No. 24-1807

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA ex rel. CHARLES BENNETT,

Plaintiff-Appellant,

v.

BAYER CORPORATION, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amici*, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Chamber of Commerce of the United States of America (Chamber), and the National Association of Manufacturers (NAM) make the following disclosures:

PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock.

The Chamber states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

The NAM has no parent company and no publicly held company has a 10% or greater ownership interest in it.

IDENTITIES, INTERESTS, AND SOURCE OF AUTHORITY TO FILE OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.87 trillion to the United States economy annually, has the largest economic impact of any major sector, and

[1] *Amici curiae* state that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. Counsel for all parties have consented to the filing of this *amicus* brief. Counsel for Relator further notes that he is unopposed to the extent this brief bears on issues raised in the lower court.

accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

PhRMA, the NAM, and the Chamber have a strong interest in this case because their members are increasingly the targets of False Claims Act (FCA) suits by private counsel proffering fraud-on-the-FDA theories that would upset those members' reliance on FDA's expert judgment in bringing to market agency-approved drugs. More broadly, *amici* are concerned about the repeated attempts by relators, as exemplified by this case, to turn run-of-the-mill allegations of regulatory violations into FCA cases under the vague banner of "fraud in the inducement."

This brief is submitted by PhRMA, the NAM, and the Chamber to describe the deleterious effects the fraud-on-the-FDA theory of liability will have if accepted under the facts pleaded by the Appellant, where FDA has expressly denied the Relator's allegations and where, by statute, FDA has the sole authority to make such determinations.

INTRODUCTION AND SUMMARY OF ARGUMENT

In this case, Relator seeks to establish a false claim for purposes of the False Claims Act (FCA) by asking a jury to overrule the U.S. Food and Drug Administration's (FDA's) approval of Cipro and Levaquin and, on that basis, then to *deem* the drugs unapproved and thus ineligible for reimbursement. But that is not a determination that even the Centers for Medicare and Medicaid Services (CMS), the agency to which the claims were submitted, could have made. Rather, by statute, Congress has mandated that CMS accept *FDA's* determination whether to approve a drug for sale and maintain such approval throughout the product lifecycle. 42 U.S.C. § 1395y(a)(1)(A). Just as CMS cannot overrule FDA's approval of a drug, neither can a private citizen, armed with a jury, do so under the FCA, as part of determining that CMS could and should have rejected the claims as ineligible. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016). Because Levaquin and Cipro were approved for sale by FDA, and because Relator has alleged no facts to establish that the drugs were not prescribed in a medically appropriate manner in any individual instance, Relator cannot establish that any claim for payment was false.

The Supreme Court, in applying the Federal Food, Drug, and Cosmetic Act's (FDCA's) prohibition against private enforcement to bar a state-law "fraud-on-the-FDA claim," stressed that any attempt to usurp FDA's exclusive responsibility to balance the statute's competing considerations could have devastating

consequences. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351-53 (2001). If a fraudulently-induced-approval theory under the FCA were upheld due to a manufacturer's purported failure to provide FDA with additional information about the drug that the agency did not mandate or request—the very theory advanced by Relator here—the consequence would be that companies would feel compelled, so as to avoid private liability, to inundate the agency with information, including information that FDA would not find material and that could obscure more important information. *Id.* Doing so would risk burying FDA in paper, such that it could not focus on its critical public health tasks.

Further, Relator cannot establish the falsity of any claims for federal reimbursement related to defendants' drugs both because Relator fails to allege any contract that was fraudulently induced, and because he has failed to demonstrate how any claim for payment could be false. That ruling should be affirmed. A reversal would risk turning the False Claims Act into "an all-purpose fraud statute" and a "vehicle for punishing garden-variety" regulatory lapses, which the Supreme Court has explicitly said that the FCA is not. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

The alleged fraud on which Relator rests—a fraud that purportedly induced FDA to approve a product for marketing—is an insufficient basis for recovery under

the FCA, and its endorsement would risk upsetting the carefully calibrated regulatory framework through which Congress has granted FDA sole authority and responsibility, relying on its wealth of expertise and experience, to weigh the risks and benefits posed by drug products, to determine what drugs to approve, and to determine when a drug approval should be withdrawn based on new data that changes the risk/benefit calculus. Critically, for purposes of this litigation, FDA is also solely responsible for prescribing, as it has done by regulation, what information should be submitted to it so that it can carry out these congressionally assigned tasks.

In order to protect FDA's exclusive authority to enforce the FDCA, and to balance competing statutory goals in doing so, Congress expressly barred both states and private parties from enforcing the FDCA. Unlike enforcement of the FDCA, with its need to balance competing interests to ensure the public health, the FCA is laser-focused on fraudulent claims for payment by government agencies. To support FCA liability, any alleged fraud must be directly tied to establishing why a claim for payment is ineligible for payment under the applicable standard. More remote allegations of fraud that cannot affect whether the claim in question meets the eligibility criteria for payment, cannot be a proper basis of an FCA suit.

This suit is a perfect illustration of the problem posed by FCA suits based on allegations of fraud not directly relevant to the conditions of payment. Under the statute governing reimbursement by CMS, claims relating to defendants'

prescription drugs were eligible for payment if those drugs were: (1) approved for sale by FDA; and (2) medically necessary and appropriate to the individual patient's condition. Relator does not allege facts relating to any particular individual patient's condition in an effort to establish that an individual's claims for payment failed to meet the second condition. And it is undisputed that defendants' products were, in fact, approved for sale at all times relevant to the case. And finally, Relator has identified no contract under which a claim was made that was induced by fraud. Thus, Relator cannot establish that any claim was false.

In this case, moreover, there is no need to speculate about the risk of inconsistency with FDA's own views about what information is important for it to review, because Relator has in fact supplied FDA with the information that was supposedly withheld, and FDA did not seek to withdraw its approval of the drugs. In such circumstances, Relator cannot ask a jury to override FDA's judgment. As a matter of law, the purported failure to disclose upon which Relator relies could not have been material to FDA's continued approval of the drugs for sale. The drugs were approved at the time claims for payment were made, and the claims for reimbursement submitted by health care providers in connection with the drugs' administration were not false. Realtor's suit must, therefore, fail for failure to demonstrate any of the elements of falsity, materiality, or causation.

Defendants have already addressed courts' recognition that a "fraud-in-the-inducement" theory of FCA liability, to the extent it is recognizable at all under the FCA, presupposes the existence of a contract that could have been "induced" by the purported fraud. *See* Bayer Br. 20-37; J&J Br. 17-29. *Amici* do not repeat that general exposition, but rather highlight in this brief how allegations by private relators of FCA liability based on regulatory fraud inevitably invade the province of the agency at issue. *Amici* note, however, that the Government's reliance on *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), for the viability of a fraudulent inducement theory of FCA liability is unavailing. U.S. Br. 11, 18-19. As explained below, that case strongly supports Defendants, not Relator. Contrary to the Government's suggestion, the Court in *Petratos* did not determine, as a "prerequisite to deciding the case," that fraud on the FDA *could* be the predicate for an FCA claim even absent a contract. U.S. Br. 19. Rather, *Petratos* stated in dictum (before proceeding to affirm dismissal of the relator's action on materiality grounds) only that FDA approval of a drug for an indication did not constitute a determination that use of the drug was "reasonable and necessary for [the] *individual patient* [in] the medical circumstances of the *individual case*." 855 F.3d at 487-88 (alteration in original). *Petratos* did not analyze a fraudulent inducement theory, and thus does not speak to the criticism the theory has garnered in the FCA context. *See, e.g., United States ex rel. Cimino v. Int'l Bus. Machs.*

Corp., 3 F.4th 412, 419 (D.C. Cir. 2021) (stating "liability under the FCA for fraudulent inducement must turn on whether the fraud caused the government to contract"); *see also id.* at 424 (Rao, J., concurring) ("The text of the FCA does not readily suggest liability for fraudulent inducement as a separate cause of action."). The Court did, in *Petratos*, go on to explain why an allegation of fraud against an agency cannot be a basis of FCA liability when the agency in question has not itself chosen to act on the alleged fraud. 855 F.3d at 489-93. As explained below, that holding likewise bars Relator's claim here.

ARGUMENT

I. Relator cannot ask a jury to overrule FDA's approval of Defendants' drugs, which would violate Congress's express grant to FDA of sole authority to exercise such regulatory judgments, as the Supreme Court recognized in *Buckman*.

Congress delegated to FDA full authority over a drug's initial approval and whether it maintains such approval over its lifecycle. This authority is not, and cannot, be shared with states, other agencies, or private citizens, as the fractured and inefficient system that would result would harm the public health and contradict Congress's statutory scheme.

A. FDA maintains authority over drug approval and labeling, which provides the basis for payment by CMS.

Claims related to the administration of a drug are eligible for reimbursement by CMS if they are "reasonable and necessary for the . . . treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). A drug is "reasonable and necessary" if (a) it

is approved by FDA, and (b) its administration is "'reasonable and necessary for the *individual patient*' based on 'accepted standards of medical practice and the medical circumstances of the *individual case*,'" which is a determination predominantly entrusted to individual doctors. *Petratos*, 855 F.3d at 487-89 (alteration in original). This Court has acknowledged that "FDA [is] best positioned to make high-level policy decisions—such as issuing . . . drug approvals," *id.* at 489, and that "*federal agencies*" (aside from individual prescribing physicians) "retain ultimate control over the [reasonable and necessary] decision," *id.* at 488. This squares with the Supreme Court's instruction that FDA itself is empowered to punish and deter fraud against the Agency while balancing other statutory objectives, and that these regulatory decisions must in turn provide leeway for "the discretion of health care professionals." *Buckman*, 531 U.S. at 348, 350.

Following drug approval, FDA maintains the authority to order drug labeling changes in light of new safety information. 21 U.S.C. § 355(o)(4). This includes determining when a labeling change must occur, what it must include, and whether a manufacturer has complied with FDA's mandates. *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 620 (2d Cir. 2016). Indeed, Congress charged FDA with the responsibility to "protect the public health by ensuring that . . . drugs are safe and effective" by "efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," which Congress

envisioned would require careful consultation with "experts in science, medicine, and public health, and . . . cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products." 21 U.S.C. § 393(b). The FCA, "even in its broadest application, was never intended to be used as a back-door regulatory regime," *Polansky*, 822 F.3d at 620 (citation omitted), particularly where such intricate regulatory frameworks are involved.

Neither a manufacturer nor a private plaintiff can mandate a labeling change in the face of FDA's rejection of such a change. *See generally In re Zofran (Ondansetron) Prods. Liab. Litig.*, 57 F.4th 327 (1st Cir. 2023) (affirming dismissal of failure-to-warn claims due, in part, to FDA's implicit rejection of plaintiff's requested labeling language). Importantly, FDA balances a variety of priorities in determining appropriate drug labeling, including an objective to "prevent overwarning, which may deter appropriate use of medical products, or overshadow more important warnings." *Id.* at 330 (quoting Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605-06 (Aug. 22, 2008)). Such assessments are conducted continuously, as FDA "considers a drug's benefit-risk assessment over the drug's lifecycle" and evaluates postmarket evidence—not just from drug manufacturers—but from "medical literature, postmarketing studies, adverse event reports, medication error reports, product quality reports, [Risk Evaluation and Mitigation

Strategies] assessment reports, patient experience data, and . . . data obtained from drugs of the same class." Food & Drug Admin., *Guidance for Industry on Benefit-Risk Assessment for New Drug and Biological Products* 22 (2023), https://www.fda.gov/media/ 152544/download.

B. Under Buckman, Relator cannot ask a jury to override FDA's approval.

This regulatory regime leaves no room for a private party like Relator to supersede FDA's judgment in approving a drug. Relator alleges that defendants Johnson & Johnson (J&J) and Bayer Corporation (Bayer) "fraudulently induc[ed] the FDA to approve, and maintain approval of[,] their drugs for a broad range of medical indications, which the FDA would never have done if it had known the full extent of the known risks of [fluoroquinolones]." A-295 (Second Am. Compl. ¶ 112). In doing so, Relator attacks FDA's decision, carefully considered and presently in force, that approval of Levaquin and Cipro remain in place.[2] Relator is also attacking FDA's determination, after full review of the evidence that Relator alleges the defendants hid from FDA, *see infra* pp. 10-11, that the entirety of Relator's proposed warning *should not* be added to the products' labeling.

[2] Indeed, Cipro 250, 500, and 750 milligram tablet products remain approved and available even in the aftermath of FDA's recent announcement (unrelated to Relator's allegations) regarding the withdrawal from sale of Cipro 100 milligram tablets for reasons of safety or effectiveness relevant to the dosing regimen for acute uncomplicated cystitis. 89 Fed. Reg. 64,921, 64,921-22 (Aug. 8, 2024).

Relator lacks the authority or expertise to contradict or question FDA's original approval decision or its determination that approval remained appropriate despite the unveiling of new risks. *See Petratos*, 855 F.3d. at 488. The system created by Congress for regulating drug approval, labeling, and reimbursement leaves no room for states, individual private parties, such as Relator, or any federal agency other than FDA to determine which drugs are worthy of FDA approval. Relator's fraud-on-the-FDA or fraud-in-the-inducement claim, which requires second-guessing the bases for FDA's well-reasoned decisions based on review of the full record it required for such review, thus cannot survive.

A contrary conclusion would undercut one of the key principles of the FCA. Relator brings his suit "in the name of the Government," 31 U.S.C. § 3730(b)(1), claiming that FDA was "fraudulently induced . . . to approve[] and maintain approval" of Cipro and Levaquin. Yet the allegations in his claim directly contradict the Agency's determination that the benefits of Cipro and Levaquin outweigh their risks for many patients and that the drugs should remain on the market despite the existence of certain adverse events of which FDA was fully aware. Relator thus does not seek to *vindicate* FDA (the supposed fraud victim), but instead to override FDA's fully informed decision.

The Supreme Court has made clear that a private party cannot ask a jury to overrule FDA's approval determinations, even on the theory that FDA's approval

was somehow the product of fraud. Per *Buckman*, the FCA's "federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and the Administration uses this authority to achieve a delicate balance of statutory objectives." 531 U.S. at 348. For this reason, the Court held in *Buckman* that fraud-on-the-FDA claims brought under state tort law would "exert an extraneous pull on the scheme established by Congress" and were therefore preempted. *Id.* at 353. Such suits would directly conflict with FDA's sole responsibility to "police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. *Buckman*'s preemption holding applies directly to any state-law FCA claims predicated on purported fraud on the FDA. If a state cannot purport to disregard FDA's actual approval for purposes of a state tort claim, neither can it do so for purposes of a state statutory cause of action, such as a state FCA law.[3]

The Supreme Court's holding in *Buckman* goes beyond private attempts to enforce the FDCA via state law. The problem *Buckman* identified was the broader one of a party other than FDA assuming to itself the authority to ask a jury to rule that an FDA drug approval was invalid because it was procured by fraud. As relevant here, Congress has further evidenced that same policy by mandating that

[3] The district court here declined to exercise supplemental jurisdiction over Relator's state law claims after determining that Relator's federal FCA claim failed to plead falsity. A-21. But Relator's state FCA claims would fail in any event for the reasons stated in the text.

CMS accept FDA's drug approval determinations as authoritative regarding whether a drug meets the threshold standard for reimbursement under Medicare or Medicaid. The Medicare and Medicaid statutes do not authorize CMS to make determinations about whether a drug should be approved for sale in the United States; rather, Congress directed that CMS should look to FDA's approval determinations to establish the threshold requirement for reimbursement. *E.g.*, 42 U.S.C. §§ 1395y(a)(1)(A), 1396r-8(k)(2)(A), 1927(k)(2); *see also Petratos*, 855 F.3d at 487-88 (citing Medicare Benefit Policy Manual, ch. 15, § 50.4.3); Medicare Benefit Policy Manual, ch. 15, § 50.4.1 ("[T]he program may pay for the use of an FDA approved drug . . . if: [i]t was injected on or after the date of the FDA's approval; [i]t is reasonable and necessary for the individual patient; and [a]ll other applicable coverage requirements are met.")). The FDCA prohibits a private party from asking a jury to second-guess FDA's approval determinations, and Medicare and Medicaid prohibit CMS from second-guessing FDA's approval determinations. Thus, there is no avenue, via the FCA, for a private party, acting as a relator suing on behalf of CMS, to ask a jury to second-guess FDA's approval determinations as part of a judgment that CMS should have treated the FDA-approved drugs in question as though they were *un*approved and therefore ineligible for reimbursement. The FCA does not allow CMS to do through a relator what CMS could not do directly under its governing statutes.

In light of the above, the First Circuit, citing *Buckman*, has specifically held that relators cannot invoke the FCA as "a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *D'Agostino*, 845 F.3d at 8. As the First Circuit explained, "[t]he FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." *Id.*

C. Crediting Relator's theory would cause New Drug Application (NDA) applicants to flood FDA with unnecessary information, compromising the drug approval process.

Relator seeks to supplant FDA's expert determination regarding how to weigh the benefits of Cipro and Levaquin against their risks with his own independent, non-expert judgment in contravention of the statutorily prescribed scheme for drug review and approval. Such a precedent was expressly criticized in *Buckman*, as it would provide applicants seeking FDA approval who fear subsequent fraud-on-the-FDA claims with "an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." 531 U.S. at 351. This would force NDA applicants to submit analyses covering myriad potential risks the Agency might find outlandish, lest they be subject to the FCA's oppressive treble damages and per-claim penalties

mandates. *Vt. Agency of Nat. Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000) (characterizing the FCA's penalty scheme as "essentially punitive").

This result becomes all the more apparent in light of FDA's current obligation to review and provide recommendations on clinical study protocol design, endpoints, and analyses that may support drug approval; review *all* relevant clinical and preclinical studies; evaluate investigators who supply clinical data; conduct statistical analyses of safety and efficacy data; evaluate how the drug will be manufactured; and approve prescribing information and patient labeling as necessary to inform the safe and effective use of drug products, among the many other tasks that require multiple teams of reviewer specialists during the NDA process. U.S. Food & Drug Admin., Review Team Responsibilities (2015), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/review-team-responsibilities. This undertaking is meant to entail a comprehensive review and analysis of all the *material* considerations necessary to determine whether a drug is safe and effective, not an exhaustive process of over-disclosure. Relator's theory, however, would force manufacturers to over-disclose information merely to reduce litigation risk and liability that could attach decades in the future. That result would not favor government efficiency or public health. Rather, such a scheme would drown FDA in unnecessary paperwork. This would inevitably cause a dramatic backlog at FDA and slow life sciences companies' ability to research, develop, and

bring to market life-saving and life-enhancing drugs. As the Supreme Court has held, Congress expressly sought to avoid such a situation by making FDA's determinations final on questions of drug approval, and precluding private parties, states, or even other federal agencies from second-guessing those determinations. Relator's FCA suit, which is premised on setting aside FDA's approval of defendants' drugs, cannot be squared with that congressional decision.

II. A relator cannot satisfy either the FCA's materiality or causation elements based on a fraud-on-the-FDA theory where FDA has specifically considered Relator's allegations and declined to withdraw approval of the drug.

Even if fraud-on-the-FDA might be a viable theory of falsity under the FCA in a particular case, Relator's allegations could not suffice on the allegations present in this case because they fail to satisfy the separate elements of causation and materiality in light of FDA's specific decision not to rescind approval of defendants' drugs notwithstanding its awareness of Relator's allegations. Considering Relator's allegations within the rubrics of materiality and causation, and contrasted with FDA's determination *not* to rescind its approval, demonstrates in concrete fashion how Relator's fraud-in-the-inducement FCA case would necessarily ask a lay jury to override the decisions of the agency itself.

A. Relator cannot satisfy materiality where FDA has reviewed his allegations and declined to rescind approval of Cipro and Levaquin.

Escobar is the leading case on materiality as an element of an FCA claim, and its analysis applies to Relator's fraud-on-the-FDA claim. There, the Court found that (1) "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material," and (2) "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 579 U.S. at 195; *see also Petratos*, 855 F.3d at 490 ("[A] misrepresentation is not 'material to the *Government's payment decision*,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance." (quoting *Escobar*, 579 U.S. at 181)). Thus, if FDA has already considered a relator's evidence of putative fraud and has decided *not* to rescind a drug's approval, then the relator fundamentally cannot show that the purported misrepresentations were material to FDA's approval, which is the prerequisite to CMS payment. That is exactly what happened in this matter.

Relator admits that FDA's approval process for Cipro and Levaquin required J&J and Bayer to submit "all data from both . . . animal and human studies" to the

Center for Drug Evaluation and Research, which evaluates new drug applications. A-268-70 (Second Am. Compl. ¶¶ 51-52). And nowhere does Relator allege that either party failed to provide the required data. Instead, Relator attacks the Defendants' analysis (i.e., aggregation) of the data and the careful FDA review that followed, including the Agency's analysis of its own studies carried out by its own personnel in 2013, its analysis of two citizen petitions filed by Relator in 2014, its decision to strengthen the drugs' safety labeling in 2016 (rather than seek to withdraw the approval for the drugs), and the Agency's reiteration in 2020 that labeling for Levaquin is currently adequate and need not contain warnings regarding Fluoroquinolone-Associated Disability or Adverse Psychiatric Events, as Relator proposes. A-283-84, A-288-89 (Second Am. Compl. ¶¶ 75-77, 92, 94); A-484-91 (June 20, 2020, FDA Letter Denying Citizen Petition).

Relator's independent analysis of postmarket adverse event data, which was conducted years after FDA approved Levaquin and Cipro and which relies on data that was not available during the FDA approval process, should not be used to contradict FDA's approval decision or render past sales of Levaquin and Cipro fraudulent. FDA has directly responded to Relator's allegations—including, most recently, in responding to his citizen petition regarding Levaquin in June of 2020.[4]

[4] Although Relator's citizen petition requested label changes only for Levaquin, FDA expressly noted that it "considered the applicability of [Relator's] requested labeling changes to systemic fluoroquinolones (i.e., ciprofloxacin, levofloxacin,

The Agency decided both that Levaquin's label need not change and that systemic fluroquinolones should remain on the market, as their benefits continue to outweigh their risks. A-487-91. That decision dooms Relator's FCA claim, as it shows his allegations could not have been material to FDA's approval of Cipro and Levaquin.

Realtor's theory, if accepted, would effectively remove Levaquin and Cipro from the market, which is precisely what FDA has declined to do. Any manufacturer could hardly continue to sell a product in face of a verdict effectively declaring the underlying FDA approval decision to be fraudulent and positing that any request for reimbursement of the product provides a basis for FCA liability. Every sale of the product could result in a submission to the federal government for reimbursement, and thus would expose the manufacturer to liability under the FCA. Notably, Relator's theory would expose manufacturers to significant liability even for drugs approved decades ago, despite the manufacturer's reasonable reliance on FDA's expert approval and labeling determinations, and based on alleged misrepresentations that occurred sometimes decades beyond the maximum 10-year statute of limitations under the FCA. 31 U.S.C. § 3731(b).

moxifloxacin, gemifloxacin, ofloxacin, and delafloxacin) as a class of drugs." A-484 n.1 (June 20, 2020, FDA letter denying citizen petition). Therefore, FDA's decision here applies to Relator's allegations regarding Cipro as well.

B. Relator's allegations also fail to satisfy the causation requirement.

That FDA has permitted the continued sale of Levaquin and Cipro, despite its full knowledge of Relator's claims, means that Relator cannot establish causation. In essence, Relator's claims resemble the tenuous, multi-step causation theory that the First Circuit has previously criticized. *See D'Agostino*, 845 F.3d at 7 (likening relator's fraudulent inducement theory to "a kick shot in billiards where the cue ball 'could have' but did not in fact bounce off the rail, much less hit the targeted ball"). *D'Agostino* found that a relator's claims—including that the defendants had fraudulently induced FDA's approval by, *inter alia*, omitting critical safety information—failed because the relator's allegations were only that a defendant's representations "could have" influenced FDA's approval decision, not that they *actually* caused FDA to grant approval of the subject medical devices. *Id.* The *D'Agostino* relator was forced into this position because FDA had never withdrawn its approval of the medical devices at issue, and CMS had never denied reimbursement, even though both agencies knew of the relator's allegations. *Id.* at 7-8.

Relator's allegations fall even further short than those in *D'Agostino*. Here, FDA has expressly rejected Relator's theory, showing that J&J and Bayer's alleged disaggregation *could not* have influenced FDA's approval determinations, as FDA has specifically considered Relator's concerns and chosen to leave approvals for

Cipro and Levaquin in place. In light of this, Relator cannot establish that his allegations, which FDA has been aware of for years, would have actually caused FDA to withhold its initial approval or thereafter to withdraw that approval—a step FDA expressly declined to take.

CONCLUSION

Because the decision below correctly held that Appellant's FCA claim failed, and because Appellant's theory of liability would improperly override the statutorily-provided authority of FDA to make drug approval decisions, *amici* respectfully urge this Court to affirm it.

Respectfully submitted,

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COMBINED CERTIFICATIONS

The undersigned, a member of the Bar of this Court, hereby certifies as follows:

1. At least one of the attorneys whose names appear on this brief is a member of the Bar of this Court.

2. This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B)(i) and 29(a)(5) because this brief contains 4,491 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

3. Service on opposing counsel is being made electronically through CM/ECF. Ten paper copies of the brief have been sent by first-class mail to the Clerk's office on the same day as this brief is being filed electronically.

4. The text of the electronic brief is identical to the text of the paper copies.

5. A virus-detection program was run on the electronic brief, and no virus was detected. The program used was Crowdstrike Falcon, program version 7.13.18308.

Dated: August 15, 2024

/s/ *Douglas Hallward-Driemeier*
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ADDENDUM

TABLE OF CONTENTS

21 U.S.C § 355

§ 355 - New drugs

(o) Postmarket studies and clinical trials; labeling

(4) Safety labeling changes requested by Secretary

(A) New safety or new effectiveness information

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not currently marketed, the holder of an approved application under subsection (j).

21 U.S.C. § 393 - Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration")

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

. . .

31 U.S. Code § 3731 - False claims procedure

(b) A civil action under section 3730 may not be brought—

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

. . .

42 U.S.C. § 1395y - Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

. . .

42 U.S. Code § 1396r–8 - Payment for covered outpatient drugs

(k) Definitions

In this section—

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (4)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] or 507 4 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act [21 U.S.C. 355(j)];

(ii)

(I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C. 331, 332(a), 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C. 352(f), 355(a)]; or

(iii)

(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

. . .

42 U.S.C. § 1927 Payment for Covered Outpatient Drugs

(2) Covered outpatient drug.—Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (4)[340]), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act[341] or which is approved under section 505(j) of such Act;

(ii)

(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations[342]) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act[343]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)

(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

. . .