
Forum on Emerging Issues

American Business and the New Social Regulation

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Beginning in 2007, many U.S. industry associations radically adjusted their national political lobbying strategies to support legislative enactment of social regulatory policy, policy that is primarily designed to address issues related to health, safety, and the environment. The regulations that are derived from such policy are generally limited to a specific issue, but they also have the power to regulate across industry boundaries. The normative justifications for environmental, health, and safety regulation often include the impact of negative externalities generated from a manufacturing process on employees and the natural environment and/or the existence of “information asymmetries” between business and the consumer concerning potentially harmful physical qualities associated with products [Dudley 2005, p. 33].

Throughout much of this decade, much of the American business community embraced an adversarial public policy

position to enacting federal environmental, health, and safety mandates. The general position of the U.S. business community is that industry regulation is often unnecessary and a costly “regulatory tax” on their operations—much of which is passed directly through to the American consumer.¹ However, their rent-seeking, nonmarket activity has recently evolved into a more cooperative approach with other public policy stakeholders, including consumer interest groups and governments, to enact new social regulatory initiatives [Lipton and Harris 2007]. Moreover, there are other times when specific industries lobby their elected representatives to enact legislation for a national regulatory framework. For many domestic industries, this appears to be one of those times. Although major industry

¹Crain [2005] calculates that the cost of all federal business regulation on the U.S. economy totals \$1.1 trillion. According to Crain, for a small business with under 20 employees, the annual cost is \$7,647 per employee, with \$4,216, or 55.1 percent, attributable to social regulation. For firms with less than 500 employees, the annual cost of federal business regulation is \$5,262 per employee, with \$1,551, or 29.4 percent. Crain argues that these results are consistent with previous studies by Hopkins [1995] and Crain and Hopkins [2001], commissioned by the U.S. Small Business Administration. Under the George W. Bush administration, Gattuso [2008] estimates that almost \$30 billion in new regulatory costs have been imposed on Americans since 2001, with \$11 billion (generated from nearly 4,000 new administrative rules) imposed in Fiscal Year 2007.

associations such as the U.S. Chamber of Commerce and the National Association of Manufacturers have continued to “stay the course” with their largely antiregulatory agendas, other industry-specific associations, such as the Toy Industry Association, the Specialty Vehicle Institute of America, and the Grocery Manufacturers Association, are supporting stricter federal regulatory controls over their products [Williamson 2008].

A confluence of legal, political, and economic factors are motivating this industry-based effort to enact new federal social regulations [Lipton and Harris 2007]. Legally, there are many industries looking for protection from product liability lawsuits and anxious to eliminate a patchwork of state product liability laws or civil legal actions. Having been unsuccessful at enacting tort reform legislation in Congress, since 2004 the Bush administration—with strong industry support—is using executive branch rule-making authority to include preemption clauses in preambles of new federal regulations. In particular, these block consumer product liability lawsuits filed under state law from being heard in state courts, where juries are more often receptive to a plaintiffs’ claim against a corporation [Yost 2008].² At the request of

²Federal preemption clauses are legally rooted in the Supremacy Clause of the U.S. Constitution (Article VI, Section 2), whereby federal law and

corporate defendants who seek legal venues less biased against them, these product liability cases are then adjudicated in the federal court system. Since 2005, such preemption clauses have been included in 51 administrative rules proposed or adopted, with 41 of these administrative rules promulgated by the U.S. Food and Drug Administration (FDA) and the National Highway Traffic Safety Administration [Yost 2008].

Politically, industry groups are concerned (and legislative activity in the 110th Congress offers reasonable justification) that the new Democrat majority in the U.S. Congress will institute a major social and economic regulatory agenda with burdensome administrative rules for the business community to implement. With the Bush administration still wielding the Presidential veto and in control of the executive rule-making process until January 20, 2009, manufacturers are hoping to acquire new regulations in 2008 that they consider less costly and burdensome to implement than what could result if both the executive and legislative branches of the federal government are Democrat-controlled in 2009. Yet, as Gattuso [2008, p. 7] argues, there are additional, and potentially costly, bureaucratic challenges that the business community must face in the last

year of a Presidential administration:

Historically, regulatory activity surges at the end of a presidential Administration. ... These surges are not random. The most likely explanation is that regulators have an institutional incentive to clear their desks before turning over the office keys to new occupants. In the process, the normal review procedure may be overwhelmed, with more costly rules slipping through the screens.

From an economic perspective, growing competition from inexpensive imports that do not meet voluntary industry standards, especially products exported from China, have motivated many industry associations to rent-seek new domestic health and safety regulatory mandates. For example, the Toy Industry Association, in response to product recalls by the Consumer Product Safety Commission (CPSC) in 2007 for lead paint contamination of Thomas & Friends trains—followed by three separate product safety recalls for Barbie, Sesame Street, and Dora the Explorer toys (all manufactured in China)—requested that the U.S. government impose safety-testing standards on all toys sold in the United States [Lipton and Story 2007].

Another example is the Specialty Vehicle Institute of America, the industry association that represents companies manufacturing all-terrain vehicles (ATVs) in the United States. This group recently backed away from opposing federal mandatory safety standards for their

vehicles, due to inexpensive Chinese-manufactured ATVs acquiring market share with products that do not meet voluntary industry safety standards [Lipton and Harris 2007]. Also, the Grocery Manufacturers Association, an industry association representing the leading food, beverage, and consumer products companies operating in the United States, has supported stricter regulation (and an increased budget) for the FDA to strengthen its safety oversight of imported food [Grocery Manufacturers Association 2008].

Given this new regulatory environment, we next examine how the Democrat-controlled 110th Congress has responded to recent political lobbying for new social regulation, with and without industry cooperation, and the effects of the U.S. Supreme Court rulings on regulation-related appeals cases on its docket.

The 110th Congress and the U.S. Supreme Court

Corporate average fuel economy standards

The 110th U.S. Congress has passed significant new social regulatory policy legislation. The most important environmental/energy regulatory policy enacted was the “Energy Independence and Security Act of 2007” in December of 2007. This Act includes a mandated increase in the Corporate Average Fuel Economy (CAFE) standard for the total fleet of passenger automobiles manufactured for sale, from the present standard of 27.5 miles per gallon (the goal established by Congress effective in 1985) to 35 miles per gallon (a 27.3 percent increase) by 2020

regulations “trump” or supersede state law and regulations [Yost 2008]. In the preamble of the administrative rule is found the federal agency’s interpretation of whether the regulation permits preemption of product liability lawsuits, with an expansive interpretation leaving little room for an allegedly aggrieved consumer to seek civil redress [Yost 2008].

(with the fuel efficiency standard gradually phased in beginning with the 2011 automobile model year). Not surprisingly, this bill was passed in spite of intensive lobbying by the automotive industry.³ Under the new CAFE standard legislation, automobile manufacturers will be able to earn energy efficiency credits when they exceed the new CAFE standards and have a choice of either “banking” the credits when not needing them or selling them to other automobile manufacturers that not meet the CAFE standard.

On April 22, 2008, the U.S. Department of Transportation (DOT) announced an even more ambitious CAFE standard proposal in the administrative rule-making process: accelerating implementation of CAFE standards for passenger vehicles and light trucks over a five-year period ending in 2015. For passenger vehicles, CAFE standards would reach 35.7 miles per gallon (a 29.2 percent increase in fuel efficiency) in 2015, and light trucks would increase from 23.5 miles per gallon in 2010 to 28.6 miles per gallon (a 21.7 percent increase in fuel efficiency) in 2015 [U.S. Department of Transportation 2008]. For cars

and light trucks, the DOT would will require a fleet-wide average of 35.0 miles per gallon by 2020 [Power 2008].

The automobile industry, or individual manufacturers, may still legally challenge the proposed administrative rule on the grounds that the agency is exceeding the implementation timetable (and passenger vehicle miles per gallon CAFE standard) included in the original legislation. Automobile manufacturers are already calling the DOT’s CAFE standards too aggressive, especially since this year will be the worst year for U.S. automobile sales in a decade, and the industry cost of implementing the fuel efficiency regulations are estimated at approximately \$46 billion [Power 2008]. Many Democrats, however, believe that the CAFE standards should be raised even further, as this would reduce gasoline demand, save consumers \$100 billion in gasoline fuel costs, and reduce the need to drill in environmentally sensitive wilderness areas [Power 2008].

Food and drug regulation

In late September 2007, with the support of the Pharmaceutical Research and Manufacturers of America [2007], the U.S. Congress passed, and President Bush signed into law, the Food and Drug Administration Amendments Act of 2007 (Public Law No. 110-85), which renews and extends the Prescription Drug User Fee (PDUF) Act of 1992. The PDUF Act grants the FDA the authority to collect fees from pharmaceutical firms to be used for laboratory-based safety review and approval of new ethical drugs and medical devices. Under the original legisla-

tion, Congress must re-authorize PDUF every five years. Under the Act’s user fee program, the FDA will increase the annual amount of user fees it collects from pharmaceutical firms from \$305.4 million to \$392.8 million, a 26.9 percent increase in funding [U.S. Food and Drug Administration 2007]. In addition, the legislation evolved into a broader-based FDA reform bill, including provisions: that strengthen agency authority over drugs already on the market (including requiring postmarket safety studies and risk evaluation mitigation for drugs exhibiting adverse effects); increasing regulatory oversight of direct-to-consumer pharmaceutical advertising (although not granting the authority to ban false or misleading drug-to-consumer advertising); granting agency authority to order drug firms to change labeling for a drug; establishing a publicly available clinical trial database; modernizing its Adverse Events Reporting system (used to collect and aggregate safety data and reporting on new safety concerns); and granting authority to establish new standards and definitions, and if necessary, recall tainted pet food.

Consumer product safety

Consumer product safety, with a focus on imported products, has received intense scrutiny by Congress. In fiscal year 2007, there were 473 product recalls involving toys and jewelry containing excessive lead, toys with dangerous magnets that can cause stomach and intestinal injuries to children, and cribs with hardware and construction failure that could potentially cause death and injury to babies, to

³Industry critics of higher CAFE standards cite the National Research Council [2002], whose study argues that by encouraging consumers to purchase smaller cars (with plastic often substituted for metal construction to meet the CAFE miles per gallon mandate), this fuel efficiency standard has contributed to thousands of deaths and injuries in the United States. Furthermore, Kleit [2004] estimates that a 50 percent increase in CAFE standards would increase environmental emissions of volatile organic compounds by 2.3 percent, nitrogen oxide emissions by 3.8 percent, and carbon monoxide emissions by 5.0 percent.

name a few [May 9th Coalition 2008]. In response to this onslaught of product recalls [Shin 2008], the resulting Consumer Product Safety Improvement Act of 2008 includes major provisions that will reform the operations of the Consumer Product Safety Commission CPSC, including:

- increasing the budget of the agency to \$136 million for FY2009 from \$80 million to \$136 million (allowing for the hiring of at least 500 full-time employees and 50 port-of-entry and overseas production facility inspectors);
- increasing the number of CPSC members from three to five;
- requiring the CPSC to maintain a publicly available, searchable Web-based site that includes any reports received by the agency of injuries, illness, death, or risk of such harm from the use of consumer products;
- requiring the CPSC to establish protocols and standards regarding design certification of products, continuing safety compliance with standards, and accrediting third-party laboratories for testing of certain products used by children seven years or younger; effectively banning lead content and three categories of phthalates (chemical ingredients used to make such plastic products as teething rings and pacifiers for infants and toddlers) in toys and other children's products;
- allowing for the state attorneys general to have the authority to help enforce federal product safety laws, with companies failing to report safety hazards or

violating product safety laws facing up to \$15 million in financial penalties (the previous financial penalty "cap" per company being \$1.8 million).

President Bush signed the bill into law on August 14, 2008.

The issue of federal preemption clauses (superseding state law) has been a topic of recent scrutiny by the U.S. Supreme Court, with it ruling overwhelmingly in favor of federal preemption authority.⁴ On February 20, 2008, the Supreme Court ruled 8-1 in *Riegel v. Medtronic Inc.* (No. 06-179) that the preemption clause in the Medical Device Amendments of 1976 to the Food, Drug and Cosmetics Act of 1938 21 U.S.C. §360k(a) bars product liability claims in state courts that challenge the safety or effectiveness of medical devices granted pre-market approval by the FDA [Greenhouse, Feder, and Harris 2008]. Medtronic Inc, along with the Bush administration, successfully argued that allowing state personal injury lawsuits against medical device manufacturers amounts to a state "requirement" that differs from FDA requirements because such complaints are based on state law, which is preempted by the federal Medical Devices Amendments of 1976 [NewsInferno.com 2008]. This Supreme Court decision bolsters the use of federal preemption

⁴On March 3, 2008, in *Warner-Lambert v. Kent* (No. 06-1498) an equally divided court (4-4, Chief Justice Roberts having recused himself because of a conflict of interest), affirmed a preemption clause case concerning a Michigan medical device fraud proceeding that involved alleged company misrepresentation to the FDA.

clauses in administrative rule-making, but it will have a limited effect on many state medical device product liability lawsuits, as most medical devices now commercially available entered the market through a different regulatory process, one in which the FDA found them to be "substantially equivalent" to those medical devices marketed before the 1976 law took effect [NewsInferno.com 2008]. Several lawmakers, including Representative Henry Waxman, Chairman of the House Oversight and Government Reform Committee, denounced the Supreme Court's decision and promised a legislative response to its ruling [Greenhouse, Feder, and Harris 2008].

Along with the *Riegel* decision, the Supreme Court ruled the same day on two other non-medical federal preemption cases: *Rowe v. New Hampshire Motor Transport Authority* (No. 06-457) and *Preston v. Ferrer* (No. 06-1463). In *Rowe*, the Supreme Court ruled 9-0 that a preemption clause in the Federal Aviation Administration Authorization Act of 1994 preempted a Maine law (enacted for public health purposes) requiring state regulation of tobacco deliveries. In *Preston*, the Supreme Court ruled 8-1 that the Federal Arbitration Act of 1925 9 U.S.C. §1 *et. seq.*, supersedes a California state law (the California Talent Agencies Act) under which the California Labor Commissioner conducts an initial review of disputes before they are submitted to arbitration. In the fall term, the Supreme Court will hear *Levine v. Wyeth* (No. 06-1249), whereby in the case of FDA approved drugs, the Bush administration (again supportive of pharma-

ceutical manufacturers) will argue that preemption against state product liability lawsuits is implicit in the structure of the statute, although the Food, Drug and Cosmetics Act of 1938 does not specify a preemption clause [Greenhouse, Feder, and Harris 2008].

The Public Policy Environment for Social Regulation

In the 111th U.S. Congress, convening in January 2009, imported food safety and global warming issues will be addressed. In the 110th Congress, several bills were introduced addressing the U.S. food safety system, but none have been scheduled for discussion in committees [Nucci and others 2008].⁵ Some of the regulatory reforms discussed in these bills include: granting mandatory product recall authority to the 15 federal government agencies administering food safety regulations; reducing existing ports of entry for agricultural product imports; proposals to combine federal food safety agencies into one federal regulatory authority; and assessing and collecting fees on food imported into the United States to fund point-of-entry and processing plant inspections [American Farm Bureau Fed-

eration 2008]. Bi-partisan efforts will certainly be undertaken to introduce a bill in both chambers of Congress incorporating many of the major safety regulatory and funding proposals found in the various bills proposed in the 110th Congress.

In June 2008, the U.S. Senate debated the “Lieberman-Warner Climate Security Act of 2008” (S.2191/3036), a bill which is designed to reduce the volume of greenhouse gases emitted in the United States by limiting greenhouse gas emissions on electric utility, transportation, and manufacturing industries. “Lieberman-Warner” would also establish a so-called cap-and-trade regime administered by the U.S. Environmental Protection Agency for greenhouse gas emissions, whereby industrial polluters would be allocated right-to-emit credits based on the volume of greenhouse gas they currently emit. The “cap” would be reduced over time, with greenhouse gas emissions reduced by 70 percent by 2050 from 2005 levels [Lieberman 2008]. This bill was stopped from proceeding by a Senate Republican filibuster that, by a vote of 48–36, prevented it from final consideration by the U.S. Senate. Senate Republicans argued that this bill would result in significant regulatory compliance costs on the U.S. economy that would not be offset by its benefits [Lieberman 2008]. Many environmental groups were lukewarm in their support for “Lieberman-Warner,” as it did not establish stronger greenhouse gas emission targets and timetables, but they look forward to introducing new legislation, similar to the “Investing in Climate Action and Protection Act” or “iCap” (HR.6186), in-

troduced by Congressman Ed Markey (D-MA) under a new Congress and President [Lance 2008]. Under HR.6186, greenhouse gas emissions will be reduced by 85 percent from 2012 levels, a moratorium will be placed on traditional coal-fired plants, 100 percent of pollution permits will be auctioned by 2020, and there will be public investment in “green” workforce training [Lance 2008].

Either John McCain or Barack Obama will be a much stronger supporter of social regulation of business than President George W. Bush has been. Senator McCain has supported higher CAFE standards and the implementation of carbon emissions trading regimes, and has referred to himself as one of the “great enemies of the pharmaceutical companies in Washington” [Javier 2008a]. Senator Obama has indicated that he is a strong supporter of environmental and labor provisions in free-trade pacts and alternative fuel projects [Javier 2008b]. He has hinted, however, that Republicans may have better ideas than Democrats when it comes to business regulations that rely on guidelines and incentives [Chipman and Shields 2008]. One conclusion appears inescapable, however: in 2009, American businesses can bank on a continuation of new federal social regulatory initiatives being introduced by an activist Congress and supportive Executive branch.

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⁵Bills introduced in the U.S. Senate include the Safe Food Act of 2007 (S.654), Human and Pet Food Safety Act of 2007 (S.1274), Imported Food Security Act of 2007 (S.1776), Fresh Produce Safety Act of 2007 (S.2077), The Food Safety Authority Modernization Act of 2007 (S.2245), Ending Agricultural Threats: Safeguarding America’s Food for Everyone (EAT SAFE) Act of 2007 (S.2418), and in the U.S. House of Representatives, the Safe Food Act of 2007 (H.R. 1148), The Assured Food Safety Act of 2007 (H.R. 2997), and The Food and Drug Import Safety Act of 2007 (H.R.3610).

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