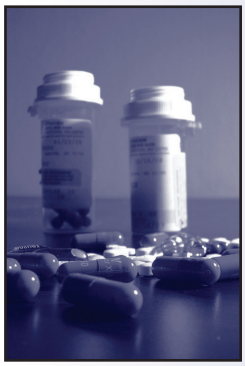

'Fifty FDAs':

An Argument for Federal Preemption of State Tort Law That is Less Than Meets the Eye

By CPR Member Scholars William Buzbee, William Funk, Thomas McGarity, and Sidney Shapiro, and CPR Staff James Goodwin and Matthew Shudtz

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Introduction

The drug and medical devices industries have long sought to deny citizens access to state courts, where these companies might be held liable for injuries caused by their potentially dangerous products. One favored tactic in that effort has been to champion the cause of federal regulatory preemption, a doctrine derived from the U.S. Constitution's Supremacy Clause, which holds that federal law is supreme, and that whenever state law conflicts with it, federal law takes precedence. In recent decades, the lawyers representing industry defendants have attempted to expand this crucial but limited doctrine, to transform it into a nearly impenetrable shield against liability under state tort law. In particular, industry lawyers have argued that the doctrine's reach should include protective regulatory actions taken by federal agencies like the Food and Drug Administration (FDA). Perhaps even more troubling, industry lawyers have also asserted that the preemptive effect of federal regulations applies to both state positive law (*i.e.*, the body of law derived from constitutions, statutes, and regulations) as well as state common law (*i.e.*, the body of law derived from judicial decisions).

The state tort law system is an important component of the nation's civil justice system. It enables individuals to seek redress for injuries caused by dangerous products and to hold manufacturers of these products accountable. Widespread preemption of state tort law would significantly undermine, if not eliminate, the rights of individuals to obtain compensation for their injuries.

Proponents of federal regulatory preemption have resorted to a number of creative and seductive policy arguments to justify their attempts to displace this important institution. Among these, the "50 FDAs" argument has been one of the most emphasized. This argument posits that the continued operation of state tort law in the fields of drug and medical device safety is tantamount to having 50 FDAs regulating the manufacture, labeling, and distribution of these products. Proponents of federal regulatory preemption contend that this threatens to create a patchwork of different health and safety standards that would unduly inhibit the ability of drug and medical device companies to compete efficiently in the national marketplace.

The "50 FDAs" argument undoubtedly packs a powerful rhetorical punch, but a closer examination reveals that it has little substantive merit. In practice, tort law is just as uniform and predictable as a unitary federal standard, and it therefore does not create any real impediment to interstate commerce. Moreover, this argument disregards the many benefits of a robust tort regime.

The purpose of this white paper is to try to put to rest the unhelpful and disingenuous "50 FDAs" argument that proponents of federal regulatory preemption have trumpeted the last few decades. First, the paper will examine the "50 FDAs" argument in greater detail, with an eye toward understanding the concerns that have motivated manufacturers of drugs and

medical devices to adopt this argument. Second, the paper will explain why the "50 FDAs" argument should be rejected. Specifically, it will argue that the concerns that purportedly motivate the argument are groundless. It will also argue that preemption of state tort law would ultimately be counterproductive, since the displacement of a vibrant state tort law system would greatly undermine the valuable role that state tort law plays in U.S. governance.

The '50 FDAs' Argument in Favor of Federal Regulatory Preemption

According to proponents of federal regulatory preemption, the state tort law system operates like 50 separate FDAs, placing an onerous regulatory burden on drug and medical device companies serving national markets. Because tort law develops independently in each state, the argument goes, drug and medical device companies risk being subjected to 50 different—and possibly discordant—regulatory standards for manufacturing, labeling, and distributing their products. Complying with 50 different standards, the argument continues, places too great a burden on companies that compete in the national marketplace. Faced with disparate regulatory standards, these companies might restrict their activities to a single state, or they might be forced to comply with the most protective state standard, even if that standard is unreasonably stringent. In either case, supporters of federal regulatory preemption argue, consumers will face higher priced goods, leading to economy-wide inefficiencies.[1]

When drug and medical device companies rely on the "50 FDAs" argument, they are implicitly expressing their preference for a unitary federal standard for regulating their products. The companies prefer such a unitary federal standard—produced by federal regulations that preempt state tort law—because, according to their argument, state tort law lacks uniformity and predictability. Companies assert that such regulatory standards are essential preconditions to their attempts to compete effectively in the national marketplace.[2] With a uniform, nationwide regulatory standard, these companies are able to take advantage of the economies of scale that come with mass producing and distributing products throughout the United States. Such economies of scale enable them to produce and distribute their products more cheaply. Furthermore, greater predictability in regulatory standards minimizes the number of upfront investments that companies must make in order to achieve compliance. These lower compliance costs also enable them to manufacture their products more cheaply.

Lastly, drug and medical device companies' preference for unitary federal standards is also likely driven by an unstated motive: their desire to keep the regulatory authority to which they are subject confined to a single institution, and one that is highly susceptible to political pressure at that. It is much easier and more cost-effective for these companies to influence or pressure the FDA, a single agency, than the vast and independent state court systems. In contrast to the state tort system, a unitary federal standard enables the drug and medical device companies to expend a lot of resources in one place in order to obtain regulatory leniency. This was especially important during the recent Bush Administration, when the FDA took a decidedly business-friendly approach to regulating drugs and medical devices, and thus was much more likely to give the manufacturers of these products a sympathetic hearing regarding their concerns.

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Rejecting the 50 FDAs Argument

State Tort Law is Both Uniform and Predictable

As will be explained, the "50 FDAs" argument rests on two assumptions. The first is that state tort law is in fact incoherent and unpredictable, as the proponents of federal regulatory preemption have repeatedly charged. But preemption supporters have never presented any concrete empirical evidence in support of this assumption. Instead, it seems, the public must accept at face value their claims that state tort law produces inconsistent and unpredictable standards across the United States.

Generally speaking, the uniformity and predictability of law depends on two considerations: the content of the law and the application of the law. A careful examination of both of these considerations supports the conclusion that state tort law is both uniform and predictable.

The Content of State Tort Law is Uniform and Predictable

The common law tort duties under which drug and medical device manufacturers operate are remarkably similar from one state to the next. This should come as no surprise as state courts and legislatures are frequently persuaded by writers of uniform laws and the *Restatements of Law* to apply consistent language in articulating common law liability rules. For example, all 50 states employ the "reasonable person" test for determining negligence. Similarly, elements of a claim for intentional infliction of mental distress and strict liability for unreasonably dangerous conduct vary imperceptibly from state to state.[3]

To be sure, the states do appear to vary in their interpretation of product liability law. Specifically, some states purport to follow a "risk-utility" test, whereas others follow the "consumer expectations" test for determining liability. The risk-utility test asks whether a reasonable person would conclude that a product's utility (as opposed to the utility of a substitute product) is outweighed by its risks, whereas the consumer-expectations test asks whether a product's danger is greater than what a reasonable consumer would expect. As Professor Douglas Kysar has shown, however, in actual practice the application of the consumer-expectations test readily collapses into the application of the risk-utility test.[4] In other words, when courts have attempted to answer the question of what a reasonable consumer might expect from a product, their analysis invariably gives way to an analysis of whether a reasonable person would conclude that a product's utility outweighs its risks. The two tests appear to address the issue of product liability from different starting points, but they nonetheless end up asking the same question about a product's risk versus its utility. Thus, while the language that courts use in instructing juries may vary from state to state, the basic concepts at issue in product liability claims are the same throughout the country, thereby negating the drug and medical device companies' concerns about uniformity and predictability.

The Application of State Tort Law is Uniform and Predictable

Since the *content* of tort law does not raise any uniformity or predictability concerns, proponents of federal regulatory preemption are left making the complaint that the lack of uniformity and predictability arises from the *application* of tort law in similar cases by different juries. Closer scrutiny reveals that this complaint is similarly misplaced.

In practice, the *application* of state tort law is generally uniform and predictable. What tends to vary across cases are the individual *judgments*. For instance, a product may be found unreasonably dangerous in one case, but not in another. Such disparities, however, are not the same thing as non-uniformity and unpredictability in application, because they normally result from differences in the facts presented in each of the cases. In particular, new facts in subsequent cases might shed new light on a manufacturer's reasonableness or unreasonableness. For example, early attempts by states and individuals to sue the tobacco companies for tort damages routinely failed, because the companies were able to mount substantive defenses that cast doubt on the addictive nature of nicotine and that challenged the causal relationship between smoking and deadly diseases.[5] Once new evidence began to emerge showing that the tobacco companies were aware of the deadly and addictive properties of their products,[6] the plaintiffs in these cases began to consistently win.[7]

To be sure, some variations in judgment can be the result of mistakes by juries, but there is no evidence that these mistakes are anything but rare. In any event, juries are just one component of the state tort law system. Other components, such as a trial court's power to grants motions to dismiss or for summary judgment before a jury hears a case, to limit the evidence a jury gets to hear, to issue a judgment for the defense notwithstanding a jury verdict, and to grant remittiturs lowering the amount of damages granted by a jury, along with the appellate system, all exist to prevent or correct these rare instances. As the series of lawsuits involving Bendectin demonstrate, the entire state tort law system working together produces results that are as uniform and predictable as would be produced under a unitary federal standard. There, despite inconsistent verdicts in trial courts, after appeal the defendants prevailed in virtually every case.[8]

Moreover, because they are based on factual differences, different judgments do not impose non-uniform or unpredictable requirements on the behavior of drug and medical device companies.[9] In fact, technically speaking, judgments in state tort law cases do not impose "requirements" at all. In contrast to federal regulations, state tort law is not meant to prescribe specific actions for people or companies to take. Instead, it is meant only to compensate victims of tortious actions. To be sure, the threat of paying compensation may create incentives that will deter people or companies from engaging in tortious conduct, but this is not the primary purpose of state tort law—and it is certainly not the same thing as prescribing specific behavior, as positive law often does.

The distinction between positive law and state tort law with regard to affecting individual or company behavior is readily apparent in the context of drug labeling. Product liability

cases involving drugs are almost always based on a "failure to warn" claim in which the plaintiff argues that the defendant company's drug caused some adverse effect that was not recognized by the FDA and was not on the label. The resolution of these cases typically turns on the question of causation—that is, did the drug in fact cause the claimed side effect? If the plaintiff proves causation, then they win the lawsuit, since, by definition, the plaintiff had not been warned about the drug's side effect. In a series of "failure to warn" lawsuits brought against a particular drug, different juries may reach different judgments on the causation question. These different judgments do not impose non-uniform or inconsistent requirements on the drug manufacturer, however. Instead, the label on the drug will remain unchanged until either the manufacturer decides to change it (either with the FDA's approval or through the "changes being effected" supplements discussed below) or until the FDA belatedly orders the manufacturer to change it. Importantly though, once the label has been changed—either with the FDA's approval or under the FDA's orders—the change applies in all 50 states. Under no circumstances would the operation of the state tort system require a drug manufacturer to have one label for Iowa and a different one for Kansas.

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In some cases, the drug or medical device manufacturer may respond to a series of "failure to warn" lawsuits, by completing a "changes being effected" supplement for the label that is at issue. "Changes being effected" supplements involve changes that manufacturers can make to their labels without prior approval from the FDA. These supplements are only permitted in instances in which the manufacturer is seeking to add to a label new information regarding the risks of using a particular drug or medical device. As with the regular process for changing drug and medical device labels, the "changes being effected" supplements process also does not raise any uniformity problems, since it too also requires that all of the labels for a drug or medical device be changed—not just those in a particular state or group of states.

Federal Standards are Not Inherently Predictable

The second assumption upon which the "50 FDAs" argument rests is that federal standards are—unlike state tort law—somehow inherently uniform and predictable. Undoubtedly, unitary federal standards are by their very nature uniform. After all, each drug or medical device goes through the FDA's approval process only once; if the drug or medical device is approved, then that approval applies equally throughout the United States. The much trickier question is whether federal standards are also predictable. Closer scrutiny reveals that they are not.

To begin with, the FDA's drug and medical device approval process is subject to the same fact-based, context-specific judgments that characterize the state tort law system. The FDA approves drugs and medical devices on a case-by-case basis just as tort cases are resolved on a case-by-case basis. Using evidence provided to it by the manufacturer, the FDA assesses the benefits and risks of the drug or medical device to determine if it produces, on balance,

a positive benefit-to-risk ratio. The FDA generally approves those drugs and medical devices that it determines to have a positive benefit-to-risk ratio. In this way, the FDA's drug and medical device approval process is governed by general standards and is undeniably *ad hoc* in nature. As such, it is subject to the same kind of unpredictable variations that occur whenever a broad standard is applied in a variety of contexts. Especially for a drug or medical device that involve a "close call" in terms of whether it will be approved, the manufacturer has no way of predicting how the FDA will decide. Nothing about the FDA approval process makes it intrinsically more predictable than state tort law.

The approval process for drugs and medical devices is further complicated by the fact that the FDA has the authority to modify or take contrary actions with regard to one of its earlier approval decisions. Thus, between the reliance on broad standards and the possibility of subsequent change to earlier approval decisions, the application of the FDA's approval process for drugs and medical devices is arguably more susceptible to the criticism of unpredictability than state tort law.

Lastly, to the extent that a drug or medical device company is subject to an FDA enforcement action, the entity that will ultimately decide whether the company complied with the applicable FDA standard will be a judge or a jury, just as in a state torts law case. Thus, in these compliance cases, the potential for unpredictable variability in judgments from jury to jury or judge to judge does not necessarily distinguish the FDA's regulatory programs from state tort law to any significant degree.[10]

State Tort Law is an Essential Part of the U.S. Government

As exemplified by the "50 FDAs" argument, advocates of federal regulatory preemption focus entirely on the benefits of supplanting state tort law with unitary federal standards—namely, the increased uniformity and predictability that unitary federal standards allegedly offer. The argument conveniently overlooks the many institutional advantages that the state tort law system offers—particularly when working in concert with federal regulatory programs.

To begin with, the state tort law system, when compared to legislatures or regulatory agencies, is a distinctly "populist" institution. As such, it offers unique advantages that are separate and apart from its instrumental benefit in compensating victims and deterring accidents or reducing intentional harms. These 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 matters of fact) as well as in the "open courts" provisions in various state constitutions. Unlike legislatures and regulatory agencies, courts must hear the tort-related complaints brought by ordinary people. Indeed, courts must always remain open, whereas the other branches can easily ignore the concerns of citizens, either by shirking their duties or by becoming captured. Moreover, average people have a closer and more direct relationship with state tort law, which is still primarily defined through the common law,

than they do with unitary federal standards, which are developed by expert agencies. Unlike federal standards, jury decisions reflect the common sense and experiences of ordinary people. Lastly, common law torts represent 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 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 its unique "populist" benefits, the state tort law system plays a crucial role in the promotion of health and safety goals. In fact, an energetic state tort law system can actually improve the effectiveness of federal regulatory programs, such as the FDA's programs for regulating drugs and medical devices.

As the U.S. Supreme Court recognized for much of the 20th century, state tort law serves as an invaluable complement to federal and state positive law in protecting public health and safety.[11] 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 tort law seeks to provide compensation to someone who has been harmed by a tortious action—*after* the action has already occurred. As explained above, the threat of paying compensation also can have a deterrent effect, even though this is not the primary purpose of the state tort law system. As such, the state tort law system supports positive law in deterring the unreasonably dangerous products and activities that it targets.[12] Hence, by providing drug and medical device manufacturers an additional incentive to manufacture, label, and distribute their products in ways that avoid harming people, state tort law reinforces the FDA's regulatory programs for these products.

The additional deterrent effect provided by the state tort law system is especially important for agencies like the FDA that 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.[13] Under these circumstances, the direct deterrent effect of federal regulatory standards becomes severely diminished, making the indirect deterrent effect of state tort law all the more important. To be sure, a vibrant state tort law system will not eliminate the problem of regulatory dysfunction at the FDA, but it can help to alleviate some of its negative consequences.

The state tort law system further enhances 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 the FDA's drug and medical device approvals, which are based on the results of a limited number of short-term clinical trials that are conducted by the drug and medical device companies and that often use test patients who are not necessarily representative of the patients for whom

the drug or medical device is ultimately intended. By definition, these studies do not catch long-term effects that manifest themselves many months or years after patients begin taking a drug or using a medical device. Without the state tort law system, however, 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.[14]

The state tort law system adds a crucial set of institutional actors who have a strong incentive to gather this new risk regulation information.[15] 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.[16] 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.[17] In this way, the information generated through state tort litigation can feed back into regulatory agencies, prompting them to reexamine past regulatory decisions, and ideally to develop better regulations.[18]

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The role that state tort law plays in monitoring and reexamining earlier regulatory decisions is particularly important in the context of the FDA's regulatory programs for drugs and medical devices—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 been and remains problematic. For example, soon after Merck's blockbuster painkiller Vioxx was first approved in 1999, evidence quickly 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.[19] 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. The state tort law system, however, can fill this gap by spurring such investigation and monitoring of previously approved drugs.[20]

State tort law also provides a strong incentive for industry to continually revaluate risk information as well.[21] 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 a strong state tort law system, 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 unitary federal standards. As a result, the failure to 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 the state tort law system provides 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 and medical device industries to report to the FDA on any post-market adverse events they encounter.[22] Together, this statutory requirement and the state tort law system will drive these industries to study and analyze new risk information in a much more timely and effective fashion.

Encouraging industries to monitor risk information is particularly important in the context of drug and medical device safety, since these industries are likely to have superior information—and have it earlier—than the FDA. Furthermore, the FDA has some regulations and procedures in place that are designed to encourage the drug and medical device companies to take a more proactive role in updating the warnings for their products. These include the regulations for "changes being effected" supplements to drug and medical device labels and the "supplemental New Drug Application" procedures. State tort law will further the objectives of these regulations and procedures by creating an additional incentive for drug and medical device companies to monitor and evaluate new risk information regarding their products, which will help them to update their product warnings in a more timely and effective manner.

By dispersing regulatory authority over a greater number of institutions (*i.e,* by including all state courts), the state tort law system reduces the likelihood that federal agencies like the FDA will become captured by the industries they regulate.

Lastly, state tort law enhances the effectiveness of the FDA's programs by providing a diversity of regulatory institutions, which is necessary to counter the problem of regulatory capture.[23] 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), the state tort law system reduces the likelihood that federal agencies like the FDA will become captured. Because the FDA and the state courts each share substantial regulatory authority over the drug and medical device industries, the value of capturing the FDA is substantially diminished. After all, even if these industries managed to secure lax regulatory standards from the FDA, their compliance with these standards does not shield them from the threat of liability for state tort claims. Moreover, it is hard to envision the drug and medical device industries capturing both the FDA and even a significant portion of the state courts, thereby making it highly unlikely that these industries would ever be able to achieve total control of every accountability mechanism to which they are subject.

The need for countering the problem of regulatory capture at the FDA has become particularly acute in recent years. During this period, there have been frequent news reports of high-ranking agency officials ignoring the advice of their expert staff when considering drug and medical device approvals.[24] One especially egregious case involved the FDA's December 2008 approval of Menaflex—a medical device developed by Regen Biologics, Inc., that is used to repair torn knee menisci—using the agency's fast-track approval procedure. In contrast to the FDA's full review procedure, the fast-track procedure does not require a medical device to undergo clinical trials in order to be approved. Without clinical

trials, the fast-track procedure increases the risk that a device will be approved without detecting any potentially dangerous risks that it might cause in patients. The medical device industry prefers the fast-track procedure, because it significantly reduces the time and costs that must be expended in order to get a product approved. Given the risks involved, FDA rules stipulate that the fast-track procedure is only meant for low-risk devices that are similar to already-existing products. FDA staff scientists opposed approving Menaflex under the fast-track procedure, since no other devices like it were already on the market. They were ultimately overruled by high-ranking agency officials, however. The staff scientists later argued that the fast-track approval was the result of pressure from Regen Biologic, rather than appropriate scientific considerations.[25] As the Menaflex incident illustrates, the FDA frequently behaves like a captured agency, leaving many Americans inadequately protected against unsafe drugs and devices. As such, it is imperative to maintain an energetic and independent state tort system that is able to continue protecting Americans when the FDA falls short.

Conclusion

Despite the claims of proponents of federal regulatory preemption, the "50 FDAs" argument does not justify displacing the state tort law system with unitary federal standards for regulating the manufacture, labeling, and distribution of drugs and medical devices. Careful examination reveals that state tort law—both in terms of its content and application—is no less uniform and predictable than a unitary federal standard. Similar careful examination also reveals that the application of federal standards does not inevitably produce predictable results. Accordingly, the drug and medical device industries have no reason to prefer a unitary federal standard, as the "50 FDAs" argument seems to suggest, other than their desire to avoid liability for the injuries they cause. Moreover, the "50 FDAs" argument disregards the many advantages of a vibrant state tort law system. In particular, the "50 FDAs" argument ignores both the "populist" advantages of the state tort law system as well as the ways in which state tort law enhances the effectiveness of FDA's programs for regulating drugs and medical devices.

In the end, it seems that the preemption supporters' real objective in making the "50 FDAs" argument is trying to avoid tort obligations altogether. The concerns with uniformity and predictability that form the basis of the "50 FDAs" argument appear to be a cover for the drug and medical device companies' substantive preference for FDA's regulatory standards. Because FDA often behaves like a captured agency, these companies can more easily affect the content of those standards. In contrast, these companies know that they cannot capture juries to the same degree, no matter how many resources they throw into a trial. In short, the "50 FDAs" argument is not really about promoting uniform and predictable regulatory standards; instead, it is about promoting uniform and predictable laxity.

Regardless of the motivations that gave rise to the "50 FDAs" argument, however, now is the time to reject it. The value of an energetic state tort law system—particularly one that works in conjunction with effective federal regulatory programs—cannot be overstated. Not only is the state tort law system one of the most important "populist" institutions in the U.S. system of governance, it plays an essential role in promoting public health and safety. FDA's programs for regulating drugs and medical devices would be severely weakened without it. As such, any further discussion regarding the complete displacement of this vital institution is fundamentally counterproductive. Instead, the interests of public health and safety demand that we recast our focus on discovering new ways to invigorate the state tort law system, so that it can continue to help protecting people from dangerous products.

End Notes

[1] *See, e.g.*, Alan Schwartz, *Statutory Interpretation, Capture, and Tort Law: The Regulatory Compliance Defense*, 2 Am. L. & Econ. Rev. 1, 17 (2000); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System,* 88 Geo. L.J. 2167, 2177-78 (2000); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 Colum. L. Rev. 277, 316-17 (1985).

[2] Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. Rev. 1353, 1371, 1385 (2006).

[3] Thomas O. McGarity, The Preemption War: When Federal Bureaucracies Trump Local Juries 216-19 (2008).

[4] Douglas A. Kysar, *The Expectations of Consumers*, 103 Colum. L. Rev. 1700, 1715-24 (2003).

[5] *See* William Haltom & Michael McCann, Distorting the Law: Politics, Media, and the Litigation Crisis 230 & note 6, 233-36 (2004); Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 Stan. L. & Pol'y Rev. 63, 71 (1997).

[6] *See* Haltom & McCann, *supra* note 5, at 237-39; Kelder & Daynard, *supra* note 5, at 76-80.

[7] *See, e.g,* Maria Shao, *A Clear Landmark in a Widening Legal Battle*, Bos. Globe, Mar. 16, 1996

[8] Michael D. Green, Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation 273-87 (1996); Richard L. Marcus, *Reexamining the Bendectin Litigation Story*, 83 Iowa L. Rev. 231, 234-39 (1997). Merrell, the drug's manufacturer, also prevailed in a separate federal case involving Bendectin that combined numerous suits brought in various federal district courts. In that case, the jury found that there was insufficient scientific evidence to establish a causal relationship between Bendectin and the claimed birth defects. Marcus, *supra*, at 236-37.

[9] *See* Bates v. Dow Agrosciences, 544 U.S. 431, 445 (2005).

[10] McGarity, *supra* note 3, at 216-19.

[11] *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).

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

[13] *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).

[14] *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.

[15] Buzbee, *supra* note 12, at 1589.

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

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

[18] Buzbee, *supra* note 12, 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).

[19] *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.).

[20] Buzbee, *supra* note 12, at 1616.

[21] McGarity, *supra* note 3, at 238.

[22] 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).

[23] Buzbee, *supra* note 12, at 1609-10.

[24] *See, e.g.*, Gardiner Harris, *F.D.A. Scientists Accuse Agency Officials of Misconduct*, N.Y. Times, Nov. 17, 2008, *available at* http://www.nytimes.com/2008/11/18/health/policy/18fda.html?_r=1.

[25] Alicia Mundy, *Political Lobbying Drove FDA Process*, Wall St. J., Mar. 6, 2009, *available at* http://online.wsj.com/article/SB123629954783946701.html.

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