No. 15-____

IN THE
Supreme Court of the United States

YAMAHA MOTOR CORP., U.S.A., YAMAHA MOTOR MANUFACTURING CORP. OF AMERICA, and YAMAHA MOTOR CO. LTD.,

Petitioners,

v.

JACKLYN MCMAHON,

Respondent.

On Petition for Writ of Certiorari To The Supreme Court of Alabama

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether state law liability, including punitive damages, that arises from an asserted unlawful violation of federal agency disclosure requirements is preempted under *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001)?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners, Defendants-Appellants below, are three corporations: Yamaha Motor Corporation, U.S.A.; Yamaha Motor Manufacturing Corporation of America; and, Yamaha Motor Company Limited.

Yamaha Motor Company Limited owns 100% of the stock of Yamaha Motor Corporation, U.S.A. Yamaha Motor Corporation, U.S.A., in turn, owns 100% of the stock of Yamaha Motor Manufacturing Corporation of America. Yamaha Motor Company Limited is not publicly traded in the United States; it is a publicly traded corporation on the Tokyo Stock Exchange in Japan. Yamaha Corporation owns more than 10% of the stock of Yamaha Motor Company Limited.

Respondent, Plaintiff-Appellee below, is Jacklyn McMahon, acting individually.

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CONSTITUTIONAL PROVISIONS

OPINIONS BELOW

The Alabama Supreme Court's order affirming the jury verdict was issued without opinion and is unreported. Pet. App. 3a. The Alabama Supreme Court's order denying Yamaha's application for rehearing was also issued without opinion and is unreported. Pet. App. 1a.

JURISDICTION

The Alabama Supreme Court entered its "No Opinion" order affirming the jury verdict on March 27, 2015, and denied Yamaha's motion for rehearing on May 22, 2015. Pet. App. 1a, 3a. Jurisdiction in this Court exists under 28 U.S.C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, provides in pertinent part:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Section 2051(b) of the Consumer Product Safety Act ("CPSA" or "the Act"), 15 U.S.C. § 2051(b), which

outlines the purpose of the Act, states in pertinent part:

> (b) The purposes of this chapter are— (1) to protect the public against unreasonable risks of injury associated with consumer products; (2) to assist consumers in evaluating the comparative safety of consumer products; (3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

CPSA § 15(b), 15 U.S.C. § 2064(b), defines a manufacturer's reporting obligations to the Consumer Product Safety Commission ("CPSC" or "Commission") as follows:

> (b) Noncompliance with applicable consumer product safety rules; product defects; notice to Commission by manufacturer, distributor, or retailer
>
> Every manufacturer of a consumer product, or other product or substance over which the Commission has jurisdiction under any other Act enforced by the Commission (other than motor vehicle equipment as defined in section 30102(a)(7) of title 49), distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product—

> (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 2058 of this title;
>
> (2) fails to comply with any other rule, regulation, standard, or ban under this chapter or any other Act enforced by the Commission;
>
> (3) contains a defect which could create a substantial product hazard described in subsection (a)(2) of this section; or
>
> (4) creates an unreasonable risk of serious injury or death,
>
> shall immediately inform the Commission of such failure to comply, of such defect, or of such risk, unless such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such defect, failure to comply, or such risk. . . .

15 U.S.C. § 2064(b). The provision also defines "substantial product hazard" as follows:

> For purposes of this section, the term "substantial product hazard" means—
>
> (1) a failure to comply with an applicable consumer product safety rule under this chapter or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission

> which creates a substantial risk of injury to the public, or
>
> (2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

15 U.S.C. § 2064(a).

STATEMENT OF THE CASE

This case concerns a significant preemption question arising from this Court's decision in *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), that is dividing the lower courts—namely, whether violations of federal reporting requirements can give rise to state common law liability. In the proceedings below, a jury found Petitioners liable under Alabama common law and awarded punitive damages against them for their asserted wanton disregard of a federal reporting requirement, CPSA § 15(b), 15 U.S.C. § 2064. The Montgomery County Circuit Court and the Alabama Supreme Court affirmed the jury's verdict. Although Petitioners repeatedly argued that the wantonness finding conflicted with, and was preempted by, the CPSA and inconsistent with *Buckman*, the Alabama courts refused to address preemption. Indeed, the Alabama Supreme Court declined to explain its reason for decision at all.

This Court has made clear, however, that state law claims that interfere with Congress's carefully calibrated regulatory reporting schemes cannot

proceed. Punishing asserted misrepresentations and omissions in required disclosures lies within the exclusive province of the pertinent federal agency. A state law imposing liability based on a violation that the agency has not even deemed to exist, interferes with that federal power. This case proves the point: the CPSC thoroughly investigated Petitioners but never entered a reporting violation finding as part of that investigation. A jury, however, necessarily found one, imposed liability under Alabama law that the CPSC did not, and awarded punitive damages even though the CPSC meted no punishment.

1. The CPSA is a comprehensive regulatory scheme designed, in relevant part, "to protect the public against unreasonable risks of injury associated with consumer products," "to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations." 15 U.S.C. § 2051(b). Under the Act, the CPSC has authority to administer and enforce its various provisions. *See* § 2053(a). Specifically, the CPSC has the power to initiate investigations and inspections, *id.* §§ 2054, 2065, levy civil monetary penalties, *id.* § 2069, bring criminal charges, *id.* § 2070, and seek injunctions and seizures, *id.* § 2071.

A fundamental feature of the CPSA is its reporting requirements. Under CPSA § 15(b), manufacturers are required to "immediately inform the Commission" of: (i) a product's failure "to comply with an applicable consumer product safety rule" or any other CPSC rule; (ii) any product "defect which could create a substantial product hazard;" and (iii) any product that "creates an unreasonable risk of serious injury or death." 15 U.S.C. § 2064(b). The

Act defines a "substantial product hazard" as a "failure to comply with an applicable consumer product safety rule . . . which creates a substantial risk of injury to the public," or "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." *Id.* § 2064(a).

A violation of § 15(b) is an "unlawful" act, *see* 15 U.S.C. § 2068(a)(4), punishable by a civil penalty of up to $100,000 for each knowing violation, capped at a $15 million total maximum penalty. *See id.* § 2069. In determining the penalty, the CPSC is required to "consider the nature, circumstances, extent, and gravity of the violation, including the nature of the product defect, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed, [and] the appropriateness of such penalty in relation to the size of the business of the person charged." *Id.* at § 2069(b). In addition, the CPSC may enjoin unlawful acts. *Id.* at § 2071(a)(1). Finally, if the CPSC determines that a product "presents a substantial product hazard" requiring public notice, or it files a court action on the ground that the product is "an imminently hazardous consumer product," it can take numerous other steps to protect public safety, including halting production and distribution. *Id.* § 2064(c)(1).

The CPSC has exclusive authority to determine whether a § 15(b) violation has occurred and, if so, the consequences. There is *no* private right of action for § 15(b) violations. *See Zepik v. Tidewater*

Midwest, Inc., 856 F.2d 936 (7th Cir. 1988); *Benitez-Allende v. Alcan Aluminio Do Brasil, S.A.*, 857 F.2d 26 (1st Cir. 1988); *see also Kloepfer v. Honda Motor Co.*, 898 F.2d 1452, 1457 (10th Cir. 1990).

2. Petitioners Yamaha Motor Corporation, U.S.A., Yamaha Motor Manufacturing Corporation of America, and Yamaha Motor Company Limited (collectively, "Yamaha") manufacture motorcycles, marine products, and other motorized products, including the Yamaha Rhino.

The Rhino is a four-wheel, open-air, two-person, off-road vehicle in which a driver and passenger can sit side-by-side in bucket seats and traverse widely varying terrains. Pet. App. 7a. When the Rhino was first released in 2003, it contained many safety features, including a steel-frame roof structure—which satisfied the Federal Motor Vehicle Safety Standard for roof-crush strength—hip guards, handholds, bucket seats, and three-point lap and shoulder seatbelts. *Id.* at 58a-60a, 63a. The Rhino was the first off-road vehicle equipped with a seat belt and foot guards. *Id.* at 61a, 64a-71a. During the first year of the Rhino's release, 2003, Yamaha received no lower extremity consumer injury reports. *Id.* at 75a. The following year, Yamaha received six lower extremity injury reports, and retained experts to evaluate the reports, as well as possibly adding doors to the Rhino. *Id.* at 53a, 72-73a. The additional testing confirmed that extremely aggressive driving was required to overturn the Rhino and that "it wasn't clear that a door would improve the safety of the vehicle." *Id.* at 79a.

On August 27, 2007, Yamaha voluntarily added doors to new Rhinos and offered free installation on

previously purchased vehicles. *Id.* at 76a, 81a. At that time the lower extremity injury rate associated with the Rhino was less than .02%. *Id.* at 76a.

3. Respondent, Jacklyn McMahon ("McMahon"), purchased a Rhino on October 21, 2006. *Id.* at 44a. On July 26, 2007, McMahon was injured after rolling over her Rhino. *Id.* at 7a. McMahon first brought suit against Yamaha on January 14, 2008, in the Circuit Court of Montgomery County, asserting claims for defective design and failure to warn under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"), common law negligence and wantonness, and breach of warranty. Pet. App. 6a-7a.

4. On September 10, 2008, while McMahon's suit was pending and over a year after her accident, the CPSC initiated an investigation of the Rhino. *Id.* at 14a-15a, 50a-51a. Yamaha cooperated with the CPSC's investigation and negotiated design modifications to the Rhino in exchange for a settlement. *Id.* at 95a. The CPSC did not find that the Rhino was "in any way defective or created any unreasonable risk of hazard." *Id.* at 47a-48a. The CPSC did not order a recall of the Rhino, opting instead for a "repair" program. *Id.* at 46a-47a. The CPSC did not find Yamaha in violation of any reporting obligations under the CPSA. *Id.* at 47a-48a.

5. The Order at issue here arose from the second appeal to the Alabama Supreme Court. Previously, that Court considered whether Yamaha was entitled to judgment on McMahon's negligence and wantonness claims after a jury returned, in thirty minutes, a unanimous verdict for Yamaha on

McMahon's AEMLD claim. Pet. App. 7a. The Court affirmed the negligence claim's dismissal on harmless error grounds given its overlap with the AEMLD claim, but reversed on wantonness, holding the claim separate from AEMLD and sufficiently supported to survive a directed verdict motion. *McMahon v. Yamaha Motor Corp.*, 95 So.3d 769, 772-74 (Ala. 2012). On remand, McMahon voluntarily dismissed her wanton failure-to-warn claim, leaving only her testing and design-based wantonness claim. Pet. App. 105a.

6. Unlike the first trial, the second trial was dominated by the post-accident CPSC investigation. *Id.* at 54a-57a. McMahon claimed that Yamaha's failure to report alleged defects to the CPSC prior to her accident constituted wantonness. *Id.* at 45a-46a. On May 1, 2013, the jury returned a verdict in McMahon's favor, awarding $1,398,341.00 in compensatory damages and $2,000,000 in punitive damages. *Id.* at 23a. The trial court entered judgment the next day.

Yamaha moved for judgment as a matter of law or, in the alternative, for a new trial. *Id.* at 92a. At the August 20, 2013 motion hearing, the trial court called the verdict "inherently wrong," *id.* at 83a, noting that "there wasn't wantonness in the second trial," *id.* at 84a, 85a, 87a, 88a, 90a, and that "there was nothing reckless about Yamaha's conduct." *Id.* at 88a. Nonetheless, the trial court denied the motion. *Id.* at 82a, 84a-85a.

7. Yamaha appealed arguing, in relevant part, that McMahon's wantonness claim was preempted under this Court's decision in *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). McMahon's

state law claim depended on an alleged violation of CPSA § 15(b)—a violation the CPSC had not found and a jury could not find without interfering with the CPSA. The jury's interference, moreover, was exacerbated by its award of punitive damages.

8. The Alabama Supreme Court affirmed in a divided 5-4 decision. Rather than address Yamaha's preemption argument, the majority entered a "No Opinion" decision. Pet. App. 3a. It did so despite the fact that the Alabama Supreme Court has never issued a decision relating to *Buckman* and thus had no precedent on which it could be reasonably relying.

9. Yamaha subsequently filed an application for rehearing, which was joined by multiple *amici*. Both Yamaha and the Alabama Defense Lawyers Association, acting as *amicus curiae*, argued that McMahon's wantonness claim was preempted, because it was dependent on the jury finding a wanton § 15(b) violation and resulted in punitive damages. Both stressed that an affirmance would necessarily decide the preemption issue contrary to this Court's precedent. The Alabama Supreme Court overruled Yamaha's application in yet another divided 5-4 decision, issuing a second "No Opinion" order. Pet App. 1a.

REASONS FOR GRANTING THE PETITION

Yamaha respectfully submits that the petition should be granted for three reasons: (i) the Alabama Supreme Court's decision is inconsistent with this Court's precedent; (ii) the decision deepens and broadens a split of authority; and, (iii) it implicates numerous, substantial policy problems.

In *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341, 348 (2001), this Court held that state law "fraud on the agency" claims based on material misrepresentations or omissions to a federal agency are impliedly preempted. The relationship between the federal agency and the regulated entity, the Court held, "is inherently federal in character." *Id.* at 347. And where Congress has conferred enforcement powers on the agency to police the relationship, state liability conflicts with the federal scheme. *Id.* at 349-50. The relationship between Yamaha and the CPSC, and CPSC's enforcement powers are virtually the same as those at issue in *Buckman*. And, the policy concerns this Court identified in *Buckman* are equally applicable here. Indeed, because the jury awarded punitive damages, the policy concerns are even greater. The Alabama Supreme Court necessarily departed from *Buckman* in affirming the jury's verdict, which conferred state liability on an allegedly wanton violation of the CPSA § 15(b) disclosure requirements.

In addition, the Alabama Supreme Court's decision implicates a significant federal question that is dividing the lower courts—namely, whether *Buckman* preemption is limited to classic "fraud on the agency" claims, or extends to other state law claims that arise from the same kind of underlying conduct. The Fifth, Sixth, and Ninth Circuits have all concluded that *Buckman* preempts all state law claims analogous to, or relying on, fraud on the agency, regardless of how the claim is titled. In contrast, the Second Circuit, and now the Alabama Supreme Court, have rejected this approach and held preemption inapplicable. Resolving the split of

authority now is necessary to correct this persistent lack of uniformity.

Finally, the question presented has substantial importance for all the reasons this Court identified in *Buckman*. Unless this Court resolves the conflict, consumers in Alabama and beyond can effectively usurp the CPSC and punish manufacturers, including awarding punitive damages, for asserted reporting violations that were never found by the federal agency. The resulting potentially massive and indeterminate state liability would create the incentive for companies to deluge the CPSC with information to avoid private suits. *See Buckman*, 531 U.S. at 351. Indeed, on the facts of this case, companies would be forced to submit § 15(b) reports where the relevant injury rate is *.02%*.

The Alabama Supreme Court's failure to articulate its reasoning should not preclude a grant of *certiorari*. Rather, that Court's refusal to explain why it was departing from a decision of this Court and the majority of federal courts only increases the importance of review.

Accordingly, every factor that the Court typically considers when deciding whether to grant a writ of *certiorari* applies here, and each demonstrates that this Court's immediate intervention is necessary.

I. THE ALABAMA SUPREME COURT ERRONEOUSLY DISREGARDED THIS COURT'S DECISION IN *BUCKMAN*.

Review is appropriate, first, because the Alabama Supreme Court disregarded this Court's decision in *Buckman v. Plaintiff's Legal Committee*, 531 U.S.

341 (2001), and did so in a manner that suggests an attempt to evade review.

In *Buckman*, this Court considered whether conflict preemption precluded a state law claim for alleged fraud on the FDA and ultimately held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348. The Court reasoned that the usual presumption against preemption did not apply, because "the relationship between a federal agency and the entity it regulates is inherently federal in character." *Id.* at 347. The Court also observed that policing federal agency rules "is hardly a field which the States have traditionally occupied such as to warrant a presumption against finding federal pre-emption." *Id.* (internal quotation marks and citation omitted).

The Court, next, examined the relevant statutory and regulatory framework, *id.* at 343-50, and concluded that it "le[ft] no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n. 4. For example, the FDA could impose civil penalties and seek injunctive relief to curb any noncompliance. *Id.* at 349. The conflict, moreover, "stem[med] from the fact that the federal statutory scheme amply empower[ed] the [agency] to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348; *see also id.* at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the

Administration's judgment and objectives."). This balance would be "skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348.

The Court also noted that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.* at 350. State law claims "would also cause applicants to fear that their disclosures to [an agency] . . . will later be judged insufficient in state court," which would give parties "an incentive to submit a deluge of information that the [agency] neither wants nor needs." *Id.* at 351.

The same analysis applies here. As a result of the Alabama Supreme Court's decision, a manufacturer can be liable under state wantonness law if it "wantonly" violates the § 15(b) CPSA reporting requirement or otherwise makes a material misrepresentation or omission to the CPSC. McMahon's claim centered on Yamaha's asserted wantonness with respect to its CPSA § 15(b) obligations. Given the heightened state of mind required for wantonness, *see* Ala. Code § 6-11-20(b)(3), McMahon's claim is fundamentally one for "fraud-on-the-agency" in connection with the alleged reporting omissions. *See Sears, Roebuck & Co. v. Harris*, 630 So. 2d 1018, 1033 (Ala. 1993).

In addition, the CPSA is, in all relevant respects, analogous to the FDCA, the regulatory scheme at issue in *Buckman*. Like the FDCA, the CPSA is a comprehensive regulatory scheme that delegates authority to the CPSC over consumer-product safety. *See* 15 U.S.C. §§ 2051-2089. With respect to the

CPSA § 15(b) reporting requirements, *id.* § 2064(b), the CPSA renders their violation an "unlawful" act, *see* 15 U.S.C. § 2068(a) (4), punishable by a civil penalty of up to $100,000 for each knowing violation, capped at a $15 million total maximum penalty. *See id.* § 2069(a) (1). In determining the penalty, the CPSC is required to "consider the nature, circumstances, extent, and gravity of the violation, including the nature of the product defect, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed, the appropriateness of such penalty in relation to the size of the business of the person charged." *Id.* at § 2069(b). In addition, the CPSC may enjoin unlawful acts. *Id.* at § 2071(a) (1). The CPSA "amply empowers the [CPSC] to punish and deter" noncompliance with § 15(b). *Buckman*, 531 U.S. at 348. Indeed, the CPSC's enforcement powers are virtually the same as the FDA's in *Buckman*. *See id.* at 349-50.

In addition, Congress provided no private right of action for § 15(b) violations; only the CPSC has authority to determine whether a reporting violation has occurred and, if so, seek a penalty or injunctive relief. *See* 15 U.S.C. § 2072(a). By conferring exclusive enforcement and remedial authority on the CPSC, Congress determined that the agency—not a jury—is clearly in the best position to evaluate whether the federal reporting requirements were breached, and if so, the appropriate penalty. Thus, the Alabama Supreme Court's decision in this case conflicts with the CPSA by skewing the enforcement balance it creates, usurping the CPSC's exclusive authority to determine § 15(b) violations,

undercutting the CPSC's responsibility to police its relationship with Yamaha vis-a-vis § 15(b), and authorizing a penalty, punitive damages, that the CPSA does not authorize.

As in *Buckman*, conflict preemption applies. State-law claims based on alleged wanton CPSC reporting failures frustrate the CPSA's operation and purpose. The CPSC is duly empowered to police and deter reporting violations—whether willful or not—and allowing state law claims based on § 15(b) violations to proceed will waste agency and court resources and lead to disparate results. Indeed, that is exactly what happened here. After thoroughly investigating the Rhino, the CPSC made no finding that Yamaha violated the CPSA's reporting requirements. *See* Pet. App. 47a-48a. But a jury in Alabama has, and awarded a penalty that the CPSC could not. This is precisely what *Buckman* forbids.

II. THE COURT SHOULD RESOLVE THE SPLIT OVER WHETHER *BUCKMAN* PREEMPTION APPLIES TO STATE LAW CLAIMS ARISING FROM CONDUCT ANALOGOUS TO FRAUD ON THE AGENCY.

Review is separately warranted to resolve a deep and persistent split that has arisen over *Buckman*'s meaning and scope. Despite *Buckman*'s clear holding, federal appellate courts and, now, the Alabama Supreme Court are divided over whether a traditional state law claim, such as a tort law claim, that is based on underlying fraud-on-the-agency *conduct* is preempted or whether *Buckman* is limited to its facts—an actual fraud-on-the-agency claim.

The Ninth, Sixth, and Fifth Circuits have held that *Buckman*'s analysis extends beyond fraud-on-the-agency claims to any state law claims that depend on asserted misrepresentations or omissions to a federal agency. *See Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012).

In *DowElanco*, for example, the Ninth Circuit held a state law claim of intentional interference with prospective economic advantage preempted because it required a finding that the defendant had committed fraud on the Environmental Protection Agency ("EPA"). 275 F.3d at 1205. In that case, the plaintiff manufactured nylon bags to protect items from pesticide fumigation, and the defendant manufactured pesticides. *Id.* at 1202. After the defendant informed the EPA that plaintiff's bags were unsafe and obtained EPA-approval to so-instruct purchasers, plaintiff sought damages for intentional interference on the theory that defendant had knowingly submitted false information to the EPA. *Id.* at 1202-03. Even though plaintiff was asserting an intentional interference claim, not a classic fraud-on-the-agency claim, the Ninth Circuit held it preempted, reasoning that the "state law claim hinges upon its contention that [defendant] committed fraud against the EPA—which is hardly 'a field which the States have traditionally occupied.'" *Id.* at 1205.

Similarly, in *Garcia*, the Sixth Circuit held preempted a Michigan statute providing that evidence of fraud on the agency could rebut a non-

liability presumption. 385 F.3d at 965-66. The court held that whether the state law claim was styled as "fraud on the agency" or tort law was "immaterial in light of *Buckman*." *Id.* at 966. In all instances, "state tort remedies requiring proof of fraud committed against the FDA are [preempted]." *Id.* "Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* Thus, the court concluded, *Buckman* preemption applies if a plaintiff's allegations require intruding on the federal regulatory scheme, regardless of the underlying claim. *Id.* More recently, the Sixth Circuit made express that "[t]he fact that [plaintiff's] substantive claims sound in negligence and strict products liability would not enable [plaintiff] to avoid preemption." *Marsh v. Genentech, Inc.*, 693 F.3d 546, 554 (6th Cir. 2012) (emphasis added).

More recently, in *Lofton*, the Fifth Circuit adopted *Garcia* and held a state failure to warn claim preempted where the underlying statute required proof that the defendant withheld or misrepresented material information to the FDA. 672 F.3d at 380. The Fifth Circuit held that *Buckman* preemption applied because the plaintiff's claim, although framed in failure-to-warn terms, effectively required proof of fraud on the FDA. *Id.*

In contrast, the Second Circuit has rejected preemption in analogous contexts. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2006), *aff'd by an equally divided court sub nom. Warner-Lambert & Co. v. Kent*, 552 U.S. 440 (2008). In *Desiano*, 467 F.3d at 95, the Second Circuit read *Buckman* to hold state tort law claims preempted

where the only alleged wrongdoing is a violation of federal law. *Id.* Because the plaintiffs' claims in *Desiano* "parallel[ed] federal safety requirements but [were] not premised principally (let alone exclusively) on [the defendant's] failure to comply with federal disclosure requirements," the Second Circuit held *Buckman* preemption inapplicable. *Id.* (internal quotation marks omitted). No other federal court of appeal has adopted the Second Circuit's interpretation of *Buckman*. In *Lofton*, the Fifth Circuit expressly rejected the Second Circuit's approach on the ground that it would "intrude[] on the competency of the FDA and its relationship with regulated entities." 672 F.3d at 380.

The Alabama Supreme Court has now effectively widened the split by necessarily joining the Second Circuit. McMahon's state law wantonness claim required the jury to find that Yamaha was required to report, but failed to report, Rhino-related injuries to the CPSC and that the CPSC would have ceased Rhino sales had the reporting violation not occurred. But, the CPSC did not find Yamaha in violation of the § 15(b) reporting requirements with respect to the Rhino. And, the CPSC never halted Rhino sales in connection with its investigation. Thus, a misrepresentation to the CPSC and usurpation of the CPSC's authority is part and parcel of McMahon's wantonness claim. According to the Ninth, Sixth and Fifth Circuits, that is sufficient to trigger preemption given the agency's interest in policing its own reporting requirements. The fact that the jury awarded a penalty, punitive damages, that the CPSA does not contemplate only furthers the conclusion.

The Court should act now to resolve this conflict. The opinions issued to date demonstrate that the conflict will not resolve over time but will worsen. Because *Buckman*'s reasoning is applicable to any federal law that requires disclosures to an agency—from the FDA, to the EPA, to the CPSC, and more—the split has the potential to broaden dramatically.

III. THE QUESTION PRESENTED IS SUBSTANTIALLY IMPORTANT.

In addition to implicating a split of authority, the question presented is significant for numerous reasons.

First, the question directly impacts federal authority. In *Buckman*, the Court's holding was primarily motivated by "the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. The Court had "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." 531 U.S. at 349 n. 4. State law claims, in contrast, would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."). This balance would be "skewed by allowing fraud-on-the-FDA claims under state tort law." *Id*. at 348. All of those concerns arise here.

Second, as this Court recognized in *Buckman*, the preemption question here implicates important policy issues. Absent preemption, state law would disrupt the "delicate balance of statutory objectives . . . sought by the Administration," and "[a]s a practical matter, . . . w[ould] dramatically

increase the burdens fac[ed]" by regulated entities, including "unpredictable civil liability." *Id.* at 348-350. As in *Buckman*, here, the Alabama Supreme Court's decision will cause manufacturers "to fear that their disclosures to the [federal government], although deemed appropriate by the [agency], w[ould] later be judged insufficient in state court." *Id.* at 351. Regulated entities would "then have an incentive to submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens" on the agency's examination of alleged fraud, in an effort to avoid being second-guessed by state juries. *Id.* That concern is particularly pronounced here given the jury's award of punitive damages, which provides a further incentive to over-disclose.

Finally, the Alabama Supreme Court's "No Opinion" should not preclude, rather separately justifies, review. Where, as here, a state court of last resort effectively decides an important federal question contrary to this Court's binding precedent and the majority of federal appellate courts, it should not be allowed to potentially evade review by refusing to explain its rationale. That is particularly true here, because Yamaha and its *amicus* repeatedly flagged the conflict the Alabama Supreme Court's decision would implicate. Thus, the Court entered the divided (5-to-4) "No Opinion" decision fully apprised of the fact that it was disregarding this Court's precedent and the view of the majority of federal courts.

Accordingly, every factor for granting *certiorari* is present here.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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