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 Circuit And For The Fifth Circuit

BRIEF FOR *AMICUS CURIAE* THE NATIONAL COALITION AGAINST CENSORSHIP IN SUPPORT OF RESPONDENTS

BIJAN ESFANDIARI
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
(310) 207-3233
BEsfandiari@BaumHedlundLaw.com

ERWIN CHEMERINSKY
Counsel of Record
UNIVERSITY OF CALIFORNIA, IRVINE SCHOOL OF LAW
4500 Berkeley Place
Irvine, CA 92697
(949) 824-7722
echemerinsky@law.uci.edu

Counsel for Amicus Curiae

[Additional Counsel Listed On Signature Page]

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INTEREST OF THE *AMICUS*[1]

The National Coalition Against Censorship (NCAC), founded in 1974, is an alliance of more than 50 national nonprofit organizations, including educational, professional, artistic, labor, religious and civil rights groups united in the conviction that freedom of thought, inquiry and expression are indispensable to a healthy democracy. Among NCAC's projects is The Knowledge Project: Censorship & Science, which educates the public and policy-makers about the importance of safeguarding the free exchange of information about scientific research and developments. The Knowledge Project advocates for greater transparency in government decision-making about science, and for the public's right to know non-classified scientific information, especially when that information implicates public health and welfare. Because the issues in this case relate to the ability of the public to receive truthful information about the risks of pharmaceuticals, participation as *amicus* in this case falls squarely within NCAC's mission. The positions advocated by the NCAC in this brief do not

[1] Petitioners and Respondents have filed blanket consents to the submission of *amicus* briefs with this Court. No counsel for a party authored any part of this brief, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae,* or its members, or counsel, made a monetary contribution to its preparation or submission.

necessarily reflect the positions of each of its participating organizations.

SUMMARY OF ARGUMENT

Petitioners' argument boils down to their contention that, in enacting the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act ("FDCA"), Congress chose to permit name-brand manufacturers unilaterally to revise their labels and issue warnings to patients and the medical community, but prohibited generic drug manufacturers from doing the same. Petitioners' argument, however, conflicts with this Court's First Amendment jurisprudence which has recognized that the First Amendment "prohibit[s] . . . restrictions distinguishing among different speakers, allowing speech by some but not others." *Citizens United v. Federal Election Comm'n*, 130 S.Ct. 876, 898-99 (2010); *see also First Nat. Bank of Boston v. Bellotti*, 435 U.S. 765, 784 (1978).

Whether "warnings" are deemed to be pure or commercial speech, Petitioners have a First Amendment right (whether actually exercised or not) to utilize a host of mediums to inform the public and medical community about the risks associated with their products. Indeed, in their opening brief, Petitioners Pliva, Inc., Teva Pharms. USA, Inc. and UDL Labs, Inc. (collectively "Pliva") readily concede they have a First Amendment right to engage in truthful speech and concede that any Governmental attempts

to chill such speech would be unconstitutional. *See* Pliva Opening Br. at 48.

Simply put, nothing in the Food, Drug and Cosmetic Act ("FDCA") ***precluded*** Petitioners from issuing additional warnings, even without FDA approval. *See* 21 C.F.R. §§ 200.5, 201.80, 314.70(c) and 314.97. Even assuming for the sake of argument, that such a statutory preclusion existed, Petitioners' would still have the right under the First Amendment to disclose known risks about their products. Conflict preemption principles do not apply if there is no conflict between federal and state law. Under the First Amendment Petitioners have a right to issue additional warnings about known risks, and under state law, they have the duty to do so. There is no conflict between state and federal law.

ARGUMENT

In *Levine*, this Court confirmed that name-brand drug manufacturers bear the primary responsibility for their label and are permitted to unilaterally issue more robust warnings than those initially approved by the FDA. *Wyeth v. Levine*, 129 S.Ct. 1187, 1198-99 (2009). Petitioners argue that, while name-brand manufacturers are free to unilaterally make labeling changes, generic manufacturers are not free to make any changes or disseminate any stronger warnings than those provided by the name-brand manufacturer and approved by the FDA. They argue that, because

their label matched the name-brand manufacturers' label, Respondents' claims are preempted. There are a number of reasons for rejecting Petitioners' preemption arguments. These include, *inter alia*: the basic presumption against preemption; the power of drug companies, pursuant to the Changes Being Effected ("CBE") statute, to issue additional warnings without pre-approval by the FDA (*see, e.g.*, 21 C.F.R. §§ 314.70(c) and 314.97); Petitioners' right to issue "Dear Doctor" letters to physicians regarding the risks; and Petitioners' failure to present clear evidence that the FDA would not have approved a labeling change. These issues were all carefully considered by the Fifth and Eighth Circuits in their respective opinions and are addressed in Respondents' principal brief. This brief is intended to focus on one narrow aspect of Petitioners' conflict preemption argument: Petitioners' First Amendment right to disseminate warnings about known risks through labeling revisions, "Dear Doctor" letters and scientific journal articles.[2]

Like all other federal laws and regulations, the FDCA and the FDA regulations must be interpreted in a manner consistent with the Free Speech Clause of the First Amendment. *Thompson v. Western States Medical Center*, 535 U.S. 357, 365 (2002). "Scientific and academic speech resides at the core of [the] First

[2] The brief addresses only the First Amendment right to disseminate information that is concededly truthful and not misleading. Other situations involving disputed facts might pose different legal questions that this brief does not address.

Amendment." *Washington Legal Foundation v. Friedma*n, 13 F.Supp.2d 51, 62 (D.D.C. 1998) ("*WLF I*"), vacated as moot by, *Washington Legal Foundation v. Henney*, 202 F.3d 331, 337, n.7 (D.C.Cir. Feb 11, 2000) ("*WLF III*"); *see also Board of Trustees of Leland Stanford Junior University v. Sullivan*, 773 F.Supp. 472, 474 (D.D.C. 1991) ("It is equally settled, however, though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression.").

In these consolidated cases, Respondents allege that Petitioners should have issued warnings about a known risk, that long term use of metoclopramide increases the risk of tardive dyskinesia. The dissemination of such "factual material of clear 'public interest'" is entitled to First Amendment protection. *Bigelow v. Virginia*, 421 U.S. 809, 822 (1975). Petitioners' argument that the Government permits name-brand manufacturers to unilaterally issue warnings but prohibits generic manufacturers from doing the same, creates a colossal First Amendment problem – under the First Amendment, Government cannot distinguish among different speakers. *Citizens United*, 130 S.Ct. at 898-99. Moreover, in addition to the impermissible restrictions based on the identity of speakers, Petitioners have an independent (and self-admitted) First Amendment right to provide information that serves the goals of the FDA regulations: informing consumers of known risks of pharmaceutical. *See, e.g.,* Pliva's Br. at 48; *Thompson*, 535 U.S. at 365.

I. Under The First Amendment, Congress Cannot Discriminate Among Different Speakers.

Petitioners readily concede that, under FDA regulations, name-brand manufacturers of Reglan (metoclopramide) can, without prior FDA approval, *unilaterally* issue warnings through labeling revisions or "Dear Doctor letters" regarding risks associated with Reglan use. *See* Pliva's Br. at 16. They contend, however, that these same FDA regulations *prohibit* generic manufacturers of the same drug from unilaterally issuing warnings. *Id.* at 30-47. In sum, they contend that, through the Hatch-Waxman Act, Congress sought to make name-brand manufacturers the favored speaker and made it criminally illegal for generic manufacturers to issue warnings in advance of the name-brand manufacturer and without the FDA's consent.

Petitioners' (and the Government's) position that name-brand manufacturers are free to issue unilateral warnings but generic manufacturers are not, is a violation of the First Amendment. In *Citizen's United*, this Court held:

> [T]he First Amendment stands against attempts to disfavor certain subjects or viewpoints. Prohibited, too, are restrictions distinguishing among different speakers, allowing speech by some but not others.

Citizen's United, 130 S.Ct. at 898-99. Accordingly, even assuming for the sake of argument that the Hatch-Waxman Act places speech restrictions

distinguishing amongst name-brand and generic manufacturers, such restrictions would not survive First Amendment scrutiny. *Id.*

Moreover, such a restriction would deny consumers access to potentially life-saving information regarding the proper use and risks associated with their drugs, a result that is wholly inconsistent with the FDA's mission. Given that generic manufacturers have the ongoing duty to record and report adverse events to the FDA (21 C.F.R. § 314.98(a)), it would be anomalous if they were prevented from informing the medical community regarding the risks they observe. Finally, in many instances, name-brand manufacturers have divisions within their companies or subsidiaries which manufacture generic drugs.[3] Thus, it makes no sense for Congress to hold that, when the manufacturer is wearing its name-brand hat, it is free to issue warnings, but, when this same manufacturer is wearing its generic-brand hat, it is prohibited from issuing warnings.

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[3] During hearings on the Hatch-Waxman Act, Congress learned that name-brand manufacturers were also producing generic drugs, which led Congressman Dennis Eckart to ask "So the big boys are playing both sides of the field on this?" Mark Novitch, M.D., the Deputy Commissioner of the FDA responded in the affirmative ("Yes . . . "). *See Drug Legislation: Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 98th Cong. (July 25, 1983). This practice continues in the modern era. For example, Sandoz Inc., one of the world's largest generic drug manufacturers is a generic drug subsidiary of Novartis Pharmaceuticals Corporation, a multi-national name-brand manufacturer.

In sum, Petitioners and the Government's argument that name-brand manufacturers are free to speak/warn the public and that generic manufacturers are restricted from doing so places an unconstitutional restriction upon generic manufacturers' and the public's First Amendment rights. *Citizen's United*, 130 S.Ct. at 882-83, 908 (First Amendment prohibits Congress from distinguishing amongst speakers); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976) (First Amendment protects the public's right to *receive* information). As this Court has aptly observed:

> When Government seeks to use its full power, including the criminal law, to command where a person may get his or her information or what distrusted source he or she may not hear, it uses censorship to control thought. This is unlawful. The First Amendment confirms the freedom to think for ourselves.

Citizen's United, 130 S.Ct. at 908. Accordingly, Petitioners contention that Congress sought to discriminate amongst manufacturers is neither supported by the Act nor permissible under the First Amendment.

II. The First Amendment Protects The Right Of All Drug Companies To Disclose Information About The Known Risks Associated With Their Products.

In addition to the impermissible discriminatory aspects outlined *supra*, Petitioners also have an *independent* First Amendment right to warn the public if they become aware of previously undisclosed risks. Respondents allege that Petitioners could and should have issued warnings regarding the known risks of tardive dyskinesia from long term use of metoclopramide, and that the failure to do so constituted negligence. The dissemination of "factual material of clear 'public interest'" is entitled to First Amendment protection. *Bigelow v. Virginia*, 421 U.S. 809, 822 (1975). The degree of protection is determined by whether warnings are deemed *pure speech* (which is afforded the highest level of protection) or if it is "*commercial speech*" (in which case it is entitled to a lower level of protection). However, irrespective of whether the warnings are deemed to be "pure speech" or "commercial speech," the First Amendment would nonetheless protect Petitioners' right to issue warnings in the present case.

(A) More Robust Warnings Than Those Contained In The FDA-Approved Label Constitute Pure, Not Commercial, Speech And Are Subject To The Most Extensive First Amendment Protection.

Warnings concerning drug risks constitute pure speech. Warnings are not given in order to enhance the sale of a product, rather, they tend to limit product sales. As such, warnings do not fall within the ambit of "commercial" speech. Even if, as Petitioners claim, FDA regulations preclude issuance of such warnings, they would be a content-based restriction on Petitioners' ability to speak and would be subject to "strict scrutiny."

Whether a given communication constitutes commercial speech is predicated on "the commonsense distinction between speech proposing a commercial transaction . . . and other varieties of speech." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 64 (1983). In *Bolger*, this Court identified three factors to use in determining whether speech is "pure" speech or "commercial" speech: (1) Whether the speech is concededly an advertisement; (2) Whether the speech refers to a specific product; and, (3) Whether the speaker has an economic motivation for disseminating the speech. *Bolger*, at 66. If ***all three factors*** are present, the speech may properly be characterized as commercial speech. *Id.*; *see also WLF I*, 13 F.Supp.2d at 64.

On a common sense level, a more robust warning of the risks of an approved drug does not comport with the *Bolger* test for commercial speech. After all, an advertisement "calls public attention to [the product], especially by emphasizing desirable qualities so as to arouse desire to buy or patronize." *WLF I*, 13 F.Supp.2d at 64. A warning about the risks in using an approved drug in a particular manner does exactly the opposite: It ***de***emphasizes the desirable qualities of the drug and emphasizes its ***un***desirable qualities. Similarly, a warning that highlights the risk of using a drug is an economic ***dis***incentive, and does not comport with the third *Bolger* factor because there is no economic motivation for disseminating the speech.

Because more robust warnings about the use of an approved drug are "pure" (as opposed to "commercial") speech, any content-based restriction is subject to the strict scrutiny standard. *Sable Communications of California, Inc. v. F.C.C.,* 492 U.S. 115, 126 (1989); *United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 813-14 (2000). Where a statute regulates speech based on content, the statute "must be narrowly tailored to promote a compelling government interest." *Playboy*, 529 U.S. at 813. Moreover, to the extent Petitioners argue they could not disseminate more robust and truthful warnings about the use of their product without prior FDA approval, or without the name-brand manufacturer's initiation, such a limitation would amount to a "prior restraint" on protected expression – which is the most serious and least tolerable infringement on First Amendment

rights. *Organization for a Better Austin v. Keefe*, 402 U.S. 415, 419 (1971); *see also The Florida Star v. B.J.F.*, 491 U.S. 524, 533 (1989).

The FDA could not possibly assert a compelling governmental interest in keeping physicians and patients in the dark about the risks associated with the drugs they are using. Such a conclusion would, in fact, be directly contrary to the FDA's mandate that it promote and enhance consumer ***safety***. *Levine*, 129 S.Ct. at 1195-96; *United States v. Dotterwiech*, 320 U.S. 277, 282 (1943); *Demahy v. Actavis, Inc.,* 593 F.3d 428, 448 (5th Cir. 2010) ("Hatch-Waxman's goals are thus tethered to those of the overall regulatory scheme – chief among them the maintenance of safety and efficacy"). The First Amendment assures that truthful speech that makes the use of drugs ***safer*** cannot be limited by the FDA's regulatory scheme.

Today, seventy percent of prescriptions are filled with generic drugs. *Mensing v. Wyeth, Inc.,* 588 F.3d 603, 607 (8th Cir. 2009); *see also* Susan Okie, *Multinational Medicines – Ensuring Drug Quality in an Era of Global Manufacturing*, 361 NEW ENG. J. MED. 737, 738 (2009). Many insurance companies only pay for generic drugs which forces patients to use generic drugs. It is, thus, all the more important that generic manufacturers warn patients and doctors about side effects once they become aware of them. *See Demahy*, 593 F.3d at 448 ("nothing about the Hatch-Waxman Amendments, and their goal of cheaper drugs, obviates the concomitant prescription that all drugs, even cheaper ones, remain safe.")

To hold that FDA regulations prohibited Petitioners' disclosure of safety risks would mean that the public would be deprived of vital health and safety information in a timely fashion. If FDA regulations operated in such a fashion, it would constitute a content-based restriction speech, which is the type of evil the First Amendment was meant to prevent. *Washington Legal Foundation v. Henney*, 56 F.Supp.2d 81, 85 (D.D.C. 1999) ("*WLF III*") ("The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity.") As such, under strict scrutiny, Petitioners' argument that the government has a compelling interest in preventing disclosure of known health risks must fail.

(B) Even If Warnings Were Deemed Commercial Speech, Petitioners Still Have A Right To Disclose Them.

Even if additional warnings were deemed "commercial speech," Petitioners have a First Amendment right to publish information about the risks of using their drugs. *Thompson*, 535 U.S. at 365. In *Thompson*, this Court struck down a ban on advertising unapproved compounded drugs in the FDA Modernization Act of 1997 (FDAMA). The Court applied the commercial speech test of *Central Hudson v. Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). Thus, this Court asked: (1) whether the speech was untruthful or misleading, or concerned unlawful

activity (characteristics that would strip the speech of First Amendment protection and end the analysis); (2) whether the Government had asserted a "substantial" interest in restricting the speech; (3) whether the Government had demonstrated that the restriction "directly advanced" such a substantial interest; and (4) whether the Government had established that the restriction was "not more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 365.

1. Issuing Warnings Is Neither Unlawful Nor Inherently Misleading.

Respondents allege that truthful additional warnings about the use of metoclopramide were necessary for the protection of the Respondents' health and safety. Petitioners argue they could not issue such warnings without first waiting for the name-brand manufacturers to act or obtaining the FDA's approval. However, it is illogical to assume that speech about known drug-related risks is "inherently misleading" if it has not been specifically endorsed by the FDA, especially when the speech at issue further advances the FDA's statutory goals.

In the context of prescription drugs, the theory that statements lacking FDA approval were inherently misleading was considered and rejected in *WLF I*. There, the FDA argued that manufacturer-funded or manufacturer-disseminated speech about off-label uses was inherently misleading. The court held that the speech was "*not untruthful or inherently misleading*

merely because the FDA has not yet had the opportunity to evaluate the claim." *Id*

In short, Petitioners' argument that warnings about known risks discovered after FDA approval of the label are "inherently misleading" is untenable. Indeed, drug manufacturers are required to report post-marketing data about adverse drug effects precisely so that patients and doctors have the benefit of the most up to date information about drug-related risks.

2. The FDA Does Not Have A "Substantial" Interest In Keeping People In The Dark Regarding Known Risks Associated With The Prescription Drugs That They Use.

It is not disputed that government agencies may seek to regulate speech for certain legitimate purposes. However, the FDA does not have a substantial interest in keeping physicians and consumers in the dark regarding life endangering or serious risks associated with the drugs that consumers use. Such a conclusion would, in fact, be directly contrary to the FDA's mandate that it promote and enhance consumer safety. *Levine*, 129 S.Ct. at 1195-96; *see also Demahy,* 593 F.3d at 448 ("Hatch-Waxman's goals are thus tethered to those of the overall regulatory scheme – chief among them the maintenance of safety and efficacy").

3. The Purported Restrictions On Speech Do Not Advance The Government's Substantial Interest In Protecting The Health And Safety Of Consumers.

This Court has repeatedly confirmed that the role of the FDCA and the FDA is to protect consumers. *Levine*, 129 S.Ct. at 1195-96; *F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) ("The labeling requirements currently imposed by the FDCA . . . require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers."); *United States v. Sullivan*, 332 U.S. 689, 696 (1948) ("[T]he Act as a whole was designed primarily to protect consumers from dangerous products.").

In light of the fact that the FDCA's primary objective is to protect consumers, that objective and interest would be undermined by Petitioners' contention that the FDA could or should prohibit warnings about the known risks of their products. *See, e.g.*, *Dotterwiech*, 320 U.S. at 282; *Levine*, 129 S.Ct. at 1195-98. The more information a physician has when prescribing a drug, the better. *See* American Medical Association, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 FOOD & DRUG LAW JOURNAL 359, 363 (1994) ("The purpose of any requirement to disseminate knowledge is to benefit patients and advance their level of care."). If the regulations were construed to restrict distribution of information about health risks, such a construction would undermine FDA's interest in promoting access to reliable scientific

and medical information and would thereby endanger the lives of patients who are prescribed medications.

This Court's First Amendment jurisprudence has long mandated that government cannot suppress truthful information – even when that information does nothing more than allow them to make better *financial* judgments about what they buy. *Virginia State Bd. of Pharmacy,* 425 U.S. at 770; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996); *Thompson*, 535 U.S. at 365. It is far more important that these First Amendment principles apply to assure that patients and their physicians have truthful information that will assist them in choosing drug products that affect consumers' health and safety and not merely their pocketbooks. An FDA regulation that limits the dissemination of truthful warnings undermines patient safety, is contrary to governmental intent and violates the First Amendment.

4. A Restriction On Warnings Is More Extensive Than Necessary.

Finally, as to the fourth factor, Petitioners' contention that the FDA does or should bar all additional warnings (including Dear Doctor letters) by generic manufacturers until approved by the FDA is more extensive than necessary because it burdens substantially more speech than necessary. *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993). First, as already noted, such a restriction would be an

unnecessary and unconstitutional prior restraint. *See, e.g., WLF II*, 56 F.Supp.2d at 85. Second, as the *WLF I* court noted, in lieu of prohibiting speech, the FDA could require "full, complete, and unambiguous disclosure by the manufacturer." *WLF I,* 13 F.Supp.2d at 73. Finally, as the *WLF I* court noted, the FDA cannot restrict the dissemination of truthful information, especially when the "truthful information may be life saving information." *WLF I,* 13 F.Supp.2d at 73. Truthful warnings are exactly the type of life-saving information that cannot be restricted and are fully protected by the First Amendment.

The FDA has long understood that completely suppressing the exchange of accurate scientific and medical information between physicians and the manufacturers of drugs and devices does not serve its public health objectives. For example, in the context of permitting drug manufacturers (both name brand and generic) to publish journal articles regarding off-label[4] (unapproved) drug uses, the FDA stated in 1994 that, "because the agency recognizes the importance of dissemination of reliable scientific information . . . , it has developed a number of policies related to dissemination of such information." 59 Fed.

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[4] "Off-label" refers to the use, prescription or marketing of an FDA-approved drug for an unapproved use, such as in an unapproved population (i.e., children) or for a condition other than for what it has been approved. *See, e.g., Knipe v. SmithKline Beecham*, 583 F.Supp.2d 553, 572, n. 21 (E.D.Pa. 2008).

Reg. 59820, 59822 (Nov. 18, 1994). In its more recent pronouncement on this issue, the FDA confirmed that manufacturers have a right to "disseminate truthful and non misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs . . . to healthcare professionals." *See* FDA, *Guidance for Industry – Good Reprint For The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices* (January 2000), available at http://www.fda.gov/Regulatory Information/Guidances/ucm125126.htm (last visited February 28, 2011). The FDA further held that, along with the dissemination of such information, the manufacturer should also disclose "*all significant risks or safety concerns known to the manufacturer . . . " Id.* Thus, contrary to the Petitioners' contention, they were not only permitted but *encouraged* to disclose any known safety problems with their drugs. For this reason alone, Petitioners' preemption argument should be rejected.[5]

Accordingly, under the First Amendment, Petitioners had a right to issue truthful additional warnings about the risks associated with prolonged use of metoclopramide.

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[5] Rejecting Petitioners' preemption argument would have the added benefit of recognizing the state's legitimate interest in protecting its citizens from negligence through application of state tort law.

III. To Avoid Constitutional Doubt, The Hatch-Waxman Act And FDA Regulations Should Be Interpreted To Allow Generic Manufacturers To Issue Additional Warnings.

Statutes, and the regulations drafted pursuant to them, must be interpreted so as to avoid constitutional doubt. *Miller v. French*, 530 U.S. 327, 336 (2000); *Almendarez-Torres v. U.S.*, 523 U.S. 224, 237-38 (1998). Petitioners claim that the Hatch-Waxman Act and applicable FDA regulations prohibited them from unilaterally making labeling changes. However, as discussed *supra,* as well as in Respondents' brief, nothing within the Act or the regulations supports Petitioners' arguments that Congress intended to prevent generic manufacturers from revealing risks discovered post-approval. Indeed, the applicable regulations confirm that Petitioners were free to issue warnings and make labeling changes. *See* 21 C.F.R. §§ 200.5, 201.80, 314.70(c) and 314.97.

More importantly, Petitioners' construction of the regulations violates the rule that a regulation must be construed in a manner that resolves any doubt against unconstitutionality. Construction of the regulation in the manner suggested by Petitioners raises constitutional concerns to the extent it would prohibit dissemination of information of hazards that have long been known, but secreted by the manufacturer for whatever reason.

IV. Because Petitioners Have A First Amendment Right To Notify Patients And Doctors About Known Risks Associated With Their Product, They Could Comply With State Law Requiring Such Warnings.

Petitioners' challenge to the Fifth and Eighth Circuit Courts' decisions is predicated solely on principles of conflict preemption. Petitioners assert they could not comply with both federal law (which, Petitioners contend, precluded warnings about known risks) and state law (which required such warnings).

But, as demonstrated above, the First Amendment protects Petitioners' right to disseminate warnings about known risks associated with the use of their drugs, even if such warnings were not contained in the FDA-approved name-brand label, regardless of whether they chose to exercise that right. Because federal law did not restrict the warnings Petitioners could issue, Petitioners could have complied with state law and issued the warnings, had they chosen to do so. There was no conflict and, hence, no conflict preemption. Tellingly, Petitioners themselves acknowl edge they have First Amendment rights to engage in speech. *See, e.g.*, Pliva Br. at 48. However, they contend that, because it is "speculative" as to what the FDA would have done in response to their exercise of their First Amendment rights, Respondents' claims should be preempted. *Id*. at 48-49. Petitioners fail to appreciate that, under *Levine*, they bear the burden of establishing preemption by presenting "clear evidence that the FDA would not have approved a

change to . . . [the] label" *see Levine*, 129 S.Ct. at 1198 – thus, their contention that the FDA's actions are "speculative" confirms that they cannot meet the demanding standard espoused in *Levine*. *Levine*, 129 S.Ct. at 1198; *see also Mensing v. Wyeth, Inc.,* 588 F.3d 603, 610 (8th Cir. 2009) ("the Supreme Court made it clear in [*Levine*] that uncertainty about the FDA's response to such measures makes federal preemption less likely"); *Dorsett v. Sandoz, Inc*., 699 F.Supp.2d 1142, 1159 (C.D.Cal. 2010) ("a mere possibility that the FDA might not have allowed an enhanced warning . . . is not enough to warrant preemption.")

Petitioners may argue that, even if the First Amendment ***allowed*** them to issue additional warnings, the First Amendment also allows them to remain silent. That is true, but misses the point. They could remain silent, however that choice would violate a duty under state law and expose them to potential liability. The point is that the state law duty is not in conflict with any federal limitation because, in fact, there is no federal limitation.

The question is this: Can a manufacturer with knowledge of a grave risk associated with its drug issue a warning to the medical community regarding that risk? Petitioners' argument that federal law prohibits them from issuing such a warning is simply wrong. Petitioners were aware of the substantial risks associated with long term metoclopramide use yet chose not to disclose it to patients and doctors. Petitioners had both a state law duty and a First

Amendment right to issue a warning regarding such risks without waiting for the FDA's confirmation or name-brand manufacturer's inclusion of the warning. Petitioners were not put to the test of choosing between compliance with state and federal law. The federal regulations do not in fact prohibit enhanced warnings reflecting current knowledge and, if they were so construed, such a construction would run afoul of the First Amendment. Petitioners could, therefore, comply with both federal and state law.

CONCLUSION

Our independence was won by those who believed public discussion and free speech should be a fundamental principle of the American government. They recognized that it is hazardous to discourage thought, innovation and debate. They knew the path of safety lies in the opportunity to discuss freely. Believing in the power of reason as applied through public discussion, our forefathers eschewed silence coerced by law.[6] Contrary to the fundamental beliefs of our forefathers, today, Petitioners claim they are prohibited from publicly disclosing risks associated with their drugs – contending they are not free to update warnings on labels, not free to send letters to

[6] This history was more eloquently outlined in Justice Brandeis' concurring opinion in *Whitney v. California*, 274 U.S. 357, 375-76 (1927), *overruled on other grounds by Brandenburg v. Ohio*, 395 U.S. 444 (1969).

physicians, and ostensibly not free to publish articles or letters in scientific journals revealing these grave risks. Petitioners' self-serving asseverations ring hollow. Had it been in their financial interest to disclose the information, they undoubtedly would have claimed the First Amendment right to do so. Instead, they seek to justify concealing information about risk and to avoid any legal consequences for injuries that resulted. First Amendment jurisprudence requires rejection of Petitioners' argument that they were precluded from issuing warnings to inform consumers and doctors about the known risks of using their products.

Respectfully submitted,

ERWIN CHEMERINSKY
Counsel of Record
UNIVERSITY OF CALIFORNIA,
IRVINE SCHOOL OF LAW
4500 Berkeley Place
Irvine, CA 92697
(949) 824-7722

BIJAN ESFANDIARI
BAUM HEDLUND ARISTEI &
GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
(310) 207-3233

SHARON J. ARKIN
THE ARKIN LAW FIRM
333 South Grand Avenue
25th Floor
Los Angeles, CA 90071
(213) 943-1344

JOAN E. BERTIN
NATIONAL COALITION
AGAINST CENSORSHIP
19 Fulton St., Suite 407
New York, NY 10038
(212) 807-6222