

January 13, 2009

Mr. Peter Orszag
Executive Office of the President-Elect
451 6th Street, NW
Washington, DC 20001

Mr. Cass Sunstein
Executive Office of the President-Elect
451 6th Street, NW
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Dear Messrs. Orszag and Sunstein:

Congratulations on your new appointments in President-elect Barack Obama's administration. Your roles at the Office of Management and Budget will be crucial to ensuring that the health and safety of American families remain the underlying goals of all federal regulations.¹ The signatories to this letter work in different areas of law and policy but are brought together by common concerns regarding federal preemption of state law. Federal regulatory agencies under the Bush Administration and at the urging of industry have been pushing courts to hold that federal regulation preempts state-law remedies even though state common law is the only avenue for individuals to seek compensation for injuries caused by most consumer products.

As a United States senator, President-elect Obama co-sponsored the Medical Device Safety Act, which was drafted in response to a recent Supreme Court ruling, *Riegel v. Medtronic*. The bill would restore injured patients' rights to hold medical device manufacturers liable for injuries caused by defective devices. We urge the President-elect and his Administration to continue to support that legislation and to take additional action to reverse the recent efforts to immunize corporations from liability under state law. Reversing these efforts will help advance President-elect Obama's policy goals in several areas, including consumer protection, financial reform, and environmental policy.

State common law and state consumer protection statutes historically have played an important role in consumer protection. Consumers use state common-law claims and consumer protection statutes to hold companies accountable for product defects and receive compensation for injuries. These state laws motivate companies to revise labels in a timely manner, improve products quickly after defects are identified, and remove from the market older products that do not provide the safety that newer ones offer.

Lawsuits seeking damages under state law provide other benefits as well. For example, discovery taken in litigation on prescription drugs and medical devices have brought to light crucial information about the risks of certain products that had never been made public or brought to the attention of the Food and Drug Administration (FDA). Similarly, state consumer protection laws complement federal efforts to protect the public from unfair and deceptive trade practices and

¹ This letter is a slightly modified version of a Dec. 23 letter sent to Ms. Sally Katzen of the Obama transition team.

false advertising to consumers. Federal preemption threatens all of these protections and societal benefits.

After unsuccessful attempts to persuade Congress to eliminate state tort liability, corporations over the past two decades have sought to shield themselves from liability by working vigorously to expand the scope of federal preemption. During the past eight years, federal regulatory agencies including the FDA, the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, and the Federal Railroad Administration boosted these arguments by inserting statements in preambles to rules, asserting that the rules preempt state tort law.

Although not binding on the courts, these statements have strongly influenced courts faced with manufacturers' arguments that they cannot be held liable under state law because their products comply with a federal standard. In many cases, courts have declared that state common-law duties and state consumer protection laws are preempted based on a nebulous "conflict preemption" theory, meaning that holding companies liable for injuries under state law would "frustrate the purpose" of federal regulation.

An October 2008 report by the House Committee on Oversight and Government Reform, entitled *FDA Career Staff Objected to Agency Preemption Policies*, sheds light on the political nature of the FDA's current position on preemption. At the FDA, political appointees in 2005 demanded that amendments to drug labeling regulations be accompanied by a lengthy preamble asserting that patients should not be able to hold drug makers liable under state law for harm caused by their products. (Federal law provides no mechanism for holding drug makers liable to patients harmed by defective or mislabeled drugs). The House report reveals that career staff at the agency objected that the preamble was "based on a 'false assumption,' 'naïve to what actually occurs in practice,' relied on 'gross overstatement,' and made 'false and misleading' assertions." Their objections were ignored because, as the communications show, the preamble was not intended to further the agency's mission of protecting patients from unsafe and ineffective drugs. It was intended to shield drug makers from liability by bolstering the preemption theory that the companies were pushing in the courts.

The change of Administration presents an opportunity to set a better course on preemption, in which the executive branch supports rather than undermines individuals' ability to obtain justice for injuries and hold corporate wrongdoers accountable. We recommend the following steps:

- *Executive Order.* The first and crucial step in addressing regulatory agencies' efforts to effect preemption is to revise Executive Order 13132, an order initially issued by President Reagan and reissued by President Clinton in 1999. Attached to this letter is a proposed draft amendment to the executive order that would help restore oversight, regulation, and appropriate liability for corporations whose products, services, or other conduct are regulated by federal agencies. The amendment (1) states that state common-law principles (codified or not) and state unfair and deceptive trade practices statutes complement federal regulation, and (2) directs agencies to refrain from making statements in their rulemaking claiming that rules, regulations, or standards preempt state-law liability of regulated entities. Prior to 2005, the agency practice of addressing state tort law in rulemaking documents was rare. Because the impetus for this change was

not health and safety, but defeating consumer protections, the Executive Order should direct an immediate end to the practice.

- *Legislation.* Another important step is the passage of the Medical Device Safety Act (MDSA), H.R. 6381 and S. 3398, a bill co-sponsored by then-Senator Obama. The MDSA would overturn the Supreme Court’s February 2008 decision in *Riegel v. Medtronic* by revising the Food, Drug, and Cosmetic Act to state that the provision that preempts state and local “requirements” for medical devices does not preempt damages actions or liability under state law.

It is time to change course and no longer immunize regulated industries from liability to consumers by expanding the scope of preemption. Efforts to restore balance in our system should begin as soon as possible. We look forward to your swift action.

Sincerely,

Nan Aron
President
Alliance for Justice

Gerie Voss
Director of Regulatory Affairs
American Association for Justice

Rachel Weintraub
Director of Product Safety and Senior Counsel
Consumer Federation of America

Ellen Bloom
Director, Federal Policy and Washington Office
Consumers Union

Ami Gadhia
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Consumers Union

Michael Calhoun
President
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Doug Kendall
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Lauren K. Saunders
Managing Attorney
National Consumer Law Center (on behalf of its
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Sally Greenberg
Executive Director
National Consumers League

Diana Zuckerman
President
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Simon Lazarus
National Senior Citizens Law Center

Nathan Newman
Interim Executive Director
Progressive States Network

David Arkush
Director, Congress Watch
Public Citizen

Edmund Mierzwinski
Consumer Program Director
U.S. Public Interest Research Group

The following draft amendment to Executive Order 13132 would (1) require federal regulatory agencies to recognize as a fundamental federalism principle that state common law, state products liability statutes, and state unfair and deceptive trade practices statutes complement federal regulation; (2) forbid agencies from including in regulatory commentary or rules language stating that the rules preempt state-law liability of regulated entities; and (3) require agencies to reverse prior actions that are inconsistent with this policy, dating back to January 2001.

Executive Order ##### of Month, Day, 2009

Amendment of Executive Order 13132 on Federalism

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to preserve state common law, it is hereby ordered that Executive Order 13132 of August 4, 1999 be amended as follows:

Section 1. Section 1 is amended by adding a new subsection (j) to read as follows: “(j) State common-law principles, state products liability statutes, and state unfair and deceptive trade practices statutes complement federal regulation by providing an invaluable incentive for regulated entities promptly to improve products and systems and to remove unsafe products from the market. In many circumstances, these state laws also provide individuals with their sole means of seeking compensation for injuries caused by the products or services of regulated entities.”

Sec. 2. Section 4 is amended by adding a new subsection (f) to read as follows: “(f) Neither in commentary or preamble accompanying the issuance of an advanced notice of proposed rulemaking or a proposed, interim, or final rule, regulation, or standard, nor in the text of any proposed, interim, or final rule, regulation, or standard, shall an agency provide that its rule, regulation, or standard preempts liability for damages under state law (including liability under common-law principles (codified or not), state products liability statutes, or unfair and deceptive practices statutes) of entities whose products or services are regulated by the agency to any person, or preempts the duties under which such liability may be based.”

Sec. 3. Section 4 is further amended by adding a new subsection (g) to read as follows: “(g) Within 90 days of the date of this Order, each agency shall review all final regulations issued within the past 12 months and all commentary or preambles set forth in connection with any notice of proposed or final rulemaking published since January 2001, to determine whether any such regulations, commentary, or preamble was not in accordance with the foregoing amendments to this Order. If any such regulation, commentary, or preamble is not in compliance with these amendments, the agency shall initiate the process for amending the regulation or disavowing the commentary, in accordance with the requirements of the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*”

Sec. 4. Section 10(c) is amended by striking the phrase “90 days after the date of this order” and inserting “immediately.”

BARACK OBAMA
THE WHITE HOUSE
January XX, 2009