UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 17-699 (BRM)(LHG)

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

The motion to dismiss[1] filed by defendants Novo Nordisk Inc. (Novo) and Sanofi-Aventis U.S. LLC (Sanofi) should be denied in its entirety, with one exception.[2] In their First Amended Complaint (Complaint),[3] plaintiffs allege that for over a decade, Novo and Sanofi fraudulently inflated the list prices of their analog insulin medications at the expense of patients whose lives depend on them. In exchange for preferred formulary positions, Novo and Sanofi artificially inflated their list prices so they could offer the nation's largest pharmacy benefit managers (PBMs) bloated "rebates" without reducing their drugs' true, net sales prices.

Drug list prices are supposed to be benchmarks—fair approximations of manufacturers' true, net prices for their drug. And for most drugs, they are. The manufacturer's sales price may be slightly higher—maybe 20 or 30% higher—but still reasonably related to its net price. This is why the vast majority of consumer

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[1] Defs.' Mot. to Dismiss First Amended Class Action Complaint, ECF No. 158. Defendants filed two briefs in support of their motion to dismiss. *See* Defendants' Memorandum of Law in Support of Motion to Dismiss the First Amended Class Action Complaint (Counts 1-5), ECF No. 158-1 (Defs.' MTD Counts 1-5); Defendants' Memorandum of Law in Support of Motion to Dismiss the First Amended Class Action Complaint (Counts 6-59), ECF No. 158-2 (Defs.' MTD Counts 6-59). This Court authorized the plaintiffs to file a single responsive brief, not exceeding 80 pages. *See* ECF No. 164.

[2] Plaintiffs acknowledge that Count Twenty-Six, under the Kentucky Consumer Protection Act, should be dismissed for lack of privity.

[3] *See* Pls. First Amended Class Action Compl., ECF No. 141. Citations herein to "¶" refer to the Complaint unless otherwise noted.

drug payments are tied directly to the drug manufacturers' published list prices. But unlike most drugs, the defendants' list prices for insulins are not reasonable related to their net prices; *they are 300% greater*. Because the defendants' analog insulins are sometimes considered therapeutically interchangeable, over the years, the largest PBMs and other institutional managers have sought rebates or price concessions from the defendants in exchange for the PBM's agreement to place the defendants' insulin in preferred formulary positions. But rather than reducing their true, net sales prices, the defendants instead exponentially increased their list prices while maintaining net prices constant. The resulting spread between list and net price enables the defendants to offer the PBMs huge "rebates" without losing any profit. The PBMs accept this scheme because they pocket a percentage of spread between the two prices; higher list prices mean higher PBM revenues. And the PBMs can market their ostensibly larger "rebates" to their plan clients. Over the course of the past decade, the defendants' list price inflation has gone completely uncontrolled; rather than publishing benchmark prices that approximate the true cost of their analog insulins, the defendants publish benchmark prices that are *300% greater*.

The defendants' artificial list price inflation has a real victim: consumers who pay for their analog insulins based on the defendants' published benchmark prices. The point-of-sale prices that consumers pay do not reflect manufacturers'

"rebates." Instead, these rebates occur in a separate, later transaction between the manufacturer and the PBM. And rebate size remains a tightly guarded secret.

Because of this fraudulent scheme, the defendants' motion to dismiss the RICO and state-law claims should be denied for the following reasons:

Plaintiffs state viable RICO claims. The plaintiffs plausibly allege that Novo and Sanofi committed mail and wire fraud by publishing artificially inflated list prices, knowing that each list price is a pricing index and that consumers pay for their analog insulins based on that fraudulently inflated index. The defendants' publication of their inflated list prices, while concealing their net prices, deceived the plaintiffs into believing that the list prices on which their out-of-pocket payments are based were reasonable and fair approximations of the actual cost of their analog insulins. The defendants publicly represent that the list prices of their analog insulins are *benchmark* prices that are *reasonable approximations* of the cost of their analog insulins and a *reasonable basis* for consumer out-of-pocket payments. Thus, by publicizing their benchmark prices, while keeping their net prices secret, the defendants deceived the plaintiffs and class members into making out-of-pocket payments for their analog insulins that are grossly inflated.

Plaintiffs allege proximate causation under RICO, which requires a "direct relation between the injury asserted and the injurious conduct alleged."[4] The

[4] *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992).

plaintiffs suffered *directly*, because the defendants set the inflated AWPs that they knew would be used *directly* to set consumer prices for their insulin. So, contrary to the defendants' argument, the plaintiffs do not seek to recover as indirect purchasers for inflated prices that are passed through to them. Instead, the defendants set the list prices that directly caused the inflated prices they have paid. And the consumer plaintiffs and putative class here are the only parties directly harmed by the defendants' conduct. The other actors in the healthcare system—the PBMs, health insurers, and pharmacies—*benefit* from the secret 300% inflation.

The plaintiffs also adequately allege six RICO enterprises. Novo formed three separate enterprises with each of the largest pharmacy benefit managers (PBMs)—CVS Health, Express Scripts, and OptumRx. And Sanofi also formed three separate enterprises with those PBMs. The defendant manufacturers contend that they did not form an enterprise with each other, but the plaintiffs alleged no such enterprise.

Plaintiffs state valid claims under state consumer protection acts. For the same reasons that plaintiffs allege a valid claim for mail and wire fraud under RICO, they also state valid claims under state consumer protection acts, including the New Jersey Consumer Fraud Act (NJCFA). Defendants' publication of fraudulent, inflated list prices is fraudulent, deceptive, and unconscionable under those statutes. And the Complaint complies with Fed. R. Civ. P. 9(b) by alleging

the defendants' scheme in great detail, putting the defendants on notice of their unlawful conduct and how it injured the plaintiffs and putative class members.

The plaintiffs also allege an ascertainable loss under the NJCFA and concrete damages under other states' laws. Damages here can be measured as the difference between the defendants' list prices for analog insulins and a reasonable approximation of the true net prices. In another case addressing the same damage issues presented here, the First Circuit affirmed the use of expert testimony to calculate damages by first establishing reasonable spreads for the drugs at issue and then comparing those reasonable spreads to the actual spreads fraudulently established by the defendants.[5] The same can be done here.[6]

In short, the motion to dismiss should be denied. Diabetes is an incurable illness; those living with type 1 or 2 diabetes must purchase insulin from diagnosis until death. The defendants' fraudulent scheme hits society's most vulnerable—the poor, the uninsured and underinsured, and the elderly—the hardest. Stories of people dying due to an inability to afford insulin are increasingly prevalent.[7] As a

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[5] *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 178 (1st Cir. 2009) (*AWP II*).

[6] And as shown below, the plaintiffs' state-law claims meet all procedural requirements, with the exception of the claim under the Kentucky consumer protection act.

[7] *See, e.g.*, Nicole Smith-Holt, *I Had to Bury My 26-Year-Old son Because He Couldn't Afford Insulin*, TruthOut (Feb. 1, 2018), http://www.truth-out.org/

result, through their artificial price inflation, the defendants have managed to unwind years of progress, transforming an eminently treatable disease back into a life-threatening condition. The defendants' acknowledgement that "pharmaceutical pricing is an important issue"[8] rings hollow where their actions are the direct cause of the plaintiffs' injuries. But when egregious benchmark price manipulation infests several segments of an industry, courts hold *all* manipulators accountable. That is what happened in *In re Pharmaceutical Industry Average Wholesale Price Litigation* (*AWP*)[9] and *In re Lupron Marketing & Sales Practices Litigation*,[10] in which the courts held that drug manufacturers may not misrepresent a grossly inflated list price as a benchmark. Indeed, *AWP II* resulted in a verdict for the plaintiffs that was affirmed by the First Circuit,[11] and *Lupron* resulted in a $150

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opinion/item/ 43397-i-had-to-bury-my-26-year-old-son-because-he-couldn-t-afford-insulin.

[8] Defs.' MTD Counts 1-5, at 4.

[9] 307 F. Supp. 2d 196 (D. Mass. 2004) (holding 21 separate pharmaceutical companies liable for their AWP inflation).

[10] 295 F. Supp. 2d 148 (D. Mass. 2003).

[11] *AWP II*, 582 F.3d at 160-161 ("[I]nflating AWPs over the actual acquisition cost created a 'spread' between the benchmark for the providers' reimbursement and the actual acquisition costs that the providers incurred. This allowed the providers to buy the drug at a secret, lower price while being reimbursed for it at a public, higher price, thereby creating a windfall each time a provider administered one of the drugs at issue.") (footnote omitted).

million dollar settlement.[12] As in those cases, the plaintiffs here state valid claims based on the fraudulent list prices established by the defendants.

II. ALLEGATIONS

Sixty-seven plaintiffs filed the Complaint on behalf of themselves and a proposed nationwide class of analog insulin consumers. ¶¶ 21-155. The class consists of people living with diabetes who paid or pay for Novo and Sanofi's analog insulins based on the defendants' published list prices: uninsured consumers, consumers in high-deductible health plans, consumers who reach the Medicare Part D donut hole, and consumers with high coinsurance rates. ¶ 282.

Novo makes the rapid-acting analog insulin, Novolog, and the long-acting insulin, Levemir. ¶ 228 (Table 2). Novo introduced Novolog to the U.S. market in 2000 and Levemir in 2005. *Id.* Sanofi manufacturers the rapid acting insulin, Apidra, and the long-acting insulin, Lantus. *Id.* Sanofi began to sell Apidra on the U.S. market in 2004 and Lantus in 2000. *Id.* In their Complaint, the plaintiffs request the Court toll the class period to the "earliest date of the Defendant Drug Manufacturers' initiation of the scheme described herein." ¶ 283.

A. Novo and Sanofi determine point-of-sale prices.

The defendants describe the "physical path" their analog insulins take to reach consumers.[13] But the physical path of delivery is irrelevant. This case is

[12] *In re Lupron Mktg. & Sales Practices Litig.*, 677 F.3d 21, 24 (1st Cir. 2012).

about the *price* of insulin at the *point of sale* to *consumers*. Novo and Sanofi determine that price by publishing list prices—also known as Average Wholesale Prices (AWP) or the mathematically-related, Wholesale Acquisition Prices (WAC)—for their analog insulins.[14] ¶ 174. As the Complaint explains, the defendants' published AWPs form the basis for consumer cost-sharing obligations at the point of sale: the "most commonly and continuously used set of reference prices in reimbursement and provider payment calculations and negotiations remains AWP." ¶ 178, *see* ¶¶ 177-81. Pharmacies and health plans use the benchmark prices (AWPs) that the defendants set to charge consumers.

Pharmacies. "The prices pharmacies quote consumers are the benchmark prices less a small discount (usually 15%)." ¶ 181. Pharmacies' reliance on AWP is the reason different chains charge roughly the same price for the same drug. A drug manufacturer sets a price for the product, and the retailer sells it based on that price, with small variations depending on the retailer's policies and contracts.

Health Insurers. Health plans typically use four types of payments to share costs with their plan members. Two are tied directly to AWP. First, most insured individuals make monthly payments in the form of insurance premiums. ¶¶ 170 (Figure 3), 172. Health insurers do not tie these premiums to any one medical

[13] Defs.' MTD Counts 1-5 at 7.

[14] AWP is usually WAC plus 20%.

expense or list price. ¶ 172. Second, some insured consumers must meet deductibles. If those consumers' pharmacy costs are not exempt from their deductible requirements, they must pay their pharmacies' point-of-sale prices (e.g., AWP minus 15%) until they hit their deductibles. Again, these point-of-sale prices are a direct product of the drug *manufacturers'* published list prices. ¶¶ 183-84, 200-03.[15] Third, other insured consumers have coinsurance obligations. Such consumers must pay a fixed percentage of their pharmacies' point-of-sale prices, again, based directly on the drug manufacturers' benchmark prices. ¶¶ 193-94, 196, 200-03. Fourth and finally, insured consumers may have co-payment obligations. Co-payments are fixed fees that insureds must pay at the point of sale; health insurers determine these fees without reference to any specific list price (for example, the co-pay for all generic drugs might be $10). ¶ 193.

An example helps clarify this payment structure. A woman with diabetes goes to her local retail pharmacy to purchase analog insulin. She has health insurance through her employer with a $2,000 deductible and 30% coinsurance after she hits that deductible. The pharmacist determines that the manufacturer has set the AWP for a box of insulin pens at $450. If she has not yet reached her deductible, she pays $382.50 (e.g., AWP minus 15%, the reimbursement rate in the

[15] High deductible plans may have co-payment or coinsurance requirements that kick in after consumers reach their deductibles. ¶ 195.

prescription drug plan) for the box of insulin at the point of sale. If she has reached her deductible, she pays $114.75 ($382.50 x 30%) for the box. ¶ 201.

Medicare Part D Plans. Those in Medicare Part D prescription drug plans must pay for their medications based on list prices. In 2017, the Medicare Part D standard plan had a $400 deductible and a 25% coinsurance obligation up to an initial coverage limit of $3,700. ¶ 199. So when Medicare Part D consumers went to pharmacies to pick up their prescriptions, they paid the pharmacies' point-of-sale prices (e.g., list price minus 15%) until they hit their $400 deductibles. *Id.* After hitting the $400 deductible, they paid 25% of the pharmacies' point-of-sale prices until they, together with their plans, spent $3,700 on drugs. Once they met that $3,700 coverage limit, the consumers fell into the Coverage Gap, more commonly known as the "Donut Hole." There, they paid 40% of pharmacies' point-of-sale prices. *Id.* Only once their total out-of-pocket spending (both before and in the Donut Hole) reached $4,950 did their Medicare Part D plan begin to shoulder 95% of their healthcare costs again. *Id.*

The proposed class in this case is limited to those consumers who have paid for their analog insulins *based directly on Novo and Sanofi's list prices*: uninsured consumers (who pay full, point-of-sale prices every time they purchase insulin), consumers in high deductible plans (who pay full, point-of-sale prices until they meet their deductibles), consumers with coinsurance requirements (who pay a large

percentage of point-of-sale prices), and consumers in Medicare Part D plans (who pay a large percentage of point-of-sale prices). ¶ 282. When Novo and Sanofi published inflated analog insulin AWPs during the class period, they forced these consumers to pay based on their inflated prices. ¶¶ 253-62. As a result, the physical path a drug takes to the consumer is irrelevant; the key issue is who sets the prices that consumers pay for their analog insulins.

B. Novo and Sanofi offered the three largest PBMs bloated "rebates" as kickbacks for preferred formulary status.

The defendants carried out their fraudulent scheme by manipulating the consumer payment structure. ¶¶ 206, 209, 240-67. Novo and Sanofi offered PBMs larger spread in exchange for preferred positions on their formularies. ¶¶ 4, 166, 204. Formularies are tiered lists of drugs where drugs in lower tiers are more affordable for consumers because health plans pay a greater portion of those drugs' prices. ¶ 5. Where two or more similar drugs appear on a health plan's formulary, doctors often prescribe the medication in the lower tier. Most health plans hire PBMs to set their formularies (and administer the pharmacy benefits they offer their plan members). The three largest PBMs—CVS Health (CVS), Express Scripts, and OptumRx—set the formularies for more than 80% of the commercially insured marketed, so they can push significant portions of the consumer market towards (or away from) particular drugs. ¶ 4.

Pharmaceutical companies that manufacture potentially interchangeable

medications—such as the analog insulins—compete for favorable treatment (or even exclusive placement) on the major PBMs' formularies. ¶¶ 5, 205. Drug companies *could* compete for such preferred formulary status by lowering their benchmark and/or net prices more than their competitors'. ¶¶ 205, 250.

But Novo and Sanofi have done the opposite. Aware that PBMs can pocket a percentage of any drug rebate they negotiate, ¶ 204, and are therefore indifferent to benchmark price growth, the defendants have decided to compete for preferred formulary positions through higher *list* prices rather than lower *net* prices. ¶¶ 206-211, 240-250. Novo recently admitted that its 2016 list prices for Novolog Vials and Pens were *317%* and *267%* greater than its net prices for those drugs. ¶ 243. From 2001 to 2016, the list prices of those drugs skyrocketed *353%* and *270%*, while their net prices remained stable, growing only 36% and 3%. *Id.* Put simply, nearly all of Novo's "price" growth was artificial list price inflation. Sanofi has done the same. Similarly, from 2007 until 2016, Sanofi's list price for Lantus grew 252%, while its net price rose only 57%. ¶ 245; *see* ¶¶ 244, 246, 248. Through this list price inflation, Novo and Sanofi have secured preferred formulary positions on the formularies of CVS, Express Scripts, and OptumRx.[16] ¶ 241.

[16] Novo and Sanofi cannot hold preferred formulary positions on the same PBM's formulary at a given time. Instead, Novo and Sanofi alternated between the PBMs over the course of the class period: some years Novo will hold the preferred position on CVS's formulary, other times Sanofi will.

C. Novo, Sanofi, and the largest PBMs make greater profits than they could absent the scheme, at the expense of consumers.

Both the defendants and the largest PBMs make more money through the scheme than they could absent it. Novo and Sanofi can secure preferred formulary positions, thereby increasing their share in the marketplace, without lowering their net prices. Without the scheme, Novo and Sanofi would have to compete for PBMs business based on real price reductions, rather than phony AWP inflation. The PBMs make more money off the defendants' growing spreads.

D. Novo and Sanofi kept their pricing scheme hidden to perpetuate it.

Those hurt by the scheme are consumers who pay for the defendants' analog insulins based on their artificial inflated prices. ¶¶ 200-02. Going back to the example of the consumer with a $2,000 deductible and 30% co-pay arrangement, the consumer pays $382.50 based on the defendant's $450 benchmark price before she hits her deductible. After meeting the deductible, she pays $114.75. But her insurer and the PBM it hired did *not* pay the remaining $276.75. In a concealed transaction, the drug manufacturer paid her PBM a "rebate." If the "rebate" was 40% of $153 ($382.50 x 40%), the manufacturer's net sales price to the PBM was $229.50 ($382.50 - $153). So when the consumer paid $382.50 for the box of insulin during her deductible period, she paid 166% of the manufacturer's net price ($382.50 divided by $229.50). And when she made a 30% coinsurance payment ($114.74), she really paid 50% ($114.75 divided by $229.50). ¶ 203.

Despite their gross AWP inflation, Novo and Sanofi continue to *affirmatively* hold out their AWPs as benchmark prices—as reasonable bases for consumer cost sharing. ¶¶ 251-62. At over 300% greater than their real, net prices, the defendants' AWPs are no longer reasonable benchmarks. And the defendants' representations to the contrary are fraudulent. Had Novo and Sanofi been honest about the true cost of their drugs, the plaintiffs would have saved millions.

III. ARGUMENT

Plaintiffs state valid claims under the proper standards. All well pleaded allegations must be accepted as true and viewed in the light most favorable to the plaintiffs.[17] The "issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims."[18]

A. The plaintiffs plausibly plead Novo and Sanofi violated RICO.

1. The Supreme Court and Third Circuit have consistently rejected defendants' entreaties to narrow RICO's reach.

To show a § 1962(c) violation, a plaintiff must prove: "(1) the existence of an enterprise affecting interstate commerce; (2) that the defendant was employed by or associated with the enterprise; (3) that the defendant participated . . . , either directly or indirectly, in the conduct or the affairs of the enterprise; and (4) that he

[17] *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 637-38 (3d Cir. 2015).

[18] *Id.* at 638 (quoting *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000)).

or she participated through a pattern of racketeering activity."[19] As the Supreme Court has held, "the statute requires no more than this."[20]

Since its passage, defendants have tried to cabin RICO's scope, complaining it provides "too easy a weapon against 'innocent businessmen.'"[21] The Supreme Court's response has been clear and consistent: "RICO is to be read broadly."[22] "RICO [i]s an aggressive initiative to supplement old remedies and develop *new methods* for fighting crime."[23] Indeed, the "fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth."[24] And the Third Circuit has enforced these directives: "In numerous instances, the Court has been asked to impose limits on how RICO may be applied, and it has consistently declined to do so. Instead, the Court has

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[19] *U.S. v. Bergrin*, 650 F.3d 257, 265 (3d Cir. 2011) (quoting *United States v. Irizarry*, 341 F.3d 273, 285 (3d Cir. 2003)).

[20] *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 497 (1985).

[21] *Id.* at 498.

[22] *Id*. at 497; *see also Boyle v. U.S.*, 556 U.S. 938, 956 (2009) (7-2 decision rejecting limitation that "enterprise" must have "an ascertainable structure beyond that inherent in the pattern of racketeering activity in which it engages"); *NOW v. Scheidler*, 510 U.S. 249, 256-62 (1994) (unanimous decision rejecting limitation that "enterprise" must have "an economic motive"); *U.S. v. Turkette*, 452 U.S. 576, 586-87 (1981) (8-1 decision rejecting limitation that "enterprise" must be legitimate entity).

[23] *Sedima*, 473 U.S. at 498 (emphasis added).

[24] *NOW*, 510 U.S. at 262 (quoting *Sedima*, 473 U.S. at 499).

repeatedly pointed to RICO's legislative history . . . as evidence that Congress intended to create a broad and powerful new statutory weapon . . . ."[25]

2. *Affirmative Misrepresentations*: Novo and Sanofi's publication of artificially inflated list prices for their analog insulins constitutes fraud.

Defendants incorrectly contend that the Complaint does not allege misrepresentations.[26] "Racketeering activity" covers "a host of so-called predicate acts, including 'any act which is indictable under . . . section 1341 (relating to mail fraud).'"[27] The "Third Circuit has made clear [] that the mail fraud statute is to be construed broadly."[28] Fraud is "measured in a particular case by determining whether the scheme demonstrated a departure from fundamental honesty, moral uprightness, or fair play and candid dealings in the general life of the community."[29]

Here, the plaintiffs allege that Novo and Sanofi committed mail and wire fraud by publishing artificially inflated AWPs by use of mail and interstate wire

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[25] *Bergrin*, 650 F.3d at 267-68.

[26] Defs.' MTD Counts 1-5, at 31-35.

[27] *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 647 (2008) (quoting 18 U.S.C. § 1961(1)(B)).

[28] *U.S. v. Stewart*, 1997 WL 688815, at *3 (E.D. Pa. Oct. 23, 1997) (citing *United States v. Martinez*, 905 F.2d 709, 715 (3d Cir.), *cert. denied*, 498 U.S. 1017 (1990)).

[29] *U.S. v. Riley*, 621 F.3d 312, 327 n.19 (3d Cir. 2010) (citation omitted).

facilities. ¶¶ 318-25.[30] The defendants know AWP is a pricing index and consumers pay for their analog insulins based on that index. ¶¶ 253-62, 323(g), 325. But instead of publishing AWPs that accurately approximated their true net prices, the defendants set AWPs for their analog insulins based on the size of the spread they sought to offer the largest PBMs. At 300% greater than net prices, their AWPs were in no way "Average Wholesale Prices." But the defendants held them out as such through publication of the prices. This is the misrepresentation for which the plaintiffs seek recovery.

a. Novo and Sanofi's publication of their analog insulin AWPs constitute affirmative misrepresentations.

The defendants misunderstand the RICO claim when they argue they "were under no legal obligation to disclose . . . the rebates they pay to PBMs."[31] This is not a case of omission. Nor is this a case where defendants inflated prices that were passed through a chain of distribution. Instead, the defendants *affirmatively* misrepresented their AWPs as benchmark prices when they were not.

Courts confronting nearly identical facts have credited the plaintiffs' theory of fraud. In *Lupron*, the district court held that excessive inflation of list prices

[30] And the defendants engaged in "[w]ritten and oral communications with U.S. government agencies and private insurers that fraudulently misrepresented what the benchmark prices were…." ¶ 322(f).

[31] Defs.' MTD Counts 1-5, at 35.

constitutes mail and wire fraud.[32] The defendants artificially increased the drug Lupron's AWP so they could offer doctors large rebates in exchange for use of the injection. The doctors (like the PBMs here) profited off the spread between the benchmark price and the net price they paid.[33] So the plaintiffs' "core allegation [was] that the AWPs for Lupron® reported by the defendants bore no resemblance to the actual prices charged by [the defendants] to doctors. . . . The AWPs rather were deliberately inflated as part of an improper marketing and sales scheme to promote Lupron® at plaintiffs' expense by funneling hidden profits to doctors."[34]

In seeking dismissal, the *Lupron* defendants relied on two inapposite decisions, *Langford*[35] and *Bonilla*,[36] which Novo and Sanofi cite to argue that they "were under no legal obligation to disclose either the rebates they pay to PBMs or the net prices they realize after paying any such rebates."[37] In *Bonilla*, Volvo

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[32] *Lupron*, 295 F. Supp. 2d at 165-68.

[33] The defendants mischaracterize *Lupron*. Because they charge their artificially inflated benchmark prices to distributors, they contend this case is distinguishable. Defs.' MTD Counts 1-5 at 40. But the defendants in *Lupron* also charged their artificial AWPs to a distributor (a subsidiary, TAP pharmaceutical), which then distributed the injection to doctors, only to award the doctors large rebates. In *Lupron*, as here, the AWP did not "bear any relationship to a reasonable interpretation of the terms 'average' or 'wholesale.'" 295 F. Supp. 2d at 160.

[34] *Id.*

[35] *Langford v. Rite Aid of Ala., Inc.*, 231 F.3d 1308 (11th Cir. 2000).

[36] *Bonilla v. Volvo Car Corp.*, 150 F.3d 62 (1st Cir. 1998).

[37] Defs.' MTD Counts 1-5 at 35. The defendants also cite *Eller v. EquiTrust Life Ins. Co.* for the premise that "a seller generally has no duty to disclose internal

purchasers sued under RICO for Volvo's practice of "charging different prices for the same car in different markets."[38] The First Circuit held that an "excessive price can be the *result* of fraud" but that "there is nothing in the law of fraud that prevents even a single seller from charging different markups in different markets so long as there is no affirmative misrepresentation."[39] Similarly in *Langford*, the Eleventh Circuit held "[d]ifferential pricing alone is not a fraudulent practice."[40]

The *Lupron* court explained why the defendants' reliance on *Bonilla* and *Langford* is misguided. The court first explained that a "good argument can go wrong when its fundamental premise is flawed."[41] The court then emphasized that "this is not a case of nondisclosure. Defendants did not stand mute."[42] Instead, the defendants held out their artificially increased AWPs as benchmark prices, fully aware that AWP is a pricing index intended to approximate the true cost of a drug, and consumers pay based on that index. Just so here. But in spite of this understanding, Novo and Sanofi continued to publish analog insulin AWPs that

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pricing policies or its method for valuing what it sells." 778 F.3d 1089, 1092-93 (9th Cir. 2015). *Eller*, again, relies on *Bonilla* and *Langford* for this proposition.

[38] *Lupron*, 295 F. Supp. 2d at 166 (describing *Bonilla*).

[39] *Bonilla*, 150 F.3d at 71.

[40] *Langford*, 231 F.3d at 1314.

[41] *Lupron*, 295 F. Supp. 2d at 167.

[42] *Id.*

were *300% greater* than their net price so they could offer enormous and secret spreads to the major PBMs. ¶¶ 251-61. As in *Lupron*, Novo and Sanofi have "trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud."[43]

AWP reinforces this conclusion. In *AWP*, the plaintiffs alleged that 42 pharmaceutical manufacturers engaged in "hidden profit-making schemes" by artificially inflating their benchmark prices, while offering the three largest PBMs "'secret spreads' between actual drug costs [(net prices)] and the prices charged to health plans . . . members [(benchmark prices)]."[44] As the court stated, the "'spreads' motivate the PBM's to put the brand-name drug on a formulary: the greater the AWP inflation, the greater the profit to the PBM from the spread."[45]

The *AWP* plaintiffs alleged the drug company defendants controlled "the setting of the AWP's" and "the distribution of marketing material used to inform the PBM's of the benefits of using AWP's."[46] Over objections similar to those made by the defendants here, the *AWP* court held that the "allegations provide a plausible fraudulent purpose (a falsely-inflated AWP)."[47] The same is true here.

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[43] *Id.*

[44] *AWP*, 307 F. Supp. 2d. at 205.

[45] *Id.* at 206.

[46] *Id.*

[47] *Id.*

b. The defendants' AWPs had no reasonable relationship to their true prices.

Novo and Sanofi argue that they never misrepresented their published AWPs as net prices. To do so, they point to an irrelevant definition of a different pricing benchmark—WAC—that is used to limit federal reimbursements under circumstances not pertinent here, i.e., reimbursement for single source drugs or biologics paid under Medicare Part B.[48]

But this response mischaracterizes the plaintiffs' claim. The plaintiffs do not allege that Novo and Sanofi misrepresented their AWPs as net prices. Instead, they allege that the defendants misrepresented their AWPs as *reasonable benchmarks for consumer payments*; *reasonable approximations of their true prices*. AWP is the reference price on which all consumer and provider payments are based. ¶¶ 176-78. The defendants knew that. ¶ 254. Rather than publishing real reference prices, the defendants contrived fictitious AWP and WACs. They set their AWPs based on the spread size they intended to offer the largest PBMs rather than their true prices. The federal definition of WAC does not provide the defendants cover to set artificial benchmark prices, ballooned to 300% of their drugs' true value.

[48] *See* 42 U.S.C. § 1395w-3a(c)(6)(B) (defining WAC as "the manufacturer's list price . . . to wholesalers or direct purchasers . . . not including prompt pay or other discounts, rebates or reductions in price"). By limiting reimbursement for Medicare Part B drug payments only to *the lesser* of actual average selling price (ASP) or WAC, the statute seeks to prevent abuse through phony list prices in the physician-administered context of Medicare Part B. *See* 42 U.S.C. § 1395w-3a(1)(4).

As the *Lupron* court explained, "[t]here is a difference between a sticker price and a sucker price."[49] In *Lupron*, the defendants argued that "AWP was a 'sticker price' and never intended to reflect the drug's true average wholesale price."[50] But the court rejected this position. "If one were confronting a modest markup of the actual AWP for Lupron® (which 300% is not)" and "if the same inflated AWP had not been used to set reimbursement rates for private purchasers and insurers, the Amended Complaint would not have been filed."[51] Just so here: if Novo and Sanofi's AWP prices were merely 20, 30, even 50% greater than their net prices, the plaintiffs would not have sued. Instead, they set AWPs that were 300% greater than net prices and kept such inflation a secret.[52]

The *AWP II* court also recognized that spreads can be so large as to render AWP fraudulent. To determine liability under state law, the court developed a spread "speed limit," defined as "the spread between the [defendant's] published AWP and the actual acquisition costs that the government and the industry expected."[53] For one drug, the court accepted expert testimony that the speed limit

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[49] *Lupron*, 295 F. Supp. 2d at 168 n.18.

[50] *Id.* at 168 n.19.

[51] *Id.*

[52] *Id.* ("[I]n their response to defendants' argument, [plaintiffs] have it exactly right: '[I]f everything [about Lupron®] was known to everybody, why did [d]efendants emphasize secrecy?'") (quoting the plaintiffs' brief).

[53] *AWP II*, 582 F.3d at 178.

should be 30%. The court then held liable all defendants whose spreads exceeded that 30% "speed limit." The First Circuit affirmed, because "it is enough to say that the issue at trial was not the existence of a spread, but the extent of it, and that the evidence presented generally supported [the experts] identification of a 30% speed limit as a conservative estimate of the outer limit of [the health insurers'] expectations."[54] In short, just because the defendants did not represent their AWPs to be net prices does not mean they can escape liability for AWP-manipulation.

Lum v. Bank of America[55] is not to the contrary. There, the plaintiffs complained that defendant banking institutions misrepresented their "prime rates" as their lowest rates. The district court dismissed and the Third Circuit affirmed because the plaintiffs failed to indicate when, where, or how the defendants represented their "prime" rates to be their lowest rate, apart from calling them "prime" rates. As the Third Circuit explained, the "meaning of the term 'prime rate' is sufficiently indefinite that it is reasonable for the parties to have different understandings of its meaning."[56] In fact, one of the defendants had explicitly told the plaintiffs that "Prime Rate . . . *is not, and should not be considered by you to represent, the lowest or the best interest rate available to a borrower at any*

[54] *Id*. at 183.

[55] 361 F.3d 217 (3d Cir. 2004).

[56] *Id*. at 226.

particular bank at any given time."[57] Here, the plaintiffs do not allege the defendants misrepresented their AWPs as the lowest prices available. Instead, they claim the defendants misrepresented (through publication) their AWPs as benchmarks, when they knew—*at 300% greater than net prices*—they were not.

Finally, the defendants erroneously argue that their "rebate" fraud does not violate the Anti-Kickback Statute (AKS),[58] and, even if it did, violations of the AKS are not RICO predicate acts. The plaintiffs do not allege that violations of the AKS are RICO predicate acts. The Complaint describes the defendants' AKS violations in the RICO count because the defendants, in their March 9, 2018 motion to dismiss brief, erroneously argued that their rebates were legal under the AKS rebate safe harbor. As courts recognize, just because a party labels its payment a "rebate" does not mean that payment is legal under the safe harbor.[59]

The Complaint discusses *U.S. ex rel. Banigan v. Organon USA Inc.*,[60] which held defendants' rebates constituted kickbacks. The plaintiffs (relators) alleged that

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[57] *Id.* at 227 (emphasis in original).

[58] The AKS provides a safe harbor for certain rebates or payments from drug manufacturers to PBMs. *See* 42 C.F.R. § 100.952 (2017).

[59] *U.S. v. Shaw*, 106 F. Supp. 2d 103, 115-16 (D. Mass. 2000) (it is not the case "that any discount, properly disclosed and appropriately reflected, is exempt from criminal liability").

[60] 883 F. Supp. 2d 277, 296 (D. Mass. 2012). The plaintiffs provided the wrong citation for this decision in the Complaint. But they did not, as the defendants contend, "egregiously mischaracterize" the case. Defs.' MTD Counts 1-5 at 41. *Banigan* indeed held the defendants' so-called "rebates" were mere kickbacks.

a pharmaceutical manufacturer (Organon) paid a pharmacy (Omnicare) illegal kickbacks in the form of market share rebates so that the pharmacy would distribute Organon's drugs over competitor products. Omnicare argued the AKS rebate safe harbor protected their market share "rebates." The court disagreed. As the court explained "[t]he safe harbor provision defines 'discount' as a 'reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction.'"[61] The term discount "does not embrace collateral kickbacks or reductions in price which are not passed on to Medicaid."[62] Because Omnicare did not disclose "the complete terms and conditions of the . . . rebate[s] (i.e., that the payments were made *to induce or in exchange for drug conversion and therapeutic interchange*)," the court held that the "kickback allegations against Omnicare [were] not protected by the discount safe harbor."[63] Just so here.

3. *Particularity*: The RICO claims are alleged with sufficient particularity.

Contrary to the defendants' argument,[64] the RICO allegations meet Rule 9(b)'s particularity requirement. "Rule 9(b) requires a plaintiff to plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was

[61] *Banigan*, 883 F. Supp. 2d at 296 (quoting 42 C.F.R. § 1001.952(h)(5)).

[62] *Id.*

[63] *Id*. (emphasis added).

[64] Defs.' MTD Counts 1-5 at 30, 31.

made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage."[65] The "Third Circuit . . . has moved toward a more lenient application of Rule 9(b)" than other circuits.[66] As the Third Circuit has stated, "[f]ocusing exclusively on the particularity requirement is 'too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules.'"[67] And the "law does not require specificity just for specificity's sake."[68] Rather, the purpose of Rule 9(b) is to provide defendants notice of the "precise misconduct with which they are charged."[69] While "allegations of 'date, place, or time' fulfill these functions, . . . nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of

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[65] *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 284 (3d Cir. 1992).

[66] *Kronfeld v. First Jersey Nat'l Bank*, 638 F. Supp. 1454, 1463 (D.N.J. 1986) (citing *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984), *abrogated in part on other grounds by Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

[67] *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (quoting *Christidis v. First Pa. Mortg. Trust*, 717 F.2d 96,100 (3d Cir. 1983)); *Seville*, 742 F.2d at 791 (stating the same).

[68] *Tirri v. Flagship Resort Dev. Corp.*, 2016 WL 6123146, at *3 (D.N.J. Oct. 19, 2016) (quoting *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 104 (D.N.J. 2011)).

[69] *Seville*, 742 F.2d at 791; *Tirri*, 2016 WL 6123146, at *3 (quoting *Smajlaj*, 782 F. Supp. 2d at 104).

substantiation into their allegations of fraud."[70] The Third Circuit has also instructed "courts [to] be 'sensitive' to the fact that application of the Rule prior to discovery 'may permit sophisticated defrauders to successfully conceal the details of their fraud.'"[71] The requirements of Rule 9(b) are relaxed in cases of corporate fraud where "it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control."[72]

Under these standards, the plaintiffs allege, with sufficient detail: (1) the defendants misrepresented their AWPs to be reasonable bases for consumer cost sharing by publishing them at regular intervals, ¶¶ 236-39, 251-55; (2) the defendants knew these representations to be false based on their real, net prices, ¶¶ 241-49, 253; (3) the plaintiffs were ignorant of the defendants' benchmark price falsity, ¶¶ 251, 254, 261; (4) the defendants intended that the plaintiffs and other intermediaries would rely on their AWPs as pricing benchmarks, ¶ 254; and (5) the plaintiffs acted upon this fraud to their detriment. ¶¶ 261-72. The plaintiffs allege the exact size of the spreads, ¶¶ 242-43 (Novo), 244-46 (Sanofi), and the dates on

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[70] *Seville*, 742 F.2d at 791; *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999), *abrogated on other grounds by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007) (quoting this language).

[71] *Shapiro*, 964 F.2d at 284 (quoting *Christidis*, 717 F.2d at 99-100).

[72] *In re Rockefeller Ctr. Props., Inc. Secs. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002).

which Novo and Sanofi published their artificially inflated AWPs. ¶¶ 236-38. The plaintiffs explain, in detail, the workings of the defendants' scheme. ¶¶ 235-67.

The only specifics not alleged are facts that are known by the defendants but unavailable to the plaintiffs, such as the employees who negotiated the rebates and the offices in which those negotiations took place. Because these specifics were impossible for the plaintiffs to obtain, Rule 9(b) does not foreclose their Complaint.[73] Even without those details, the Complaint puts the defendants "on notice of the precise misconduct with which they are charged."[74] Thus, under the Third Circuit's "functional and flexible approach to Rule 9(b),"[75] the plaintiffs have adequately pleaded fraud.

The plaintiffs here modeled their pleadings after those in *Lupron* and *AWP*. In both those cases, the defendants mounted Rule 9(b) challenges. And, in both, the courts ruled against the defendants. *Lupron* recognized it was "true . . . that the Amended Complaint d[id] not identify specific instances of mailings, or the use of

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[73] *See Seville*, 742 F.2d at 791; *In re Ins. Brokerage Antitrust Litig.*, 2016 WL 5219456, at *7 (D.N.J. Sept. 20, 2016) (plaintiffs adequately described the circumstances of the alleged fraud even though their complaint lacked certain specifics); *Kronfeld*, 638 F. Supp. at 1463-65 ("[W]hile not alleging the factual context or exact words of the misrepresentations, the complaint here does describe the nature and subject of the representations at issue with some specificity.").

[74] *Seville*, 742 F.2d at 791. That "alleged transactions are numerous and took place over an extended period of time" also supports this conclusion. *In re Sunrise Sec. Litig.*, 793 F. Supp. 1306, 1312 (E.D. Pa. 1992).

[75] *Kronfeld*, 638 F. Supp. at 1465.

facsimile transmissions, or the telephone." But it nonetheless held the complaint was "reasonably specific as to the nature of the materials that are alleged to have been distributed in furtherance of the scheme."[76]

Similarly, the *AWP* court acknowledged "Plaintiffs have not alleged specific communications for each enterprise."[77] But it nonetheless ruled "that relaxation of pleading requirements is permitted where information is in a defendant's sole possession."[78] The court emphasized that "[s]uch relaxation is particularly appropriate here where most of the Defendants have conceded that AWP's represent only an 'undiscounted sticker price' that has no direct relation to the

[76] *Lupron*, 295 F. Supp. 2d at 170. The plaintiffs "specifie[d] eight categories of documents that are alleged to have been disseminated by mail or wire in furtherance of the scheme, including: (1) marketing materials promoting the AWP spread; (2) the submissions of the AWP to the *Red Book*; (3) communications related to the distribution of free samples; (4) inaccurate credit memos and invoices sent to physicians; (5) communications regarding junkets and the TAP into the Future program; (6) communications with government agencies misrepresenting the AWP; (7) similar misleading communications with patients and health insurers; and (8) the receipt of payments for Lupron®." *Id.* The plaintiffs here specify the same categories of documents. *See* ¶ 322. *Lupron* also acknowledged the First Circuit's admonition (like the Third Circuit) that "[i]n an appropriate case, where, for example the specific allegations of the plaintiff make it likely that the defendant used interstate mail or telecommunications facilities, and the specific information as to use is likely in the exclusive control of the defendant, the court should make a *second* determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to amend the defective complaint." 295 F. Supp. 2d at 171 (quoting *New Engl. Data Serv., Inc. v. Becher*, 829 F.2d 286, 290 (1st Cir. 1987)) (emphasis in original).

[77] *AWP*, 307 F. Supp. 2d at 206.

[78] *Id.* (citing *Efron v. Embassy Suites (P.R.), Inc.*, 223 F.3d 12, 16 (1st Cir. 2000)).

actual average price they charge for their drugs and that this is a widespread pricing and reporting practice."[79] This reasoning is equally applicable here, where Novo and Sanofi control all the rebate information and have admitted the same. ¶¶ 242-46. Indeed, the only reason the plaintiffs pieced together the defendants' fraud was because the defendants recently admitted how much lower their net prices were to shift blame onto the major PBMs. *Id*.

4. *Causation*: Novo and Sanofi's artificial price inflation has directly injured the plaintiffs here—consumers that pay for insulin based on the defendants' benchmark prices.

Novo and Sanofi's fraudulent misrepresentations regarding their benchmark prices directly caused the plaintiffs' injuries. The defendants erroneously argue: (1) the plaintiffs lack standing because they are indirect purchasers, and (2) the plaintiffs do not allege proximate causation. Novo and Sanofi misinterpret RICO's "direct injury" requirement (its proximate cause requirement) as a separate "direct purchaser" requirement. The defendants would have this Court import antitrust law's "direct purchaser" limitation into the RICO jurisprudence, despite the Supreme Court's repeated admonitions against narrowing RICO's scope. Unlike antitrust law, RICO has no "direct purchaser" requirement but instead requires the plaintiffs to allege they are direct *victims* of the defendants' unlawful conduct, in

[79] *Id*.

order to show the defendants *proximately* caused their injuries. Here, the consumer plaintiffs are the only direct victims of Novo and Sanofi's pricing fraud.

a. RICO requires a direct relation between the injury asserted and the injurious conduct alleged.

The defendants' argument that the RICO claim is barred by a supposed "indirect purchaser rule" is wrong on the law and facts.[80] Legally, the defendants' argument confuses RICO's "direct injury" requirement with antitrust law's "direct purchaser" rule. In the antitrust context, the Supreme Court has established a bright-line rule that only direct purchasers have standing to sue manufacturers for violating federal antitrust law.[81] But this rule does not apply in the RICO context when the defendant defrauds consumers directly. As the Supreme Court has repeatedly explained, proximate cause under RICO is a "demand for some direct relation between the injury asserted and the injurious conduct alleged."[82] Here, as shown throughout this brief, the inflated consumer price for defendants' insulins is directly tied to the injurious conduct of setting artificial, fraudulent AWPs.

Applying antitrust law's "direct purchaser" rule to a RICO claim of fraudulent pricing that directly defrauds consumers runs contrary to the Supreme

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[80] Defs.' MTD Counts 1-5 at 26-29.

[81] *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977).

[82] *Holmes*, 503 U.S. at 268; *accord*, *Bridge*, 553 U.S. at 654; *Hemi Grp., LLC v. City of N.Y.*, 559 U.S. 1, 9 (2010); *Anza v. Ideal Supply Corp.*, 547 U.S. 451, 457 (2006).

Court's admonition in *Holmes* and *Bridge* that RICO's direct injury requirement not be construed as "a black-letter rule that will dictate the result in every case."[83] As stated in *Sedima*, a "previous [legislative] proposal to add RICO-like provisions to the Sherman Act had come to grief in part precisely because it 'could create inappropriate and unnecessary obstacles in the way of . . . a private litigant [who] would have to contend with a body of precedent—appropriate in a purely antitrust context—setting strict requirements on questions such as 'standing to sue . . . .'"[84]

The defendants' indirect purchaser argument is also wrong on the facts. Courts do not apply antitrust law's indirect purchaser rule to RICO cases like this, because the consumers' place in the chain of distribution is irrelevant—the plaintiffs pay prices *directly* based on the defendants' fraudulent AWPs *irrespective of the prices other intermediaries within the chain pay*. The issue is not that the defendants overcharged more direct purchasers who passed through those overcharges indirectly to consumers. The issue is that the defendants' grossly misrepresented the pricing benchmarks used to *directly* set consumer prices. Put another way, the harm the plaintiffs allege does not "flow[]" "from the misfortunes visited upon a third person"[85] but instead directly from the fraudulent AWPs.

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[83] *Holmes*, 503 U.S. at 272 n.20 (citation omitted).

[84] *Sedima*, 473 U.S. at 498-99 (citing the Congressional record).

[85] *Holmes*, 503 U.S. at 268-69.

The cases cited by the defendants to support their indirect purchaser argument involve pass through of overcharges, not a fraud that directly affected the prices the plaintiffs paid. In *McCarthy v. Recordex Service, Inc.*,[86] the plaintiffs alleged that hospitals and photocopiers violated the Sherman Act and RICO by overcharging their attorneys for photocopies of their medical records. As to the plaintiffs' antitrust claims, the district court granted summary judgment and the Third Circuit affirmed. As the Third Circuit explained, the plaintiffs had contingency arrangements with their attorneys and were not responsible for any photocopy fees absent recovery, so they had no antitrust injury.[87]

The court then quickly disposed of the plaintiffs' RICO claims, because "plaintiffs have conceded that, if they lacked antitrust standing, they also lacked RICO standing."[88] In so holding, the court recognized that "[i]ndirect *victims*" lack "RICO standing."[89]And summing up its antitrust and RICO holdings, the court

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[86] 80 F.3d 842 (3d Cir. 1996).

[87] *Id*. at 853. One plaintiff did not have a contingency arrangement, but her "attorney *never paid* the photocopying charges but rather obtained the needed copies from opposing counsel. Therefore, [plaintiff] (and indeed, even her attorney) cannot show any injury—much less antitrust injury."" *Id.* at 854 (emphasis in original).

[88] *Id*. at 855.

[89] *Id.* at 854 (emphasis added). The RICO cases *McCarthy* cites demonstrate that direct victims of injurious conduct have RICO standing, while indirect victims do not. *See Wooten v. Loshbough*, 951 F.2d 768, 770 (7th Cir. 1991) (plaintiff won a judgment against a printing press before the defendants bankrupted it, so she was not a purchaser at all but instead an indirect *victim*); *County of Oakland v. City of*

characterized the dispositive issue as "whether plaintiffs are 'direct purchasers.'"[90] That was true in *McCarthy*, where the plaintiffs only overpaid if and when a more direct purchaser—their attorneys—overpaid and passed on the overpayment. Here, in contrast, the plaintiffs overpay based *directly* on the defendants' fraudulent AWPs, so that pass-through is not an issue.

Novo and Sanofi also rely on another inapposite case, *Hale v. Stryker Orthopedics*,[91] in which the plaintiffs claimed that their coinsurance payments were too large, without alleging that those payments were directly based on any prices set by the defendants. Here in contrast, the plaintiffs claim the defendants set fraudulently inflated AWPs, knowing that plaintiffs would pay for their insulin based *directly* on those AWPs.[92] The defendants' artificial price inflation directly forced the plaintiffs to pay higher prices based directly on AWPs. ¶¶ 336-43.

Detroit, 866 F.2d 839, 849 (6th Cir. 1989) (counties who bought sewerage services from the city of Detroit at inflated prices had standing to sue under antitrust law and RICO); *Carter v. Berger* 777 F.2d 1173, 1176 (7th Cir. 1985) ("the *directly injured* party should receive a complete recovery, no matter what") (emphasis added); *Terre Du Lac Ass'n, Inc. v. Terre Du Lac, Inc.*, 772 F.2d 467, 472-73 (8th Cir. 1985) (plaintiff sufficiently alleged direct injury); *Imagineering, Inc. v. Kiewit Pac. Co.*, 976 F.2d 1303, 1311 (9th Cir. 1992) ("there must be a direct relationship between the injury asserted and the injurious conduct alleged").

[90] *Id.*

[91] 2009 WL 321579, at *3 (D.N.J. Feb. 9, 2009).

[92] The other decisions the defendants cite to support their position that *Illinois Brick*'s direct purchaser rule "is an insurmountable obstacle to plaintiffs' RICO claims" are antitrust decisions that do not involve or discuss RICO. *See* Defs.' MTD Counts 1-5 at 28-29 (citing *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77

The Third Circuit's decision in *Avandia* directly supports plaintiffs' theory of injury here and shows that indirect purchasers can assert RICO claims if they are direct victims of the injurious conduct. In *Avandia*, the issue was whether a drug manufacturer's fraudulent misrepresentations regarding the efficacy of its drug proximately caused health insurer plaintiffs to overpay for the drug in violation of RICO. The *Avandia* plaintiffs were third-party payors (TPPs), which did not directly purchase Avandia from the manufacturer GSK but instead reimbursed a pharmacy that purchased Avandia in a chain of distribution.[93] That distribution chain did not preclude the RICO claim, because the issue was whether the pharmaceutical company's misrepresentations directly caused the health insurers to pay a higher price for the drug than they otherwise would have. So the Third Circuit explained that the "conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint -- the misrepresentation of the heart-related risks of taking Avandia that caused

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(3d Cir. 2011); *Link v. Mercedes-Benz of N. Am., Inc.*, 788 F.2d 918 (3d Cir. 1986); *Del. Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116 (9th Cir. 2008); *In re Brand Name Prescription Drugs Antitrust Litig.*, 248 F.3d 668 (7th Cir. 2001)). None of those cases involved manipulation by the defendants of prices that were used to *directly* set prices paid by consumers.

[93] Compl. of United Food and Commercial Worker and Participating Emp'r Welfare Fund ¶ 12, *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 2:10-cv-02475, ECF No. 7 (E.D. Pa. Aug. 20, 2010) ("UFCW Fund has paid all or part of the cost of its participants' purchases…. The pharmacy collects a co-payment from the participant and bills the UFCW Fund (through a prescription benefit manager) for the remaining cost of Avandia purchases.").

TPPs and PBMs to place Avandia in the formulary."[94] Similarly here, the conduct that caused the plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the Complaint—the fraudulently inflated AWPs that directly caused the plaintiffs to pay inflated prices for their insulin.

The Second Circuit's decision in *Desiano v. Warner-Lambert Co.*[95] further supports the plaintiffs' claims here. The facts of *Desiano* mirror those of *Avandia*. And as in *Avandia*, the court held that the health insurer plaintiffs and their insureds were the direct victims.[96] The Court explained that "this and other courts have long recognized the right of HBPs to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices."[97] Just so here: the consumers are not merely paying an overcharge that pharmacies and health insurers have passed on, as in *McCarthy*. Instead, the consumers are paying an overcharge based directly on the defendants' published benchmark prices.

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[94] *See Avandia*, 804 F.3d at 641-46; *see also In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004) (holding, in an antitrust decision, that a pharmaceutical company's alleged misrepresentations regarding its drug, Coumadin, caused health insurers and consumers a direct economic harm through the "the excess money plaintiffs paid defendants for the [defendant's drug] that they claim they would not have [paid] but for Defendant's fraud").

[95] 326 F.3d 339 (2d Cir. 2003).

[96] *Id.* at 350 n.10 ("the insurance companies have a claim for 90 percent of the overpayment in the purchase price, and the patients have a claim for 10 percent of the same overpayment").

[97] *Id.* at 350.

b. The Complaint satisfies the proximate causation requirement.

Applying the three *Holmes* factors for proximate causation, the plaintiffs meet RICO's proximate cause requirement. First, plaintiffs' damages are ascertainable[98]: they are the difference between the defendants' AWP for their analog insulins and their true net prices (plus a reasonable markup). The Court need only decide whether the defendants' published AWPs bore a reasonable relationship to their analog insulins' net prices. In *AWP II*, the court relied on this methodology to assess liability, and the First Circuit affirmed.[99]

Second, the Complaint here raises no apportionment difficulties.[100] First, the PBMs knew the defendants' benchmark prices were false benchmarks, as did many of their insurer clients who received a portion of the rebates. Therefore, the defendants' conduct did not deceive these intermediaries, and they suffered no harm. As to the insurers who were deceived by the defendants' benchmark price inflation, each "[insurer] and its patient co-payer has its own, segregable, claim for economic harm, to the extent of their respective co-pay."[101]

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[98] *Id.* at 269.

[99] *AWP II*, 582 F.3d at 178.

[100] *Holmes*, 503 U.S. at 269.

[101] *Desiano*, 326 F.3d at 350.

Finally, the consumers here are the only ones who can be "counted on to vindicate the law as private attorneys general."[102] The other actors in the healthcare system *benefit* from the defendants' secret rebate scheme: the PBMs, institutional health insurers, and pharmacies may take a cut of the defendants' "rebates". So those entities are unharmed by the defendants' conduct, and they have an active incentive to preserve the fraud. Only consumers, who pay based *only* benchmark prices at the point of sale, have reason to stop the defendants' artificial price inflation. ¶ 343.

In the two decisions most factually similar to this one, *Lupron* and *AWP*, the courts dispensed with similar proximate cause arguments. In *Lupron*, the court first explained that "RICO requires "some direct relation between the injury asserted and the injurious conduct alleged.'"[103] The court then ruled that "Defendants' challenge to this element of plaintiffs' RICO claims borders on the frivolous."[104] The *AWP* court agreed with that ruling, explaining that "[i]n the private, end-payor context, the harm alleged by Defendants' alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs based on the AWP's."[105] Here, as in *Lupron*, the defendants "instigated both the culpable

[102] *Holmes*, 503 U.S. at 269-70.

[103] 295 F. Supp. 2d at 174-75 (quoting *Holmes*, 503 U.S. at 268).

[104] *Id*. at 175.

[105] 307 F. Supp. 2d at 207.

and the innocent intermediaries to commit acts that were not only foreseeable but intended."[106] And as the *AWP* court explained, "[t]he conclusion that proximate cause exists is supported by the reasoning set forth in *Holmes*: the Defendants do not argue that there would be any particular difficulty in allocating damages; there are no other victims that will be sharing in the amounts claimed by Plaintiffs; and as the Plaintiffs are the ones directly injured, no other party is better placed to vindicate their interests."[107]

The Third Circuit's *Avandia* decision again directly supports this conclusion. The injury in *Avandia* parallels that alleged here: health insurers overpaid for a diabetes medication based on the defendant drug company's fraudulent marketing.[108] Just as the defendants here argue intermediaries (pharmacies and health insurers) break the chain of causation, GSK argued "that the presence of intermediaries, doctors and patients, destroys proximate causation because they were the ones who ultimately decided whether to rely on GSK's misrepresentations."[109] Citing the Supreme Court's decision in *Bridge*, the Third Circuit held that the insurers' injury was a "foreseeable and natural consequence of

[106] 295 F. Supp. 2d at 175.

[107] 307 F. Supp. 2d at 208.

[108] *Avandia*, 804 F.3d at 639.

[109] *Id*. at 645.

[the] scheme."[110] The plaintiffs in *Avandia* "allege[d] that drug manufacturers are well aware that [health insurers] cover the cost of their drugs and describe the alleged RICO scheme as consisting of 'deliberately misrepresenting the safety of [their drugs] so that Plaintiff and members of the Class paid for this drug.'"[111] Just so here: Novo and Sanofi are "well aware" consumer payments are based on the defendants' benchmark prices. In their Complaint, the plaintiffs "describe the alleged RICO scheme as consisting of deliberately misrepresenting" these prices "so that Plaintiff and members of the Class paid" them.[112] "This fraudulent scheme could have been successful only if plaintiffs paid for [analog insulin based on benchmark prices], and this is the very injury that plaintiffs seek recovery for."[113]

The *Avandia* defendant further argued that proximate causation was lacking because the plaintiffs failed to allege they would have paid less absent its fraud (i.e., that they would have purchased cheaper, alternatives drugs).[114] Just so, Novo and Sanofi fault the plaintiffs for failing to allege that the pharmacies would have charged them less absent Novo and Sanofi's fraud.[115] But as the Third Circuit

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[110] *Id*.

[111] *Id*.

[112] *Id.*

[113] *Id*.

[114] *Id*. at 644-54.

[115] Defs.' MTD Counts 1-5 at 49-50 ("[E]ven if defendants disclosed the net price they realized after accounting for PBM rebates, there is no basis for

countered in *Avandia*, the plaintiffs need not show pharmacies would have changed their behavior; they must only show the defendants' analog insulins "cost too much" due to the defendants' fraud.[116] Had Novo and Sanofi published AWPs that approximated their true, net prices—that were 20 or 30% greater than net prices, not 300% greater—the plaintiffs and the proposed class would have saved hundreds of millions. ¶¶ 16, 260-216, 341-343.

c. The Complaint satisfies the "but for" causation requirement.

The defendants also appear to argue that the plaintiffs lack but-for causation. According to the defendants, their misrepresentations "have no connection to the prices plaintiffs ultimately paid for insulin."[117] They claim "[k]nowing the details of the rebates would not have entitled consumers to any corresponding discount,

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concluding that the prices consumers pay at the pharmacy counter . . . would have been any different."). To support this position, defendants cite a Delaware district court decision holding, *at summary judgment*, that the plaintiffs failed to *produce evidence* showing how the rebates at issue "could have acted to increase the amount of money that plaintiffs had to pay for their mobile homes." *Arthur v. Guerdon Indus., Inc.*, 827 F. Supp. 273, 280 (D. Del. 1993). The defendants ignore that at the motion to dismiss stage, the court credited the plaintiffs' RICO theory under § 1962(a) and (b), dismissing the § 1962(c) theory only because the plaintiffs failed to plead an "enterprise" distinct from the RICO "person." *Vietman Veterans of Am., Inc. v. Guerdon Indus., Inc.*, 644 F. Supp. 951, 957-58 (D. Del. 1986). Here, as in *Arthur*, plaintiffs' factual allegations must be accepted as true at the dismissal stage.

[116] *Avandia*, 804 F.3d at 644-54.

[117] Defs.' MTD Counts 1-5 at 50.

nor would it have in any other way altered the prices pharmacies charge at the counter—which, again, are not set by defendants."[118]

This is patently wrong. Consumers pay based on the defendants' list prices, their AWPs. This is what the plaintiffs allege in the Complaint, ¶ 341, and this is well known in the industry. Had the defendants published reasonable pricing benchmarks—based on the true costs of their drugs, rather than the artificial spreads they used to give rebates to PBMs—the plaintiffs would have saved millions.[119]

5. *Valid RICO Enterprise*: The plaintiffs adequately alleged the defendants directed enterprises with a shared common purpose.

The plaintiffs adequately allege that the Manufacturer-PBM Insulin Pricing Enterprises shared a "common purpose," and that the defendants operated and

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[118] *Id.*

[119] *See Utah v. McKesson Corp.*, 2011 WL 2884922, at *4-5 (N.D. Cal. July 19, 2011). The facts of *Utah* were identical to those of *AWP* and parallel those here. The plaintiffs, the Utah's Medicaid program, alleged that a drug wholesaler, McKesson, engaged in a scheme to inflate AWPs and, therein, its distribution charges. "Utah alleges that it in fact paid rates based on the AWPs, and that it continued to pay those rates even as they increased due to McKesson's fraudulent concealment . . . ." *Id.* at *4. In response, McKesson made the same argument that Novo and Sanofi advance here: "Utah did not allege in its complaint an alternate course of conduct that it would have taken had it known the true reasons for the increase in the AWPs." *Id.* at *5. The court disagreed: "Utah has sufficiently alleged that it was McKesson's fraud—as opposed to any other factor—that caused its reimbursement rates to increase. Utah is not also required to plead what measures it would have taken had McKesson chosen to disclose the basis for the AWP increases." *Id.*

managed those enterprises' affairs. The defendants' arguments to the contrary ask this Court to construe RICO more narrowly than either the Supreme Court or Third Circuit permits. In *Boyle v. United States*,[120] the Supreme Court resolved a circuit split on the required attributes of association-in-fact enterprises, rejecting several limitations appellate courts had imposed on the "enterprise" concept. An enterprise must have only "three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose."[121] As the Third Circuit has explained, *Boyle* endorses a "capacious construction" of the term "enterprise."[122]

a. The alleged enterprises share common fraudulent purposes.

Novo and Sanofi erroneously contend the Manufacturer-PBM Insulin Pricing Enterprises do not share a common purpose. To support this position, they cite a handful of banal truisms from California district courts[123] and a Seventh

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[120] 556 U.S. 938 (2009).

[121] *Id.* at 946.

[122] *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 366 (3d Cir. 2010).

[123] *See* Defs.' MTD Counts 1-5 at 43 (citing *Shaw v. Nissan N. Am., Inc.*, 220 F. Supp. 3d 1046, 1054 (C.D. Cal. 2016) (holding that plaintiffs need not allege the RICO enterprise's "common purpose" was fraudulent, but reminding that RICO does not criminalize ordinary business relationships); *In re Jamster Mktg. Litig.*, 2009 WL 1456632, at *4-5 (S.D. Cal. May 22, 2009) (holding that plaintiffs' alleged enterprise failed because the plaintiffs' allegation were "too vague and imprecise to adequately allege the existence of an associated-in-fact enterprise"); *Gomez v. Guthy-Renker, LLC*, 2015 WL 4270042, at *5-6 (C.D. Cal. July 13, 2015) (same)).

Circuit decision holding the plaintiff met the "common purpose" requirement (reversing the district court's contrary holding).[124] Meanwhile, the defendants ignore the Third Circuit's interpretation of the common purpose requirement as well as the two district court decisions directly on point.

In *In re Insurance Brokerage Antitrust Litigation*,[125] the Third Circuit held the plaintiff insurance purchasers adequately alleged a RICO enterprise with a common purpose. There, an insurance broker, Marsh, "had solicited rigged bids [from insurers] for insurance contracts, and had received improper contingent commission payments in exchange for steering its clients to a select group of insurers."[126] As the Third Circuit explained, the broker and insurers' shared "common interest" was "to increase profits by deceiving insurance purchasers about the circumstances surrounding their purchase."[127]

So too here. Novo and Sanofi's shared common interest with each of the individual PBMs is to increase profits by deceiving the plaintiffs as to their analog insulins' true prices. ¶¶ 254, 302-09, 334-35. The defendants published artificially

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[124] *See id.* (citing *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 655-56 (7th Cir. 2015) (holding that the plaintiffs adequately alleged more than a "run-of-the-mill commercial relationship because the entities involved in the enterprise had an "unusual degree of economic interdependence" and did not operate completely separately for the purposes of the scheme at issue)).

[125] 618 F.3d 300 (3d Cir. 2010).

[126] *Id.* at 309.

[127] *Id.* at 376.

inflated list prices so they could offer the PBMs a form of "rigged bid" in exchange for preferred formulary status. The PBMs, like Marsh, obtained improper contingency payments—the rebates—in exchange for their roles. The plaintiffs then overpaid for their analog insulins based on the defendants' misrepresentations.

AWP credited the plaintiffs' near-identical "common purpose" allegations, holding that the common purpose the drug manufacturers and PBMs shared was the false inflation of AWPs to increase kickbacks size (rebates).[128] The PBMs in *AWP* (as here) were not "indifferent as to whether the AWP spread exist[ed]"; instead, "their financial interest" lay in the defendants' spread inflation.[129] ¶¶ 210, 255.

The defendants' arguments to the contrary either ignore the plaintiffs' allegations or mischaracterize them. First, the defendants offer a disjunctive and excessively literal reading of the plaintiffs' allegations, pointing out that the defendants and PBMs do not physically administer insulin; PBMs do not purchase insulin; and manufacturers do not buy it.[130] True. But the enterprises' *common* purpose is to facilitate all three: to sell analog insulins at artificially inflated AWPs to increase rebate size.

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[128] *AWP*, 307 F. Supp. 2d at 206 ("These allegations provide a plausible common fraudulent purpose (a falsely-inflated AWP) . . . .").

[129] *Id.* at 204.

[130] Defs.' MTD Counts 1-5 at 42.

Next, the defendants contend the plaintiffs' allegations are "self-contradictory" because CVS could not form an enterprise with Novo at the same time as Sanofi did.[131] But this is not what the plaintiffs allege. The plaintiffs allege that, over the course of a lengthy class period, Novo and Sanofi formed enterprises with each of the three largest PBMs at varying points. Novo and Sanofi alternated as to which held the preferred position on each of the PBMs' formularies. This is why plaintiffs who have held the same insurance for years were switched between the defendants' analog insulins. That these enterprises alternated does not undermine the plaintiffs' allegations because the linkages between each PBM and each defendant manufacturer were contractually and systematic. ¶ 312 (Novo), ¶ 313 (Sanofi). Only through discovery can the plaintiffs determine when each enterprise existed.

Finally, the defendants argue the plaintiffs' allegation that "each enterprise 'shares a common purpose of perpetuating use of insulin benchmark prices as the basis for consumer cost-sharing and out-of-pocket payments'"[132] fails because "plaintiffs have not plausibly alleged that defendants have any preference regarding how those terms are set."[133] Not so. As the Complaint explains, the "Defendant Drug Manufacturers concealed their analog insulins' net prices and

[131] *Id.* at 44-45.

[132] Defs.' MTD Counts 1-5 at 45 (quoting ¶ 304).

[133] *Id*. at 45.

prevented the plaintiffs and class members from knowing what these prices were to ensure the PBMs could and would benefit from the spread between the net and benchmark prices." ¶ 254. "If consumers did not understand benchmark prices as reasonable approximations of the cost of their analog insulins—as reasonable basis for their cost-sharing obligations, PBMs and health insurers would not be able to use the defendants' benchmark prices as a basis for consumer cost-sharing. If the PBMs could not use these benchmark prices as a basis for reimbursement, the spread between benchmark and net price would evaporate. Without a spread to sell, the Defendant Drug Manufacturers would have nothing to offer PBMs in exchange for preferred formulary status except lower real prices." *Id*. Put simply, using AWP as a basis for consumer cost-sharing forms the foundation for the entire scheme. Without it, there is no spread to sell.

b. The defendants conduct the affairs of the alleged enterprises.

Novo and Sanofi incorrectly argue the plaintiffs do not adequately allege the defendants conducted the alleged enterprises.[134] In *Reves v. Ernst & Young*, the Supreme Court held § 1962(c) requires "defendants [to] conduct[] or participat[e] in the conduct of the 'enterprise's affairs,' not just their own affairs."[135] And in *Insurance Brokerage*, the Third Circuit offered an analytic tool to evaluate whether

[134] Defs.' MTD Counts 1-5 at 47.

[135] *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

a defendant conducts the enterprise's affairs, as opposed to just his own. The *Insurance Brokerage* district court dismissed one of the plaintiffs' alleged enterprises (the Marsh-centered enterprise) for exactly the reason the defendants urge here: "it was 'not convinced' that 'Defendants operated' the alleged . . . enterprise's affairs 'rather than Defendants' own affairs.'"[136] Reversing, the Third Circuit explained it "will often be the case that the interests of the enterprise are congruent with those of its members; such congruence presumably provides the incentive for members to participate in the enterprise."[137] To distinguish defendants who merely pursue their *own* interests from those who pursue the *enterprise's*, courts should assess whether the "defendants band together to commit violations they cannot accomplish alone then they cumulatively are conducting the association-in-fact enterprise's affairs, and not [simply] their own affairs."[138] In *Insurance Brokerage*, the insurer-defendants' "alleged collaboration in the Marsh-centered enterprise, most notably the bid rigging, allowed them to deceive insurance purchasers *in a way not likely without such collusion*."[139]

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[136] *Ins. Brokerage*, 618 F.3d at 378 (quoting the district court).

[137] *Id.*

[138] *Id.* (alterations in original omitted) (quoting Gregory P. Joseph, Civil RICO: A Definitive Guide 106, 332 (3d ed. 2010)).

[139] *Id.* (emphasis added).

Similarly, Novo and Sanofi's participation in the enterprises enable them to accomplish something more—preferred formulary status without real price reductions—than they could without the enterprises. Without their artificial-price-inflation scheme, the defendants would have competed for preferential treatment on the PBMs' formularies by lowering their real, net prices. Through promotion of the benchmark-price inflation scheme, they were able to secure the same preferred positions without real price reductions. Confronted with the same arguments, the *AWP* court held that "the Defendants were not simply acting legally to promote their products, but rather promoted the fraudulent AWP scheme."[140]

The out-of-circuit decision the defendants rely on credits *Insurance Brokerage*'s reasoning. In *United Food*,[141] the plaintiffs alleged that Walgreens and a drug company, Par Pharmaceuticals, joined together to fill prescriptions with Par's drug over alternatives. The Seventh Circuit explained that in *Insurance Brokerage*, the defendants' "cooperation [] fell outside the bounds of the parties' normal commercial relationships. Companies competing for business in a legitimate market that assigns business through bidding do not disclose their bids

[140] *AWP*, 307 F. Supp. 2d at 207 ("Defendants argue that, at best, the AMCC alleges that they were simply conducting their own affairs, not participating in the enterprises."); *see also Lupron*, 295 F. Supp. 2d at 171-72 (same).

[141] *United Food & Commercial Workers Unions & Emp'r Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 855-56 (7th Cir. 2013).

to one another in advance."[142] In contrast, the alleged cooperation between Walgreens and Par in *United Food* was the acquisition and sale of medications, conduct which any pharmacy and drug company must engage in to distribute medications. Here, the defendants' conduct mirrors that in *Insurance Brokerage*, not *United Food.* Companies "competing for business in a legitimate market that assigns business through bidding" lower their real, net prices to win such bids.

6. *RICO Conspiracy*: The plaintiffs adequately plead a RICO conspiracy.

The defendants incorrectly contend that the Complaint does not adequately allege a RICO conspiracy.[143] "Under § 1962(d), it is unlawful to conspire to violate any of the substantive provisions of RICO."[144] The Supreme Court has held "a defendant may be held liable under § 1962(d) even where its own actions would not amount to a substantive RICO violation."[145] Such a claim must only allege "an endeavor which, if completed, would satisfy all of the elements of a substantive

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[142] *Id.* at 856.

[143] Defs.' MTD Counts 1-5, at 51-54.

[144] *Ins. Brokerage*, 618 F.3d at 372 (citing 18 U.S.C. § 1962(d)).

[145] *Id.* (citing *Salinas v. United States*, 522 U.S. 52, 65 (1997) (a conspirator can violate § 1962(d) "in any number of ways short of agreeing to undertake all of the acts necessary for the crime's completion")); *see Smith v. Berg*, 247 F.3d 532, 537 (3d Cir. 2001) (under *Salinas*, a defendant "who opts into or participates in a conspiracy" to violate § 1962(c) may be liable "even if the defendant did not personally agree to do . . . any particular element" of the § 1962(c) violation).

[RICO] offense."[146]

The plaintiffs allege the defendants "violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c)." ¶ 348. The defendants mischaracterize the plaintiffs' conspiracy theory when they argue that the plaintiffs "do not offer *any* allegations of an agreement between Sanofi and Novo Nordisk, and instead acknowledge that defendants are 'competitors.'"[147] The defendants ignore the fact that the Complaint alleges that Novo and Sanofi each entered three separate conspiracies with each PBM (CVS, Express Scripts, and OptumRx) for a total of six enterprises.[148] As Count Two for violation of § 1962(d) states, the "object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity." ¶ 2. So the plaintiffs do not, as the defendants claim, "allege that defendants violated section 1962(d) by 'agreeing and conspiring' *with one another* 'to violate 18 U.S.C. § 1962(c).'"[149] Instead, the six conspiracies at issue are between each of the two defendants and each of the three PBMs, ***not*** between the defendants.

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[146] *Salinas*, 522 U.S. at 65; *Ins. Brokerage*, 618 F.3d at 373 (same).

[147] Defs.' MTD Counts 1-5, at 52.

[148] *See* ¶¶ 312-314 (describing the six enterprises, which also constitute conspiracies under section 1962(d)).

[149] Defs.' MTD Counts 1-5 at 51 (emphasis added).

B. The plaintiffs plausibly pleaded Novo and Sanofi violated the New Jersey Consumer Fraud Act.

The defendants erroneously contend the plaintiffs' New Jersey Consumer Fraud Act (NJCFA) claims should be dismissed.[150] The NJCFA is to be construed liberally in favor of consumers.[151] As the New Jersey Supreme Court has emphasized, "[b]ecause the fertility of the human mind to invent new schemes of fraud is so great, the [NJ]CFA does not attempt to enumerate every prohibited practice, for to do so would severely retard its broad remedial power to root out fraud in its myriad, nefarious manifestations."[152]

The elements of a NJCFA claim are (1) an unlawful practice; (2) an ascertainable loss; and (3) a causal relationship between the unlawful conduct and the ascertainable loss.[153] Under the NJCFA, a practice can be unlawful even if the merchant acts in good faith and no one is, in fact, misled or deceived; the central element is the *capacity* to mislead.[154] The NJCFA also does not require proof of reliance[155] or intent to deceive.[156]

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[150] *Id*. at 54-60.

[151] *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 15 (1994).

[152] *Gonzalez v. Wilshire Credit Corp.*, 207 N.J. 557, 576 (2011).

[153] *Id*.

[154] *See Cox*, 138 N.J. at 16-17.

[155] *See Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 607 (1997).

[156] *See id.* at 605; *Cox*, 138 N.J. at 17-18.

a. *Unlawful Conduct*: Novo and Sanofi's artificial benchmark-price inflation was fraudulent and unconscionable under the NJCFA.

Plaintiffs adequately allege unlawful conduct under the NJCFA, which applies to "any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation."[157] *First*, as explained in the RICO section,[158] the defendants' actions constitute deception, fraud, and misrepresentation. By publishing their analog insulin AWPs, the defendants misrepresented them as reasonable pricing benchmarks.

Second, the defendants' conduct constitutes an unconscionable and unfair practice under the NJCFA. As the New Jersey Supreme Court has explained, the "standard of conduct contemplated by the unconscionability clause is good faith, honesty in fact and observance of fair dealing. The need for application of the standard is most acute when the professional seller is seeking the trade of those most subject to exploitation—the uneducated, the inexperienced and the people of low incomes."[159] Courts interpret "unconscionable" liberally to effectuate the

[157] N.J.S.A. § 56:8-2.

[158] *See supra* Argument Part I.B.

[159] *Kugler v. Romain*, 58 N.J. 522, 544 (1971) (emphasis added). *Kugler* was decided before the NJCFA prohibited "unconscionable commercial practices." *See id.* at 525. The legislature added that phrase that in L. 1975, c. 294, § 1.

NJCFA's purpose and "'balance the interests of the consumer public and those of the sellers.'"[160]

The Third Circuit recently recognized that practices not cognizable as fraud can constitute unfair practices under the NJCFA. In *Cottrell v. Alcon Laboratories*,[161] the Court held that consumers had standing to bring a NJCFA claim for the defendant's decision to package its medicated eye drops in a way that forced consumers to waste a portion of their drops. The plaintiffs alleged the practice was unfair, not fraudulent.[162] The district court in *Cottrell* dismissed the NJCFA claims, relying on a Seventh Circuit decision (*Eike*) the defendants cite here. *Eike* held that the plaintiffs' claims were "based simply on [their] dissatisfaction" with the defendants' prices.[163] The Third Circuit disagreed, explaining that the NJCFA and other statutes "prohibit business practices that are 'unfair' or 'unconscionable' in addition to practices that are fraudulent, deceptive, or misleading; these terms are defined separately and differently in the text of the statutes and in relevant case law interpreting them."[164] Thus, the plaintiffs' claims

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[160] *D'Agostino v. Maldonado*, 216 N.J. 168, 184 (2013) (quoting *Kugler*, 58 N.J. at 543-44).

[161] 874 F.3d 154, 165-67 (3d Cir. 2017), *cert. denied sub nom. Alcon Labs., Inc. v. Cottrell*, 2018 WL 1427616 (U.S. May 21, 2018).

[162] *Cottrell*, 874 F.3d at 166.

[163] *Eike v. Allergan, Inc.*, 850 F.3d 315, 317 (7th Cir. 2017).

[164] *Cottrell*, 874 F.3d at 166.

were not "mere grumblings that Defendants' products were priced too high or packaged inefficiently."[165] They were allegations of unconscionable conduct cognizable under the NJCFA.

So too here. Apart from fraud, the plaintiffs plausibly allege the defendants' artificial price inflation constitutes an unfair business practice.[166] Novo and Sanofi knew their artificial AWP increase would cause the plaintiffs to overpay for their drugs. They knew the plaintiffs—the sick, the elderly, the poor, and uninsured—are among the most vulnerable members of society. ¶¶ 218, 268-69, 272. And unlike other excessively priced consumer products, where an individual may simply forgo purchase, the plaintiffs here cannot. ¶¶ 231-33. The defendants' decision to take advantage of this class's vulnerabilities is unconscionable.

b. *Ascertainable Loss*: Novo and Sanofi's artificial price inflation caused the plaintiffs a fixed financial loss.

To meet the NJCFA's ascertainable loss requirement, the plaintiffs must "produce evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss."[167] There are no fixed rules as to how a plaintiff must

[165] *Id.*

[166] *See Kugler*, 58 N.J. at 545-547 (interpreting NJCFA to permit invalidation of sales contracts where, although the purchasers received something of value, the value received was unconscionably disproportionate to the price paid).

[167] *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 249 (2005).

calculate her loss,[168] and the statute does not "require that the loss . . . must be pled beyond a reasonable degree of certainty."[169] Thus, the plaintiff need not plead a specific dollar amount to survive a motion to dismiss.[170] The plaintiff need only allege a definite, measurable loss as opposed to a hypothetical one.[171]

Under those standards, the plaintiffs' damages are readily quantifiable. The "difference in value between the product promised and the one received"[172] is the difference between the defendants' AWPs for analog insulins and a reasonable approximation of the true net prices. In *AWP II*, the First Circuit affirmed the use of expert testimony on what reasonable spreads for the drugs at issue would be and compared them to the actual spreads to ascertain liability and damages.[173] The same can be done here. For example, experts could testify that a reasonable spread

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[168] *See Romano v. Galaxy Toyota*, 399 N.J. Super. 470, 479-81 (App. Div. 2008) (discussing methods for calculating ascertainable loss in different types of consumer fraud cases); *Hammer v. Vital Pharms., Inc.*, 2012 WL 1018842, at *8 (D.N.J. Mar. 26, 2012) (discussing "at least three recognized theories of ascertainable loss").

[169] *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 335 (D.N.J. 2014) (alterations in original) (quoting *Arcand v. Bros. Int'l Corp.*, 673 F. Supp. 2d 282, 300 (D.N.J. 2009)); *Tirri*, 2016 WL 6123146, at *3.

[170] *Dzielak v*, 26 F. Supp. 3d at 336; *In re Gerber Probiotic Sales Practices Litig.*, 2013 WL 4517994, at *5 n.4 (D.N.J. Aug. 23, 2014).

[171] *Shelton v. Restaurant.com, Inc.*, 543 F. App'x 168, 170 (3d Cir. 2013); *Mickens v. Ford Motor Corp.*, 900 F. Supp. 2d 427, 446 (D.N.J. 2012) (no level of specificity required in pleading ascertainable loss).

[172] *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 99 (D.N.J. 2011).

[173] *AWP II*, 582 F.3d at 178 (First Circuit affirming).

between AWP and net price for Novolog is 20%, while the real spread is 60%, such that the plaintiffs' ascertainable loss would be the 40% difference.

The defendants incorrectly contend the plaintiffs impermissibly rely on an "exceedingly amorphous 'price inflation' theory."[174] To support this argument, they cite *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*,[175] which undermines their argument. In that case, the plaintiffs alleged that "misrepresentations made during the course of Schering's off-label marketing plan drove up the market prices of the Subject Drugs and, as a consequence, caused the Plaintiffs to purchase Temodar and the Intron Franchise Drugs at prices higher than they would have paid in the absence of the off-label marketing."[176] The court rejected that theory, explaining that "[i]n reality, the price of prescription drugs are fixed by pharmaceutical manufacturers, not the market."[177] Just so here. Plaintiffs do not allege that the market set inflated insulin prices but rather that the defendants explicitly fixed the inflated AWPs, directly causing the plaintiffs to pay inflated prices.[178]

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[174] Defs.' MTD Counts 1-5 at 60.

[175] *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604 (D.N.J. July 10, 2009).

[176] *Id*. at *21.

[177] *Id*.

[178] The other *Schering-Plough* case cited by the defendants is inapposite. In *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (N.J. Super. Ct.

And the defendants cite an inapposite case, *Dugan v. TGI Fridays, Inc.*,[179] in which the plaintiffs "postulate[d] that by virtue of its policy of leaving beverage prices off its menu, TGIF was able to inflate beverage prices across its market without reducing customer demand." Here in contrast, the plaintiffs allege that the defendants fraudulently inflated their AWPs by as much as 300% over their true net prices, knowing that plaintiffs would pay inflated prices based directly on those AWPs. That is not a market inflation theory. It is a claim that defendants directly set fraudulent prices, where the damages can be set by proof of what reasonable spreads would be compared them to the actual spreads.

c. *Particularity*: The plaintiffs plead their NJCFA claims with sufficient particularity.

The plaintiffs plead their NJCFA counts that sound in fraud (Count 3-4) with sufficient particularity. To satisfy Rule 9(b), "the pleadings must 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."[180] The plaintiffs allege how much the defendants inflated their AWPs, when they inflated them, why they did so, and

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App. Div. 2003), the plaintiffs alleged that "the fact of advertising the products caused the prices to rise both for the ones that are effective and for these, allegedly ineffective, products as well." Plaintiffs here do not allege that advertising caused inflated pricing but instead that the defendants directly set an inflated price.

[179] 231 N.J. 24, 60 (2017).

[180] *Tirri*, 2016 WL 6123146, at *3 (quoting *Smajlaj*, 782 F. Supp. 2d at 84).

with whom they worked to do so.[181] The only specifics not provided are those that are solely within the defendants' knowledge or control. Such specifics cannot and need not be alleged.[182] The Complaint puts Novo and Sanofi "on notice of the precise misconduct with which they are charged."[183] And finally, Rule 9(b) does not apply to the plaintiffs' unconscionable practices allegations, ¶¶ 397-406, which do not depend on allegations of fraud.[184].

C. The plaintiffs plausibly plead Novo and Sanofi violated the state consumer protection laws of the other 49 states.

a. Plaintiffs allege fraudulent, unfair, and unconscionable conduct.

For the reasons set forth in the RICO and NJCFA sections, Novo and Sanofi's artificial price inflation is fraudulent under the state laws of the other 49 states. And as the Third Circuit recently explained in *Cottrell*, "unfair" and "unconscionable" conduct means something different than "fraud."[185] Here, the

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[181] *See supra* Part I.C.

[182] *Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d at 216.

[183] *Seville*, 742 F.2d at 791. The fact that the "alleged transactions are numerous and took place over an extended period of time" also supports this conclusion. *Sunrise*, 793 F. Supp. at 1312.

[184] *Plumbers Local Union No. 690 Health Plan v. Apotex Corp.*, 2017 WL 1822277, at *7 (D.N.J. May 4, 2017) (for NJCFA claims, "Rule 9(b) applies to the extent each such claim 'rests on falsehood or misrepresentations'; Rule 8(a) applies to the extent it rests on 'regulatory violations or unconscionable business practices.'").

[185] 874 F.3d at 165-67.

plaintiffs—who have no choice but to purchase analog insulin—allege that the defendants exploited their age, sickness, and lack of understanding regarding the complexities of the U.S. drug pricing system to overcharge them. Such conduct is unfair and unconscionable.[186]

b. The plaintiffs' state-law claims satisfy Rule 9(b).

Without citing a single allegation in the Complaint, Novo and Sanofi erroneously assert the plaintiffs' state law claims are merely "threadbare recitations of the statutes asserted."[187] In fact, paragraphs 407 to 427 of the Complaint set forth a detailed description of defendants' wrongdoing applicable to all state-law claims. The Complaint then details the elements of each state-law claim, as well as how the defendants violated each statute. ¶¶ 428-866.

The defendants rely on an inapposite decision, *McGarvey v. Penske Automotive Group, Inc.*, in which the plaintiffs did "not even set forth the elements of the fifteen causes of action they assert . . . or explain how the fifteen listed

[186] *AWP II*, 582 F.3d at 160 ("The district court found that AstraZeneca had caused the publication of false and inflated average wholesale prices ('AWPs'), a price used as a benchmark for various reimbursement plans, for its physician-administered drug Zoladex (goserelin acetate), thereby creating a windfall for the appellant's physician customers and causing injury to the government, insurers, and patients who were forced to pay inflated prices…. Discerning no material factual or legal infirmity in the district court's disposition of the case, we affirm."); *Kugler*, 58 N.J. at 545-47 (interpreting the NJCFA to permit the invalidation of sales contracts where, although the purchasers received something of value, the value received was unconscionably disproportionate to the price paid).

[187] Defs.' MTD Counts 6-59 at 5.

statutes apply to the facts of this case."[188] Here in contrast, the plaintiffs set out all the elements of each state-law claim and explain in detail how the defendants violated the statute at issue.[189] The plaintiffs also allege their state-law claims sounding in fraud with sufficient particularity.[190] As explained previously, in the RICO and NJCFA sections, the plaintiffs detailed how much they inflated their AWPs, when they inflated them, why they did so, and with whom they worked to do so.

c. The plaintiffs allege proximate causation.

As explained in the RICO section, the plaintiffs adequately allege the defendants proximately caused the plaintiffs' injuries. The defendants' artificial benchmark price inflation *directly* caused the plaintiffs to overpay for their analog insulins by forcing them to pay higher prices at the point of sale. ¶¶ 336-343. Had

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[188] 639 F. Supp. 2d 450, 465 (D.N.J. 2009), *vacated in part on other grounds on reconsideration*, 2010 WL 1379967 (D.N.J. Mar. 29, 2010).

[189] *See In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 378-79 (E.D.N.Y. 2010) (distinguishing *McGarvey* in holding that "Plaintiffs have drawn the connection between the statutes and defendant's offending conduct," which is "sufficient for defendant and the Court to draw inferences that the elements exist"). The other case the defendants cited is also inapposite. *See In re Suboxone (Buprenorphine Hydrochloride & Naxolone) Antitrust Litig.*, 2017 WL 4642285, at *13 (E.D. Pa. Oct. 17, 2017) (after holding that plaintiffs failed to state claims under antitrust laws, the court explained that "Plaintiffs fail to identify any activities by [the defendant], aside from those set forth in support of the federal antitrust claims, that would invoke liability under any of the identified state statutes").

[190] As explained before, Rule 9(b) does not apply to the plaintiffs' state law claims of unconscionable or unfair practices.

the defendants published AWPs that approximated the true prices of their drugs—rather than set their AWPs based on the spreads they sought to offer PBMs—the plaintiffs would have paid far less. Because "the proximate cause requirements of RICO [are] more stringent than those of most states,"[191] the plaintiffs can meet the state-law proximate cause requirements just as they meet RICO's.

d. The plaintiffs' alleged damages are not speculative.

Novo and Sanofi further argue the plaintiffs' alleged damages are too "amorphous."[192] This argument directly conflicts with *Avandia*, where the Third Circuit held the plaintiff health insurers stated viable RICO injuries because their "damages do not depend on the effectiveness of the Avandia that they purchased, but rather on the inflationary effect that GSK's allegedly fraudulent behavior had on the price of Avandia."[193] The defendants ignore this binding authority.[194]

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[191] *Desiano*, 326 F.3d at 348.

[192] Defs.' MTD Counts 6-59 at 8.

[193] 804 F.3d at 640; *see also In re Warfarin Sodium Antitrust Litig.*, 391 F.3d at 531 (health insurers "like individual consumers, suffered direct economic harm when, as a result of DuPont's alleged misrepresentations, they paid supracompetitive prices for Coumadin").

[194] The defendants rely on two out-of-circuit decisions and a state-law decision. All are inapt. *See In re Hannaford Bros. Co. Customer Data Sec. Breach Litig.*, 660 F. Supp. 2d 94, 100-01 (D. Me. 2009) ("The plaintiffs' claimed damages for temporary lack of access to funds or credit, the annoyance from cancelled hotel reservations, and the embarrassment of obtaining a family loan . . . are speculative and therefore unrecoverable."); *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1332 (S.D. Fla. 2007) (plaintiffs continued taking Lipitor despite arguing that "there is no scientific support for the claim that Lipitor reduces the risk of heart disease in

D. The plaintiffs' state law claims meet all procedural and legal requirements.

a. A class representative from each state is unnecessary.

Novo and Sanofi erroneously assert that plaintiffs "must establish standing as to each of the state laws they seek to assert by alleging facts showing that they suffered injury in each state."[195] Defendants ignore Third Circuit precedent that belies their argument. In *In re Prudential Insurance Co.*,[196] the plaintiffs brought claims under both federal and state law, alleging improper sales and marketing practices by the life insurer Prudential. There were only six named plaintiffs (two married couples and two individuals) who brought claims under federal securities law and the laws of all 50 states.[197] The district court certified a nationwide class and approved a settlement. The Third Circuit affirmed.

In so doing, the Third Circuit rejected the defendants' argument the district court could not exercise Article III jurisdiction over "the federal claims of plaintiff Dorfner, the claims of persons with purely state law claims, and the panoply of

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women or elderly patients"); *Kantner v. Merck & Co.*, 2007 WL 3092779 (Ind. Super. Ct. Apr. 18, 2007) ("Ms. Kantner concedes her claim is no longer for 'excessive price' and that Vioxx is not worth less than previously thought.").

[195] Defs.' MTD Counts 6-59 at 10.

[196] *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283 (3d Cir. 1998).

[197] *Id*. at 293 n.11.

'other' sales claims."[198] The court explained that "whether an action presents a 'case or controversy' under Article III is determined vis-a-vis the named parties."[199] And "'[o]nce threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense.'"[200] The court also rejected the "contention that predominance is defeated because the class claims are subject to the laws of the 50 states."[201] In short, the Third Circuit held Article III was satisfied even though only six named plaintiffs (from four states) represented the class for claims under the laws of all 50 states.[202]

The Third Circuit has since explained that its analysis in *In re Prudential* is not limited to settlement classes.[203] "Nothing in *In re Prudential* [] limited its reach to that of absent *settlement* class members. . . . Nor has our application of *In re Prudential* been limited solely to settlement classes."[204] And the court reaffirmed

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[198] *Id*. at 300.

[199] *Id.* at 306.

[200] *Id*. at 306-07 (quoting 1 Newberg on Class Actions § 2.05 (3d ed. 1992)).

[201] *Id*. at 315.

[202] Defendants cite two district court cases in which the plaintiffs brought only state-law claims. Those courts do not even discuss the Third Circuit's holding in *In re Prudential*, let alone attempt to distinguish it. *See Plumbers Local*, 2017 WL 4235773, at *13; *In re Niaspan Antitrust Litig.*, 2015 WL 8150588, at *3 (E.D. Pa. Dec. 8, 2015).

[203] *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353 (3d Cir. 2015).

[204] *Id.* at 362 n.4 (emphasis in original).

that "[i]n the context of class actions, Article III standing is 'determined vis-a-vis the named parties.'"[205] So there is no merit to defendants' argument the plaintiffs lack standing to assert claims of putative class members under the laws of states in which they neither reside nor were injured.[206]

Defendants misread *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*,[207] which they cite for the proposition that "plaintiffs must have standing as to each claim in the complaint."[208] *Schering Plough* cites the Supreme Court's decision in *DaimlerChrysler Corp. v. Cuno*[209] for that proposition. But *DaimlerChrysler* was *not* a class action and did *not* address the issue raised by the defendants here. Instead, the Court first held that "state taxpayers have no standing under Article III to challenge state tax or spending decisions simply by virtue of

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[205] *Id.* (quoting *McCray v. Fidelity Nat'l Title Ins. Co.*, 682 F.3d 229, 243 (3d Cir. 2012) (quoting *Prudential*, 148 F.3d at 306)).

[206] *See In re Thalomid & Revlimid Antitrust Litig.*, 2015 WL 9589217, at *17 (D.N.J. Oct. 29, 2015) (rejecting argument that "plaintiffs lack Article III standing to assert claims on behalf of putative class members under the laws of states in which they either have not alleged an injury or do not reside" and explaining that whether plaintiffs "may pursue these claims is better left for the class certification stage because 'the issue now [becomes] one of compliance with the provisions of Rule 23, not one of Article III standing.'" (quoting *In re Prudential*, 148 F.3d at 307)); *Ramirez v. STi Prepaid LLC*, 644 F. Supp. 2d 496, 505 (D.N.J. 2009) (citing *In re Prudential* and explaining that "the fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants' calling cards is immaterial").

[207] 678 F.3d 245 (3d Cir. 2012).

[208] Defs.' MTD Counts 6-59 at 9.

[209] 547 U.S. 332, 352 (2006).

their status as taxpayers."[210] The Court then rejected the plaintiffs' attempt to "leverage their standing to challenge the municipal property tax exemption into a challenge to the franchise tax credit," because "a plaintiff must demonstrate standing for each claim he seeks to press."[211] Here, in contrast, the plaintiffs do not have separate "claims" within the meaning of *DaimlerChrysler*. Instead, they base *all* federal and state-law causes of action on the same claim that Novo and Sanofi deceived them into overpaying for insulin, just as all causes of action in *In re Prudential* were based on one claim of misconduct.

b. There is no basis to dismiss claims for products that the named plaintiffs did not purchase.

Defendants erroneously argue that plaintiffs lack standing to bring claims relating to products they did not purchase.[212] Defendants ignore *Marcus v. BMW of North America, LLC*, where the Third Circuit held that "[w]hen a class includes purchasers of a variety of different products, a named plaintiff that purchases only one type of product satisfies the typicality requirement if the alleged misrepresentations or omissions apply uniformly across the different product types."[213] District courts within the circuit have followed this directive.[214] Here,

[210] *Id*. at 346.

[211] *Id.* at 350-351, 352.

[212] Defs.' MTD Counts 6-59 at 11-12.

[213] 687 F.3d 583, 599 (3d Cir. 2012).

Novo and Sanofi's "misrepresentations or omissions apply uniformly across the different" insulins. Rather than cite *Marcus*, defendants rely on two cases decided before *Marcus*, which are inconsistent with this decision.[215]

c. The statutory bars on consumer class actions do not apply to the plaintiffs' lawsuit.

Defendants incorrectly contend that statutory bars to class actions apply to eight of the plaintiffs' state law claims.[216] Federal Rule of Civil Procedure 23 governs class actions in federal courts so long as applying it does not "abridge, enlarge or modify any substantive right."[217] In *Shady Grove*, a plaintiff filed a federal class action seeking statutory penalties even though the New York statute

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[214] *Accord Riaubia v. Hyundai Motor Am.*, 2017 WL 3602520, at *2 (E.D. Pa. Aug. 22, 2017) ("The more persuasive cases cited by the parties confirm this [rule that plaintiffs have standing] in class actions where, like this one, absent members were allegedly injured by the same non-conforming feature of different models of the same product, manufactured or distributed by the same defendants based on uniform representations."); *Neuss v. Rubi Rose LLC*, 2017 WL 2367056, at *6 (D.N.J. May 31, 2017) ("[T]he Court declines to dismiss Plaintiffs' claims as they relate to the products that Plaintiffs have not purchased."); *Cannon v. Ashburn Corp.*, 2016 WL 7130913, at *4 (D.N.J. Dec. 7, 2016) ("Plaintiffs have standing to bring claims regarding the wines with no original price that they have themselves purchased. Whether Plaintiffs also have standing to pursue claims regarding other wines is a question not yet ripe for resolution. The Court will consider this at the class certification stage . . . .").

[215] *See* Defs.' MTD Counts 6-59 at 11 (citing *Lieberson v. Johnson & Johnson Consumer Co., Inc.*, 865 F. Supp. 2d 529 (D.N.J. 2011) and *Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275 (D.N.J. 2011)).

[216] Defs.' MTD Counts 6-59 at 13-14.

[217] *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 407 (2010).

at issue prohibited class actions. The Supreme Court held Rule 23 governed, and the case could proceed as a class action despite the state statute.

Defendants ignore binding Third Circuit precedent that interprets *Shady Grove*. In *Knepper v. Rite Aid Corp.*,[218] a defendant argued that allowing an opt-out class action alleging state laws violations to proceed alongside a separately-filed Fair Labor Standards Act (FLSA) opt-in action would violate the Rules Enabling Act because section 216(b) of FLSA bars opt-out classes. The Third Circuit disagreed.[219] "Under the plurality's view [in *Shady Grove*], any supposed substantive purpose underlying § 216(b) is irrelevant, and we need only determine whether Rule 23 'really regulates procedure,' which the Court has already concluded it does."[220] And "[u]nder the concurrence's view [in *Shady Grove*], the regulation of class relief under § 216(b) is procedural, and class certification does not implicate the Rules Enabling Act."[221] As a result, under "either view," the defendant's argument "fail[ed]."[222]

So too here: any supposed, substantive purpose of the state-law, class actions bars is irrelevant because Rule 23 really regulates procedure (the *Shady Grove*

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[218] 675 F.3d 249 (3d Cir. 2012).

[219] *Id*. at 265.

[220] *Id*.

[221] *Id.*

[222] *Id.*

plurality view) and class certification does not implicate the Rules Enabling Act (the *Shady Grove* concurrence view). As a result, the defendants' argument fails. Indeed, this Court holds that *Shady Grove* permits class certification under state laws that bar class actions in state court.[223] But the defendants ignore these decisions, instead cherry picking a few district court cases from other circuits that are inconsistent with *Knepper*.[224]

d. Only one state consumer protection act requires privity.

Defendants incorrectly contend that the consumer protection statutes of six states apply only if the plaintiffs are direct purchasers or otherwise in privity with the manufacturer.[225] Plaintiffs acknowledge they lack privity under Kentucky law, but defendants' argument under all other state laws lack merit.

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[223] *See, e.g.*, *In re Volkswagen Timing Chain Prod. Liab. Litig*., 2017 WL 1902160, at *24 (D.N.J. May 8, 2017) (rejecting argument "that the Colorado, Georgia, and South Carolina Plaintiffs' claims must be dismissed because those states do not recognize classwide claims for damages"); *In re Liquid Aluminum Sulfate Antitrust Litig.*, 2017 WL 3131977, at *25 (D.N.J. July 20, 2017) ("while the subject statutes may prohibit the Illinois, Alabama, and South Carolina statutory claims from proceeding as class actions, such a bar is inapplicable to this action" under *Shady Grove*).

[224] Defendants cite *Delgado v. Ocwen Loan Servicing, LLC*, 2017 WL 5201079 (E.D.N.Y. Nov. 9, 2017). *Delgado* is inconsistent with Third Circuit law. It is also inconsistent with *Lisk v. Lumber One Wood Preserving, LLC*, 792 F.3d 1331, 1336 (11th Cir. 2015), which held that the Alabama statute restricting class actions "does not apply in federal court. Rule 23 controls." And defendants rely on *Plaza 22, LLC v. Waste Mgmt. of La., LLC*, 2015 WL 1120320, at *2 (M.D. La. Mar. 12, 2015), which did not even acknowledge *Shady Grove*.

[225] Defs.' MTD Counts 6-59 at 14-15.

The Arizona Consumer Fraud Act (ACFA)[226] does not require privity, and the defendants cited authority recognizes that. In *Sutter Home Winery, Inc. v. Vintage Selections, Ltd.*,[227] the plaintiff did not purchase *anything* from the defendant, either as a direct or indirect purchaser. The court explained that the plaintiff "is not a buyer, nor is it the target of deceptive advertising."[228] Here, plaintiffs are both buyers and the targets of the deceptive representations.

The District of Columbia Consumer Protection Procedures Act (DCCPPA)[229] does not require privity. The defendants cite an inapposite decision where the court held "[s]ince no transaction was consummated, section 28-3904(r) does not apply, and [the plaintiff's] allegations that defendants made an 'unconscionable offer' in violation of the DCCPPA fails as a matter of law."[230] The defendants ignore that courts allow indirect purchasers to sue under DCCPPA.[231]

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[226] Ariz. Rev. Stat. § 14-1522, *et seq*.

[227] 971 F.2d 401, 407 (9th Cir. 1992).

[228] *Id.*; *see J-Hanna v. Tucson Dodge Inc.*, 2011 WL 4625759, at *2 (D. Ariz. Oct. 5, 2011) (despite lack of privity, indirect purchaser could bring claim for fraud under ACFA; distinguishing *Sutter Home* on the ground that the plaintiff was not even a "subsequent purchaser" from defendant).

[229] D.C. Code § 28-3901, *et seq.*

[230] *Robinson v. Deutsche Bank Nat'l Tr. Co.*, 932 F. Supp. 2d 95, 103 (D.D.C. 2013).

[231] *See, e.g.*, *Pecover v. Elec. Arts Inc.*, 2010 WL 8742757 (N.D. Cal. Dec. 21, 2010) (certifying class of indirect purchasers for DCCPPA claim); *In re Chocolate Confectionary Antitrust Litig*., 602 F. Supp. 2d 538, 583-584 (M.D. Pa. 2009) (DCCPPA "creates an indirect purchaser cause of action").

Under Chapter 93A (the Massachusetts consumer protection law), the defendants ignore binding decisions holding "a plaintiff need not have purchased the product directly from the defendant" to have a claim.[232] The defendants instead cite an inapposite 1991 district court decision in which the defendants "had no dealings, direct or indirect, with Plaintiffs."[233]

The Vermont Consumer Fraud Act[234] also does not require privity. In *Elkins v. Microsoft Corp.*,[235] the Vermont Supreme Court explained that "consumers can generally sue under § 2461(b) even though they are indirect purchasers of a good or service from the defendant."[236] Defendants ignore *Elkins* and instead cite a non-

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[232] *See Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1223 (Mass. 2018) ("To satisfy the 'trade or commerce' requirement in a failure to warn claim under G. L. c. 93A, § 9, a plaintiff need not have purchased the product directly from the defendant."); *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 762 N.E.2d 303, 314 (Mass. 2002) ("G.L. c. 93A [i]s a clear statement of legislative policy to protect Massachusetts consumers through the authorization of [] indirect purchaser actions.").

[233] *See* Defs.' MTD Counts 6-59 at 15 n.12 (citing *John Boyd Co. v. Bos. Gas Co.*, 775 F. Supp. 435 (D. Mass. 1991)).

[234] Vt. Stat. Ann. Tit. 9, § 2451, *et seq*.

[235] 817 A.2d 9 (Vt. 2002).

[236] *See id*. at 20 and 14 ("[A] privity requirement would seriously undermine the utility of the Act. Virtually all of the representations about the quality and features of a modern automobile are made by manufacturers, most through national and regional media advertisements. If we enforced a privity requirement, the consumer could not reach the perpetrator of consumer fraud.").

precedential, inapposite Second Circuit decision where the court explained that the product at issue "is not available for consumer purchase."[237]

Finally, defendants cite a case in which U.S. District Court for the District of Idaho held that Idaho's Consumer Protection Act (Idaho CPA)[238] denies standing to those injured "merely" as the result of "a contemplated transaction with no contract."[239] But that Act allows a remedy for all purchasers who pay for goods.[240]

e. The plaintiffs adequately allege reliance.

Novo and Sanofi erroneously argue that six plaintiffs do not plead reliance under state law.[241] In *Volkswagen Timing Chain*, this Court rejected that argument, explaining that the "Complaint sufficiently pleads reliance on Defendant's alleged

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[237] *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 435 (2d Cir. 2015) (non-precedential).

[238] Idaho Code § 48-601, *et seq*.

[239] *Moto Tech, LLC v. KTM N. Am., Inc.*, 2013 WL 6446239, at *3-4 (D. Idaho Dec. 9, 2013).

[240] *In re Chrysler-Dodge-Jeep EcoDiesel Mktg., Sales Practices & Prods. Liab. Litig.*, 295 F. Supp. 3d 927, 1021-22 (N.D. Cal. 2018). The court rejected the argument (urged by defendants here) that *Taylor v. McNichols*, 243 P.2d 642, 662 (Idaho 2010), requires a direct contract between the plaintiff and defendant to confer standing. *See also Johnson v. Ford Motor Co.*, 2015 WL 7571841, at *10 (S.D. W. Va. Nov. 24, 2015) (rejecting argument that a car purchaser could not sue Ford under Idaho CPA because she was not a direct purchaser).

[241] Defs.' MTD Counts 6-59 at 15-16. Plaintiffs do not concede that they must plead and prove reliance under the laws of the eight states identified by defendants. However, because the plaintiffs adequately allege reliance under those laws, this Court need not address whether those laws require reliance.

misrepresentations and/or omissions."[242] Similarly, here, plaintiffs adequately allege reliance, as explained above in Part I.D.

f. The plaintiffs adequately allege that sales to residents of certain states constitutes wrongdoing within those states.

Novo and Sanofi incorrectly contend that five state-law claims must be dismissed for lack of wrongdoing within the state.[243] All the cases the defendants cite involve nonresidents transactions that had no connection *whatsoever* to the state whose laws the plaintiffs invoked. In contrast, the plaintiffs here bring all claims on behalf of consumers who *reside* and *purchase* insulin in the particular states whose laws they invoke.

The Illinois Consumer Fraud and Deceptive Business Practices Act (ICFA)[244] applies to claims by Illinois residents who purchase deceptively-marketed products in that state.[245] Here, the ICFA applies to the claims of Illinois

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[242] *Volkswagen*, 2017 WL 1902160, at *24.

[243] Defs.' MTD Counts 6-59 at 16-17.

[244] 815 Ill. Comp. Stat. § 505, *et seq*.

[245] *Barbara's Sales, Inc. v. Intel Corp.*, 879 N.E.2d 910 (Ill. 2007). In *Barbara*, plaintiffs claimed that, "in a massive worldwide advertising campaign," Intel deceived Illinois consumers. The Illinois Supreme Court held "the relevant policy interest of Illinois would be to apply Illinois law to the claims of Illinois consumers, while excluding those claims which do not have a strong connection to Illinois." *Id.* at 921. The Court also explained "the circuit court was correct to limit the class to Illinois consumers only, as the Illinois Consumer Fraud Act applies to transactions that occur 'primarily and substantially' in Illinois." *Id*. at 925. The Court held that transactions by Illinois consumers occurred substantially and primarily in Illinois even though the claims were based on a "massive worldwide

consumers only. Defendants cite an inapposite decision filed by "eighteen Latin American corporations and individuals."[246]

Under the New Hampshire Consumer Protection Act,[247] the "most natural way to read [RSA § 358-A:2] is to construe it to cover a defendant's extra-territorial acts if those acts affect travel or commerce within the state."[248] A defendant may not "injure trade or commerce in New Hampshire" but then "escape liability under RSA § 358-A by remaining outside the state."[249] Defendants cite an irrelevant decision in which no New Hampshire purchase occurred at all.[250]

The New York decision Novo and Sanofi cite undermines their argument under New York's consumer protection act.[251] In *Goshen v. Mutual Life Insurance Co. of New York*,[252] the Court of Appeals held that under § 349, "the transaction in

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advertising campaign" and Intel is a "Delaware corporation with its principal place of business in California." *Id.* at 912.

[246] *De David v. Alaron Trading Corp.*, 2015 WL 2208407, at *1 (N.D. Ill. May 7, 2015).

[247] N.H. Rev. Stat. § 358-A:1, *et seq.*

[248] *Harbour Capital Corp. v. Allied Capital Corp.*, 2009 WL 2185449, at *8-9 (D.N.H. July 22, 2009).

[249] *Id.*

[250] *See* Defs.' MTD Counts 6-59 at 17 n.14 (citing *Mueller Co. v. U.S. Pipe & Foundry Co.*, 2003 WL 22272135 (D.N.H. Oct. 2, 2003)).

[251] N.Y. Gen. Bus. Law §§ 349-350.

[252] 774 N.E.2d 1190 (N.Y. 2002).

which the consumer is deceived must occur in New York."[253] The plaintiff "purchased his policy and paid his premiums in Florida, through a Florida insurance agent. Plainly, for purposes of section 349, any deception took place in Florida, not New York."[254] Unlike in *Goshen*, the putative New York class members purchased insulin in New York, where the deception occurred. Many courts have held that overcharges allegations for drugs purchased in New York state claims under § 349, no matter where the wrongful conduct occurred.[255]

The only cases the defendants cite regarding the Tennessee Consumer Protection Act (TCPA)[256] undermine their argument. In *Encore Medical, L.P. v. Jay Kennedy, D.C.*, the court explained that the "TCPA cannot reasonably be construed to govern conduct occurring throughout the entire United States simply because it somehow relates to a business that was, at one time, located in Tennessee."[257] But the court allowed the plaintiff discovery "in order to tie its

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[253] *Id*. at 1195.

[254] *Id*. at 1196.

[255] *See, e.g.*, *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1173 (N.D. Cal. 2015); *In re Suboxone (Buprenorphine Hydrochloride & Naxolone) Antitrust Litig*., 64 F. Supp. 3d 665, 702 (E.D. Pa. 2014); *In re DDAVP Indirect Purchaser Antitrust Litig*., 903 F. Supp. 2d 198, 228 (S.D.N.Y. 2012).

[256] Tenn. Code Ann. § 47-18-101, *et seq*. The TCPA is to "be liberally construed" to "protect consumers and legitimate business enterprises from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within this state." *Id.* § 47-18-102(2).

[257] 2013 WL 839838, at *31 (W.D. Pa. Mar. 6, 2013).

TCPA claims to specific transactions occurring in Tennessee."[258] Here, Tennessee class members purchased insulin in Tennessee and properly allege TCPA claims.

With respect to the Wisconsin Deceptive Trade Practices Act (DTPA),[259] the Wisconsin Supreme Court has stated that the DTPA's purpose "includes protecting Wisconsin residents from untrue, deceptive, or misleading representation made to induce action."[260] The defendants cite an inapposite case, *Calnin v. Hillard*, in which a U.S. district court explained "there is no evidence of contact between the State of Wisconsin and Stephen F. Schonke's transactions, an element essential to his § 100.18 claim."[261] Here in contrast, the insulin sales at issue took place in Wisconsin. Courts have applied the DTPA to plaintiff purchases in Wisconsin based on fraudulent, nationwide marketing campaigns.[262]

g. The claims under Missouri and Ohio should not be dismissed.

There is no merit to the defendants' argument that the plaintiffs' claim under the Ohio Consumer Sales Practice Act (OCSPA) must be dismissed for failure to "allege rules or judicial decisions under which an alleged practice has been found

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[258] *Id*. at *32.

[259] Wis. Stat. § 110.18.

[260] *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 732 N.W.2d 792, 802 (Wis. 2007).

[261] 2008 WL 336892, at *13 (E.D. Wis. Feb. 5, 2008).

[262] *See, e.g.*, *In re GM LLC Ignition Switch Litig.*, 257 F. Supp. 3d 372, 446-460 (S.D.N.Y. 2017) (allowing claim by Wisconsin purchasers under DTPA).

to be deceptive."[263] First, that argument "is not appropriate at the motion-to-dismiss stage; it belongs at the class certification or summary judgment stages."[264] Second, the plaintiffs allege the defendants' conduct is deceptive under Ohio rules, because "the Ohio CSPA prohibits suppliers from representing that 'a specific price advantage exists, if it does not.'"[265]

Novo and Sanofi's argument that the plaintiffs failed to engage in informal dispute resolution under the Mississippi Consumer Protection Act is similarly meritless.[266] Under *Shady Grove*, such a bar is not enforceable in federal courts, which have dispute resolution procedures under 28 U.S.C. § 652(a) that take place *after* an action is filed.[267]

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[263] Defs.' MTD Counts 6-59 at 17.

[264] *Chapman v. Tristar Prods., Inc.*, 2016 WL 6216135, at *4 (N.D. Ohio Oct. 25, 2016); *accord In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 684 F. Supp. 2d 942, 948 (N.D. Ohio 2009) (same).

[265] ¶ 732 (quoting Ohio Rev. Code Ann. § 1345.02(b)(8)); *see Gerboc v. ContextLogic, Inc.*, 2016 WL 6563684 (N.D. Ohio Nov. 4, 2016) (plaintiffs stated claim under OCSPA for deceptive pricing, based on § 1345.02(b)(8), explaining that "Ohio CSPA and accompanying administrative provisions prohibit deceptive price comparisons by suppliers").

[266] Defs.' MTD Counts 6-59 at 17-18 & n.15.

[267] *See Prado v. Allstate Texas Lloyd's*, 2016 WL 9414132 (W.D. Tex. Nov. 16, 2016) (under *Shady Grove*, state-law mediation requirements did not apply, because 28 U.S.C. § 652 and Fed. R. Civ. P. 16 govern dispute resolution). Defendants cite a district court decision that did not consider whether, under *Shady Grove*, plaintiffs in federal court must attempt dispute resolution under state law before filing suit. *See Humphrey v. CitiBank NA*, 2013 WL 5407195, at *6 (N.D. Miss. Sept. 25, 2013).

IV. CONCLUSION

The plaintiffs request the Court deny the defendants' motion to dismiss the First Amended Complaint, with the sole exception of the Kentucky consumer protection act, which plaintiffs agree requires privity.[268]

[268] If this court dismisses one or more counts, the plaintiffs request that the dismissal be without prejudice. Before their March 29, 2018 amendments to the complaint, none of the plaintiffs' amendments were substantive but rather were consolidations. *See* Class Action Complaint, *Donald Chaires, et al. v. Sanofi U.S., et al.*, No. 1:17-cv-10158, ECF No. 6 (D. Mass. Feb. 2, 2017); Complaint & Demand for Jury Trial, *Donald Chaires, et al. v. Novo Nordisk, et al.*, No. 17-cv-00699, ECF No. 1 (D.N.J. Feb. 2, 2017); Consolidated Class Action Complaint, *Chaires v. Novo Nordisk Inc.*, No. 17-cv-00699, ECF No. 18 (D.N.J. Mar. 17, 2017); *In re Insulin Pricing*, No. 17-cv-00699, ECF No. 82 (D.N.J. Dec. 26, 2017).

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Respectfully submitted,

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