No. 19-1069

In The
Supreme Court of the United States

TAKEDA PHARMACEUTICAL COMPANY LIMITED,
TAKEDA PHARMACEUTICALS USA, INC.,
AND ELI LILY AND COMPANY,

Petitioners,

v.

PAINTERS AND ALLIED TRADES DISTRICT
COUNCIL 82 HEALTH CARE FUND, ET AL.,

Respondents.

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

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTED

When drug companies fraudulently conceal a drug's cancer risk for the express purpose of increasing sales, and three patients and a health plan spend money for that drug they would not have spent had the risk been disclosed:

(1) Is the connection between the companies' fraud and the money lost by the patients and health plan sufficiently "direct" to satisfy the proximate causation requirement under the Racketeer Influenced and Corrupt Organizations Act (RICO)?

(2) Is the money lost by the patients and health plan an "injury-in-fact" that confers standing under Article III?

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INTRODUCTION

Drug companies that defraud patients and health funds should not be immune from liability under RICO, especially when, at the pleading stage the fraud is so well documented. Petitioner drug companies, accompanied by their industry-funded amici, want this Court to overturn the Ninth Circuit's decision and create blanket immunity for drug companies to engage in marketing fraud. They claim this lawsuit involves attenuated levels of causation, unsupportable under RICO, and that the Respondents—three diabetes patients and a health fund (or third-party payer ("TPP"))—suffered no injury. They seek this immunity notwithstanding a well-documented, decade-long fraud designed to make billions by surreptitiously exposing diabetics to a carcinogen. The federal judge who presided over the multidistrict litigation ("MDL") for seven years and the ten-week bellwether personal injury trial, explained the gravity of the Petitioner drug companies' wrongdoing:

> [F]rom the beginning of their commercial alliance, Takeda and Lilly were aware of the possibility that Actos posed an increased risk of bladder cancer. . . . Takeda and Lilly consistently demonstrated their sales, competitive edge, and profits were more important to them than their most vulnerable customers. . . . Takeda and Lilly engaged in ***grievously reprehensible behavior***. . . . Takeda and Lilly, in the name of and in pursuit of profits reaching into the billions of dollars, chose to hide the information which would have

> allowed the FDA and the physicians to . . . regulate and selectively prescribe in the manner contemplated by the system of health care[.]

In re Actos (Pioglitazone) Prod. Liab. Litig. ("Actos II"), No. 6:11-MD-2299, 2014 WL 5461859, at *24, *27 (W.D. La. Oct. 27, 2014) (emphasis added). The Petitioner drug companies knew that concealing the bladder cancer risk would significantly increase Actos sales. They knew this because, early on, they researched the impact of a bladder cancer warning on prescribing behavior and learned that 75% of doctors would refuse to prescribe Actos to diabetics if it increased the risk of bladder cancer. This market research was confirmed nearly a decade later in 2011 when the FDA uncovered the deception and forced a bladder cancer warning. Sales plummeted by 80%.

Respondent-Plaintiffs were direct victims of this fraud. They paid for prescriptions of Actos that they would not have otherwise purchased had the bladder cancer risk been disclosed, whether directly for themselves or for their beneficiaries. The three Respondent-patients seek the money they spent out-of-pocket on Actos. The health fund, Painters and Allied Trades District Council 82 Health Care Fund ("Painters"), seeks recovery for those prescriptions that would not have been filled had the Petitioner drug companies followed the law and disclosed the cancer risk. Indeed, Painters' prescriptions dropped from 460 per month, prior to the bladder cancer warning, to 91 claims per month after the warning. Using a robust regression analysis, which

is used in pharmaceutical cases in every circuit, Painters intends to calculate what percentage of those claims would not have been submitted had the bladder cancer risk been disclosed.

The Ninth Circuit, drawing on well-established Supreme Court precedent, held that the facts alleged by Respondent-Plaintiffs plausibly support proximate causation under RICO. RICO proximate cause requires a direct relation between the alleged RICO violation and the plaintiff's injury. The Ninth Circuit held that the RICO violation, i.e., fraudulent concealment of bladder cancer, directly caused the Respondents' alleged injury, i.e., money paid for additional purchases of Actos, because the structure of the U.S. health care system forces patients and TPPs to bear the economic harm of fraudulent marketing. And, while others may also be exposed to the fraud, including physicians and pharmacy benefit managers, the first and only economic injury is born by the patients and TPPs, the very plaintiffs in this case. After all, RICO is specifically meant to deter the type of fraudulent racketeering these Petitioner drug companies perpetrated for over a decade.

Petitioner drug companies ask that this Court upend the Ninth Circuit's decision, arguing that there is an entrenched circuit split between the First, Third, and Ninth Circuits and the Second and Seventh Circuits. A careful review of the underlying cases, however, undermines this assertion. First, there is no circuit split regarding proximate causation for individual patients. In fact, there is near-consensus among

the circuits that individual patients who paid out-of-pocket for a drug because of a RICO violation satisfy the proximate cause requirement under RICO. Second, despite expressing concerns about proximate causation for TPPs in the class context, the Second Circuit has specifically indicated that proximate causation is possible. To the extent there is any circuit split regarding TPPs, it is limited to the Seventh Circuit. Finally, while the Seventh Circuit appears to depart from the First, Third, and Ninth Circuits on the specific issue of whether the TPP needs to be exposed to the underlying fraud (as opposed to just the prescribers), because Painters (along with everyone else) was exposed to the fraud, this case is not the appropriate vehicle to resolve this issue. Indeed, even under the Seventh Circuit's caselaw, this case alleges proximate causation.

The Ninth Circuit also held, in a footnote, that the Respondent-Plaintiffs sufficiently allege Article III standing because they lost money due to fraudulent conduct. Petitioner drug companies claim this view of the law conflicts with the Third and Fifth Circuits. However, upon closer inspection, this is simply not true. The Third and Fifth Circuits specifically recognize that lost money, caused by fraud, qualify as an injury-in-fact sufficient to confer Article III standing.

The Ninth Circuit's decision for this case does not conflict with the other circuits and it does not warrant this Court's review.

STATEMENT OF THE CASE

I. The Fraud: For Over a Decade, Petitioner Drug Companies Concealed Actos's Bladder Cancer Risk to Sell Greater Quantities of the Drug

Actos, chemically known as pioglitazone, is a medication for type II diabetics. Ninth Circuit Excerpts of Record ("ER") 19. Actos works at the cellular level by activating the gamma receptor that controls gene expression, rendering cells more sensitive to insulin and, in turn, able to better process blood sugar. ER.19-20. Unfortunately, Actos also activates the alpha receptor, which causes (among other things) cells in the bladder to mutate and develop into cancer. ER.29-31. The Petitioner drug companies, Takeda and Lilly, both knew Actos could cause bladder cancer, but they deliberately concealed and misrepresented that risk to increase sales for over a decade.

The story starts in the 1980s when Takeda—a Japanese chemical company—wanted to break into the lucrative U.S. pharmaceutical marketplace. ER.20-21. Takeda entered into a joint venture with the Upjohn Company—an established U.S. pharmaceutical manufacturer—to develop Actos. *Id.* However, by 1993, early pre-clinical animal trials suggested that Actos was not safe, so Upjohn pulled out of the project. ER.21. When the FDA, and others, inquired about Upjohn's withdrawal, Takeda falsely stated it was a "business decision," not related to safety concerns. ER.22.

In 1996, Takeda's rodent cancer study showed abnormal bladder cell and tumor formation. *Id.* In response, Takeda enlisted a scientist to develop a sham explanation that the tumors were due to the unique physiology of the rats, not found in humans. Called the "Cohen Hypothesis," Takeda knew the theory was false, but nonetheless used it to quiet any concerns related to cancer. ER.23.

In 1999, before FDA approval, Takeda reached out to Lilly. Takeda needed an established U.S. drug company to help sell Actos. ER.24. During negotiations, Lilly specifically identified "bladder cancer" as one of the "Most Significant Adverse Event Risks for Pioglitazone." ER.25, 182. In turn, Takeda agreed to indemnify Lilly for any personal injury claims, including bladder cancer, as part of a co-promotion agreement. ER.27. Under that agreement, Takeda and Lilly also agreed to act as distributors and "co-promoters" of Actos for a period of seven years, from 1999-2006. ER.25. Each company's names and/or logos would appear with equal prominence. ER.25-26. Lilly was charged with detailing physicians (800,000 a year), participating in clinical studies, reporting adverse events, post-marketing surveillance, and communicating with the FDA. *Id.* Following the seven-year period, the agreement provided for a three-year period during which Lilly received royalties. *Id.*

FDA approved Actos in July 1999 and, immediately, the Petitioner drug companies started aggressively promoting Actos. ER.49. They promoted Actos by claiming that, in addition to activating the gamma

receptor, which helped increase insulin sensitivity, it also activated the alpha receptor that was believed, at that time, to reduce bad cholesterol. ER.29. However, in 2002, Takeda received a call from the FDA alerting it to a bladder cancer problem with a new class of drugs that also treated type II diabetes by activating the gamma and alpha receptors. ER.30. The FDA immediately terminated their development and noted that one of the studies that used Actos as a comparator suggested Actos promoted bladder cancer. ER.30-31. The FDA specifically noted that "the Division is becoming concerned" because "the Division does *not feel that the general population is being adequately informed* about the possible risk[.]" ER.31 (emphasis added).

Petitioner drug companies did not change the label. Instead, they convened a high-level "Actos FDA Response Meeting" where they outlined a strategy. ER.32-33. That strategy included sticking to "Sam Cohen's hypothesis despite many challenges[,]" arguing "against clinical testing[,]" making sure to "not 'turn over any stones[,]'" and paying "experts at every opportunity." *Id.* Ultimately, the ploy worked. The petitioner drug companies convinced the FDA that Actos did not activate the alpha receptor and, therefore, did not increase the risk of bladder cancer. ER.33-34.

The Petitioner drug companies, however, had a problem. They had marketed Actos as an alpha agonist for years. *See* ER.34-35. One consultant explained: "the FDA is thumping you with the thought that mixed agonists cause bladder cancer and we just spent the last 4 months fighting this . . . given the FDA[']s insistence

that 'mixed agonists' are the bad guys, the first is to get away from them." ER.34. Another executive cautioned, "[I] don't think that marketing the mixed agonist stuff will in any way make up for the loss in revenue . . . from the 'cancer' stigmata[.]" ER.35. So, the Petitioner drug companies instructed their salesforce and marketing personnel to destroy all materials indicating any alpha activity. ER.132-33, 152-53.

In early 2003, the Petitioner drug companies proposed conducting market research about how a bladder cancer risk would affect sales, but that effort was largely rejected because "market research on possible label language around bladder cancer would risk public awareness . . . any of the proposed changes . . . would have an impact on sales[.]" ER.35. So, instead of a full-blown survey, the Petitioner drug companies organized a targeted and confidential survey with physicians. ER.35-36. The study proposed a world in which an oral anti-diabetic like Actos was associated with bladder cancer and explored how such a warning would affect the decision-making of physicians. *Id.* Physicians responded negatively. One prescriber stated "Bladder tumors? That would change my thinking altogether. I would not be likely to use the product." *Id.* Another stated "[i]f there is a risk of bladder tumors, I would definitely not use it." *Id.* In total, interest declined "greatly" in 75% of the surveyed physicians. *Id.*

In 2005, a clinical trial (PROactive) completed. ER.38-39. During the trial, nineteen people developed bladder cancer, fourteen in the Actos group and five in

the control group—a statistically-significant increase in bladder cancer. ER.38. However, when the study was published, the paper reported fourteen cases of bladder cancer in the Actos group and six in the placebo group. ER.41-42. By adding in an additional tumor to the placebo group, the elevated rate was no longer statistically significant. *Id.* The additional tumor was benign and, per the study's protocol, should not have been counted. *Id.* It was deliberately added to hide the bladder cancer finding. Petitioner drug companies then added false tumor counts to the Actos label and stated that there was *no* causative link to bladder cancer. ER.42-43.

Around this same time, Petitioner drug companies performed a statistical analysis of the FDA's adverse event database, which showed a signal for bladder cancer for Actos. ER.39. However, Takeda edited the table to omit this statistical analysis from the reports provided to the FDA. *Id.* Takeda's Vice President over its Pharmacovigilance Department instructed their reviewers to underreport adverse events, stating that "adverse event reporting is one thing, but Takeda's profitability comes first." ER.45.

Also, around this time, Takeda finished its first preliminary analysis of data collected from the Kaiser Permanente Northern California ("KPNC") database, monitoring the incidence of bladder cancer in Actos users. *Id.* The analysis revealed a statistically significant increased bladder cancer risk for people taking Actos. *Id.*

In late 2005, Takeda was getting ready to submit the PROactive and KPNC data to the FDA, but Takeda executives were concerned it might prompt a bladder cancer warning. ER.39-40. Anticipating potential FDA action, Takeda predicted the "likely 'worst case scenario' could be for the Agency to ask for an immediate label change incorporating bladder cancer findings[.]" ER.40-41.

An FDA medical reviewer who reviewed the data, noted the PROactive data was improperly reported and that, when properly calculated, there was a statistically significant tripling of the risk of bladder cancer. ER.43. He also noted that the Cohen hypothesis did not properly explain the bladder tumors observed in the rodent studies and that, because dual gamma/alpha agonists were known to cause bladder cancer, Actos likely did as well. ER.43-44. The reviewer specifically recommended that the Petitioner drug companies add a bladder cancer warning to the label. ER.44. The companies refused.

In 2009, interim results of the KPNC data showed that Actos increased the risk of bladder cancer by nearly 500%. ER.45. The Petitioner drug companies could not explain it away anymore. On September 17, 2010, the FDA announced an official investigation into the bladder cancer risk. ER.45. Then, in June 2011, the European Medicines Agency suspended the use of pioglitazone products in France and Germany because of bladder cancer risk. ER.46. A week later, the FDA determined that Actos increased the risk of bladder

cancer and directed Takeda to add a warning to the Actos label. *Id.*

As Takeda's marketing department and executives predicted, once the bladder cancer warning was made, Actos sales collapsed. ER.47-48. Between the initial FDA alert in September 2010 and the final warning in June 2011, Actos sales plummeted by 80%, just as the Petitioner drug companies predicted in 2003. *Id.* In August 2012, Actos went generic, and Takeda lost market exclusivity over Actos. *Id.* However, by concealing and misrepresenting the bladder cancer risk for over decade, from 1999 to 2010, the Petitioner drug companies were able to make billions of dollars selling Actos by concealing the bladder cancer risk.

II. The MDL: Unanimous Federal Jury Awards Historic $9 Billion Punitive Damage Award and Presiding Federal Judge Confirms the Petitioner Drug Companies' Conduct Was "Grievously Reprehensible"

In 2011, an MDL was formed in the Western District of Louisiana, which sought to address thousands of bladder cancer personal injury claims. In January 2014, the first bellwether case went to trial. After thirty-seven days of trial, including testimony from twenty-nine witnesses, a unanimous jury returned a verdict against the Petitioner drug companies in favor of Terrance Allen. ER.53. The jury awarded $9 billion in punitive damages—$6 billion against Takeda and $3 billion against Lilly. *Id.*

Upholding the verdict, the district court presiding over the multi-month trial and multi-year MDL explained:

> Beyond merely failing to warn, Plaintiffs presented evidence Takeda and Lilly obfuscated and worked to conceal relevant information from the scientific and medical communities, the FDA, the public, . . . concerning an association between Actos use and an increased risk of bladder cancer—again, all in the pursuit of profits. . . . [T]his intentional conduct reflects the Defendants' deliberate choice, in effect, to sacrifice an identifiable group of individuals in pursuit of profit. . . . [P]rescribing physicians were denied the information necessary to make a medically-informed decision as to whether it was medically prudent for someone . . . to take Actos. . . . [N]either of Mr. Allen's doctors would have prescribed Actos to Mr. Allen had they known of the risks that Takeda and Lilly knew . . . diabetics fighting for control over their disease had other viable alternatives. . . . Takeda and Lilly acted to protect their sales and profits at the expense of Mr. Allen's, and others like him, health and life, with wanton and reckless disregard of the effects of their actions.

In re Actos® (Pioglitazone) Prod. Liab. Litig. ("Actos I"), No. 6:11-MD-2299, 2014 WL 12776173, at *37 (W.D. La. Sept. 5, 2014). Ultimately, the district court reduced the punitive damage award, but confirmed that Takeda's and Lilly's conduct was "grievously reprehensible." *Actos II*, 2014 WL 5461859, at *24. The personal

injury claims settled shortly thereafter for $2.4 billion, but that settlement did not address the widespread economic harms caused by the fraud.

III. The Lawsuit: Three Patients and a Health Fund Seek Recovery of Money Lost Paying for Actos They Would Not Have Lost Had the Petitioner Drug Companies Disclosed the Bladder Cancer Risk

This lawsuit seeks recovery for the economic harm caused by the Petitioner drug companies fraudulent conduct in exposing millions of Americans to a carcinogen without their consent. The Petitioner drug companies made over $30 billion selling Actos between 1999 and 2011. Some of those sales were, unquestionably, induced by fraud, i.e., would never have occurred had the Petitioner drug companies been honest about the bladder cancer risk. This lawsuit does not seek recovery for all monies paid for Actos, just the windfall the Petitioner drug companies made because of the fraud.

Respondent-Plaintiffs assert RICO claims and various consumer protection claims under California, New Jersey, and Florida law.[1] Each Respondent-Plaintiff asserts they would have spent less (or no) money for Actos had the Petitioner drug companies disclosed

[1] The original complaint also asserted consumer protection claims under Missouri, Minnesota, and Massachusetts law. The dismissal of the Missouri and Minnesota claims were affirmed by the Ninth Circuit and Respondents abandoned their Massachusetts claim on appeal.

the bladder cancer risk on the Actos label, starting in 1999. Whether this case can proceed as a class action has not been litigated. The Respondent-Plaintiffs are at the pleading stage. So, the only issue is whether, individually, these three patients and a health fund alleged sufficient facts to state a claim.

Consumers Snyder, Cardarelli, and Buckner are from California, New Jersey, and Florida respectively. They each paid, out-of-pocket, for Actos prescriptions—money they would not have paid had the Petitioner drug companies disclosed the bladder cancer risk. ER.57-65.

Painters is a health and welfare benefit fund. ER.56. In the year prior to the FDA's September 2010 alert indicating the FDA would be investigating an Actos-bladder cancer association, Painters Fund was reimbursing approximately 460 Actos claims per month. ER.57. Immediately after the alert, claims for Actos dropped 20%, to approximately 364 Actos claims per month. *Id.* Then, after the FDA issued an official bladder cancer warning in June 2011, claims plummeted by another 50%, to approximately 188 claims per month. *Id.* In the last month before Actos went generic, in August 2012, Painters Fund only received 91 claims for Actos. *Id.* That drop, from 460 claims per month to 91 claims per month reflects an 80.2% drop in payments—all a direct result of the cancer warning.

IV. Procedural History: Reversing the District Court, the Ninth Circuit Applied Well-Established Legal Principles and Concluded the Patients and Health Plan Have Standing under RICO and Article III

This lawsuit was originally filed in the MDL in July 2014. After being stayed for three years, the case was transferred to the Central District of California in October 2017. There, the Petitioner drug companies moved to dismiss. The district court dismissed the RICO claims with prejudice in a single-paragraph minute order. Appendix.57a-58a. Then, in another minute order, the district court dismissed the state claims, some with prejudice and others with leave to amend. Appendix.46a-55a. The district court did not address or rule on any Article III issue because the issue was never raised. Respondent-Plaintiffs stood on the pleadings and appealed.

The Ninth Circuit reversed the district court's RICO ruling and its dismissal of the California, New Jersey, and Florida consumer claims. The Ninth Circuit also rejected the Petitioner drug companies' Article III challenge—raised for the first time on appeal—in a footnote in an unpublished decision. *See* Appendix.40a, n.1.

Regarding RICO, the Ninth Circuit carefully reviewed this Court's precedent regarding proximate causation. Relying on the Court's unanimous decision in *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008) and the functional test established in *Holmes v.*

Sec. Inv'r Prot. Corp., 503 U.S. 258 (1992), the Ninth Circuit held that "[b]ecause Plaintiffs were immediate victims of Defendants' alleged fraudulent scheme to conceal Actos's risk of bladder cancer, the alleged RICO violation . . . has a direct relation to Plaintiffs' alleged harm."[2] Appendix.16a-17a.

The Ninth Circuit went on to analyze other-Circuit precedent regarding proximate causation in civil RICO pharmaceutical cases and identified an "apparent" split regarding "whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP." Appendix.31a. After considering sister circuit decisions, the Ninth Circuit held that "although prescribing physicians serve as *intermediaries* between Defendants' fraudulent omission of Actos's risk of causing bladder cancer and Plaintiffs' payments for Actos, prescribing physicians do not constitute an *intervening cause* to cut off the chain of proximate cause." Appendix.32a. Focusing "on the direct relation between the

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[2] In reaching this holding, the Ninth Circuit did not rely "on the '*Bridge* precedent alone,' " nor did it "equat[e] the directness requirement with a foreseeability test" as the Petitioner drug companies boldly assert. Cert.Pet.11. The Ninth Circuit explained that the *Bridge* precedent would be sufficient, itself, to find proximate causation here, but specifically went on to apply the *Holmes* factors. Appendix.16a-17a. Not once did the Ninth Circuit, in assessing directness mention foreseeability, let alone equate it. Rather, the issue of foreseeability arose only in assessing potential intervening causes, i.e., prescribing physicians, nearly ten pages later. To suggest that the Ninth Circuit equated the directness test with foreseeability is simply untrue.

alleged violation and alleged injury" the Ninth Circuit reasoned that because "Actos was a *prescription* drug, it was *required* to be prescribed by physicians. Hence, it was perfectly foreseeable that physicians who *prescribed* Actos would play a causative role in Defendants' alleged fraudulent scheme to increase Actos's revenues." *Id.*

The Ninth Circuit also reasoned that allowing the existence of prescribing physicians to sever proximate causation—even though the Petitioner drug companies' fraudulent scheme assumed and relied on this fact to effectuate the fraud—would not serve the purpose of imposing a proximate causation requirement; it would simply insulate drug manufacturers "from liability for their fraudulent marketing schemes[.]" Appendix.33a. Physicians were duped by the Petitioner drug companies into thinking Actos was safe to prescribe, so prescribing Actos was a product of Petitioners' conduct, not independent, unforeseeable conduct severing causation. The Ninth Circuit explained that "[p]roximate cause exists to 'limit a person's responsibility for the consequences of that person's own acts.'" *Id.* (quoting *Holmes*, 503 U.S. at 268). And that "[h]ere, Plaintiffs seek to hold Defendants liable for the consequences of their own acts and omissions toward Plaintiffs: the money spent by Plaintiffs to purchase Actos." *Id.*

Regarding Article III standing, the Ninth Circuit made short work of the Petitioner drug companies' argument: "Plaintiffs alleged that they purchased Actos, which they would not have done absent Defendants'

fraudulent scheme to conceal Actos's risk of bladder cancer. Thus, Plaintiffs have alleged an injury in fact sufficient to support Article III standing." Appendix.40a-41a, n.1.

WHY THE PETITION SHOULD BE DENIED

I. This Case Is Not the Proper Vehicle to Resolve Any Circuit Split Related to RICO Proximate Causation in Pharmaceutical Fraud Cases

A. From *Holmes* to *Bridge*: Proximate Causation Under RICO Requires a Direct Link between the RICO Violations and the Loss of Business or Property

"RICO is to be read broadly." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 497 (1985). While the statute was originally designed to combat organized crime, the statute has become "a tool for everyday fraud cases brought against respected and legitimate enterprises." *Id.* at 499 (quotation omitted). Broadly speaking, there are two parts of a civil RICO claim. The first part is the "RICO violation" defined by 18 U.S.C. § 1962. The second is "RICO standing" as defined by 18 U.S.C. § 1964(c).

Here, the Ninth Circuit's decision regarding proximate causation concerns RICO standing, which requires an injury to business or property "by reason of" the RICO violation. This "by reason of" language is broad and, on its own, does not impose any *per se* proximate causation requirement. *Holmes*, 503 U.S. at 266.

Nonetheless, in *Holmes*, drawing on ideas of justice and pragmatism, the Court created a proximate causation requirement for civil RICO. *Id.* at 268-69. The Court explained, "[a]t bottom, the notion of proximate cause reflects ideas of what justice demands, or of what is administratively possible and convenient." *Id.* at 268 (quotation omitted). Because proximate causation attempts to "limit a person's responsibility for the consequences of that person's own acts" in a way that appeals to fairness and the realities of enforcement, it avoids liability when the "complained of harm flow[s] merely from the misfortunes visited upon a third person by the defendant's acts." *Id.* at 268.

In *Holmes*, the Court used various phrases to define proximate cause, such as "some direct relation between the injury asserted and the injurious conduct alleged," *id.* at 268, and whether "the link is too remote" between the conduct and the harm suffered, *id.* at 271. But, at base, the proximate causation analysis focuses on directness, i.e., whether the relationship between the wrongful conduct and injury are sufficiently "direct" such that imposition of liability is fair and practical. *Id.* at 272, n.20.

The Court outlined three considerations for imposing, and ultimately understanding, this directness requirement: First, indirect injuries make it "difficult . . . to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors." *Id.* at 269. Second, indirect injuries could "force courts to adopt complicated rules . . . to obviate the risk of multiple recoveries." *Id.* Third,

allowing indirectly injured victims to pursue claims is unjustified because "directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant" to the indirectly injured. *Id.* at 269-70. Because these factors justify imposing a proximate causation requirement, they are important touchstones in assessing, for any given case, whether the plaintiff has alleged proximate causation. The Court cautioned, however, that "the infinite variety of claims that may arise make it virtually impossible to announce a black-letter rule that will dictate the result in every case." *Id.* at 272, n.20 (quoting *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 536 (1983)). The circumstances in each case and whether the imposition of liability is both fair and practical is, by definition, a fact-intensive inquiry.

Since *Holmes*, the Court has found proximate cause lacking when the conduct directly causing the harm was distinct from the actions that gave rise to the fraud. In *Anza v. Ideal Steel Supply Corp.*, a plaintiff alleged that a competitor caused it harm by defrauding the state tax authority and, then, used the proceeds of that fraud to offer lower prices to attract more customers. 547 U.S. 451, 458 (2006). The Court held there was insufficient proximate causation because plaintiff's harm was caused by "a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State.)." *Id.*

In *Hemi Group, LLC v. City of New York*, Hemi committed fraud by selling cigarettes to city residents

and failing to submit reports to the state. 559 U.S. 1, 9 (2010). "Without the reports from Hemi, the State could not pass on the information to the City" and "[t]he City thus could not pursue those customers for payment." *Id.* A plurality of Justices concluded causation was even more attenuated than *Anza* and *Holmes* because "Hemi's obligation was to file the . . . reports with the State, not the City, and the City's harm was directly caused by the customers, not Hemi." *Id.* Again, like *Holmes* and *Hemi*, the conduct causing the harm, i.e., failure of customers to pay taxes, was distinct from the alleged RICO violations, i.e., failure of Hemi to file reports.

In *Bridge*, the Court *did* find proximate causation. 553 U.S. at 658. Bidders at a county tax lien auction alleged they were harmed by other bidders' fraudulent scheme to obtain more bids at the auction, thereby depriving the plaintiff of the opportunity to secure more valuable liens. *Id.* at 642-43. The scheme involved making false affidavits to the county in violation of a county rule designed to ensure fair distribution of liens during the auction. *Id.* The defendants argued that plaintiffs could not establish proximate causation because the misrepresentations were directed at the county, not the plaintiffs, so any injury caused was too attenuated. *Id.* at 653. A unanimous Court rejected this argument, holding that the "alleged injury—the loss of valuable liens—[was] the direct result of petitioners' fraud." *Id.* at 658. The Court explained that proximate cause "is a flexible concept that does not lend itself to 'a black-letter rule that will dictate the

result in every case.'" *Id.* at 654. And, drawing on traditional proximate causation principles, the Court explained that "[i]t was a foreseeable and natural consequence of petitioners' scheme to obtain more liens for themselves that other bidders would obtain fewer liens" and that the three *Holmes* factors weighed in favor of finding proximate causation. *Id.* at 658.

B. There Is No Circuit Split Regarding Proximate Causation for Individual Patients

As an initial matter, there is no circuit split concerning proximate causation for patient plaintiffs. The Ninth Circuit specifically noted this lack of conflict. *See* Appendix.31a, n.13. No Circuit, including the Seventh and Second, has held that proximate causation for individual patients is improper under RICO. Indeed, the Seventh and Second Circuit holdings suggest the *opposite*. In *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, the Seventh Circuit noted that individual patients, as opposed to TPPs, were directly injured because "[t]he patients' health and financial costs come first in line temporally[,]" suggesting that establishing proximate causation for individual patients is not only possible, but preferable. 873 F.3d 574, 576 (7th Cir. 2017). And, in *UFCW Local 1776 v. Eli Lilly & Co.*, the Second Circuit expressly stated that individual claims alleging a quantity effect theory could be "viable." 620 F.3d 121, 136 (2d Cir. 2010). Should the Court grant *certiorari* in this case, it will be tasked with ruling on an issue, i.e., proximate causation for individual

patients, for which there is no disharmony among the circuits.

C. The Second Circuit Is Not in Conflict with the First, Third, and Ninth Circuits

Petitioner drug companies misrepresent the position of the Second Circuit. They claim the Second Circuit in *UFCW Local 1776* held that proximate cause could not be established in pharmaceutical RICO cases. *See* Cert.Pet.16. This is simply not true. In *UFCW*, the Second Circuit specifically recognized that a TPP could establish proximate causation with proper evidence. 620 F.3d at 136 ("The quantity effect theory, however, is less attenuated, and while that theory cannot support class certification, it is not clear that the theory is not viable with respect to individual claims by some TPPs[.]"). And then, later, the Second Circuit reiterated this point in *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, *Sergeants*, citing *In re Neurontin* for the proposition that "[i]t may be possible for a plaintiff to establish its own claim . . . using aggregate statistical proof—i.e., without having to show the individual reliance of thousands of prescribing doctors[.]"). 806 F.3d 71, 74-78 (2d Cir. 2015); *e.g.*, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 871539, at *12 (N.D. Ohio Feb. 21, 2020) (finding Second Circuit precedent *supported* proximate causation for a TPP in pharmaceutical RICO claim).

D. To the Extent there Is a Circuit Split Regarding Proximate Causation for TPPs, It Is Limited to Claims Involving Fraudulent Off-Label Promotion

Pharmaceutical RICO cases are divided into cases alleging fraudulent off-label promotion and cases involving "on-label" fraud. While both involve fraud, they depart on *how* that fraud is perpetrated.

Fraudulent off-label promotion occurs when the drug company promotes the use of a drug directly to physicians for an indication that is not approved by the FDA (off-label) and for which the drug company knows is not safe and/or effective. *See*, *e.g.*, *Sidney Hillman*, 873 F.3d at 575 (alleging fraudulent off-label promotion of Depakote for "schizophrenia, dementia, and attention deficit hyperactivity disorder (ADHD)"); *In re Neurontin Mktg. & Sales Practices Litig. ("Neurontin I")*, 712 F.3d 21, 28 (1st Cir. 2013) (alleging fraudulent off-label promotion of Neurontin for "bi-polar" "neuropathic pain" "migraines" and "doses greater than 1800 mg/day[.]"); *UFCW Local 1776*, 620 F.3d at 127 (alleging fraudulent off-label promotion of Zyprexa for "anxiety, depression, and dementia."); *In re Testosterone Replacement Therapy Prod. Liab. Litig. ("Testosterone I")*, 159 F. Supp. 3d 898, 903 (N.D. Ill. 2016) (alleging fraudulent off-label promotion of testosterone for indications such as "erectile dysfunction, diabetes, AIDS, cancer, depression, and obesity."). The fraud circumvents FDA regulation by directly misleading prescribing doctors about the drug. For example, in *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, the

defendant drug company falsely promoted two antidepressants as effective in treating children when the drug company's own pediatric studies specifically indicated they were not. 915 F.3d 1, 8 (1st Cir. 2019). By fraudulently promoting the off-label efficacy of the drug, the drug company was able to sell millions of useless (and potentially dangerous) prescriptions to children and their families.

On-label fraud—so called to distinguish it from off-label fraud—is not limited to prescribers. It involves fraudulently misrepresenting or concealing some material aspect of a drug to *everyone*, primarily through the drug's label (which is supposed to contain all material information about a drug, 21 C.F.R. § 201.56(a)). *E.g.*, *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 636 (3d Cir. 2015) (alleging that drug company deliberately concealed serious cardiovascular risks associated with diabetes drug); *Sergeants*, 806 F.3d at 74-78 (2d Cir. 2015) (alleging that drug company fraudulently concealed safety and efficacy issues regarding antibiotic); *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 341-44 (2d Cir. 2003) (alleging that drug company concealed serious liver risks associated with diabetes drug). Unlike fraudulent off-label promotion, on-label fraud is directed at the entire medical community—including the FDA. It permeates and effects all levels of the pharmaceutical marketplace, from manufacture to payment.

This lawsuit clearly falls into the category of on-label fraud. Respondent-Plaintiffs make no allegation

of off-label promotion. Rather, Respondent-Plaintiffs allege that the Petitioner drug companies fraudulently concealed, and at times fraudulently misrepresented, the risk of bladder cancer *on* the Actos label: "Defendants' conduct has been directed at consumers, third-party payors, and prescribers in all states in a uniform manner—using the same misleading and deceptive drug labels[.]" ER.67. The Petitioner drug companies knew the risk of bladder cancer was dispositive for 75% of prescribing physicians and that fact was proven when sales of Actos dropped 80% once the FDA forced Takeda to warn about bladder cancer. ER.36, 57.

The way the courts consider fraudulent off-label promotion and on-label fraud in the context of RICO proximate causation is different and that difference likely accounts for the apparent split identified by the Ninth Circuit. *See* Appendix.23a-35a. Indeed, the Ninth Circuit specifically identified this distinction when it held that "[t]here is a difference between fraudulent promotion of 'off-label' uses for a prescription drug as in *Sidney Hillman* . . . and *UFCW Local 1776*, . . . and fraudulent failure to warn of a drug's known risk . . . as in this case." Appendix.33a. The circuit split, to the extent it may exist, is limited to cases alleging fraudulent off-label promotion. There is no disharmony among the circuits for cases, like this one, involving on-label fraud.

1. There Is a Circuit Split Regarding Proximate Causation for Claims Involving Fraudulent Off-Label Promotion, But This Case Will Not Resolve It

In the context of fraudulent off-label promotion, there is a circuit split about whether the fraudulent statements must also have been made directly to the TPP to satisfy the proximate causation requirement.

In *In re Neurontin Mktg. & Sales Practices Litig. ("Neurontin II")*, 712 F.3d 51 (1st Cir. 2013) and *In re Neurontin Mktg. & Sales Practices Litig. ("Neurontin III")*, 712 F.3d 60 (1st Cir. 2013), which involved fraudulent off-label promotion of the drug Neurontin, the First Circuit held that direct misrepresentations made to the prescribing doctors, not to the TPP, could satisfy RICO proximate causation. *Neurontin II*, 712 F.3d at 58-59; *Neurontin III*, 712 F.3d at 66-68. The court correctly reasoned, based on this Court's unanimous *Bridge* decision, that "the injury to the" TPP was direct because TPPs were "the primary and intended victims of [Pfizer's] scheme to defraud . . . Pfizer knew that . . . almost all off-label Neurontin prescriptions written by physicians would be paid for by TPPs[.]" *Neurontin III*, 712 F.3d at 67; *accord Neurontin II*, 712 F.3d at 58-59 ("Aetna was the intended victim of defendants' fraudulent scheme and [] Aetna's economic injury was a 'foreseeable and natural consequence' of this scheme. That is so even if the scheme involved making misrepresentations to doctors about Neurontin's off-label

effectiveness instead of making those misrepresentations directly to Aetna itself."). That physicians were initially exposed to the fraud, like the county in *Bridge*, did not change the fact that TPPs were the most directly injured. This reasoning has been followed by the Third and Ninth Circuits and, to some extent, the Second Circuit.[3]

Conversely, in *Sidney Hillman*, the Seventh Circuit focused on the temporal relationship of the fraud, noting that the first exposed to the fraud (not necessarily the first injured) was the physician through the off-label promotion. 873 F.3d at 577-78. Because so many things could influence a physician's decision, "improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence." *Id.* at 578. To allege proximate causation under *Sidney Hillman*, the TPP must allege that there were direct misrepresentations to the TPP—the TPP cannot rely on the fraudulent conduct directed to the physicians. *See*, *e.g.*, *In re Testosterone Replacement Therapy Prod. Liab. Litig. ("Testosterone II")*, No. 14 C 1748, 2018 WL 3586182, at *9

[3] *See Avandia*, 804 F.3d at 636 ("GSK argues that the presence of intermediaries, doctors and patients, destroys proximate causation because they were the ones who ultimately decided whether to rely on GSK's misrepresentations. But *Bridge* precludes that argument."); Appendix.32a ("[P]rescribing physicians do not constitute an intervening cause to cut off the chain of proximate cause."); *see also Sergeants*, 806 F.3d at 97 ("[I]t may be possible for a plaintiff to establish its own claim . . . without having to show the individual reliance of thousands of prescribing doctors[.]" (citing *Neurontin I*, 712 F.3d at 45-47)).

(N.D. Ill. July 26, 2018) (holding that *Sidney Hillman* requires direct misrepresentations in fraudulent off-label promotion RICO case); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 871539, at *11 (N.D. Ohio Feb. 21, 2020) (same). This direct misrepresentation requirement—clearly at odds with *Bridge*—is where the First and Seventh Circuit part ways.

To the extent the Court wants to resolve this nuanced, industry-specific circuit split, this case is simply not the right vehicle. This case does not depend on fraudulent off-label promotion to establish proximate causation. And, the concerns raised by the Seventh Circuit in *Sidney Hillman*, i.e., the concerns that are driving this apparent circuit split, are not at issue in this case.

In *Sidney Hillman*, the court expressed concern that "comparing the patients' health costs (and out-of-pocket co-pays) with the Payors' costs may be difficult[.]" 873 F.3d at 577. But here, that issue is easily addressed. For the consumer plaintiffs, the exact out-of-pocket expenses are alleged. ER.165-66. For Painters, the money paid for Actos, and thus is subject to damages, does not overlap with any copays made by the underlying patients. *See* ER.165. So, separating those costs is not difficult—indeed, it is already done.

Next, the court stated "[i]t would not be proper to calculate damages by assuming that all off-label prescriptions are improper" because, if the TPP had not paid for Depakote, it "would have paid for some other

drug that physicians would have prescribed in lieu of Depakote." *Sidney Hillman*, 873 F.3d at 577. Here, Painters does not seek recovery for every Actos prescription, just those it would not have had to pay had the bladder cancer been disclosed. ER.165. And, to the extent those payments need to be offset by the cost of a less expensive alternative, those alternatives are alleged in the complaint as well. ER.80.

Finally, the court expressed concern that "some physicians were apt to write such prescriptions whether or not [the drug company] promoted off-label uses" and that "[d]isentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices would be difficult[.]" *Sidney Hillman*, 873 F.3d at 577. Put into the context of this case, the worry is that some physicians may have decided to prescribe Actos even if the bladder cancer risk was known, and some patients may have even filled those prescriptions. But, the court acknowledged that these concerns can be addressed by a proper regression analysis. In *Sidney Hillman*, the underlying complaint did not provide any data that would make the viability of such a regression analysis plausible. Here, not so. Painters attaches documents from the Petitioner drug companies evidencing the effect of a bladder cancer risk on sales—including a clandestine physician survey—and alleges, in detail, national sales data and Painters' specific, month-by-month, prescription data. Unlike the plaintiffs in *Sidney Hillman*, here, there is

no "absence of data . . . in showing plausible causation[.]" *Id.*[4]

It is not clear this case would fair any differently in the Seventh Circuit. Thus, even if the Court wants to address the nuanced circuit split regarding whether direct misrepresentations are required under a fraudulent off-label promotion theory, this case is just not the right vehicle to address it. This case involves on-label fraud directed to everyone.

2. There Is No Circuit Split Regarding Proximate Causation for Claims Involving On-Label Fraud, Which Is What This Case Alleges

There is no circuit split regarding proximate causation for the type of fraud alleged here, i.e., on-label fraud. Every circuit court to consider this type of pharmaceutical RICO claim has acknowledged that proximate causation can be established for TPPs. In *Avandia*, the alleged fraud involved concealing a cardiovascular risk for a diabetes drug, which caused TPPs to purchase more of the drug than they otherwise

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[4] Moreover, the *Sidney Hillman* court was concerned about whether any regression analysis had ever been published looking at the effect of off-label promotion on sales. 873 F.3d at 577. Remarkably, since this case was on appeal, a regression analysis looking at the impact of Actos prescriptions in Korea following a bladder cancer warning has, in fact, been published. *See* Han Eol Jeong et al., *Prescribing trend of pioglitazone after safety warning release in Korea*, 25 AM. J. MANAGED CARE 11, e342-e348 (Oct. 2019).

would have. 804 F.3d at 635-36. There, the Third Circuit concluded proximate causation was alleged. In *Desiano*, the fraud involved concealment of serious liver risks for a diabetes drug, which caused TPPs to pay for more of the drug than they otherwise would have. 804 F.3d at 636. And there, the Second Circuit held that proximate cause was sufficiently alleged while applying the *Holmes* factors.

In *Sergeants*, the fraud involved concealing facts about the efficacy and safety of an antibiotic, i.e., on-label fraud. 806 F.3d at 74-78. At the summary judgment phase, the Second Circuit concluded that the plaintiff failed to present reliable evidence that the fraud caused the TPP to pay for more prescriptions. *Id.* at 77. But, far from categorically foreclosing such a claim, the court specifically left open the possibility that such evidence *could* be presented to sustain it. *Id.* at 78; *see also Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 (11th Cir. 2011) (upholding dismissal of on-label fraud claim due to lack of allegations linking the fraud to the paid prescriptions, not because a claim would be impossible).

Cases involving on-label fraud do not, like fraudulent off-label promotion claims, rely on the ability of off-label promotion to inspire a doctor's prescription. Instead, on-label fraud focuses on the gravity of the concealed or misrepresented fact, here bladder cancer, and whether, absent that fraud, it is plausible that at least one prescription (only one is required for standing) would not have been filled. Here, where the fraud involves a risk of cancer and the data indicates a

precipitous drop in prescriptions following the public disclosure of the cancer risk—both nationally and specifically for Painters—it is plausible that at least one of Painter's thousands of prescriptions would not have been filled. Under any standard, whether the Court adopts the Seventh or First Circuit approach, the facts of this case, bolstered with over five-hundred pages of exhibits attached to the complaint—would survive *any* pleading challenge.

II. The Court Should Not Grant *Certiorari* on the Article III Question Because There Is No Meaningful Circuit Split that This Case Could Address

Petitioner drug companies argue that there is a split between the Ninth Circuit and the Third and Fifth Circuits regarding whether the loss of money spent on a product because of fraud is, itself, an injury-in-fact sufficient to confer Article III standing. Citing the Third Circuit's decision in *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278 (3d Cir. 2018) and the Fifth Circuit's decision in *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002), Petitioner drug companies argue that the Ninth Circuit's decision here "squarely conflicts with the decisions of the Third and Fifth Circuits." Cert.Pet.24. Not true. The Petitioner drug companies' interpretation of *Johnson & Johnson* and *Rivera* is simply incorrect. The allegations in this case would meet the Article III requirements articulated in *Johnson & Johnson* and *Rivera*.

In *Johnson & Johnson*, the Third Circuit held that a plaintiff could establish Article III standing if facts are alleged such that "a factfinder could conclude that Johnson & Johnson has been able to sell more Baby Powder than it could have had it informed consumers of the alleged health risks." 903 F.3d at 292; *see also id.* at 293 ("Estrada similarly fails to show . . . that Johnson and Johnson has sold more Baby Powder than it otherwise could have."). And, because the plaintiff in *Johnson & Johnson* "alleged [a] desire to purchase Baby Powder in the future despite knowing of its alleged health risks" it was simply implausible that she sustained any injury from Johnson & Johnson's alleged concealment of the health risk. *Id.* at 292. Moreover, the Third Circuit also held that "to allege that she has suffered an economic injury as a result of simply purchasing Baby Powder, Estrada must allege that she purchased Baby Powder that was worth less than what she paid for." *Id.* at 287. And because the plaintiff failed to allege that the Baby Powder was less valuable than what she bargained for, any alleged injury was simply too speculative. *Id.* at 288.

None of these issues exist here. At no time have any of the Respondent-Plaintiffs alleged that they received any benefit from Actos. And, repeatedly, Respondent-Plaintiffs allege that taking Actos increases the risk of bladder cancer. While, none of the Respondent-patients have, at this time, been diagnosed with bladder cancer, each alleges that had the Petitioner drug companies disclosed the bladder cancer risk, they would never have purchased the drug. They also all

allege that, once they learned of the cancer risk, they stopped purchasing it. Similarly, for Painters, following public disclosure of the bladder cancer risk, the number of prescriptions for Actos plummeted by 80%. The Respondent-Plaintiffs also allege that concealment of the bladder cancer risk led to "an overvaluation of the drugs, which resulted in monies being lost by the member (through co-pays) and by Plaintiff Painters Fund (through reimbursement)." ER.56. These allegations meet the Article III standard in *Johnson & Johnson*.[5] *See*, *e.g.*, *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 553-55 (E.D. Pa. 2019) (under *Johnson & Johnson* payments for a drug that would not have occurred absent the fraud satisfies Article III standing).

Similarly in *Rivera*, the Fifth Circuit held that the plaintiff lacked Article III standing because the plaintiff failed to allege that "had Wyeth acted 'lawfully' (produced a safer drug or provided more extensive warnings), the physicians would not have prescribed—*and* the plaintiffs would not have purchased" the drug.

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[5] Furthermore, in *Johnson & Johnson*, the Third Circuit specifically held that injury tied to a less expensive alternative would also satisfy Article III standing. 903 F.3d at 282 ("Under the alternative product theory, a plaintiff might successfully plead an economic injury by alleging that, absent the defendant's conduct, she would have purchased an alternative product that was less expensive."). Here, Respondent-Plaintiffs allege that there are "other less expensive alternatives, i.e., metformin, sulfonylureas, and Avandia. Because Plaintiff[s] . . . (as well as the FDA and medical community) were unaware of Actos' bladder cancer risk, they were more likely to purchase Actos as opposed to a competing O[ral] A[nti] D[iabetic]." ER.80.

283 F.3d at 321. Indeed, the plaintiff did "not even indicate[ ] what additional warnings Wyeth should have included[.]" *Id.* Nothing tied the alleged unlawful conduct to the money spent on the drug. *Id.* at 319 ("Rivera's claim to injury runs something like this: Wyeth sold Duract; Rivera purchased and used Duract; Wyeth did not list enough warnings on Duract, and/or Duract was defective; other patients were injured by Duract; Rivera would like her money back."). Under that set of allegations, the court held that Article III standing was not alleged. Here, there is no such problem. The consumers allege that had the Petitioner drug companies disclosed the risk of bladder cancer, they would not have purchased the drug. And, Painters alleges that the lack of bladder cancer warning caused prescribers and members to submit claims to pay for Actos they otherwise would never have submitted. Unlike the plaintiffs in *Rivera*, there is a clear link between the alleged fraud and the economic injuries sustained.

III. The Ninth Circuit Decision Strikes the Right Balance of Ensuring Only Meritorious Claims Are Allowed to Proceed

The Petitioner drug companies argue that the Ninth Circuit's decision needs to be overturned because "the Ninth Circuit's decision creates an irresistible incentive for countless TPPs and other insurance providers, as well as other plaintiffs, to burden the court with speculative and attenuated RICO claims against manufacturers of pharmaceuticals and a range of other products." Cert.Pet.30. In effect, the Petitioner

drug companies demand absolute immunity from well documented, meritorious claims involving pharmaceutical fraud. This over-reaching plea for immunity should be rejected.

When put in context, the scope and impact of the Petitioner drug companies' fraud is staggering. The Petitioner drug companies made over $30 billion by deliberately concealing a cancer risk with their drug and they did so by causing millions of vulnerable diabetic patients to be exposed to a carcinogen against their will—conduct the well-informed MDL court characterized as "grievously reprehensible." And, while thousands of people who contracted or died from bladder cancer were able to settle for approximately $2.4 billion, the economic windfall these Petitioner drug companies made remains unchallenged. Far from promoting meritless claims, the availability of civil RICO to challenge fraudulent conduct by drug companies is one of the only remaining checks on those members of the drug industry who put profit before safety. Indeed, allowing such drug companies to profit from fraud disadvantages the drug companies that market within the bounds of law. As the Ninth Circuit explained, if bad drug companies are allowed to "hide behind prescribing physicians" when they commit fraud, then "drug manufacturers would be insulated from liability for their fraudulent marketing schemes[.]" Appendix.33a.

To avoid meritless claims, courts routinely require civil RICO plaintiffs to jump over unique hurdles. For example, in this case, the district court required the

Respondents to file a fifty-page, single-spaced RICO disclosure statement with over 500 pages of exhibits before any of the Petitioner drug companies even had to respond to the complaint—a document the Petitioner drug companies were allowed to review and study for three years before filing their motion to dismiss. While such precautions are, themselves, extreme, what the Petitioners and their industry-sponsored amici ask of this Court, i.e., complete immunity, goes too far and belies their arguments for what they really are—a license to profit from fraud without recourse. These Petitioner drug companies fraudulently made billions by exposing millions of vulnerable diabetic patients to a carcinogen. The Ninth Circuit's decision should not be disturbed.

CONCLUSION

For the foregoing reasons, this Court should not grant this petition or disturb the Ninth Circuit's decision.

Respectfully submitted,

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