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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 18-1010

_____

IN RE: AVANDIA MARKETING, SALES
AND PRODUCTS LIABILITY LITIGATION

UFCW Local 1776 and Participating Employers Health
and Welfare Fund; J.B. Hunt Transport Services, Inc.,

Appellants

_____

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(District Court Nos. 2-07-md-01871, 2-10-cv-02475, 2-11-cv-04013)
District Judge: Hon. Cynthia M. Rufe

_____

Argued: March 6, 2019

_____

Before: SMITH, *Chief Judge*, AMBRO and RESTREPO,
Circuit Judges.

(Filed: December 17, 2019)

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OPINION OF THE COURT

RESTREPO, *Circuit Judge*.

Plaintiffs, two health benefit plans ("Plans"), appeal the District Court's grant of summary judgment in favor of Defendant, GlaxoSmithKline LLC ("GSK"), the manufacturer of the prescription drug Avandia. The Plans brought suit against GSK under various state consumer-protection laws and the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. ch. 96 ("RICO"), based on, among other things, GSK's marketing of Avandia. The District Court granted summary judgment in favor of GSK on the Plans' claims, finding, in relevant part, that (i) the Plans' state-law consumer-protection claims were preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9 ("FDCA"); (ii) the Plans had failed to identify a sufficient "enterprise" for purposes of RICO; and (iii) the Plans' arguments related to GSK's alleged attempts to market Avandia as providing cardiovascular "benefits" were "belated." The Plans assert that the District Court erred in granting summary judgment, and we agree.

Applying the guidance recently provided by the Supreme Court in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), we hold that the Plans' state-law consumer-protection claims are not preempted by the FDCA. With respect to their RICO claims, the Plans should have been given the opportunity to seek discovery prior to the District Court's granting summary judgment on such claims. Further, from the inception of this litigation, the Plans' claims have centered on GSK's marketing of Avandia as providing superior

cardiovascular outcomes—in other words, cardiovascular *benefits*—as compared to other forms of treatment, and therefore, the District Court's refusal to consider the Plans' "benefits" arguments was in error because those arguments were timely raised.

Therefore, for the reasons that follow, we will reverse in part and vacate in part the order of the District Court granting summary judgment in favor of GSK, and we will remand to the District Court for further proceedings consistent with this opinion.

I.

In May 1999, the Food and Drug Administration ("FDA") approved Avandia (Rosiglitazone), a drug developed by GSK, for the treatment of type-2 diabetes. Prior to the development of Avandia and similar drugs, physicians primarily treated type-2 diabetes by prescribing metformin and/or sulfonylureas. GSK, however, marketed Avandia at a much higher price point than metformin and sulfonylureas: a one-month supply of Avandia cost approximately $220, approximately $140 of which typically was covered by patients' health benefit plans, whereas a one-month supply of metformin or sulfonylureas cost approximately $50, about $45 of which typically was covered by patients' health benefit plans.

Despite this cost differential, health benefit plans—including the Plans—placed Avandia on their formularies as a "covered" drug. The Plans, for example, determined that it was advantageous to cover the cost of Avandia because GSK allegedly marketed Avandia as being capable of both controlling a patient's blood sugar levels *and* reducing

cardiovascular risk, the latter of which is particularly pertinent to type-2 diabetes patients, 65% of whom suffer fatal cardiovascular-related illnesses or complications. Metformin and sulfonylureas—the drugs that constituted the "standard of care" for type-2 diabetes prior to Avandia's development—did not decrease cardiovascular risk, and therefore, according to the Plans, GSK presented Avandia as a cost-effective alternative to those drugs. As a result, health benefit plans covered a large portion of the expenses related to patients' prescriptions for Avandia, resulting in approximately $2.2 billion in U.S. sales in 2006 alone.

In 2006, however, concerns arose that Avandia may in fact *increase* certain cardiac risks. In August of that year, GSK submitted a Prior Approval Supplement to the FDA, in which GSK sought approval to add information to Avandia's label regarding the results of a recent meta-analysis of various clinical trials. The meta-analysis, "ICT-42," demonstrated that use of Avandia was associated with a statistically significant increase in myocardial ischemic events—events during which the heart does not receive adequate oxygen because blood flow to it is reduced. In May 2007, GSK submitted an update to its Prior Approval Supplement, offering a new formulation of its proposed warning with respect to myocardial ischemic events that would, among other things, make the warning more prominent and clear.

Three days after GSK submitted the update to its Prior Approval Supplement, the *New England Journal of Medicine* published a study authored by Dr. Steve Nissen regarding Avandia ("Nissen Study"), in which Dr. Nissen concluded that Avandia "was associated with a significant increase in the risk of myocardial infarction and with an increase in the risk of death from cardiovascular causes that had borderline

significance." J. App. 1064. Following the release of the Nissen Study, a representative of GSK held a telephone conversation with an official at the FDA regarding progress on the FDA's review of the Prior Approval Supplement. According to GSK's representative, who wrote a memo memorializing the details of the conversation, the FDA official advised that another official within the FDA was "calling for withdrawal of [the] approval" of Avandia, and thus, it was difficult for FDA officials to agree on labeling language for Avandia. Sealed App. 655–56. GSK's representative then proposed implementing the labelling changes with respect to myocardial ischemic events through the Changes Being Effected ("CBE") process, which permits a drug manufacturer to implement a change to its label *prior* to approval of such label by the FDA. The FDA official "strongly advised against proceeding" through the CBE process, stating that doing so "may give legitimacy to Dr. Nissen's data" and "will make people think that GSK must have other information." *Id.* at 656. The FDA official concluded the conversation by reminding the GSK representative that he "knew the regulations," which state that the drug manufacturer is ultimately responsible for making the decision to pursue a labelling change through the CBE process. *Id.*

On June 8, 2007, the FDA sent a letter ("Letter") to GSK regarding the Prior Approval Supplement. In the Letter, the FDA stated that it had "reviewed the data provided [by GSK in its Prior Approval Supplement] and f[ou]nd [that] the information presented [was] inadequate" and that, therefore, the Prior Approval Supplement was "not approvable." *Id.* at 660. The FDA stated that it had "concluded that the pooled data require[d] further analysis to adequately convey the potential risk for increased cardiac ischemia associated" with

use of Avandia. In particular, the FDA stated that it had "identified certain subgroups of patients . . . that may be particularly vulnerable to experiencing an ischemic event" while using Avandia. *Id.* The FDA then directed GSK to provide additional information "to address the deficiency" in the Prior Approval Supplement, including "[d]ata from studies included in a meta-analysis performed by Dr. Steven Nissen published in the *New England Journal of Medicine* that were not included in [GSK's] pooled analysis," as well as data from various other clinical trials. *Id.* at 661.

The FDA expressed its view that the "potential risk of increased cardiac ischemia [was] a significant finding that may impact a large proportion of patients with type[-]2 diabetes," and as a result, the FDA scheduled a joint meeting of two FDA advisory committees ("Joint Meeting") "to discuss the findings from th[e Prior Approval Supplement] submission, additional data recently requested, and accruing information from ongoing clinical trials" of Avandia. *Id.* The FDA stated that the "outcome of th[e Joint M]eeting w[ould] be particularly germane to any labeling or other regulatory action needed for [Avandia] and should be factored into any resubmission to address the above deficiencies." *Id.*

Later in 2007, the FDA required GSK to implement various changes to Avandia's label. Subsequent to issuing the Letter, the FDA directed GSK to add a black-box warning to Avandia's label with respect to the risk of congestive heart failure that (i) advised physicians and patients that Avandia "cause[s] or exacerbate[s] congestive heart failure in some patients," (ii) instructed physicians to "observe patients [taking Avandia] carefully for signs and symptoms of heart failure," and (iii) warned patients with certain heart conditions not to take Avandia. J. App. 708. Following the Joint Meeting, the

FDA additionally directed GSK to add a black-box warning to Avandia's label with respect to the risk of myocardial ischemic events, advising physicians and patients that a "meta-analysis of 42 clinical studies . . . , most of which compared Avandia to placebo, showed Avandia to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction" and that "[t]hree other studies . . . , comparing Avandia to some other approved oral antidiabetic agents or placebo, have not confirmed or excluded this risk." *Id.* at 743. The FDA also required GSK to include a longer explanation of the data with respect to the risk of myocardial ischemic events elsewhere on Avandia's label.

Approximately three years later, in 2011, the FDA again directed GSK to revise the warning on Avandia's label, including the black-box warning, with respect to the risk of myocardial ischemic events. By that time, GSK had completed fifty-two (52) clinical trials. The FDA's required warning advised physicians and patients that "[a] meta-analysis of 52 clinical trials . . . , most of which compared Avandia to placebo, showed Avandia to be associated with a statistically significant increased risk of myocardial infraction" and that "[b]ecause of the potential increased risk of myocardial infarction, Avandia [was] available only through a restricted distribution program." *Id.* at 786. In a memorandum accompanying its direction to implement the labelling changes, the FDA noted that the "evidence pointing to a cardiovascular ischemic risk with [Avandia] is not robust or consistent," but that "[n]evertheless, there are multiple signals of concern, from varied sources of data, without reliable evidence that refutes them." *Id.* at 1397.

In November 2013, however, following the readjudication of a particular clinical trial ("RECORD Trial"), the FDA concluded that while "[o]ne cannot entirely discount

the results of the meta-analysis" that associated Avandia with a statistically significant increased risk of myocardial ischemic events, "the totality of the available evidence does not support a marked signal of cardiovascular harm." *Id.* at 1656. The FDA determined that, following the readjudication of the RECORD Trial, Avandia "does not appear to be associated with an increased risk of major adverse cardiovascular events or death, although a small amount of residual uncertainty remains." *Id.* at 1657. The FDA directed GSK to revise Avandia's label "to reflect the current level of knowledge regarding [its] cardiovascular risk." *Id.*

In 2014, GSK revised Avandia's label pursuant to the FDA's direction. GSK removed information regarding the restricted-distribution program from the label and information regarding the risk of myocardial ischemic events *from the black-box warning only*. The revised label, however, continued to warn physicians and patients elsewhere on the label that "[i]n a meta-analysis of 52 double-blind, randomized, controlled clinical trials . . . , a statistically significant increased risk of myocardial infarction with Avandia versus pooled comparators was observed"—this information simply was no longer included in the black-box warning, but this warning nonetheless appeared elsewhere on the label. *Id.* at 829. Avandia's label continued to include a black-box warning that (i) advised physicians and patients that Avandia "cause[s] or exacerbate[s] congestive heart failure in some patients," (ii) instructed physicians to "observe patients [taking Avandia] carefully for signs and symptoms of heart failure," and (iii) warned patients with certain heart conditions not to take Avandia. *Id.* at 825. These warnings remain on Avandia's label to this day.

II.

The Plans brought suit alleging that GSK falsely marketed Avandia and concealed data with respect to its potential cardiovascular risks and side effects, thereby violating RICO and various state consumer-protection laws. The Plans assert that they would not have placed Avandia on their formularies if GSK had disclosed the cardiovascular risks that are in fact associated with Avandia. In other words, the Plans would not have covered the cost of Avandia, which was considerably more expensive than alternatives, if they had known that Avandia not only did not reduce cardiovascular risk in type-2 diabetes patients but also *increased* cardiovascular risk as compared to those alternatives.

The Plans first filed suit in May 2010, and their cases subsequently were consolidated in a multi-district litigation case, which also included consumer and personal-injury suits filed by other plaintiffs. In November 2010, GSK filed a motion to dismiss the Plans' complaints, arguing that the Plans lacked standing to bring claims under RICO. In October 2013, the District Court denied GSK's motion, and, in October 2015, we affirmed the decision of the District Court on an interlocutory appeal. *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig. (Avandia I)*, 804 F.3d 633, 646 (3d Cir. 2015).

In May 2016, GSK filed a motion for summary judgment. It argued that it was entitled to summary judgment because, among other things, the Plans' state-law consumer-protection claims were preempted by the FDCA and the Plans had failed to identify a distinct "enterprise" for purposes of RICO. The Plans opposed the motion.

In December 2017, the District Court granted summary judgment in favor of GSK. First, the District Court refused to consider the Plans' arguments that GSK falsely marketed Avandia as providing cardiovascular *benefits* in comparison to alternatives because such arguments were "belated." Unsealed App. 4. The District Court noted that the Plans "seemed to [have] shift[ed] their allegations to focus on Avandia's benefits, rather than the risks," and stated that it only would "address GSK's motion for summary judgment as to [the Plans'] state law claims on cardiovascular *risk*." *Id.* at 3–4. It stated that it would not "entertain" any of the Plans' "benefits" arguments "at th[at] juncture" due to their "belated" nature. *Id.* at 4.

Second, the District Court found that the Plans' state-law consumer-protection claims were preempted by the FDCA under the doctrine of "impossibility" preemption. It found that three separate facts established "clear evidence" that the FDA would not have approved a change to Avandia's label with respect to cardiovascular risks: (a) "the FDA rejected GSK's [Prior Approval Supplement]," (b) "the FDA advised against using the CBE process to unilaterally change the label," and (c) "the FDA ultimately concluded that there was no increased cardiovascular risk with Avandia use in relation to comparators." *Id.* at 24. With respect to the Prior Approval Supplement, the District Court found that the "rejection of GSK's proposed label on the basis of inconclusive data, considered with other evidence, constitutes clear evidence that the FDA would not have approved the label change . . . , particularly where . . . the FDA wanted to conduct further review of the data." *Id.* at 24–25. Regarding the FDA's advising against using the CBE process, the District Court found that an FDA representative's statements—that she

"strongly advised" against using the CBE process and that initializing that process would be "looked on with suspicion" and would "pull the rug out" from the FDA's then-current plans for reviewing Avandia's label—"shows that the FDA advised against using [the] CBE [process] to make the proposed label change prior to November 2007." *Id.* at 25. Finally, the District Court placed an emphasis on the FDA's "remov[al of] the black[-]box warning and restricted[-]access information from Avandia's label," as well as the FDA's "current conclusion that a link between Avandia use and increased cardiovascular risk does not exist." *Id.* at 26. In summary, the District Court found that the "FDA would not have approved of a warning for increased cardiovascular risk in Avandia versus competitors earlier than 2007 . . . and would not approve one now." *Id.*

Third, the District Court concluded that the Plans failed to identify an "enterprise" that satisfies the "distinctiveness" requirement of RICO. Specifically, it determined that "GSK was conducting its own business in selling Avandia, and thus . . . GSK is both the person and the enterprise." *Id.* at 16. Because "RICO liability 'depends on showing that the defendants conducted or participated in the conduct of the *enterprise's* affairs, not just their *own* affairs,'" the District Court found that the Plans had not adequately alleged that an "enterprise" existed because they merely alleged that the "enterprise" in this case consisted of "GSK and its agents." *Id.* (emphasis in original) (quoting *Reeves v. Ernst & Young*, 507 U.S. 170, 185 (1993)).

The Plans timely appealed. They also appealed two orders of the District Court that maintained the vast majority of the summary-judgement record under seal. We considered that appeal in *In re Avandia Mktg., Sales Practices and Prods.*

Liab. Litig. (Avandia II), 924 F.3d 662, 680 (3d Cir. 2019), in which we vacated the District Court's sealing orders.

III.

The District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1332(d), and we have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review over a district court's grant of summary judgment. *Reedy v. Evanson*, 615 F.3d 197, 210 (3d Cir. 2010). When a district court grants summary judgment without considering a declaration filed by the nonmoving party under Federal Rule of Civil Procedure 56(d), however, we review for abuse of discretion the district court's decision to disregard the Rule 56(d) declaration. *Shelton v. Bledsoe*, 775 F.3d 554, 568 (3d Cir. 2015).

A.

With the benefit of the Supreme Court's recent guidance in *Merck*, which was decided following oral argument in this case and well after the District Court's issuance of its memorandum opinion,[1] we hold that the Plans' state-law consumer-protection claims are not preempted by the FCDA, and we therefore will reverse the District Court's order granting summary judgment in favor of GSK on such claims.

In *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009), the Supreme Court recognized that "it has remained a central premise of federal drug regulation that the manufacturer [of a pharmaceutical] bears responsibility for the content of its label

[1] We subsequently ordered the parties to submit supplemental letter briefs discussing *Merck*'s effect, if any, on the disposition of this case.

at all times" and that the manufacturer "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." Thus, when it "bec[o]me[s] apparent" that a drug poses a certain risk to the health and safety of persons taking it, the manufacturer of the drug "ha[s] a duty to provide a warning that adequately describe[s] that risk." *Id.* at 571. The manufacturer may warn persons of that risk by altering the drug's label through the CBE process, which "permit[s] it to provide such a warning before receiving the FDA's approval." *Id.*

Under the FDCA, however, the FDA "retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications." *Id.* Therein lies the conflict that may give rise to impossibility preemption: even though a drug manufacturer has the responsibility under state consumer-protection laws to accurately label a drug and may change the label pursuant to the CBE process prior to receiving approval from the FDA, it may reject a label change at any time if it considers the drug to be "mislabeled" under the FDCA. Thus, a situation may occur in which a drug company seeks to change its label to add a warning that it believes is required by state consumer-protection laws, but the FDA considers the drug "mislabeled" under the FDCA in light of the new warning that was added to the label. In that situation, it would be impossible to comply with both state and federal law. In resolving this conflict, the Supreme Court struck a balance in *Wyeth*, holding that the FDCA does not preempt state-law consumer-protection claims regarding the labeling of a drug "absent clear evidence that the FDA would not have approved a change to [the drug]'s label." *Id.*

After we indicated in *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 284 (3d Cir. 2017), *vacated*, *Merck*, 139 S. Ct. 1668, that it would be helpful for the Supreme Court to "clarif[y] or buil[d] out the doctrine" espoused in *Wyeth*, the Supreme Court provided such interpretive guidance in *Merck*. "[C]lear evidence," as used in *Wyeth*'s core holding, means "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." 139 S. Ct. at 1672. Thus, to "show[] that federal law prohibited [a] drug manufacturer from adding a warning that would satisfy state law," the drug manufacturer must demonstrate that (1) "it fully informed the FDA of the justifications for the warning required by state law" and (2) "the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Id.* at 1678.

GSK has failed to satisfy either prong of *Merck*'s two-prong test, and it therefore is not "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). First, GSK has not shown that "it fully informed the FDA of the justifications for the warning required by state law." *Merck*, 139 S. Ct. at 1678. In the Letter, the FDA itself stated that it had "reviewed the data provided [by GSK] and f[ou]nd [that] the information presented is *inadequate*." Sealed App. 660 (emphasis added). Further, the FDA indicated that GSK needed to submit various data and information "in order to address the *deficiency* of this application." *Id.* at 661. Thus, GSK cannot demonstrate that the FDA was "fully informed . . . of the justifications for the warning," *Merck*, 139 S. Ct. at 1678, because the FDA itself

stated that it was "inadequate[ly]" informed of the justifications for the warning, Sealed App. 660.

GSK argues that it "fully informed" the FDA because GSK (1) provided all "material" information to the FDA and (2) did not have access to the information that the FDA requested until *after* the latter issued the Letter, but these arguments are unavailing. GSK concedes that the FDA requested additional data and information in the Letter, yet GSK argues that none of the data and information that the FDA *actually requested* in the Letter was "material" to its proposed warning on cardiac risk, and that therefore, the FDA was "fully informed" for purposes of *Merck*. This argument turns the regulatory regime on its head. The FDA, not GSK, is the entity with power to approve or refuse a change to a drug's label, and in making such a decision, it has the statutory authority to conclude that the data and tests submitted by a manufacturer were not "adequate" or that there is "insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling." 21 C.F.R. §§ 314.125(b)(2), (4). GSK is not the arbiter of which data and information is or is not "material" to the FDA's decision to approve or reject a change to a drug's label—the FDA, and only the FDA, can determine what information is "material" to *its own* decision to approve or reject a labelling change.

Additionally, by arguing that it did not have access to the FDA's requested data and information until after the FDA's issuance of the Letter, GSK undermines its own argument that the FDA was "fully informed." *Merck* noted that "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." 139 S. Ct. at 1679. Thus we

read *Merck* as holding that, in order to prove impossibility preemption, the drug manufacturer must show that the "FDA would not approve changing the drug's label" and that the FDA was "fully informed . . . of the justifications for the [proposed] warning" *at the time that the FDA rejected the proposed warning*. *Id.* at 1678. In other words, the upshot of *Merck* is that a drug manufacturer must show that the FDA made a fully informed decision to reject a change to a drug's label in order to establish the "demanding defense" of impossibility preemption. *Id.* at 1678. If the question of whether the FDA was "fully informed" was not tethered in time to the question of whether the FDA indeed rejected the proposed warning, the "fully informed" prong of the test espoused in *Merck* would be rendered superfluous.

Thus, if GSK wishes to rely on the Letter as proof that the FDA rejected its proposed label change, it must also demonstrate that the FDA possessed all the information it deemed necessary to decide whether to approve or reject the proposed warning *at the time it issued the Letter*. By arguing that it did not have the FDA's requested data and information until *after* the FDA issued its letter, however, GSK is, in effect, conceding that the FDA was not "fully informed" at the time of the Letter's issuance. For that reason, among the others outlined above, GSK cannot satisfy the first prong of the test espoused in *Merck*.

Second, GSK cannot show that the "FDA . . . informed [it] that the FDA would not approve changing the drug's label to include [the relevant] warning." *Id.* at 1678. GSK directs the Court's attention to the Letter as proof that the FDA rejected the proposed warning. The Letter indeed stated that GSK's Prior Approval Supplement for a label change was "not approvable," but the FDA indicated that this was so because

the "information presented [by GSK wa]s inadequate." Sealed App. 660. The FDA then required GSK to "amend the supplemental application," stating that "[a]ny amendment should respond to all the *deficiencies* listed" in the Letter. *Id.* at 661 (emphasis added). Thus, it is clear from the very text of the Letter that the FDA did not consider GSK's Prior Approval Supplement "not approvable" because it was unconvinced of the need for a strong warning on myocardial ischemic events; rather, the FDA considered the Prior Approval Supplement "not approvable" because it contained various "deficiencies" that the FDA required GSK to ameliorate prior to the FDA's making a final determination. At most, the Letter indicates that it is *possible* that the FDA could have rejected the label change *after* receiving the various data and information it requested from GSK, but as the Supreme Court has reiterated, the "possibility of impossibility [is] not enough." *Merck*, 139 S. Ct. at 1678 (alteration in original) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 n.8 (2011)). We nevertheless need not speculate regarding the *possibility* that the FDA would have rejected the proposed warning upon the receipt of the requested data and information because it indeed *ordered* GSK to include various warnings regarding cardiac risks on Avandia's label shorty after issuing the Letter, which alone undermines GSK's position that the Letter represents a rejection of its proposed warning.

Finally, we are not persuaded by any of GSK's arguments that the Plans' claims are preempted because GSK allegedly was unable to avail itself of the CBE process for various reasons. GSK primarily argues that it could not use the CBE process to introduce a warning on ischemic risks prior to mid-2006, when it submitted its Prior Approval Supplement. GSK reasons that ICT-42 served as the basis for its belief that

an ischemic-risk warning should be included on the label, and because that study was completed in mid-2006, it did not have the "newly acquired information" necessary to make a labeling change prior to that time. This argument, however, is undermined by GSK's own admissions. For example, GSK itself described the results of "ICT-37," a meta-analysis completed a year earlier in August 2005, as "generally similar" to ICT-42, and GSK stated that "[a]ny numerical differences [between the meta-analyses] were not clinically significant." Sealed App. 861. Thus, at the very least, it appears that GSK could have used the CBE process to add an ischemic-risk warning as early as August 2005 because, by GSK's own admission, ICT-37 and ICT-42 indicated similar results and had clinically insignificant numerical differences.[2] Further, GSK cannot rely on its informal phone conversations with an FDA official to claim that it could not pursue a label change through the CBE process, nor can GSK rely on the stock language at the end of the Letter, which advised GSK that Avandia "may be considered to be misbranded under the [FDCA] if it is marketed with the[proposed] changes before approval of this supplemental application." *Id.* at 661. An informal phone conversation with an FDA official is not an "agency action taken pursuant to the FDA's congressionally delegated authority," *Merck*, 139 S. Ct. at 1679, and the stock language at the end of the Letter is a simple statement of the law: if a manufacturer makes a label change pursuant to the CBE process (i.e., without seeking the prior approval of the FDA), the manufacturer *always* runs the risk that the FDA will

[2] We take no position with respect to whether GSK could have used the CBE process, or otherwise sought to change Avandia's label, to add an ischemic-risk warning prior to August 2005.

later reject the label change and consider the drug as "mislabeled," *see* 21 C.F.R. § 314.70(c)(7). Finally, GSK's argument that it could not implement a black-box warning through the CBE process is a red herring—the Plans are not arguing that GSK should have added the black box *itself* through the CBE process, but rather that GSK should have added the *content* of the black-box warning *anywhere* on the label.

GSK thus has failed to demonstrate that the Plans' state-law consumer-protection claims are preempted by the FDCA, and GSK therefore is not entitled to summary judgment on those grounds. Therefore, we will reverse the order of the District Court granting summary judgment in favor of GSK on the Plans' state-law consumer-protection claims.

B.

The District Court erred in granting summary judgment on the Plans' RICO claims without giving the Plans the benefit of discovery on those claims.

"[A] Court 'is obligated to give a party opposing summary judgment an adequate opportunity to obtain discovery.'" *Doe v. Abington Friends Sch.*, 480 F.3d 252, 257 (3d Cir. 2007) (quoting *Dowling v. City of Philadelphia*, 855 F.2d 136, 139 (3d Cir. 1988)). "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." *Shelton*, 775 F.3d at 568.

Rule 56(d) provides that "[i]f a 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." Fed. R. Civ. P. 56(d). "[D]istrict courts usually grant properly filed requests for discovery under Rule 56(d) 'as a matter of course' . . . ." *Shelton*, 775 F.3d at 568 (quoting *Murphy v. Millennium Radio Grp. LLC*, 650 F.3d 295, 309–10 (3d Cir. 2011)). "This is particularly true when there are discovery requests outstanding or where relevant facts are under control of the party moving for summary judgment." *Id.* A district court abuses its discretion when it grants summary judgment in favor of the moving party "without even considering" a Rule 56(d) declaration filed by the nonmoving party. *See id.*

The Plans never received discovery related to their RICO claims, including with respect to whether an "enterprise" existed for purposes of RICO, and thus when GSK moved for summary judgment on the Plans' RICO claims, the Plans submitted a detailed Rule 56(d) declaration regarding the lack of discovery on the issues related to RICO. *See* J. App. 2195–2198. They subsequently filed a supplemental Rule 56(d) declaration, further elaborating on their need for discovery on RICO-related issues. *See id.* at 2272–76.

The District Court granted summary judgment in favor of GSK on the Plans' RICO claims without considering their Rule 56(d) declaration and their supplemental Rule 56(d) declaration. This was an abuse of discretion, especially as the District Court granted summary judgment on the ground that the Plans could not prove the existence of an "enterprise," information related to which is "under control of the party

moving for summary judgment"—in this case, GSK.[3] *Shelton*, 775 F.3d at 568. We therefore vacate the District Court's order granting summary judgment in favor of GSK on the Plans' RICO claims, and we remand to the District Court to give proper consideration to the Plans' Rule 56(d) declarations.

IV.

Finally, we note that, on remand, the District Court must consider the Plans' arguments that GSK marketed Avandia as providing cardiovascular *benefits*. These arguments and claims are not "belated"; the Plans have pursued this line of argument since the outset of this litigation. In the Plans' complaint itself, the Plans alleged that they "rel[ied] upon [GSK]'s promises of superior treatment *and better cardiovascular outcomes* compared with the older diabetes drugs" in determining that it was worth the increased cost to cover Avandia. J. App. 1273. They alleged that "better cardiovascular outcomes" were a crucial part of GSK's alleged fraudulent marketing: "[t]he notion that Avandia would actually lower diabetics' cardiovascular risk was critical to Avandia's marketing" because GSK "needed justification for the steep price difference between Avandia and the older established diabetes drugs." *Id.* at 1291. While a portion of the Plans' claims center on the assertion that GSK should have disclosed on its label the true nature of the increased cardiovascular *risk* that was presented by Avandia as compared to cheaper alternatives, the increased risk is only relevant to the

[3] We refuse to construe the District Court's grant of summary judgment in favor of GSK on the Plans' RICO claims as a dismissal on the pleadings pursuant to Rule 12(c), particularly because the Plans' RICO claims previously survived a Rule 12(b)(6) motion to dismiss. *See Avandia I*, 804 F.3d at 646.

Plans' claims insofar as the Plans make the following argument: GSK failed to warn of Avandia's true cardiovascular *risk*, and thus, GSK was continuing—by omission—to promote Avandia as capable of *lowering* patients' cardiovascular risk, and GSK thereby continued to induce the Plans to cover the cost of Avandia based on this perceived "benefit" of lowering cardiovascular risk. *Id.* at 1316. In short, the Plans have never argued that GSK promoted Avandia as capable of actually *improving* patients' cardiovascular health, but rather as capable of *lowering cardiovascular risk* when compared to cheaper alternatives, which indeed is a "benefit."

Because the Plans have raised, throughout these proceedings, arguments that GSK marketed Avandia as providing cardiovascular *benefits*, it was error for the District Court to refuse to consider those arguments. *See, e.g.*, *Hillman v. Resolution Tr. Corp.*, 66 F.3d 141, 144 (7th Cir. 1995). Therefore, on remand, the District Court needs to give proper consideration to these arguments.

V.

For the reasons stated above, we will reverse the order of the District Court granting summary judgment in favor of GSK on the Plans' state-law consumer-protection claims, vacate the order of the District Court granting summary judgment in favor of GSK on the Plans' RICO claims, and remand to it for proceedings consistent with this opinion. On remand, the District Court shall give proper consideration to the Plans' Rule 56(d) declarations, as well as their arguments that GSK marketed Avandia as providing cardiovascular benefits.