March 10, 2014

Via the Federal eRulemaking Portal: http://www.regulations.gov

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Request for Public Comments Regarding the Proposed Rulemaking on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (Nov. 13, 2013), Docket No. FDA-2013-N-0500**

To Whom It May Concern:

We submit the following comments to highlight the important benefits that will flow from the U.S. Food and Drug Administration's (FDA) proposal to revise its regulations governing the procedures for changing product labeling to reflect certain types of newly acquired information in order to extend to generic drug manufacturers the same ability to use the "changes being effected" supplement process (hereafter "CBE changes") to implement such labeling changes that is currently only available to "brand name" drug manufacturers. This rulemaking will help to ensure that state civil justice systems are able to play an active role in safeguarding the public against unreasonably dangerous generic drugs, as they are able to do with brand name drugs. As explained in greater detail below, state civil justice systems offer several unique institutional advantages that complement and reinforce the FDA's regulatory programs. Because of the resulting synergies, these two legal institutions can deliver significant public health and safety benefits when they are permitted to function effectively in tandem with one another. We urge that the FDA fully account for these benefits as it works toward finalizing this critical rulemaking.

I. THE PROPOSED RULE WOULD ENSURE THAT STATE CIVIL JUSTICE SYSTEMS ARE ABLE TO PLAY AN ACTIVE ROLE IN SAFEGUARDING THE PUBLIC AGAINST UNREASONABLY DANGEROUS GENERIC DRUGS

Once completed, the proposed rulemaking would have the effect of overturning the U.S. Supreme Court's unfortunate decision in the 2011 case of *Pliva v. Mensing*[1]. In that case, the Court relied on the fact that the FDA's current regulations do not permit generic drug manufacturers to make CBE

[1] 131 S.Ct. 2567 (2011).

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changes in holding that federal law preempted plaintiffs' state tort law failure-to-warn claims that alleged that a generic drug's labeling failed to provide adequate warning of particular health risks. The Court reasoned that since the FDA's current labeling regulations prevented generic drug manufacturers from making CBE changes to update their labels to warn consumers against any newly discovered risks, it would be impossible for those same generic drug manufacturers to fulfill a separate state tort law duty to provide such warnings through adequate labeling. The impossibility of complying with both legal duties simultaneously compelled the Court to find that the FDA's regulations preempted the plaintiffs' state tort law claims.

This rulemaking would enable generic drug manufacturers to make CBE changes to update their labels—just as name brand drug manufactures are able to do now—making it possible for these manufacturers to fulfill their state tort law duty to provide consumers with adequate warnings regarding newly emerged risks posed by their products. The rulemaking would therefore eliminate any justification for federal preemption of state tort failure-to-warn claims brought against generic drug manufacturers. Without federal preemption, the state civil justice systems could once again resume an active role in policing generic drug safety.

II. VIBRANT STATE CIVIL JUSTICE SYSTEMS COMPLEMENT AND REINFORCE THE FDA'S REGULATORY PROGRAMS SO THAT THEY ARE BETTER ABLE TO PROTECT THE PUBLIC AGAINST UNREASONABLY DANGEROUS DRUGS

Federal preemption by the FDA's regulatory programs of state tort law failure-to-warn claims involving unreasonably dangerous generic drugs is fundamentally counterproductive. This arrangement denies the critical role that robust state civil justice systems play in the U.S. system of governance in general as well as in safeguarding the public in particular. In the area of name brand drug safety, the synergistic benefits that these two legal institutions deliver when working together is well established. The proposed rulemaking would ensure that state civil justice systems are able to work in concert with the FDA's regulatory programs so that similar synergistic benefits will be delivered in the area of generic drug safety.

State civil justice systems, when compared to legislatures or regulatory agencies, offer unique advantages that are separate and apart from their instrumental benefit in compensating victims and deterring accidents. These non-instrumental advantages are recognized and preserved in the Seventh Amendment of the U.S. Constitution (*e.g.*, the right to jury trials in common law suits; juries deciding issues of fact) as well as in the "open courts" provisions in various state constitutions. Unlike legislatures and regulatory agencies, courts must pay attention to the tort-related complaints brought by ordinary people. Indeed, courts must always remain open, whereas the other branches sometimes ignore the concerns of citizens, either by shirking their duties or by becoming captured. Moreover, average people have a closer and more direct relationship to the substance of state tort law, which is still primarily defined through the common law, than they do with complex and often highly technical federal standards, which are developed by expert agencies. This is because the common law of torts represents an organic, evolving set of principles about civil wrongs. Accordingly, it remains open to reinterpretation and modification—particularly by average people—to cover newly recognized wrongs. Citizens used nuisance litigation to address pollution long before the Environmental Protection Agency came into existence. Similarly, tort suits were an important component of the early civil rights movement and the movement against sexual harassment before Congress adopted laws to address these issues.

In addition to their unique "populist" benefits, state civil justice systems play a crucial role in the promotion of health and safety goals. As the U.S. Supreme Court recognized for much of the 20th century, state civil justice systems serve as an invaluable complement to federal and state positive law in protecting public health and safety.[2] Positive law, such as federal regulatory standards, seeks to proscribe certain actions—*before* these actions occur—to deter individuals and firms from harming the health and safety of others. In contrast, state civil justice systems seek to provide compensation to someone who has been harmed by an unreasonably dangerous product or activity—*after* the harm has already occurred. In addition to this compensatory role, civil justice systems reinforce the efforts of positive law to prevent harm before it occurs. Specifically, the threat of paying compensation to victims can also have a deterrent effect, even though this is not the primary purpose of state civil justice systems. In this way, state civil justice systems support positive law by deterring the unreasonably dangerous products and activities before they harm others.[3]

The synergistic dynamic that exists between federal regulation and state civil justice systems is present the area of drug safety. In particular, state civil justice systems currently provide name brand drug manufacturers an additional incentive to manufacture, label, and distribute their products in ways that avoid harming consumers, even beyond what is specifically required by applicable laws and regulations.

Indeed, the additional deterrent effect provided by state civil justice systems is especially important for agencies such as the FDA that at times have become characterized by regulatory dysfunction. Regulatory dysfunction occurs when agencies fail to regulate hazards that can and should be regulated or when they fail to implement or enforce the regulations they have issued. These failures can occur for a variety of reasons, including shortfalls in funding, outdated authorizing statutes, political interference, and a demoralized civil service.[4] Under these circumstances, the direct deterrent effect of federal regulatory standards is severely diminished, making the indirect deterrent effect provided by state civil justice systems all the more important. To be sure, vibrant state civil justice systems will not completely reverse the problem of regulatory dysfunction at the FDA, but they can help to alleviate some of its negative consequences.

State civil justice systems further enhance the effectiveness of federal regulatory programs by encouraging key stakeholders to continuously generate and evaluate new information related to risk regulation. This informational role is particularly important for monitoring the safety of the FDA's initial drug approvals, which are based on the results of a limited number of short-term clinical trials that are conducted by the drug manufacturers and that often use test patients who are not necessarily representative of the patients who ultimately use the drug. By definition, these studies do not catch long-term effects that manifest themselves many months or years after

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[2] *See* United Construction Workers v. Laburnum Construction Corp., 347 U.S. 656 (1954); Int'l Union v. Russell, 356 U.S. 634 (1958); Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984); English v. General Electric Co., 496 U.S. 72 (1990).

[3] William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1588-89 (2007).

[4] *See, e.g.*, H. COMM. ON OVERSIGHT AND GOVERNMENT REFORM, MAJORITY STAFF REPORT, FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES (2008) (discussing how, during the George W. Bush Administration, the White House not only "played a significant role" in including preemption provisions into the preamble of FDA regulations, but also "pressured the agency to reject the concerns of career experts" regarding these preemption provisions).

patients begin taking a drug. Without state civil justice systems, it is unlikely that data about post-market problems would ever be collected or analyzed, particularly since the FDA simply does not have the resources to follow up on all of the adverse events reports that they receive.[5]

State civil justice systems add a crucial set of institutional actors who have a strong incentive to gather this new risk regulation information.[6] The goal of a monetary recovery by plaintiffs and their lawyers can lead to civil discovery and the revelation of information not considered when past regulatory decisions were made. This information might have been overlooked, withheld, or perhaps not yet in existence when the regulatory agency conducted its review years earlier.[7] In contrast, regulatory agencies often lack any incentive to gather information about past regulatory actions, since the laws under which they operate rarely require or encourage them to reexamine and reassess these past actions.[8] In this way, the information generated through tort litigation can feed back into regulatory agencies, prompting them to reexamine past regulatory decisions, and ideally to develop better regulations.[9]

The role that state civil justice systems play in monitoring and reexamining earlier regulatory decisions is particularly important in the context of the FDA's regulatory programs for drugs—areas in which information is constantly evolving. For example, the relative efficacy or risks of a drug generally becomes clearer over time and with clinical use, but FDA efforts to investigate and monitor drugs after approval has at times been problematic. For example, soon after Merck's blockbuster painkiller Vioxx was first approved in 1999, evidence began to mount that use of the drug doubled the risk of heart attacks. By one estimate, between 88,000 and 139,000 Americans suffered a heart attack or stroke as a result of taking Vioxx before Merck finally took the drug off store shelves in 2004.[10] The FDA was not able to detect this problem sooner, however, because it did not have the resources to monitor the long-term risks of Vioxx after it had been approved. State civil justice systems, however, can fill this gap by spurring such investigation and monitoring of previously approved drugs.[11]

State civil justice systems also provide a strong incentive for corporate actors to continually revaluate risk information.[12] Encouraging industries to monitor risk information is particularly important in the context of drug safety, since members of the drug industry are likely to have superior information—and have it earlier—than the FDA. The desire to avoid tort liability encourages industries to monitor risk information with an eye toward reducing health and safety risks. In the absence of vibrant state civil justice systems, however, industries generally face strong incentives to avoid gathering new risk information, since the discovery of new information might lead to the strengthening of any applicable federal standards. As a result, the failure to

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[5] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: SHORTCOMINGS IN FDA'S PREMARKET REVIEW, POSTMARKET SURVEILLANCE, AND INSPECTIONS OF DEVICE MANUFACTURING ESTABLISHMENTS (2009), *available at* http://www.gao.gov/new.items/d09370t.pdf.

[6] Buzbee, *supra* note 3, at 1589.

[7] *Id*. at 1598-99; Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068-70 (2000).

[8] Thomas O. McGarity, *Some Thoughts on "Deossifying" The Rulemaking Process*, 41 DUKE L.J. 1385, 1401 (1992).

[9] Buzbee, *supra* note 3, at 1583; Thomas O. McGarity, *The Regulation-Common Law Feedback Loop in Non-Preemptive Regimes*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION, ch.11 (William W. Buzbee ed., 2009).

[10] *FDA, Merck, and Vioxx: Putting Safety First?: Hearing Before the S. Comm. on Finance*, 108th Cong., 2004 (statement of David J. Graham, MD, PHD, Assoc. Dir. for Sci. & Med., Office of Drug Safety, U.S. Food & Drug Admin.).

[11] Buzbee, *supra* note 3, at 1616.

[12] THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES 238 (2008).

discover new risk information might ensure that inappropriately lax standards remain in place for a long time, placing consumer health and safety at unreasonable risk. Moreover, the incentive that state civil justice systems provide to industry to monitor new risk information also serves to reinforce a key provision of the Food and Drug Administration Amendments Act of 2007, which requires the drug industry to report to the FDA on any post-market adverse events they encounter.[13] Together, this statutory requirement and state civil justice systems will help to induce the drug industry to study and analyze new risk information in a much more timely and effective fashion.

Lastly, state civil justice systems enhance the effectiveness of the FDA's programs by providing a diversity of regulatory institutions, which is necessary to counter the problem of regulatory capture.[14] Regulatory capture occurs when an industry is able to exert control over an agency that has been charged with regulating it, so that the agency acts in the industry's interest rather than in the public interest. The typical results of captive agencies are lax regulations that impose little in the way of compliance costs on the regulated industry, but inadequately protect public health and safety. By dispersing regulatory authority over a greater number of institutions (*i.e.*, by including all state courts), state civil justice systems reduce the likelihood that federal agencies like the FDA will become captured. Because the FDA and the state courts each share substantial authority to hold the drug industry accountable, the value of capturing the FDA is substantially diminished. Even if the industry managed to secure lax regulatory standards from the FDA, their compliance with these standards would not necessarily shield them from the threat of liability for state tort claims. Moreover, it is hard to envision the drug industry capturing both the FDA and even a significant portion of the state courts, thereby making it highly unlikely that this industry would ever be able to achieve total control of every accountability mechanism to which it is subject.

III. CONCLUSION

We support the FDA's proposed regulation, and we urge the FDA to work as expeditiously as possible to finalize this action. As described in the comments above, this rulemaking will deliver significant public health and safety benefits by enabling state civil justice systems to play an active role in safeguarding the public against unreasonably dangerous generic drugs. We thank you for the opportunity to provide these comments, and we are happy to discuss them with you in further detail.

Sincerely,

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[13] Alice K. Marcee, *Expanded Access to Phase II Clinical Trials in Oncology: A Step Toward Increasing Scientific Valiadity and Compassion*, 63 FOOD & DRUG L.J. 439, 445 (2008).
[14] Buzbee, *supra* note 3, at 1609-10.

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