



IN THE SUPREME COURT OF THE STATE OF DELAWARE

<p>TEAMSTERS LOCAL 237 WELFARE FUND; LOCAL 237 TEAMSTERS RETIREES' BENEFIT FUND; LOCAL 237 TEAMSTERS-PLAINVIEW-OLD BETHPAGE CENTRAL SCHOOL DISTRICT HEALTH AND WELFARE TRUST FUND; LOCAL 237 TEAMSTERS-NORTH BABYLON SCHOOL DISTRICT HEALTH AND WELFARE TRUST FUND; LOCAL 237 TEAMSTERS-BRENTWOOD SCHOOL DISTRICT HEALTH AND WELFARE TRUST FUND; AND LOCAL 237 TEAMSTERS-SUFFOLK REGIONAL OFF-TRACK BETTING CORPORATION HEALTH AND WELFARE TRUST FUND, on behalf of themselves and all others similarly situated,</p> <p style="text-align: center;">Plaintiffs-Below, Appellants,</p> <p style="text-align: center;">v.</p> <p>ASTRAZENECA PHARMACEUTICALS LP; AND ZENECA, INC.,</p> <p style="text-align: center;">Defendants-Below, Appellees.</p>	<p>No. 415, 2015</p> <p>APPEAL FROM THE OPINION AND ORDER DATED JULY 8, 2015 OF THE SUPERIOR COURT OF THE STATE OF DELAWARE IN C.A. NO. N04C-11-191-VLM</p>
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TABLE OF CONTENTS

	Page
A. <i>Avandia</i> Does Not Support Appellants’ Theory of Causation	2
B. <i>Avandia</i> Does Not Allow Appellants to Claim “Injury” Based On Their Voluntary Decision to Reimburse for Nexium	5

TABLE OF AUTHORITIES

Page(s)

Federal Cases

In re Avandia Marketing, Sales Practices & Product Liability Litigation,
--- F.3d. ---, 2015 WL 6445640 (3d Cir. Oct. 26, 2015)*passim*

In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.,
2013 WL 5761202 (E.D. Pa. Oct. 23, 2013) 1

Desiano v. Warner-Lambert Co.,
326 F.3d 339 (2d Cir. 2003) 3, 4

In re Neurontin Mktg. & Sales Practices Litig.,
712 F.3d 21 (1st Cir. 2013)..... 3, 4

In re Warfarin Sodium Antitrust Litigation,
391 F.3d 516 (3d Cir. 2004) 4

Appellants' Reply Brief relies heavily on in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, --- F.3d. ---, 2015 WL 6445640 (3d Cir. Oct. 26, 2015), where the Third Circuit affirmed the denial of a motion to dismiss RICO claims brought by third-party payers ("TPPs"). The *Avandia* plaintiffs alleged that the defendant (GSK), in marketing a diabetes drug, fraudulently concealed significant safety risks that ultimately led the FDA to prohibit doctors from prescribing it except in limited circumstances. *Id.* at *2-3. In pleading causation and injury, the TPP plaintiffs did not merely allege deception of the general public. Rather, they expressly alleged that they "included Avandia in their formularies and covered Avandia at favorable rates *in reliance* on these misrepresentations by GSK." *Id.* at *3 (emphasis added).¹

In contrast, the TPP appellants here do not and cannot allege that they themselves even received AstraZeneca's marketing, much less acted in reliance on it, in deciding to cover Nexium. They also do not allege that Nexium poses a safety risk that would have prevented a reasonable physician from prescribing it. These distinctions highlight why Appellants' claims here fail as a matter of law.

¹ *See also id.* (noting allegation that "the TPPs themselves relied upon those misrepresentations in making formulary decisions"); *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 2013 WL 5761202, at *2, 10 & n.54 (E.D. Pa. Oct. 23, 2013) (plaintiffs alleged marketing to TPPs affecting formulary decisions: "Plaintiffs are TPPs who allege that they themselves relied on misinformation GSK provided.").

A. *Avandia* Does Not Support Appellants' Theory of Causation

Appellants argue that *Avandia* supports their theory of causation by holding that a TPP's overpayment for a deceptively advertised drug constitute a sufficiently direct injury. Reply 2-4. In *Avandia*, however, the TPP plaintiffs themselves allegedly relied on the deceptive conduct in choosing to put *Avandia* on their formularies, thus providing a direct causal link between the challenged conduct and their injury in paying for *Avandia* prescriptions. In explaining why patients and physicians did not break the causal chain, the Third Circuit emphasized that the issue was not about whether “a doctor’s decision to prescribe *Avandia* or a patient’s decision to take *Avandia* caused plaintiffs’ injuries.” *Avandia*, 2015 WL 6445640, at *8. Instead, “[t]he conduct that allegedly caused plaintiffs’ injuries is ... the misrepresentation of the heart-related risks of taking *Avandia* that *caused TPPs and PBMs to place Avandia in the formulary.*” *Id.* (emphasis added).

Unlike the TPPs in *Avandia*, Appellants here do not allege that the marketing they seek to challenge affected their decision to place Nexium in their formularies or those of their PBMs. That cannot be their theory, because – knowing all they claim to know of the “truth” about Nexium – they still have it in their formularies. Instead, their theory of injury necessarily and wholly depends on their speculation that, in the absence of the challenged advertising, some of their members’ prescribing physicians would have prescribed a less expensive

alternative to Nexium. As the Superior Court observed and AstraZeneca has explained, courts routinely dismiss TPP claims under these circumstances, especially when, as here, Appellants cannot even allege what, if any, misrepresentations their members' physicians actually were exposed to. AAB 11-15 & n.8.

Appellants also use *Avandia* as an excuse to discuss other cases that they otherwise inexplicably failed to cite in their Opening Brief, such as *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003), and *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). See Reply 2 n.3, 5, 6-7. AstraZeneca addressed those cases in briefing before the Superior Court and would have discussed them in the Answer had Appellants cited them.² Like *Avandia*, these cases serve only to highlight the key allegations that Appellants here cannot plead.

In *Desiano*, the TPP plaintiffs pleaded that “had they not been deceived by the Defendants’ misrepresentations about the safety of Rezulin, they would have taken steps so as not to purchase Rezulin,” including “exclud[ing] it altogether from their approved schedules.” 326 F.3d at 349 n.9. Those allegations, the court held, established that “the harm to the insurers was *not indirectly caused as a result*

² See B187-89 (responding to such cases in briefing below); AAB 15 n.9 (observing that Appellants’ Opening Brief abandoned reliance on cases they had cited involving direct TPP deception).

of the Defendants' misleading of others; the insurers were *directly harmed* by the deception practiced on *them*." *Id.* (emphasis added).

Likewise, in *Neurontin*, the TPP alleged that its "employees directly relied on Pfizer's misrepresentations in preparing monographs and formularies." 712 F.3d at 40. Moreover, the plaintiffs alleged that the drug was "*ineffective* for the promoted off-label uses," rather than claiming injury merely because physicians could have prescribed a cheaper alternative. *Id.* at 46-48 (emphasis added). The First Circuit noted that the "cheaper alternative drug" theory "has been rejected by numerous courts," and "we do not pass on the 'cheaper alternatives' theory." *Id.* at 48 n.20.

Here, unlike in *Avandia*, *Desiano*, or *Neurontin*, there is no dispute that Nexium is safe and effective, and Appellants do not allege that they themselves received any marketing or were deceived. Appellants solely assert the indirect-causation, "cheaper alternative drug" theory that numerous courts have rejected, that *Desiano* and *Neurontin* cast doubt upon, and that was not at issue in *Avandia*.³

³ *Avandia* and Appellants' Reply also cite *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516 (3d Cir. 2004), but *Warfarin* – which only evaluated issues in the context of a class settlement – was an antitrust case premised on TPPs' paying supracompetitive pricing. See B187-88. *Avandia* cites *Warfarin* for the proposition that a TPP's payment for a drug may be actionable when the injury is caused by unlawful behavior, but *Avandia* does not establish that a sufficient causal connection exists under the facts alleged here.

B. *Avandia* Does Not Allow Appellants to Claim “Injury” Based on Their Voluntary Decision to Reimburse for Nexium

Appellants also cite *Avandia* in response to the point that their voluntary decision to cover Nexium also prevents them from alleging causation and injury. *See* AAB 6, 16-18; Reply 8-9. Contrary to what Appellants assert, *Avandia* did not hold that a TPP can allege injury despite keeping the drug on its formulary after filing suit. *See* Reply 9. The court simply found it unclear from the complaint *whether* the plaintiffs “knew the full scope” of the alleged fraud and failed to change their coverage. *Avandia*, 2015 WL 6445640, at *9. Here, Appellants knew the “full scope” of the alleged fraud when they filed this action in 2004, and they admit in their 2014 amended complaint that they continue to pay for Nexium. AAB 17-18.

Moreover, because *Avandia* involved allegations of an unsafe drug and deception affecting the TPP’s formulary decision, it did not address the issue presented here. TPPs exercise business judgment in deciding whether to include a drug on their formulary, and physicians have no duty to choose a drug based on what is the cheapest alternative for the TPP. Thus, TPPs like Appellants suffer no cognizable “injury” when (a) they do not allege being deceived in their business

decisions; and (b) physicians have prescribed a medically appropriate, safe and effective drug (like Nexium) that the TPP has voluntarily agreed to cover.⁴

For the foregoing reasons, AstraZeneca respectfully requests that this Court affirm the judgment dismissing the Second Amended Complaint with prejudice.

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⁴ For this reason, the analogy to shoplifting in a bookstore – as cited in the Reply at page 9 – is inapt. Store owners do not make a business judgment to allow shoplifting. They make a business judgment about what books to carry. If a customer buys a certain book, the seller cannot complain that alternative books yield better profit margins. Similarly, TPPs are in the business of deciding whether to cover a drug. If a physician exercises medically appropriate judgment to prescribe a drug the TPP has decided to cover, the TPP suffers no injury.

CERTIFICATE OF SERVICE

I, Michael P. Kelly, Esquire, hereby certify that, on November 16, 2015, a true and correct copy of the foregoing Appellees Sur-Reply Brief has been served on the following counsel listed below via File & ServeXpress:

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