REDACTED

No. 18-1010
United States Court of Appeals
For the Third Circuit

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND
and J.B. HUNT TRANSPORT SERVICES, INC.

Plaintiff-Appellants

v.

GLAXOSMITHKLINE LLC

Defendant-Appellee

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

MDL No. 07-md-01871; Civ. A. Nos. 2:10-cv-02475-CMR & 2:11-cv-04013-CMR

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CORPORATE DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1, the Plaintiff-Appellants state as follows:

Plaintiff-Appellant United Food and Commercial Workers Local 1776 and Participating Employers Health and Welfare Fund (UFCW) has no parent corporations, and no publicly held company owns 10% or more of its stock.

Plaintiff-Appellant J.B. Hunt Transport Services, Inc. (J.B. Hunt) has no parent corporations, and no publicly held company owns 10% or more of its stock.

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JURISDICTIONAL STATEMENT

UFCW and J.B. Hunt bring this lawsuit on behalf of a proposed class of United States health benefit providers (the plans) that purchased the branded prescription drugs Avandia, Avandamet, and Avandaryl (collectively, Avandia). The plans allege that GlaxoSmithKline LLC (GSK) concealed cardiovascular risk data about Avandia and falsely marketed the product in violation of the Racketeer-Influenced and Corrupt Organizations Act (RICO)[1] and state consumer protection laws.

Subject matter jurisdiction over the RICO claims exists under 28 U.S.C. §§ 1331, 1337 and 15 U.S.C. § 15. Subject matter jurisdiction over the state law claims exists under 28 U.S.C. § 1332(d) because at least one member of each of the putative classes is a citizen of a different state from defendant GSK and the amount in controversy in each case exceeds the sum or value of $5,000,000, exclusive of interest and costs.[2] Appellate jurisdiction exists under 28 U.S.C. § 1291 because the district court granted summary judgment to GSK on all claims in a final order on December 7, 2017.[3] The plans timely appealed on January 2, 2018.[4]

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[1] 18 U.S.C. §§ 1961-1968.

[2] JA-1275 (¶16) (complaint of UFCW (UFCW-complaint)).

[3] JA-0004.

[4] JA-0001.

STATEMENT OF ISSUES

1. *Dismissal of plaintiffs' allegations regarding GSK's false claim of cardio-protective benefits*. Fundamental due process requires a district court to address the claims or defenses of a party based on the applicable procedural rules or substantive law. A proposed class of U.S. health-benefit providers has claimed – in their complaints, in defeating a Rule 12(b)(6) motion, in defending an interlocutory appeal to this Court, and at summary judgment back before the district court – that GSK falsely marketed Avandia as cardio-protective for diabetic patients (when it was not), costing the plaintiffs billions in unnecessary prescriptions. Misapprehending this claim as "new," and without indicating a procedural or legal basis to do so, the district court dismissed the claim. Did the court err when it refused to "entertain[]" the plaintiffs' claims that GSK false marketed Avandia as providing "cardiovascular benefits"?[5]

2. *Dismissal of plaintiffs' allegations regarding GSK's concealment of Avandia's cardiovascular risks.* Under the Supreme Court's decision in *Wyeth v. Levine*,[6] the Food Drug and Cosmetics Act (FDCA) preempts a plaintiff's state law claim that a drug maker failed to warn of a drug defect only where there is "clear

[5] JA-1290-91 (¶74), JA-1453, SA-1035 (raised); SA-1035, SA-1760-61, JA-2331 (objected to); USA-04 (ruled upon).

[6] 555 U.S. 555 (2009).

evidence" the FDA would have rejected the requested warning. Since 2007, the FDA has *required* GSK to warn of Avandia's cardiovascular risks through the description of short-term, long-term, and observational clinical trials and studies on the drug's label. To this day, the first page of Avandia's label contains a black box warning for potential heart failure. Misunderstanding that this black box had been removed, did the district court err when it ruled clear evidence established the FDA would have rejected addition of accurate cardiovascular warnings to Avandia's label prior to 2007?[7]

3. *Dismissal of the plaintiffs' RICO allegations*. Under RICO and the law of this Circuit, when a corporation joins with third parties to pursue a common fraudulent purpose, the resulting association-in-fact enterprise meets RICO's distinctiveness requirement, and the corporation can be held liable for its role. The plans allege that GSK joined with another pharmaceutical company, an independent physician, and a number of third-party marketing firms to falsely promote Avandia as cardio-protective while hiding the drug's real cardiovascular risks. Misapprehending these third parties as GSK's "agents," did the district err

[7] JA-1269-73 (¶¶1-9), JA-1289-92 (¶¶ 71-77), JA-1326-34 (¶¶ 202-70), SA-1045-58 (raised); SA-1045-58 (objected to); USA-24-26 (ruled upon).

when it ruled the plans' RICO allegations failed to meet the statute's distinctiveness requirement?[8]

[8] JA-1279-80 (¶¶30, 35), JA-1319-23 (¶¶171-88), SA-1059-62 (raised); SA-1059-62 (objected to); USA-16 (ruled upon).

STATEMENT OF RELATED CASES

There is one case related to this appeal pending before District Court for the Eastern District of Pennsylvania: *County of Santa Clara v. SmithKline Beecham Corp., d/b/a GlaxoSmithKline, LLC*, MDL 07-md-1871, Civ. A. No. 10-cv-1637. This action was previously before the Third Circuit in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015).

STATEMENT OF THE CASE

This case arises from the largest healthcare fraud in U.S. history. In 2012, GSK paid over $650 million to settle federal and state civil charges that it falsely promoted Avandia to physicians and other health care providers as providing cardiovascular benefits it did not. GSK also paid a $250 million criminal fine to settle charges that, between 2001 and 2007, GSK concealed data concerning the cardiovascular safety of Avandia. Together with charges related to two other drugs, GSK agreed to pay a total of $3 billion.[9]

Cardiovascular disease is leading cause of death for the 27 million Americans living with type-2 diabetes. As of 1999, the standard of care for type-2 diabetes consisted of two inexpensive drugs: metformin and sulfonylureas. But these drugs did nothing to address type-2 diabetics' elevated cardiovascular risks. As a result, medications that both treated high blood sugar *and* reduced cardiovascular risk were needed.

GSK exploited that need in order to sell Avandia. Launched in 1999, GSK's Avandia was considerable more expensive than metformin or sulfonylureas. Yet, it

[9] Press Release, Dep't of Justice, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

became the standard of care, bringing in billions annually, because GSK promised it would reduce type-2 diabetics' inherent cardiovascular risks.

There was just one problem: Avandia did not reduce cardiovascular risk; it *increased* it. What's worse, GSK knew this before it sold a single tablet of Avandia on the U.S. market. The company's own clinical trials revealed Avandia elevated cholesterol ratios – a known risk factor for heart disease – and cardiac risk in type-2 diabetics. Yet, through a scientifically dishonest marketing campaign in combination with a selective publication strategy, GSK and its associates managed to conceal this lie for nearly a decade.

In 2007, the New England Journal of Medicine exposed GSK's fraud. Two researchers aggregated data from GSK's clinical trials and found Avandia was associated with increased, not reduced, cardiovascular risk.

The reaction to this revelation was swift and severe. The FDA required GSK to place a black box warning on Avandia's label. Pharmacy Benefits Managers (PBMs) dropped it from their formularies. Doctors stopped prescribing it. Congress enacted a new law requiring pharmaceutical companies to disclose the results of all clinical trials. And consumers, health plans, and the federal government filed lawsuits against GSK.

By 2012, GSK reached its $3 billion settlement with DOJ. Two years prior, a proposed class of private health plans brought similar charges against GSK,

seeking damages for their unnecessary purchases of Avandia, at inflated prices, over the course of a decade. Filed in 2010, that case was consolidated with a massive (mostly mass tort) MDL (the Avandia MDL).

GSK moved to dismiss in 2010; the motion was denied in 2013. But the district court certified an interlocutory appeal of this decision in 2014. In October 2015, this Court affirmed denial of the 12(b)(6) motion. Back before the district court in 2016 – and with all other aspects of the Avandia MDL nearly concluded – the district court permitted GSK to present a summary judgment motion even though the plans had not yet been permitted an opportunity to conduct discovery specific to their claims. In its summary judgment motion, GSK argued: (1) the FDCA preempted the plans' state law claims, and (2) the plans did not adequately plead a RICO enterprise. A year and a half later, the district court granted GSK's motion for summary judgment, basing its dismissal on three grounds.

First, the court misunderstood *half* of the plans' factual allegations – that GSK falsely promoted Avandia as cardio-protective when it had no scientific basis to do so – as "new." Based on this misapprehension, the court decided it would "not entertain[]" a critical piece of the plans' claims.[10]

Second, the district court mistakenly believed the FDA permitted GSK to remove, during the pendency of this case, the black box warning on the drug's

[10] USA-04 (summary judgment decision).

label concerning Avandia's cardiovascular risks. Based on this and similar misimpressions regarding the FDA's position, the district court found the FDA's actions preempted the plans' state law claim that GSK concealed Avandia's cardiovascular risks between 1999-2007.

Third, the district court mischaracterized all third parties that helped GSK mismarket Avandia as cardio-protective and mitigate evidence of its cardiovascular risks as mere "agents" of GSK. Based on this misconstruction, the court incorrectly ruled the plans' RICO allegations failed to plead an "enterprise" distinct from GSK itself.

This case involves the exact same misrepresentations, the same indifference to patient welfare, the same exploitation of the diabetes epidemic, and the same criminal irresponsibility as GSK's massive 2012 fraud settlement with the federal and state governments. The private health plans seek to recover, under RICO and state law, only what the government has already obtained for public plans. At the motion to dismiss stage, the district court credited the plans' theory. In an interlocutory appeal, the Third Circuit affirmed. When GSK asked the Supreme Court to weigh in, it denied certiorari. No basis for dismissal of the private payer claims exists. The judgment should be vacated, the matters remanded for full discovery and trial.

FACTS

A. Cardiovascular disease is the leading cause of death in patients with type-2 diabetes.

The greatest threat to those living with type-2 diabetes is cardiovascular disease: more than 65% of the 27 million Americans living with type-2 diabetes diabetics will die of cardiovascular causes.[11] As a result, "reduction of cardiovascular risk is a primary goal of any diabetes treatment."[12] Control of type-2 patients' cholesterol is also necessary, as high total cholesterol ratios[13] are known risk factors for heart disease.[14]

By the late 1990s, treatment for type-2 diabetes consisted of inexpensive oral medications – sulfonylureas and metformin – that lower patient blood sugar levels.[15] But these drugs did nothing to lower type-2 patients' inherent cardiovascular risks.

In the 1990s, pharmaceutical companies began to market a new class of type-2 medications – thiazolidinediones (TZDs) – that lower blood sugar levels by treating insulin resistance. On May 25, 1999, the FDA approved one such TZD:

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[11] JA-1065 (Nissen study).

[12] JA-0039 (motion to dismiss decision).

[13] The relevant cholesterol ratios are: total cholesterol over High-Density Lipoprotein (HDL, the "good" cholesterol) and Low-Density Lipoprotein (LDL, the "bad" cholesterol) over HDL.

[14] SA-0690 (¶¶81-82) (expert report of John Abramson (Abramson)).

[15] JA-1277-78 (¶¶23, 25, 26) (UFCW-complaint).

Avandia (generic name rosiglitazone).[16] And two months later, it approved another: Actos (generic name pioglitazone).[17] GSK priced Avandia significantly higher than metformin and sulfonylureas. In the early 2000s, a one-month supply of Avandia sold for around $220 (with patients' health plans typically covering between $135 and $140 per prescription), whereas metformin and sulfonylureas cost only $45 to $55 (with health plans covering $40 to $50).[18] GSK's justification for this price differential was simple: Avandia both lowers blood sugar levels *and* reduces inherent cardiac risks, making it superior to metformin and sulfonylureas.

B. Pre-1999: GSK knew Avandia *increased* cardiovascular risks.

Yet before Avandia ever entered the U.S. market, GSK knew this claim was false. In 1997, GSK ran a clinical trial, Study 011, [redacted].[19] This outcome defeated the whole purpose of Avandia, and GSK knew it. As one senior GSK official wrote: "[redacted]

[16] JA-0955 (FDA approval letter).

[17] Food & Drug Admin. Ctr. for Drug Evaluation & Research, Actos Approval (July 15, 1999), https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/021073A_Actos_appltr.pdf.

[18] JA-0012-13 (3d Cir. decision).

[19] SA-0033-34 (Study 011); SA-0792 (¶¶436-37) (Abramson).

[redacted]

[redacted]"[20]

Completed March 1998, GSK's Study 079 showed that Avandia, [redacted]

[redacted]

[redacted]

[redacted].[21] Two months later, Study 020 [redacted].[22]

GSK's Study 093, completed April 1998, [redacted]

[redacted]. At the end of the study, [redacted]

[redacted]

[redacted].[23] Patients treated with

Avandia [redacted]

[redacted].[24]

When aggregated, the data from GSK's early clinical trials showed [redacted]

[redacted]

[redacted]

[20] SA-0029 (email of GSK vice-president).

[21] SA-0056-57 (Study 079); SA-0800-01 (¶¶469-72) (Abramson).

[22] SA-0043-44 (Study 020); SA-0793-97 (¶442, 454) (Abramson). [redacted]

[23] SA-0073-74 (Study 093); SA-0806 (¶490) (Abramson).

[24] SA-0073-74 (Study 093); SA-0806-07 (¶491) (Abramson).

[redacted]

In sum, before GSK sold a single tablet of Avandia in the U.S., it knew its data indicated the drug [redacted]

C. 1999 to May 2007: Despite its knowledge, GSK marketed Avandia as reducing cardiovascular risk.

Rather than informing physicians, plans, PBMs, and patients of these serious risks, GSK did the exact opposite. Capitalizing on the dearth of information regarding the link between cardiovascular disease and diabetes, GSK peddled a false syllogism. It told the medical community that insulin resistance was the core defect leading to cardiovascular complications in type-2 diabetics. [redacted]

[25] SA-0684 (¶56) (Abramson).

[26] *Id*.

[redacted]

[redacted][27] The slide below illustrates this assertion.[redacted]

But GSK's insulin resistance story was fiction. As another GSK official wrote, [redacted]

[redacted]."[29]

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[27] SA-0101 (GSK strategic planning document emphasizing that GSK must "[e]ntrench the concept of insulin resistance as the primary culprit in long term [cardiovascular] complications"); SA-0090 (2000 medical marketing meeting slides); SA-0719, 734 (¶178, 236) (Abramson); SA-0105 (2000 email attachment); SA-0093-94 (CME monograph).

[28] SA-0738 (Abramson).

[29] SA-0106 (2000 email attachment) (emphasis added).

With a criminal disregard for this reality, GSK kicked off one the largest false marketing campaigns in the history of the pharmaceutical industry. To make their prescription and formulary decisions, doctors, PBMs and other stakeholders rely on four principal sources of information: (1) reported results of clinical trials; (2) drug marketing materials; (3) continuing medication education (CMEs) seminars and lectures; and (4) drug labels. GSK and its associates infected all four.

1. GSK manipulated or hid unfavorable clinical trial results.

Randomized, controlled clinical trials are the "gold standard" by which the medical community evaluates prescription drugs.[30] Doctors are expected to rely on these trials when making treatment decisions,[31] and many consider the under-reporting of clinical trials – or the burying of bad results – "scientific misconduct."[32] [redacted][33]

But after Glaxo Wellcome merged with SmithKline Beecham to form GSK, [redacted]

[30] JA-0984 (chapter in medical textbook).

[31] *Id.*

[32] JA-0865 (academic article).

[33] SA-0108 (2001 GSK Publication Policy Proposal).

[redacted]

[redacted].”[34]

GSK then manipulated the results of key Avandia trials so unfavorable results appeared positive. For example, GSK [redacted], completed in 2000, [redacted].[35] In reality, [redacted] [redacted][36] What’s more, [redacted] [redacted]*s*. As GSK’s principal statistician warned, [redacted] [redacted][37]

GSK similarly misrepresented the results of Study 011. When GSK published this study, it reported that [redacted]

[34] SA-0110 (2001 GSK Publication Policy Proposal).

[35] SA-0726 (¶¶202-04), SA-0802 (¶¶475-76) (Abramson); SA-0983-84 (¶¶1100, 1103); SA-0091 (2000 medical marketing meeting slides).

[36] SA-0155-56 (Study 080).

[37] SA-0228 (email from GSK principal statistician). [redacted]

[redacted][38] However, it declined to disclose the more important result: [redacted] GSK also misrepresented the results of studies 020, 024, 090, 093, 094, and 108, among many others.[40]

GSK hid other studies entirely. Until 2007 (when the truth about Avandia began to emerge), no law required drug companies to disclose unfavorable clinical trial results – either to the FDA or the public.[41] GSK exploited this oversight. For example, GSK did not publish [redacted].[45] When a GSK employee inquired

[38] JA-0870 (academic article).

[39] SA-0033-34 (Study 011); SA-0792-93 (¶440-41) (Abramson).

[40] SA-0793-802 (¶¶442-546) (Abramson).

[41] In 2007, Congress enacted the Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823, requiring the disclosure of all clinical trials, other than Phase I trials.

[42] SA-0056-57 (Study 079); SA-0171 (email from GSK vice-president); SA-0800-01 (¶471-72) (Abramson).

[43] SA-0171 (email from GSK vice-president).

[44] SA-0063 (Study 096).

[45] SA-0812 (¶509) (Abramson).

[redacted]

In fact, [redacted][48] In this proposal, GSK cited an "[redacted]

[redacted]

2. GSK falsely marketed Avandia through direct advertisements to doctors and others.

GSK also misled doctors and other health care professionals through direct marketing materials. In spite of Avandia's associated cardiovascular risks, GSK marketed Avandia as "[redacted]"[50] As one public relations firm put it: "[redacted]

[46] SA-0171 (email from GSK vice president).

[47] *Id.*

[48] SA-0109 (2001 GSK Publication Policy Proposal).

[49] *Id.*

[50] SA-0744 (¶270) (Abramson).

[redacted][51]

In 2002, GSK listed its key marketing goals as:

- [redacted]
- [redacted]
- [redacted]

GSK relied heavily on these false claims to market Avandia to PBMs, the entities in control of health plan formularies. GSK told a "[redacted]" to [redacted][53]: even if one pill of Avandia cost more than one pill of metformin or a sulfonylurea, covering prescriptions of Avandia would reduce larger health costs down the road (such as those associated with heart disease) making the investment in Avandia economically sound.

[51] SA-0738 (¶248) (Abramson).

[52] SA-0760-61 (¶323-24) (Abramson).

[53] SA-0084 (1999 Avandia Launch Plan).

GSK showed equal disregard for Avandia's negative impact on patient cholesterol levels. Despite numerous clinical trials to the contrary, GSK instructed its drug representatives to "[redacted]"[54] In fact, GSK used its unfavorable clinical trial results to *promote* Avandia. In the marketing graphic below, [redacted][55]

[redacted]

As previously explained, these studies – when properly interpreted – were averse to Avandia. But through key omissions and distortions, GSK presented them

[54] SA-0966 (¶1053) (Abramson).

[55] SA-0983-84 (¶¶1100-03) (Abramson).

positively.[56] Privately, GSK executives acknowledged that [redacted] ”[57]

3. GSK falsely promoted Avandia through CME programs.

GSK also used CME programing as a platform to spread misinformation about Avandia. Required by a majority of states to maintain medical licensure, CMEs “serve to maintain, develop, or increase the knowledge, skills, and professional performance” of physicians.[58] GSK developed a CME program called the “[redacted].[59] In these courses, [redacted]” and “[redacted]”[60] But the GSK-funded materials they used made no mention of [redacted]. To ensure attending physicians internalized GSK’s false claims, [redacted]

[56] *Id*.

[57] SA-0087 (email from GSK’s principal statistician).

[58] JA-0968 (academic article).

[59] SA-0170 (Cardio-Alliance emails); SA-0742 (¶263) (Abramson).

[60] SA-0093-94 (CME monograph).

[redacted][61]

4. GSK did not warn of Avandia's cardiovascular risks on Avandia's drug label.

Finally, physicians and all other health care professionals rely on the information provided in manufacturers' drug labels when making their coverage and prescription decisions. When Avandia first entered the market, its label did not mention any cardiovascular risk at all.[62] In February 2001, GSK added information regarding the cardiovascular risks associated with combination Avandia and insulin treatment.[63] GSK also added a warning that "Avandia, like other [TZDs], alone or in combination with other antidiabetic agents, can cause fluid retention, which may exacerbate or lead to heart failure."[64] But the label made no mention of GSK's studies showing Avandia to be associated with increased cardiovascular risk or elevated cholesterol levels.

[61] SA-0095-96 (CME monograph).

[62] JA-0577-98 (1999 Label).

[63] JA-0612 (2001 Label).

[64] *Id.*

From launch in 1999 until early 2007, GSK's false marketing made Avandia a blockbuster success. In 2006 alone, Avandia commanded [redacted] in U.S. sales [redacted].[65] By 2007, Avandia had become a standard treatment for Americans living with type-2 diabetes.

D. 2007-2010: Avandia's true cardiovascular risk data emerged.

On May 21, 2007, Dr. Steven Nissen and Cathy Wolski aggregated the results of 42 GSK clinical trials and found that, relative to all pooled comparators (metformin, sulfonylurea, insulin, and placebo), Avandia was associated with a statistically significant, *43% increase* in risk of heart attack (the Nissen study).[66] In other words, when the results of 42 different trials – some which tested Avandia versus metformin, others which test Avandia versus a placebo, etc. – were combined, Avandia increased risk of heart attack 43% more than all the other comparators combined.

On July 30, 2007, the FDA convened an advisory committee to address the Avandia revelation. FDA officials presented data showing Avandia had no cardiovascular benefits whatsoever: "[n]o macrovascular benefits," "[n]o microvascular benefits," "no clear advantage over other oral anti-diabetes drugs for

[65] SA-1131 (¶148) (Plans' Fact Proffer).

[66] JA-1065-66, 1076 (Nissen study) (Table 5).

a variety of intermediate outcomes," and "no unique advantage over [Actos]."[67] Avandia only posed *cardiovascular risks.*

The advisory committee voted overwhelmingly to place a black box warning – the strictest warning the FDA can demand[68] – on the front of Avandia's label.[69] Added on August 14, 2007,[70] this black box warned of Avandia's potential cardiovascular risks.[71] The black box remains on the Avandia label to this day.

In November 2007, GSK further disclosed, for the first time, the cardiovascular results of Avandia's shorter- and longer-term trials on its label. GSK explained that a meta-analysis of 42 clinical trials revealed "an increased risk of myocardial ischemia with AVANDIA versus pooled comparators" and "[a]n increased risk of myocardial ischemic events with AVANDIA" versus a placebo.[72] GSK also added a bullet point regarding these result to the drug's black box warning.[73] GSK also added a description of three large, long-term, prospective, randomized, and controlled clinical trials to Avandia's label. As GSK explained,

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[67] JA-1089 (2007 FDA slide show).

[68] *See* 21 C.F.R. § 201.57(c)(6)(i).

[69] JA-1085-086 (summary of minutes FDA 2007 meeting).

[70] JA-1090 (2007 FDA letter to GSK).

[71] JA-0708.

[72] JA-0747.

[73] JA-0742-43.

these trials did not show a "statistically significant[] differen[ce]" between Avandia and comparators for three clinical endpoints (major adverse cardiovascular events,[74] myocardial infarction, and total mortality).[75] Thus, while the long-term data did not show Avandia was *worse* than comparators, it debunked GSK's position that Avandia offered *improved* results over comparators.

Throughout 2007, numerous tort actions were filed against GSK for its failure to warn of Avandia's cardiovascular risks. In October of 2007, these cases were consolidated in the Eastern District of Pennsylvania under MDL No. 1871.[76] This MDL eventually covered all consumer and personal injury cases regarding Avandia.

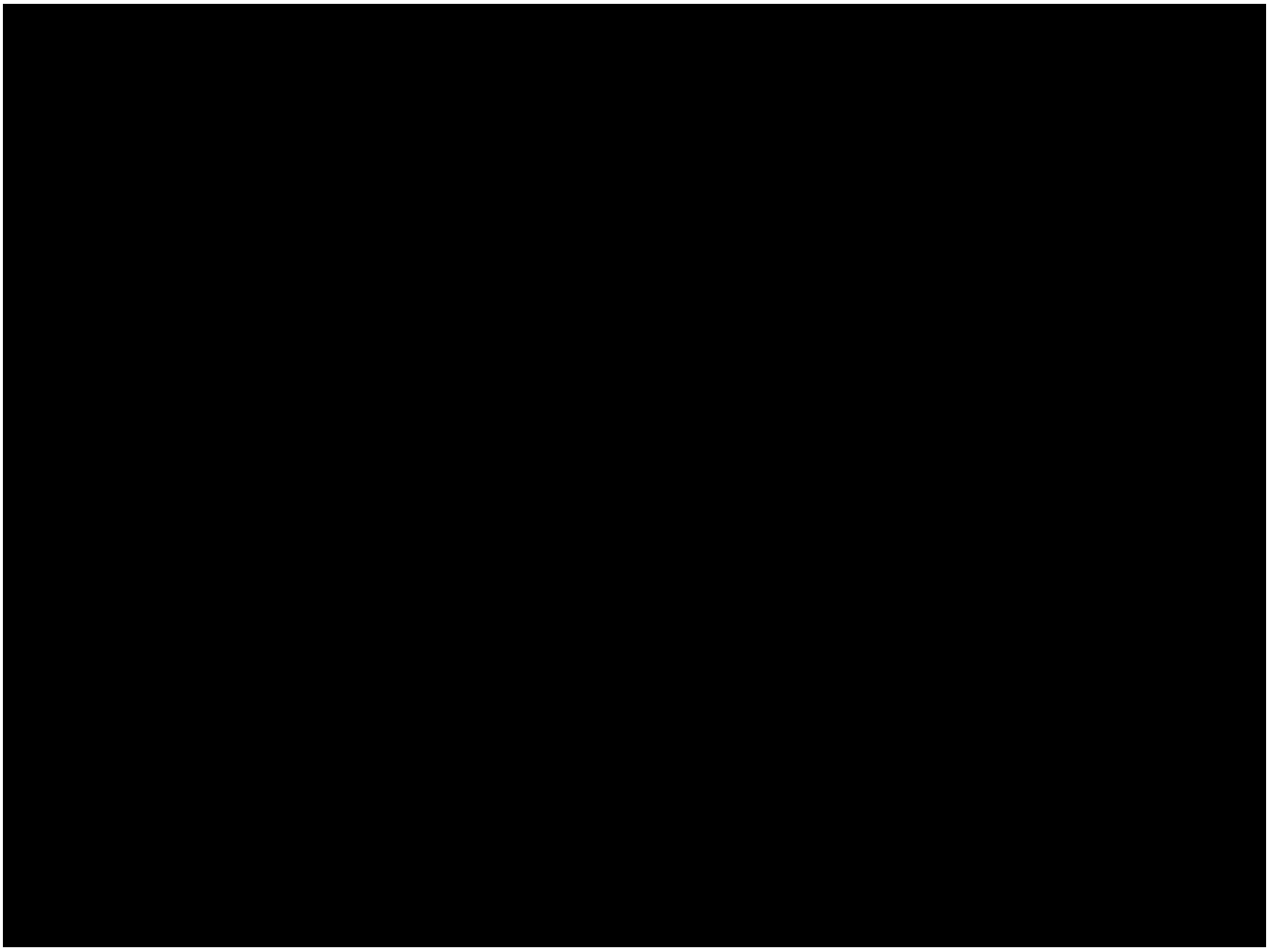
GSK's disclosure of Avandia's cardiovascular risks led to a precipitous decline in its sales. As the figure below demonstrates, [redacted][77]

[74] The term "major adverse cardiovascular events" (MACE) refers a composite of three types of events: cardiovascular death, myocardial infarction (heart attack), and stroke. JA-749 (May 2007 label).

[75] *Id.*

[76] JA-0060 (Dkt. 1).

[77] SA-1680 (Avandia sales data).



Changing formal recommendations take time, but, by 2009, the American and European Diabetes Associations published joint rankings of the available diabetes treatments. Avandia "[was] not recommended."[78] By 2010, the U.S. Senate Finance Committee concluded its report on GSK fraud: the "totality of the evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public."[79]

[78] JA-1108.

[79] JA-0012 (3d Cir. decision).

In short, once the healthcare community learned of Avandia's true cardiovascular profile, physicians stopped prescribing it. "[redacted]."[80]

In May 2010, the first health plan filed suit in Pennsylvania.[81] By this time, GSK had already lost about 85% of its Avandia sales. Seven months later, GSK moved to dismiss the plan's class action claims under Rule 12(b)(6).[82]

E. 2010-2011: The FDA required GSK to add further cardiovascular warnings to Avandia's label.

Meanwhile, in July 2010, the FDA reconvened the advisory committee to update its Avandia safety evaluation.[83] First, the FDA criticized the results of a long-term clinical trial GSK conducted (the RECORD trial).[84] This open-label trial

[80] SA-0670 (¶14) (Abramson).

[81] JA-0566. UFCW amended this complaint on August 20, 2010. *Id.*; JA-1269. The other plaintiff-appellant in this case, J.B. Hunt, filed its class action complaint a year later on June 20, 2011. JA-0573.

[82] JA-0567 (Dkt. 16). When J.B. Hunt filed its complaint, the action was stayed pending GSK's motion to dismiss. JA-0573-74 (Dkt. 5, 12).

[83] JA-1239 (2010 FDA meeting transcript).

[84] JA-1244-66 (2010 FDA meeting transcript). While GSK published an interim version of this study in 2007, the final version was only released in 2009. JA-1135 (RECORD study).

compared patients taking Avandia plus metformin or a sulfonylurea to patients taking a combination of metformin and sulfonylurea. While RECORD showed no statistically significant increase in cardiovascular hospitalization or death (the study's primary endpoints) in patients treated with Avandia as compared to those treated with metformin and sulfonylurea,[85] many at the FDA were skeptical of its results. Of particular concern was the study's open-label design: both the *physicians* and *the trial subjects* knew whether they received Avandia or some other drug.[86]

Second, FDA officials presented an updated meta-analysis of the shorter-term clinical trials. By 2010, the number of short-term trials had grown to 52. This meta-analysis concluded that Avandia was associated with a statistically significant increase in ischemic cardiac risk versus pooled comparators.[87]

Third, FDA officials presented a review of observational studies comparing cardiovascular outcomes in elderly, diabetic patients treated with Avandia and Actos. These studies not only failed to "suggest[] a protective cardiovascular effect of [Avandia] compared to [Actos]," they "consistently show[ed] a clinically

[85] JA-1135 (RECORD study).

[86] JA-1246 (2010 FDA meeting transcript).

[87] JA-1224, 1232-35 (2010 FDA meeting slides).

meaningful increased risk of adverse cardiovascular outcomes, notably, acute myocardial infarction, [i.e., heart attack]."[88]

Based on this review, the FDA imposed three conditions on the continued marketing of Avandia: (1) implementation of a Risk Evaluation and Mitigation Strategy (REMS) that would restrict access to Avandia; (2) commission of an independent re-adjudication of the RECORD trial's results; and (3) a "full clinical hold" on a then-pending clinical trial comparing Avandia and Actos.[89]

With respect to Avandia's label, GSK added notice of the new REMS restriction to Avandia's black box warning in 2011.[90] It also added a description of the observational trials to the body of the label.[91] The 2011 label then cautioned that the (now 52-study) meta-analysis found a statistically significant increase in risk of myocardial infarction, not just myocardial ischemia, with Avandia versus pooled comparators.[92] The label continued to note that the longer-term trials found "a statistically non-significant increase in the risk of myocardial infarction for

[88] JA-1267-68 (2010 FDA meeting transcript).

[89] JA-1396-97 (2010 FDA Decisional Memorandum).

[90] JA-0786 (2011 label).

[91] JA-0794.

[92] JA-0790-91. Myocardial ischemia is the narrowing of the arteries that bring blood and oxygen to the heart. Left untreated, ischemia can lead to heart attack (myocardial infarction).

AVANDIA versus comparator medications."[93] Again, while this data did not show Avandia was *worse* than comparators, it showed it was *no better* with respect to death or major adverse cardiovascular events.

F. 2013-2014: The FDA ended the Avandia restriction program but did not direct GSK to remove the cardiovascular warnings from its label.

In June 2013, the FDA again reconvened the advisory committee after completion of the RECORD re-adjudication. The re-adjudication found "no statistically significant difference" between Avandia and metformin/sulfonylurea "for the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure."[94] Thus, again, while the results showed Avandia was no worse than metformin and sulfonylurea in terms of death or major adverse cardiovascular outcomes,it also showed Avandia was no better. And while the RECORD data was quantitatively robust, the re-adjudication could not mitigate the study's fundamental flaw – that treatment allocation had been un-blinded.[95] As a result, some committee members recognized "unresolved concerns regarding increased [cardiovascular] risk with" Avandia persisted.[96]

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[93] JA-0793.

[94] JA-1656 (2013 FDA Decisional Memorandum).

[95] JA-1638 (2013 FDA Decisional Memorandum).

[96] JA-1575 (summary of minutes FDA 2013 meeting).

In October of 2013, the district court denied GSK's motion to dismiss the plans' case.[97] Four months later the district court certified its decision for interlocutory appeal.[98] On April 15, 2014, this Court accepted that appeal.[99]

In May 2014, at the recommendation of the FDA, GSK removed mention of the REMS program from Avandia's black box.[100] However, the FDA *did not instruct GSK to remove the black box itself.* Instead, the black box continued to warn that Avandia may "cause or exacerbate congestive heart failure in some patients"; "AVANDIA is not recommended in patients with symptomatic heart failure"; and "[i]nitiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated."[101]

Nor did the FDA instruct GSK to remove the label's discussion of the 52-trial meta-analysis.[102] While mention of this meta-analysis was removed from the black box, the FDA explicitly stated that "[s]ome description of the meta-analysis findings and observational data could remain."[103]

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[97] JA-0037.

[98] JA-1676-77.

[99] JA-1678.

[100] JA-1641 (2013 FDA Decisional Memorandum); JA-0825 (2014 label).

[101] JA-0825.

[102] JA-0829.

[103] JA-1641 (2013 FDA Decisional Memorandum).

As for its description of the longer-term trials (which now included the re-adjudicated RECORD study), the 2014 label again stated that "no statistically significant differences" were observed for major adverse cardiac events "between AVANDIA and metformin or a sulfonylurea."[104]

Finally, the 2014 label, like the 2011 label, informed that three observational studies in elderly diabetic patients found Avandia was associated with a statistically significant increased risk of "all-cause mortality" (total number of deaths) when compared to use of Actos.[105] The 2014 label remains in effect today.

G. 2015-2017: The Third Circuit affirmed the motion to dismiss denial, and the case returned to the district court.

On October 26, 2015, the Third Circuit affirmed the district court's denial of GSK's motion to dismiss.[106] GSK then petitioned the Supreme Court for a writ of certiorari, [107] which the Court denied.[108]

On February 1, 2016, some six years after the plans first filed their class actions, the district court issued a pretrial order consolidating their lawsuits and directing the parties to submit a case management schedule.[109] By this time, GSK

[104] JA-0829 (2014 label).

[105] JA-0830.

[106] JA-0009.

[107] JA-1929.

[108] JA-2165.

[109] JA-1895.

had settled the vast majority of the consumer and personal injury actions in the Avandia MDL. But before the health plans could engage in discovery specific to their claims against GSK, the district court allowed GSK to move for summary judgment.

On May 20, 2016, GSK filed its motion.[110] The preemption aspect of GSK's motion was predicated on the FDA's conclusion that the RECORD re-adjudication showed Avandia was no worse than its comparators[111] (i.e., that it found "no statistically significant difference" between Avandia and metformin/sulfonylurea for "the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure"[112]). GSK did not argue, as it could not, that federal law preempted the plans' claims that GSK falsely marketed Avandia as reducing type-2 diabetics' inherent cardiac risks. Nor that federal law preempted the plans' claim that GSK concealed data showing Avandia posed similar cardiovascular risks to its comparators. As to the plans' RICO claim, GSK argued for the first time that the plans' enterprise – as alleged – failed RICO's distinctiveness requirement.

[110] JA-0534 (Dkt. 4871).

[111] JA-2123 (GSK moving brief).

[112] JA-1656 (2013 FDA Decisional Memorandum).

The health plans opposed. The plans first pointed out that the gravamen of their lawsuit is GSK falsely promoted Avandia as having *better* cardiovascular outcomes than its comparators. This was the reason health plans covered this significantly more expensive medication despite the availability of safe alternatives. The plans showed that the black box warning, along with extensive other cardiovascular warnings, remain on Avandia's label to this day. And the plans demonstrated how the alleged Avandia Promotion Enterprise met RICO's distinctiveness requirement under this Court's jurisprudence.

Nonetheless, on December 7, 2017, the district court granted GSK's motion.

SUMMARY OF THE ARGUMENT

Three errors require reversal of the district court's decision.

First, the district court denied the plans due process when it refused to consider their claims that GSK violated RICO and state consumer protection law by affirmatively marketing Avandia as cardio-protective. The plans have pressed these allegations at every stage of this litigation. Indeed, at the motion to dismiss stage, the district court acknowledged the false marketing aspect of the plans' case. Yet, at summary judgment, it tossed out these claims as "belated" without explanation.[113] This was error.

[113] USA-04.

Second, the district court incorrectly ruled the FDA would not have permitted GSK to warn of Avandia's associated cardiovascular risks prior to 2007. Under *Wyeth* the FDCA preempts the plans' state law claims that GSK concealed Avandia's cardiovascular risks only if "clear evidence" shows the FDA would have rejected such warnings.[114] Here, the plans merely claim GSK should have informed the public of its clinical trial results from the late 1990s and early 2000s showing Avandia posed cardiovascular risks. Indeed, such information currently appears on Avandia's label. But at GSK's urging, the district court misunderstood the FDA as requiring GSK to remove such cardiovascular warnings from Avandia's label – most importantly, Avandia's black box warning.[115] That never happened. These factual errors necessitate reversal.

Third, the district court erroneously held the plans' alleged RICO enterprise failed to meet the distinctiveness requirement because GSK's co-conspirators were merely its "agents." All of GSK's co-conspirators – a rival pharmaceutical company, an independent physician, and various third-party marketing firms, were independent actors that helped GSK falsely promote Avandia. Under this Court's precedent, such an alleged enterprise meets RICO's distinctiveness requirement.

[114] 555 U.S. at 571.

[115] JA-0025-26 (emphasis added).

ARGUMENT

I. The standard of review is *de novo*.

The Third Circuit exercises "plenary review of a district court's grant of summary judgment."[116] The district court's dismissal of all the plans' claims is subject to *de novo* review.

Summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[117] A factual dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[118] The moving party bears the burden to "demonstrate the absence of a genuine [dispute] of material fact."[119] When deciding summary judgment, courts must draw "[a]ll reasonable inferences from the record . . . in favor of the nonmoving party" and refrain from "weigh[ing] the evidence or assess[ing] credibility."[120]

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[116] *Goldenstein v. Repossessors Inc.*, 815 F.3d 142, 146 (3d Cir. 2016).

[117] *Id.* (quoting *Thomas v. Cumberland Cty.*, 749 F.3d 217, 222 (3d Cir. 2014)).

[118] *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

[119] *Id.* (alteration in original) (quoting *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 250 (3d Cir. 2001)).

[120] *Id.* (first alteration in original) (quoting *MBIA Ins. Corp. v. Royal Indem. Co.*, 426 F.3d 204, 209 (3d Cir. 2005)).

II. The district court erroneously dismissed as "belated" the plans' claims that GSK falsely marketed Avandia as cardio-protective.

At summary judgment, GSK mischaracterized as "new" the plans' factual allegations that GSK: (i) concealed cardiovascular data showing Avandia was no better than its comparators and (ii) falsely promoted Avandia as reducing type-2 diabetics' cardiovascular risks, i.e., as providing cardiovascular benefits. The district court accepted the argument, ruling it would "not entertain[] at this juncture" any claims based on the "cardiovascular benefits" of Avandia. It then dismissed all claims based on those allegations with prejudice.[121] This was clear error.

A. The plans are entitled to have their long-pleaded facts and claims adjudicated on the merits.

Fundamental due process entitles the health plans to have all their claims heard on the merits. It is axiomatic that a district court cannot simply dismiss claims or factual allegations as "belated" when they have been properly raised and argued.[122] In *Hillman v. Resolution Trust Corp.*, for example, the Seventh Circuit

[121] USA-04.

[122] *See, e.g., Children First Found., Inc. v. Legreide*, 373 F. App'x 156, 157 n.1 (3d Cir. 2010) (vacating dismissal of due process claims where the "district court failed to address the crux of Plaintiffs' argument"); *E.E.O.C. v. TBC Corp.*, 532 F. App'x 901, 902 (11th Cir. 2013) (finding the district court erred in granting summary judgment against the Equal Employment Opportunity Commission when it "refused to address the issue of mixed motives on the ground that it was untimely raised"); *Kinney v. Holiday Co.*, 398 F. App'x 282, 283 (9th Cir. 2010) (vacating

considered the district court's "refus[al] to consider [the defendant's] argument that plaintiffs introduced insufficient evidence regarding [the] purported fraud" at summary judgment.[123] As here, the *Hillman* district court's purported reason for tossing aside the issue was "the judge's perception that the [defendant] had waited too long to raise the argument."[124] The Seventh Circuit found error and reversed, explaining that the argument was "clear throughout" the course of the case.[125]

B. The plans have consistently alleged that GSK falsely marketed Avandia as reducing type-2 diabetics' inherent cardiovascular risks and concealed heart-risk data.

The plans have been clear through this litigation that their RICO and state law claims are based, in large part, on GSK's false marketing of Avandia as cardio-protective and GSK's concealment of cardiovascular risk data showing Avandia is no better than its comparators. The entire reason Avandia became a blockbuster success in the early 2000s despite the availability of more affordable alternatives was because GSK falsely claimed Avandia, unlike the alternatives, *reduced* type-2 diabetics' inherent cardiovascular risks. After two researchers revealed Avandia did not reduce such risks – in fact, it posed at least the same

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summary judgment on the plaintiff's FMLA claim, "which the district court failed to consider").

[123] 66 F.3d 141, 144 (7th Cir. 1995).

[124] *Id.*

[125] *Id.* (citing defendant's reply memorandum in support of its motion for summary judgment).

cardiovascular risks as its comparators – its sales declined precipitously. The scientific debate since 2007 has centered on whether, based on mixed study results, one should conclude Avandia is *worse* than its alternatives.

The complaints. The plans' complaints alleged GSK violated RICO and state law by promoting Avandia as a type-2 medication that, "unlike the older diabetes drugs, [] had the additional benefit of actually lowering diabetics' cardiovascular risks."[126] This "notion" – "that Avandia would actually lower diabetics' cardiovascular risk" – "was critical to Avandia's marketing."[127] It was the "needed justification for the steep price difference between Avandia and the older established diabetes drugs."[128]

The Rule 12(b)(6) oppositions. When GSK moved to dismiss, the plans again emphasized the effect of GSK's false marketing. "Relying upon GSK's promises of superior treatment and better cardiovascular outcomes compared to older, less costly diabetic drugs, [plans] such as Plaintiffs included Avandia on their formulary and paid a premium for a drug that was not superior."[129] GSK and its associates accomplished the Avandia marketing fraud, the plans explained, by

[126] JA-1290-91 (¶74).

[127] *Id*.

[128] *Id*.; *see also* JA-1269-70, 1271, 1291, 1293-95, 1298-99, 1342, 1328-29 (UFCW-complaint ¶¶1, 6, 76, 81-90, 98, 100, 145, 218).

[129] JA-1453.

representing that "'Avandia was better at lowering blood sugar than other established drugs, thus claiming superior efficacy' and that Avandia 'had the additional benefit of actually lowering diabetics' cardiovascular risks.'"[130]

The district court's Rule 12(b)(6) denial. The district court acknowledged these allegations in its 2013 decision: "[The plans] and PBMs relied, in part, on GSK's representations about the safety and efficacy of Avandia, *including promises of better cardiovascular outcomes compared with other diabetes drugs*, when deciding whether and how to include Avandia on their formularies."[131] Indeed, the court recognized that "GSK marketed and promoted Avandia as a safe and effective treatment for Type II diabetes that would control blood sugar levels in individuals better than other established medications and thus would *lower a user's cardiovascular risk* and *improve overall health*."[132] The plans, it explained, "paid for Avandia, which was not as safe as marketing materials suggested, rather than covering the cost of less risky and less costly alternatives which physicians would have otherwise prescribed" based on "GSK's scheme to mislead the public, including physicians and insurers, with regard to Avandia's safety."[133]

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[130] *Id*. (quoting UFCW-complaint ¶80).

[131] JA-0039-40 (emphasis added).

[132] JA-0039 (emphasis added).

[133] JA-0047.

This Court's affirmance. This Court also acknowledged these allegations: "GSK deliberately concealed the significant safety risks associated with the use of Avandia and continued *to promote Avandia as a safer treatment for diabetes* despite the known risks of heart attack and disease."[134]

The summary proceeding. When GSK simply ignored this claim at summary judgment, the plans' reminded the district court of it. In the second sentence of their opening brief, the plans explained "[redacted]"[135] The plans then attempted to expose GSK's obfuscation: "[redacted]."[136] In their sur-reply, the plans again stressed that they "[redacted]"[137] And at oral argument, the plans reminded the court that stating Avandia lacks cardio-protective benefits is just another way of saying

[134] JA-0013 (emphasis added). The Court further emphasized that this case centered on GSK's "market[ing of] Avandia as a *more effective and safer alternative* to the cheaper, existing Type II oral medications." JA-0010 (emphasis added).

[135] SA-1035.

[136] SA-1036.

[137] SA-1760-61 (emphasis in original).

Avandia does not reduce type-2 diabetics' inherent cardiovascular risks; *the reduction of risk is a benefit*. Thus, "whether one calls that a benefit or one calls that a risk, it's just opposite sides of the same coin."[138] In short, this case has always been about GSK's promotion of Avandia "as having improved or better cardiovascular outcomes than other medications."[139]

C. There is no doctrinal basis for the district court's decision.

The plans' false marketing claims are far from belated: as in *Hillman*, they were raised "throughout."[140] And, as in *Hillman*, the district court's failure to address them requires reversal.

The legal basis for the district court's decision to discard the plans' false marketing claims is unclear. The court did not articulate a procedural or substantive basis for its ruling. Ostensibly, the court issued this decision under Federal Rule of Civil Procedure 56. However, the court explicitly indicated it was not addressing the false marketing claims under a preemption analysis.

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[138] JA-2331 (Summary Judgment Hearing Transcript).

[139] JA-2333. Parts of the district court's summary judgment decision seem to acknowledge the plans' false marketing theory: "Plaintiffs relied in part on GSK's representations that Avandia was a safe medication for Type II diabetes that controlled blood sugar levels better than other available medications, such as metformin and sulfonylurea." USA-03.

[140] *Hillman*, 66 F.3d at 144.

It is possible the district court intended to dismiss the false marketing claims under Rule 12(b)(6). But GSK did not attack the adequacy of the plans' allegations; it only argued, in a supplemental memorandum, that the allegations did not exist until late in the proceedings. And the district court had already upheld these allegations in 2013, when it denied GSK's 2010 motion to dismiss.

Perhaps the district court intended to dismiss the plans' false marketing claim under Rule 41(b). But such a dismissal makes no sense. GSK never moved to dismiss these facts (and the claims related to them) for lack of prosecution. And the district court also did not mention this rule. Irrespective, the district court never followed the requirements for Rule 41(b) under *Poulis v. State Farm Fire & Casualty Co.*[141] Nor could *Poulis*'s test be met.

At bottom, it appears the district court labored under the misunderstanding (fostered by GSK's advocacy) that the plans failed to brief their false marketing allegations until their sur-reply. But the plans' asserted these claims in their complaints, at the 12(b)(6) stage, and before this Court. In failing to consider the plans' allegations (bolstered by a substantial factual record) that GSK falsely

[141] 747 F.2d 863 (3d Cir. 1984); *see also United States ex rel Cressman v. Solid Waste Servs., Inc.*, 665 F. App'x 166, 168-69 (3d Cir. 2016) (reversing dismissal of *qui tam* action for lack of prosecution).

marketed Avandia as cardio-protective, the district court denied the plans their fundamental due process right to the adjudication of their class action lawsuit.[142]

III. Federal law does not preempt the plans' state law claims because it was possible, consistent with the FDA's actions, for GSK to refrain from promoting Avandia as cardio-protective and warn of Avandia's cardiovascular risks.

Far from precluding cardiovascular warnings, the FDA's regulation of Avandia from 2007 to 2014 demonstrates GSK should have provided three types of cardiovascular warnings much earlier: (1) that Avandia is not cardio-protective, (2) that Avandia poses cardiovascular risks similar to its comparators, and (3) that some data actually shows Avandia presents greater cardiovascular risks than other anti-diabetic drugs. The district court did not address the first, it is unclear what it intended for the second, and it rejected the third. But under a proper analysis, none are preempted.

There are "three types of preemption: express preemption, field preemption, and implied conflict preemption."[143] GSK concedes that only implied preemption is at issue here.[144] "[I]mplied conflict preemption exists when, 'under the circumstances of [a] particular case, [the state law] stands as an obstacle to the

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[142] *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807-08 (1985) (recognizing that class action plaintiffs have "a constitutionally recognized property interest" in the adjudication of the class action).

[143] *Deweese v. Nat'l R.R. Passenger Corp.*, 590 F.3d 239, 245 (3d Cir. 2009).

[144] JA-2126.

accomplishment and execution of the full purposes and objectives of Congress.'"[145] Also known as impossibility preemption, this form occurs when it is "impossible for a private party to comply with both state and federal requirements."[146]

A. Federal law does not preempt a proposed warning absent "clear evidence" the FDA would have rejected that warning.

The Supreme Court has long recognized a presumption against preemption[147] and instructs courts to avoid preemption where possible.[148] In line with this directive, this Court has cautioned against "lightly infer[ring]" preemption where "state compensatory regimes have traditionally played an important role."[149]

Regulation of false drug marketing is one such area: "It has long fallen within the province of states to safeguard the health and safety of their citizens."[150] Consonant with this "historic primacy,"[151] it is the states – through their consumer

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[145] *Deweese*, 590 F.3d at 246 (alterations in original) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

[146] *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

[147] *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

[148] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

[149] *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 249 (3d Cir. 2008).

[150] *Desiano v. Warner-Lambert & Co.* (*Desiano II*), 467 F.3d 85, 86 (2d Cir. 2006), *aff'd sub nom.*, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008).

[151] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

protection acts – that primarily protect consumers from "false or deceptive advertising" of prescription drugs.[152]

In *Wyeth*, the Supreme Court emphasized that even as Congress "enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs," it has taken "care to preserve state law."[153] The "FDCA and the state law consumer protection statutes [continue to] serve complementary, though somewhat overlapping, roles."[154] The FDCA "is not focused on the truth or falsity of advertising claims," but instead protects the public by ensuring that prescription drugs are "safe, effective and not misbranded."[155]

Drug makers – not the FDA – bear the responsibility for ensuring the accuracy of their product labels. It "remain[s] a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."[156] Although

[152] *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 371 (E.D.N.Y. 2010); *see Desiano II*, 467 F.3d at 86.

[153] 555 U.S. at 567 (quotation marks omitted).

[154] *Bayer*, 701 F. Supp. 2d at 370-71.

[155] *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (internal quotation marks omitted).

[156] *Wyeth*, 555 U.S. at 570-71.

some label changes require FDA approval,[157] the FDA's "changes being effected" (CBE) guidelines enable manufacturers to "add or strengthen a contraindication, warning, precaution, or adverse reaction" "that is intended to increase the safe use of the drug product" without the FDA's prior approval.[158] In fact, "prior to 2007, the FDA lacked the authority to order manufacturers to revise their labels."[159] "When Congress granted the FDA this authority, it reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval."[160]

This regulatory structure laid the foundation for the Supreme Court's decision in *Wyeth*.[161] There, a plaintiff alleged a drug maker's failure to add certain warnings to its drug label violated state law. The drug maker argued the FDA's regulation of the drug's label preempted the plaintiff's state law claim. The Court disagreed, holding that "absent clear evidence that the FDA would not have approved a change [to the drug's] label," a court cannot conclude "it was impossible for [the drug maker] to comply with both federal and state

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[157] *See* 21 C.F.R. § 314.70(b).

[158] *Wyeth*, 555 U.S. at 568 (quoting 21 U.S.C. § 314.70(c)(6)(iii)(A), (C)).

[159] *Id.* at 571.

[160] *Id.*

[161] *Id*.

requirements."[162] As the Court emphasized in *Wyeth*, the "clear evidence" standard is a "demanding" one.[163] There, the drug maker failed to meet the standard because it "d[id] not argue that it attempted to give the kind of warning" the plaintiffs requested "but was prohibited from doing so by the FDA."[164]

In *In re Fosamax*,[165] this Court recognized *Wyeth*'s "clear evidence" standard as an evidentiary one. It "specifies how *difficult* it will be for the manufacturer to convince the factfinder that the FDA would have rejected a proposed label change. The manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases, but by 'clear evidence.'"[166] Thus, where the available evidence "is more compelling than that in *Wyeth* but no 'smoking gun' rejection letter from the FDA is available," jury trial is necessary.[167] Only where the FDA has explicitly rejected the type of change requested can summary judgment be granted.

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[162] *Wyeth*, 555 U.S. at 571.

[163] *Id.* at 573.

[164] *Id.* at 572.

[165] 852 F.3d 268, 293 (3d Cir. 2017).

[166] *Id*. at 285 (emphasis added).

[167] *Id.* at 294.

B. It was possible for GSK to refrain from falsely marketing Avandia as cardio-protective and comply with FDA requirements prior to 2007.

At no point did the FDA force GSK to promote Avandia as cardio-protective. Instead, the FDA *required* GSK to warn that Avandia had no cardio-protective benefits. Therefore, the FDA's actions do not preempt the plans' state law claims that GSK should not have marketed Avandia as cardio-protective; they complement them.

Courts routinely hold federal law does not preempt a plaintiff's ability to recover, under state law, for false drug marketing. For example, in *Desiano v. Warner-Lambert Co.* (*Desiano I*),[168] the Second Circuit analyzed a hypothetical that perfectly parallels the facts of this case.

> [A] defendant drug company markets a "new," much more expensive drug claiming it is a great advancement (safer, more effective, etc. than metformin – the standard diabetes drug) when in fact the company is simply replicating the metformin formula and putting a new label on it. In other words, the only difference between metformin and the "new" drug is the new name and the higher prescription price (paid almost entirely by the insurance company). In that case, the "new" drug would be exactly as safe and effective as metformin, and thus there could be no injury to any of the insurance company's insured. Nevertheless, the insurance companies would be able to claim . . . that the defendants

[168] 326 F.3d 339 (2d Cir. 2003).

> *engaged in a scheme to defraud it, and that the company suffered direct economic losses as a result*.[169]

This is the exact scenario – down to the comparator drug, metformin – at issue here. GSK advertised Avandia as "safer, more effective, etc. than metformin,"[170] when it was not. Were this Court "to conclude that Appellants' claims were preempted, [it] would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers."[171]

Similarly, in *In re Bayer Corp.*, the Southern District of New York held the FDCA's regulation of branding did not preempt plaintiffs' false marketing and promotion claims.[172] There, Bayer marketed two of its drugs as providing the recommended daily dosage of both aspirin and calcium or aspirin and phytosterols. But neither product did (each contained only the daily recommended dosage of aspirin).[173] When plaintiffs brought state-law false marketing claims, Bayer argued preemption. The court disagreed. "This is a traditional claim of consumer

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[169] *Id.* at 350 (emphasis added).

[170] *Id.*

[171] *Desiano II*, 467 F.3d at 95.

[172] 701 F. Supp. 2d at 376.

[173] *Id.* at 364-65.

misrepresentation, not an attempt to enforce the FDCA's labeling requirements."[174] "[T]he combination products were *advertised* as appropriate for long-term use even though they were not; Bayer Calcium was *advertised* as a source of calcium even though it was not; and Heart Advantage was *marketed* as reducing cholesterol and providing cardiovascular benefits even though" it did not.[175] Thus, even though Bayer's false marketing "touch[ed] on areas regulated by the FDA, and may even require reference to FDA definitions,"[176] the plaintiffs' claims "sound[] in traditional principles of state law and *would give rise to recovery even had the FDCA never been enacted*."[177]

Courts within this Circuit have similarly recognized state law's role in policing false drug advertising. In *In re Tylenol*, the plaintiffs alleged that the makers of Extra Strength Tylenol knew the recommended dose of that drug, or doses just above the recommended maximum, could cause liver damage resulting in death.[178] The plaintiffs claimed that the drug makers' decision to market their product as "safe and effective" despite this knowledge amounted to fraud, in

[174] *Id.* at 375.

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

[176] *Id.*

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

[178] MDL No. 2436, 2015 WL 7076012, at *1 (E.D. Pa. Nov. 13, 2015).

violation of state law.[179] The district court agreed: "[T]he crux of the claims is that the defendants disseminated false or inaccurate information . . . to the decedent herself."[180] Thus her fraudulent marketing claims were "based on a duty found in Alabama's state law regarding fraudulent misrepresentation."[181]

Just so here. The FDA never required GSK to falsely claim that Avandia had "[redacted]" [redacted] and [redacted]" "[redacted]" when it did not.[182] It was not impossible for GSK to be honest about Avandia's failure to reduce type-2 diabetics' inherent cardiac risks. The plans' false marketing claims sound in traditional principles of state law.

In fact, the FDA's requested label changes *compliment* the plans' allegations, not contradict them. The November 2007 label addressed, for the first time, whether Avandia had cardiovascular benefits. As the label explained, "[t]here have been no clinical studies establishing conclusive evidence of macrovascular

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[179] *Id.* at *2.

[180] *Id.* at *8 (citing *Brasher v. Sandoz Pharm. Corp.*, Nos. CV-98-TMP-2648-S, CV-98-TMP-2650-S, 2001 WL 36403362, at *7 (N.D. Ala. Sept. 21, 2001)).

[181] *Id.*; *see Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207, 1215 (E.D. Cal. 2013) (holding "it would not be impossible for Defendants to simultaneously comply with its FDA labeling duties and its duty not to engage in false or misleading advertising under" state law).

[182] SA-0094 (CME monograph).

risk reduction with AVANDIA or any other oral antidiabetic drug."[183] That warning remains on the label to this day.

C. It was possible for GSK to disclose Avandia's cardiovascular risks and comply with FDA requirements prior to 2007.

The plans allege that GSK concealed data showing Avandia posed cardiovascular risks – at least similar to those of other type-2 diabetes drugs. This allegation does not conflict with any FDA regulations. Far from forbidding such warnings, the FDA actually *required* them once the Nissen study brought them to light in 2007.

1. Since 2007, the FDA has required GSK to warn of Avandia's associated cardiovascular risks.

Since 2007, the FDA has either required or permitted GSK to warn of Avandia's cardiovascular risks. And GSK has done so on *five* different sections of the label.

The black box warning. After the Nissen study's release, the FDA required GSK to add a black box warning to the front of Avandia's label.[184] That boxed warning indicated Avandia can "cause or exacerbate congestive heart failure in some patients."[185] It also recommended against prescribing Avandia to patients

[183] JA-750.

[184] JA-1090 (2007 FDA Letter to GSK).

[185] JA-0708.

with symptoms of heart failure.[186] Since added in August 2007, these warnings have remained on Avandia's label in a black box.[187]

Meta-analysis of clinical trials. In November 2007, the FDA required GSK to add information to the label regarding the 42-trial meta-analysis. As the November 2007 label explained, the meta-analysis showed "an increased risk of myocardial ischemia with AVANDIA versus pooled comparators" and "[a]n increased risk of myocardial ischemic events with AVANDIA" versus a placebo.[188]

In May 2011, GSK updated the label's description of the meta-analysis. The now 52-study meta-analysis found "a statistically significant increased risk of *myocardial infarction* [i.e., heart attack] with AVANDIA versus pooled comparators."[189] Such a risk was also found for the placebo-controlled trials.[190] Nonetheless, the 2011 label noted the meta-analysis did not find Avandia to be associated with a statistically significant increased risk of major adverse cardiovascular events (myocardial infarction, stroke, and cardiovascular death) relative to pooled comparators and relative to the placebo-controlled trials.[191] The

[186] *Id.*

[187] JA-0825.

[188] JA-0747.

[189] JA-0791.

[190] *Id*.

[191] *Id.*

FDA required GSK to add a bullet point describing the meta-analysis results to Avandia's black box.

When the FDA required GSK to revise Avandia's label again in May 2014, the data regarding the meta-analysis was removed from the black box. But it remained on the label. GSK continued to report the meta-analysis found "a statistically significant increased risk of myocardial infarction with AVANDIA versus pooled comparators" as well as placebo-controlled trials.[192] The label also continued to note the meta-analysis did not find a statistically significant increased risk of major adverse cardiovascular events for Avandia versus pooled comparators and versus the placebo-controlled trials.[193] This information remains on Avandia's label to this day. As does the black box warning.

Long-term clinical trials. In 2007, GSK also added a discussion of its long-term, prospective, randomized, controlled clinical trials. As the 2007 label explained, these studies did not show a "statistically significant[] differen[ce] between Avandia and comparators" for three clinical endpoints (major adverse cardiovascular events, heart attack, and total mortality).[194] The label further noted

[192] JA-0829.

[193] *Id.*

[194] JA-0749.

that data from these trials regarding whether Avandia increased risk of heart attack relative to pooled comparators was "inconclusive."[195]

In 2011, the label's discussion of the long-term trials went somewhat further, advising that the long-term trials found "a statistically non-significant increase in the risk of [heart attack] for AVANDIA versus comparator medications."[196]

In 2013, the RECORD re-adjudication found "no statistically significant difference between [Avandia] and metformin/sulfonylurea for the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure."[197] Put another way, the re-adjudication showed Avandia did not pose *worse* risks in terms of major adverse cardiovascular outcomes than more affordable alternatives.

Based on this result, the FDA instructed GSK to add a description of RECORD's results to Avandia's label.[198] That description read: "Non-inferiority was demonstrated for the primary endpoint, cardiovascular hospitalization or cardiovascular death, for AVANDIA compared" with metformin plus sulfonylurea.[199] In other words, Avandia was not worse than metformin plus

[195] JA-0750.

[196] JA-0793.

[197] JA-1656 (2013 FDA Decisional Memorandum).

[198] JA-1668 (FDA Letter to GSK).

[199] JA-0828 (2014 label).

sulfonylurea. The 2014 label characterized these results as "*consistent with*" the earlier "long-term, prospective, randomized, controlled clinical trials";[200] None of the previous labels claimed Avandia caused a statistically significant increase in risk of major adverse cardiovascular events relative to comparators.

Observational studies in the elderly. In May 2011, the FDA required GSK to add information regarding observational studies of treatment with Avandia versus Actos in elderly diabetic patients. The 2011 label warned these studies found a "statistically significantly increased [] risk of all-cause mortality compared to use of ACTOS."[201] In other words, Avandia, relative to Actos, increased the risk of death in older diabetic patients. Several years later, GSK [redacted].[202] [redacted].[203] And the observational trial warning remains on the label today.[204]

The medication guide. The Nissen study's release also caused GSK to change its medication guide.[205] In November 2007, the guide warned "AVANDIA may increase . . . risk of angina (heart-related chest pain) or myocardial

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

[201] JA-0794.

[202] SA-1226 (¶82) (Second Abramson Report)

[203] *Id*.

[204] JA-0830 (2014 label).

[205] A medication guide is a detachable portion of the label intended to be reviewed with the patient by the pharmacist.

infarction."[206] When GSK and the FDA negotiated the 2014 label changes, GSK requested the label read: "[redacted] [207] But the FDA rejected this language and required the guide to continue warning: "AVANDIA may increase the risk of a heart attack."[208] The 2014 guide remains in effect today.

The echocardiographic study. Finally, beginning in 2006, the FDA required GSK to include results from a 52-week echocardiographic study of patients with congestive heart failure on Avandia's label. The required warning stated "more cardiovascular adverse events were observed with AVANDIA treatment compared to placebo."[209] Since added, this warning has not left Avandia's label.[210]

2. The contents of Avandia's FDA-approved labels show GSK could have warned of the drug's cardiovascular risks and complied with FDA requirements.

The labeling history demonstrates the FDA has not only permitted, but required, GSK to warn of Avandia's cardiovascular risks over the years. To this day, a boxed warning for cardiovascular risk appears on Avandia's label; a

[206] JA-0781.

[207] SA-1683 (GSK proposed 2014 medication guide).

[208] JA-0862 (2014 label).

[209] JA-0696 (2006 label).

[210] JA-0826 (2014 label).

warning that a large meta-analysis found Avandia to be associated with increased risk of heart attacked versus pooled comparators and versus placebo-controlled trials appears on Avandia's label; a warning that observational trials showed Avandia, relative to Actos, to be associated with increased death in elderly diabetics appears on Avandia's label, and; a warning that "AVANDIA may increase the risk of a heart attack"[211] appears in its medication guide.

Nonetheless, at summary judgment, GSK argued the FDA reached a sweeping conclusion in 2013 (after the RECORD re-adjudication) that "the scientific evidence does not indicate an increased cardiovascular risk with Avandia."[212] That statement does not mean the FDA concluded Avandia was cardio-protective, nor that it decided Avandia posed less cardiovascular risk than other diabetic agents – the current label states the opposite.

But it is also untrue the FDA prohibited GSK from presenting data showing Avandia posed greater cardiovascular risks than its comparators. To the contrary, the FDA-approved label *currently* reports the results of the 52-trial meta-analysis showing "a statistically significant *increased* risk of *myocardial infarction* [i.e., heart attack] with AVANDIA versus pooled comparators."[213] And Avandia's label

[211] JA-0862 (2014 label).

[212] JA-2131; *see* JA-2135-37.

[213] JA-0829 (2014 label).

continues to disclose, over GSK's objection, the observational studies. A black box warning that Avandia can "cause or exacerbate congestive heart failure in some patients"[214] still appears on the first page of the label. And the medication guide, over GSK's protest, still states Avandia "may increase the risk of a heart attack."[215]

To be sure, the FDA recognized the RECORD re-adjudication found there was "no statistically significant difference" between Avandia and metformin/sulfonylurea for "the risk of death or major adverse cardiovascular outcomes, other than the known class effect of heart failure."[216] And the FDA acknowledged that long-term trials (such as RECORD) are generally favorable to short-term trials with fewer data points. But the FDA did not conclude the meta-analysis was irrelevant. As the FDA noted in its 2013 decisional memorandum regarding RECORD, this re-adjudication could not address "residual concerns about RECORD," in particular, that the trial was not blinded.[217] And although RECORD found "the rate of myocardial infarction [associated with Avandia] was not significantly increased relative to comparators (metformin and sulfonylureas)," "the point estimate for myocardial infarction in RECORD trend[ed] adversely."[218]

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[214] JA-0825 (2014 label).

[215] JA-0862 (2014 label).

[216] JA-1656 (2013 FDA Decisional Memorandum).

[217] JA-1638 (2013 FDA Decisional Memorandum).

[218] JA-1637 (2013 FDA Decisional Memorandum).

So, in 2013, the FDA explicitly told GSK that "[s]ome description of the meta-analysis findings and observational data *could remain*" on Avandia's label.[219] And the FDA forbid GSK from removing the warning that "Avandia may increase the risk of a heart attack."[220]

For this case, the debate whether Avandia does, or does not, pose worse cardiovascular risks than its comparators plays only a small role (if any). While the RECORD study suggests Avandia is not worse than treatment with metformin and sulfonylurea as to two endpoints, those same results show Avandia poses cardiovascular risks similar to its comparators – debunking the entire basis upon which GSK built the Avandia empire.

The plans have never asked for anything more than the cardiovascular warnings currently on the label.[221] At summary judgment, the plans emphasized that Avandia's current cardiovascular warnings "[are] entirely consistent with the allegations that have been pressed by the [plans] here . . . all throughout."[222] The

[219] JA-1641 (2013 FDA Decisional Memorandum) (emphasis added).

[220] JA-0862 (2014 label).

[221] *See, e.g.*, JA-1289 (¶71) (alleging that GSK's should have warned Avandia was "associat[ed] with increased risk of heart attacks and heart-related diseases"); JA-1318 (¶166(h)) (clarifying that one of the questions common to all Class members was: "whether Defendants failed to warn adequately of the adverse effects of Avandia"); JA-1425 (Plans' Motion to Dismiss Opposition).

[222] JA-2337 (Summary Judgment Hearing Transcript).

plans "[redacted]."[223] The FDA's current acceptance of that label prove the viability of the plans' requested warnings.

D. The district court erroneously held it was impossible for GSK to disclose, before 2007, data regarding Avandia's cardiovascular risks.

At summary judgment, the district court concluded clear evidence established the FDA would not have permitted GSK to implement – at any point in time, including up to today – "a warning for increased cardiovascular risk in Avandia versus comparators."[224] This was error.

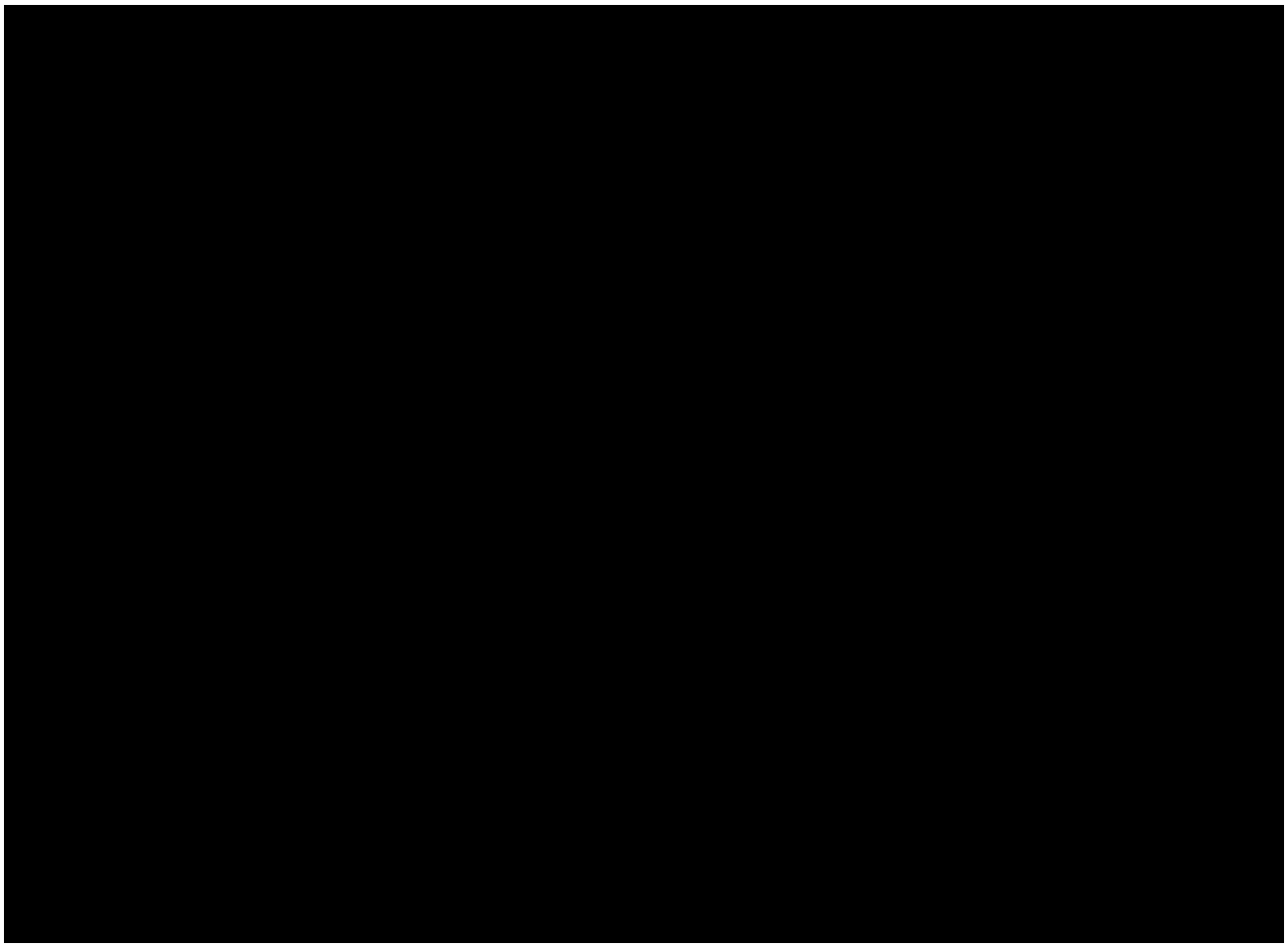
a. The district court addressed the incorrect time period.

The plans claim GSK falsely promoted Avandia from its launch in 1999 until the FDA forced GSK to reveal its true cardiovascular risks in 2007. Thus, the critical time period in this case is 2000 to 2006, when the vast majority of Avandia's sales occurred. [225]

[223] SA-1758 (Plans' Summary Judgment Sur-Reply).

[224] USA-26.

[225] SA-1680 (Avandia sales data).



At summary judgment, GSK presented *no* evidence, let alone *clear* evidence, that the FDA would have prohibited GSK from disclosing, in the 1999 to 2006 period, its clinical trial data documenting Avandia's cardiovascular risks.[226] And in its summary judgment opinion, the district court made no attempt to assess whether the FDA would have rejected a proposed cardiovascular warning during that period. The district did not address that issue because GSK did not argue it.

[226] JA-2134-39.

Instead, GSK's summary judgment briefing focused on three pieces of evidence: the FDA's rejection of PAS changes in 2006, a conversation between a GSK employee and an FDA official in 2007, and the current FDA label. The district court accepted all three as clear evidence of impossibility.

b. The district court's PAS ruling was erroneous.

First, the district court relied on the FDA's rejection of certain label changes GSK proposed in late 2006 as "clear evidence" of impossibility.[227] Drug manufacturers can apply for "major changes" to a drug's label by filing a "Prior Approval Supplement" (PAS) with the FDA.[228] Unlike CBE changes, the FDA must approve PAS changes before they can be made. [redacted]

[227] USA-24-25.

[228] 21 C.F.R. § 314.70(b).

[229] SA-0539, 563-66 (GSK 2006 PAS).

[230] SA-0463-64 (GSK 2006 Submission to FDA).

On May 21, 2007, the New England Journal of Medicine published the Nissen study.[231] This bombshell put the FDA in crisis mode: the agency had to reconsider the safety of a widely prescribed drug that had dominated the market for nearly a decade. Unsurprisingly, on June 4, 2007, [redacted], the district court inferred "clear evidence that the FDA would not have approved of a warning for increased cardiovascular risk in Avandia versus comparators earlier than 2007."[234] This inference strains credulity.

The more plausible inference is: in light of Nissen study, the FDA wanted to ensure GSK's proposed label changes were sufficiently robust. The FDA did not reject GSK's PAS because it was worried the proposed changes *over-exaggerated*

[231] JA-1064 (Nissen study).

[232] SA-0660 (FDA letter to GSK).

[233] SA-0661 (FDA letter to GSK).

[234] USA-26.

Avandia's cardiovascular risks; instead, it was concerned that the proposed PAS was *not strong enough*. Just so, two and a half months later, the FDA required GSK to add cardiovascular warnings – including a black box – that were *stronger* than GSK's proposed PAS. The district court's failure to draw this reasonable (and more plausible) inference in the plans' favor at summary judgment constitutes reversible error.[235]

The 2006 PAS discussion is neither "more compelling [evidence] than that in *Wyeth*" nor a "'smoking gun' rejection letter from the FDA."[236] The FDA ultimately did not reject the heightened cardiovascular warns; it *required* them. Therefore, under *Fosamax*, the district court erred in granting summary judgment.

c. The district court's CBE ruling was erroneous.

Next, the district court relied on GSK's notes from a call GSK had with an FDA official on May 24, 2007 – three days after the release of the Nissen study. [redacted] Nonetheless, the notes also state the official reminded GSK that "'[redacted]

[235] *Goldenstein*, 815 F.3d at 146.

[236] *Fosamax*, 852 F.3d at 294.

[237] SA-0656 (Record of teleconference between GSK and FDA).

[redacted].

This exchange is the opposite of clear evidence of impossibility; the opposite of a "'smoking gun' rejection letter from the FDA."[239] To the extent more than one inference can be drawn from the letter, that inference, again, should have been drawn in the plans' favor. And as this evidence is less strong than that in *Wyeth*, the clear evidence determination should have gone to a jury.

d. The district court's 2014 label ruling was erroneous.

Lastly, the district court held that the 2014 label – the label currently in place– "constitute[d] clear evidence that [the FDA] would not have approved of changes to the label prior to 2007."[240] This conclusion stems from the district court's misreading of the facts: the district court believed the "FDA required a black box warning on increased cardiovascular risk in 2007, and later, after conducting extensive research, concluded that the black box warning *should be removed* because the data did not support such an association."[241]

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[238] *Id*.

[239] *Fosamax*, 852 F.3d at 294.

[240] JA-0025.

[241] JA-0025-26.

This is simply untrue. The black box *still* appears on GSK's Avandia label today, warning that Avandia can "cause or exacerbate congestive heart failure in some patients."[242] The box further recommends against prescribing Avandia to "patients with symptomatic heart failure."[243] And the body of Avandia's label details these cardiovascular risks, including description of the meta-analysis and the observational trials.

The district court's misapprehension may stem from the FDA's directive that GSK remove the bullet point discussing the REMS restriction from the 2014 black box. Despite removal of this bullet, *the black box remained*. The plans are not arguing that GSK should have added a REMS restriction to the label prior to 2007. Instead, the plans contend that GSK could and should have added cardiovascular warnings, *like those on the current label*, prior to 2007.

The district court's misreading may also stem from the FDA's 2013 decisional memorandum on the RECORD re-adjudication. But, as previously explained, the RECORD study in no way vitiated the meta-analysis' findings or forced GSK to remove discussion of them from Avandia's label. Contrary to the district court's holding, the 2014 label continues to warn that clinical trials found Avandia to be associated with cardiovascular risks at least as great as those of

[242] JA-0825 (2014 label).

[243] *Id.*

cheaper alternatives. This is the warning GSK should have provided prior to 2007. Had it done so, doctors would not have prescribed, and plans would not have covered, a more expensive medication that posed at least the same cardiovascular risks as its cheaper alternatives (and possibly more).

E. The Arkansas state safe harbor does not immunize GSK's fraudulent marketing.

The Arkansas state safe harbor statute also does not sanction GSK's fraudulent marketing of Avandia. At summary judgment, GSK argued that the Arkansas safe harbor mandated the dismissal of the plans' Arkansas Deceptive Trade Practices Act claims.[244] Arkansas's safe harbor provides that this law does not apply to "[a]ctions or transactions specifically permitted under laws administered by . . . [a] regulatory body or officer acting under statutory authority of . . . the United States."[245] According to the district court, the state safe harbor applied because "GSK [did] not ma[k]e statements on the label that were not approved by the FDA."[246]

This conclusion misses the point. The FDA did not approve GSK's failure to warn of Avandia's cardiovascular risks because, until 2007, the FDA did not understand the full extent of those risks. Nor did the district court consider GSK's

[244] JA-2150.

[245] Ark. Code § 4-88-101(3).

[246] USA-18.

affirmative misrepresentations of Avandia as cardio-protective, which the FDA also did not sanction. When the Nissen study exposed these misrepresentations, the FDA took immediate action.

IV. The district court erred in dismissing the plans' RICO claims because the alleged association-in-fact enterprise – GSK alongside independent actors – is functionally distinct from the defendant – GSK.

The district court erred as a matter of law in dismissing the plans' RICO claims. The plans pleaded a RICO enterprise – GSK alongside a second pharmaceutical company, independent doctors, and third-party marketing firms – that was distinct from the defendant – GSK.

A. A corporate RICO "person" is distinct from the association-in-fact "enterprise" it directs when that enterprise is comprised of functionally independent actors working together to pursue a common course of unlawful conduct.

RICO provides "[i]t shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."[247] The alleged RICO "enterprise" must be distinct from the alleged RICO "person" (the defendant); the "enterprise" cannot "simply [be] the same 'person' referred to by a different name."[248] The statute "both protects a legitimate

[247] 18 U.S.C. § 1962(c).

[248] *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 161 (2001).

'enterprise' from those who would use unlawful acts to victimize it" and "the public from those who would unlawfully use an enterprise (whether legitimate or illegitimate) as a 'vehicle' through which 'unlawful . . . activity is committed.'"[249]

Where an association-in-fact "enterprise" consists of a corporation, its employees, subsidiaries, and/or agents and the RICO "person" is the corporation, a "fact-intensive" analysis is necessary to determine whether the "enterprise" and the "person" are distinct.[250] Courts of appeals recognize a "corporation can act only through its employees, subsidiaries, or agents."[251] Therefore, if a corporate defendant can always be held "liable for participating in an enterprise comprised only of its agents . . . then RICO liability will attach to any act of corporate wrong-doing and the statute's distinctness requirement will be rendered meaningless."[252] Nonetheless, not all "agents" or "subsidiaries" are mere extensions of the corporation itself; concluding otherwise would render the statute largely ineffective against corporate wrongdoers. Courts, therefore, hold that an association-in-fact

[249] *Id.* at 164 (alteration in original) (quoting *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 259 (1994)).

[250] *In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 491 (6th Cir. 2013).

[251] *U1it4less, Inc. v. Fedex Corp.*, 871 F.3d 199, 205 (2d Cir. 2017), *cert. denied*, 138 S. Ct. 1559 (2018).

[252] *Id.* at 205-06; *see Cedric*, 533 U.S. at 163 (liability "depends on showing that the defendants conducted or participated in the conduct of the '*enterprise's* affairs,' not just their *own* affairs" (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993)).

enterprise composed of a corporation and its agents or subsidiaries is distinct from the corporation as the RICO person "when they are functionally separate, as when they perform different roles within the enterprise or use their separate legal incorporation to facilitate racketeering activity."[253]

The Third Circuit, in particular, has been clear: "an 'association-in-fact' enterprise can exist – and satisfy the 'distinctiveness' requirement – when it is comprised of members that are a mixture of individual persons and 'entities that they control.'"[254] And while the members of the enterprise must share a common purpose, an association-in-fact can form "for purposes that primarily benefit one

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[253] *ClassicStar*, 727 F.3d at 492; *see Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412 (3d Cir. 1993). Based on the *specific* facts at hand, *ClassicStar* held a corporation and its subsidiaries were "sufficiently distinct . . . to satisfy the statute's distinctness requirement." 727 F.3d at 493-94.

[254] *United States v. Bergrin*, 650 F.3d 257, 266 (3d Cir. 2011) (quoting *United States v. Masters*, 924 F.2d 1362, 1366 (7th Cir. 1991)); *see Jaguar Cars, Inc. v. Royal Oaks Motor Car Co., Inc.*, 46 F.3d 258, 266 n.5 (3rd Cir. 1995) (noting that the enterprise alleged in *Reves*, 507 U.S. 170, may have met the distinctiveness requirement if the plaintiffs had pleaded it as an association-in-fact enterprise between the defendant corporation and the outside auditing firm that helped the corporation carry out its fraud). Commentators agree with this understanding of the RICO distinctiveness requirement. *See, e.g.*, Barry Boise & Eric Wolfish, *Attacking Tort Claims Masquerading Under Rico*, Pepper Hamilton (2016), http://www.pepperlaw.com/resource/27816/1G0 (noting that "if an enterprise consists of a mix of company employees and other persons or entities (such as consulting physicians and speakers who are not acting in an agency capacity), then a distinctiveness defense is less likely to succeed." (citing *Bergrin*, 650 F.3d at 266 and *Coleman v. Commonwealth Land Title Ins. Co.*, 684 F. Supp. 2d 595, 611 (E.D. Pa. 2010))).

member or operate[] with total dependence on one member" and still meet the distinctiveness requirement.[255]

Following this directive, courts within this Circuit hold that an association-in-fact "enterprise" comprised of a corporate "person" and independent third parties or entities that have business relationships with it satisfies the distinctiveness requirement. "[A]n association-in-fact enterprise in which the RICO defendant or 'person' is a corporation and the enterprise consists of the defendant corporation and other members who are under a contractual obligation with the defendant" satisfies the distinctiveness requirement.[256]

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[255] *Bergrin*, 650 F.3d at 274; *see In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 378 (3d Cir. 2010).

[256] *Schwartz v. Lawyers Title Ins. Co.*, 680 F. Supp. 2d 690, 705 (E.D. Pa. 2010) (citing *Hanrahan v. Britt*, No. 94-4615, 1995 WL 422840, at *7 (E.D. Pa. July 11, 1995) (concluding the defendant Amway was distinct from the alleged association-in-fact enterprise consisting of Amway and its network of distributors) and *In re Countrywide Fin. Corp. Mortg. Mktg. & Sales Practices Litig.*, 601 F. Supp. 2d 1201, 1212-13 (S.D. Cal. 2009) (finding Countrywide and its organization of mortgage brokers with whom it contracted to sell loans issued by Countrywide constituted a valid association-in-fact enterprise)); *see Devon Drive Lionville, LP v. Parke Bancorp, Inc.*, No. 15-cv-3435, 2016 WL 7475816, at *10 (E.D. Pa. Dec. 29, 2016) (alleged enterprise satisfied the distinctiveness requirement where the "enterprise [was] alleged to consist of a corporation and its employees as well as a third-party outside of the corporate structure"); *Mega Concrete, Inc. v. Smith*, No. 09-4234, 2013 WL 3716515, at *13 (E.D. Pa. July 15, 2013) (alleged enterprise comprised of a corporation, its chief executive, and an accounting clerk employed by a separate company, met the distinctiveness requirement because the enterprise "involve[d] a third-party member who does not come within the other members' corporate sphere," which "tends to negate the notion that the enterprise is [the corporation]"); *Levine v. First Am. Title Ins. Co.*, 682 F. Supp. 2d 442, 459 (E.D. Pa. 2010) (alleged enterprise consisting of the defendant and outside agents it hired

B. GSK is distinct from the independent entities who helped it misrepresent Avandia's cardiovascular risks.

The plans allege that GSK – the RICO "person" – participated in a pattern of racketeering activity through the Avandia Promotion Enterprise – the association-in-fact "enterprise." That enterprise consisted of GSK (along with its employees and agents), Dr. Stephen Haffner (a professor of medicine at the University of Texas Health Sciences Center), Bristol-Myers Squibb (BMS, a pharmaceutical company), Sir Colin Dollery (an external consultant to GSK), and other independent consultants, public relations firms, and distribution agents hired by GSK. Each of these enterprise members took steps to effectuate the enterprise's common fraudulent purpose, i.e. "marketing Avandia as safe for its intended uses, while suppressing evidence to the contrary and improperly inducing physicians to prescribe Avandia."[257] Each were aware of at least some of the issues facing Avandia, including unfavorable clinical trial results, but promoted Avandia to physicians, PBMs, and plans as safer anyway.[258] Importantly, the independence of

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to perform searches and settlement services satisfied the distinctiveness requirement; the agents were "separate, independent entities who do not function as subsidiaries or employees of" defendant and thus plaintiffs had satisfied the ""person' and 'enterprise' distinctness requirement").

[257] JA-1320 (¶174) (UFCW-complaint).

[258] *See, e.g.*, JA-1296 (¶91) (Dr. Haffner leaked the Nissen study to GSK so that GSK could get out ahead of it); SA-0739 (¶¶250-51) [redacted]

GSK's associates enabled the enterprise to accomplish more than GSK could have accomplished alone.

District courts have twice held that nearly identical enterprises satisfy the distinctiveness requirement. *In re Neurontin*, the District of Massachusetts held that Pfizer and various marketing firms it hired to promote its drug, Neurontin, formed a valid association-in-fact enterprise.[259] As here, the *Neurontin* "complaints allege[d] that Defendants formulated 'tactical plans' with the marketing firms to promote Neurontin on an ongoing basis, and that there was regular communication between the marketing firms and Defendants."[260]

Likewise, in *Meijer, Inc. v. Ranbaxy Inc.*, the District of Massachusetts held that a pharmaceutical company was distinct from the auditing firm it hired to convince the FDA its manufacturing facilities were FDA-compliant (when they were not). [261] The pharmaceutical company argued the auditing firm "was merely an agent."[262] The court disagreed. "Plaintiffs state that [the auditing firm] intended to deceive the FDA, agreed to 'give Ranbaxy's responses to the FDA a patina of

[259] 433 F. Supp. 2d 172, 178-84 (D. Mass. 2006).

[260] *Id.* at 183 (internal citations omitted).

[261] No. 15-cv-11828, 2016 WL 4697331, at *22-25 (D. Mass. Sept. 7, 2016).

[262] *Id.* at *22.

legitimacy,' and '[knew] that the information transmitted to the FDA regarding its audits would be materially misleading.'"[263]

Just so here. The third parties involved in the Avandia Promotion Enterprise knew that the information transmitted to physicians, plans, and PBMs regarding Avandia would be materially misleading. But they did so anyway – to advance the common goal of selling more Avandia despite its cardiovascular risks.

C. The district court erroneously concluded the alleged "enterprise" was merely GSK.

At summary judgment, GSK argued that the plans' alleged Avandia Promotion Enterprise failed the distinctiveness requirement because "GSK was both the person operating the enterprise and the enterprise itself."[264] The district court accepted this mischaracterization stating that, under the allegations, GSK was merely conducting its '"*own* affairs,"' not the '"*enterprise's* affairs."'[265]

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[263] *Id.* at *23 (citations omitted, alteration in original); *see also Living Designs, Inc. v. E.I. Dupont de Nemours & Co.*, 431 F.3d 353, 361-62 (9th Cir. 2005) (plaintiffs alleged the RICO "person" was DuPont and the "enterprise" consisted of DuPont, the law firms it hired, and the expert witnesses the law firm retained in defending numerous products liability actions; the Ninth Circuit held there was "no question" that such an enterprise was wholly separate and distinct from the "person," DuPont)

[264] JA-2145. GSK could have made this argument at the motion to dismiss stage six years earlier. But it did not. Instead, it waited until summary judgment, after the district court and this Court had already twice upheld the plans' RICO allegations.

[265] USA-16 (quoting *Reeves*, 507 U.S. at 185).

This holding is in error. Accepting the plans' allegations as true,[266] as the district court must, the pleaded enterprise more than satisfies RICO's distinctiveness requirement.

First, unlike most cases where RICO distinctiveness is at issue,[267] the enterprise members here are independent from GSK. This is not a case where the alleged enterprise is merely a corporation and its employees or subsidiaries. Nor is this a case where the enterprise members are mere agents of GSK; GSK has no "right to control the actions" of the other enterprise members – the "hallmark of an agency relationship."[268] Instead, the alleged enterprise is combination of separate pharmaceutical companies, doctors, and marketing firms.

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[266] Although made in the context of a motion for summary judgment, the district court's RICO holding was based solely on the allegations in the plans' complaints, due to the lack of discovery on the RICO issue. USA-16. Where, as here, "the district court dismisses an action for failure to state a claim on the face of the pleadings on a motion for summary judgment, a motion so decided is functionally equivalent to a motion to dismiss." *Melo v. Hafer*, 912 F.2d 628, 633 (3d Cir. 1990) (internal quotation marks omitted). As a result, the district court should have granted the motion "only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff[s]," it found that plans failed to allege a distinct enterprise or that the allegations "lack facial plausibility." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011).

[267] *See, e.g.*, *U1it4less*, 871 F.3d at 206-07; *ClassicStar*, 727 F.3d at 492-93; *Riverwoods Chappaqua Corp. v. Marine Midland Bank, N.A.*, 30 F.3d 339, 343-45 (2d Cir. 1994).

[268] *Castle Cheese, Inc. v. MS Produce, Inc.*, No. 04-cv-878, 2008 WL 4372856, at *9 (W.D. Pa. Sept. 19, 2008).

Take BMS, for example. To launch Avandia, GSK and BMS entered into a co-promotion agreement, wherein BMS agreed to help promote Avandia in exchange for GSK's promotion of BMS's brand of metformin, Glucophage (Avandia and metformin are usually prescribed together).[269] As an equal co-promoter, BMS was not a mere "employee" or "agent" of GSK. Instead, BMS was a distinct pharmaceutical company, lending its independent credibility to the enterprise's fraudulent purpose.

Nor did GSK control Dr. Haffner. A prominent diabetes researcher at the University of Texas, Dr. Haffner was neither an employee nor an agent of GSK. He was able to function independently from GSK even if GSK's funding of his activities likely influenced his conduct and research results.

Second, the independence of GSK's associates enabled the enterprise to accomplish more than GSK could have accomplished alone. This Court explained the importance of such a scheme in *Insurance Brokerage*. There, insurance purchasers alleged that defendant insurers along with insurance brokers and carried out a large-scale bid-rigging scheme.[270] The district court "was 'not convinced' that 'Defendants operated' the alleged [] enterprise's affairs 'rather than

[269] JA-1279 (¶30) (complaint's description of the co-promotion arrangement).

[270] 618 F.3d at 309.

Defendants' own affairs.'"[271] This Court reversed: "if 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."[272] The "alleged collaboration" in the enterprise at issue "allowed [the brokers] to deceive insurance purchasers in a way not likely without such collusion."[273]

Here, the independence of BMS, Dr. Haffner, and third-party marketing firms allowed the enterprise to deceive physicians, plans, and PBMs in a way GSK could not on its own. Their independence was key to the enterprise's success; it provided their promotion of Avandia with the illusion of objectivity. Because BMS is typically a *competitor* to GSK, its promotion of Avandia appeared an independent decision, based on Avandia's efficacy.[274] Because Haffner was a well-respected physician and researcher in the field, not GSK's employee, his articles denying Avandia's health risks and/or claiming that Avandia could reduce cardiovascular risk factors appeared credible.[275] And because the third-party

[271] *Id.* at 378 (quoting the district court).

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

[273] *Id.*

[274] JA-1279 (¶30), JA-1320 (¶¶173-74) (UFCW-complaint).

[275] JA-1280 (¶35), JA-1320 (¶¶173-74) (UFCW-complaint).

marketing firms that spread the false messages did not appear connected to GSK, their promotion of Avandia seemed all the more trustworthy. It was GSK's strategic partnerships with independent actors that enabled it to "deceive [physicians, plans, and PBMs] in a way not likely without such collusion."[276]

Third, GSK's status as the primary beneficiary of the Avandia Promotion Enterprise does not undermine its validity. The Third Circuit highlighted this point in *Bergrin*: "Neither the District Court nor the Appellees cite any authority that stands for the proposition that there is no 'enterprise' if an association-in-fact forms for purposes that primarily benefit one member or operates with total dependence on one member."[277] *Bergrin* considered an analogous association-in-fact enterprise. The Bergrin Legal Enterprise (BLE) consisted "of five individuals and four corporations"[278]: a lawyer (Bergrin), four drug dealers, two law firms (including Bergrin's law firm), a realty investment group, and a restaurant. As here, the *Bergrin* district court ruled that the alleged association failed to meet the distinctness requirement, reasoning: "'The Bergrin Law Enterprise' as pleaded is essentially Paul Bergrin, the licensed attorney, by another name."[279]

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[276] *Ins. Brokerage*, 618 F.3d at 378.

[277] 650 F.3d at 274.

[278] *Id.* at 269.

[279] *Id.* at 272 (quoting the district court).

This Court reversed. "The notion that the BLE 'is essentially Paul Bergrin' cannot be reconciled with the indictment's allegations that other individuals and entities joined together to form an 'association-in-fact' enterprise—*i.e.*, a 'union or group of individuals associated in fact although not a legal entity.'"[280] The government's indictment "apprise[d] the defense that the Government [would] seek to prove that the [enterprise] [was] a distinct entity, not merely a different name for the individual RICO defendants."[281] Thus, "each individual defendant was merely a part of, not an alter ego of, the 'association-in-fact' enterprise."[282] The BLE "satisfied "the 'distinctiveness' requirement" even though it was "comprised of members that are a mixture of individual persons and 'entities that they control.'"[283]

The Avandia Promotion Enterprise, like the BLE, consisted of "persons and entities that associated and engaged in a course of conduct . . . for several common purposes (*e.g.*, to make money, expand [Avandia's sales], etc.) and was an 'ongoing organization' (though an informal one)."[284] As in *Bergrin*, these

[280] *Id.* at 273 (quoting 18 U.S.C. § 1961(4)).

[281] *Id.* at 269.

[282] *Id.*

[283] *Id.* at 266 (quoting *Masters*, 924 F.2d at 1366); *see Coleman v. Commonwealth Land Title Ins. Co.*, 684 F. Supp. 2d 595, 611-12 (E.D. Pa. 2010).

[284] *Bergrin*, 650 F.3d at 269.

independent entities "operated as a unit" to falsely promote Avandia.[285] Thus, even though the Avandia Promotion Enterprise was "comprised of members that are a mixture of individual persons and entities that they control,"[286] "each individual defendant was merely a part of, not an alter ego of, the 'association-in-fact' enterprise."[287]

Here, the district court's ruling stems from its misinterpretation of a recent Eleventh Circuit decision, *Ray v. Spirit Airlines, Inc.*[288] There, the plaintiffs alleged that Spirit Airlines, together with Spirit officers and executives, an online ticketing sale company, a public relations firm, and various software consultants formed an enterprise to sell airline tickets with hidden fees.[289]

Like its sister courts, the Eleventh Circuit explicitly acknowledged that "outside vendors may be distinct" for RICO purposes.[290] The problem in *Ray* was the alleged enterprise members – the outside vendors – did not share "a common

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[285] *Id.*

[286] *Id.* at 266 (internal quotation marks omitted).

[287] *Id.* at 269.

[288] 836 F.3d 1340 (11th Cir. 2016). The district court also relied on *Albert Einstein Medical Center v. Physicians Clinical Services*, No. 90-cv-3387, 1991 WL 280274 (E.D. Pa. Dec. 20, 1991). USA-16. But that decision is distinguishable for the same reasons as *Ray*. Furthermore, *Einstein* was decided before the Supreme Court's and this Court's subsequent clarifications of the distinctiveness requirement in *Cedric*, *Jaguar Cars*, and *Bergrin*.

[289] *Ray*, 836 F.3d at 1345-46.

[290] *Id.* at 1357.

purpose with Spirit to misrepresent the [hidden fees]." As a result, they were mere agents of Spirit, not distinctive enterprise members.[291] In so holding, *Ray* relied on similar decisions where the outside vendors had no knowledge of the enterprise's fraud or else did not involve "outside" persons at all.[292]

Here, BMS, Dr. Stephen Haffner, Sir Colin Dollery, and the other third-party marketing firms *shared* GSK's fraudulent purpose. For example, Dr. Haffner leaked a copy of the Nissen study to GSK so that GSK could preemptively prepare a response. Dr. Haffner obtained the Nissen study in advance of its publication because the New England Journal of Medicine asked him to peer-review a confidential draft.[293] In leaking the study to GSK, Dr. Haffner was not an innocent agent of GSK; he was an active participant in the scheme to undermine the truth

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[291] *Id*.

[292] *See id.* at 1356 (citing *Cruz v. FXDirectDealer, LLC*, 720 F.3d 115, 121 (2d Cir. 2013) (holding that two corporations that were "legally separate but 'operate[d] within a unified corporate structure' and [were] 'guided by a single corporate consciousness'" did not meet the distinctiveness requirement); *Fitzgerald v. Chrysler Corp.*, 116 F.3d 225, 226-28 (7th Cir. 1997) (affirming dismissal where the enterprise consisted of Chrysler corporation, subsidiaries, franchised dealers, and trusts controlled by Chrysler, which the court called a "Chrysler family"); *Riverwoods*, 30 F.3d at 343-44 (rejecting an enterprise consisting of corporation and three of the corporation's vice-presidents); *Bd. of Cty. Comm'rs of San Juan Cty. v. Liberty Grp.*, 965 F.2d 879, 886 (10th Cir. 1992) ("[T]he appellees point to no evidence that the alleged association and its activities were anything more than Liberty Group going about its ordinary business of dealing in securities by and through its officers and employees.")). These cases all predate *Cedric*.

[293] JA-1296 (¶91) (UFCW-complaint).

about Avandia's risks. Similarly, one public relations firm GSK hired [redacted]

V. The district court erred in granting summary judgment without permitting any discovery on the RICO enterprise issue.

The district court further erred by granting summary judgment to GSK on the plans' RICO enterprise allegation without first allowing the plans to take discovery on this issue. The court compound this error by ignoring the plans' Rule 56(d) declaration on this point.

As this Court has emphasized, "a court 'is obliged to give a party opposing summary judgment an adequate opportunity to obtain discovery.'"[295] "If discovery is incomplete, a district court is rarely justified in granting summary judgment, unless the discovery request pertains to facts that are not material to the moving party's entitlement to judgment as a matter of law."[296] Under Rule 56(d), "[i]f a

[294] SA-0739 (¶¶250-51) (Abramson).

[295] *Doe v. Abington Friends Sch.*, 480 F.3d 252, 257 (3d Cir. 2007) (quoting *Dowling v. City of Phila.*, 855 F.2d 136, 139 (3d Cir. 1988)).

[296] *Shelton v. Bledsoe*, 775 F.3d 554, 568 (3d Cir. 2015) (citations omitted). Ordinarily, in the face of such a Rule 56(d) declaration, "a continuance of a motion for summary judgment for purposes of discovery should be granted almost as a matter of course." *Costlow v. United States*, 552 F.2d 560, 564 (3d Cir. 1977) (considering predecessor Rule 56(f)). That the district court ignored the declaration and did not allow additional time for discovery further indicates the court intended

nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order."[297]

This Court recently reversed the Middle District of Pennsylvania because it granted summary judgment to a defendant without considering the plaintiff's Rule 56(d) declaration.[298] In *Shelton*, an inmate at a Pennsylvania prison filed a class action lawsuit alleging the warden and other correctional officers violated the Federal Tort Claims Act.[299] Defendants not only opposed class certification, but also asked the district court to dismiss Shelton's claims or else grant summary judgment in their favor. At this point, "[n]o discovery requests were filed by either party; no disclosures were provided; and no discovery occurred."[300] Shelton attached a Rule 56(d) declaration to his opposition brief explaining that he needed discovery to properly respond.[301] The district court ignored Shelton's 56(d) declaration and granted summary judgment to the defendants.

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to treat the motion for summary judgment as a motion to dismiss on the pleadings. *See Melo*, 912 F.2d at 633-35.

[297] Fed. R. Civ. P. 56(d).

[298] *Shelton*, 775 F.3d at 568.

[299] *Id.* at 557-58.

[300] *Id.* at 558.

[301] *Id.*

This Court reversed, emphasizing that where "discovery is incomplete, a district court is rarely justified in granting summary judgment."[302] As the Court observed, district courts "usually grant properly filed requests for discovery under Rule 56(d) 'as a matter of course.'"[303] "This is particularly true when there are discovery requests outstanding or where relevant facts are under control of the party moving for summary judgment."[304] Because "the district court granted summary judgment to the defendants *without even considering the declaration that Shelton's attorney filed in response to defendants' motion for summary judgment*," it abused its discretion. [305]

The plans ask this Court to reverse for the same reasons. In May 2010, when UFCW filed the first of the plans' complaints, GSK had already produced discovery in consumer and personal injury cases. The plans gained access to this

[302] *Id.* at 568.

[303] *Id.* (quoting *Murphy v. Millennium Radio Grp. LLC*, 650 F.3d 295, 309-10 (3d Cir. 2011)).

[304] *Id.*

[305] *Id.* (emphasis added); *see St. Surin v. Virgin Islands Daily News*, 21 F.3d 1309, 1315 (3d Cir. 1994) (holding the district court should have resolved the plaintiff's Rule 56(f) motions (the precursor to 56(d)) "before proceeding to the merits of the newspaper's summary judgment motion"); *Dowling v. City of Phila.*, 855 F.2d 136, 139 (3d. Cir. 1988) ("The court is obliged to give a party opposing summary judgment an adequate opportunity to obtain discovery.").

discovery, some of which was relevant to their claims. It was not, however, relevant to the RICO enterprise issue.

On September 7, 2010, UFCW served initial discovery requests on GSK, seeking production of the information the plans needed to prove the alleged Avandia Promotion Enterprise.[306] GSK refused to respond, claiming UFCW's discovery requests were premature, duplicative, and unnecessary.[307] UFCW then took this dispute to the special discovery master.[308]

But before the district court could weigh in, GSK moved to dismiss both the consumers' and the plans' cases.[309] With the agreement of the Plaintiffs' Steering Committee in the consumer class action cases, all economic loss discovery was stayed pending the outcome of GSK's 12(b)(6) motions.[310]

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[306] JA-1384 (Document Request No. 7 seeking "contractors, or other individuals retained, or otherwise hired, by Defendants including but not limited to the co-promotion agreement between GSK and Bristol-Myers Squibb, Dr. Stephen Haffner and/or Sir Colin Dollery to promote, detail, sell, market, or otherwise communicate information regarding the Avandia in the United States"); JA-1372-73 (interrogatory Nos. 15-17); JA-1341-54 (Notice of Rule 30(b)(6) Deposition Regarding Sales and Marketing).

[307] JA-1415-16 (UFCW's letter to Special Master Shestack explaining that GSK refused to respond to plans' discovery request); JA-1392-1394 (parties' joint proposed agenda for the court's September 2010 conference explaining their differing positions on discovery).

[308] JA-1415 (UFCW's letter to Special Master Shestack regarding discovery).

[309] JA-1414.

[310] JA-1391 (¶1(b)) (parties' joint proposed agenda for the court's September 2010 conference).

Discovery in the plans' cases remained on hold for nearly six years while GSK's motion to dismiss was briefed, argued, decided,[311] and appealed.[312] When the case finally returned to the district court in 2016, the court required the parties to submit proposals regarding the scope and sequence of discovery moving forward.[313] The parties could not agree: the plans wanted more information than GSK was willing to provide.[314]

On April 4, 2016, the district court issued Case Management Order No. 1 (CMO 1), requiring GSK to produce discovery on only three limited issues: (1) the RECORD re-adjudication, (2) deposition transcripts from a related public entity litigation, and (3) GSK's communications with the four plans.[315] The initial production requirement was limited because the court wanted to wait for the outcome of the pending certiorari petition before ordering more discovery. CMO 1 explicitly acknowledged that the plans would "require additional information

[311] On October 23, 2013, three-and-a-half years after they were filed, the district court denied GSK's motions to dismiss the plans' claims. JA-0037-59.

[312] JA-1678-80 (Third Circuit order granting leave to file an interlocutory appeal).

[313] JA-1976 (court's order).

[314] JA-1977-98 (parties' competing proposals).

[315] JA-2014-15 (CMO-1).

particularly relevant to the claims of [the plans] that were not the subject of previous discovery in this MDL."[316]

When GSK unexpectedly moved for summary judgment on *all* of the plans' claims, the plans submitted a Rule 56(d) declaration on July 1, 2016, detailing the lack of discovery on the RICO enterprise question. The declaration explained the plans' intention to take sufficient depositions to discover GSK's RICO-related activities:

- "Safety claims made or developed by GSK *with its paid consultants, public relations firms, consulting firms, marketing firms, or recruited thought leaders* to patients, physicians, and payors;"
- "Claims regarding decreased insulin resistance made by GSK *with its paid consultants* to patients, physicians and payors;"
- "GSK's use of *ghostwriters, consultants, or other entities* to manipulate the medical literature."[317]

The declaration also described the plans' intention to take discovery from a variety of third-party sources.[318] The declaration indicated that this discovery would raise genuine issues of material fact, or perhaps even provide the basis for an affirmative motion for summary judgment on the plans' RICO claims.[319] On January 31, 2017,

[316] JA-2013 (CMO-1).

[317] JA-2196 (¶5) (emphasis added).

[318] JA-2196-97 (¶6).

[319] JA-2197 (¶9).

the plans submitted an even more detailed, revised declaration in response to GSK's Supplemental Statement of Facts. [320] Both declarations stressed the need for discovery related to the plans' RICO claims. Nonetheless, the district court ignored these declarations and granted summary judgment to GSK on the RICO enterprise issue.

The plans now ask the Court to reverse for the same reasons as *Shelton*. The plans, like Shelton, filed a Rule 56(d) declaration detailing why discovery was needed before summary judgment could be decided. But, as in *Shelton*, the district court disregarded that declaration. Therefore, as in *Shelton*, the district court committed reversible error.

CONCLUSION

For the foregoing reasons, the plans respectfully ask this Court to reverse all aspects of the district court's rulings, vacate the judgment, and remand the case for further proceedings.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation set forth in this Court's Order of May 29, 2018 because it contains 17,972 words, excluding those parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because it has been prepared in a proportionately-spaced typeface using Microsoft Word in Times New Roman, 14-point font for text and footnotes.

3. The undersigned certifies, in accordance with Local Rule of Appellate Procedure 28.3(d), that he is a member of the Bar of the United States Court of Appeals for the Third Circuit, having been admitted on July 20, 2015.

4. The electronic version of this brief was checked for computer viruses using Sophos. No computer virus was detected.

5. The undersigned certifies seven copies of the brief will be sent in hard copy to the United States Court of Appeals for the Third Circuit and one copy will be sent to GSK within 5 days of this filing pursuant to Local Appellate Rule 31. The hard copies of this brief are identical to the electronically filed version.

/s Thomas M. Sobol
Thomas M. Sobol

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system.

Dated: June 4, 2018

/s/ Thomas M. Sobol
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