No. 25-1818

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

UNITED STATES EX REL. PENELOW, *et al.*,

Plaintiffs-Appellees,

v.

JANSSEN PRODUCTS, LP,

Defendant-Appellant.

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

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLANT

James C. Stansel
Julie Ritchie Wagner
Melissa B. Kimmel
Kelly Goldberg
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, DC 20004

Counsel for Amicus Curiae the Pharmaceutical Research and Manufacturers of America

Pat Fogarty
ADVANCED MEDICAL TECHNOLOGY ASSOCIATION
1301 Pennsylvania Avenue, NW
Suite 400
Washington, DC 20004

Counsel for Amicus Curiae the Advanced Medical Technology Association

Douglas Hallward-Driemeier
Kellie Combs
Diana K. Cieslak
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

Attorneys for Amici Curiae the Pharmaceutical Research and Manufacturers of America, and the Advanced Medical Technology Association

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amici*, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed) make the following disclosures:

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

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

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 laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical-technology association representing device, diagnostics, and digital-technology manufacturers that are transforming health care through earlier disease detection, less-invasive medical procedures, and more-effective treatments. Its more than 600 member companies span every field of medical science and range from cutting-edge startups to multinational manufacturers. AdvaMed's member

[1] *Amici curiae* state that counsel for all parties have consented to the filing of this amicus brief. 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.

companies are dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards.

PhRMA and AdvaMed have a strong interest in this case because their members are increasingly the targets of False Claims Act (FCA) suits by private relators proffering theories of liability based on the so-called "off-label" promotion of drugs or medical devices that are inconsistent with CMS's rules and regulations regarding the eligibility of drugs and devices for reimbursement by federal programs, would interfere with FDA's authority to regulate new drugs and medical devices, and would chill doctors' ability to learn important scientific information and base their medical judgments on that data. More broadly, *amici* are concerned about the repeated attempts by relators, as exemplified by this case, to create FCA liability based entirely on a manufacturer's sharing of scientific information about unapproved uses of its FDA-approved drug or device.

This brief is submitted by PhRMA and AdvaMed to describe the deleterious effects that would result if the legal theory advanced by Relators, and adopted by the district court, were endorsed by this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

The verdict Relators obtained against Defendant Janssen Products, LP—holding it liable under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, for claims related to two of Janssen's HIV drugs—is based on a critical legal error. Under the district court's flawed jury instructions, the jury was permitted to find Janssen liable under the FCA without concluding that the claims at issue were actually ineligible for payment under the relevant standards. The district court's post-trial ruling confirmed the court's confusion in this critical regard.

The lower court erred by stating incompletely and incorrectly the legal standards for when prescription drugs are eligible for reimbursement by federal health care programs and thus when such prescriptions can give rise to false claims under the FCA. In its various formulations of the governing law, the district court repeatedly stated (incorrectly) that prescription drugs' eligibility for reimbursement turns on whether those drugs were prescribed (or promoted) for uses different from the uses approved by the federal Food and Drug Administration (FDA)—so-called "off-label" uses. The district court instructed the jury that off-label uses are categorically ineligible for reimbursement and that any claims for off-label prescriptions were thus inherently false. In denying post-judgment relief, the district court articulated a related, but equally erroneous, proposition—that any drug that

has been promoted for off-label use is categorically ineligible for reimbursement and claims for reimbursement of those drugs are therefore categorically false.

Contrary to the district court's pronouncements, however, federal statutes and regulations permit federal health care programs to pay for FDA-approved drugs in at least some circumstances when those drugs have been prescribed for uses different than those approved by FDA. Such uses are not inherently inappropriate, and claims are not fraudulent simply because they involve such uses. Instead, these uses can be critically important, such as for patients with diseases for which there are no approved drugs on the market. Indeed, federal regulators recognize that in certain circumstances off-label uses have become the standard of care for treating some conditions and diseases. And, as the Department of Justice's own amicus filings in other matters have confirmed, federal reimbursement is not conditioned on a manufacturer's compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). The Government has many tools to address violations of the FDCA; off-label promotion does not, however, itself render the manufacturer liable under the FCA.

Affirming this verdict would not just be legally erroneous, it would have severe adverse implications for the provision of medical care in the United States. Prescription drug and device manufacturers might curtail the lawful sharing of critical scientific information about off-label uses or health care providers might refrain from lawfully prescribing a product for such uses, even when medically

appropriate, for fear of being hauled into court by a relator wielding the FCA as a weapon. Relatedly, Congress has tasked FDA with regulating the evaluation and approval of new drugs and medical devices and their uses. Congress has authorized the Centers for Medicare and Medicaid Services (CMS) to determine whether to pay for medical care using those drugs or devices. In both statutes, however, Congress has been clear that these federal agencies are not to interfere with the practice of medicine according to accepted standards. This verdict would upset that careful balance and permit private parties to interfere with the practice of medicine, something that even FDA and CMS are precluded from doing. Finally, by making manufacturers' speech about off-label uses, even those of critical concern to patients and their doctors, an automatic basis for FCA liability, the district court's erroneous statement of law would put the FCA on a collision course with the First Amendment. That construction should surely be avoided. This Court should vacate the judgment below and remand for further proceedings consistent with an accurate understanding of the standards governing federal reimbursement.

ARGUMENT

I. THE DISTRICT COURT ERRED BY APPLYING AN INCORRECT LEGAL STANDARD FOR DETERMINING WHETHER A DRUG ALLEGEDLY PROMOTED OR PRESCRIBED OFF-LABEL IS ELIGIBLE FOR FEDERAL REIMBURSEMENT.

The jury instructions and post-trial rulings below were infused with legal error. As a result, the jury was permitted to find FCA liability even where the drug

in question was prescribed in a manner that may have satisfied the governing standards for reimbursement.

A. Federal law allows reimbursement for drugs that have been prescribed off-label if the use is recognized as medically accepted.

Health care providers are permitted to exercise their clinical judgment and prescribe FDA-approved drugs for any medically appropriate use, not just those uses that are consistent with the FDA-approved Prescribing Information (PI). *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 619-20 (2d Cir. 2016); *see also* 21 U.S.C. § 396.[1] Notably, these so-called off-label uses of prescription drugs can be of critical importance, and, in some instances, may even constitute a medically-recognized standard of care. *See, e.g.*, *Buckman*, 531 U.S. at 351 & n.5 (noting that "off-label use is generally accepted" and citing a legal journal article for the proposition that off-label use "often is essential to giving patients optimal medical care"); *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) (collecting authorities); *see also Polansky*, 822 F.3d at 614. Indeed, off-label use is particularly

[1] FDA explicitly recognizes that a health care provider may determine, after analyzing a patient's particular circumstances, that an off-label use is "medically appropriate" for that particular patient. *See* U.S. Food & Drug Admin., *Understanding Unapproved Use of Approved Drugs "Off Label"*, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (last updated Feb. 5, 2018).

widespread in rare diseases, oncology, and psychiatry, especially in elderly and pediatric populations. *See* Carmen-Maria Rusz, et al., *Off Label Medication: From a Simple Concept to Complex Practical Aspects*, 18 Int'l J. Env't Rsch. & Pub. Health 10447, at 2 (Oct. 4, 2021), https://doi.org/10.3390/ijerph181910447. As the Second Circuit explained, "the FDA has expressly advised physicians that, unlabeled uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature, and . . . physicians commonly exercise professional medical judgment and prescribe drugs for uses not within the indications articulated by the FDA." *Polansky*, 822 F.3d at 620 (citation modified) (quoting *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009)). FDA has also acknowledged that, in some instances, it is entirely permissible for prescription drug manufacturers to disseminate information about off-label uses of their drugs. *See, e.g.*, U.S. Food & Drug Admin., *Guidance for Industry: Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers* (2025), https://www.fda.gov/media/184871/download.

Given the important role that off-label uses can play in the practice of medicine, federal health care programs—such as Medicare, Medicaid, and the AIDS Drug Assistance Program (ADAP)—will pay for claims related to these uses in

certain circumstances. In the Medicare program, there are two primary requirements for prescription drug coverage: the use of the drug must be "reasonable and necessary," and the drug must be prescribed for a "medically accepted indication." 42 U.S.C. § 1395y(a)(1)(A); *id.* § 1395w-102(e)(1), (e)(3)(A), (e)(4) (incorporating definitions from 42 U.S.C. § 1396r-8(k)(6)); *id.* § 1395x(t)(2); *see also United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487-88 (3d Cir. 2017).[2] Administration of a drug is considered "reasonable and necessary" if the drug has been approved by FDA and the administration in question is "reasonable and necessary for [the] individual patient" based on "accepted standards of medical practice and the medical circumstances of the individual case." *Petratos*, 855 F.3d at 487-89 (quoting Medicare Benefit Policy Manual, ch. 15, § 50.4.3) (citation modified).

A "medically accepted indication" is one that "has been approved by the FDA *or* supported by research in certain authoritative compendia" of clinical research and medical standards of practice. 42 U.S.C. § 1395w-102(e)(1), (e)(3)(A), (e)(4); *id.* § 1396r-8(d)(1)(B)(i), (g)(1)(B)(i), (k)(3), (k)(6); *Polansky*, 822 F.3d at 615; Brief

[2] In *Petratos*, the Court was largely relying on the statute, rules, and guidance concerning Medicare Part B, which typically covers drugs that cannot be self-administered by a beneficiary (in other words, Part B does not generally cover drugs that come in pill form). Part D also generally pays for drugs that are reasonable and necessary and prescribed for a medically accepted indication. *See generally Dobson v. Sec'y of Health & Hum. Servs.*, No. 20-11996, 2022 WL 424813, at *1-2 (11th Cir. Feb. 11, 2022).

for the United States as Amicus Curiae in Support of Neither Party *in United States ex rel. Solis v. Millenium Pharms., Inc.*, No. 15-16953, 2016 WL 6833796, at *4-5 & n.2 (9th Cir. Nov. 17, 2016) (hereinafter "Gov't *Solis* Br."). Thus, under the express terms of the statute, a medically accepted indication can include both on-label and off-label uses.

Under the Medicaid and ADAP programs, state agencies have been granted the authority to craft and implement reimbursement requirements that are not coextensive with the Medicare requirements. *See, e.g.*, Appellant Br. 31-32 (citing 42 U.S.C. § 1396r-8(d)(1)(B)(i); 42 C.F.R. § 440.230(d)). As a result, some states' prescription drug coverage criteria differ from Medicare's requirements and are not limited to covering uses specified in a compendia. *See, e.g.*, Cal. Code Regs. tit. 22, § 51313(c)(4). For example, California's Medicaid program will pay for an off-label use that "represents reasonable and current prescribing practices," which are determined by "[r]eference to current medical literature" or "[c]onsultation with provider organizations, academic and professional specialists." *Id.* Michigan's Medicaid program explicitly excludes from its prescription drug pre-authorization program, and thus implicitly supports payment for, any "prescription drug that is recognized in a generally accepted standard medical reference" to treat HIV or AIDS. Mich. Comp. Laws § 400.109h(1)(d).

Taking these authorities together, federal health care programs will pay for FDA-approved drugs prescribed for an unapproved use under certain circumstances. These programs generally require that use be medically reasonable and necessary for the particular patient and be supported by a respected source, such as a compendia or the medical literature. It follows, therefore, that a claim for reimbursement from a federal health care program for an off-label prescription is not automatically false. Such a claim would only be false if the use did not satisfy the program's requirements for payment. *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 345 (D. Mass. 2011). Consequently, in the Medicare program (and many state Medicaid programs), such a claim would only be potentially false if it was: not medically reasonable, not medically necessary, or not supported by a respected medical source (either a citation in a compendia of clinical research or other medical literature, depending on the pertinent reimbursement standard).

Notably, the Department of Justice has twice, including once before this Court, participated as *amicus* to clarify that neither off-label marketing *nor* off-label use of a drug inherently makes a claim for reimbursement false for purposes of the FCA. The Government has stated that "[p]ayment under government health programs is not generally conditioned on a manufacturer's compliance with various FDA procedures, or its compliance with the [FDCA]" concerning off-label

promotion. Brief for the United States as Amicus Curiae in Support of Neither Party *in United States ex rel. Petratos v. Genentech Inc.*, No. 15-3805, 2016 WL 3012033, at *26 (3d Cir. May 23, 2016) (hereinafter "Gov't *Petratos* Br."); *see also* Gov't *Solis* Br., 2016 WL 6833796, at *4-5 & n.2. Thus, as the Government has made clear, a relator cannot establish FCA liability *merely* by demonstrating that a manufacturer's activity constituted off-label promotion that violated the FDCA. *See* Gov't *Solis* Br., 2016 WL 6833796, at *5 n.4; Gov't *Petratos* Br., 2016 WL 3012033, at *27. Courts, likewise, have held that "off-label promotion alone cannot sustain a successful FCA action." *Nowak*, 806 F. Supp. 2d at 345. Instead, as the Department of Justice and other federal courts have recognized, FDA has other tools available to regulate in this area, and discretion about how and when to do so.

In sum, although some off-label uses of a drug may be ineligible for reimbursement and can give rise to false claims if payment is nonetheless sought, claims for unapproved uses that meet the program's coverage criteria are eligible for payment. There is no support in the law for the proposition that just because a drug is promoted or prescribed for an unapproved use all claims relating to such use are categorically false. Despite the lack of support for holding pharmaceutical manufacturers liable under the FCA solely for the off-label promotion of drugs, that is precisely what the jury was instructed to do in this matter.

B. The district court misstated the reimbursement standard when instructing the jury on falsity.

The district court's instruction on falsity misstated the law. It is axiomatic that jury instructions must "accurately and fairly set[ ] forth the current status of the law." *Lichtenstein v. Univ. of Pittsburgh Med. Ctr.*, 598 F. App'x 109, 112 (3d Cir. 2015) (non-precedential) (alteration in original) (quoting *Douglas v. Owens*, 50 F.3d 1226, 1233 (3d Cir. 1995)). Jury instructions must be analyzed "as a whole" to ascertain "whether . . . they properly apprised the jury of the issues and the applicable law." *Givaudan Fragrances Corp. v. Krivda*, 639 F. App'x 840, 847 n.20 (3d Cir. 2016) (non-precedential) (quoting *Tigg Corp. v. Dow Corning Corp.*, 962 F.2d 1119, 1123 (3d Cir. 1992)). The instructions here failed to properly educate the jury on the standard for reimbursement of prescription drugs under federal law.

The applicable law here, the FCA, "is not 'an all-purpose antifraud statute.'" *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)). Rather, a "violation of government regulations or engagement in private fraudulent schemes does not impose liability under the FCA unless the provider submits false or fraudulent claims to the government for payment based on these wrongful activities." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004); *see also D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016); *United States ex rel. Clausen v. Lab'y Corp. of Am., Inc.*, 290

F.3d 1301, 1311 (11th Cir. 2002). To determine whether an FCA violation has occurred, the jury must therefore be asked to decide "whether the claim[s] submitted to the government as reimbursable w[ere] in fact reimbursable, based on the conditions for payment set by the government." *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 97 (3d Cir. 2020).

As stated above, under the relevant reimbursement rules, Medicare Part D plans will pay for a prescription drug either when it is prescribed for an FDA-approved use *or* when it is prescribed for a use that is supported by a compendia citation (even if that use is off-label). *See supra* pp. 6-7; *see also* Gov't *Solis* Br., 2016 WL 6833796, at *4-5 & n.2. These are each independently sufficient methods of meeting the "medically accepted indication" standard. Therefore, a proper articulation of what suffices for a medically accepted indication would present these as two alternative, independently adequate criteria.

The district court, however, incorrectly instructed the jury that *both* an FDA-approved use and a compendia citation were required to meet the "medically accepted indication" standard. As a result, the jury was misinformed of the standard for determining when a drug is reimbursable. The district court instructed the jury that "a claim made to a federal health care program is false if it seeks reimbursement for a prescription that is not eligible for reimbursement." Appx2211. This instruction, when reviewed in isolation, accurately describes the law—however, jury

instructions are reviewed "as a whole." *Givaudan Fragrances*, 639 F. App'x at 847 n.20 (quoting *Tigg*, 962 F.2d at 1123). Reading Instruction 19.1 together with an earlier instruction, Instruction 17, reveals that, taken together, the instructions were flawed.

Instruction 17 stated that "eligib[ility] for reimbursement" is determined by whether "federal health care programs . . . will cover and pay for a drug that is used for a 'medically accepted indication,' which means *any FDA-approved use on the label* ***that is*** *supported by one or more citations in certain drug compendia*." Appx2202 (emphasis added). That instruction defined a medically accepted indication as requiring *both* "any FDA-approved use on the label" *and* a use "supported by one or more citations in certain drug compendia." *Id.* This instruction incorrectly converts two alternative bases for payment by Medicare into two necessary elements of a single basis. But satisfying *either* requirement can support eligibility for reimbursement, and neither requirement is dependent upon the other. The district court erred by using a phrase "that is," signifying that *both* were required, when it should have used a disjunctive (such as "*or*") to link the two alternatives.

Instructions 19.1 and 17, taken together, would permit (indeed require) the jury to find falsity whenever a drug was prescribed for a use not expressly included in the PI. Under these instructions then, any prescription for an indication that is

supported by at least one compendia citation, but did not receive FDA approval, would be deemed categorically ineligible for federal reimbursement, *see* Appx2202, even though Medicare expressly permits reimbursement in such circumstances.

These instructions were also incomplete. Although the district court appears to have attempted to instruct the jury on the payment eligibility requirements under Medicare Part D, it made no attempt to instruct the jury on the different payment eligibility requirements under the various state Medicaid programs or the ADAP. These programs are allowed to restrict coverage to drugs that are medically indicated and reasonable and necessary, but are not required to do so. As a result, the precise state coverage rules differ, and they do not all mirror the federal Medicare rules. *See supra* pp. 6-7. For example, some states provide coverage for unapproved uses of FDA-approved drugs that are supported by the medical literature beyond solely the compendia. *See id.* Because Relators failed to establish the different rules for each of these payors, *see* Appellant Br. 32-33, the court lacked the information to properly instruct the jury on these requirements.

This incomplete and distorted recitation of the law effectively makes manufacturers liable under the FCA on the basis of off-label promotion allegations *even if* the drug is ultimately reimbursable. But "[w]hether a claim for payment is 'false' for purposes of liability under the FCA, in the off-label promotion context, turns on whether the claim is reimbursable under the relevant federal program, i.e.

Medicaid or Medicare," not simply whether off-label promotion has occurred. *United States ex rel. Worsfold v. Pfizer Inc.*, No. 09-11522, 2013 WL 6195790, at *3 (D. Mass. Nov. 22, 2013) (citation modified). Indeed, the Government itself has made clear that "[p]ayment under government health programs is not generally conditioned on a manufacturer's compliance with various FDA procedures, or its compliance with the [FDCA]" concerning off-label promotion. Gov't *Petratos* Br., 2016 WL 3012033, at *26.

For the reasons set forth below, *see infra* pp. 19-25, leaving this instructional error unaddressed could result in sweeping FCA liability not only for manufacturers, but also for health care providers. Additionally, by making FDA approval for a particular use an absolute prerequisite for reimbursement, the district court's erroneous instructions come perilously close to converting the FCA into a tool used to regulate the practice of medicine, which Congress specifically declined to do. *See infra* pp. 19-22. Because the district court's instruction misstated the law, the jury verdict must be set aside on that basis alone.

C. The district court's post-trial order confirmed the court's mistaken understanding of the relevant law.

Although the erroneous jury instructions are sufficient grounds to vacate the verdict, the district court's order denying Defendant's motion for judgment as a matter of law confirmed and compounded the court's incorrect understanding of the relevant legal standards. In its order denying that motion, the lower court concluded

that Relators had meet their burden at trial because they introduced evidence demonstrating that Defendant marketed its two HIV drugs for off-label uses, because, in the district court's erroneous view, "this [off-label] marketing violated an express condition of payment for reimbursement." Appx244. In this statement, the district court (incorrectly) equated the off-label promotion of a drug with ineligibility for payment.

The lower court doubled down on this understanding as it evaluated the evidence presented at trial. In concluding that sufficient evidence existed to support the jury's finding of materiality, the court cited testimony from Defendant's president, who testified—categorically—that the Government would not reimburse claims for drugs if those claims were the result of off-label marketing. Appx242. The court's reliance on this testimony highlights its apparent, but mistaken, view that *any* off-label promotion by the manufacturer would necessarily render *all* resulting claims false. Appx241-43. Instead of recognizing that liability could attach only if any off-label prescriptions were not eligible for reimbursement, the district court appears to have been operating under a mistaken impression of automatic FCA liability for all instances of off-label marketing.

Payment under Government health care programs is *not* conditioned on a drug manufacturer's compliance with the FDCA, as the Government has itself made clear, including in a filing before this Court. *See* Gov't *Petratos* Br., 2016 WL 3012033,

at *26; *see also* Gov't *Solis* Br., 2016 WL 6833796, at *12 n.4. Consequently, any marketing statements about a drug that are arguably inconsistent with the FDA-approved label for that drug do not, on their own, render all subsequent uses of that drug ineligible for reimbursement by federal health care programs. The statutes governing payment have no requirements related to the *marketing* of a drug; instead those statutes exclusively focus on the *use* of a drug. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(i), (g)(1)(B)(i), (k)(3), (k)(6). Nor does mere off-label *use* of a drug make all subsequent claims submitted for that drug false. Rather, as explained above, the law is clear that federal health care programs will pay for the off-label use of FDA-approved drugs in some circumstances. *See Petratos*, 855 F.3d at 487-88. It follows then, that any off-label communications about a drug do not transform all claims for reimbursement for that drug into false claims under the FCA.

The district court's erroneous jury instructions and its subsequent mischaracterization of the law in the order denying Defendant's motion are different manifestations of the same error—the court mistakenly believed, and led the jury to believe, that the falsity of any claims could be determined based solely on whether the drug in question had been promoted or used off-label.[3] This is plainly not the

[3] The district court's misunderstanding of the payment criteria for prescription drugs also infected its analysis of the FCA's materiality requirement. *See generally* Appellant Br. 18-23.

case, and the judgment below, which depended on that fundamental misunderstanding of the law, must be set aside.

D. Applying the correct legal standards, Relators failed to prove their FCA theory.

Had the district court applied the correct legal standards for reimbursement, Relators' FCA claims would have failed for lack of sufficient proof. When a manufacturer engages in off-label promotion, thus exposing a provider to information about potential off-label uses of the product, it is not the case that all subsequent prescriptions written by that provider are necessarily false claims, or that the manufacturer's promotion was a substantial factor in causing any false claims to be submitted. *See* Appellant Br. 39-43. Relators' theory of liability against Janssen, which did not itself submit any claims for payment, was that Janssen had "caused" false claims to be presented to the Government for payment. *See* 31 U.S.C. § 3729(a)(1)(A). Thus, to hold Janssen liable, Relators were required to present evidence that (i) Defendant's alleged promotion actually impacted the prescribing decisions of physicians, (ii) that those physicians then prescribed Defendant's drugs to their patients for off-label uses, and (iii) that Government health care programs would not have paid for those particular off-label uses for those particular patients. *See Petratos*, 855 F.3d at 491 (explaining that the defendant's conduct must be "integral to a causal chain leading to payment" (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2014))); *see also*

Polansky, 822 F.3d at 619 (recognizing that, given the various decisionmakers involved in prescribing and dispending a prescription medication that "it is unclear just whom [the defendant] could have caused to submit a 'false or fraudulent' claim").

Relators did not attempt to make any such showing. The record is devoid of any evidence that any doctor prescribed Defendant's HIV drugs for an off-label use because of Defendant's communications. Nor does it contain testimony from Government witnesses about the circumstances in which each of the specific federal health care programs at issue would have paid (or not paid) for any of those purportedly off-label prescriptions. Relators would have needed to present sufficient evidence that the prescriptions for Defendant's HIV drugs did not meet the payment criteria for the specific federal program at issue. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); *id.* § 1395w-102(e)(3)(A); *id.* § 1396r-8(d)(1)(B)(i), (g)(1)(B)(i), (k)(3), (k)(6). Because Relators did not make such a showing, they failed to support a verdict in their favor.

II. ALLOWING THE JURY VERDICT TO STAND WOULD SEVERELY IMPAIR THE PROVISION OF CARE TO PATIENTS IN WAYS CONGRESS AFFIRMATIVELY SOUGHT TO AVOID, WHILE RAISING SIGNIFICANT CONSTITUTIONAL CONCERNS.

Allowing a jury to hold a defendant liable under the FCA simply because that defendant promoted or prescribed for unapproved uses a federally reimbursed drug

or device is not only legally incorrect, it would also seriously impair the provision of health care in the United States.

A. Affirming the district court's judgment would chill manufacturers from discussing and providers from prescribing drugs and devices for off-label uses, effectively turning the FDA into a regulator of the practice of medicine, which Congress expressly sought to avoid.

If this billion-dollar judgment for Relators is permitted to stand, it would fundamentally alter the carefully crafted regime that regulates pharmaceutical manufacturers' dissemination of information about prescription drugs and the circumstances under which federal health care programs will pay for those drugs. Affirming this verdict would allow private individuals to undermine and second-guess decisions that Congress has decided are better left to FDA, CMS, and individual health care providers. Critically, if the district court's ruling were affirmed, patient care could suffer.

Subjecting pharmaceutical manufacturers and providers to FCA liability simply for promoting or prescribing drugs for off-label uses, under the reasoning employed by the district court, would substantially and inappropriately transform the regulatory regime governing the promotion and dissemination of prescription drugs. Congress did not permit FDA to regulate the practice of medicine, nor did it permit private parties to attempt to do so via enforcement of the FDCA. But the district court's decision effectively gives private parties precisely that power by

turning every manufacturer's alleged off-label promotion and every provider's off-label prescribing into grounds for FCA liability.

Congress has charged FDA with, among other things, exercising its expertise to protect public health by ensuring that prescription drugs and medical devices are safe and effective for their intended uses. 21 U.S.C. § 393(b)(2)(B) & (C). Congress just as clearly, however, limited FDA's authority, making it clear that FDA cannot regulate the practice of medicine. *See, e.g.*, 21 U.S.C. § 396 (codifying a physician's ability to prescribe or administer a legally marketed medical device for any condition or disease); 21 C.F.R. § 312.2(d) (carving out from the regulatory regime governing clinical investigations of new drugs the "use in the practice of medicine for an unlabeled indication" of an approved drug); *see also Caronia*, 703 F.3d at 153 (collecting authorities). Accordingly, once a prescription drug or device is FDA-approved, physicians are generally permitted to exercise their medical judgment to prescribe the drug or device for *any* use, not just those uses that are FDA-approved. *See Buckman*, 531 U.S. at 350; *Polansky*, 822 F.3d at 614, 619-20.

Congress and CMS have devoted similar care and attention to ensuring that the conditions under which prescription drugs are eligible for reimbursement by federal health care programs give health care providers room to practice medicine without undue federal interference. *See supra* pp. 4-8. Just as it did with FDA's authorizing statutes, Congress has expressly stated that nothing in the Medicare

statutes provides federal regulators with control over the practice of medicine. 42 U.S.C. § 1395. Instead, the independent decisions made by individual medical providers plays a key role in this regulatory framework. *See, e.g.*, *Buckman*, 531 U.S. at 350 (noting that "FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals"); *Petratos*, 855 F.3d at 488-89 (Congress intended "the physician to be a key figure in determining what services are needed and consequently reimbursable" by federal health care programs (quoting *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989))).

There is no place in these federal statutes for private citizens, who lack the necessary authority or expertise, to assume (via an FCA action) authority over the practice of medicine that even FDA and CMS do not have. Put another way, because even FDA is not authorized under the FDCA to regulate the practice of medicine, a private relator should not be permitted to effectively restrict the practice of medicine by asserting FCA liability predicated *solely* on the basis of a purported FDCA violation. *Polansky*, 822 F.3d at 620. As this Court has previously recognized, "FDA [is] best positioned to make high-level policy decisions," *Petratos*, 855 F.3d at 489, and "federal agencies retain ultimate control over the [reasonable and necessary] decision," *id.* at 488. Other courts are in agreement. *See D'Agostino*, 845 F.3d at *8-9 ("If jurors in a single *qui tam* case" could second-guess FDA, then

"FDA's responsibility to police fraud consistently with the Administration's judgment and objectives might be undercut." (emphasis added)); *Polansky*, 822 F.3d at 620. Undergirding these decisions is a recognition that 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). As a result, courts have wisely restricted the ability of relators to inject themselves into this regulatory regime and second guess the decisions of both federal agencies and individual medical professionals.

Underlying these decisions is also the recognition that regulation via relator litigation would not provide the pharmaceutical industry or health care providers with the kind of guidance that would enable them to ensure that they stay within the bounds of the law. Indeed, Congress expressly precluded private enforcement of the FDCA. *See* 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349. Allowing relators to do that indirectly, via FCA litigation, would undermine FDA's ability to carefully balance competing (and sometimes conflicting) interests present in this area. *Cf. Buckman*, 531 U.S. at 349 (observing that Congress gave FDA considerable enforcement discretion because under the relevant "statutory and regulatory framework . . . FDA pursues difficult (and often competing) objectives").

Permitting enforcement of the FDCA via private litigation under the FCA would further deprive pharmaceutical manufacturers of predictability regarding

when they may share information regarding off-label uses. Leaving the precise contours of what constitutes permissible promotion to FCA actions initiated by relators would offer the industry no way to seek clarity as to what would (and would not) be permitted ahead of taking any particular action. *Cf. United States ex rel. Polansky v. Pfizer, Inc.*, 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012) ("[T]here are protections required for the implementation of prohibitory regulations (for example, the right to public comment or administrative challenge), which the [FCA] cannot be used to circumvent."). Notably, there is also no evidence in the record that FDA ever choose to take action against Defendant with respect to the allegations concerning these drugs.

Moreover, there is no principle that would effectively limit the impact of the district court's ruling here. The consequences of permitting relators to second-guess federal regulators likely would be that no manufacturer could afford to share *any* truthful and non-misleading information about potential off-label uses of their drugs, and no health care provider could afford to prescribe drugs for those off-label uses, even when science would support doing so. Manufacturers would necessarily refrain from providing scientifically relevant information about unapproved uses if doing so could subject them automatically to liability under the FCA. Such a rule would *undermine* the policy goals of FDA, which has affirmatively recognized that there are circumstances in which it is desirable for manufacturers to be able to share

scientific information about off-label uses with medical providers. *See, e.g.*, U.S. Food & Drug Admin., *Guidance for Industry: Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers* 10-11 (2025), https://www.fda.gov/media/184871/download; *see also Caronia*, 703 F.3d at 153 (collecting authorities noting that FDA has affirmatively recognized off-label use of prescription drugs as of critical importance, and, in some instances, the medically recognized standard of care); *Polansky*, 822 F.3d at 614.

This chilling effect would extend beyond manufacturers, however. Physicians and other clinicians may also refrain from prescribing a drug for an off-label use, even if the use of that drug is supported by medical compendia and is reasonable and necessary for particular patients, for fear of risking their actions later being called into question by a relator and a jury. A manufacturer's FCA liability in an off-label promotion case for "causing" a false claim to be presented presupposes that the health care provider who submitted the claim has itself presented a "false claim," and could likewise face FCA liability for doing so. This potential liability could discourage health care providers from prescribing drugs for uses that have been extensively reported on in the medical literature and have become the standard of care.

Given the importance of unapproved uses of approved products, chilling their use would cause patient care to suffer. A fear of FCA liability might make potentially life-saving care (that is available to some patients) unavailable to the beneficiaries of federal health care programs. More broadly, given the myriad of federal health care programs and the complex nature of the American health insurance system, some providers might be wary of prescribing drugs for off-label use to any of their patients, regardless of insurance coverage, simply out of fear of running afoul of the law. This Court should not endorse a district court ruling that could bring about this cascade of unintended and undesirable consequences.

B. The judgment below, if allowed to stand, would raise significant Constitutional concerns.

Finally, the Court should vacate the judgment because of the significant Constitutional concerns that are raised by imposing FCA liability on the mere fact of a manufacturer's off-label promotion. Because the jury was instructed that it could find Defendant liable under the FCA if the jury concluded that Defendant was promoting its drugs for off-label uses, affirming this verdict raises serious First Amendment concerns.

It is well-established that truthful and non-misleading commercial speech is protected by the First Amendment. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-64 (1980). The value of information, and the protection of speech, is especially important "in the fields of medicine and public

health, where information can save lives"—a reality that has led the Supreme Court to reaffirm the First Amendment protection for such speech. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011). That is especially so with respect to speech about off-label uses of drugs by physicians, which is entirely lawful. *See Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 193-94 (1999) (holding that attempts to prohibit or chill truthful speech about lawful conduct is subject to strict scrutiny). Any legal action taken by, or on behalf of, the Government to restrict truthful commercial speech promoting a drug must therefore be carefully scrutinized to avoid running afoul of the First Amendment. Accordingly, in determining when to impose liability for off-label drug promotion, the Court should construe the various statutes and regulations at issue in a way that avoids these Constitutional difficulties. *See Skilling v. United States*, 561 U.S. 358, 406 (2010).

The Second Circuit squarely addressed the First Amendment issues posed by restrictions on pharmaceutical promotion in *Caronia*. 703 F.3d at 160. There, a sales consultant for a pharmaceutical company was found guilty of conspiring to introduce a misbranded drug into interstate commerce based on his promotion of an FDA-approved drug for unapproved uses. *Id.* at 157-59. On appeal, the consultant argued that the FDCA's prohibitions on off-label promotion unconstitutionally restricted speech. *Id.* at 160. Applying heightened scrutiny to this content-based speech, the Second Circuit "decline[d] the government's invitation to construe the

FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers . . . because such a construction . . . would run afoul of the First Amendment." *Id.* at 162; *see also id.* at 164-65. The district court's judgment here would chill First Amendment protected speech in precisely the same way the criminal conviction in *Caronia* did, albeit using the FCA, rather than the FDCA. For the same reasons the Second Circuit saw the need to construe the FDCA in a way that would not directly regulate manufacturers' speech, this Court similarly should construe the FCA in way that avoids restricting protected speech, albeit indirectly.

Because allowing this jury verdict to stand would raise significant First Amendment concerns, it must be vacated. *See Skilling*, 561 U.S. at 406; *see also Caronia*, 703 F.3d at 160. Here, the jury was permitted to impose liability on Defendant merely for arguably making statements promoting uses for its HIV drugs that were inconsistent with the FDA-approved labels for those drugs. Such statements do not, on their own, necessarily render all subsequent claims for reimbursement for those drugs false under the FCA. To the extent liability was imposed on Defendant *simply* because of its protected commercial speech, and not because it caused claims to be submitted that actually violated the Government's reimbursement requirements, such liability would jeopardize Defendant's First

Amendment rights. To avoid such an outcome, the jury's verdict cannot be permitted to stand.

CONCLUSION

Because the jury instructions contained significant legal errors that, if allowed to stand, would have significant and deleterious effects on patient care, *amici* respectfully urge this Court to vacate the judgment below and remand for further proceedings.

Respectfully submitted,

/s/ Douglas Hallward-Driemeier

Douglas Hallward-Driemeier
Kellie Combs
Diana K. Cieslak
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

Attorneys for Amici Curiae the Pharmaceutical Research and Manufacturers of America, and the Advanced Medical Technology Association

James C. Stansel
Julie Ritchie Wagner
Melissa B. Kimmel
Kelly Goldberg
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, DC 20004

Counsel for Amicus Curiae the Pharmaceutical Research and Manufacturers of America

Pat Fogarty
ADVANCED MEDICAL TECHNOLOGY ASSOCIATION
1301 Pennsylvania Avenue, NW
Suite 400
Washington, DC 20004

Counsel for Amicus Curiae the Advanced Medical Technology Association

July 21, 2025

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 6,436 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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: July 21, 2025

/s/ Douglas Hallward-Driemeier
DOUGLAS HALLWARD DRIEMEIER

ADDENDUM

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21 C.F.R. § 312.2 - Applicability

* * * * *

(d) Unlabeled indication. This part does not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 314 or of a licensed biological product.

21 U.S.C § 337 – Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

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

* * * * *

(b) Mission

The [Food and Drug] Administration shall—

* * * * *

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

* * * * *

(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;

21 U.S.C § 396 – Practice of medicine

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

31 U.S.C. § 3729 – False claims

(a) Liability for certain acts.--

(1) In general.–Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [28 U.S.C. 2461 note; Public Law 104-410], plus 3 times the amount of damages which the Government sustains because of the act of that person.

42 U.S.C. § 1395 – Prohibition against any Federal interference

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

42 U.S.C. § 1395w-102 – Prescription drug benefits

* * * * *

(e) Covered part D drug defined

(1) In general

Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title;

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary); or

(C) for the period beginning on December 29, 2022, and ending on September 30, 2025, an oral antiviral drug that may be dispensed only upon a prescription and is authorized under section 360bbb-3 of Title 21, on the basis of the declaration published in the Federal Register by the Secretary of Health and Human Services on April 1, 2020 [85 Fed. Reg. 18250 et seq.], and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

* * * * *

(3) Application of general exclusion provisions

A prescription drug plan or an MA-PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1395y(a) of this title applied to this part;

* * * * *

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

(I) "prescription drug plan or MA-PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r-8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r-8(k)(6) of this title.

(B) Conflict of interest

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1396r-8(g)(1)(B)(i)(III) of this title meets the requirement in the third sentence of section 1395x(t)(2)(B) of this title.

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1396r-8(g)(1)(B)(i) of this title as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1395x(t)(2)(B) of this title.

42 U.S.C. § 1395x – Definitions

* * * * *

(t) Drugs and biologicals

* * * * *

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has [4] a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

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.C. § 1396r-8 - Payment for covered outpatient drugs

* * * * *

(d) Limitations on coverage of drugs

(1) Permissible restrictions

* * * * *

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6))

* * * * *

(g) Drug use review

(1) In general

* * * * *

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System;

* * * * *

(k) Definitions

In this section—

* * * * *

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

* * * * *

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

Cal. Code Regs. tit. 22, § 51313

* * * * *

(c) Drugs not on the Medi-Cal List of Contract Drugs and not excluded in Section 51313.3 are covered subject to prior authorization in accordance with Section 51003.

* * * * *

(4) Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:

(A) Reference to current medical literature.

(B) Consultation with provider organizations, academic and professional specialists.

Mich. Comp. Laws § 400.109h - Prior authorization process for prescription drugs under medical assistance program; limitations; applicability

(1) If the department develops a prior authorization process for prescription drugs as part of the pharmaceutical services offered under the medical assistance program administered under this act, the department shall not require prior authorization for the following single source brand name, generic equivalent of a multiple source brand name, or other prescription drugs:

* * * * *

(d) A prescription drug that is recognized in a generally accepted standard medical reference to prevent acquisition of or to treat human immunodeficiency virus infection or complication of the human immunodeficiency virus or acquired immunodeficiency syndrome.