No. 12-1058

IN THE SUPREME COURT OF ARKANSAS

ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA, INC., and/or JANSSEN, LP, and JOHNSON & JOHNSON, INC.,

Appellants,

v.

STATE OF ARKANSAS, ATTORNEY GENERAL, *ex rel.* DUSTIN McDANIEL, ATTORNEY GENERAL,

Appellee.

On Appeal from the Circuit Court of Pulaski County, Arkansas
The Honorable Timothy D. Fox, Circuit Judge

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN, INC., IN SUPPORT OF APPELLEE

Scott L. Nelson
D.C. Bar. No. 413548
snelson@citizen.org
Allison M. Zieve 424786
D.C. Bar. No.
azieve@citizen.org
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
(202) 588-7795 (fax)

John L. Burnett
Ark. Bar No. 77021
jburnett@laveyandburnett.com
LAVEY & BURNETT
904 W. 2nd Street
Little Rock, AR, 72201
(501) 376-2269
(501) 372-1134 (fax)

Annabelle Imber Tuck
Ark. Bar No. 77032
annabelletuck@ymail.com
34 Marcella Drive
Little Rock, AR 72223
(501) 868-6372
(501) 868-6372 (fax)

Attorneys for Public Citizen, Inc.

June 18, 2013

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

SUMMARY OF ARGUMENT ..... Arg 1

ARGUMENT ..... Arg 2

I. The State's Statutory Claims Easily Pass Muster Under Ordinary Principles of Federal Preemption. ..... Arg 2

II. *Buckman* Does Not Require Preemption in This Case. ..... Arg 7

CONCLUSION ..... Arg 17

TABLE OF AUTHORITIES

Page(s)

Cases:

Altria Group, Inc. v. Good,
555 U.S. 70 (2008)..... Arg 3

Arizona v. United States,
132 S. Ct. 2492 (2012)..... Arg 16

Bates v. Dow Agrosciences LLC,
544 U.S. 431 (2005)..... Arg 5, 13, 14 16, 17

Bausch v. Stryker Corp.,
630 F.3d 546 (7th Cir. 2010) ..... Arg 10

Buckman Co. v. Plaintiffs' Legal Committee,
531 U.S. 341 (2001).....*passim*

Chamber of Commerce of U.S. v. Whiting,
131 S. Ct. 1968 (2011)..... Arg 12

Ciba-Geigy Corp. v. Alter,
309 Ark. 426, 834 S.W.2d 136 (1992) ..... Arg 3

Desiano v. Warner-Lambert & Co.,
467 F.3d 85 (2d Cir. 2007), *aff'd by an equally divided court*,
Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008) ..... Arg 10

Gade v. National Solid Wastes Management Assn.,
505 U.S. 88 (1992)..... Arg 14

Hughes v. Boston Scientific Corp.,
631 F.3d 762 (5th Cir. 2011) Arg10, 12, 13, 14

Medtronic, Inc. v. Lohr,
518 U.S. (1996)..... Arg 5, 6, 7, 9, 13, 14

In re Pharm. Indus. Average Wholesale Price Litig.,
582 F.3d 156 (1st Cir. 2009)..... Arg 3, 4, 7

Pharm. Research & Mfrs. of Am. v. Walsh,
538 U.S. 644 (2003)..... Arg 4

Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947)..... Arg 15

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008)..... Arg 6, 7, 13, 14

Stengel v. Medtronic Inc.,
704 F.3d 1224 (9th Cir. 2013) ..... Arg 10

Wisc. Dept. of Health & Family Servs. v. Blumer,
534 U.S. 473 (2002)..... Arg 4

Wyeth v. Levine,
555 U.S. 555 (2009).....*passim*

SUMMARY OF ARGUMENT

Defendants in cases nationwide asserting state-law product liability, consumer protection, and statutory claims—including both claims brought by private plaintiffs and, as in this case, by state government officials—have in recent years increasingly asserted defenses based on federal preemption. Sometimes those defenses rest on express preemption provisions of federal statutes or on outright conflict between federal and state law, but in many other cases they have a far more nebulous basis, resting on the assertion that state law is impliedly preempted because it stands as an obstacle to the fulfillment of the policies underlying some federal statute or statutory scheme. All too often, such arguments invite the sort of "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives" that "would undercut the principle that it is Congress rather than the courts that preempts state law." *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)).

The preemption arguments asserted here by appellants ("Janssen") reflect exactly this sort of misuse of the doctrine of implied conflict preemption. Based on a misreading of the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), Janssen's arguments would, if accepted, divest the State of Arkansas of its firmly established power to pursue important

objectives of the State—among them, advancing public health, preventing frauds against the State, and protecting the public fisc—by enforcing legal standards that, far from conflicting with federal law, mirror it. Nothing in *Buckman*, a narrow ruling that held only that a claim based solely on alleged fraud against the federal Food and Drug Administration (FDA) was preempted, justifies the sweeping result Janssen seeks. Unlike the type of claim held preempted in *Buckman*, the State's claims in this case under the Medicaid Fraud False Claims Act and the Deceptive Trade Practices Act advance traditional state interests that entitle them to a strong presumption against preemption, and their incorporation of federal-law standards presents no conflict with federal law that can overcome that presumption.

ARGUMENT

I. The State's Statutory Claims Easily Pass Muster Under Ordinary Principles of Federal Preemption.

Janssen's argument that Arkansas is prohibited from making a violation of a federal-law requirement a basis for recovery under its Medicaid antifraud law is directly contrary to ordinary principles of preemption, which prohibit state laws from *contradicting* federal law, not from paralleling it. There is no general principle that prohibits states from enforcing federal-law standards. Rather, outside of fields where there is an exclusive federal interest, states have the power to impose sanctions for violations of federal law. *Whiting*, 131 S. Ct. at 1983. Indeed, such state laws, like state laws generally, enjoy a powerful "presumption against

pre-emption" if they fall within a field of legislation (such as measures to protect public health or the public fisc) that states have historically occupied. *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009). The presumption dictates that state laws not be set aside "unless that was the clear and manifest purpose of Congress." *Id*. at 565 (citations omitted); *accord Ciba-Geigy Corp. v. Alter*, 309 Ark. 426, 439, 834 S.W.2d 136, 142 (1992).

Here, the state laws at issue operate on subjects of undoubted state authority. The protection of public health, which is advanced by adequate disclosures regarding the safety of prescription drugs, is an area in which states have historically shared authority with the federal government. *See Wyeth*, 555 U.S. at 565 & n.3; *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008). Likewise, state laws, like those in question here, aimed at "policing deceptive conduct" by providing a "remedy for deceptive practices by a manufacturer against its customers" are directed at "a traditional area of state concern." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 177 (1st Cir. 2009). Moreover, the U.S. Supreme Court has made clear that federal regulation has not occupied the field of drug safety in general, or of prescription drug labeling in particular, so as to displace traditional state authority over matters relating to health and safety and the protection of consumers against misleading or deceptive commercial messages. *See Wyeth*, 555 U.S. at 573-81. State law thus "offers an additional, and important

layer of consumer protection that complements FDA regulation" with respect to prescription drug labeling, *id*. at 579, and state laws in this area receive the full protection of the presumption against preemption. *Id*. at 565 & n.3.

A state, moreover, has a strong interest in policing its own expenditures in the operation of a program such as Medicaid, a venture in "cooperative federalism" in which states play a key role and may exercise a "range of permissible choices." *Wisc. Dept. of Health & Family Servs. v. Blumer*, 534 U.S. 473, 495 (2002). State Medicaid programs reflect shared state and federal interests in advancing public health by providing medical services to the needy, as well as ensuring that government financial resources are put to their best use, by, for example, encouraging the use of drugs that are safe, medically effective, and cost-effective. *See Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 663-64 (2003) (plurality opinion). Where state and federal governments "are pursuing 'common purposes'" in this manner, "[t]he presumption against federal pre-emption of a state statute designed to foster public health … has special force." *Id*. at 666; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 175 (holding that the application of state antifraud statutes to Medicare drug pricing issues is not preempted in light of the regulatory role reserved for states by the Medicare laws).

Consistent with these principles, the U.S. Supreme Court has repeatedly emphasized that, when states are operating within fields of traditional state

authority, they may provide legal remedies that incorporate, and impose liability for, violations of federal standards. In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), for example, the Court held that states may provide remedies for violations of the labeling requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and recognized that efforts by state officials to ensure compliance with the federal act were well within the authority of the states. The Court explained:

> States have ample authority to review pesticide labels to ensure that they comply with *both federal and state labeling requirements*. Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense thereby imposing its own sanctions on pesticide manufacturers who violate federal law.

Id. at 442 (emphasis added). As Justice Thomas, joined by Justice Scalia, put it more succinctly in his concurring opinion, "States are free to impose liability predicated on a violation of the federal standards set forth in FIFRA and in any accompanying regulations promulgated by the Environmental Protection Agency …." *Id*. at 455 (Thomas, J., concurring in part and dissenting in part).

Similarly, in cases involving federal requirements imposed on medical devices under the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA), the U.S. Supreme Court has twice affirmed the authority of states to remedy violations of federal requirements. First, in *Medtronic, Inc. v. Lohr*, 518 U.S. (1996), all the members of the Court agreed that

the states could impose liability for violations of regulatory requirements promulgated by the FDA. The majority in *Lohr* explicitly held that state-law tort claims based on a device manufacturer's conduct that allegedly "violated FDA regulations" were not preempted. *Id*. at 494. The four Justices who concurred in part and dissented in part fully agreed with the majority that state-law claims seeking "damages for … alleged violation of federal requirements" are not preempted. *Id*. at 513 (O'Connor, J., concurring in part and dissenting in part).

Later, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court was even more explicit. Even while holding that, under an express preemption provision in the MDA, states could not allow claims that would impose duties on medical device manufacturers that go beyond those imposed by specifically applicable federal laws and regulations, the Court reiterated that state-law claims based on violation of federal standards are not preempted. A state, the Court said, may "provid[e] a damages remedy for claims *premised on* a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. at 330 (emphasis added; citing *Lohr*, 518 U.S. at 495).

Notably, the provisions of the FDCA applicable to prescription drugs such as the one at issue in this case do not include a preemption provision similar to the one for medical devices that was at issue in *Riegel* and *Lohr*. *See Riegel*, 552 U.S. at 327. The U.S. Supreme Court held in *Wyeth* that the absence of such a

preemption provision for prescription drugs was a strong indication of congressional intent to allow greater scope for state-law regulation of drugs than of medical devices. 555 U.S. at 574-75. Given that states are allowed to enforce federal requirements applicable to medical devices under *Lohr* and *Riegel*, it follows *a fortiori* that they must be able to do so with respect to requirements applicable to prescription drugs.

II. *Buckman* Does Not Require Preemption in This Case.

The U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, on which Janssen principally relies, addresses only what one federal appellate court has described as a "narrow scenario" in which plaintiffs assert a purported state-law claim based on alleged fraud on a federal agency. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 176. *Buckman* holds only that "fraud-on-the-FDA" claims premised solely on a violation of a duty to a federal agency fall outside the scope of a state's traditional power to regulate matters of health and safety and are preempted by federal law. *Buckman*, 531 U.S. at 347-48. The decision's core holding is that claims that a defendant violated duties owed *only* to the FDA under federal law are preempted because they trench on the agency's power to police fraud against itself. *Id*. at 348. At the same time, however, *Buckman* emphasizes that states may make conduct actionable under state law when that conduct not only violates a duty to the federal agency, but also

falls within traditional state-law authority, *see id.* at 352-53—the scope of which includes such matters as public health and safety, consumer deception, and the performance of state-government functions. *Buckman* does not hold that a state may not give content to legal requirements it may legitimately impose on its own authority by incorporating federal-law requirements that serve parallel purposes, and reading *Buckman* to preempt such claims would be contrary to the longstanding presumption against preemption of state law.

A. In *Buckman*, the plaintiffs claimed that the defendant had violated its duty of candor to the FDA by making "fraudulent representations to the Food and Drug Administration … in the course of obtaining approval to market" a medical device. *Id.* at 343. Specifically, they alleged that the defendant had misrepresented the intended use of the device so as to streamline the process by which the FDA reviewed the device. *See id.* at 343-46. They alleged further that, "[h]ad the representations not been made, the FDA would not have approved the device[] …." *Id.* at 343. Based on these features of the plaintiffs' claim, the Supreme Court's opinion repeatedly emphasized that the claim was a "fraud-on-the-FDA" or "fraud-on-the-agency" claim. *Id*. at 347, 348, 350, 351, 352.

As described by the Court, the feature of the *Buckman* "fraud-on-the-FDA" claim that was critical to the Court's analysis was that the claim was not based on any subject that the state had its own interests in regulating, *id*. at 352, but entirely

on duties arising from "the relationship between a federal agency and the entity it regulates." *Id*. at 347. Thus, the sole interest that the claim sought to advance was to "punish and deter fraud against the [FDA]." *Id.* at 348. That objective, the Court stressed, was one in which the states had no independent interest, and it was also one already fully served by the "federal statutory scheme[, which] amply empowers the FDA to punish and deter fraud." *Id.* Allowing state law to "[p]olic[e] fraud against federal agencies," *id*. at 347, the Court stated, would interfere with the federal statutory scheme by "skew[ing]" the "balance sought by the [FDA]" in enforcing prohibitions on fraud under the FDCA. *Id*. at 348. Thus, as the Court summed up its narrow holding, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

At the same time, however, *Buckman* stated that its preemption reasoning did not extend to actions that rested on "traditional" state-law duties, *id*. at 352, and it stressed that where an alleged breach of duty did not arise "solely by virtue of [federal] disclosure requirements," *id*. at 353, a plaintiff may maintain a "state-law caus[e] of action that parallel[s] federal safety requirements," *id.*, as the Court had previously held in *Lohr*. Thus, as lower federal courts applying *Buckman* have explained, state-law claims that are premised on a duty imposed by a state statute or common-law principle for the protection of the public—as opposed to protection

of the federal agency—do not arise "solely" out of a violation of federal requirements, even when breach of those federal requirements is the basis of a finding that a breach of the state-law duty has occurred. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007), *aff'd by an equally divided Court*, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008). Accordingly, courts have held that *Buckman* does not preclude plaintiffs from relying on proof of violations of FDA standards as the basis of negligence or failure-to-warn claims if those violations amount to a breach of some state-law based duty toward the plaintiff. *See, e.g.*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 557-58 (7th Cir. 2010).

The claims at issue here likewise fall into the broad realm that *Buckman* leaves unpreempted. Unlike in *Buckman*, the State is not intruding into areas of exclusive federal authority, but acting in fields where it has undisputed power: advancement of public health and safety, protection of consumers against deception, and ensuring the effective expenditure of public funds. The State's law looks to federal requirements not (as in a preempted "fraud-on-the-FDA" claim) to regulate the relationship of drug manufacturers with the FDA and to punish a breach of a duty owed exclusively to the agency, but to give content to state-law duties designed to protect public health, informed consumer choice, and the State's

Medicaid program. Federal law does not preempt the State from considering Janssen's violation of FDA labeling requirements as part of the basis for finding a breach of a duty owed to the State under the Medicaid program—a duty to truthfully provide information required by applicable laws in marketing its products for use by Medicaid recipients.

The State's claims also differ from the *Buckman* fraud-on-the-FDA claim in another important respect: They do not require any hypothetical consideration about what regulatory action the agency would have taken if the agency had not been "defrauded." Members of the Court in *Buckman* expressed particular concern about the possibility that fraud-on-the-agency claims would require "speculation as to the FDA's behavior in a counterfactual situation" and interfere with federal policy by "second-guessing the FDA's decisionmaking." 531 U.S. at 354 (Stevens, J., concurring in the judgment). But unlike the fraud claim in *Buckman*, the State's claims that the Janssen's labeling contained inadequate warnings about the risks of its drugs—warnings that were primarily the responsibility of the manufacturer, not the FDA, and that the manufacturer could have strengthened unilaterally, *see Wyeth*, 555 U.S. at 568-71—are not claims that the FDA would have taken some different action had Janssen not violated the duty alleged. Hence, they do not require the court to explore the issue of reliance by the FDA, to reconstruct what the agency would have done if it had not been misled, or to second-guess its

regulatory action or reaction in any way. Because they "do[] not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*," *Hughes*, 631 F.3d at 775, the State's claims here avoid one of the principal concerns underlying *Buckman*'s preemption doctrine.

Similarly, Janssen's invocation of *Buckman*'s concerns about over-deterrence if state law were permitted to police manufacturers' duties of candor to the federal agency (*see Buckman*, 531 U.S. at 347-48) is unavailing here. Janssen contends that allowing state Medicaid programs to require drug labels to truthfully provide information required by federal drug labeling laws risks upsetting some delicate balance that would be maintained by making federal regulation exclusive; the result, Janseen predicts, will be to create incentives for drug manufacturers to over-disclose risks. But Janssen's argument overlooks that, under *Wyeth*, state law can impose extremely substantial liability on manufacturers for failing to disclose risks, even where that failure is *not* shown to violate FDA requirements. The Court in *Wyeth* rejected the argument that such state-law liability would upset the balance sought by federal regulation and, indeed, recognized that imposing liability under state law for inadequate labeling is beneficial because it helps "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth*, 555 U.S. at 579. If that is the case, imposing liability for

mislabeling that already violated federal requirements can hardly be viewed as sufficiently disruptive to deserve preemption.

Aside from these matters of policy, expanding *Buckman* to preempt any state law that provides a remedy for a violation of FDA requirements would make a mockery of the U.S. Supreme Court's repeated statements that states may make federal-law violations under the FDCA and similar laws actionable under state law. Both in *Lohr*, which preceded *Buckman* by less than five years, and then in *Bates*, which followed *Buckman*, the Supreme Court emphasized not only that states are free to impose tort liability for conduct that violates federal law, but that they can make the violation of federal law the *basis* for liability under state law by "explicitly incorporat[ing] federal standards as an element of a cause of action." *Bates*, 544 U.S. at 447; *see also Lohr*, 518 U.S. at 495 (claim that defendant "violated federal regulations" not preempted); *id*. at 513 (O'Connor, J., dissenting) (agreeing that MDA does not preempt "a state cause of action [that] seeks to enforce an FDCA requirement"). Further, *Bates* said that a state could make violation of a federal standard a state *offense*. 544 U.S. at 442. More recently, the Court in *Riegel* reiterated that a state may "provid[e] a damages remedy for claims premised on a violation of FDA regulations." 552 U.S. at 330. Extending *Buckman* to prohibit states from incorporating federal standards in their own laws in this way would, as the U.S. Court of Appeals for the Fifth Circuit emphasized in *Hughes*, be

"inconsistent with the Supreme Court's reasoning in *Riegel*, decided long after *Buckman*." 631 F.3d at 775.

The Court's insistence in *Lohr*, *Bates*, and *Riegel* that states are not barred from providing remedies for conduct that violates federal law has meaning only if *Buckman* is read narrowly to proscribe only state efforts to enforce duties owed solely to the FDA, such as the "fraud-on-the-FDA" claim held preempted in *Buckman* itself. If a state, in the exercise of its traditional functions of protecting the public against defective medical products or inadequate warnings about the dangers of medical products, and ensuring that state funds are expended only on drugs that carry proper warnings, creates a statutory remedy whose premise is that a drug manufacturer owes the state a duty that corresponds to FDA requirements, such a statute is not impliedly preempted. *See Buckman*, 531 U.S. at 353 (recognizing that *Lohr* permits such parallel remedies).

B. Reading *Buckman* broadly to preempt the State's statutory claims here would not only undermine the Court's statements in *Riegel*, *Bates*, and *Lohr* that states may offer such remedies, but would also run afoul of the presumption against preemption—the principle that the "historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565. In *Buckman*, the Supreme Court held the presumption inapplicable because the state-law claim on its face was an

attempt to enforce a duty that had no analog in traditional state common-law doctrines—the duty of candor owed by manufacturers to a federal agency. *See Buckman*, 531 U.S. at 347. Properly confined to "fraud-on-the-agency" claims or other claims that are similarly premised solely on the alleged violation of a duty owed by the defendant to a federal agency under federal law, *Buckman* does not conflict with the presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 347.

While *Buckman*'s reasoning forecloses application of the presumption against preemption to claims that serve only to police obligations owed to the federal government, it does not weaken the presumption as applied to state laws that serve traditional state interests. *Id*. at 353. As the U.S. Supreme Court pointed out in *Wyeth*, *Buckman*'s holding that the presumption did not apply in that case rested critically on the fact that the case "involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply." *Wyeth*, 555 U.S. at 565 n.3. Extending *Buckman* to a case such as this one, in which the claim does not seek to remedy the breach of a duty to the FDA, but looks to federal law only to give content to the

manufacturer's state-law law duties to warn doctors and patients of the risks of medical products and to provide accurate information to ensure that Medicaid funds are properly spent on safe and beneficial medications, would run directly up against the presumption against preemption as articulated in *Wyeth*.[1]

Given the applicability of the presumption against preemption, this Court has a "duty to accept the reading disfavoring preemption." *Bates*, 544 U.S. at 449. Preemption is appropriate only if congressional intent to displace traditional state

[1] Janssen's invocation of *Arizona v. United States*, 132 S. Ct. 2492 (2012), in which the U.S. Supreme Court held that Arizona was precluded from penalizing certain violations of federal immigration law, is as far afield as its reliance on *Buckman*. The relevant holding in *Arizona* rested on the view that the federal government had exclusively occupied the field in the areas covered by the federal provisions that the state sought to enforce. *Id*. at 2501-03. *Wyeth* demonstrates that there is no federal field preemption here. *See* 555 U.S. at 574-75. Indeed, *Arizona*'s citation of *Buckman* in support of its field preemption theory, *see* 132 S. Ct. at 2502-03, only underscores the narrowness of *Buckman*'s reasoning, and its inapplicability to state laws that deal with subjects that are not exclusively within federal purview, as is the relationship between federal agencies and regulated entities.

tort remedies is "clear and manifest." *Id.* (citations omitted). *Buckman*, which calls for preemption only of actions that interfere with federal policy by imposing liability solely on account of breaches of duties owed only to the federal government, reveals no manifest congressional intent to preempt state regulatory statutes that serve state interests by incorporating federal standards. Far from conflicting with federal policy, such claims "would seem to aid, rather than hinder, the functioning" of federal law. *Bates*, 544 U.S. at 451. Faced with a choice between taking a broad or narrow reading of *Buckman*, the presumption against preemption commands this Court to take the latter.

CONCLUSION

For the foregoing reasons, this Court should reject Janssen's contention that the claims against it are preempted by federal law and affirm the judgment below.

Respectfully submitted,

Scott L. Nelson
D.C. Bar. No. 413548
snelson@citizen.org
Allison M. Zieve
D.C. Bar. No. 424786
azieve@citizen.org
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
(202) 588-7795 (fax)

John L. Burnett
Ark. Bar No. 77021
jburnett@laveyandburnett.com
LAVEY & BURNETT
904 W. 2nd Street
Little Rock, AR, 72201
(501) 376-2269
(501) 372-1134 (fax)

Annabelle Imber Tuck
Ark. Bar No. 77032
annabelletuck@ymail.com
34 Marcella Drive
Little Rock, AR 72223
(501) 868-6372
(501) 868-6372 (fax)

Attorneys for Public Citizen, Inc.

Dated: June 18, 2013

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of June, 2013, a copy of the foregoing was served by United States mail, postage prepaid, upon the following:

Charles C. Lifland, Esq.
O'MELVENY & MYERS, LLP
400 South Hope Street
Los Angeles, CA 90071

Stephen D. Brody, Esq.
O'MELVENY & MYERS, LLP
1625 Eye Street, NW
Washington, D.C. 20006

Edward M. Posner, Esq.
Gregg W. Mackuse, Esq.
DRINKER BIDDLE & REATH, LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103

Thomas F. Campion, Esq.
DRINKER BIDDLE & REATH, LLP
500 Campus Drive
Florham Park, NJ 07932

James M. Simpson, Esq.
Laura H. Smith, Esq.
Robert S. Shafer, Esq.
Martin A. Kasten
FRIDAY, ELDREDGE & CLARK, LLP
400 West Capitol Avenue, Suite 2000
Little Rock, AR 72201

Jay Shue, Esq.
Brad Phelps, Esq.
ATTORNEY GENERAL'S OFFICE
323 Center Street, Suite 200
Little Rock, AR 72201-2610

Caitlin Sinclair Hall, Esq.
David Charles Frederick, Esq.
Derek Tam Ho, Esq.
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL, PLLC
Sumner Square
1615 M Street, NW, Suite 400
Washington, DC 20036

Fletcher Trammell, Esq.
Robert Cowan, Esq.
Michael Perrin, Esq.
Elizabeth Dwyer, Esq.
Justin Jenson, Esq.
BAILEY PERRIN BAILEY
440 Louisiana Street, Suite 2100
Houston, TX 77002

The Honorable Timothy D. Fox
Circuit Court of Pulaski County, Arkansas
401 W. Markham, Suite 210
Little Rock, Arkansas 72201

_____

John L. Burnett