No. 15-1525

In The Supreme Court of the United States

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, ALLIED SERVICES DIVISION WELFARE FUND,

Petitioners,

v.

SANOFI-AVENTIS U.S. LLP, SANOFI-AVENTIS U.S., INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Petitioners, third party payors of health benefits, asserted RICO claims alleging that, but for Aventis' alleged misrepresentations regarding its FDA-approved drug Ketek, doctors would not have prescribed, and Petitioners thus would not have paid for, some number of Ketek prescriptions. Petitioners offered no evidence that a single doctor prescribed Ketek as a result of the alleged misrepresentations. And Petitioners' expert, by Petitioners' own choice, did not analyze or opine on causation, but rather addressed only a purported correlation. On this record, the district court denied class certification and granted summary judgment for Aventis on Petitioners' individual claims, finding inadequate class-wide or individualized proof of causation. A unanimous panel of the Second Circuit affirmed.

The question presented is whether Petitioners' generalized correlation evidence was insufficient to establish either class-wide or individual but-for causation.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, both sanofi-aventis U.S. LLP and sanofi-aventis U.S. Inc. are wholly-owned, indirect subsidiaries of Sanofi-Aventis, a French corporation with its principal place of business located at 174 avenue de France, 75013 Paris, France.

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The opinion of the court of appeals (Pet App. 1a-48a) is reported at 806 F.3d 71. The order of the district court denying class certification (Pet. App. 116a-126a) is reported at 2011 U.S. Dist. LEXIS 36454. The order of the district court granting summary judgment (Pet. App. 49a-115a) is reported at 20 F. Supp. 3d 305.

JURISDICTION

The judgment of the court of appeals was entered on November 13, 2015. A petition for rehearing was denied on February 18, 2016 (Pet. App. 129a). Justice Ginsburg granted an extension of time to file a petition for writ of certiorari until June 17, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATEMENT

Petitioners ask this Court to review a fact-based decision by the district court, affirmed under an abuse of discretion standard of review by the Second Circuit, evaluating the sufficiency of evidence offered to prove but-for causation in a class action involving RICO claims against a drug manufacturer. Petitioners alleged that Respondents (collectively referred to herein as "Aventis") misrepresented the safety and efficacy of the drug Ketek, leading to increased prescriptions of Ketek by physicians that Petitioners ultimately paid for. However, Petitioners did not present

any evidence that a single physician prescribed Ketek as a result of the alleged misrepresentations, deciding instead to argue that but-for causation was established based on a correlation. The Second Circuit held that Petitioners' correlation evidence was insufficient to prove but-for causation on a classwide basis and likewise failed to raise a triable issue of fact as to whether Petitioners themselves had been injured by any alleged fraudulent marketing.

1. a. Ketek is the brand name for the prescription drug telithromycin, the first FDA-approved antibiotic in a class of antibiotics known as ketolides. 2d Cir. JA 666, 723-24. From its initial approval for marketing in the United States in April 2004, through February 2007, Ketek was FDA-approved for three uses: treatment of (1) community-acquired pneumonia ("CAP"), (2) acute bacterial exacerbation of chronic bronchitis ("AECB"), and (3) acute bacterial sinusitis ("ABS"). *Id.* at 4350-51.

Prior to its approval by FDA in 2004, Ketek was subjected to a rigorous and thorough scientific review process. Ketek's pre-approval review included three distinct cycles of regulatory review by FDA. 2d Cir. JA 1877-85, 3263-65, 3807-11, 3921-23. In total, Ketek's approval application included numerous controlled Phase III clinical trials and data from experience in nearly four million patients taking Ketek in other countries. *Id.* at 1883-84, 3336-37, 3814-28. Ketek's new drug application included one of the largest bodies of information available for any antibiotic at the time

of initial approval. *Id.* at 671-73, 1883-84, 3336-37, 3814-28.

b. Ketek's safety profile is similar to other antibiotics in its class. While it is true that Ketek is associated with certain side effects, "[e]very drug [available to physicians to treat AECB and ABS] has the potential [for] serious and life-threatening complications." 2d Cir. JA 2498; *see, e.g.*, *id.* at 4084, 4112. In its pre-approval safety review, FDA's Division of Drug Risk Evaluation noted that "telithromycin-associated hepatotoxicity appears to be similar in severity and pattern to medicines" in another class of antibiotics, the macrolides. *Id.* at 3857.

c. The Petitioners' case hinges on their assertion that Ketek was neither safe nor effective and that, in order to gain FDA approval, Aventis misled FDA about certain results in one of Aventis' pre-approval clinical trials called "Study 3014." *See* Pet. Br. 6, 10. Prior to the submission of Study 3014's final report to FDA, Aventis identified certain specific deviations from good clinical practices by Dr. Anne Kirkman-Campbell, who was one of the investigators for Study 3014. 2d Cir. JA 673. Aventis investigated these deviations, aggressively pursued corrective action, and documented the deficiencies found and the remedial action taken. *Id.* at 3457-565, 3574-76, 3749-63. FDA then conducted its own review and ultimately determined that Dr. Kirkman-Campbell falsified records. *See id.* at 3789-91. Aventis fully cooperated in all of FDA's extensive investigations into the conduct of Study 3014, including

the investigation of Dr. Kirkman-Campbell. *See id.* at 4033-38, 4052, 4400.

It is undisputed that FDA did *not* utilize Study 3014 as a basis for approving Ketek. 2d Cir. JA 643, 4308-09, 4539. However, FDA neither excluded nor ignored the adverse event reports or any safety signal that emerged from Study 3014. Rather, FDA "reviewed the study for safety findings that would have counted against the drug." Pet. App. 9a; *see also* 2d Cir. JA 1883.

Aventis did not withhold or "obscure[]" (Pet. Br. 10) any information related to Study 3014 in order to gain FDA approval for Ketek. Pet. App. 35a n.6. FDA ultimately based its approval of Ketek on substantial data derived from other clinical trials and the successful record of limited adverse events flowing from nearly four million courses of treatment with Ketek in other countries, where Ketek had been approved for sale since 2001. *Id.* at 10a; 2d Cir. JA 1883, 3814-15, 3856-57. Moreover, Aventis did not utilize Study 3014 in its post-approval promotion of Ketek in the United States. 2d Cir. JA 1597.

d. Like all prescription drugs, Ketek was subjected to post-marketing surveillance as required by federal regulations. 2d Cir. JA 671, 1885-86, 4126-27. Following the required post-marketing surveillance, Aventis reported to FDA adverse events potentially associated with Ketek. As a result, the safety profile of Ketek, like the safety profile of every marketed prescription drug, continued to evolve after its approval. *See id.* at 1885-86, 3829-920, 3954-82, 4150-51.

Aventis worked closely with FDA and with regulators in Europe to understand the implications of Ketek's post-marketing adverse event reports and to continue to evaluate the safety profile of Ketek as compared to other marketed antibiotics. 2d Cir. JA 1886; *see generally id.* at 3829-920. For example, Aventis worked with FDA to create a revised label for Ketek that strengthened the warnings about the potential risks for a specific subgroup of patients taking Ketek. *Id.* at 1886, 3997.

e. On December 14-15, 2006, FDA convened a meeting with the Anti-Infective Drug Advisory Committee (the "Committee") to discuss Ketek. 2d Cir. JA 1887, 4389, 4420-21. At this meeting, the Committee considered whether the data then available supported the continued marketing of Ketek for each of the drug's three approved uses. *Id.* at 1887, 4395-96, 4421. "The consensus of the Committee was that the hepatic toxicity of [Ketek] appeared similar to other antibiotics." *Id.* at 677. Ultimately, the Committee supported the continued marketing of Ketek for the treatment of CAP but recommended to FDA that the indications for AECB and ABS be withdrawn. *Id.* at 1887, 4395.

The Committee's recommendation was not, as the Petitioners assert, based solely or even predominately on concerns about Ketek's safety. Rather, the Committee's decision was based in substantial part on the FDA's recent change to its requirements for FDA approval. 2d Cir. JA 1887, 4396, 4649-50. Like all other antibiotics on the market in 2004, Ketek was approved by FDA based upon non-inferiority efficacy studies,

which required a showing that Ketek was not inferior in efficacy to other standard treatments currently approved. Pet. App. 6a-7a; 2d Cir. JA 677, 4387. About two months before the Committee's meeting, on October 23, 2006, FDA had announced a new superiority requirement for antibiotic trials. 2d Cir. JA 677, 1887; *see also id.* at 4397. Under this new standard, in order to approve an antibiotic for a specific indication, FDA required some showing that the proposed new antibiotic is more effective than another for a specific indication, not simply comparable. 2d Cir. JA 677, 4397. Based primarily on this changing efficacy standard, the Committee recommended withdrawal of Ketek's indications for AECB and ABS. Pet. App. 20a; *see also* 2d Cir. JA 1887, 4395-96, 4649-50. The Committee voted to allow approval for these indications at a later time, subject to the required superiority studies. 2d Cir. JA 4396.

f. After learning of the agency's decision, Aventis decided to terminate its rebate contracts for Ketek and to stop promoting Ketek in the United States. 2d Cir. JA 1630, 1717-23. Nonetheless, Ketek remains on the market today as an FDA-approved prescription drug for the treatment of CAP. *Id.* at 1104; *see id.* at 1732. In addition, Ketek is an approved prescription drug for AECB, ABS, and CAP in Europe and elsewhere in the world.[1] *Id.* at 1970.

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[1] In 2009, sales of Ketek surpassed €13,000,000 in France alone. 2d Cir. JA 2032.

2. Petitioners are third-party health benefit payors who filed RICO claims against Aventis contending that, but for Aventis' alleged misrepresentations about the safety and efficacy of Ketek, doctors would not have prescribed, and the Petitioners would not have paid for, Ketek prescriptions. Thus, Petitioners present a *quantity-effect* theory of liability and damages.[2]

The undisputed evidence showed that there are a number of different factors that drive a physicians' decision to prescribe a certain drug. Even the Petitioners' medical experts admitted that the process by which physicians make prescribing decisions is highly individualized and involves the consideration of a variety of factors and types of information. *See* 2d Cir. JA 662-65, 733-36, 2043-48, 2316, 2494-509, 2928-39.

The Petitioners adduced no evidence that a single doctor prescribed Ketek as a result of Aventis' alleged misrepresentations. Although the Petitioners engaged several medical doctors to testify as experts in this case, not one testified that he was misled by Aventis' alleged fraud or that he knew of any physicians who had been misled. *See* 2d Cir. JA 2037, 2043, 2045, 2476, 2479, 2481, 2494, 2934. As a result, the record is devoid of any evidence that even a single physician would not have prescribed Ketek but for the alleged fraud.[3]

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[2] This theory is different than a *price-effect* theory under which a plaintiff alleges that it paid a higher premium for prescriptions as a result of the alleged fraud.

[3] There also was no evidence in the record that any of the Petitioners or any of the prescription benefit managers they

The only purported evidence of but-for causation presented by the Petitioners was a chart created by economist Dr. Meredith Rosenthal depicting a decline in Ketek sales over a period of time. *See* Pet. Br. 9, Fig. 1. However, Dr. Rosenthal admitted that her chart was *not* intended to show that the events listed in the chart (a February 2006 public health advisory issued by FDA and FDA's February 2007 withdrawal of two of Ketek's indications) *caused* any drop in Ketek sales. 2d Cir. JA 2941-42.

Dr. Rosenthal acknowledged that many factors could have accounted for the decline in Ketek sales, including: the seasonality of Ketek prescriptions (2d Cir. JA 2930); the cessation of field promotion (*id.* at 2924); the entry of other generic antibiotics into the market (*id.* at 2929); and the withdrawal of rebate contracts (*id.* at 2931). Dr. Rosenthal also admitted that she did not attempt to isolate the effects of these various individual factors on the decline in Ketek sales. *Id.* at 2924. And contrary to the Petitioners' assertion, Dr. Rosenthal did not testify that a regression analysis in this case was "statistically unwarranted." Pet. Br. 22. Rather, she explained that she was not retained "to undertake a cause and effect analysis" and that the chart provided merely a "descriptive analysis." 2d Cir. JA 2941-42. She "did not do an imperical [*sic*] analysis of causation in this case." *Id.* at 2926.

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consulted relied on the alleged misrepresentations when deciding whether to pay, or how much to pay, for Ketek.

3. The district court denied class certification and granted summary judgment in favor of Aventis because Petitioners' evidence was not sufficient to support class certification or to create a triable issue of fact.

a. Following the close of discovery, the Petitioners moved to certify a class of all third-party payors that paid or incurred costs for Ketek prescriptions between April 1, 2004, and February 12, 2007. After briefing and an evidentiary hearing, Magistrate Judge Reyes recommended that class certification be denied because the Petitioners could not establish RICO causation through common proof. 2d Cir. JA 1371-76. The district court adopted the recommendation and denied class certification. Pet. App. 126a.

b. Aventis then moved for summary judgment on the Petitioners' individual claims. Magistrate Judge Reyes recommended that the district court grant Aventis' motion as to all claims because the Petitioners' generalized proof of causation – Dr. Rosenthal's opinion testimony – was not sufficient to create a triable issue of fact as to whether any physician relied on Aventis' alleged fraud. *See* 2d Cir. JA 1454-69. The district court adopted Judge Reyes' recommendation and entered summary judgment for Aventis.[4] *See* Pet. App. 114a.

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[4] The district ordered that Petitioners amend certain state law claims (not at issue here) raised in their complaint, and further granted leave to Aventis to move for summary judgment on those claims after they were amended. Pet. App. 114a. Rather

4. A unanimous panel of the Second Circuit affirmed the district court because, "on this record" (Pet. App. 41a), the generalized correlation evidence adduced by Petitioners was insufficient to support a reasonable inference of either classwide or individual but-for causation.

a. Relying on the reasoning in its prior decision in *UFCW Local 1776 v. Eli Lilly Co. ("Zyprexa")*, 620 F.3d 121 (2d Cir. 2010), the Second Circuit held that the district court did not abuse its discretion in denying class certification. Although the court agreed with Petitioners that *Zyprexa* does not foreclose class certification for all RICO claims brought against a drug manufacturer, it held that *Zyprexa*'s reasoning applied to bar Petitioners' attempt to certify a class in *this* case because Petitioners' evidence was insufficient to establish classwide but-for causation. Pet. App. 2a.

The Second Circuit held that, although the evidence adduced by Plaintiffs showed that Ketek has risks, the evidence also showed that all antibiotics used to treat respiratory infections have risks, and that Ketek's risks were well within the range of similar anti-infectives. Pet. App. 38a. Petitioners' argument that Ketek presented a "threefold" increase in serious side effects was flawed because it was based on results from Study 3014, which the Petitioners themselves

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than amend their claims, Petitioners stipulated that summary judgment would be granted as to any further amended claims, and the parties jointly asked that the case be dismissed in its entirety. 2d Cir. JA 1532-35. On June 12, 2014, the District Court dismissed the case. *Id.* at 1536.

stated were unreliable. *Id.* at 40a. "[O]n this record" (*id.* at 41a), the court held that the Petitioners' "generalized proof is insufficient to establish RICO causation for each member of the putative class." *Id.* at 34a.

The Petitioners' causation theory was based on the premise that prescribing doctors' decisions were one-dimensional and focused solely on the safety of Ketek. Pet. App. 34a-35a. And the Petitioners purported to show but-for causation based on a decline in the sales of Ketek following the FDA's public health advisory[5] and Ketek's label change in 2006. *Id.* at 35a. The Second Circuit rejected this method as a means of proving classwide causation because it showed only correlation: "Ketek's declining sales may have been correlated with the issuance of the FDA's public health advisory and with Ketek's label revision, but mere correlation does not demonstrate causation." *Id.* at 36a. The correlation-based inference of causation was particularly weak here because the Petitioners made no attempt to control for other factors that may have affected the drop in Ketek's sales (such as Aventis terminating Ketek's rebate contracts and ceasing field promotion of Ketek). *Id.* at 36a-37a & n.7.

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[5] The advisory concerned an upcoming article in *Annals of Internal Medicine* reporting on three cases of hepatoxicity in patients taking Ketek. The assertion that the public health advisory caused a decline in Ketek sales was always a non-sequitur. The advisory did not urge physicians to discontinue prescribing Ketek, nor did it question the overall safety or efficacy of Ketek. *See* 2d Cir. JA 3984-85.

The Second Circuit was careful to explain, however, that it is *not* impossible to certify a class in a RICO mail-fraud case with generalized proof of causation. *See* Pet. App. at 2a, 28a, 31a, 37a. For example, if a drug is so dangerous that no reasonable physician would prescribe it but for a misrepresentation regarding the drug's safety, a reasonable jury could infer based solely on a precipitous drop in sales that prescriptions were written in reliance on that misrepresentation. *Id.* at 37a. However, the record in this case did not support such a conclusion because it showed (1) Ketek's risks "were well within the range of dangerousness typical of similar anti-infectives," (2) Ketek's sales did not drop to zero following FDA's health advisory, which would be expected if physicians' prescribing decisions were truly one-dimensional and based solely on safety, and (3) Ketek's "sales declined in a manner consistent with the cyclical manner in which sales had declined during the same months the previous year." *Id.* at 38a-39a.

The Second Circuit held that it is not reasonable to infer simply from a decline in sales that all Ketek prescriptions were written in reliance on the alleged misrepresentations about Ketek's safety given the number of factors that enter into doctors' prescribing decisions. *Id.* at 41a. The court stated: "To ultimately find a defendant liable, a jury must be able to base its decision on something firmer than speculation." *Id.* at 43a.

Notably, the Second Circuit distinguished the "simplistic nature of Dr. Rosenthal's analysis" from the

regression analysis that the First Circuit held was sufficient to show causation in *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013). Pet. App. 45a. In that case, the First Circuit held that when individual physicians' reliance on a pharmaceutical company's misrepresentations form a necessary link in the causal chain, such reliance can be proved with sufficiently powerful aggregate evidence (as opposed to individual physician testimony). *Id.* at 46a. But "[h]ere, [the Petitioners'] causation evidence – apparently by their own choice – is akin to the simplistic proof introduced by the *Zyprexa* plaintiffs, and not to the far more sophisticated proof offered in *Neurontin*." *Id.*

b. The Second Circuit's decision on class certification "necessarily dispose[d] of the summary judgment question as well: if Plaintiffs' RICO claims cannot be proved by generalized proof and Plaintiffs have adduced no *individualized* proof (which they have not), Plaintiffs' claims cannot survive summary judgment." Pet. App. 3a. In affirming the denial of summary judgment, the Second Circuit again "reaffirmed" that a third-party payor is not foreclosed from using generalized proof to establish but-for causation (*i.e.*, without having to show individual reliance by each physician). *Id.* at 47a. However, such generalized proof must be more than the mere "correlation evidence offered by [the Petitioners] here[, which was] no more probative as to whether Aventis's alleged fraud caused Plaintiffs themselves to suffer an injury than it [was]

as to whether that alleged fraud caused an injury to each HBP in the putative class." *Id.* at 48a.

ARGUMENT

The Second Circuit's limited holding does not create or add to a conflict in the circuit courts. Contrary to Petitioners' assertions, the Second Circuit did not declare a rule that doctors' prescribing decisions always break the chain of causation in a RICO case. In fact, the court's decision does not address or decide the issue of proximate causation. The issue presented for review by Petitioners is not present in this case. Accordingly, the petition for writ of certiorari should be denied.

I. The Second Circuit's Fact-Bound Decision Does Not Create or Add to Any Circuit Conflict.

The Second Circuit's decision, when properly viewed as being limited to the sufficiency of the evidence presented, is not in conflict with that of any other circuit court. Although the Petitioners assert that "the Second Circuit's view of proximate causation is likewise at odds with its sister circuits" (Pet. Br. 19), the Second Circuit's opinion does not even address proximate causation, much less declare an all-encompassing rule that doctors always break the chain of causation. Rather, the court ruled that in "*this* case" (Pet. App. 2a), "on this record" (*id.* at 41a), the Petitioners' generalized proof was not sufficient to establish

but-for causation. On this point, the Second Circuit is not at odds with any other circuit court.

1. Both the Second Circuit and First Circuit agree that their respective decisions are not in conflict. In this case, the Second Circuit distinguished the "simplistic" correlation evidence presented by the Petitioners from the robust regression analysis presented by the plaintiffs in *Neurontin*. Pet. App. 45a. Likewise, the First Circuit in *Neurontin* distinguished the Second Circuit's decision in *Zyprexa* because the plaintiffs in *Zyprexa*, like the Petitioners here, adduced only generalized correlation evidence that was not sufficient to prove causation. *Neurontin*, 712 F.3d at 46-47.

2. In addition, the Second Circuit's opinion here is not at odds with the Third Circuit's decision in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015). In *Avandia*, the Third Circuit denied the defendant's *motion to dismiss* – it did not decide whether and to what extent aggregate evidence can establish classwide or individual but-for causation in a class action brought by a health benefit plan. *Id.* at 647 ("At this stage in the litigation, plaintiffs need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence of proximate causation. They have done that here.") (internal quotation marks omitted).[6]

[6] Although *Avandia*, unlike this case, actually addressed the issue of whether doctors' prescribing decisions break the chain of causation, this Court declined to grant the petition, as it has done on other occasions in the recent past in cases involving claims of

3. Similarly, the Ninth Circuit's decision in *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 225 (9th Cir. 2010), is also different from *Zyprexa, Neurontin*, and this case. Whatever precedential value the unpublished decision in *United Food* has, it was decided on a motion to dismiss (in part for failing to plead fraud with particularity under Rule 9(b)); it contains no holding that doctors' decisions break the causal chain; and it does not address or decide what evidence is sufficient to prove but-for causation in a case like this.

4. The Petitioners' assertion that the Second Circuit's opinion in this case creates or contributes to a split in the circuits is unfounded. Correctly construed, the Second Circuit's opinion decided only the sufficiency of the circumstantial evidence presented in this case to prove but-for causation. This unique and otherwise unremarkable holding does not merit review by this Court.

II. This Case Is Not a Viable Vehicle to Review the Question Presented in the Petition.

This case is not a viable vehicle for reviewing the issue presented in the Petition because the Second

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fraudulent drug marketing. *See GlaxoSmithKline LLC v. Allied Servs. Div. Welfare Fund ("Avandia")*, 136 S. Ct. 2409 (2016); *Pfizer Inc. v. Kaiser Found. Health Plan, Inc. ("Neurontin")*, 134 S. Ct. 786 (2013); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Eli Lilly & Co. ("Zyprexa")*, 564 U.S. 1046 (2011).

Circuit did not address or decide the issue. In petitioning this Court, the Petitioners contend that "a fundamental disagreement has arisen over what constitutes an intervening cause that snaps the chain of causation under RICO." Pet. Br. 1. According to the Petitioners, the Second Circuit held that the intervening actions of prescribing physicians interrupt the chain of causation to make a finding of proximate causation under RICO "impossible" in cases alleging that a drug company fraudulently exaggerated a drug's safety and efficacy to boost its sales. Pet. Br. 15. However, as noted before, the Second Circuit did *not* hold that the presence of doctors breaks the causal chain, nor did the Second Circuit's decision address, much less decide, any issue related to *proximate* causation.

1. The Second Circuit decided only two issues, both of which concerned the sufficiency (or lack thereof) of the Petitioners' evidence offered to establish *but-for* causation. First, based "on this record," the Second Circuit held that the district court did not abuse its discretion in denying class certification because the Petitioners' generalized "correlation evidence" was insufficient to prove classwide but-for causation. Pet. App. 34a-45a. And second, the court affirmed the district court's conclusion that, in the absence of any other proffered evidence, the Petitioners' correlation evidence was insufficient to permit a reasonable jury to conclude that the named plaintiffs had been injured as a result of Aventis' alleged fraud. *Id.* at 47a-48a.

In deciding both of these issues, the Second Circuit never ruled that the presence of doctors breaks the

causal chain under RICO making a finding of causation "impossible." Pet. Br. 15. In fact, the court's opinion does not address that issue at all. But more importantly, on the issue that was before the court – the sufficiency of the Petitioners' evidence to establish but-for causation – the Second Circuit went out of its way to make clear that aggregate evidence *could* be used to establish causation in a case like this: "We have recognized, however, that plaintiffs may be able to prove class-wide causation based on first-party reliance *without* an individualized inquiry into whether each class member relied on the defendant's misrepresentation if 'circumstantial evidence' generates a sufficiently strong inference that all class members did, in fact, rely." Pet. App. 29a. The court explained repeatedly that, although the Petitioners' evidence here fell short, it is possible to prove classwide causation in a case such as this despite the presence of doctors in the causal chain. *Id.* at 2a, 31a, 37a.

2. To support their petition, the Petitioners ignore the Second Circuit's actual holding and mischaracterize the court's opinion. As just one example, the Petitioners say that the Second Circuit "has firmly held that a drug company's misrepresentations 'cannot be a but-for, much less proximate, cause of the plaintiffs' injury.'" Pet. Br. 18 (citing Pet. App. 27a-28a). What the Court actually said is that "if the person who was allegedly deceived by the misrepresentation (plaintiff or not) would have acted in the same way regardless of the misrepresentation, then the misrepresentation cannot be a but-for, much less proximate,

cause of the plaintiff's injury." Pet. App. 27a-28a. And the opinion goes on in the very next paragraph to state that because of the difficulty of proving reliance using generalized proof, "it is quite difficult, *though not impossible*, to certify a class in a RICO mail-fraud case." *Id.* at 28a (emphasis added). This statement alone refutes the notion that the "rule" in the Second Circuit is that the prescribing behavior of physicians always breaks the chain of causation.

3. The question set out in the petition is not presented by this case. Here, the Second Circuit has only decided that the Petitioners, "apparently by their own choice" (Pet. App. 46a), did not produce evidence sufficient to establish but-for causation, either on a class-wide or individual basis. The decision has no effect beyond its unique facts – the Second Circuit expressly stated that its decision turned on the specific record evidence before it regarding Ketek and the specific causation evidence adduced by the Petitioners. Further review by this Court is not warranted.

CONCLUSION

For the reasons set forth above, the Court should deny the Petition for Writ of Certiorari.

Respectfully submitted,

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