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

In the Supreme Court of the United States

PLIVA, INC., ET AL., PETITIONERS

v.

GLADYS MENSING, RESPONDENT

ACTAVIS ELIZABETH, LLC, PETITIONER

v.

GLADYS MENSING, RESPONDENT

ACTAVIS INC., PETITIONER

v.

JULIE DEMAHY, RESPONDENT

ON WRITS OF CERTIORARI TO THE UNITED STATES COURTS OF APPEALS FOR THE EIGHTH AND FIFTH CIRCUITS

BRIEF FOR THE NATIONAL CONFERENCE OF STATE LEGISLATORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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Statement of Interest*

Amicus the National Conference of State Legislatures (NCSL) is a bipartisan organization that serves the legislators and staffs of the Nation's 50 States, its commonwealths and territories. NCSL provides research, technical assistance, and opportunities for policymakers to exchange ideas on the most pressing state issues. NCSL advocates for the interests of state governments before Congress and federal agencies, including the Food and Drug Administration (FDA), and it regularly submits briefs amicus curiae to this Court in cases that raise issues of vital state concern.

In *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), this Court held that the federal regulatory regime governing pharmaceuticals does not preempt state law failure-to-warn claims against the manufacturer of a brand name drug. Petitioners here claim that various federal regulations relating to generic drugs should be interpreted to preempt traditional state law remedies as to manufacturers of generic drugs. Like *Wyeth*, in which NCSL submitted a brief opposing preemption, this case implicates several areas of core concern and special expertise for NCSL, its members, and their respective States.

The state interests implicated here are many and vital. The formulation of public policy on health

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* Pursuant to Supreme Court Rule 37.6, amicus affirms that no counsel for a party authored this brief in whole or in part and that no person other than amicus and its counsel made a monetary contribution to its preparation or submission. All parties' letters consenting to the submission of amicus briefs have been filed with the Clerk's office.

care, insurance, safety, and welfare, including regulation of medicine and pharmacy, have historically been the responsibility of the States. Consumer protection and providing means of redress for personal injuries have also been the province of state legislatures and courts.

State legislatures have decades of experience with the issues most directly implicated in this case. Even before the 1984 Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (FDCA), States were at the forefront of efforts to control public and private health care costs through policies aimed at increasing the availability and public acceptance of generic drugs. Moreover, state legislatures across the country have considered and enacted significant civil justice reform measures, carefully weighing complaints about the fairness, predictability and efficiency of liability rules. While different States have taken different approaches, these efforts typically represent serious efforts to reconcile important state interests in promoting safety and providing redress with reducing litigation and health care costs.

States have a strong interest in vindicating the presumption against preemption and the presumption's corollary: that, consistently with the Constitution, decisions to oust States from areas of their traditional authority, even when fully within Congress's powers, should be made by Congress. Not only is that the branch of government in which States enjoy representation, but neither courts nor administrative agencies are as well-equipped to evaluate the complex, competing policy considerations that preemption questions typically present.

Indeed, this case vividly illustrates the reasons for adhering to the constitutional allocation of policymaking authority – and the dangers of free-form judicial or administrative preemption.

SUMMARY OF ARGUMENT

The plea at the heart of this case fails for the same reason as the one rejected in *Wyeth*: the absence of any showing that Congress intended to divest States of their historic power to provide a remedy against those whose defectively marketed products caused injury. Federalism is not only a principle, but a system of government: As mentioned, providing compensation for injured citizens and regulating health care professions are not merely areas where the States claim jurisdiction by tradition, but ones where they have responsibilities that federal authorities do not share.

This Court's precedents counsel great hesitation before accepting claims of implied preemption, and for good reason. Implied preemption based upon penumbras and emanations from federal regulation, and facile claims of federal administrative inconvenience, deprives States of their best, constitutionally promised means of upholding their duly enacted policies: their representation in Congress. In this case, the argument against preemption is overwhelming because Congress displayed no intent to disturb States' longstanding and complementary role. Petitioners' claims of "irreconcilable conflict" are painfully thin and are disavowed by the agency on whose behalf they are ostensibly asserted.

Under the regime petitioners advocate, an individual prescribed the same drug bearing the same inadequate warning and injured thereby will be denied recourse – either because the pharmacist elected to fill the prescription with a generic drug, or because the insurer or State's Medicaid law provides for or insists on generic substitution. Such a rule would unsettle bedrock assumptions that have guided state law in this field for decades. All of the States have adopted carefully drawn policies on generic substitution, which encourage and often require the dispensing of generic drugs except where the patient has a specific medical need for the brand drug. These policies have been a major factor in expanding demand for generic drugs. The bizarre, disparate liability regime for brand and generic drugs that petitioners posit would put both health care providers and patients in a quandary and would cause the confusion and reluctance to accept bioequivalent drugs that petitioners claim are critical federal concerns.

In the absence of any indication that Congress intended such a regime, petitioners advance arguments based on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981) (*ArkLa*), to the effect that tort duties of care are incompatible with the FDA's exercise of its statutory responsibilities. *Buckman* has little if any relevance to this case. As the *Wyeth* Court explained in rejecting a similar *Buckman*-based argument, claims based upon traditional common law duties do not resemble the novel "fraud on the FDA" third-party claim at issue in *Buckman*.

ArkLa and *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), are no more helpful. Like *Buckman*, both cases entailed attempts to have a state court overturn a particular federal agency decision on a matter within the core of the agency's jurisdiction. Here, petitioners do not attack any FDA decision, and the agency's approval of an abbreviated new drug application (ANDA) or its corresponding label is not a determination that warnings are adequate for all time. On the contrary, consistent with the common law, the agency requires that warnings be modified as new risk information develops. Indeed, for reasons *Wyeth* highlighted, the regime here is nearly the opposite of the "filed rate" approach to utility rate regulation at issue in *ArkLa*. Tort liability gives regulated parties practical incentives to take actions – updating warnings to reflect new information – that serve core federal safety objectives. Those same objectives would be undermined by a "filed-rate" type rule requiring adherence to outdated warnings no matter what the circumstances.

Equally unavailing are petitioners' efforts to derive general preemption principles claim from broad *language* in the *Buckman* and *ArkLa* opinions. They worry that state law might "skew" a tacit federal balance; that a federal standard may be a ceiling rather than a floor; or that state law might lead to unwelcome burdens on federal regulators. But such amorphous concerns are less arguments for preemption here than for unrestricted preemption everywhere, including anywhere the federal government has acted or could have, but did not.

ARGUMENT

I. BROAD CLAIMS OF IMPLIED PREEMPTION LIKE THOSE ADVANCED HERE ARE INCONSISTENT WITH OUR CONSTITUTIONAL FRAMEWORK AND THREATEN TO UNDERMINE STATE GOVERNMENT AND ADMINISTRATION

The preemption plea at the heart of this case is in every way extraordinary. Petitioners do not identify any statutory basis for preemption. Nor do they seriously argue that Congress considered displacing any state law, including traditional state common law remedies, in enacting the FDCA or the Hatch-Waxman Amendments. Rather, petitioners invite the Court to invalidate the laws of fifty States and upset decades of state-level policymaking based on a claimed "conflict" between the common law duties and a disputed agency interpretation of certain of its regulations – indeed, one for which the agency itself disclaims preemptive intent or effect.

Under the Constitution and this Court's precedents, such claims warrant severe skepticism. Precisely because the Constitution limits the power to displace state law to "laws of the United States," *i.e.*, acts that have withstood a carefully crafted legislative process hedged with safeguards for "States *qua* States," such claims must clear "a high threshold." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring). A lesser standard would undercut "the principle that it is Congress rather than the courts that pre-empts state law." *Id.* at 111. *See also Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act, let alone pre-

empt the [law] of a sovereign State, unless and until Congress confers power upon it."); *cf. Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) (with "implied" rights of action, "[a]gencies may play the sorcerer's apprentice but not the sorcerer himself").

Indeed, insistence on a congressional warrant for preemption takes on greater significance as judicial enforcement of limits on federal power has ebbed, and the federal government has not only claimed, but pervasively exercised, authority in numerous areas previously left to the States. *See Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991) ("[I]nasmuch as this Court in *Garcia* [*v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 550-54 (1985)], has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise."); *Wyeth*, 129 S. Ct. at 1205-17 (Thomas, J., concurring in the judgment).

It is telling that petitioners' amici assert that "only the FDA can see the whole picture." Generic Pharm. Ass'n Br. 27-28. But such faith in the peripheral vision of federal administrators is misplaced. Single-subject administrative agencies are not empowered to consider, let alone act upon, the broad range of interests and perspectives state legislatures must weigh. For example, in this case, it is undisputed that compensation for persons injured by prescription drugs is simply not within the FDA's mandate.[1]

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[1] Thus, while the FDA regularly adverts to its reluctance to intrude on the "practice of medicine" as a reason broadly to allow off-label uses of drugs, it is States

Indeed, all too often, federal agencies have scant interest in seeing as much of "the whole picture" as they could. NSCL's amicus brief in *Wyeth* described a stark example: Although Executive Order 13,132 ("Federalism") (Aug. 4, 1999) requires in the plainest terms that every agency provide to "all affected State and local officials" advance notice, and appropriate opportunity to be heard, whenever they "propose[] to act through adjudication or rule-making to preempt State law," the FDA had afforded no consultation and prepared no "federalism impact statement" for the 2006 regulatory preamble considered in *Wyeth*. This preamble had purported, for the first time, to preempt tort suits against drug manufacturers. *See* NCSL Br. 2 (explaining that NCSL Executive Branch Liaison had requested, but had been denied a copy of the proposal, on which the FDA accepted comments from industry groups); *see also* Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 783 (2004) (reporting that "only five" federalism impact statements had been filed "for the over 11,000 final rules" reviewed).

Much of the same may be said of courts. Although 28 U.S.C. § 2403(b) requires notice to a State's Attorney General whenever "the constitutionality of any statute of that State" affecting the public interest is drawn in question," providing the State with the litigation rights (far stronger protection than the administrative regime applicable, though

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that are responsible for oversight of the medical professions – and that have a strong and independent interest in ensuring that physicians are kept fully up-to-date about hazards associated with prescription drugs.

casually disobeyed, in *Wyeth*), this rarely, if ever occurs in implied preemption cases.

Finally, lax and casual standards for administrative agency conflict preemption create powerful incentives to bypass Congress entirely, particularly since in Congress – where States are represented – preemption proposals can be contested. Under our federal system, congressional debates over the appropriate role for state law should be the "main event," rather than a mere "tryout" prefatory to an agency preemption decision. *Wainwright v. Sykes*, 433 U.S. 72, 90 (1977). To paraphrase Justice Scalia, "only the most sporting of [industry interest groups]," would run the legislative gauntlet and seek preemption from Congress, if statutory silence plus an agency preamble (or brief), or a generalized claim of agency diversion, were enough to extinguish venerable common law rules nationwide. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 548 (1992) (dissenting in part).

II. PETITIONERS' PROPOSED RULE OF BROAD IMMUNITY FOR GENERIC DRUG MANUFACTURERS FROM STATE LAW WOULD IMPAIR IMPORTANT STATE INTERESTS AND WOULD DISRUPT STATE HEALTH CARE AND CONSUMER PROTECTION POLICY

The immunity for manufacturers of generic drugs would have significant adverse consequences for the States as the principal protectors of their citizens' health, safety, and welfare; as guardians of the public fisc; and as licensors and regulators of their health care professionals. Petitioners' rule would create an odd disparity, invisible and unfathomable to ordinary consumers, between the legal remedies

respecting brand versus generic drugs. It would, in practical effect, make States financially responsible for injuries caused by the negligence of a class of for-profit corporations. It would give doctors and patients incentives not to select cost-saving generic substitutes. It would undermine basic premises of state legislation concerning substitution of generic drugs. While petitioners profess concerns about hypothetical burdens on the federal agency (going far beyond even those expressed by the agency), they entirely ignore the drastic implications their rule would have for the state-federal balance.

A. State Generic Substitution Laws Have Played an Important Role in the Development of Generic Drug Markets and Illustrate the States' Vital Interest in this Area

Partially in response to the enactment of Medicaid in 1965, and with the active encouragement of the FDA and the Federal Trade Commission (FTC), every State adopted laws permitting substitution of generic drugs between 1970 and 1984.[2] State

[2] Many States drew guidance from the FDA's 1979 Model Drug Product Selection Act, which encouraged States to permit pharmacists to select cheaper generic drug equivalents for brand name prescriptions by requiring doctors to affirmatively indicate when substitution was not allowable. *See* 44 Fed. Reg. 2932 (1979); FTC, Bureau of Consumer Protection, Drug Product Selection (1979). Twenty-three States adopted or amended their generic drug substitution laws after the Model Act's promulgation. *See* Kenneth W. Shafermeyer, *et al.*, *The FDA Orange Book: Expectations Versus Realities*, 1 J. PHARM. & L. 13, 17 (1991). *See also, e.g.*, Nevada State Legislature, Background Paper 79-11, Generic v. Brand Name Drugs at 6 (1979).

"generic substitution" policies have also contributed significantly to the dramatic growth in the use of generic drugs.

All the States and the District of Columbia now have statutes providing for the substitution of generic drugs when a prescription refers to a brand drug.[3] These laws encourage, and often require, that pharmacists fill a prescription identifying a brand drug with a medically equivalent, lower-cost generic

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[3] ALA. CODE § 34-23-8; ALASKA STAT. § 08.80.295; ARIZ. REV. STAT. § 32-1963.01; ARK. CODE ANN. § 17-92-503; CAL. BUS. & PROF. CODE § 4073; COLO. REV. STAT. § 12-22-124; CONN. GEN. STAT. § 20-619; DEL. CODE ANN. tit. 24, § 2549; D.C. CODE § 48-803.02; FLA. STAT. § 465.025; GA. CODE ANN. § 26-4-81; HAW. REV. STAT. § 328-92; IDAHO ADMIN. CODE r. 27.01.01.188; 225 ILL. COMP. STAT. 85/25; IND. CODE § 16-42-22-8; IOWA CODE § 155A.32; KAN. STAT. ANN. § 65-1637; KY. REV. STAT. ANN. § 217.822; LA. ADMIN. CODE tit. 46, § 2511; ME. REV. STAT. ANN. tit. 32, § 13781; MD. CODE ANN., HEALTH OCC. § 12-504; MASS. GEN. LAWS ch. 112, § 12D; MICH. COMP. LAWS § 333.17755; MINN. STAT. § 151.21; MISS. CODE ANN. § 73-21-117; MO. REV. STAT. § 338.056; MONT. CODE ANN. § 37-7-505; NEV. REV. STAT. § 71-5403; NEV. REV. STAT. ANN. § 639.2583; N.H. REV. STAT. ANN. § 318:47-d; N.J. STAT. ANN. § 24:6E-7; N.M. STAT. § 26-3-3; N.Y. EDUC. LAW § 6816-a; N.C. GEN. STAT. § 90-85.28; N.D. CENT. CODE § 19-02.1-14.1; OHIO REV. CODE ANN. § 4729.38; OKLA. STAT. tit. 59, § 353.13; OR. REV. STAT. § 689.515; 35 PA. CONS. STAT. § 960.3; R.I. GEN. LAWS § 5-19.1-19; S.C. CODE ANN. § 39-24-30; S.D. CODIFIED LAWS § 36-11-46.1 -46.4; TENN. CODE ANN. § 53-10-205; 22 TEX. ADMIN. CODE § 309.3; UTAH CODE ANN. § 58-17b-605; VT. STAT. ANN. tit. 18, § 4605; VA. CODE ANN. § 54.1-3408.03; WASH. REV. CODE § 69.41.120; W. VA. CODE § 30-5-12b; WIS. ADM. CODE DHS § 107.10; WYO. STAT. § 33-24-149.

when one is available – unless the prescribing health professional has specifically directed that only the brand drug be used (often called a "Dispense as Written" instruction), or (in some jurisdictions) if the patient refuses substitution.[4] While state laws preserve physicians' discretion to specify that only brand drugs be dispensed, some require an express determination by the prescriber that the brand drug is "medically necessary,"[5] or forbid the pre-marking of prescription forms to preclude generic substitution, or require that "brand only" specifications be hand-written.[6]

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[4] For example, the Minnesota statute in respondent Mensing's case, *see* J.A. 402, provides that, if the doctor prescribes a brand drug and specifies "Dispense as Written," or "D.A.W.," the pharmacist shall dispense the specified brand drug, but that if the prescriber does not so specify, and "there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects." MINN. STAT. § 151.21(2), (3). *See also* LA. ADMIN. CODE tit. 46, § 2511 (statute at issue in *Demahy*).

[5] *E.g.*, TENN. CODE ANN. § 53-10-204(a)(1) (defining medical necessity as situations where "[a]n adverse reaction previously experienced by the patient to a generic equivalent" or a generic equivalent "has previously been demonstrated as ineffective for the patient"; or "[a]ny other clinically based prescriber determined need").

[6] *See, e.g.*, S.D. CODIFIED LAWS § 36-11-46.2; 22 TEX. ADMIN. CODE § 309.3(c)(2)(A),(C).

Recognizing that potential tort liability could affect physicians' willingness to allow generic substitution, or pharmacists' willingness to substitute generic for brand drugs even though authorized by the prescription, many States have enacted laws shielding health professionals from suits for substituting generic drugs in accordance with state law.[7]

The generic substitution statutes also attest to States' interest in ensuring that patients are aware of their options concerning generic substitution. Some States require that prescription forms make clear whether the physician has directed that only the brand drug be dispensed;[8] others require pharmacists to inform patients of lower-priced prescription options;[9] while still others require pharmacies to post prominent signs informing

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[7] *E.g.*, KAN. STAT. ANN. § 65-1637(c)(2) (physicians); N.Y. EDUC. LAW § 6816-a(6)(d); N.D. CENT. CODE § 19-02.1-14.1; 35 PA. CONS. STAT. § 960.6(B).”). *See also* ARIZ. REV. STAT. § 32-1963.01(G) (pharmacists); ALASKA STAT. § 08.80.295(b); MD. CODE ANN., HEALTH OCC. § 12-504(h).

[8] *E.g.*, WASH. REV. CODE § 69.41.120. (“[T]he prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words 'DISPENSE AS WRITTEN'. Under the line at the left side shall be clearly printed the words 'SUBSTITUTION PERMITTED'”).

[9] *E.g.*, HAW. REV. STAT. § 328-92(a) (requiring that pharmacists, when filling a prescription for a brand drug, “offer the consumer an equivalent generic drug product” upon request, “inform the consumer of the savings,” and “[i]nform the consumer of the consumer's right to refuse substitution”).

customers of their option of filling their prescriptions with generic alternatives.[10]

State policies favoring generic substitution are given special force in the context of publicly-funded programs such as Medicare, Medicaid and State Children's Health Insurance (SCHIP). Some generic substitution statutes distinguish between governmentally financed health care programs and private insurance or self-funding patients. *See, e.g.*, IND. CODE §§ 16-42-22-8, 16-42-22-10. Many States require that prescriptions for patients whose drug expenses are covered by those programs be filled with generic drugs.[11] The Federal government has

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[10] For example, Connecticut requires each pharmacy to post, on a sign bearing large block letters posted at the prescription counter, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." CONN. GEN. STAT. § 20-619 (d). *See also* FLA. STAT. § 465.025 (7); IDAHO ADMIN. CODE r. 27.01.01.188; OR. REV. STAT. § 689.515.

[11] "Since 2000, there has been a steady trend toward increased mandatory generic substitution. In 2005, nearly all states * * * reported that they require generics to be dispensed when available." Henry J. Kaiser Family Foundation, State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey (October 2005). *See also* William H. Shrank, *et al.*, *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1384 (2010) (discussing varieties of mandatory generic substitution and patient consent laws affecting state Medicaid programs); *id.* at 1386 Ex. 1 (table).

actively encouraged these policies. *See, e.g.*, 42 U.S.C. § 1396b(z)(2)(E); Office of Inspector General, Department of Health and Human Services (HHS), Generic Drug Utilization in State Medicaid Programs at i (2006) ("The [HHS] Centers for Medicare & Medicaid Services (CMS) has encouraged generic drug substitution * * * as a safe and effective way for States to increase generic drug utilization and reduce costs.").

B. Petitioners' Proposed Tort Immunity for Generic Manufactures Would Seriously Unsettle State Policy

The broad tort immunity sought here would have far-reaching and problematic consequences for the laws just summarized, and the important state interests and policies these serve. States have encouraged the substitution of generic drugs because of the significant benefits these drugs' lower costs offer for state citizens, and for state-funded public health and insurance programs. They have proceeded on the premise that (save for unusual instances of individual medical need), generic drugs are not, from citizens' perspective, materially different from brand ones, except for the lower price.

Granting the federal law tort immunity petitioners seek would mean that, contrary to appearances, there is, in fact, a significant – but latent – difference between every brand and every generic drug from the perspective of doctor and patient. If a consumer is injured as a result of an inadequate warning on a brand drug, he would have recourse under state law against the manufacturer. But if the injury was caused by "*the same*" warning on a bioequivalent generic drug, the injured person

has no remedy against a manufacturer who knew of the danger but did nothing to prevent it.

Such a regime is not only "bizarre" from the perspective of the unwitting consumer, *see Demahy*, 593 F.3d at 449, but it would present serious problems for States. The state generic substitution laws just discussed – which have been enacted with the active encouragement of the federal government (and without objection from generic drug manufacturers) – have informed citizens that they should not hesitate to accept generic alternatives, even when their doctor has prescribed the brand drug. Often, particularly in the case of poorer citizens under programs like Medicaid, these policies provide that they *must* accept the generic alternative. Similarly, the statutes have encouraged or required physicians to allow generic substitution unless there is a *medical* reason for specifying the brand, and, in many circumstances, have mandated that pharmacists fill prescriptions for brand drugs with generic substitutes.

Petitioners' preemption rule would undermine basic premises of this regime. Consumers without medical or pharmacy degrees would be unlikely to be aware of this major disparity between the legal incidents flowing from the choice between brand and generic drugs. Out of candor to their citizens, States might well alter their rules, to inform the public of that potentially significant disparity between products they have been repeatedly told are "the same." And disseminating the message that "MANUFACTURERS OF GENERIC DRUGS CANNOT BE LIABLE FOR FAILURE TO WARN OF HEALTH RISKS ASSOCIATED WITH THEIR PRODUCTS" could lead some patients – at least

those financially able to do so – to spurn generic drugs, undermining the policies of the Hatch-Waxman Act and state generic substitution laws alike.

Immunity for manufacturers would also have significant repercussions for States in their capacity as regulators of the health care professions. State laws shielding physicians and pharmacists from liability for allowing or undertaking generic substitution reflect the commonsense reality that legal liability rules can influence the behavior even of highly trained professionals concerning the choice between medically equivalent drugs. If generic drug manufacturers are immune, however, some doctors may be deterred from allowing generic substitution, knowing that they alone could face liability if a generic drug caused their patient to suffer injury. If they specified the brand name drug, however, the situation would be markedly different. Even doctors who did not share that concern or chose not to act on it might feel qualms about relegating their patient – at least without express consent – to a drug whose manufacturer would be immune from suit when it failed to disclose information that would have prevented grievous harm. (Whether such action would be permissible under current laws limiting brand specification to "medical necessity" is unclear.) And, of course, physicians' very ability to treat their patients effectively depends upon their receiving up-to-date and comprehensive information concerning health risks associated with drugs.

Indeed, this calls attention to two very basic embarrassments in petitioners' argument. First, while their plea for preemption depends almost entirely on the notion that Congress or the FDA

require "sameness" for generic and name-brand drugs, these arguments are made in service of a rule of permanent *difference*. Second, the more modest purposes that "sameness" actually serves in the regime – structuring the *process* by which manufacturers make required label changes to warn properly against newly known risks, to avoid unnecessary consumer confusion – would be particularly undermined. Whatever individual regulators or physicians or insurers decided, the clear, coherent, and largely uniform message concerning substitution would be compromised.

A rule by which generic drug manufacturers can remain silent despite knowledge of serious risks would impair States' vital interest in promoting the health and safety of their citizens, *see Wyeth*, 129 S. Ct. at 1202-03 ("State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly"); *cf. Bruesewitz v. Wyeth LLC*, No. 09-152, 2011 WL 588789 (U.S. Feb. 22, 2011) ("Design-defect torts, broadly speaking, have two beneficial effects: (1) prompting the development of improved designs, and (2) providing compensation for inflicted injuries.").

Immunizing generic drug manufacturers would not only deprive injured citizens of compensation, but would leave others, often state governments, financially responsible for their care. "[S]tates' traditional authority to provide tort remedies to their citizens," *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984), exists not only because the political community's moral concern for its members' welfare and interest in compensation, but also because, when a person becomes injured or severely disabled, the State will often bear many of the costs

of providing medical care, rehabilitation, and family support services.

The immunity petitioners claim simply was not part of the legal background against which States adopted their prescription drug laws, including the generic substitution statutes that played such a critical role in promoting the generic drug industry. Had Congress – in 1984, or at any point since – actually proposed to preempt state tort remedies against manufacturers of generic drugs, States would have had the opportunity to present their objections through their political representatives in Congress, "the principal means chosen by the framers to ensure the role of the States in the federal system." *Garcia*, 469 U.S. at 550, 551 n.11 (citing, *inter alia*, Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954)).[12]

III. PETITIONERS' OBSTACLE PREEMPTION ARGUMENTS FAIL

As an alternative to their conflict "impossibility" arguments, Petitioners Pliva, *et al.* and their amici seek to enlist this Court's "implied[] preempt[ion]" decision in *Buckman*, 531 U.S. at 347, insisting that reversal here follows from the holding or reasoning of that case and others, such as *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981)

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[12] As the statutory regime in *Bruesewitz* illustrates, on those rare occasions where Congress decides, in the face of truly compelling policy concerns, to preempt traditional State tort law, it typically acts with a scalpel, not a chain saw.

(*ArkLa*), claimed to rest on the same "principle." But these arguments reflect an extravagant misreading of these decisions. Petitioners' reading violates first principles of this Court's preemption jurisprudence, and would allow the casual, unconsidered overriding of settled state policies in a host of areas, with consequences as disruptive as those we have just summarized.

A. *Buckman* Does Not Support Preemption Here.

To begin, contrary to the impression fostered by petitioner's brief, *Buckman* is hardly a milestone in this Court's federalism and preemption jurisprudence. It has appeared in a majority opinion only once, when the Court in *Wyeth* observed that the "dissent's reliance [on it was] * * * especially curious," as *Buckman* had "involved state-law fraud-on-the-agency claims," and had expressly distinguished tort suits involving "health and safety," 129 S. Ct. at 1231 n.3. The Court in *Buckman* rebuffed a decidedly non-traditional tort cause of action, ostensibly pleaded under Pennsylvania common law, whereunder a person injured by an FDA-approved medical device could recover from a contractor involved in securing federal approval by showing that the consultant had deceived the agency. In holding that cause of action preempted, *Buckman* emphasized that ordinary preemption principles were inoperative, because, unlike claims in cases like *Medronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), and *Silkwood* "based on traditional state tort law principles" and implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," 531 U.S. at 342, "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally

occupied,'" *id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). And whereas the duties sued upon in the earlier cases were independent of federal statutes, the novel cause of action in *Buckman* owed "its existence" to the FDCA. 531 U.S. at 353.

Not only would the "very subject matter" of the claim in *Buckman* be defendants' "relationship" and compliance with requirements governing regulated parties' "dealings with" the agency – which the Court observed were "inherently federal in character" – but a judgment for plaintiffs would have effectively impugned the validity of the FDA approval decision, *see* 531 U.S. at 347 (describing allegation that "improperly given market clearance" led to injury).

Buckman contrasted "clear evidence * * * that Congress intended [these statutory duties to] be enforced exclusively by the Federal Government" with *Silkwood*, in which Congress had disclaimed interest in displacing "adequate remedies for those injured." 464 U.S. at 257. The *Buckman* Court noted that the tort would intrude on the agency's authority to determine and calibrate its own response to misconduct directed toward it by a regulated party, and did so unnecessarily, given the manifold ways the "federal statutory scheme amply empowers FDA to punish and deter fraud against the Administration," 531 U.S. at 348.

To summarize the *Buckman* decision is to appreciate why the case does not support the preemption claim here. Unlike the exotic theory of recovery there, the duties on which the plaintiffs' claims are based are ones traditionally imposed under state common law. *See* 531 U.S. at 352 (""Silkwood's claim was not based on any sort of

fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care").[13] Accord *Wyeth*, 129 S. Ct. at 1195 n.3. Respondents' claims here do not "exist solely by virtue" of federal requirements, *Buckman*, 531 U.S. at 353 (distinguishing *Lohr,* 518 U.S. at 481), and the gravamen of those claims is not to "police" the "relationship" between federal agencies and regulated entities. Instead, respondents seek only compensation for a breach of traditional common law safety duties running from the manufacturer of a product to an injured consumer. Federal law, and the federal agency, enter the picture not because they are the font (let alone the sole source) of the plaintiffs' claim, but because the defendant has asserted that a verdict could be inconsistent with federal obligations. And there is no claim here that these suits impinge on the FDA's discretion in responding to misconduct in regulated entities' "dealings with" the agency. See Holmes v. *Sec. Investor Prot. Corp.*, 503 U.S. 258, 269-70 (1992) ("[D]irectly injured victims can generally be counted on to vindicate the law * * * without any of the

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[13] Indeed, at oral argument in *Buckman*, the United States, which took an aggressively pro-preemption position, acknowledged that traditional common law claims were not preempted: "The fraud claim is preempted, but if there is negligent design, negligent manufacturing, *failure to warn*, common law malpractice, all of those claims *are available*, but insofar as they would be asserting an essential element of the claim would be that the FDA was defrauded, that is an area of exclusive federal concern, and the State common law cause of action would be preempted." No. 98-1768, Tr. at 21 (emphasis added).

problems attendant upon suits by plaintiffs injured more remotely."). To the contrary, federal law provides that a generic drug is misbranded if the label lacks adequate warnings of a serious risk for which there is reasonable evidence of an association *See* 21 U.S.C. § 352(f)(2), 21 C.F.R. § 201.57(e). If presented with a recommendation to cure an existing situation of misbranding, the FDA would surely act.

Perhaps most fundamentally, the claims here, unlike those in *Buckman* and *ArkLa,* do not entail any sort of collateral attack on an agency action or decision. Here, the plaintiffs do not complain that the FDA's approval of the NDA for Reglan, or of ANDAs for metoclopramine, were invalid or harmful or the cause of their injuries. *See Buckman*, 531 U.S. at 347 (claim that "improperly given market clearance" led to injury); *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 549 (2008) (explaining that claims held preempted in *Riegel v. Medronic, Inc.*, 552 U.S. 312, 336-37 (2008), had "sought to impose different requirements on precisely those aspects of the device that the FDA had approved"); *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314, 2011 U.S. Lexis 1711 at *16-*22 (distinguishing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).

Respondents here claim that defendants' adherence to a label that failed to warn of risks that became known post-marketing was irresponsible and harmful, in violation of duties state law (as well as the FDCA) has long imposed. The FDA denies that its approval of respondents' drugs (or labels) may be treated as its judgment of adequacy for all times. Indeed, *Wyeth* settles that responsibility for the label (and for adequate warnings) is the manufacturer's, not the agency's, and that the federal labeling

obligation (like the state warning duties) depend on the hazards *currently* known, not those at the time of the agency's NDA or ANDA decisions. *See* 129 S. Ct at 1197-98.

These fundamental differences also explain why *ArkLa* and *Kalo Brick* lend no support for preemption here. Both those decisions arose from state court suits that sought to attack decisions of federal agencies on matters over which Congress had given the agencies "exclusive and plenary" authority. *Kalo Brick*, 450 U.S. at 321. In *Kalo Brick*, a shipper sought to recover under Iowa law for damages resulting from an interstate railroad's decision to abandon track – action the Interstate Commerce Commission specifically considered and approved. In holding the suit preempted, the Court emphasized that the "exclusive and plenary nature of the Commission's authority to rule on carriers' decisions to abandon lines [was] critical" to a congressional scheme developed after "'[m]ultiple control' ha[d] proved 'detrimental to the public interest,'" describing the suit as "little more than an attempt by a disappointed shipper to gain from the Iowa courts the relief it was denied by the Commission." *Id.* at 320, 324. Even under these circumstances, the Court took care to assure itself that preemption would "not leave a shipper in respondent's position without a remedy if it is truly harmed." *Id.* at 331.

ArkLa applied an even more venerable rule of plenary federal agency jurisdiction: the "filed rate doctrine," which forbids parties subject to administrative rate regulation, such as the natural gas producer in *ArkLa* (which was regulated by the Federal Power Commission) from collecting rates

other than the one "filed" and approved by the agency. 453 U.S. at 573.

Although the FDA regime here and the one in *ArkLa* may bear a superficial similarity – the FPC approved Hall's rate, and FDA approved petitioners' labels – they are actually in relevant respects polar opposites: The premise of the "filed rate doctrine" (and the holding of *ArkLa*) is that a final agency judgment of reasonableness may not be revisited (even by the agency itself); in contrast, it is a *violation* of the federal statute here (as well as of the common law) to continue to give agency-"approved" warnings once the manufacturer possesses drug risk information showing they are inadequate, *see* 21 C.F.R. § 201.57(e).

The premises of and purposes served by the unusually stringent rate doctrine are also strikingly different: strict enforcement of publicly-filed rates is essential to combating a primary "evil" against which those laws are directed – price discrimination, collecting differing rates from similarly-situated customers. And the stringency of the doctrine works against *regulated* parties, like the gas seller in *ArkLa*, holding them to arrangements *they made* and represented to the agency were "reasonable" (but did not turn out well) *until they file and obtain agency approval for more favorable ones.* Those disadvantaged by inadequate drug labels, in contrast, are blameless members of the general public, whose bodily injuries could have been prevented through due care.

While a filed-rate regime gives those regulated strong incentive to file and seek approval of higher rates as soon as they become aware of changed circumstances that would make those "reasonable,"

the incentives here, as *Wyeth* recognized, are wholly different: Labels (accurately) warning consumers and physicians that products are more dangerous than currently represented – and may safely be used only for weeks instead of months – are not in regulated parties' commercial interest. A regime that allowed generic manufacturers a complete defense based on the inaction of a brand-name maker, even when the generic company is well aware of the deficiency (and even when, as with some 32% of drugs, the brand-name company has simply left the field, *see* Resp. Br. at 20 & n.24) is even further from the core safety purposes of the statute. Of course, the "harshness" of finality rules of the sort in *ArkLa*, which hold regulated parties to the *economic* consequences of their own decisions, is not readily compared to that of a regime that would lead to unnecessary, irreversible physical harm for members of the public the safety regime is meant to protect. *See Burnet v. Cornado Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting) (in economic regulation, it is more important that a matter be "settled than that it be settled right").

This case would be closer to *ArkLa* if, instead of relying on FDA's initial approval of their ANDA (subject to modification as new risk information emerged), petitioners were seeking preclusion based on an *actual* agency decision – *e.g.*, a ruling against a citizen petition by generic manufacturers seeking approval of warnings reflecting the later-developed information suggesting that the risk of tardive dyskinesia had been significantly understated and that prolonged use is more dangerous than first recognized. But that is not what happened. Here there is no such agency decision to impugn; and no

claim that petitioners did other than sit on their hands.

To be sure, petitioners' efforts to more accurately warn the public *could* ultimately meet with FDA disapproval. Like the manufacturer's argument in *Wyeth*, however, that argument confuses the statute's *primary* requirements and objectives – adoption of currently adequate safety warnings by *all* manufacturers – with the particular procedures the agency has adopted for accomplishing them, in an orderly fashion to prevent undue confusion. And as in *Wyeth*, there is no reason here to assume (let alone any evidentiary basis for concluding) that the agency would have stood in petitioners way. *Cf. Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant * * * pre-emption"). Indeed, in this case, the FDA, eventually ordered a new, "black box" label for this drug.

These cases do not ask a state court (or federal courts applying state law) to overturn or impeach *any* FDA decision. Moreover, Congress did not provide that the FDCA is an "exclusive form of regulation" for drug warnings. As *Wyeth* affirms, this is an area in which state and federal law have coexisted for generations, and federal law has never attempted to install federal remedies for persons injured as a result of defective warnings.

B. Petitioners' Efforts to Invent Sweeping New Implied Conflict Preemption Doctrines Based upon Language from *Buckman* Should Be Rejected

Rather than acknowledge differences that are fundamental, petitioners and *amici* seek to extract

language in *Buckman*, *ArkLa* and *Kalo Brick* from the context in which it appears. They attempt to derive a set of preemption "principles" strong enough to be availing here, arguing that any tort claim that entails consideration of an agency decision to act or not to act is preempted. They extend this argument to any decision that has the potential to incidentally result in "additional burdens" on an agency or its personnel, Pliva Br. at 30 (quoting *Buckman*, 531 U.S. at 351) – or "interfere" with what could be considered an agency decision not to act – is preempted. But the "rules" they identify are contrary in multiple central respects to controlling precedent, and ignore basics of the relationship between federal and state law.

First, what petitioners would deride as "speculation," Pliva Br. 48-49 – considering what would have happened – is no incident of an exotic tort cause of action; it is a feature inherent in common law litigation (indeed, virtually all litigation). Their suggestion that *Buckman*, *Arkla*, and *Kalo* rest on a categorical rule against any state law consideration of federal agency activities simply wishes away the critical common feature of those cases. All involved collaterally attacking an agency's decision on a matter within its exclusive, plenary jurisdiction.[14] Indeed, the expansive reading of

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[14] While the attack in *Buckman* was not presented as an attack on the substance of the *agency's* decisionmaking, the claim concerned a subject – responding to fraud – no less within the aggrieved agency's primary jurisdiction, *see* 531 U.S. at 349 n.3, and the judgment sought would have necessarily implied the invalidity of the agency's action approving the device.

those cases cannot survive *Wyeth*, where preemption was rejected though the plaintiff's ultimate ability to recover in tort (the same tort as here) depended on essentially the same issue raised here: whether the agency *would have* approved a label with warnings that accurately reflected currently known risks. The fact that this question could or would enter a court's analysis did not warrant preemption there, and it does not make federal regulation a "critical element" in the sense meant by *Buckman*. As noted, *Buckman* involved duties running to the agency and the entire cause of action owed its existence to federal law.

Petitioners' only response – the only one possible – is that brand-name manufacturers may provisionally change labels pending FDA approval, whereas (they say) generic manufacturers must obtain approval first,– meaning that the question arises as part of plaintiffs' case in chief and is therefore an "element." Pliva Br. 50-54. But this is untenable for several reasons.

At the outset, it would be a strange rule of *obstacle* preemption that distinguished between two causes of action that entail courts' undertaking the same inquiry – whether the federal agency would have approved a safer label. And the extent to which the statute or agency regulations constrain generic manufacturers' powers to take "unilateral" (temporary) action to give warnings is itself a disputed question. (Though the agency advances a somewhat narrower understanding of powers retained by generic manufacturers than do respondents, it does so in the context of expressly disclaiming preemptive effect or intent for its interpretation).

But even if petitioners' account were accepted, it only highlights internal tensions basic to their position. It simultaneously emphasizes the formal distinction between the "elements" of a cause of action (as against defenses) while at the same time denying any significance to the contours of the actual state laws (of Louisiana and Minnesota) under which respondents sued. Indeed, it would presumably be within the state law's ken to allow plaintiffs to carry any proof burden by relying on a presumption, stated in *Wyeth* and grounded in experience as well as statutory text, that the FDA would not have disapproved more accurate and effective warnings. *See* 21 U.S.C. § 352(f)(2), 21 C.F.R. § 201.57(e).

Federal courts – even this Court – are not authoritative expositors of state law, and it would be surprising for categorical preemption rules to depend on federal determination of what qualifies as an "element" for pleading a state tort cause of action. Neither federal action nor "exclusively" federal law plays a role remotely like in *Buckman*, where plaintiffs were third parties seeking to enforce particular duties owed only to the federal agency in the context of a prior presumptively-valid agency decision. The Court recognized that explicitly, explaining that some, but not every, federal law duties can be sued upon – distinguishing between regulations that parallel common law duties to the public and those running to the agency. 531 U.S. at 353.

Worse still for petitioners, their logically (if not legally) conceivable basis for distinguishing this case from *Wyeth* is fatally inconsistent with their reliance on the position taken by the United States in

Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008) (per curiam affirmance by equally divided Court). In that case, one primary argument *against* preemption was that the issue of fraud on the agency only arose in the course of overcoming a defense, *see Louisville & N.R. Co. v. Mottley*, 211 U.S. 149, 153 (1908), and the government as amicus argued that the compliance defense would be readily made out in every case – so the real issue in cases under the Michigan law would be the same as in *Buckman. See* U.S. *Kent* Amicus Br. at 31 (asserting that distinction between "'element' and . . . 'affirmative defense' [is] "immaterial" and that "no reason" why "label would matter" under *Buckman*); *cf. Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 320 (2005) (allowing federal jurisdiction over state-law claim with "dispositive and contested federal issue at [its] heart").

Of course, the arguments pressed in that brief are of no more legal or precedential significance than those the same agency advanced – without success – in *Wyeth*; indeed, there was a substantial overlap between the two. *See* U.S. *Wyeth* Amicus Br. 25-26, and the Executive Branch has since taken a materially different view of these questions, *see* Memorandum on Preemption, 2009 Daily Comp. Pres. Doc. 384, at 1 (May 20, 2009); *Riegel*, 552 U.S. at 327 ("The agency's earlier position *** is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agency's position.").

But accepting the Solicitor General's position in *Kent* would not entitle petitioners to prevail here. In that case, the government argued that, notwithstanding the source of the duty enforced, the

express focus on fraud against the FDA interfered with the "'inherently federal'" relationship between the agency and regulated parties, so that, under *Buckman*, the presumption against preemption did not apply. U.S. *Kent* Amicus Br. at 15. Here, by contrast, respondents' state-law claims do not require them to prove the FDA was defrauded; the focus is on whether the defendant had information about serious health risks associated with its product. The state law theory does not require a court to revisit and scrutinize a past agency decision and declare it tainted. And the claim here, unquestionably, is subject to the presumption against preemption.

Petitioners' other arguments depend on taking statements the *Buckman* opinion offered in support of its limited, unexceptionable holding as the building blocks for a preemption regime entirely unencumbered by principles settled in controlling decisions of this Court, including recent and unanimous ones. Of course, assertions that leaving state law claims unpreempted would "impose" costs or exert "extraneous pull" (Pliva Br. 61) (quoting *Buckman*, 531 U.S. at 353), entail tightly circular reasoning: the "pull" of state tort liability is "extraneous" only if Congress's had in fact intended a "scheme" of field preemption. *Compare Wyeth*, 129 S. Ct. at 1202 (describing "state law as a complementary form of drug regulation"); *see generally Gade*, 505 U.S. at 110 (Kennedy, J., concurring) (argument that "assumes that Congress intended exclusive federal jurisdiction" is "not an application of our pre-emption standards *** but a conclusory statement of pre-emption").

And the unanimous decision in *Williamson*, refusing preemptive effect to an agency *decision* not to impose a requirement, definitively inters the notion that *every* instance of agency inaction may be treated as a "delicate balance" that state law may not "skew." *See Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314, 2011 U.S. Lexis 1711 at *20 (U.S. Feb. 23, 2011) (to "infer from the mere existence of [agency] cost-effectiveness judgment" a bar to state law would impermissibly "treat all such federal standards as if they were maximum[s]"). *See also Altria Group*, 129 S. Ct. at 551 n.14 (refusing to rely on agency inaction to support preemption claim "when that inaction is in part the result of the [defendant's] failure to disclose study results").

As for claims of burdens on agency decisionmaking or personnel, these are surely self-serving and doubtful on their own terms. It cannot be the law that any development in state law that might have the effect of encouraging prospective defendants to provide more information to or seek more discovery from federal agencies – a factor that certainly could arise in many a products liability, environmental, or state consumer protection case, among others – serves as a basis for deeming such state claims *preempted*. *See, e.g., Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005) ("quite wrong" to treat changes a verdict might "'induce'" as a "requirement"). Even when pressed by federal officials, such assertions do not merit – or receive – uncritical acceptance: "mere 'administrative convenience,'" *Frontiero* v. *Richardson*, 411 U.S. 677, 688 (1973), is not a transcendent constitutional value, and in *Clinton v. Jones*, 520 U.S. 681 (1997), the Court resisted claimed distraction as a basis for a discretionary postponement of a trial against the

President of the United States, declining to credit a "predictive judgment" of "a deluge of * * * litigation," noting that other "[s]itting Presidents have responded to court orders to provide testimony and other information." *Id.* at 704. *See also Gonzales v. O Centro Espirita Beneficente U.D.V.,* 546 U.S. 418, 435-36 (2006) ("The Government's argument echoes the classic rejoinder of bureaucrats throughout history": If I make an exception for you, I'll have to make one for everybody, so no exceptions").

The arguments from deluge and distraction here are stranger still. First, the federal agency that petitioners claim to protect does not agree that any kind of broad preemption is required on that basis. Moreover, the "information deluge" they warn against is not so much a prediction as a threat. In practice, the premise that more information is a good thing, *see Thompson v. Western States Med. Ctr.*, 535 U.S. 337, 375 (2002), applies when the subject matter is late-emerging information concerning serious safety hazards of consumer products. If petitioners and others did in fact flood the agency with useless information, there is every reason to assume the FDA has ample tools at its disposal, short of nationwide preemption of state law remedies for injured parties, to manage the quantum of what is submitted.

Indeed, the notion that a potentially increased inflow of "unwanted" information or incidental distraction of federal agency personnel could be a serious argument in favor of displacing a vast swath of traditional state law and policy is an index of how far petitioners' claims stray from the core principles of federalism undergirding this Court's preemption doctrine – and of how important it is to guard

against expansive, causal claims of "implied preemption."

Conclusion

The judgments of the courts of appeals should be affirmed.

Respectfully submitted,

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