial through evidence that is common to the class rather than individual to its members.'" *Reinig*, 912 F.3d at 127–28 (citation omitted). *See also id.* at 128 ("[A] district court must look first to the elements of the plaintiffs' underlying claims and then, 'through the prism' of Rule 23, undertake a 'rigorous assessment of the available evidence and the method or methods by which [the] plaintiffs propose to use the evidence to prove' those elements."); *Neale*, 2021 WL 3013009, at *9 ("To establish predominance, Plaintiffs must show that a group trial of [the] action will not devolve into a series of mini trials concerning causation or injury."); *Smith*, 2007 WL 1217980, at *9 ("The focus of the predominance inquiry is on liability, not damages."). Plaintiffs have not satisfied the predominance requirement as to their Proposed Novo Nordisk and Sanofi Multi-State Classes because whether each putative class member suffered a substantial injury caused by Defendants' conduct, which was not reasonably avoidable and not outweighed by any countervailing benefits, raises multiple fact-intensive individualized questions that overwhelm any common ones and cannot be proven with common evidence.

Even assuming putative class members suffered a substantial injury that was reasonably avoidable and not outweighed by countervailing benefits, other fact-specific individualized inquiries would be required to determining whether Defendants' conduct *caused or was likely to cause* that injury. Plaintiffs' proposed classes include insured consumers with deductible and coinsurance obligations but exclude consumers with flat co-payment plans. Consumers have options when choosing an insurance plan and might, and in some cases did, elect trade-offs such as selecting a higher premium plan for lower deductible or a plan with co-payment obligations rather than coinsurance obligations. (*See* ECF No. 576 at 32–33 (citing evidence showing some proposed class members "declined insurance coverage knowing they would bear higher out-of-pocket costs" or "consciously chose to trade lower premiums for higher out-of-pocket costs on prescription drugs").) For each putative class member, the reasons for selecting a particular insurance plan and the ability to elect or switch to a different insurance plan at any time during the proposed class periods raises fact-intensive, individualized questions relevant to determining whether they suffered a substantial injury that was reasonably avoidable. Additionally, some members may not have known they would be exposed to the inflated list prices while others may have known but accepted the trade-offs in exchange for paying lower premiums and/or lower deductibles or coinsurance, among other reasons specific to them. *See Porsche Cars*, 140 So.3d at 1099 ("When the individual knowledge and experience of the consumer is an important element of the cause of action and its defense, there can be no class-wide proof that injury was not reasonably avoidable.")

Where the class members are insured through different insurers offering various benefits plans, an individualized inquiry is necessary to determine whether the cost each class member paid was reasonably avoidable. *Adelson v. U.S. Legal Support, Inc.*, 715 F. Supp. 2d 1265, 1278 (S.D.

Fla. 2010) (finding "individualized inquiry is necessary to determine whether the [] charges were reasonably known and avoidable"). Plaintiffs' argument that a jury can decide whether it is reasonable to expect consumers to change their benefits plan further highlights this point—common questions do not predominate because individualized inquiries are required to determine whether or not a class member had the ability to reasonably avoid a substantial injury. Even assuming Plaintiffs could show this, additional individualized inquiries would also be required to determine whether Defendants' alleged conduct caused those injuries and that those injuries were not outweighed by any benefit to consumers or competition.

The availability of cost-saving options each putative class member may or may not have had further complicates class treatment. For uninsured class members, some may have been eligible for financial assistance programs while others may not have been. Some pharmacies offer coupons or discount cards to reduce the cost to consumers, while other pharmacies do not. A determination into whether each putative class member could have availed himself or herself of these and other cost-saving programs to avoid or mitigate their costs stemming from the allegedly inflated list prices would likewise require an individualized inquiry into the circumstances of each putative class member.

The financial cost a putative class member experiences based on those rebates is relevant in assessing whether that class member suffered a substantial injury that was not reasonably avoidable and whether Defendants' conduct in setting the list prices for their analog insulin products was unfair or unconscionable. Further, pharmacies also play a role in the purchase price for Defendants' analog insulin products, "[redacted] (ECF No. 576 at 35 (quoting Thompson Decl. ¶

13 (Ex. 55)).) Therefore, whether each putative class member benefitted from these rebates requires various individualized inquires, and, additionally, a consumer who benefited from Defendants' rebates raises individualized questions different from those of consumers who did not benefit from Defendants' rebates.

Plaintiffs' argument that Defendants fail to prove that passed-through rebates offset any class member's losses (*see* ECF No. 577 at 7–8) misses the point. Plaintiffs' unfair practices theory is based on Defendants allegedly artificially inflating the list prices for their analog insulin products to offer PBMs rebates at the expense of consumers. But if all or some of those rebates are passed along to consumers, this raises individualized questions concerning whether they suffered a "substantial injury," whether those injuries were reasonably avoidable, and whether those injuries were outweighed by any benefit to them. This also raises individualized questions regarding whether Defendants' conduct caused those injuries and accordingly whether Defendants' conduct constitutes an unfair act under the FTC's three-part test. Because these essential elements of the putative class members' claims under the sixteen states' consumer fraud statutes cannot be proved at trial through evidence that is common to the class rather than individual to its members, predominance is defeated with respect to Plaintiffs' Proposed Novo Nordisk and Sanofi Multi-State Classes.

The individualized issues among putative class members are further compounded by variations among the sixteen state consumer protection statutes encompassed in Plaintiffs' Proposed Multi-State Classes. The differences among the sixteen state consumer protection laws present individualized issues that overwhelm common questions of law and fact and defeat predominance. *See Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 180 (3d Cir. 2014) (noting "[i]n a multi-state class action, variations in state law may swamp any common issues and defeat

predominance" in a case where the plaintiffs, like Plaintiffs here, proposed nationwide classes for purposes of trial, not settlement, and stating settlement classes "do not pose the types of management problems that can arise in a nationwide class action trial" because courts "are not as concerned with formulating some prediction as to how [variances in state law] would play out at trial" and accordingly "need not inquire whether the varying state treatments of indirect purchaser damage claims at issue would present the type of 'insuperable obstacles' or 'intractable management problems' pertinent to certification of a litigation class" (quoting *Sullivan*, 667 F.3d at 303–04)).

Indeed, the consumer protection statutes of different states require the consideration of different factors in assessing unfair conduct. For example: (1) Louisiana's consumer protection statute extends only to "egregious actions," *see Cheramie Servs. v. Shell Deepwater Prod.*, 35 So. 3d 1053, 1060 (La. 2010) (noting "the range of prohibited practices under LUTPA is extremely narrow" and concluding "only egregious actions involving elements of fraud, misrepresentation, deception, or other unethical conduct will be sanctioned based on LUTPA")[42]; (2) Iowa's consumer protection statute considers whether an ordinary consumer would anticipate a factor that contributes to assessing an unavoidable injury, *see State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 37 (Iowa 2013) ("A course of conduct contrary to what an ordinary consumer would anticipate contributes to a finding of an unfair practice.")[43]; (3) Maryland's consumer protection statute "still

[42] To the extent Plaintiffs contend the Louisiana statute still prohibits substantially injurious conduct and therefore Louisiana's bar on egregious actions does not create disparities among the state consumer protection laws (*see* ECF No. 577 at 22), that argument is unpersuasive because a jury could find Defendants engaged in unfair conduct that substantially injured class members but was not egregious.

[43] Plaintiffs contend there is no disparity among the state consumer protection statutes because Iowa's statute applies the same three-part test for unfair acts. (ECF No. 577 at 23.) While true that Iowa's statute applies the same three-part test for unfair acts, Iowa law considers a unique

applies a stricter 'unsophisticated consumer' standard" as opposed to the reasonable consumer standard under the three-part FTC test, *see Luskin's, Inc. v. Consumer Prot. Div.*, 726 A.2d 702, 708 (Md. 1999); (4) Massachusetts's consumer protection statute recognizes adherence to industry standards or customs as one factor supporting a finding of no unfairness, *see James L. Miniter Ins. Agency, Inc. v. Ohio Indem. Co.,* 112 F.3d 1240, 1251 (1st Cir. 1997); and (5) Maine's consumer protection statute "expressly does not apply to conduct in compliance with the orders or rules of, or a statute administered by, a federal, state or local governmental agency," *see Laing v. Clair Car Connection*, Civ. A. No. 01-516, 2003 WL 1669624, at *3 (Me. Super. Ct. Jan. 29, 2003) (citation omitted). To the extent Plaintiffs argue these are merits issues irrelevant at the class certification stage, a "court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits—including disputes touching on elements of the cause of action." *In re Hydrogen Peroxide*, 552 F.3d at 307; *see also In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 529 (3d Cir. 2004) ("[T]he district court must determine whether variations in state laws present the types of insuperable obstacles which render class action litigation unmanageable.").

The consumer protection statutes of the sixteen states encompassed in Plaintiffs' Proposed Novo Nordisk and Sanofi Multi-State Classes contain are not uniform in determining whether conduct constitutes "unfair" acts or practices. Several courts considering putative multi-state classes that implicated various consumer protection statutes have similarly concluded the laws vary in significant ways. *See, e.g.*, *Vista Healthplan, Inc. v. Cephalon, Inc.*, Civ. A. No. 06-01833, 2015 WL 3623005, at *36 (E.D. Pa. June 10, 2015) ("[C]ourts in this circuit confronted with proposed multi-state consumer protection classes have concluded that the laws vary in significant

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contributing factor to a finding of an unfair practice. *See State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 530 (Iowa 2005) (considering conduct an ordinary consumer would not anticipate as a factor contributing to the unavoidable injury).

ways."); *Karnuth v. Rodale, Inc.*, Civ. A. No. 03-742, 2005 WL 1683605, at *4 (E.D. Pa. July 18, 2005) ("The consumer fraud statutes of the various states are not uniform."); *Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206, 219 (E.D. Pa. 2000) ("State consumer protection acts vary on a range of fundamental issues."). The disparities among the states in defining "unfair" acts presents individualized questions that overwhelm common issues and defeat predominance. Therefore, class certification of Plaintiffs' Proposed Novo Nordisk and Sanofi Multi-State Classes is inappropriate because variations among state consumer protection laws do not satisfy the predominance requirement. *In re EpiPen Mktg., Sales Pracs. & Antitrust Litig.,* Civ. A. No. 17-md-02785, 2020 WL 1873989, at *57 (D. Kan. Feb. 27, 2020) (holding "the variations among state consumer protection laws preclude predominance and thus make it inappropriate to certify the state consumer protection claims as a class action under Rule 23(b)(3)").

Therefore, Plaintiffs' motion to certify the Proposed Novo Nordisk Multi-State Class and the Proposed Sanofi Multi-State Class under Rule 23(b)(3) is **DENIED.**

3. Proposed Novo Nordisk and Sanofi Texas Classes, Proposed Kansas Classes, and Proposed Utah Classes

Plaintiffs argue the Proposed Novo Nordisk Texas Class, Proposed Sanofi Texas Class, the Proposed Kansas Classes, and the Proposed Utah Classes should all be certified under Rule 23(b)(3) for alleged unconscionable acts under the respective statutes of those states. (ECF No. 575 at 88, 94–95.) Plaintiffs contend common issues predominate under the laws of Kansas and Utah because the unconscionability standards under those laws "will not require any individualized evidence (other than the class members' individual damages)" and "[D]efendants' conduct is identical as to all class members." (*Id.* at 94 (citations omitted).) Plaintiffs likewise assert individualized evidence will not be required to prove liability and aggregate damages under the Texas Deceptive Trade Practices Act, which they state can be shown with common evidence. (*Id.*

at 94–95 (citations omitted).) Plaintiffs submit the cases Defendants cite to in opposition are wrong and do not defeat predominance. (ECF No. 577 at 13–14, 33–35; ECF No. 597 at 14–17.) Plaintiffs further claim class certification is appropriate for these state-specific classes because all proposed class members belong to a captive market and Defendants' pricing scheme was uniform for all proposed class members. (ECF No. 577 at 13–14.)

Defendants argue the Proposed Novo Nordisk and Sanofi Texas Classes, the Proposed Kansas Classes, and the Proposed Utah Classes should not be certified under Rule 23(b)(3) because they all fail to satisfy the predominance requirement as "proof of the essential elements of the cause of action requires individual treatment." (ECF No. 576 at 29 (citing cases).) Defendants contend Plaintiffs' unconscionability claims require highly individualized inquiries into the specific facts underlying each proposed class member's claim, including the consumer's individual circumstances, the context of their purchases of Defendants' analog insulin products, "whether the consumer was in fact injured, whether a particular Defendant's conduct caused any such injury (as opposed to third parties or other factors), whether the consumer had options to avoid that injury, and whether the consumer realized countervailing benefits from rebates." (*Id.* at 29, 38–41, 56–59.) Defendants assert Plaintiffs' unconscionability theory under the laws of Texas, Kansas, and Utah cannot be adjudicated on a class-wide basis. (*Id.* at 29, 38–41.)

Defendants further claim other state-specific issues prevent these classes from being certified. For example, Defendants state Utah does not authorize monetary relief in class actions. (*Id.* at 57 (citing *Miller v. Corinthian Colls., Inc.*, 769 F. Supp. 2d 1336, 1342 (D. Utah 2011)).) Defendants also note a Texas district court, in an insulin pricing case similar to the one here, recently dismissed a claim under the Texas Deceptive Trade Practices Act ("TDTPA") because it found the plaintiffs' allegations "'masquerade[d]' as 'consumer protection' claims despite

mirroring 'prohibited antitrust' claims under federal law" in an apparent attempt to avoid the indirect purchaser bar. *Harris Cnty. v. Eli Lilly & Co.*, Civ. A. No. 19-4994, 2022 WL 479943, at *13 (S.D. Tex. Feb. 16, 2022).

The TDTPA prohibits "[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce" and provides "[a] consumer may maintain an action where any of the following constitute a producing cause of economic damages or damages for mental anguish . . . (3) any unconscionable action or course of action by any person[.]" Tex. Bus. & Com. Code Ann. § 17.46(a) (2019); *id.* § 17.50 (2005). The TDTPA defines an "[u]nconscionable action or course of action" as "an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." *Id.* § 17.45(5). "The term 'gross' should be given its ordinary meaning, and therefore, the resulting unfairness must be 'glaringly noticeable, flagrant, complete and unmitigated.'" *Lon Smith & Assocs. v. Key*, 527 S.W.3d 604, 623 (Tex. App. 2017) (quoting *Dwight's Disc. Vacuum Cleaner City, Inc. v. Scott Fetzer Co.*, 860 F.2d 646, 650 (5th Cir. 1988)). "For an action to be unconscionable under the [T]DTPA definition as a matter of law in a class-action lawsuit, the action would have to be detrimental to every class member no matter the circumstances presented." *Peter G. Milne, P.C. v. Ryan*, 477 S.W.3d 888, 914 (Tex. App. 2015). Unconscionability "requires proof of each consumer's knowledge, ability, experience, or capacity." *Lon Smith & Assocs.*, 527 S.W.3d at 624.

The Kansas Consumer Protection Act ("KCPA") proscribes "supplier[s]" from engaging "in any unconscionable act or practice in connection with a consumer transaction." Kan. Stat. Ann. § 50-627(a) (1998). The KCPA provides the question of whether an act or practice is unconscionable is a question for the court. *Id.* § 50-627(b). While the KCPA does not define

unconscionability, it lists examples of certain circumstances a court should consider in determining whether an act or practice is unconscionable.[44] *State ex rel. Stovall v. DVM Enters., Inc.*, 62 P.3d 653, 657 (Kan. 2003). The Kansas Supreme Court also identified ten relevant factors courts could consider in determining whether conduct is unconscionable.[45] *Tomlinson v. Ocwen Loan*

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[44] In determining whether an act or practice is unconscionable, courts shall consider circumstances including but not limited to the following:

> (1) The supplier took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factor; (2) when the consumer transaction was entered into, the price grossly exceeded the price at which similar property or services were readily obtainable in similar transactions by similar consumers; (3) the consumer was unable to receive a material benefit from the subject of the transaction; (4) when the consumer transaction was entered into, there was no reasonable probability of payment of the obligation in full by the consumer; (5) the transaction the supplier induced the consumer to enter into was excessively onesided in favor of the supplier; (6) the supplier made a misleading statement of opinion on which the consumer was likely to rely to the consumer's detriment; and (7) except as provided by K.S.A. 50-639, and amendments thereto, the supplier excluded, modified or otherwise attempted to limit either the implied warranties of merchantability and fitness for a particular purpose or any remedy provided by law for a breach of those warranties.

Kan. Stat. Ann. § 50-627(b) (1998).

[45] These ten factors include:

> (1) The use of printed form or boilerplate contracts drawn skillfully by the party in the strongest economic position, which establish industry wide standards offered on a take it or leave it basis to the party in a weaker economic position [citations omitted]; (2) a significant cost-price disparity or excessive price; (3) a denial of basic rights and remedies to a buyer of consumer goods [citation omitted]; (4) the inclusion of penalty clauses; (5) the circumstances surrounding the execution of the contract, including its commercial setting, its purpose and actual effect [citation omitted]; (6) the hiding of clauses which are disadvantageous to one party in a mass of fine print trivia or in places which are inconspicuous to the party signing the contract [citation omitted]; (7) phrasing clauses in language that is incomprehensible to a layman or that divert his attention from the problems raised by them or the rights given up through them; (8) an overall imbalance in the obligations and rights imposed by the bargain; (9) exploitation of the

Servicing, LLC, Civ. A. No. 15-1105, 2015 WL 7853957, at *4 (D. Kan. Dec. 3, 2015) (citing *DVM Enters.*, 62 P.3d at 658). "When evaluating whether conduct is unconscionable under [the KCPA], courts consider whether the sale price of the product at issue grossly exceeded the price at which similar products were readily obtainable and whether the consumer was able to receive a material benefit from the subject of the transaction." *Nieberding v. Barrette Outdoor Living, Inc.*, 302 F.R.D. 600, 609 (D. Kan. 2014). Determining unconscionability under the KCPA "ultimately depends upon the facts in a given case." *DVM Enters.*, 62 P.3d at 657.

The Utah Consumer Sales Practices Act ("UCSPA") prohibits unconscionable acts or practices "by a supplier in connection with a consumer transaction . . . whether it occurs before, during, or after the transaction. Utah Code Ann. § 13-11-5(1) (1973). Whether an act or practice is unconscionable is a question for the court, and, in determining this, "the court shall consider circumstances which the supplier knew or had reason to know." *Id.* §§ 13-11-5(2), -5(3); *see also Gallegos v. LVNV Funding LLC*, 169 F. Supp. 3d 1235, 1245 (D. Utah 2016) (noting "[t]he standard for proving unconscionability [under the UCSPA] is high"). "The UCSPA aims to 'protect consumers from suppliers who commit deceptive and unconscionable sales practices' and 'to encourage the development of fair consumer sales practices.'" *Cotte v. CVI SGP Acquisition Tr.*, Civ. A. No. 21-00299, 2022 WL 464307, at *2 (D. Utah Feb. 15, 2022) (quoting Utah Code Ann. § 13-11-2(2)-(3)). The doctrine of unconscionability under contract law is applicable in assessing unconscionability under the UCSPA. *See Wade v. Jobe*, 818 P.2d 1006, 1017 (Utah 1991); *see also In re Zetia Ezetimibe Antitrust Litig.*, Civ. A. No. 18-2836, 2019 WL 1397228, at

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> underprivileged, unsophisticated, uneducated and the illiterate [citation omitted]; and (10) inequality of bargaining or economic power.

DVM Enters., 62 P.3d at 658 (alterations in original).

*32 (E.D. Va. Feb. 6, 2019) (noting that Utah courts interpret "unconscionable" conduct under the UCSPA using contract law definitions). "Procedural unconscionability focuses on the manner in which the contract was negotiated and the circumstances of the parties, . . . and can be characterized as the 'absence of meaningful choice' and a 'gross inequality of bargaining power.'" *Wade*, 818 P.2d at 1017 (citing *Res. Mgmt. Co. v. Weston Ranch & Livestock Co.*, 706 P.2d 1028, 1041–42 (Utah 1985)). "Substantive unconscionability examines the relative fairness of the obligations assumed; it requires terms 'so one-sided as to oppress or unfairly surprise an innocent party,' . . . or 'an overall imbalance in the obligations and rights imposed by the bargain.'" *Id.* (quoting *Res. Mgmt.*, 706 P.2d at 1041; *Bekins Bar V Ranch v. Huth*, 664 P.2d 455, 462 (Utah 1983)).

For many of the same reasons Rule 23(b)(3)'s predominance requirement is not satisfied for Plaintiffs' Proposed Nationwide Classes and Proposed Novo Nordisk and Sanofi Multi-State Classes, Plaintiffs likewise do not satisfy predominance for their Proposed Novo Nordisk and Sanofi Texas Classes, Proposed Kansas Classes, and Proposed Utah Classes because individual questions predominate over any common ones that may exist and the Court is not convinced the essential elements of the putative class members' claims brought under these states' individual consumer protection laws are capable of proof at trial through evidence that is common to the class rather than individual to its members. Determining whether Defendants engaged in unconscionable acts or practices requires an individualized inquiry into the specific facts of each putative class member's particular circumstances. *See, e.g.*, *DVM Enters.*, 62 P.3d at 657 ("Generally, whether an action is unconscionable under the KCPA is a question of law subject to unlimited review. However, the determination of unconscionability ultimately depends upon the facts in a given case. Thus, to a great extent, the determination is left to the sound discretion of the trial court to be determined on the peculiar circumstances of each case."); *Ryan*, 477 S.W.3d at 913–14 (reversing

class certification of TDTPA unconscionability claim because "determining whether [defendant's] actions were unconscionable requires evaluation of each member's individual circumstances"); *see also Res. Mgmt.*, 706 P.2d at 1041 (finding for unconscionability, "a court must assess the circumstances of each particular case"); *Frederick v. S. Star Cent. Gas Pipeline, Inc.*, Civ. A. No. 10-1063, 2011 WL 3880902, at *3 (D. Kan. Sept. 2, 2011) ("There are significant distinctions among class members that render the question of unconscionability one that is individual to each purported class member rather than common to the group. . . . 'A question is not common . . . if its resolution turns on a consideration of the individual circumstances of each class member.'" (quoting *Hershey v. ExxonMobil Oil Corp.*, No. 07-1300, 2011 WL 1234883, at *5 (D. Kan. Mar. 31, 2011))); *Haskins v. First Am. Title Ins. Co.*, Civ. A. No. 10-05044, 2014 WL 294654, at *15 (D.N.J. Jan. 27, 2014) (denying motion for class certification after finding the putative class was "not readily ascertainable and that individualized fact-finding [would] overwhelm issues common to the proposed class"); *In re Copley Pharm., Inc.*, 161 F.R.D. 456, 458 (D. Wyo. 1995) (noting "individual issues of causation and damages were present and that those issues were not proper for class adjudication"); *In re Katrina Canal Breaches Consol. Litig.*, 258 F.R.D. 128, 132, 134 (E.D. La. 2009) (finding individual issues predominated over those common to the proposed class where the court found "that individual issues exist[ed] with regards to damages, affirmative defenses, and causation" and noting "[t]he weight of the Fifth Circuit's case law holds that where damages cannot be calculated using a mechanical formula, but instead require individualized assessment, predominance generally does not exist"); *Adams v. Fed. Materials Co.*, Civ. A. No. 05-90-R, 2006 WL 3772065, at *6 (W.D. Ky. Dec. 19, 2006) ("Courts have found that individual issues of damages need not defeat predominance. However, significant individual issues of causation and affirmative defenses, combined with individual issues of damages, may defeat any claims of

predominance of common issues. Where the individualized issues will destroy the utility of a class adjudication and necessitate "mini trials" to determine issues relevant to each class member, common issues do not predominate. Combined individual issues of proof regarding liability, causation, defenses, and damages may also defeat predominance. In particular, serious individual issues of causation make a case unsuitable for class adjudication." (citations omitted)).

Assessing each putative class member's claim and determining Defendants' liability under these state statutes would require delving into various individualized factual issues including but not limited to (1) the role that a particular member's insurer and affiliated PBM played in allocating rebate savings; (2) the decisions a particular member made when selecting an insurance plan(s), or choosing not to be insured, at any time during the applicable class period; (3) the list price at the time of a consumer's purchase, the corresponding net price, and the ultimate purchase price the consumer paid, minus any rebates, coupons, discounts, or other financial assistance; and (4) whether the consumer could have reasonably avoided allegedly overpaying for Defendants' analog insulin products. Setting aside the issue of individual damages (which would likewise require multiple fact-specific individualized inquiries to determine), the Court cannot conceive how Plaintiffs can prove Defendants' liability under the applicable state consumer protection statutes with common evidence and without delving into evidence individual to each putative class member's claims. Accordingly, the Court finds predominance is defeated as to Plaintiffs' Proposed Novo Nordisk and Sanofi Texas Classes, Proposed Kansas Classes, and Proposed Utah Classes, making class certification for these classes under Rule 23(b)(3) unsuitable.[46]

Therefore, Plaintiffs' motion to certify the Proposed Novo Nordisk Texas Class, the

[46] Having determined Plaintiffs fail to satisfy Rule 23(b)(3)'s predominance requirement for all of their proposed classes, the Court need not address Rule 23(b)(3)'s superiority requirement.

Proposed Sanofi Texas Class, the Proposed Kansas Classes,[47] and the Proposed Utah Classes under Rule 23(b)(3) is **DENIED**.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion to Exclude the Expert Testimony of Dr. Meredith Rosenthal (ECF No. 593) is **GRANTED IN PART and DENIED IN PART,** and Plaintiffs' Motion for Class Certification pursuant to Federal Rule of Civil Procedure 23 (ECF No. 574) is **DENIED**. An appropriate Order follows.

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE

Dated: January 24, 2024

[47] Notwithstanding the present analysis, although Plaintiffs seek certification of single-state classes under the Kansas statute, as Defendants note (ECF No. 576 at 39–40 n.8), the TAC asserts no unconscionability claim under Kansas law, and the Court cannot certify a class regarding claims not pled. (ECF No. 411 ¶¶ 724–31 (alleging "deceptive conduct" and "deceptive practices" in violation of the Kansas CPA).) *See also Anderson v. U.S. Dep't of Hous. & Urban Dev.*, 554 F.3d 525, 529 (5th Cir. 2008) ("The district court's authority to certify a class under Rule 23 does not permit it to structure a class around claims not pled."); *Simington v. Lease Fin. Grp., LLC*, 2012 WL 6681735, at *8 (S.D.N.Y. Dec. 14, 2012) ("This Court cannot certify a class to litigate a claim not pled."). Additionally, based on the parties' joint filing at ECF Nos. 508 and 508-1, the Court understands Plaintiffs are not currently asserting any claims against Sanofi under the Kansas Consumer Protection Act; therefore, the Court has no basis upon which to grant class certification as to Plaintiffs' Proposed Sanofi Kansas Class. Accordingly, Plaintiffs motion to certify the Proposed Kansas Classes is also denied for these additional reasons.