Nos. 09-993 VIDE 09-1039, 09-1501

In The Supreme Court of the United States

PLIVA, INC., *ET AL.*, 09-993 *vide* 09-1039, *Petitioners*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH LLC, 09-1039 *vide* 09-993, *Petitioner*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS INC., 09-1501, *Petitioner*,

v.

JULIE DEMAHY, *Respondent*.

On Writs of Certiorari to the U.S. Courts of Appeals for the Fifth and Eighth Circuits

REPLY BRIEF OF PETITIONERS PLIVA, INC.; TEVA PHARMS. USA, INC.; AND UDL LABS, INC.

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March 23, 2011

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INTRODUCTION

Respondents virtually abandon the primary position they took below, and which most lower courts have adopted—that generic companies are subject to state-law failure-to-warn liability no less than branded companies, because they have no less power than branded companies to alter their warnings unilaterally. As the government explains, that position is manifestly incorrect. In contrast to branded companies, federal law precludes generic companies from altering their warnings unilaterally. That fundamentally distinguishes *Wyeth*. Here, generic companies are prohibited from altering their warnings not only by "specific agency regulation[s] bearing the force of law," *cf. Wyeth v. Levine*, 129 S. Ct. 1187, 1203 (2009); *id.* at 1204 (Breyer, J., concurring), but by the Hatch-Waxman Act itself.

That should be the beginning and end of this case. Under conflict preemption principles as old as our republic, state law cannot punish petitioners for using the warnings federal law compelled them to use. *See Gibbons v. Ogden*, 22 U.S. 1, 210 (1824). And because courts across the country are allowing juries to render massive verdicts—including punitive damages—based on the false premise that generic defendants simply could have printed new labels, it is essential that this Court reverse *Demahy*'s holding that generic companies can act unilaterally.

Undeterred, respondents seek to avoid federal law's preemptive effect by asserting a novel alternative theory. They claim that even if federal law precluded petitioners from communicating different warnings *to them*, petitioners should have

communicated with *a federal agency* that has sole authority to approve generic warnings, and which in turn *might have* authorized a change. That theory, which hinges on a hypothetical state-law "duty to ask FDA," provides no refuge.

To begin with, the very existence of that duty is dubious. Though respondents assert their claims are "traditional," neither they, the lower courts, nor their *amici* identify any case recognizing this exotic *state-law* duty to communicate with a *federal agency*. Instead, they simply assume its validity, and then seek to mold the malleable contours of that novel duty to their needs.

This Court need not resolve respondents' state-law contentions, however, because federal law preempts their state-law theory in any event. The Supremacy Clause forecloses state-law claims that depend on speculation about how a federal agency would exercise its exclusive authority, *Arkansas La. Gas Co. v. Hall* ["*Arkla*"], 453 U.S. 571 (1981), or that otherwise impose or enforce duties to a federal agency, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Those principles are dispositive.

As respondents eventually concede, FDA's hypothetical response to a proposed labeling change is "relevant" (*read*: dispositive) to whether federal law allows their claims to proceed. Resp. Br. 41 n.35. *Arkla* therefore is indistinguishable. It held that the plaintiffs' traditional breach-of-contract claims were preempted because federal law gave the Federal Power Commission sole authority to approve gas rates (just as federal law gives FDA sole authority to approve generic labeling), and because speculating about how FPC might have exercised that authority

usurped FPC's authority (just as speculating about FDA's response here would usurp *its* authority).

The government's alternate claim that respondents' *state* claims can proceed *only* because they are premised on violations of an alleged *federal* duty to ask FDA fares no better. That novel federal duty is as dubious as the novel state-law duty respondents concoct. Indeed, it rests on the same "inherently suspect" source *Wyeth* rejected: a preamble the government admits is not tied to a "formal regulation." *Compare* U.S. Br. 21 *with Wyeth*, 129 S. Ct. at 1201.

But even if that alleged *federal* duty does exist, it would not support *state-law* claims. As *Buckman* recognized (at the government's urging), Congress gave the *federal* government exclusive authority to enforce obligations to communicate *to FDA*, because communications between regulated parties and their *federal* regulators are inherently *federal*. The government's current position directly conflicts with its past representations, and the government hardly tries to reconcile it.

Make no mistake: Petitioners are not suggesting they have no obligation to ensure the safety of their products, or that they are immune from liability. *Federal law* requires generic companies to communicate adverse event data to FDA, and *the federal government* has plenary authority to enforce those obligations. But as the government recognized in *Buckman*:

> If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law,

> how best to obtain the information they need and how to sanction those who fail to provide such information.

Br. of the U.S. as *Amicus Curiae*, *Buckman*, 2000 WL 1364441, *18 (Sept. 13, 2000) ["*Buckman* Br."]. The government's desertion of its *prevailing* position in *Buckman* is inexplicable—and this Court should not countenance its attempt to abdicate the enforcement authority Congress reserved to the United States.

ARGUMENT

I. FEDERAL LAW PREEMPTS STATE-LAW CLAIMS THAT PETITIONERS WERE OBLIGATED TO ALTER THEIR WARNINGS.

The government's brief confirms that petitioners "could not properly have invoked the CBE or PAS process, or sent [a Dear Doctor] letter." U.S. Br. 12. Instead, federal law precludes generic companies from unilaterally altering their warnings, by repeatedly requiring that branded and generic warnings be "the same." *See* PLIVA Br. 30-47; U.S. Br. 14-19. The ordinary operation of the Supremacy Clause thus bars state-law failure-to-warn claims: Generic companies cannot simultaneously fulfill a federal duty to provide "the same" warnings and a state-law duty to provide "different" ones. *See, e.g.*, *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985); *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

A. Petitioners Could Not Have Used The CBE Process.

Respondents no longer defend *Demahy*'s remarkable assertion that the sameness requirements apply only before approval, JA534-35. Instead, and despite FDA's longstanding position that generics may not use the CBE process to deviate from the branded warnings, *see* PLIVA Br. 19-20, 32-36, 41-43, respondents now insist that the sameness requirements do not actually preclude generics from using different warnings at all—and thus that petitioners unilaterally could have executed changes via CBE. Resp. Br. 33-35.

Their contention rests on an FDA regulation that allows generics unilaterally to implement certain "'labeling revisions made to comply with current FDA labeling guidelines or other guidance.'" *Id.* 34 (quoting 21 C.F.R. § 314.94(a)(8)(iv)). But there is a simple reason why even *Demahy* did not invoke this narrow exception: FDA did not issue "labeling guidelines or other guidance" that would have allowed petitioners to alter their metoclopramide warnings, so there was never a pertinent FDA guidance with which such changes would have "compl[ied]." *See also* U.S. Br. 16 n.7. And construing this narrow exception to permit changes absent a prior FDA directive would swallow the sameness rule, by allowing disparate warnings any time a generic company wants. Respondents' distortion of this narrow exception is meritless.

B. Petitioners Could Not Have Used The PAS Process.

Respondents no longer claim that the PAS regulation's authorization for changes that "are not

limited to" those specifically enumerated somehow overrides the regulation's specific "except[ion]" of changes "described in [the CBE subsection]." *Compare* 21 C.F.R. § 314.70(b)(2) *with id.* § 314.70(b)(2)(v)(A). Instead, they now assert that the "except clause" simply grants the option of altering warnings through either a PAS or CBE. Resp. Br. 32.

That contrived interpretation does not help respondents, however, because "FDA does not interpret its regulation that way." U.S. Br. 17. Instead, FDA construes the "except" clause consistent with its plain meaning—as excepting from the PAS process any changes subject to the CBE process. *See id.* Respondents do not even try to argue that FDA's interpretation is "plainly erroneous or inconsistent with the regulation," and FDA's view thus is "controlling." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quotation omitted).[1]

C. Petitioners Could Not Have Sent A "Dear Doctor" Letter With Different Warnings.

Finally, respondents assert that petitioners could have sent a Dear Doctor letter ("DDL") with different warnings, because such letters are "promotional labeling" allegedly "not subject to [the sameness]

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[1] The sameness requirements would in any event "prevent approval of a PAS [that would] diverge from the RLD's approved labeling." U.S. Br. 17. While FDA nonetheless claims it "would not have ignored" an improper PAS, *id.* 18, FDA still would have had to approve the proposed change for the RLD before petitioners could have implemented and delivered it. *See* Br. 46 n.14; *see also infra* § 2.

requirement." Resp. Br. 36. That assertion is groundless. Generic and branded "labeling" must be "the same," *e.g.*, 21 U.S.C. § 355(j)(2)(A)(v), and "labeling" is all-encompassing: It includes "all labels and other written, printed, or graphic matter" regarding drugs. 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2).

Respondents claim there is a "critical regulatory distinction" between labeling approved during FDA's initial review and post-approval promotional labeling. Resp. Br. 36. But that merely retreads *Demahy*'s false dichotomy between pre- and post-approval warnings, with equally unavailing results. DDLs are not "freestanding," but instead must be read "in tandem" with the approved labeling to which they relate—and so by law must be fully "'consistent with'" it. U.S. Br. 18-19 (quoting 21 C.F.R. § 201.100(d)(1)). That makes sense. The *sameness* requirements would be irrelevant if generics could evade them simply by dispatching *different* product warnings through other channels.

Because that is precisely how respondents assert petitioners should have used DDLs, their argument cannot be squared with FDA's regulations or Hatch-Waxman's premise: that generic and branded warnings must be "the same," because generic and branded products are therapeutically "the same." Federal law thus precludes claims that petitioners should have dispatched a DDL whose content deviated from petitioners' FDA-mandated warnings.

At bottom, generic companies are powerless to change their warnings unilaterally, and federal law thus preempts respondents' failure-to-warn claims.[2]

II. FEDERAL LAW PREEMPTS STATE-LAW CLAIMS THAT PETITIONERS WERE OBLIGATED TO ASK FDA FOR A LABELING CHANGE.

Effectively conceding that petitioners could not have changed their warnings unilaterally, respondents spend most of their brief arguing that *state law* can sanction petitioners' failure *to ask FDA* for a labeling change. That theory of liability has no basis in traditional state tort law, and is in any event foreclosed by *Arkla* and *Buckman*.

A. Respondents' Theory Is Unprecedented.

Respondents first assert that petitioners are "plucking a phrase out of context from [*Mensing*]" and "mischaracterizing Plaintiffs' claims." Resp. Br. 40. According to them, their claims are "traditional inadequate-warning claims, not the hypothetical 'take steps' claims imagined by Defendants." *Id.* 44. While respondents' *complaints* may have asserted "traditional" failure-to-warn claims, the novel theory of liability respondents advanced *in the appellate*

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[2] Finally, respondents assert that petitioners could have filed a "citizen's petition" asking FDA to modify the warnings. Resp. Br. 35-36 (citing 21 C.F.R. § 10.30). Neither respondent raised this claim below, so neither appellate court addressed it. Waiver aside, FDA still would have had to approve such a petition before petitioners could have acted—just as FDA would have had to approve a PAS. *Supra* n.1.

courts—which gave rise to the decisions under review—is far from "traditional."

Indeed, petitioners are not alone in "imagining" that respondents now assert a novel state-law duty *to ask FDA*: The appellate courts likewise "imagined" that respondents were invoking "a duty under state law … to propose stronger warnings" to FDA, JA413, because that is *precisely* how respondents described their claims. In Ms. Demahy's words, Actavis "could have sought to strengthen its warnings … through the [PAS] process [and its] *failure even to seek such approval was both negligent and actionable*." Br. of Appellee, *Demahy*, 2009 WL 6297313, *28-*29 ["*Demahy* Br."] (Mar. 30, 2009) (emphasis added). Ms. Mensing used the very same words. Appellant's Opening Br., *Mensing*, 2008 WL 5707474, *30-*31 ["*Mensing* Br."] (Feb. 20, 2008).

Respondents are free to abandon that theory if they wish. In that case, the decisions should be reversed and judgment entered for petitioners: Again, federal law preempts traditional failure-to-warn claims because it is impossible for petitioners to comply with both a federal duty to issue *the same* warnings FDA approved for the branded product and a state-law duty to issue *different* warnings.

To the extent respondents continue pursuing their novel theory of liability, however, it is unprecedented. As petitioners noted in their opening briefs, neither appellate court cited any authority recognizing this novel theory. They simply assumed the existence of a "duty under state law … to propose stronger warnings" to FDA, and then rejected preemption. JA413-14; *see also* JA555-56; JA558-59.

Respondents do no better here. They cite only two state-law cases, Resp. Br. 29-30, and neither involved a defendant who lacked the legal authority to warn consumers directly, yet nonetheless was held liable for failing to ask another party (much less *a federal agency*) for permission to use different warnings. *McCormack v. Hankscraft Co.*, 154 N.W.2d 488, 495 (Minn. 1967) (manufacturer of steam vaporizer could have warned consumer injured by "scalding hot" device); *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254 (5th Cir. 2002) (brand manufacturer could have warned consumers and physicians of drug risks, and did so). The cases respondents' *amici* cite likewise are inapposite. Br. of Torts Profs. 36-37 (cases holding that tobacco and all-terrain vehicle manufacturers could have warned users); Br. of Admin. Law & Civ. Pro. Profs. 23-24 (cases holding that commercial silica and heart valve manufacturers could have warned users).

Respondents' failure to identify such a case is not surprising. In our federal republic, there is no tradition of *States* regulating communications to *federal agencies*. *Buckman*, 531 U.S. at 353.

B. *Wyeth* Does Not Support Respondents' Theory.

Respondents nonetheless strain to fit their novel failure-to-ask-FDA claims into *Wyeth*'s framework, but it provides no support. *Wyeth* addressed traditional failure-to-warn-the-user claims, and this Court allowed the claims to proceed only because the CBE process allowed Wyeth to alter its warnings unilaterally: There is "an FDA regulation that permits a [branded] manufacturer to make certain changes to its label *before receiving the agency's*

approval." 129 S. Ct. at 1196 (emphasis added); *see also id*. at 1198 ("[T]he CBE regulation permitted [Wyeth] to provide such a warning *before receiving the FDA's approval*.") (same); *id*. at 1199 ("The CBE regulation permitted Wyeth to *unilaterally* strengthen its warning.") (same).

Respondents try to escape the obvious import of those statements by asserting that *Wyeth*'s CBE holding was immaterial. Resp. Br. 46. That claim is astonishing. The parties vigorously contested the CBE issue, *e.g.*, Br. for Pet'r, *Wyeth*, 2008 WL 2273067, *34-*40 (May 27, 2008); Br. of Resp., *Wyeth*, 2008 WL 3285388, *37-*43 (Aug. 7, 2008) ["Levine Br."], and the Court's resolution of that dispute was critical. Indeed, as the government acknowledges here, Wyeth's ability to use the CBE process is precisely what averted a conflict between its state-law duty and federal law. U.S. Br. 25 n.13 ("Wyeth had a duty to provide a warning … and FDA's procedures gave Wyeth the means to do so. Wyeth, therefore, did not find itself in an impossible situation calling for preemption.") (quotations omitted). That is why the Court repeatedly stressed that Wyeth could have executed a CBE. 129 S. Ct. at 1196, 1198, 1199.

Respondents nonetheless claim that *Wyeth* turned on the proposition that "the manufacturer bears responsibility for … its label," rather than on "the availability of a single procedure, CBE." Resp. Br. 45-46. But those are two sides of the same coin:

> [T]he CBE regulation … both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA

> approval.... Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to [do so] before receiving the FDA's approval.

129 S. Ct. at 1198.

That reasoning compels a finding of preemption here. As set forth above, the CBE process does *not* allow generics to deliver new warnings without prior FDA approval. Instead, federal law *precludes* generics from exercising the powers it gives branded companies. Together with the sameness mandate (which *requires* generics to use the branded company's FDA-approved warnings), the fact that federal law withholds CBE authority from generic companies indicates that they do *not* have "ultimate responsibility" for the warnings they are obligated to use. *Cf. Wyeth*, 129 S. Ct. at 1198; *see also Abbreviated New Drug Application Regulations—Final Rule*, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) ("[T]he [generic] labeling must be the same as the [branded] labeling because the [branded] product is the basis for [generic] approval."); *id.* ("FDA will determine whether the labeling for the generic and [branded] drugs should be revised.").

Indeed, FDA's approach when a branded company withdraws its product from the market powerfully illustrates this point. Though the Agency designates one of the remaining generic companies to serve as the new reference listed drug, it has made clear that FDA—not the designated generic company—bears responsibility for updating the product warnings:

> ANDAs that refer to [the withdrawn product] may be approved by [FDA] if all other legal and regulatory requirements for the approval

> of ANDAs are met. *If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling*.

Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39629, 39630 (July 19, 2007) (emphasis added). That policy underscores the fact that generics simply do not bear the same obligations as branded companies.

Despite this, respondents claim *Wyeth* requires petitioners to prove that FDA would have rejected a proposed change. Resp. Br. 45. But as the government again acknowledges, *Wyeth*'s brief discussion of this point flowed directly from its holding that branded companies can act unilaterally. That meant Wyeth could establish a conflict between state and federal law *only* by proving that FDA would have *rescinded* a change:

> "Wyeth had a duty to provide a warning…," and FDA's procedures gave Wyeth the means to do so. Wyeth, therefore, did not find itself in an impossible situation calling for preemption. In those circumstances, the Court understandably insisted upon "clear evidence" before it could "credit Wyeth's contention that the FDA would have prevented it from adding a stronger warning."

U.S. Br. 25 n.13 (quoting *Wyeth*, 129 S. Ct. at 1198-99).

By contrast, petitioners here have borne their burden of proving the "impossible situation" Wyeth

could not: Hatch-Waxman itself is "clear evidence" that petitioners cannot alter their warnings. It thus is plaintiffs—not defendants—who must speculate that FDA would have *approved* a proposed change.[3]

C. *Arkla* Forecloses Respondents' Theory.

Whatever the contours of this novel state-law theory, *Arkla* bars respondents' claims. In direct contrast to *Wyeth*—where the plaintiff's claims could have proceeded without referencing FDA—respondents' novel theory of liability necessarily runs *through FDA*, because it depends on claims that petitioners *should have asked FDA* to approve a labeling change. *Demahy* Br., 2009 WL 6297313, *28-*29; *Mensing* Br., 2008 WL 5707474, *30-*31.

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[3] Recognizing this straightforward point, respondents assert they need not speculate about FDA's response, because their claims only require proof that the existing warnings' inadequacy caused their injuries. Resp. Br. 42-44. But the secondary authorities respondents cite describe garden-variety failure-to-warn claims, where a defendant can warn consumers directly. Here, FDA's decisionmaking severs any link between the challenged conduct—what respondents below called petitioners' "failure even to seek … approval" from FDA, *e.g.*, *Demahy* Br., 2009 WL 6297313, *28-*29—and respondents' injury. Without FDA approval, petitioners' failure to request a change could not have impacted respondents, and there would be no basis for imposing liability under basic state-law principles. *See, e.g.*, *Meany v. Meany*, 639 So.2d 229, 233 (La. 1994) (requiring "a causal relationship between the defendant's alleged negligent act and the plaintiff's injuries"); *Hudson v. Snyder Body, Inc.*, 326 N.W.2d 149, 157 (Minn. 1982) (requiring proof that defendant's "breach of duty was the proximate cause of plaintiff's injury"). That is why the Eighth Circuit recognized that respondents' theory ultimately rested on "speculation" about "what the FDA might have done." JA414.

That explains why respondents eventually concede that FDA's hypothetical response limits their ability to recover, even if they say that is so as a matter of federal rather than state law. *See* Resp. Br. 41 n.35.

That puts these cases on all fours with *Arkla*—where federal law likewise circumscribed the plaintiffs' recovery, because only FPC had authority to approve gas rates (just as FDA alone has authority to approve generic labeling changes). As *Arkla* explained, the lower court's judgment impermissibly rested on

> an assumption that the higher rate respondents might have filed with [FPC] was reasonable. Otherwise, there would have been no basis for that court's conclusion that [FPC] would have approved the rate. But under the filed rate doctrine, [FPC] alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged.

Arkla, 453 U.S. at 580-81 (citation omitted).

Respondents try to limit *Arkla* to the filed-rate context, asserting that the Natural Gas Act gave FPC the exclusive right to approve gas rates, while "'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.'" Resp. Br. 55 (quoting *Wyeth*, 129 S. Ct. at 1200). But Congress (and FDA) plainly *did* intend that generic and branded product warnings be "the same," which is why respondents retreat to claims that "Defendants could have *sought FDA approval* for stronger warnings." Resp. Br. 22 (emphasis added). Put simply, at the point where respondents' claims come to depend on FDA's pre-

approval—a decision that *by definition* is vested in FDA, *see* U.S. Br. 7—*Arkla* is indistinguishable.[4]

The government's attempt to distinguish *Arkla* fares no better. Indeed, it directly contradicts the government's position in *Buckman* and *Warner-Lambert*, where it relied on *Arkla* to advocate preemption of the state-law claims in those cases—which, as here, sought to enforce alleged state-law duties to communicate with FDA. *See, e.g.*, *Buckman* Br., 2000 WL 1364441, *25-*26 (relying on *Arkla*); Br. for the U.S. as *Amicus Curiae*, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008), 2007 WL 4218889, *20-*21 (Nov. 28, 2007) (same) ["*Warner-Lambert* Br."]. The government *now* asserts that *Arkla* and its progeny are inapposite because they involved "the extraordinarily comprehensive authority the agencies in question had in their respective fields." U.S. Br. 30-31. And it expressly disavows its prior

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[4] Respondents also claim they need not speculate about FDA's hypothetical response because FDA ultimately ordered a labeling change and because evidence allegedly would have supported that change earlier. Resp. Br. at 38-39. But as Actavis well explains, FDA had the information respondents cite *years* before ordering a change—and even then, FDA rejected the principal change respondents are demanding. Actavis Reply Br. 14-17. In any event, respondents' characterization of the non-record evidence (and especially the self-serving claims of Ms. Demahy's physician and *amicus curiae* Dr. Graves) is hotly contested. If the Court allows respondents' claims to proceed, those issues will be vigorously litigated—and the Court should not prejudice potential future proceedings by lending credence to the inaccurate factual claims set forth in those briefs.

submissions to this Court, claiming they were offered "without the benefit of … *Wyeth*." U.S. Br. 31.

Those putative justifications for the government's about-face are meritless. *Arkla* did not depend on FPC's broad authority to regulate interstate gas distribution; it turned on the fact that the specific matter about which the Louisiana courts speculated—whether "the Commission would have approved the rate," *Arkla*, 453 U.S. at 581—fell within FPC's exclusive jurisdiction. *See id.* at 581-82 ("[T]he Commission alone is empowered to make *that judgment*.... The court below [thus] usurped a function that Congress has assigned to a federal regulatory body.") (emphasis added). That is equally true here: Only FDA can approve a generic warning change, and without its prior approval, petitioners could not have delivered any other warning.

Nor does *Wyeth* undermine the government's prior reliance on *Arkla*. To the contrary, *Wyeth*'s CBE holding meant the Court did not need to address *Arkla*'s dispositive implications for the claims respondents allege. Indeed, the plaintiff's fall-back argument in *Wyeth* foreshadowed the very claims here: She argued that Wyeth at least *could have sought* changes "by submitting a supplemental application for FDA approval," and further asserted that state law did not "require … changes *without* seeking FDA's approval." Levine Br., 2008 WL 3285388, *37 (emphasis original). Wyeth in turn replied that *Arkla* foreclosed Levine's alternate theory of liability, because it would assign "juries the speculative task of determining whether and when FDA would have approved a particular hypothetical labeling change." Reply Br. for Pet'r, *Wyeth*, 2008

WL 4264481, *12 & n.7 (Sept. 15, 2008) (citing *Arkla*).

Wyeth declined to address those arguments, of course, because its CBE holding made doing so unnecessary. *Wyeth* thus provides no support for the government's decision to abandon its settled understanding of *Arkla*, and casts no doubt on *Arkla*'s dispositive application to respondents' novel theory of liability.

D. *Buckman* Forecloses The Government's Alternative Claims.

Though the government agrees with petitioners that federal law precludes generics from altering their warnings unilaterally, it apparently dislikes the preemptive result that follows. It thus seeks to evade that outcome by cobbling together a novel federal duty that just happens to mirror respondents' novel state-law claims. That effort is deeply flawed, but even on its own terms, the government's theory runs headlong into *Buckman*.

1. Federal Law Did Not Obligate Petitioners To Propose Labeling Changes To FDA.

The government begins by asserting—for the first time ever—that "ANDA holders … have a duty *under federal law* to propose appropriate changes to approved labeling." U.S. Br. 14 (emphasis added). That the government *alone* makes this argument is the first sign of trouble: When even the plaintiffs fail to assert that their state-law claims mirror a preexisting federal duty, it is a sure indication that the alleged federal duty is made from whole cloth.

The government nonetheless purports to locate this duty in 21 C.F.R. § 201.57. But § 201.57 does not say that companies (whether branded or generic) have a duty "*to propose* appropriate changes," U.S. Br. 14 (emphasis added), or "*seek to* revise their labeling." *Id.* 20 (same). Instead, it says that product warnings *actually* "shall be revised" when new information warrants. 21 C.F.R. § 201.57.

As petitioners previously explained (and the government effectively concedes), generic companies could not fulfill the *actual* § 201.57 duty if it applied to them. *See* PLIVA Br. 37-41. After all, the sameness requirements prohibit generics from revising their warnings unilaterally. That strongly indicates that § 201.57 does *not* independently apply to generics: Federal law typically does not demand the impossible. Moreover, that language was promulgated in 1979, five years *before* Hatch-Waxman's enactment. *See Content and Format Labeling for Human Prescription Drugs—Final Rule*, 44 Fed. Reg. 37434, 37463 (June 26, 1979). That likewise indicates that the § 201.57 duty applies to branded companies who (unlike generics) *can* revise their warnings unilaterally through the CBE process (promulgated in 1965).

These points readily explain why—until now—FDA repeatedly made clear that generic companies are *not* independently subject to § 201.57, and why—until now—FDA never construed § 201.57 to impose the novel federal duty the government first identifies in its merits-stage brief. Instead, FDA consistently explained that generic companies comply with § 201.57 by ensuring that their labeling is "the same as" the branded labeling. PLIVA Br. 38-40 (quoting

Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics—Proposed Rule, 65 Fed. Reg. 81082, 81098 (Dec. 22, 2000); *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products—Final Rule*, 71 Fed. Reg. 3922, 3928 (Jan. 24, 2006)).

The government makes no effort to reconcile its litigating position with the views FDA repeatedly expressed during formal rulemaking proceedings. Instead, it relies on a comment in the preamble to a different final rule, U.S. Br. 20 (quoting 57 Fed. Reg. at 17961), and then concedes that "FDA has not promulgated a formal regulation for th[e] process" it claims was "contemplated" there. *Id*. 20-21. If that curious approach to administrative law sounds familiar, it is: In *Wyeth*, the government likewise relied on a preamble issued without notice or opportunity for comment, and this Court rejected it as "inherently suspect." *Wyeth*, 129 S. Ct. at 1201; *cf. id*. at 1204 (Breyer, J., concurring) (noting FDA's failure to rely on "lawful specific regulations").

In any event, the government's preambular theory fails on its own terms. The preamble did not even cite 21 C.F.R. § 201.57—much less "explain[] how ANDA holders should discharge their duty to provide adequate warnings" apart from mirroring the approved branded labeling. U.S. Br. 20. And rather than impose a legal *duty* on generic companies to request labeling revisions, it stated only that "*if* an ANDA holder *believes* that new safety information should be added, it *should* provide adequate supporting information to FDA, and *FDA*

will determine whether the labeling … should be revised." 57 Fed. Reg. at 17961 (emphasis added).

Unlike "shall" or "must," the word "should" does not impose legal duties. *See, e.g.*, *United States v. Maria*, 186 F.3d 65, 70-72 (2d Cir. 1999); *Marshall v. Anaconda Co.*, 596 F.2d 370, 375-76 (9th Cir. 1979); *Baptist Healthcare Sys. v. Sebelius*, 646 F. Supp. 2d 28, 35 (D.D.C. 2009). Even if it did, the duty would arise only "*if* an ANDA holder *believes*" a change is warranted, not when litigants (or FDA) later assert it was. 57 Fed. Reg. at 17961. Finally, the preamble's conclusion that "*FDA will determine*" whether to accept proposed changes, *id.*, fatally undermines the government's claim that juries are free to speculate about how FDA would have exercised powers that the Agency expressly reserved *to itself*. *Arkla*, 453 U.S. at 581.

Equally unprecedented is the government's assertion that a generic product which complies with the sameness mandate nonetheless can be "misbranded" if its manufacturer fails "to seek" a labeling change from FDA. U.S. Br. 26. The government relies on § 201.57 and the preamble for this point, but neither supports this extravagant claim (as explained above). Nor does the government identify any case in Hatch-Waxman's 27-year history where it brought a misbranding claim based on this novel theory. *See Wyeth*, 129 S. Ct. at 1197 (questioning FDA's theory of misbranding because FDA never brought suit under that theory). And the theory in any event is absurd: Misbranding turns on the label's content, not on whether the company contacted FDA; the label is either misbranded or not, and it is hard to see how sending FDA a letter

changes that. At bottom, it defies logic to say a generic product can be misbranded when it bears the very label federal law requires. *Cf. SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 27 (2d Cir. 2000) (generic label that complied with sameness requirement cannot plausibly give rise to copyright infringement liability).

If FDA wants to establish a new federal duty to propose labeling changes, it can start rulemaking tomorrow. But it has no business urging this Court to impose an unprecedented federal duty that just happens to mimic respondents' unprecedented state-law theory.

2. Only The United States Can Enforce A Duty To Communicate With FDA.

Even if federal law did obligate petitioners to request a labeling change from unknown "points of contact" within FDA, U.S. Br. 21, *Buckman* forecloses state-law claims effectively seeking to enforce that duty. As this Court recognized, "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [law]: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" 531 U.S. at 349 n.4 (quoting 21 U.S.C. § 337(a) (alteration original)); *id.* at 352 ("[W]e have clear evidence that Congress intended that the [statute] be enforced exclusively by the Federal Government.") (citing § 337(a)).

Indeed, allowing *state-law* claims that petitioners allegedly failed to communicate *with FDA* raises the precise concerns the government expressed (and this

Court adopted) in *Buckman*: that private actions eviscerate FDA's enforcement discretion, by disrupting its ability to determine both *whether* and *how* to pursue alleged violations of the duties companies owe FDA. *Id.* at 349-51. In the government's words, private enforcement would:

(1) "permit juries in different States to reach judgments that differ from FDA's" about whether companies violated their duties to FDA, and "impose massive liability, when FDA would not find any misconduct";

(2) "distort the penalty scheme established by the statute," by providing remedies Congress withheld; and

(3) "interfere with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue," by allowing juries to "substitute their judgments for FDA's as to the appropriate sanction."

Buckman Br., 2000 WL 1364441, *23-*24 (quotations omitted; citing *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 380 (2000); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)); *see also Warner-Lambert* Br., 2007 WL 4218889, *18-*19 ("[T]he FDCA gives FDA 'complete discretion' to pursue those remedies that, in the agency's judgment, best fit a violation…. Awards of damages … interfere with FDA's determination of the appropriate remedy.") (quoting *Heckler v. Chaney*, 470 U.S. 821, 835 (1985)).

The government again fails to square its current position with its past ones. Instead, it simply asserts that "there is no reason to suppose a conflict between

federal and state law if both demand the same conduct." U.S. Br. 26. But that equally was true in *Buckman* and *Warner-Lambert*, where the state-law claims targeting defendants' communications to FDA fully mirrored federal disclosure requirements. The government nonetheless argued—and *Buckman* agreed—that such claims were preempted because they involved communications *to a federal agency*:

> If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how to sanction those who fail to provide such information.

Buckman Br., 2000 WL 1364441, *18; *see also Buckman*, 531 U.S. at 347-48 ("[P]etitioner's dealings with the FDA [are] prompted by [federal law], and the very subject matter of petitioner's statements [to FDA are] dictated by [it]s provisions.").[5] As in *Wyeth*, the government's "dramatic change in position" divests it of deference. 129 S. Ct. at 1203.

Respondents seek to distinguish *Buckman* by asserting that their "traditional failure-to-warn claims long 'predated the federal enactments in question.'" Resp. Br. 57 (quoting *Buckman*, 531 U.S. at 353). But that simply is not so: As in *Buckman*,

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[5] As for the government's claim that *Buckman* is distinguishable because it involved a "collateral attack" on a prior FDA decision, U.S. Br. at 31, that was the concurrence's view—not the Court's (or the government's). *See Buckman*, 531 U.S. at 354-55 & n.2 (Stevens, J., concurring).

respondents' novel theory hinges on claims that petitioners were obligated to disclose information *to FDA*.[6] Once respondents resort to arguing that petitioners were obligated to communicate *with FDA*, the claims are no longer "independent of the federal statutes that establish federal regulatory agencies and require regulated entities to make certain disclosures to those federal agencies." *Buckman* Br., 2000 WL 1364441, *18. Instead, the federal framework is "a critical element." *Buckman*, 531 U.S. at 353. Federal law thus forecloses respondents' novel theory of liability.

CONCLUSION

The judgments should be reversed.

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[6] Indeed, *Buckman* distinguished *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), on precisely that ground—noting that neither involved communications to a federal agency, but respectively "arose from the manufacturer's alleged failure to use reasonable care in the production of the product," *Buckman*, 531 U.S. at 352, and "the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Id.*

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