

FILED
RECORDS
AND
BRIEFS

No. 05-578

IN THE
Supreme Court of the United States

LOUIS F. GILLIGAN AND GREGORY M. UTTER,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Sixth Circuit**

**OPPOSITION TO PETITION FOR WRIT OF
CERTIORARI**

THOMAS M. PARKER
PARKER, LEIBY, HANNA &
RASNICK, LLC
388 South Main Street
Suite 402
Akron, OH 44311
(330) 253-2227

PATRICK F. MCCARTAN
(*Counsel of Record*)
STEPHEN G. SOZIO
JONES DAY
901 Lakeside Avenue
Cleveland, OH 44114-1190
(216) 586-3939

JESSE A. WITTEN
JULIA C. AMBROSE
JONES DAY
51 Louisiana Avenue, NW
Washington, D.C. 20001
(202) 879-3939

Counsel for Respondent

U.S. SUPREME COURT

CORPORATE DISCLOSURE STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly-held company owns 10 percent or more of Respondent's stock.

TABLE OF CONTENTS

	Page
CORPORATE DISCLOSURE STATEMENT	i
TABLE OF AUTHORITIES	iii
STATEMENT OF THE CASE.....	1
REASONS FOR DENYING THE WRIT	5
I. THE INTERPRETATION OF THE PHRASE “BASED UPON” IS AN INCONSEQUEN- TIAL ISSUE THAT DOES NOT WAR- RANT THIS COURT’S ATTENTION	6
A. The Issue Is Relevant To Only a Narrow Category of <i>Qui Tam</i> Cases, and This Court Has Declined to Consider the Issue at Least Six Times.....	6
B. The Sixth Circuit, Like the Clear Majority of Circuits, Correctly Interpreted the Statutory Language	8
II. THE SUPPOSED “CONFUSION” AMONG THE CIRCUITS REGARDING THE PHRASE “ALLEGATIONS OR TRANS- ACTIONS,” IF THERE IS “CONFUSION” AT ALL, IS NOT AN ISSUE WORTHY OF THIS COURT’S ATTENTION.....	10
III. THIS CASE IS A POOR VEHICLE TO CONSIDER THE PETITIONERS’ QUESTIONS BECAUSE IT RAISES AN ISSUE OF FIRST IMPRESSION THAT CALLS INTO QUESTION THIS COURT’S JURISDICTION	13
CONCLUSION.....	17

TABLE OF AUTHORITIES

	Page
Cases	
<i>Browder v. Director, Department of Corrections</i> , 434 U.S. 257 (1978)	16
<i>Connecticut National Bank v. Germain</i> , 503 U.S. 249 (1992)	10
<i>Cooper v. Blue Cross & Blue Shield of Florida, Inc.</i> , 19 F.3d 562 (11th Cir. 1994)	6, 8
<i>Federal Recovery Services, Inc. v. United States</i> , 72 F.3d 447 (5th Cir. 1995)	3, 6, 8
<i>Hibbs v. Winn</i> , 542 U.S. 88 (2004)	10, 16
<i>Kemp v. Medtronic, Inc.</i> , 231 F.3d 216 (6th Cir. 2000)	2, 3, 4
<i>Minnesota Association of Nurse Anesthetists v.</i> <i>Allina Health System Corp.</i> , 276 F.3d 1032 (8th Cir. 2002)	6, 8
<i>Missouri v. Jenkins</i> , 495 U.S. 33 (1990)	15
<i>United States ex rel. Biddle v. Board of Trustees</i> <i>of Stanford University</i> , 161 F.3d 533 (9th Cir. 1998)	6, 8
<i>United States ex rel. Doe v. John Doe Corp.</i> , 960 F.2d 318 (2d Cir. 1992)	6, 8
<i>United States ex rel. Findley v. FPC-Boron</i> <i>Employees' Club</i> , 105 F.3d 675 (D.C. Cir. 1997)	passim

TABLE OF AUTHORITIES
(continued)

	Page
<i>United States ex rel. Fine v. Advanced Sciences, Inc.</i> , 99 F.3d 1000 (10th Cir. 1996)	6, 8
<i>United States ex rel. Foundation Aiding Elderly</i> <i>v. Horizon West</i> , 265 F.3d 1011 (9th Cir. 2001)	11
<i>United States ex rel. Haycock v. Hughes Aircraft Co.</i> , 98 F.3d 1100 (9th Cir. 1996)	15
<i>United States ex rel. Jones v. Horizon Healthcare Corp.</i> , 160 F.3d 326 (6th Cir. 1998)	6, 11
<i>United States ex rel. Lu v. Ou</i> , 368 F.3d 773 (7th Cir. 2004)	14
<i>United States ex rel. McAllan v. City of New York</i> , 248 F.3d 48 (2d Cir. 2001)	14
<i>United States ex rel. McKenzie v. BellSouth</i> <i>Telecommunications, Inc.</i> , 123 F.3d 935 (6th Cir. 1997)	9
<i>United States ex rel. Merena v. SmithKline</i> <i>Beecham Corp.</i> , 205 F.3d 97 (3d Cir. 2000)	7
<i>United States ex rel. Mistick PBT v. Housing</i> <i>Authority of City of Pittsburgh</i> , 186 F.3d 376 (3d Cir. 1999)	6, 8
<i>United States ex rel. Petrofsky v. Van Cott, Bagley,</i> <i>Cornwall, McCarthy</i> , 588 F.2d 1327 (10th Cir. 1978)	14

TABLE OF AUTHORITIES
(continued)

	Page
<i>United States ex rel. Reagan v. East Texas Medical Center Regional Healthcare System</i> , 384 F.3d 168 (5th Cir. 2004)	7
<i>United States ex rel. Russell v. Epic Healthcare Management Group</i> , 193 F.3d 304 (5th Cir. 1999)	14
<i>United States ex rel. Siller v. Becton Dickinson & Co.</i> , 21 F.3d 1339 (4th Cir. 1994)	6, 9
<i>United States ex rel. Springfield Terminal Railway v. Quinn</i> , 14 F.3d 645 (D.C. Cir. 1994)	11
<i>United States ex rel. Stinson, Lyons, Gerlin & Bustamonte, P.A. v. Prudential Insurance Co.</i> , 944 F.2d 1149 (3d Cir. 1991)	3
<i>United States v. Bank of Farmington</i> , 166 F.3d 853 (7th Cir. 1999)	6, 9
<i>United States v. Swan</i> , 230 F.3d 1040 (7th Cir. 2000)	15
<i>Vermont Agency of Natural Resources v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000)	15
<i>Young v. Harper</i> , 520 U.S. 143 (1997)	16
 Federal Statutes, Regulations & Rules	
21 U.S.C. § 360e	4
28 U.S.C. § 2101	13
31 U.S.C. § 3730	<i>passim</i>

TABLE OF AUTHORITIES
(continued)

	Page
21 C.F.R. § 814.46	4
Fed. R. App. P. 4(a)	14
Fed. R. App. P. 35(c)	13
Fed. R. App. P. 40(a)	13, 14, 15, 16
Miscellaneous	
Robert L. Stern, <i>et al.</i> , <i>Supreme Court Practice</i> (8th ed. 2002).....	16
Sup. Ct. Rule 13	13, 15, 16
Sup. Ct. Rule 13.3	13, 15, 16

STATEMENT OF THE CASE

The False Claims Act. Petitioners Louis F. Gilligan and Gregory M. Utter brought this action under the *qui tam* provisions of the False Claims Act (“FCA”). The *qui tam* provisions permit private parties, known as “relators,” to file suit under seal for themselves and for the United States alleging fraud against the federal government. *See* 31 U.S.C. § 3730(b). While the case is under seal, the United States is required to investigate the relator’s allegations and decide whether to intervene and take over the litigation. *See id.* § 3730(b) & (c)(1)-(2). If the Government intervenes and takes over the litigation, the relator is entitled to receive up to 25 percent of whatever the Government recovers. *See id.* § 3730(d)(1). If the Government does not intervene, the relator can prosecute the action and receive up to 30 percent of any eventual recovery. *See id.* § 3730(d)(2).

The FCA, however, contains a number of exceptions to federal court jurisdiction over *qui tam* actions. *See id.* § 3730(e). One of those exceptions, the “public disclosure bar,” is relevant here. It provides:

No court shall have jurisdiction over an action . . . based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Id. § 3730(e)(4)(A) (footnote omitted).

Petitioners’ *Qui Tam* Claims. Respondent Medtronic, Inc. manufactures medical devices. It formerly manufactured Models 4004 and 4004M pacemaker leads (“4004/M leads”).

Petitioners allege that prior models of pacemaker leads suffered failures due to metal ion oxidation (“MIO”), and

that Medtronic tried to combat MIO problems by applying a “platinum sputter” coating to conductor coils within the 4004/M leads. Their Complaint alleges that Medtronic defrauded the FDA by representing that the Model 4004 and 4004M leads would be entirely coated with 500 angstroms of platinum sputter, but after gaining FDA approval, changed the engineering specifications to permit leads to be manufactured with platinum sputter coatings of between 100 and 1,000 angstroms and 85 percent coverage. According to Petitioners, as a result of this change, Medtronic marketed pacemaker leads that were different from what the FDA had approved.

Petitioners then contend that, by selling supposedly non-FDA-approved leads, Medtronic caused physicians and hospitals to unwittingly submit false claims to Medicare, because Medicare only covers implantation of FDA-approved devices. Medtronic did not submit any claims to Medicare, and Medicare did not pay Medtronic any money. Rather, it was the physicians and hospitals who used leads manufactured by Medtronic that submitted claims to Medicare, and Medicare paid them.

The Government investigated Petitioners’ allegations, but declined to intervene. Petitioners have since prosecuted this action on their own.

This is not the first time that Petitioners have raised these claims. In fact, the Sixth Circuit previously rejected their claims as unfounded. In *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), decided while this *qui tam* action was under seal, Petitioners served as lawyers for plaintiffs in a products liability action. In that case, Petitioners made the same allegations as they made in their *qui tam* complaint concerning Medtronic’s supposed marketing of non-FDA-approved leads. Affirming summary judgment for Medtronic in *Kemp*, the Sixth Circuit sharply rejected Petitioners’ claims:

Our review of the record leaves us firmly convinced that plaintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick *represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record.* Both in their briefs and in oral argument, plaintiffs repeatedly asserted that the Model 4004M specifications, as originally designed, call for a platinum sputter barrier a "uniform 500 angstroms thick." *Plaintiffs' statements find no support in the record. Indeed, we think that the record flatly contradicts plaintiffs' position.*

231 F.3d at 230 (emphasis added). In a word, in *Kemp*, the Sixth Circuit found Petitioners' accusations against Medtronic to be "specious." *Id.* at 231.

Accordingly, the Sixth Circuit has already concluded that a lead manufactured with between 100 and 1,000 angstroms of platinum sputter and 85 percent coverage satisfied the terms of FDA approval. *See Kemp*, 231 F.3d at 230-32. Petitioners' current assertion that "the leads Medtronic sold were different from the ones that had been approved by the FDA" (Pet. 5) is the very claim rejected in *Kemp*.¹

Moreover, contrary to Petitioners' assertion, there is no record evidence that Medtronic ever changed the quality or

¹ In addition, by bringing this *qui tam* action, Petitioners appear to have usurped an opportunity that belonged to the *Kemp* plaintiffs, and placed themselves in competition with their own clients to recover against Medtronic over the same allegations. *See* Pet. 5 (admitting that Petitioners learned of Medtronic's supposed wrongdoing while "conducting discovery in a different lawsuit"). The Third Circuit has pointed out the conflict-of-interest problems that arise from "a lawyer arrogating to himself or herself a *qui tam* action based on information learned in the service of a client." *United States ex rel. Stinson, Lyons, Gerlin & Bustamonte, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1161 n.10 (3d Cir. 1991); *see also Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995) (objecting to attorneys usurping from their client the decision whether to file a *qui tam* action).

quantity of the platinum sputter applied to the conductor coils in the 4004/M leads. Medtronic made a documentation change to the specifications to reflect the development of more sensitive measuring technology. If the method of making the product never changed (as counsel for Petitioners conceded at oral argument before the district court, *see* 6th Cir. J.A. 1398-99), then Petitioners' contention that FDA approval for the devices was automatically revoked is factually wrong. (Pet. 4-5). Moreover, as a legal matter, Petitioners' theory that FDA approval was automatically revoked ignores that revocation of FDA approval requires notice and a hearing, followed by formal agency action, none of which occurred here. *See* 21 U.S.C. § 360e(e)(1); 21 C.F.R. § 814.46.

The decision below. In this case, the Sixth Circuit did not reach the merits, as it had in *Kemp*. Rather, it held that the district court lacked jurisdiction due to the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A). The Court found that the allegations in Petitioners' *qui tam* complaint were based upon allegations made against Medtronic in prior products liability litigation. App. 9a.

The Sixth Circuit noted that Medtronic presented filings from a number of products liability lawsuits and FDA administrative reports, but concluded that it needed to consider only one of the products liability actions, *North v. Medtronic*, No. 97-2-16954-2SEA (Wash. Sup. Ct. 1997), to determine that the public disclosure bar was triggered. App. 9a.

North was a products liability action in which the plaintiff alleged that Medtronic "represented to the FDA that it had cured the causes of the past unacceptably high failure rates of the prior leads because it used a platinum sputter coating and stress-relieved insulation for the . . . lead." 6th Cir. J.A. 954. The *North* complaint further alleged, *inter alia*, that (1) Medtronic failed to "rework[]" to add appropriate protection" to the leads after performance failures were

observed; (2) there was “fraud surrounding the manufacture” of the pacemaker leads; and (3) the leads “deviated” from design specifications (6th Cir. J.A. 956, 959, 961).

The Sixth Circuit explained that “several prior products liability cases, including *North*[,]” triggered the public disclosure bar, although it mentioned only *North* by name. App. 9a.²

Petitioners’ statement that the prior products liability suits were “wholly different from Petitioners’ federal FCA suit” is inaccurate. (Pet. 7). The Sixth Circuit reviewed the pleadings from *North* and other cases and reached a different conclusion from the Petitioners. App. 10a.

REASONS FOR DENYING THE WRIT

Petitioners now seek this Court’s review, claiming (1) that the lower court’s interpretation of the statutory phrase “based upon” conflicts with the holdings of a minority of circuits to have addressed the issue, and (2) that its interpretation of the phrase “allegations or transactions” has added to “confusion” in the circuits. (Pet. 9-16). The Petition correctly points out the existence of a circuit split concerning the meaning of “based upon,” but overlooks the very narrow category of cases in which the interpretation of that phrase would make any practical difference, overstates the existence of any lower court “confusion” regarding the term “allegations or transactions,” and ignores the difficult jurisdictional issue that makes this case an inappropriate vehicle to address the questions posed by the Petition.

² Medtronic also introduced pleadings from, among other prior product liability cases, *Haley v. Medtronic, Inc.*, No. 94-4113 (C.D. Cal. 1994); *Daniel v. Medtronic, Inc.*, No. 97-1191 (M.D. Tenn. 1997), and *Redente v. Medtronic, Inc.*, No. 97-649-CIV-T-26C (M.D. Fla. 1997), which made similar allegations that Medtronic used platinum sputtering to cure past lead failures and/or manufactured defective leads or leads that did not conform to FDA specifications.

For the reasons discussed more fully below, this Court's review is unwarranted.

I. THE INTERPRETATION OF THE PHRASE "BASED UPON" IS AN INCONSEQUENTIAL ISSUE THAT DOES NOT WARRANT THIS COURT'S ATTENTION

A. The Issue Is Relevant To Only a Narrow Category of *Qui Tam* Cases, and This Court Has Declined to Consider the Issue at Least Six Times.

Petitioners' suggestion that the proper interpretation of the term statutory term "based upon" merits this Court's attention vastly overstates its importance. Although two circuits have adopted a minority position on this issue (Pet. 9-11), the circuit split is of little practical consequence in the vast majority of *qui tam* complaints brought under the FCA.³ In fact, the issue is relevant only if: (1) the Government does not intervene; and (2) the relator is not an "original source"

³ The decision below did not deepen or extend the existing split of authority. At least nine circuit courts—the Sixth Circuit among them—had already interpreted the phrase "based upon" broadly to require only that the allegations in a *qui tam* complaint be similar to or supported by a prior public disclosure. See, e.g., *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992); *United States ex rel. Mistick PBT v. Housing Auth. of City of Pittsburgh*, 186 F.3d 376, 394-402 (3d Cir. 1999); *Fed. Recovery Servs.*, 72 F.3d at 451; *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 332 (6th Cir. 1998); *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1044-47 (8th Cir. 2002); *United States ex rel. Biddle v. Bd. of Trs. of Stanford Univ.*, 161 F.3d 533, 538 (9th Cir. 1998); *United States ex rel. Fine v. Advanced Sciences, Inc.*, 99 F.3d 1000, 1006 (10th Cir. 1996); *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 567 (11th Cir. 1994); *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997). Only two circuits have required that a *qui tam* complaint be "derived from" a prior public disclosure to trigger the jurisdictional bar. See, e.g., *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1347-49 (4th Cir. 1994); *United States v. Bank of Farmington*, 166 F.3d 853, 863 (7th Cir. 1999).

of the information underlying the suit. If the Government elects to intervene and take over the litigation, the public disclosure bar does not divest the court of jurisdiction. *See, e.g., United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 103 (3d Cir. 2000). Furthermore, if the relator is an “original source,” the public disclosure bar does not apply. *See, e.g., United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg’l Healthcare Sys.*, 384 F.3d 168, 175 (5th Cir. 2004). In short, Petitioners’ claim that the decision below “threatens the continued viability of” the FCA is greatly exaggerated. (Pet. 8).

This Court repeatedly has recognized the unimportance of the issue. It has declined at least six opportunities to consider the issue. *See, e.g.,* Petition for Writ of Certiorari, *United States ex rel. King v. Hillcrest Health Ctr., Inc.*, No. 01-956, at 6-11 (U.S. Dec. 28, 2001), *cert. denied*, 535 U.S. 905 (2002); Petition for Writ of Certiorari, *United States ex rel. Mistick PBT v. Housing Auth. of City of Pittsburgh*, No. 99-969, at 16-23 (U.S. Dec. 8, 1999), *cert. denied*, 529 U.S. 1019 (2000); Petition for Writ of Certiorari, *United States ex rel. Biddle v. Bd of Trs. for Stanford Univ.*, No. 98-1268, at 9-17 (U.S. Jan. 28, 1999), *cert. denied*, 526 U.S. 1066 (1999); Petition for Writ of Certiorari, *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, No. 97-850, at 11-16 (U.S. Nov. 21, 1997), *cert. denied*, 522 U.S. 1077 (1998); Petition for Writ of Certiorari, *United States ex rel. Findley v. FPC-Boron Employees’ Club*, No. 97-157, at 6-10 (U.S. June 16, 1997), *cert. denied*, 522 U.S. 865 (1997); Petition for Writ of Certiorari, *United States ex rel. Siller v. Becton Dickinson & Co.*, No. 94-106, at 12-15 (U.S. July 15, 1994), *cert. denied*, 513 U.S. 928 (1994).

Petitioners nevertheless claim that the issue now urgently demands this Court’s attention, insisting that, absent this Court’s review, the holding below “will . . . discourage private citizens with knowledge of . . . fraud [against the Government] from blowing the whistle.” (Pet. 25) That argument misapprehends the operation of the public

disclosure bar, regardless of the interpretation of the “based upon” language. No private citizen with *direct and independent* knowledge of fraud will be “discouraged” from bringing a *qui tam* lawsuit by a broad interpretation of the “based upon” language, because such an individual can satisfy the “original source” *exception* to the bar in any event. See 31 U.S.C. § 3730(e)(4)(B) (defining original source as “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information”).

Importantly, the public disclosure bar in no way affects the Government’s right to pursue claims under the False Claims Act. It applies only in cases in which the Government *declines* to intervene. Nor does the issue presented by the Petition have any bearing on the substantive obligations of government contractors. The proper interpretation of “based upon” affects only the ability of relators who are *not* “original sources” to bring *qui tam* actions where there has been a prior public disclosure.

In short, this case does not warrant this Court’s attention.

B. The Sixth Circuit, Like the Clear Majority of Circuits, Correctly Interpreted the Statutory Language.

The Sixth Circuit’s application of longstanding circuit precedent interpreting the statutory term “based upon” agrees with the clear majority of circuits to have considered the issue. Eight other circuits agree with the Sixth Circuit. *John Doe Corp.*, 960 F.2d at 324 (2d Cir.); *Mistick PBT*, 186 F.3d at 394-402 (3d Cir.); *Fed. Recovery Servs.*, 72 F.3d at 451 (5th Cir.); *Minn. Ass’n of Nurse Anesthetists*, 276 F.3d at 1044-47 (8th Cir.); *Biddle*, 161 F.3d at 538 (9th Cir.); *Fine*, 99 F.3d at 1006 (10th Cir.); *Cooper*, 19 F.3d at 567 (11th Cir.); *Findley*, 105 F.3d at 688 (D.C. Cir.). The Sixth Circuit’s interpretation of “based upon,” in keeping with the

majority view, is faithful to both the statutory language and to the purpose of the public disclosure bar.

The public disclosure bar reflects Congress's judgment that there is no need to induce private citizens to "blow the whistle" where information regarding fraud has already been publicly disclosed. *See, e.g., United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 943 (6th Cir. 1997); *Findley*, 105 F.3d at 690. The purposes underlying the public disclosure bar are appropriately served by a rule that interprets the term "based upon" to encompass prior disclosures that are substantially similar to the allegations in a subsequent *qui tam* action; in those cases, the Government is adequately placed on notice of the possible existence of fraud by the public disclosure, and a later *qui tam* suit raising "similar" allegations is simply unnecessary.

In this case, the Sixth Circuit correctly discerned that a prior public disclosure sufficient to put the Government on notice of the "possibility of fraud" triggered the public disclosure bar. (App. 10a). This case represents nothing more than a fact-dependent application of the settled majority interpretation of the statutory language. The outcome was perfectly in keeping with the intent of the public disclosure bar.

The minority rule followed by two circuits, in contrast, would render superfluous the "original source" exception to the public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A) & (B). According to the minority rule, a *qui tam* lawsuit is barred by the public disclosure bar only when the allegations made in that suit are directly "derived from" a prior public disclosure—meaning that the relator obtained the precise information on which his suit is based directly from the earlier disclosure. *See Bank of Farmington*, 166 F.3d at 863; *Siller*, 21 F.3d at 1348. In such a case, the relator *could never* be an original source with "direct and independent knowledge" (31 U.S.C. § 3730(e)(4)(B)) because, by

hypothesis, his lawsuit used information derived from some previously publicly disclosed source.

The minority rule, which interprets “based upon” to mean “derived from,” would render meaningless the “original source” exception, which requires relators to have “direct and independent knowledge.” 31 U.S.C. § 3730(e)(4)(B). *See Findley*, 105 F.3d at 683. Petitioners’ proposed interpretation of “based upon” thus contradicts the rule of statutory interpretation that a statute should be read so that none of its provisions are rendered meaningless. *See, e.g., Hibbs v. Winn*, 542 U.S. 88, 101 (2004); *Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 253 (1992).

Because the Sixth Circuit, like the clear majority of circuits, has correctly interpreted the phrase “based upon” in keeping with the purposes of the public disclosure bar, this Court’s review is unnecessary.

II. THE SUPPOSED “CONFUSION” AMONG THE CIRCUITS REGARDING THE PHRASE “ALLEGATIONS OR TRANSACTIONS,” IF THERE IS “CONFUSION” AT ALL, IS NOT AN ISSUE WORTHY OF THIS COURT’S ATTENTION

Petitioners also urge the Court to consider the interpretation of the “allegations or transactions” language in the public disclosure bar, contending that the circuit courts have not uniformly interpreted the language to require a particular quantum or nature of prior disclosure in order to trigger the jurisdictional bar. Petitioners vastly overstate the supposed “confusion.” Rather, the existing case law merely reflects the highly fact-specific inquiry required to determine whether allegations in a *qui tam* action are substantially similar to information and allegations contained in prior public disclosures.

As Petitioners implicitly acknowledge by their careful use of the term “confusion,” there is no true circuit split in the lower courts regarding the kind or amount of prior public disclosure necessary to trigger the bar. Petitioners merely

point out that appellate courts, including the Sixth Circuit⁴, sometimes have described the quantum of prior disclosure needed to trigger the bar by analogy to a mathematical formula, *see, e.g., Springfield Terminal Ry.*, 14 F.3d 645, and sometimes have described the kinds and amounts of information that constitute a prior public disclosure without using that analogy. *See, e.g., United States ex rel. Found. Aiding Elderly v. Horizon W.*, 265 F.3d 1011 (9th Cir. 2001). But Petitioners fail to recognize that the “prior public disclosure” inquiry is, by its very nature, highly fact-dependent. Whether allegations in a *qui tam* complaint are similar enough to publicly disclosed allegations to trigger the jurisdictional bar depends on a multitude of case-specific factors. There is no circuit “confusion,” but only a number of cases each decided on its own particular facts.

Hoping to sow “confusion” where none exists, Petitioners unfairly characterize the Sixth Circuit’s opinion, suggesting that the Sixth Circuit found “*general* allegations of fraud . . . previously asserted against Medtronic” (Pet. 17 (emphasis in original)) sufficient to trigger the jurisdictional bar. This conclusion, Petitioners suggest, is “at odds” with the decisions of other circuits, which have supposedly required something more. *See* Pet. 19 (citing, *inter alia*, *United States ex rel. Found. Aiding Elderly v. Horizon W.*, 265 F.3d 1011 (9th Cir. 2001)). In fact, the Sixth Circuit found that *specific* prior public disclosures contained information about the same alleged fraudulent acts

⁴ To the extent that the Petition suggests that the Sixth Circuit applied a “rule” for measuring the kind or amount of prior disclosure sufficient to trigger the jurisdictional bar that conflicts with the “rules” applied in other circuits, Petitioners do not fully describe the opinion below. In fact, the Sixth Circuit applied the same mathematical formulation Petitioners urge (Pet. 16-17), as originally developed by the D.C. Circuit in *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994). *See* App. 19a (citing the Sixth Circuit’s decision in *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 331 (6th Cir. 1998)).

Petitioners alleged in their *qui tam* complaint. In particular, the Sixth Circuit found that prior disclosures contained information about both the true state of facts and the false state of facts as supposedly represented by Medtronic, as well as specific disclosures of the alleged fraud itself. *See* App. 9a.

As noted, the Sixth Circuit relied on the complaint in a prior products liability action, *North v. Medtronic, Inc.*, No. 97-2-16954-2SEA (Wash. Super. Ct. July 7, 1997) (6th Cir. J.A. 946-984) to find a prior public disclosure. Petitioners contend that the *North* complaint discloses different allegations from those in Petitioners' *qui tam* complaint, not allegations that “specifically identify the nature of the fraud.” Pet. 19 (quoting *Findley*, 105 F.3d at 687). Petitioners overlook the fact that the *North* complaint was only one of a number of prior public disclosures that Medtronic cited; in fact, Medtronic presented documents from 17 prior civil actions and three administrative reports, all of which disclosed the allegations of fraud on the FDA at the heart of Petitioners' *qui tam* complaint. *See* App. 9a. The Sixth Circuit noted the existence of numerous public disclosures but found the bar triggered by the first of them, the *North* complaint, without the need to rely on the others. *Id.*

What Petitioners complain about is not that the courts have adopted conflicting standards to determine what constitutes a prior public disclosure, but that the *application* of the standard to widely varying facts has led to differing outcomes—and, in particular, to the dismissal of their complaint. *See* Pet. 22. The Petition asks this Court not to determine the proper *rule* for measuring whether a prior disclosure satisfies the public disclosure bar, but to correct what they believe is an improper *application* of the public disclosure bar to the facts of this case. Because there is no “conflict” and no “confusion,” and because of its fact-bound nature, this issue does not warrant the Court's attention.

III. THIS CASE IS A POOR VEHICLE TO CONSIDER THE PETITIONERS' QUESTIONS BECAUSE IT RAISES AN ISSUE OF FIRST IMPRESSION THAT CALLS INTO QUESTION THIS COURT'S JURISDICTION

Even if the Court were inclined to review the questions raised in the Petition, this case does not present an appropriate vehicle for doing so. The case comes burdened with an unresolved jurisdictional question that would require this Court to decide a close question of first impression (and one not presented in this Petition): whether a *qui tam* relator in a suit in which the Government has declined to intervene is bound by the 14-day time limit for private parties to file petitions for rehearing or the 45-day time limit applicable to the Government. *See* Fed. R. App. P. 40(a).

There is substantial reason to question whether this Court has jurisdiction to entertain the Petition if Petitioners' petition for rehearing was in fact untimely under Fed. R. App. 40. Supreme Court Rule 13 requires that a petition for a writ of certiorari be filed within 90 days of the judgment of the court of appeals. Under Supreme Court Rule 13.3, the 90-day time limit runs from the date the court of appeals denies a rehearing petition but only "if a petition for rehearing *is timely filed* in the lower court." (Emphasis added.) Therefore, if Petitioners' petition for rehearing before the Sixth Circuit was not timely filed—a difficult question that the courts of appeals have yet to address—Rule 13 and 28 U.S.C. § 2101(c) provide that this Court lacks jurisdiction over the Petition. This Court's jurisdiction turns on whether Petitioners made a "timely" petition for rehearing before the Sixth Circuit.

Federal Rule of Appellate Procedure 40(a) establishes the time within which a petition for panel rehearing must be filed (and Fed. R. App. P. 35(c) incorporates the same deadlines as applicable to a petition for rehearing *en banc*). It creates a dual deadline: A petition for hearing must

ordinarily “be filed within 14 days after entry of judgment,” *except* “in a civil case, if the United States or its officer or agency is a party, the time within which any party may seek rehearing is 45 days after entry of judgment, unless an order shortens or extends the time.” Fed. R. App. P. 40(a)(1). The Rule does not expressly address the deadline for *qui tam* relators in cases in which the Government does not intervene.

Petitioners, as relators bringing an action under the FCA’s *qui tam* provisions, sought rehearing well after the expiration of the 14-day time period but within 45 days. Their petition was untimely, however, because the United States *declined to intervene* in Petitioners’ *qui tam* suit. The United States was therefore not a “party” to the action under Fed. R. App. P. 40(a).

Whether a relator in a case in which the Government declines to intervene has 14 or 45 days to file a petition for rehearing appears to be a question of first impression. This Court would be required to confront that question—without the benefit of any development of the issue in the lower courts—to ensure itself that Petitioners’ request for rehearing (and, it follows, their Petition) was timely.⁵

⁵ The difficulty of this issue is demonstrated by judicial disagreement over on the deadline applicable to the filing of a notice of appeal in a *qui tam* case in which the Government has not intervened. Like Rule 40, Federal Rule of Appellate Procedure 4 sets up a dual deadline that depends upon whether the United States is a “party.” The Rule requires that a notice of appeal be filed within 30 days after the entry of judgment, unless the United States or its officer or agency is a party, in which case the deadline is 60 days. See Fed. R. App. P. 4(a)(1)(A)-(B). Two circuits apply the 30-day deadline in *qui tam* cases in which the Government has not intervened. See *United States ex rel. Petrofsky v. Van Cott, Bagley, Cornwall, McCarthy*, 588 F.2d 1327, 1329 (10th Cir. 1978); *United States ex rel. McAllan v. City of New York*, 248 F.3d 48, 51 (2d Cir. 2001). By contrast, three circuits apply the 60-day deadline. *United States ex rel. Lu v. Ou*, 368 F.3d 773, 775 (7th Cir. 2004); *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304,

The better rule is that the shorter time period under Fed. R. App. 40(a) applies to relators. To begin with, as this Court explained in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 773-74 & n.4 (2000), a relator is an *assignee* of claims that belong to the United States. A relator does not “become” the United States in a *qui tam* suit. As an assignee of claims belonging to the United States, a relator is subject to the 14-day time limit under Rule 40(a), not the longer time limit reserved to the United States. Moreover, as a practical matter, the Government is given a longer period of time to file because many layers of approval within the Government are required at the appellate stage of litigation. By contrast, relators need only to confer with themselves. Under that logic, Petitioners were untimely in filing their petition for rehearing before the Sixth Circuit, presumably making this Petition for a writ of certiorari untimely as well.

If this Court concludes that Petitioners did not timely file the rehearing petition before the Sixth Circuit, then this Court would lack jurisdiction over the Petition, because a party must file a petition for a writ of certiorari within 90 days of the appellate court’s judgment (not mandate). See Sup. Ct. R. 13 & 13.3; *United States v. Swan*, 230 F.3d 1040 (7th Cir. 2000) (absent a timely and appropriate petition for rehearing, the 90-day time limit to file a petition for a writ of certiorari runs from entry of the judgment of the Court of Appeals). The 90-day time limit for seeking review in this Court is jurisdictional. “Title 28 U.S.C. § 2101(c) requires that a petition for certiorari in a civil case be filed within 90 days of the entry of the judgment below. This 90-day limit is mandatory and jurisdictional.” *Missouri v. Jenkins*, 495 U.S. 33, 45(1990).

308 (5th Cir. 1999); *United States ex rel. Haycock v. Hughes Aircraft Co.*, 98 F.3d 1100, 1102 (9th Cir. 1996).

As noted, a “timely” petition for rehearing before the Court of Appeals can extend the time for filing a petition for a writ of certiorari. *See* Sup. Ct. R. 13.3; *see also, e.g.*, Robert L. Stern, *et al.*, *Supreme Court Practice*, at 355 (8th ed. 2002) (“The consistent practice of the Court has been to treat petitions for rehearing *that are timely and properly presented to the federal or state court below* as tolling the start of the period in which a petition for certiorari must be sought”) (emphasis added). *Cf. Browder v. Director, Dep’t of Corrs.*, 434 U.S. 257, 267 (1978) (Supreme Court lacked jurisdiction because Petitioner had failed to make a timely petition for rehearing before the district court). Petitioners were not, however, timely in their request for rehearing in the Sixth Circuit. Moreover, Petitioners did not seek leave to file an untimely request for rehearing, nor did the Sixth Circuit grant them leave.⁶ Thus, Petitioners were required to file their Petition in this Court within 90 days of the Sixth Circuit’s April 6, 2005 judgment, which they failed to do. They did not file their Petition in this Court until October 31, 2005, which was 118 days late.

Even if the Court were inclined to address the questions the Petition poses, it should await a more appropriate vehicle for doing so—one not burdened with jurisdictional problems.

⁶ Medtronic did not have an opportunity to raise the untimeliness of Petitioners’ petition for rehearing before the Sixth Circuit, because the Sixth Circuit did not request a submission in response to the petition. *See* Fed. R. App. P. 40(a)(3) (“Unless the court requests, no answer to a petition for panel rehearing is permitted.”). The Sixth Circuit denied the petition for rehearing in a brief order that did not consider whether the request was timely. App. 1a-2a. This case is, therefore, unlike *Hibbs v. Winn*, 542 U.S. 88, 98 (2004), in which the Court of Appeals on its own motion asked the parties to brief whether the case should be reconsidered *en banc*, and also unlike *Young v. Harper*, 520 U.S. 143, 147 n.1 (1997), in which the Court of Appeals expressly granted leave to file the rehearing petition two days beyond the time allowed by Fed. R. App. 40(a).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

THOMAS M. PARKER
PARKER, LEIBY, HANNA &
RASNICK, LLC
388 South Main Street
Suite 402
Akron, OH 44311
(330) 253-2227

PATRICK F. MCCARTAN
(Counsel of Record)
STEPHEN G. SOZIO
JONES DAY
901 Lakeside Avenue
Cleveland, OH 44114-1190
(216) 586-3939

JESSE A. WITTEN
JULIA C. AMBROSE
JONES DAY
51 Louisiana Avenue, NW
Washington, D.C. 20001
(202) 879-3939
Counsel for Respondent

December 7, 2005