

NOT FOR PUBLICATION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 Defendants Novo Nordisk, Inc. (“Novo Nordisk”), Sanofi-Aventis U.S. LLC (“Sanofi”), and Eli Lilly and Company’s (“Eli Lilly”) (collectively, “Defendants”) Motion to Strike or Dismiss (ECF No. 744) the Fourth Amended Class Action Complaint (“Fourth Amended Complaint”) (ECF No. 732) pursuant to Federal Rules of Civil Procedure 12 and 15. Plaintiffs filed an opposition to Defendants’ Motion (ECF No. 747), and Defendants filed a reply (ECF No. 754). Having reviewed the submissions filed in connection with Defendants’ Motion, for the reasons set forth below and for good cause having been shown, Defendants’ Motion to Strike is **DENIED** and Defendants’ Motion to Dismiss is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

A. Factual Background

This action arises out of Plaintiffs’ challenge to Defendants’ allegedly unfair and unconscionable pricing scheme for their analog insulin products. (*See* ECF No. 732.) Plaintiffs are analog insulin consumers who filed the Fourth Amended Complaint on behalf of themselves and all others similarly situated, divided into three classes:

Nationwide mail-order RICO class

All individual persons in the United States and its territories who, in a mail order purchase, paid any portion of the purchase price to

acquire a prescription of Humalog, Humalog Jr. Kwikpen, Humalog Kwikpen, Humalog Kwikpen 50/50, Humalog Kwikpen 75/25, Humalog Mix 50/50, Humalog Mix 75/25, Basaglar KwikpenFiasp, Fiasp Flextouch, Levemir, Levemir Flextouch, Novolog, Novolog Flexpen, Novolog Flexpen Mix 70/30, Novolog Mix 70/30, Tresiba, Lantus, Lantus Solostar, Toujeo Solostar, or Toujeo Maxsolostar from CVS Caremark, OptumRx, and/or Express Scripts, Inc. at a price determined by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale.

Nationwide consumer fraud deception class under New Jersey law

All individual persons in the United States and its territories who paid any portion of the purchase price to acquire a prescription of Humalog, Humalog Jr. Kwikpen, Humalog Kwikpen, Humalog Kwikpen 50/50, Humalog Kwikpen 75/25, Humalog Mix 50/50, Humalog Mix 75/25, Basaglar KwikpenFiasp, Fiasp Flextouch, Levemir, Levemir Flextouch, Novolog, Novolog Flexpen, Novolog Flexpen Mix 70/30, Novolog Mix 70/30, Tresiba, Lantus, Lantus Solostar, Toujeo Solostar, or Toujeo Maxsolostar[] at a price determined by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale.

Single-state consumer fraud deception damages classes

All individual persons in Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Wisconsin, Wyoming who paid any portion of the purchase price for any prescription of Humalog, Humalog Jr. Kwikpen, Humalog Kwikpen, Humalog Kwikpen 50/50, Humalog Kwikpen 75/25, Humalog Mix 50/50, Humalog Mix 75/25, Basaglar KwikpenFiasp, Fiasp Flextouch, Levemir, Levemir Flextouch, Novolog, Novolog Flexpen, Novolog Flexpen Mix 70/30, Novolog Mix 70/30, Tresiba, Lantus, Lantus Solostar, Toujeo Solostar, or Toujeo Maxsolostar[] at a price determined by reference to a list price, AWP (Average Wholesale Price), and/or WAC (Wholesale Acquisition Price) for purposes other than resale.

(*Id.* ¶¶ 307; 27–175.) Defendants are entities that manufacture and sell prescription medications, including analog insulin products.¹ (*Id.* ¶¶ 176–78.) Defendants set the Wholesale Acquisition Cost (“WAC”), also known as the list price, for their prescription drugs, including analog insulin products. (*Id.* ¶ 199.) 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”) and drug manufacturers negotiate rebates. (ECF No. 732 ¶ 201.) WAC is related to, but not the same as, Average Wholesale Price (“AWP”).² (*See id.* ¶¶ 192, 199.)

Branded prescription drugs in the United States move through a complex distribution chain through which drug manufacturers typically sell their products to wholesalers at a negotiated price; wholesalers in turn sell the products to various providers including hospitals, clinics, and retail pharmacies, who then distribute the products to patients who are prescribed these products. (*Id.* ¶¶ 183–87, 190.) Downstream charges generally flow from the manufacturer to the wholesalers, from the wholesalers to the retailer, and from the retailer to “the consumer and her health plan.” (*Id.* ¶ 188.) For any of the mail-order pharmacies, the “downstream charges are from manufacturer to the PBM-mail order pharmacy, and PBM-mail order pharmacy to the consumers and health

¹ Defendant Eli Lilly is incorporated in Indiana with its principal place of business in Indiana. (ECF No. 732 ¶ 176.) Defendants Novo Nordisk and Sanofi are both incorporated in Delaware with their principal places of business in New Jersey. (*Id.* ¶¶ 177–78.) 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 Lantus and Toujeo. (*Id.* ¶¶ 176–78.)

² *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).

plans.” (*Id.*) However, upstream charges flow from PBMs and/or health benefit providers back to the manufacturers. (*Id.* ¶ 189.) “[U]pstream charges are price discounts that the defendant drug manufacturers kickback to PBMs and their health insurer clients in the form of rebates,” which “typically occur well after the point-of-sale transactions, in a lump sum, on a quarterly basis.” (*Id.*)

The way patients pay for prescription drugs vastly differs from the way wholesalers, PBMs, and health insurers pay for those same products. (*Id.* ¶ 192.) The prices for the products distributed in this chain differ for each participating entity. (*Id.*) 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.* ¶¶ 190–202.) Patients typically pay in one of several ways depending on the manufacturer’s list price. (*Id.* ¶ 193.) 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 “all of the [wholesaler’s] point-of-sale transaction price.” (*Id.* ¶ 194.) Third, for uninsured patients, also known as cash-paying patients regardless of payment method, they typically pay a usual and customary price. (*Id.* ¶ 195.)

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.* ¶¶ 185, 201.) Formularies have different tiers that affect the prices insured consumers pay. (*See id.*) Typically, drugs in preferred formulary positions have lower out-of-pocket patient costs, while consumers usually shoulder more of the cost for drugs in disfavored formulary positions. (*Id.* ¶ 216.) Insurance plans include different cost-sharing and coverage terms. (*See id.* ¶¶ 191, 208–14.) A deductible is the amount a consumer must spend

before the insurer begins sharing in those costs. (*Id.* ¶¶ 208, 218.) Insured consumers pay their insurer monthly premiums that are often based in part on the deductible level. (*See id.* ¶¶ 207–08.) In addition to their deductibles, insured consumers may also make co-payments or coinsurance payments for their healthcare costs. (*Id.* ¶ 216.) 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.* ¶¶ 216–18.) “Plans that cover prescription drugs right away, not requiring patients to reach deductibles first, usually require copayments or coinsurance contributions for every drug purchase.” (*Id.* ¶ 218.)

“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.* ¶ 216.) “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.* ¶ 217.) 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 or the insurer’s PBM pays the pharmacy a fixed percentage of the drug’s list price” and the patient also usually pays a portion of the purchase price out-of-pocket for that medication. (*Id.* ¶¶ 190–91.)

Drug manufacturers may offer rebates to an insurer’s PBM to gain formulary access for their prescription drugs. (*Id.* ¶¶ 14, 201.) PBMs then independently decide whether to pass along rebates to the health insurer. (*Id.* ¶¶ 9, 226.) PBMs may retain a portion of the rebate before passing the remainder of the cost on to the health insurer. (*Id.* ¶¶ 2, 10–11, 353.) Some health insurers who receive those rebate savings can then choose to pass along some or all of those savings to their

customers. (*Id.* ¶¶ 208–14, 216–21.) 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. (*See 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. (*Id.* ¶¶ 1–7, 14.) Plaintiffs contend Defendants artificially inflated the list prices for their analog insulin products to compete for preferred positions on the PBMs’ drug formularies by offering increased rebates to PBMs. (*Id.*) Plaintiffs claim they and the putative class members suffered harm because they overpaid for Defendants’ analog insulin products based on a fraudulently inflated list price. (*Id.* ¶¶ 15–16, 287.) Defendants’ “compensation structure first requires the drug manufacturers to deceptively report list price increases completely divorced from market forces, research and development costs, or the value of the products.” (*Id.* ¶ 19.) Consumers “rely on the drug manufacturers to report prices that reflect the true value of the drug in the marketplace” when they “pay for insulin at the pharmacy counter or through the mail.” (*Id.*) Plaintiffs premise this pricing scheme on Defendants’ alleged unfair 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.³ (*Id.* ¶¶ 227–33.)

³ However, Plaintiffs and Defendants both generally agree that paying rebates to PBMs in the pharmaceutical industry is legal. (*See id.* ¶ 14 (“While rebates may be common in the pharmaceutical industry, the sizes of the rebates offered in the analog insulin market are not.”); ECF No. 744 at 22–24.)

According to Plaintiffs, Defendants found a way to “game th[e] system” 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—sometime around the early-2010s, when Defendants’ list prices began trending in a different direction from the net prices they were offering to PBMs and insurers. (*Id.* ¶¶ 6–11, 227–31, 264–5, 282–87.) “Net prices” are 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. (*Id.* ¶ 6–7.) Net prices may fluctuate as they necessarily depend on a particular PBM’s negotiations with Defendants. (*See id.*)

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. (*Id.* ¶¶ 11, 353, 383.) 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.* ¶¶ 10–11, 201, 231, 269.) 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 their “efforts to conceal [their] pricing structures for 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.* ¶¶ 286, 368.)

B. Procedural History

On April 20, 2021, Plaintiffs filed their Third Amended Class Action Complaint. (ECF No. 411.) Defendants filed a Partial Motion to Dismiss the Third Amended Class Action Complaint

(ECF No. 422), which the Court granted in part and denied in part (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). Plaintiffs then filed a Motion for Class Certification on September 20, 2022. (ECF Nos. 574, 575.) Before the Court could decide the pending motion, Defendants filed a Motion to Exclude the Expert Testimony of Plaintiffs’ expert Meredith Rosenthal, Ph.D.⁴ (ECF No. 593.) On January 24, 2024, the Court granted in part and denied in part Defendants’ Motion to Exclude Expert Testimony, and the Court denied Plaintiffs’ Motion for Class Certification. The Court ordered Plaintiffs “to file a Fourth Amended Complaint with new proposed classes.” (ECF No. 722.)

⁴ Prior to resolution of these pending motions, on May 26, 2023, Plaintiffs and Defendant Eli Lilly entered into a settlement agreement resolving Plaintiffs’ claims as to Eli Lilly. (ECF No. 735.) That same day, Plaintiffs filed an unopposed motion for Preliminary Approval of the Proposed Settlement between Plaintiffs and Eli Lilly. (ECF No. 639.) Plaintiffs’ Motion (ECF No. 639) was subsequently opposed by the States of Illinois, Nebraska, and Utah via their Motion to Intervene and Objection to Preliminary Approval of Class Action Settlement (ECF No. 651). On June 22, 2023, this Court issued an Order appointing Hon. Joseph A. Dickson, U.S.M.J. (ret.) as mediator in this matter. (ECF No. 644.) Following further discussions between the parties, on July 24, 2023, Plaintiffs filed an Amended Class Action Settlement Agreement for the Court’s preliminary approval. (ECF No. 656.) The State of Arkansas filed a letter of July 25, 2023 seeking to join the pending Motion to Intervene and Objection to Preliminary Approval of Class Action Settlement filed by the States of Illinois, Nebraska, and Utah. (ECF No. 659.) The States of Montana, Kansas, Kentucky, and Hawaii and the Commonwealth of Puerto Rico likewise requested to join the Motion to Intervene and Objection to Preliminary Approval of Class Action Settlement. (ECF Nos. 666, 669, 674, 693.) A separate Motion to Intervene and Objection to Preliminary Approval of Class Action Settlement was filed by the States of Mississippi, Minnesota, and Arizona on August 15, 2023. (ECF No. 672.) Following this Court’s denial of Plaintiffs’ Motion for Class Certification (*see* ECF Nos. 721, 722), on April 15, 2024, Plaintiffs and Eli Lilly submitted a letter terminating the July 24, 2023 Amended Class Action Settlement Agreement (ECF No. 656-1) and withdrawing Plaintiffs’ Motion for Preliminary Approval (ECF No. 639).

Plaintiffs filed their Fourth Amended Complaint on March 11, 2024. (ECF No. 732.) On May 20, 2024, Defendants filed their Motion to Strike or Dismiss Plaintiffs' Fourth Amended Complaint. (ECF No. 744.) Plaintiffs filed an opposition (ECF No. 747), and Defendants filed a reply⁵ (ECF No. 754).

II. LEGAL STANDARD

A. Motion to Strike

A court may, upon motion or *sua sponte*, “strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). “The purpose of a motion to strike is to simplify the pleadings and save time and expense by excising from a plaintiff’s complaint any redundant, immaterial, impertinent, or scandalous matter which will not have any possible bearing on the outcome of the litigation.” *Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) (internal quotations omitted). However, “[b]ecause of the drastic nature of the remedy, . . . motions to strike are usually ‘viewed with disfavor’ and will generally ‘be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.’” *Id.* (citing *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F. Supp. 200, 217 (D.N.J. 1993)); *see also Newborn Bros. Co. v. Albion Eng’g Co.*, 299 F.R.D. 90, 94 (D.N.J. 2014) (reiterating “a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party” (quoting *F.T.C. v. Hope Now Modifications, LLC*, Civ. A. No. 09-1204, 2011 WL 883202, at *1 (D.N.J. Mar. 10, 2011))).

⁵ Defendants requested permission to file an overlength reply in support of its Motion to Strike or Dismiss Plaintiffs' Fourth Amended Complaint. (ECF No. 751.) Plaintiffs opposed the request. (ECF No. 752.) The Court granted Defendants' request (ECF No. 753) and is considering Defendants' overlength brief (ECF No. 754).

“A court possesses considerable discretion in disposing of a motion to strike under Rule 12(f).” *Kim v. Baik*, Civ. A. No. 06-3604, 2007 WL 674715, at *5 (D.N.J. Feb. 27, 2007) (citing *River Rd. Dev. Corp. v. Carlson Corp.-Northeast*, Civ. A. No. 89-7037, 1990 WL 69085, at *2 (E.D. Pa. May 23, 1990)). “Motions to strike are decided on the pleadings alone.” *United States ex rel. LaGamba v. Gershen*, Civ. A. No. 19-16615, 2022 WL 1291384, at *2 (D.N.J. Apr. 29, 2022) (quoting *Hanover Ins. Co. v. Ryan*, 619 F. Supp. 2d 127, 132 (E.D. Pa. 2007)).

B. Motion to Dismiss

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is “required to accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to [the non-moving party].” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). “[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). However, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of a cause of action’s elements will not do.” *Id.* (alteration in original) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is

liable for the misconduct alleged.” *Id.* at 663 (citing *Twombly*, 550 U.S. at 556). This “plausibility standard” requires the complaint to allege “more than a sheer possibility that a defendant has acted unlawfully,” but it “is not akin to a ‘probability requirement.’” *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). “Detailed factual allegations” are not required, but “more than an unadorned, the-defendant-unlawfully-harmed-me accusation” must be pled; it must include “factual enhancements” and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citations omitted). In assessing plausibility, the court may not consider any “[f]actual claims and assertions raised by a defendant.” *Doe v. Princeton Univ.*, 30 F.4th 335, 345 (3d Cir. 2022).

“Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* (alteration in original) (quoting Fed. R. Civ. P. 8(a)(2)). Indeed, after *Iqbal*, conclusory or “bare-bones” allegations will no longer survive a motion to dismiss: “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* at 678. To prevent dismissal, all civil complaints must set out “sufficient factual matter” to show that the claim is facially plausible, allowing “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 663. The Supreme Court’s ruling in *Iqbal* emphasizes that a plaintiff must show that the allegations of his or her complaints are plausible. *See id.* at 670.

While, generally, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that “a court

may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56].” *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any “document *integral to or explicitly relied upon* in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (quoting *Shaw v. Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)). However, “[w]hen the truth of facts in an ‘integral’ document are contested by the well-pleaded facts of a complaint, the facts in the complaint must prevail.” *Princeton Univ.*, 30 F.4th at 342.

III. DECISION

A. Motion to Strike

Defendants argue that Plaintiffs’ Fourth Amended Complaint “exceeds the limited scope of the leave to amend that this Court granted,” and therefore should be stricken. (ECF No. 744-1 at 9–15.) Defendants assert this Court granted Plaintiffs permission to file an amended complaint “with new proposed classes” (ECF No. 722 at 2), but that “Plaintiffs have disregarded the scope of that leave, and instead are seeking to reset the entire case—as if their RICO claims had not already been dismissed multiple times, and as if they had not discarded their fraud theory at the class-certification stage” (ECF No. 744-1 at 9).

Defendants claim it would be “overwhelmingly prejudicial” to allow Plaintiffs to “radically alter their complaint in this fashion” because Plaintiffs have not previously advanced “their RICO claims based on allegations that some subset of consumers purchased insulin from mail-order pharmacies.” (*Id.* at 11.) Defendants continue that they would be prejudiced by allowing Plaintiffs to “resuscitat[e] their fraud theory,” which Plaintiffs made clear they were abandoning at the class-certification stage. (*Id.* at 12.) Defendants additionally contend that Plaintiffs unreasonably delayed in amending their complaint at this stage. (*Id.* at 13–14.) Defendants argue Plaintiffs made

sweeping changes to their Fourth Amended Complaint an in attempt to overcome the Court's dismissal of Plaintiffs' RICO claims based on the indirect-purchaser rule nearly five years ago. (*Id.*) As Defendants see it, Plaintiffs now, for the first time, "contend . . . that some named plaintiffs qualify as direct purchasers because they purchased from mail-order pharmacies." (*Id.* at 13.) Defendants further assert Plaintiffs restructured their Fourth Amended Complaint to assert fraud-based classes, which Plaintiffs had the opportunity to do when they moved for class certification. (*Id.* at 14.) Finally, Defendants allege that Plaintiffs' amendments are futile, as the Fourth Amended Complaint could not withstand a motion to dismiss. (*Id.* at 15.)

Plaintiffs counter the "Court's [O]rder granting leave to file a Fourth Amended Complaint contains no language that limits the scope of the amendment" and they "have amended their complaint in response to and consistent with this Court's class certification opinion." (ECF No. 747 at 2–10.) According to Plaintiffs, the Fourth Amended Complaint continues to allege the same three legal theories: "(1) state law consumer deception; (2) state law unfair/unconscionable business practices; and (3) federal racketeering." (*Id.* at 7.) Plaintiffs concede their amendments amount to:

- Proposing three new classes: (1) a nationwide RICO class (for consumers who purchased directly from PBM enterprise members); (2) a nationwide consumer fraud class; and (3) single-state consumer fraud classes;
- Revising the introduction (with visuals) to better explain plaintiffs' theory of consumer deception;
- Including allegations (with visuals) to explain why the proposed RICO mail order class members are direct purchasers;
- Updating numbers, figures, and charts, where possible, to account for more recent data since the filing of the original complaint; and

- Amending allegations to address any concerns raised by the Court in its class certification opinion and support the new proposed classes.

(*Id.* at 7–8.) Plaintiffs further contend Defendants will not be prejudiced by the above revisions.

(*Id.* at 8.) Finally, Plaintiffs argue the amended complaint was not delayed and will not require additional fact discovery, and, nevertheless, the ongoing MDL will ensure litigation of these claims. (*Id.* at 8–10.)

Leave to amend a complaint “[is] addressed to the sound discretion of the district court.” *Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 272 (3d Cir. 2001). “A limited grant of leave to amend does not entitle Plaintiffs to amend the complaint outside the scope of that leave.” *T.J. McDermott Transp. Co., Inc. v. Cummins, Inc.*, Civ. A. No. 14-4209, 2017 WL 11476192, at *2 (D.N.J. Jan. 17, 2017). “Where an amendment has been made impermissibly without leave of the court, Rule 12(f) is the correct instrument with which to correct the complaint.” *Id.* “[C]ourts may strike material that exceeds a court’s limited grant of leave to amend[.]” *Gershen*, 2022 WL 1291384, at *3; *see also Tenny J. Commc’ns, Inc. v. Verizon N.J., Inc.*, Civ. A. No. 19-19183, 2022 WL 1912390, at *2 (D.N.J. June 2, 2022) (same).

Defendants move to strike the entirety of the Fourth Amended Complaint because it “exceeds the limited scope of the leave to amend that this Court granted.” (ECF No. 744-1 at 9.) While the decision to strike a pleading is left to this Court’s discretion, Rule 12(f) motions are not favored. *See Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 325 F.R.D. 90, 95 (D.N.J. 2018) (holding that motions to strike are “highly disfavored”); *see also Martin v. Hudson Farm Club, Inc.*, Civ. A. No. 18-2511, 2019 WL 3759539, at *2 (D.N.J. Aug. 9, 2019). Striking portions of a party’s pleading is a “drastic remedy” that is only appropriate “when the grounds for striking it are readily apparent from the face of the pleadings.” *Jurista v. Amerinox Processing, Inc.*, 492 B.R.

707, 740 (D.N.J. 2013). While the Court agrees that allowing Plaintiffs’ amendments in their entirety would be prejudicial to Defendants at this stage in litigation, the striking of Plaintiffs’ entire Fourth Amended Complaint—though a close call—is not necessary. *See U.S. v. Bos. Sci. Neuromodulation Corp.*, Civ. A. No. 11-1210, 2014 WL 4402118, at *4 (D.N.J. Sept. 4, 2014) (noting motions to strike pleadings are not favorite, “and if there is doubt, it shall be resolved in favor of maintaining the pleading.”). Instead of striking the Fourth Amended Complaint, the Court will grant Defendants’ Motion to Dismiss Plaintiffs’ federal RICO claims with prejudice, as discussed below.

B. Motion to Dismiss

Defendants argue, in the alternative, the Court should dismiss Plaintiffs’ Fourth Amended Complaint with prejudice. (ECF No. 744-1 at 15–16.) Defendants contend this Court has already considered and dismissed Plaintiffs’ RICO claims. (*Id.* at 15.) Defendants further assert Plaintiffs’ state-law claims should be dismissed because (1) Plaintiffs’ deception-based state-law claims are preempted by federal law, and (2) Plaintiffs’ unfairness-based state-law claims rely on either a price-inflation and/or price gouging theory that this Court invalidated, and these claims violate the dormant Commerce Clause because Plaintiffs are seeking to use state consumer protection laws to dictate nationwide list prices. (*Id.* at 15–31.) As discussed below, Defendants’ motion to dismiss is granted in part and denied in part.

1. RICO

Defendants argue Plaintiffs’ repleaded RICO claims fail because they “do not plausibly allege that they directly purchased insulin products from any Defendant.” (ECF No. 744-1 at 16.) Defendants assert Plaintiffs’ claims are both precluded under the law of the case doctrine and are barred by the indirect-purchaser rule, as previously decided. (*Id.*) The Court agrees.

a. Law of the Case

Defendants argue Plaintiffs’ RICO claim should be dismissed based on the law of the case doctrine, which prevents a party from relitigating an issue already decided by the Court in a particular case. (ECF No. 744-1 at 16–19.) Defendants claim the Court previously “dismissed Plaintiffs’ RICO claim based on its determination that they are indirect purchasers and thus lack standing to sue under RICO.” (*Id.* at 16–17.) Defendants contend “Plaintiffs attempt to resurrect [their RICO claims] on the basis that some named plaintiffs supposedly ‘have RICO standing as ‘direct purchasers’” because they allegedly purchased insulin from (non-party) ‘PBM mail-order pharmacies’ operated by (non-party) PBMs.” (*Id.* at 17 (quoting ECF No. 732 ¶¶ 325, 366–67).) Plaintiffs generally agree with Defendants’ argument, conceding “the law of this case holds that [the] direct purchaser rule applies to Plaintiffs’ RICO claims.” (ECF No. 747 at 12–13.) However, Plaintiffs insist they were entitled to revise and narrow their RICO claims to “only consumers who made *mail order* purchases directly from the alleged enterprises.” (*Id.*) The Court disagrees.

The “law of the case” doctrine holds that “a rule of law announced in a case should later be applied to the same issues in subsequent stages in the litigation.” *Saint-Jean v. Palisades Interstate Park Comm’n*, 49 F.4th 830, 836 (3d Cir. 2022) (internal quotation marks omitted). However, the law of the case doctrine does not preclude a court from revisiting its own decisions in the same case where: “(1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice.” *Pub. Int. Rsch. Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d Cir. 1997). “This rule of practice promotes the finality and efficiency of the judicial process by protecting against the agitation of settled issues.” *ACLU v. Mukasey*, 534 F.3d 181, 187 (3d Cir. 2008) (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)).

At issue is Plaintiffs' most recent iteration of their complaint. Plaintiffs filed their initial Complaint with this Court on February 2, 2017. (ECF No. 1.) After the consolidation of this action with several other related actions, Plaintiffs filed their First Amended Class Action Complaint on March 29, 2018, bringing RICO claims against all three Defendants.⁶ (ECF No. 131.) In deciding Defendants' Motion to Dismiss Plaintiffs' First Amended Class Action Complaint, this Court dismissed Plaintiffs' RICO claims without prejudice, finding Plaintiffs lacked standing under the indirect-purchaser rule. (ECF No. 252 at 25 ("Plaintiffs . . . adequately pled the various elements of a RICO claim, [but] they failed to allege that they directly purchased the analog insulin from Defendants.").)

Plaintiffs then filed their Second Amended Class Action Complaint on March 18, 2019, repleading their RICO claims against all Defendants. (ECF No. 255.) Plaintiffs did not amend their RICO allegations to claim that Plaintiffs purchased their analog insulins directly from Defendants, but rather, Plaintiffs sought an injunction to restrain Defendants from reporting benchmark prices that do not approximate their true net prices. (*Id.* ¶¶ 379–430.) The Court again dismissed Plaintiffs' RICO claims, holding that a private party may not seek equitable relief under RICO. (ECF No. 304 at 6–7.)

Plaintiffs filed their Third Amended Class Action Complaint on April 20, 2021. (ECF No. 411.) Plaintiffs again restated their RICO allegations, however, noting:

Plaintiffs assume the Court's rulings, *see* ECF Nos. 305 and 252, on the plaintiffs' claims for damages and injunctive relief under RICO will apply equally to the plaintiffs' Third Amended Complaint, as the plaintiffs have not amended their allegations to claim that the plaintiffs purchase their analog insulins directly from the Defendant

⁶ Plaintiffs filed a corrected First Amended Class Action Complaint on April 6, 2018. (ECF No. 141.)

Drug Manufacturers. The plaintiffs will only keep these claims in the complaint for appellate purposes.

(*Id.* at 126, n.43.) Because Plaintiffs made clear that they were not pursuing their federal RICO claims in the Third Amended Class Action Complaint, Defendants did not move to dismiss any federal RICO counts. (*See generally* ECF No. 422-1.) However, in Plaintiffs’ most recent iteration of their complaint, the Fourth Amended Complaint, Plaintiffs reassert their federal RICO claims. (ECF No. 732 ¶¶ 320–89.) Notably, Plaintiffs’ footnote explaining that they were not reasserting their federal RICO claims, which have been dismissed twice, has been removed from Plaintiffs’ pleading. (*See generally id.*)

First, as a general matter, Plaintiffs’ restructuring and reassertion of their RICO claims goes beyond the scope of this Court’s Order requiring Plaintiffs “file a Fourth Amended Complaint with new proposed classes.” (ECF No. 722 at 2.) Plaintiffs admit that they revised their most recent pleading to “[i]nclud[e] allegations (with visuals) to explain why the proposed RICO mail order class members are direct purchasers.” (ECF No. 747 at 7.) This alone is sufficient to dismiss Plaintiffs’ RICO claims with prejudice. *See In re Chemed Corp.*, Civ. A. No. 13-1854, 2017 WL 1712530, at *13 (D. Del. Apr. 25, 2017) (“When a court grants a party leave to amend for a specific purpose, and that party files a proposed amended complaint that exceeds the bounds of what was permitted, courts routinely dismiss the excess counts or claims.”); *see also Palmieri v. Intervet Inc.*, Civ. A. No. 19-22024, 2024 WL 3199976, at *3 (D.N.J. June 26, 2024) (“Indeed, where, like here, Plaintiffs ‘exceed[] the scope of the Court’s leave to amend[] it is true that courts have discretion to reject and dismiss an amended complaint that exceeds the allowed scope.’” (alterations in original) (quoting *O’Reilly Plumbing and Constr., Inc. v. Lionsgate Disaster Relief, LLC*, Civ. A. No. 19-24, 2024 WL 2774942, at *5 (D.V.I. May 29, 2024)); *cf. In re Revlimid & Thalomid Purchaser Antitrust Litig.*, Civ. A. No. 21-2045, 2024 WL 3387356, at *4 (D.N.J. July

3, 2024) (ordering that “Defendants may allege arguments relating to proper scope of any such amended pleading in their subsequent Motions to Dismiss, if any Defendant believes that any Amended Complaint raises theories of allegations beyond those such that Defendant contends were permitted by the Court’s grant of leave to amend”).

Moreover, and as asserted by Defendants, this Court has already dismissed these federal RICO claims—twice. (*See generally* ECF Nos. 252, 304.) Under the law of the case doctrine, “when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.” *In re Cont’l Airlines*, 279 F.3d 226, 233 (3d Cir. 2002) (quoting *Christianson*, 486 U.S. at 816). As a result, a litigant is not provided with “a second opportunity to litigate a matter that has been fully considered by a court of coordinate jurisdiction, absent unusual circumstances.” *Krys v. Aaron*, 106 F. Supp. 3d 472, 480 (D.N.J. 2015). Plaintiffs accepted the Court’s previous dismissals of their RICO claims and made an obvious choice not to move for reconsideration of the dismissal of their claims, admitting in their Third Amended Class Action Complaint they were aware the Court dismissed these claims. (ECF No. 411 at 126 n.43.) Plaintiffs neither assert that there is new evidence available, that new supervening law controls, nor that the Court’s prior decision was erroneous. *See Pub. Int. Rsch. Grp. of N.J.*, 123 F.3d at 117. As such, the law of the case governs, and Plaintiffs’ RICO claims (Counts One and Two) are **DISMISSED WITH PREJUDICE**.

b. Indirect-Purchaser Rule

Defendants argue that Plaintiffs’ federal RICO claims should also be dismissed because “binding precedent requires dismissal of Plaintiffs’ claims because they *still* are indirect purchasers and therefore lack RICO standing.” (ECF No. 744-1 at 19–21.) Plaintiffs assert they have standing to bring these claims because the “[d]iabetics who bought insulin directly from the three PBMs

named as enterprise members in the complaint (via those PBMs' mail order pharmacies) are direct purchasers. (ECF No. 747 at 13–26.) Because the Court has already dismissed these claims, the Court declines to address these arguments.

2. State-Law Claims

Defendants assert Plaintiffs' state-law claims should be dismissed. (ECF No. 744-1 at 22–31.) Defendants contend Plaintiffs' deception-based state-law claims are preempted by federal law, which controls how manufacturers publish WAC prices. (*Id.* at 22–24.) Defendants also argue Plaintiffs' unfairness-based state-law claims fail for several reasons: (1) Plaintiffs' price-inflation theory has been recognized by this Court as invalid; (2) Plaintiffs cannot use consumer protection statutes to prosecute price-gouging claims; and (3) Plaintiffs' unfairness claims violate the dormant Commerce Clause. (*Id.* at 24–31.)

a. Deception Claims

Defendants contend Plaintiffs' deception claims must be dismissed as preempted. (ECF No. 744-1 at 22–24.) Defendants argue “Plaintiffs contend that Defendants' list prices (i.e., the Wholesale Acquisition Cost, or ‘WAC’) are ‘false’ because they do not reflect the rebates that Defendants pay PBMs, and that Defendant should have reported WAC differently.” (*Id.* at 22.) According to Defendants, these claims are preempted because federal law requires pharmaceutical manufacturers to report WACs excluding any rebates or other reductions in price. (*Id.*) Plaintiffs counter that their claims have not changed since this Court sustained them in 2019.⁷ (ECF No. 747 at 27–28.) Regardless, Plaintiffs claim that Defendants mischaracterize their claims, which assert

⁷ Plaintiffs cite to similar arguments raised in Defendants' Motion to Dismiss the First Amended Class Action Complaint. (ECF No. 747 at 28 (citing to ECF No. 158-1 at 32–33).) This Court sustained Plaintiffs' claims in its February 15, 2019 Opinion granting in part and denying in part Defendants' Motion to Dismiss the First Amended Class Action Complaint.

“[D]efendants should have *set* the list price in a way that reflects the true price of the drug,” not that “[D]efendants should have ‘*reported* WAC differently.’” (*Id.* at 28.)

The Supremacy Clause of the United States Constitution provides “the Laws of the United States . . . shall be the supreme Law of the Land,” and a state law is invalid if federal law preempts state law. U.S. Const. art. VI, cl. 2. Impossibility preemption, or conflict preemption, “exists where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 463 (3d Cir. 2021) (quoting *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015)). “The question for ‘impossibility’ [preemption] is whether the private party could independently do under federal law what state law requires of it.” *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 709 (3d Cir. 2018) (alteration in original) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)). Impossibility preemption has been recognized as a “demanding defense.” *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

Pursuant to federal law under Medicare, manufacturers are required to report a single “wholesale acquisition cost” or WAC for each product they sell quarterly. 42 U.S.C. § 1395w-3a(f)(1). Federal regulations define WAC 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.*” *Id.* at (c)(6)(B) (emphasis added). Notably, federal regulations do not specify how to calculate list prices; list prices are determined by the manufacturer. *See generally* 42 U.S.C. § 1395, *et seq.*

Defendants cite to this Court’s Opinion regarding Plaintiffs’ class certification motion (ECF No. 725) to demonstrate preemption, noting that “this Court has already explained [it] ‘does not see’ how it could require Defendants to report WACs in some other manner ‘without causing

Defendants to violate federal law.” (ECF No. 744-1 at 22 (citing *In re Insulin Pricing Litig.*, Civ. A. No. 17-00699, 2024 WL 416500, at *28 (D.N.J. Feb. 5, 2024).) However, in that class certification Opinion, this Court noted that Plaintiffs clarified “they are seeking to enjoin Defendants ‘from continuing to report artificially inflated list prices that do not approximate their true net prices to [PBMs.]’” *In re Insulin Pricing Litig.*, 2024 WL 416500, at *26. Specifically, this Court noted it “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.” *Id.* at *28.

The Court is not persuaded that Plaintiffs seek to enjoin Defendants from reporting WAC in accordance with federal Medicare regulations. (See ECF No. 747 at 28 (“Plaintiffs do not argue [D]efendants should have ‘*reported* WAC differently’; they argue [D]efendants should have *set* the list price in a way that reflects the true price of the drug.”); *id.* at 28–29 (“We are not asking the [D]efendants to report their net prices rather than their pre-rebate prices; we are asking them *not to artificially inflate their AWPS in the first place.*”).) Moreover, Defendants have not identified any Medicare provision enjoining them from making additional disclosures in conjunction with quarterly reporting of the WAC. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 174–75 (1st Cir. 2009) (finding Massachusetts consumer protection statute neither conflicted with nor was preempted by Medicare Part B reimbursement rates, and therefore state was not precluded from invoking the statute to find a drug manufacturer liable for seeking reimbursements which did not reflect the discounts and rebates in the reported average wholesale prices); see also *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 724 F. Supp. 3d 1174, 1193 (D. Or. 2024) (finding it was possible to comply with both public-interest exception in Oregon law that imposed obligation on pharmaceutical manufacturers to report information about new

prescription drugs and historical information about pricing did not interfere with the objectives of the Defend Trade Secrets Act).

As such, this Court finds that Defendants have not demonstrated any such conflict or impossibility preemption. Therefore, Defendants' Motion to Dismiss Plaintiffs' deception claims is **DENIED**.

b. Unfairness Claims

Defendants contend that Plaintiffs' unfairness claims fail as a matter of law because Plaintiffs' price-inflation and price-gouging theories of unfairness are not cognizable. (ECF No. 744-1 at 24–28.) Plaintiffs respond that their unfairness theory has been upheld not only by this Court, but also by other New Jersey courts. (ECF No. 747 at 33–35.)

i. Price Inflation

Defendants assert Plaintiffs' "unfairness claims boil down to a theory of price inflation." (See ECF No. 744-1 at 24–25.) Defendants assert that "price inflation theory is not a cognizable theory of damages for consumer protection claims under New Jersey law." (*Id.* at 25 (quoting *In re Insulin Pricing Litig.*, 2024 WL 416500, at *37–38 (internal quotation marks omitted)).) Plaintiffs retort that their unfairness theory has already been upheld not only by this Court as well as by other New Jersey courts.⁸ (ECF No. 747 at 33–35.)

While Plaintiffs are correct that this Court has previously upheld Plaintiffs' consumer protection claims, the Court specifically sustained these claims under Plaintiffs' fraud theory—not under their unfairness theory. (See *generally* ECF No. 252 at 25–31 (evaluating Plaintiffs under

⁸ Plaintiffs additionally advised they "do not plan to move to certify any counts in the Fourth Amended Complaint alleging violations of state statutes prohibiting unfair and unconscionable business practices," however, Plaintiffs pleaded these violations to preserve those claims for appeal. (ECF No. 747 at 33.)

Fed. R. Civ. P. 9(b) standard).) As this Court pointed out in its Opinion denying class certification, Plaintiffs, upon the “apparent abandonment of their fraud theory for liability,” have not sufficiently alleged a benefit of the bargain theory nor shown they have suffered an ascertainable loss under the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, *et seq.* (“NJCFA”). (ECF No. 725 at 85.) This Court specifically analyzed the sufficiency of Plaintiffs’ consumer protection claims based on a theory of unfair and unconscionable conduct and found Plaintiffs claims did not “adequately show an ascertainable loss.”⁹ (*Id.* at 86–87.)

Plaintiffs contend they have a viable unconscionability theory based on the court’s holding in *Pollard v. AEG Live, LLC*, Civ. A. No. 14-1155, 2014 WL 4637017 (D.N.J. Sept. 16, 2014). (ECF No. 747 at 34–35.) In *Pollard*, plaintiff claimed she overpaid for concert tickets because the defendant ticket vendor “wrongfully manipulated the market for tickets to the concerts by withholding an amount of tickets in excess of the amount permitted” by a since-repealed New Jersey statute—N.J. Stat. Ann. § 56:8-35:1 (“Section 35.1”). 2014 WL 4637017, at *6. The court distinguished the plaintiff’s claims from other “price inflation allegations [which] implicate a ‘fraud on the market’ approach” because this plaintiff claimed defendant “wrongfully manipulated the market for tickets to the concerts by withholding an amount of tickets in excess of the amount permitted by Section 35.1 and thus drove up the ticket price by reducing the supply available to the general public.” *Id.* The court specifically distinguished this matter from other cases involving unconscionable commercial practices based on “the substance of the statutory violation.” *Id.* In

⁹ See also ECF No. 725 at 87 (“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.”).

other words, the court distinguished *Pollard* from claims, such as those of Plaintiffs, based on Section 35.1, which has since been repealed. *Id.* at *6–7.

Consistent with this Court’s Opinion regarding class certification (ECF No. 725), this Court finds that Plaintiffs have not sufficiently alleged an ascertainable loss under the NJCFA. Accordingly, Plaintiffs’ consumer protection unfairness claims are **DISMISSED WITH PREJUDICE**.

ii. Price Gouging

Defendants additionally posit Plaintiffs’ price gouging theory of liability is not cognizable by the NJCFA or any other state consumer protection law identified in the Fourth Amended Complaint. (ECF No. 744-1 at 25–28.) Defendants further contend that many states, including New Jersey, have enacted specific price gouging statutes that are limited to specific circumstances.¹⁰ (*Id.* at 27.) Plaintiffs counter Defendants repeat the same arguments they made about price gouging in their motion to dismiss the First Amended Class Action Complaint, which this Court rejected. (ECF No. 747 at 33 n.98.) Because the Court has already dismissed Plaintiffs’ unfairness claims, the Court declines to address these arguments as moot.

c. Dormant Commerce Clause

Defendants argue Plaintiffs’ consumer protection claims for both deception and unfairness fail because enforcement of same would violate the dormant Commerce Clause. (ECF No. 744-1 at 28–31.) Defendants first contend Plaintiffs’ claims would have the effect of regulating the prices for all sales of insulin across nearly every state, directly violating the dormant Commerce Clause. (*Id.* at 28–29.) Defendants further assert that even if Plaintiffs’ claims did not directly regulate out-

¹⁰ For example, the New Jersey price-gouging statute prohibit “excessive and unjustified price increases in the sale of certain merchandise during declared states of emergency,” such as “earthquakes, fires, floods or civil disturbances.” N.J. Stat. Ann. § 56:8-107.

of-state conduct, they would still run afoul of the dormant Commerce Clause “because ‘the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.’” (*Id.* at 30–31 (alteration in original) (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970))). Plaintiffs maintain this is not true because “[s]tate consumer protection statutes do not set price controls; they merely require the [D]efendants to be honest about their true prices.” (ECF No. 747 at 36–37.)

“The dormant Commerce Clause ‘prohibits the states from imposing restrictions that benefit in-state economic interests at out-of-state interests’ expense, thus reinforcing the principle of the unitary national market.’” *Am. Trucking Ass’n, Inc. v. Whitman*, 437 F.3d 313, 318 (3d Cir. 2006) (quoting *Cloverland-Green Spring Dairies, Inc. v. Pa. Milk Mktg. Bd.*, 298 F.3d 201, 210 (3d Cir. 2002) (“*Cloverland I*”). The dormant Commerce Clause “therefore prohibits a state from impeding free market forces to shield in-state businesses from out-of-state competition.” *Id.* “This behavior, i.e., building up one state’s economy to the detriment of other states’ economies, is the type of behavior that constitutes ‘discriminatory’ conduct violative of the dormant Commerce Clause.” *Defense Distributed v. Platkin*, 697 F. Supp. 3d 241, 265 (D.N.J. 2023).

Any statute that “discriminates against interstate commerce on its face or in effect” is “subject to heightened scrutiny.” *Freeman v. Corzine*, 629 F.3d 146, 158 (3d Cir. 2010) (quoting *Am. Trucking Ass’n*, 437 F.3d at 319). “‘The party challenging the statute has the burden of proving’ that the statute is discriminatory.” *Loki Brands, LLC v. Platkin*, Civ. A. No. 24-9389, 2024 WL 4457485, at *10 (D.N.J. Oct. 10, 2024) (quoting *Cloverland-Green Spring Dairies, Inc. v. Pa. Milk Mktg. Bd.*, 462 F.3d 249, 261 (3d Cir. 2006) (“*Cloverland II*”). If the challenging party meets that burden, the opposing party “must demonstrate (1) that the statute serves a legitimate local interest, and (2) that this purpose could not be served as well by available non-discriminatory

means.” *Am. Trucking Ass’n*s, 437 F.3d at 319 (citing *Cloverland I*, 298 F.3d at 210–11). If the challenging party does not meet its burden of showing that the statute is discriminatory, courts use “the balancing test set forth in *Pike*[], to determine whether the burdens on interstate commerce substantially outweigh[] the putative local benefits.” *Cloverland II*, 462 F.3d at 258. The *Pike* balancing test is crucial because “[s]tates may not impose regulations that place an undue burden on interstate commerce, even where those regulations do not discriminate between in-state and out-of-state businesses.” *Heffner v. Murphy*, 745 F.3d 56, 70–71 (3d Cir. 2014) (quoting *United States v. Lopez*, 514 U.S. 549, 579–80 (1995)).

Defendants essentially argue Plaintiffs’ consumer protection claims would create extraterritorial effects by effectively regulating the nationwide list prices Defendants may set, thereby regulating transactions that occur wholly outside the state. (ECF No. 744-1 at 29.) However, the Supreme Court has rejected the argument that the dormant Commerce Clause implies an “almost *per se*” rule forbidding the enforcement of state laws that have the functional effect of controlling commerce outside the state:

In our interconnected national marketplace, many (maybe most) state laws have the “practical effect of controlling” extraterritorial behavior. State income tax laws lead some individuals and companies to relocate to other jurisdictions. Environmental laws often prove decisive when businesses choose where to manufacture their goods. Add to the extraterritorial-effects list all manner of libel laws, securities requirements, charitable registration requirements, franchise laws, tort laws, and plenty else besides. Nor, as we have seen, is this a recent development. Since the founding, States have enacted an immense mass of [i]nspection laws, quarantine laws, [and] health laws of every description that have a considerable influence on commerce outside their borders. [An] “almost *per se*” rule against laws that have the “practical effect” of “controlling” extraterritorial commerce would cast a shadow over laws long understood to represent valid exercises of the States’ constitutionally reserved powers. It would provide neither courts nor litigants with meaningful guidance in how to resolve disputes over

them. Instead, it would invite endless litigation and inconsistent results.

Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 374–75 (2023) (first and second alterations in original) (internal quotation marks and citations omitted). “[T]he dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach absent protectionist intent or effect.” *N.J. Staffing Alliance v. Fais*, 110 F.4th 201, 207 (D.N.J. 2024). Here, Defendants do not explain how uniformly applying consumer protection statutes to all manufacturers, regardless of location, is “designed to benefit in-state economic interests by burdening out-of-state competitors.” *Nat'l Pork*, 598 U.S. at 369 (quoting *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38 (2008)). Therefore, Defendants fail to demonstrate that Plaintiffs’ consumer protection claims discriminate against out-of-state manufacturers.

Defendants further argue Plaintiffs’ claims should be struck down under the *Pike* balancing test. (ECF No. 744-1 at 30–31.) “*Pike* provides that nondiscriminatory state regulations are valid under the Commerce Clause ‘unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.’” *N.J. Staffing Alliance v. Fais*, Civ. A. No. 23-02494, 2023 WL 4760464, at *11 (D.N.J. July 26, 2023), *aff'd*, 110 F.4th 201 (2024) (alteration in original) (quoting *Nat'l Pork*, 598 U.S. at 394 (Roberts, C.J., concurring in part and dissenting in part)). As the party challenging Plaintiffs’ claims under consumer protection statutes, Defendants must establish that the burdens imposed on interstate commerce clearly outweigh the local benefits. *See Loki Brands*, 2024 WL 4457485, at *10.

Defendants contend that the burden Plaintiffs are seeking to impose—“necessarily regulating prices for *all* sales of [insulin] products to wholesalers, nationwide”—outweighs any local benefits bestowed by consumer protection statutes. (ECF No. 744-1 at 29.) Plaintiffs counter that the “[s]tate consumer protection statutes do not set price controls; they merely require the

[D]efendants to be honest about their true prices.” (ECF No. 747 at 36–37.) Plaintiffs further assert that the *Pike* balancing test favors their claims in that “the potential benefits to people with diabetes (i.e., avoiding needless pain, suffering, and death) outweigh[] the burden on commerce imposed (i.e., reduced corporate profits).” (*Id.* at 39.) Given Plaintiffs’ and Defendants’ conflicting contentions regarding Plaintiffs’ claims, this Court finds dismissal of Plaintiffs’ claims based on dormant Commerce Clause concerns to be premature. “The fact-intensive character of” the *Pike* balancing test “counsels against a premature dismissal.” *Colon Health Ctrs. of Am., LLC v. Hazel*, 733 F.3d 535, 546 (4th Cir. 2013); *see also Selvaggi v. Borough of Point Pleasant Beach*, Civ. A. No. 22-00708, 2024 WL 303677, at *19 (D.N.J. Jan. 26, 2024) (finding plaintiffs’ dormant Commerce Clause claim would benefit from further factual development and dismissal at the pleadings stage would be premature). Accordingly, Defendants’ Motion to Dismiss Plaintiffs’ consumer protection claims for both deception and unfairness is **DENIED**.

IV. CONCLUSION

For the reasons set forth above, Defendants’ Motion to Strike or Dismiss the Fourth Amended Complaint (ECF No. 744) is **GRANTED IN PART** and **DENIED IN PART**. An appropriate Order follows.

Date: December 31, 2024

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