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Killing Americans by Stifling Medical Innovation: The Medical Device "Safety" Act of 2009

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One of the most spectacular achievements of American ingenuity over the past 50 years has been the development of numerous medical devices that prolong life and improve the health of suffering individuals. From pacemakers and implantable cardiac defibrillators to self-monitoring blood glucose kits and insulin pumps, new medical technology has improved the health of countless individuals. Such innovation depends on large amounts of investment capital and a regulatory environment that protects the public without unneeded complexity and liability risk. The Medical Device Safety Act of 2009 threatens both of these requirements.

This misnamed bill would effectively gut existing federal law by reversing the Supreme Court's decision in *Riegel v. Medtronic, Inc.*,[1] which ruled that federal regulation of certain medical devices by the Food and Drug Administration (FDA) preempted state tort law. The bill would make the researchers, developers, and manufacturers of medical devices subject to the conflicting laws and regulations of the federal government and 50 different states, subjecting them to abusive and punitive tort litigation in state courts and judicial "hellholes" like West Virginia.[2] It would also impose high levels of regulatory and litigation risk, thereby discouraging investors from providing the capital needed to develop and manufacture life-saving medical devices. This kind of legislation would impair the health and lead to the death of Americans.

Talking Points

- The misnamed Medical Device "Safety" Act of 2009 (MDSA) would gut the carefully crafted regulation of medical devices by the Food and Drug Administration, exposing developers to the conflicting laws and regulations of 50 different states and subjecting them to abusive and punitive tort litigation.
- Litigation is not well suited to the task of regulating medical device safety—juries focus on the risk to one person who has been injured, not the overall benefit a medical device offers to a multitude of patients. The FDA considers the interests of all potential users, including those who would suffer without access to new medical treatments if juries in all 50 states were free to contradict the FDA's expert determinations.
- MDSA would impose high levels of regulatory and litigation risk, discouraging investors from providing the capital needed to develop and manufacture life-saving medical devices.

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Medical Technology and Health Care

Cardiovascular disease is the leading cause of death and disability in the United States.[3] In recent years, new drugs and "[i]mprovements in medical technology" have "improved survival rates significantly."[4] Among the key innovations in the treatment of heart disease are medical devices like implantable cardiac defibrillators that can treat "deadly [irregular] heart rhythms" and "lower the risk of dying by up to 50 percent in some patients who have heart disease."[5]

Strokes are the third leading cause of death in the United States, and the leading cause of adult disability;[6] yet stroke mortality rates have significantly declined in the past 20 years, falling from 96.2 to 60.8 per 100,000 persons. Contributing to this substantial improvement in the prognosis for stroke sufferers have been innovative drug therapies as well as advances in brain and vascular imaging technology that "enable more rapid diagnosis and treatment."[7] Strokes are just one area in which innovative medical devices have dramatically improved health outcomes for Americans.

The gains from these advances in health technology are clear. From 1980 to 2005, the annual death rate declined from 1,039.1 to 798.8 per 100,000 persons; life expectancy from birth increased by 4.1 years; and disability rates for people over 65 declined from 26.2 in 1980 to 19.7 per 100 persons in 2000.[8]

In 2004 alone, spending on medical devices and *in vitro* diagnostics totaled $111.7 billion, or about 6 percent of total national health expenditures, an increase from only $35 billion in 1989.[9] While spending on medical devices has grown at about the same rate as national health care expenditures overall, it has grown "far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index."[10] From 1989 to 2004, medical device prices increased at an annual rate of only 1.2 percent compared to 5 percent for the Medical Consumer Price Index and 2.8 percent for the Consumer Price Index, thereby suggesting that the industry "is highly competitive."[11] This relatively slow rate of medical device price increases occurred during a period in which new and inno-

1. Riegel v. Medtronic, Inc.,128 S.Ct. 999 (2008).
2. West Virginia is rated as the worst judicial "hellhole" in the United States by the American Tort Reform Foundation for its anti-business rulings—it has a "history of plaintiff-biased decisions, paying damages to those who are not injured, allowing mass trials…rejecting long-established legal principles and welcoming plaintiffs' lawyers from other states to take advantage of its generous rulings." THE AMERICAN TORT REFORM FOUNDATION, JUDICIAL HELLHOLES, 2008/2009 iii, *available at* http://www.atra.org/reports/hellholes/report.pdf.
3. Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention, http://www.cdc.gov/dhdsp/ (last visited Aug. 3, 2009).
4. MEDTAP INTERNATIONAL, THE VALUE OF INVESTMENT IN HEALTH CARE 2, 5 (2004), *available at* http://www.aha.org/aha/content/2004/pdf/Value_Report.pdf.
5. NATIONAL HEART LUNG AND BLOOD INSTITUTE, HOW WILL AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR AFFECT MY LIFESTYLE, *available at* http://www.nhlbi.nih.gov/health/dci/Diseases/icd/icd_lifestyle.html.
6. Centers for Disease Control and Prevention, Stroke Facts and Statistics, http://www.cdc.gov/stroke/stroke_facts.htm (last visited Aug. 3, 2009).
7. MEDTAP INTERNATIONAL, *supra* note 4, at 6, 7.
8. *See generally* National Center for Health Statistics, Center for Disease Control and Prevention, at http://www.cdc.gov/ (last visited Aug 3. 2009).
9. ROLAND "GUY" KING AND GERALD F. DONAHOE, THE AMERICAN MEDICAL STUDENT ASSOCIATION, ESTIMATES OF MEDICAL DEVICE SPENDING IN THE UNITED STATES 2 (2007), *available at* http://www.amsa.org/business/King%20Paper%20Medical%20Device%20Spending.pdf.
10. *Id.* at 4.
11. *Id.*

vative technology was a "significant driver of changed medical practice," from "stents to implantable defibrillators to artificial hips and knees to new imaging modalities to new diagnostic tests to new surgical tools." Yet the cost of such devices has remained surprisingly "constant as a share of total national health expenditures."[12]

These statistics demonstrate that new medical devices and technology have been essential components in the improved health and survivability of Americans suffering from various medical ailments from heart disease to stroke to diabetes. The key to the development of new medical devices has been a uniform set of rules that promotes public welfare and innovation. This uniformity is the result of federal preemption and a federal regulatory system administered through the FDA that protects the health and safety of the public while allowing innovation and providing incentives for investors to fund the huge development costs.

Current Regulatory Structure

The Medical Device Amendments of 1976[13] (MDA) to the Federal Food, Drug, and Cosmetic Act imposed a detailed federal oversight regime on medical devices. The MDA bars common-law claims challenging the safety and effectiveness of a medical device that has received premarket approval by the Food and Drug Administration, but allows some state claims to be exempted from federal preemption. Prior to these amendments, "the introduction of new medical devices was left largely for the States to supervise as they saw fit."[14] In 1996 the Supreme Court held that plaintiffs could still bring state law claims under state and local requirements that are equal to, or substantially identical to, federal requirements.[15] Under FDA regulations, state or local requirements are preempted only when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device...thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific" FDA requirements.[16]

Codified at 21 U.S.C. § 360(k), the MDA was passed in part because the Dalkon Shield, an intrauterine contraceptive device that was linked to serious infections, several deaths, and a large number of pregnancies, "demonstrated the inability of the common-law tort system to manage the risks associated with dangerous devices."[17] The Dalkon Shield lawsuits forced other manufacturers of intrauterine devices to remove them from the market despite the fact that no questions had been raised about their safety. By 1992, every major U.S. pharmaceutical company except for one had "withdrawn from the field of contraceptive research and development." As a result, the U.S. was soon "lagging behind other countries in the availability of modern contraceptives."[18]

The MDA's preemption provision states that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effec-

12. *Id.*

13. The Medical Device Amendments of 1976, Pub. L. 94-295 (1976).

14. *Riegel* at 1002 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 475–476 (1996)).

15. *See* Medtronic, Inc. v. Lohr, 518 U.S. 468 (1996).

16. 21 C.F.R. § 808.1(d) (1995).

17. *Riegel* at 1003 (citations omitted).

18. The Safety of Medical Products Regulated by FDA: Hearing before House Committee on Oversight and Government Reform, 110th Cong. 7 (2008) (statement of Dr. Randall Lutter, Deputy Commissioner for Policy, Food and Drug Administration), *available at* http://www.fda.gov/NewsEvents/Testimony/ucm101513.htm [hereinafter statement of Dr. Randall Lutter].

> tiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[19]

The MDA provides three distinct levels of oversight for medical devices. These levels are assigned depending on the risk the device in question poses to human beings.[20] The lowest level of oversight is Class I, General Controls, which are for devices such as elastic bandages and examination gloves that are not "for a use in supporting or sustaining human life" and do "not present a potential unreasonable risk of illness or injury."[21]

Class II, Special Controls, are for devices like powered wheelchairs and surgical drapes that are subject to additional controls such as "performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines…and other appropriate actions."[22]

Class III, Premarket Approval, applies the FDA's highest standard of regulation. Devices such as replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators are assigned to Class III because they are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury" and it cannot be established that a less stringent classification would "provide reasonable assurance of the safety and effectiveness of the device."[23]

The premarket approval process for Class III devices is "one of the most scientifically rigorous processes in the world."[24] Manufacturers have to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission."[25] The multivolume and extensive submission materials required by the FDA also include full reports on all studies of the device; its components, ingredients, and properties; and the methods used for its manufacture, processing, packing, and installation. Before deciding whether to approve the device, the FDA may use an outside panel of experts to review the device.[26]

In 1976, however, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed reviews under its new MDA responsibilities. Consequently, it grandfathered in devices sold before the MDA's effective date—at least until the FDA promulgated a regulation requiring premarket approval.[27] Similarly, new devices that the FDA considers to be "substantially equivalent" to another device that was grandfathered in do not have to undergo the premarket approval process.[28] The Supreme Court has held that approval of a medical device like a pacemaker by the FDA through the "substantially equivalent" review process did not preempt state tort claims

19. 21 U.S.C. § 360(k)(1976).

20. *Id*. § 360(c).

21. *Id*. § 360c(a)(1)(A).

22. *Id*. § 360c(a)(1)(B).

23. *Id*. § 360c(a)(1)(C).

24. Ernst Berndt and Mark Trusheim, The Economic Impacts of Eliminating Federal Preemption for Medical Devices on Patients, Innovation, and Jobs 24 (2009), *available at* http://www.advamed.org/NR/rdonlyres/DCC3B34A-6257-4A3F-ADE4-4093904178CD/0/EmbargoedBerndtTrusheimPreemptionPaper.pdf.

25. *Lohr* at 477.

26. *Riegel* at 1004.

27. 21 U.S.C. §§ 360c(f)(1), 360e(b)(1).

28. *Id*. § 360c(f)(1)(ii). The FDA's "substantially equivalent" review procedure is commonly called the Section 510(k) process. In 2005, the FDA granted premarket approval to 32 new devices and found 3,148 devices to be substantially equivalent to existing devices. *See Riegel* at 1004.

because that review is "focused on *equivalence*, not safety."[29]

Premarket approval is granted by the FDA only if it finds that there is a "reasonable assurance" that the device is "safe" and "effective" under the "conditions of use prescribed, recommended, or suggested in the proposed labeling."[30] The FDA is charged with "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."[31] Thus, the FDA does something that individual juries are usually unable to do—balance the benefit that a device may hold for a large group of individuals against the potential harm it may cause directly or through side effects to a small number of individuals, including potential plaintiffs. In fact, the agency may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives."[32] To emphasize this point, the Supreme Court in the *Riegel* case cited the FDA's approval (through its Humanitarian Device Exemption) of a "ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent."[33]

This is exactly the type of device that no manufacturer would provide to the market if it were liable in state court tort actions. Almost no jury, faced with the case of a child who had died using such a device, and provided with evidence of a 50 percent failure rate, could understand the concept of the failure rate being worth the benefit to the other 50 percent of children with progressive heart disease whose lives are prolonged (and who will not be present in the courtroom). It is almost certain that the emotions of the moment would overwhelm the members of any jury. As Justice Alito so aptly said in his dissent in *Wyeth v. Levine*, "juries tend to focus on the risk of a particular product's design or warning label" for one specific person who has been injured.[34] They do not look at the overall benefit a particular drug or medical device may offer to a multitude of patients. But the FDA is tasked with taking the long view and considering the interests of all potential users, including those who would suffer without access to new medical treatments if "juries in all 50 states were free to contradict" the FDA's expert determinations.[35]

Furthermore, a manufacturer's compliance obligations do not end after FDA premarket approval. There are comprehensive reporting requirements, particularly of any death or injuries attributed to the device, and no changes can be made in the device's design, manufacturing process, labeling, or any other attribute that would affect its safety or effectiveness without prior FDA approval.[36]

Riegel v. Medtronics

In 2008 in *Riegel v. Medtronics,* the Supreme Court held that the FDA's premarket approval process established federal requirements that preempted state law claims. The plaintiff in *Riegel* underwent a coronary angioplasty after suffering a myocardial infarction. He sued Medtronic asserting common-law claims under New York law for negligence, strict liability, and implied warranty after the balloon catheter Medtronic manufactured that was used to try to dilate his coronary artery ruptured. Riegel developed a heart block and underwent emergency coronary bypass surgery.[37]

29. *Lohr* at 493 (citations omitted).

30. 21 U.S.C. § 360e(d)(2). Thus, the FDA also determines whether the proposed labeling is correct and not misleading.

31. *Id.* § 360c(a)(2)(c).

32. *Riegel* at 1004.

33. Id.

34. Wyeth v. Levine, 555 U.S. ____(2009), Slip Op., dissenting op. at 23.

35. *Id.*

36. 21 U.S.C. §§ 360e(d)(6)(A)(i), 360i.

37. *Riegel* at 1005.

In examining the issues present in *Riegel*, the Supreme Court pointed out that the FDA's premarket approval of the balloon catheter was basically a "federal safety [and effectiveness] review." Safety and effectiveness were also the "very subjects of the Riegels' common-law claims," bringing the state law claims within the preemption of the MDA.[38] Excluding common-law duties from preemption would not make any sense, particularly because a jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."[39] A jury will not apply the cost-benefit analysis applied by the experts at the FDA: "How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?"[40]

The Supreme Court's holding in *Riegel* was "not an innovation in the law,"[41] and it was not even a close case. Six of the justices joined the majority opinion written by Justice Scalia and an eighth member of the Court, Justice Stevens, joined in part of the opinion and concurred in the judgment. The decision did not hold that there is complete and total preemption of all claims against manufacturers of medical devices. Rather, as one commentator has stated:

> [I]ts scope is couched within a system of supreme federal regulation and supplementary common law claims. The Court's finding…was the next step in a jurisprudence that finds preemption when federal requirements have been satisfied. However, this preemption only applies to medical devices that undergo the extensive premarket approval process; manufacturers who do not comply or who perpetrate fraud are likely to find themselves still subject to tort liability…the Supreme Court's MDA-related decisions have struck a balance—protecting consumer safety through a complementary system of federal regulation and state civil actions.[42]

Under both the *Riegel* holding and the Supreme Court's prior decision in *Medtronic v. Lohr*, "medical device preemption of products liability claims has very limited scope."[43] There is no federal preemption for devices that have not gone through the premarket approval process, and that includes "all of the class I and class II devices and the vast majority of class III devices."[44] Less than 1 percent of devices are entitled to federal preemption.[45] The state tort system still catches the cases "that fall through the cracks in federal safety regulation—if the cracks are the result of manufacturer noncompliance. Manufacturers are not immunized from tort suits if they violate FDA regulations."[46]

Medical Device Safety Act of 2009

The Medical Device Safety Act of 2009 (MDSA)[47] would void the federal preemption provisions of § 360(k) by adding a third paragraph:

38. *Id.* at 1007.

39. *Riegel* at 1008.

40. *Id.*

41. H.R. 1346 The Medical Device Safety Act of 2009: Hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, 111th Cong. 2 (2009) (statement of Richard M. Cooper) [hereinafter statement of Richard M. Cooper].

42. *The Supreme Court—Leading Cases*, 122 HARV. L. REV. 276, 414-415 (2008), *available at* http://www.harvardlawreview.org/issues/122/nov08/leadingcases/riegel_v_medtronic.pdf.

43. Statement of Richard M. Cooper, *supra* note 41, at 8.

44. *Id.*

45. Statement of Dr. Randall Lutter, *supra* note 18, at endnote 2.

46. *The Supreme Court—Leading Cases*, *supra* note 42, at 412.

47. S. 540, 111th Cong. (2009); H.R. 1346, 111th Cong. (2009).

> (c)No Effect on Liability Under State Law—Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.[48]

The biggest irony in this proposal to overturn the *Riegel* decision and amend the MDA to eliminate all federal preemption for medical devices is that the facts of the case demonstrate the very need for such preemption. Riegel did not suffer any injuries because of a manufacturing or design defect—the catheter failed because Riegel's doctor used the device contrary to the explicit use instructions approved by the FDA for the catheter. The surgeon inserted the catheter in Riegel's right coronary artery that was "diffusely diseased and heavily calcified" despite the fact that the device's labeling specifically stated that "use was contraindicated for patients with diffuse or calcified stenoses." Further, the catheter only burst after the surgeon inflated it five times to a pressure of 10 atmospheres—even though the label warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres.[49] There is no question that Riegel had a viable malpractice claim against his surgeon, but the frivolous and unwarranted nature of his claim against Medtronics for "negligent" manufacture is obvious.

The misuse of the balloon catheter also illustrates another issue common to medical devices: "[m]any [] medical devices are used in life sustaining situations where incorrect use…can lead to adverse events." These devices are advanced technologies "that have no precedents" and often have "finite lives, lives that are often shorter than the expected remaining lives of those patients who benefit from them."[50] But eliminating preemption would allow litigation against manufacturers for risks that are inherent in the use of such innovative technologies.

On May 12, 2009, the Health Subcommittee of the U.S. House of Representatives Committee on Energy and Commerce held a hearing on the MDSA. One of the witnesses, Michael Kinsley, starkly echoed the problems noted by the Supreme Court in the *Riegel* case. Kinsley is a journalist who, for 30 years, has covered "the damage done to our economy and to our country by excessive litigation in general and lawsuits over medical care gone wrong in particular."[51] Kinsley also suffers from Parkinson's disease and is only "walking around at all" because of new drugs (that did not exist when he was first diagnosed) and a surgical treatment called "Deep Brain Stimulation" that implanted pacemaker-type batteries and wires in his brain. As Kinsley testified:

> We all want the government to protect us from dangerous drugs and devices. But we don't want the government to prevent us from getting helpful or even lifesaving drugs and devices. Yet the most important drugs and devices are both. They save lives, and they can cost lives. The government's job is to weigh the risks against the benefits.
>
> And here's where it gets messy. We have two completely independent systems for making the same decision…one is the [FDA]—a national government agency staffed by experts and mandated to take into account both the potential benefits and the potential dangers. The decisions it makes set a uniform standard for everyone in every state.
>
> The other system is tort law, administered by thousands of non-expert judges and jurors in 50 state courts…Differences in state law or just the randomness of juries produce dozens of different answers...The

48. This amendment would "take effect as if included in the enactment of the" MDA in 1976 and would "apply to any civil action pending or filed on or after the date of enactment of this Act." S. 540, *supra* note 47, § 2(b).

49. *Riegel* at 1005.

50. BERNDT AND TRUSHEIM, *supra* note 24, at 18.

51. H.R. 1346, The Medical Device Safety Act of 2009: Hearing before the Subcommittee on Health of the House Committee on Energy and Commerce, 111th Cong. (2009) (statement of Michael Kinsley).

> direct cost is horrendous: delivering a dollar to a victim costs far more than a dollar in expenses—mostly lawyers' bills.
>
> The indirect cost is immeasurable. Lawsuits focus on the victim of some medical product. By their nature, they undervalue the benefit that same product has brought to other users, or even to the victim herself.
>
> Forced to choose between these two systems for making essentially the same decision…anyone sensible would choose the FDA. But in real life the situation is even crazier: we have both systems simultaneously. And…whichever one draws a more restrictive line, wins…[P]roduct manufacturers have no idea when or how the standard might change, and you have a perfect arrangement for discouraging drug and device manufacturers from developing new products, like the ones that allow people like me to go about our business…[52]

As the former chief counsel of the FDA during the Carter Administration, Richard Cooper, pointed out, state product liability cases function as "a type of regulation of manufacturers' conduct."[53] But that regulation is administered *ad hoc* by judges and juries and only focuses on the particular allegedly injured plaintiff "without the presence in the courtroom of those users of the product who have benefited from it."[54]

State product liability lawsuits that challenge the FDA's determinations of the "safety, efficacy and appropriate labeling" of medical devices will have "detrimental effects to public health." They will decrease the public's access to essential and life-saving treatments "through decreases in availability or even the removal of beneficial products from the market." The requirement for additional and potentially conflicting warnings on labels required by state laws will "cause confusion or deter the use of beneficial medical products."[55]

The high risk of loss in product liability lawsuits is almost guaranteed to eliminate the willingness of venture capitalists to fund medical device research, development, and manufacturing. The average medical device company only generates "a pre-tax margin of approximately 20 percent, with approximately 35 percent of that paid to various governments as taxes."[56] Thus, a medical device:

> sold for $2,500 (a high price medical device) will generate $325 in profit. To pay a $2 million settlement [the average product liability cost for wrongful death in 2001] requires selling 6,154 devices, 6,153 of which performed with no issues. Thus a [] medical device must achieve at least a 99.984 percent quality performance to breakeven and must do even better to return any funds to the company and shareholders."[57]

Under the above circumstances, just one or two liability suits would eliminate all profitability and "undoubtedly result in investors fleeing…and a slowing in desperately needed new product innovations."[58]

Even if manufacturers do not completely withdraw a product, the risk incurred by varying state jury verdicts will force them to restrict the states in which they sell and market their medical devices. Medical "tourism" is a guaranteed result, with those individuals who can afford to pay for medical devices—either through personal wealth or good health coverage—traveling to those states in which

52. *Id.*

53. Statement of Richard M. Cooper, *supra* note 41.

54. *Id.*

55. Statement of Dr. Randall Lutter, *supra* note 18, at 6.

56. BERNDT AND TRUSHEIM, *supra* note 24, at 18.

57. *Id.* at 19.

58. *Id.* at 13.

products needed for their diseases are still available. This exact scenario occurred in "the early days of laser eye surgery, when the more advanced devices were available in Canada but not in the United States…20 percent of a British Columbia laser eye clinic caseload was self-referred Americans seeking second and third generation laser equipment that had not been approved in the U.S."[59]

Childhood vaccines provide a good example of how tort liability lawsuits can eliminate access to a needed medical product. One of the medical guarantees inherent in vaccination is that while immunization prevents large numbers of individuals from contracting a particular disease, it is also guaranteed that a small number of individuals will have an adverse (and potentially fatal) reaction to the immunization. However, the benefit provided to the majority of individuals immunized clearly outweighs the detriment to the small number of individuals harmed by the vaccine. Yet a series of lawsuits filed against vaccine manufacturers in the 1970s not only caused several critical vaccines—including ones for diphtheria, tetanous toxinoids, pertussis (DPT), polio, and measles—to dramatically increase in price, but threatened to eliminate their manufacturers entirely.

An official from one of these companies testified that its "potential liability from lawsuits [over the DPT vaccine] was over two hundred times greater than its annual sales."[60] State tort lawsuits threatened to eliminate the vital vaccines that are essential to the health of America's children—they only remained available because Congress passed the National Childhood Vaccine Injury Act that shielded manufacturers from liability from the small number of individuals adversely affected by these overwhelmingly life-saving immunizations.[61]

It is also important to note that in a time of economic recession, the elimination of federal preemption—in addition to hurting (and killing) patients—will have other adverse effects. For example, unemployment will rise as manufacturers' costs increase to cover added risk and as the industry contracts when manufacturers inevitably decrease or eliminate the development and marketing of medical devices. Job losses in the medical device industry will also have a multiplier effect in the broader economy. A recent study estimated "the national job multiplier across the entire medical technology industry at 4.47 with one important segment—invitro diagnostics—possessing a job multiplier over 8. [C]apital expenditures on plant and equipment per worker in medical devices exceed that in the overall manufacturing industries by a substantial 26 percent."[62] Thus, the MDSA will have a damaging effect on the American economy by eliminating jobs across the industrial sector.

Government expenses related to health care in the Medicare and Medicaid programs will increase because restrictions on the availability of medical devices will negatively affect the health of covered beneficiaries, leading to higher overall health care costs. As a recent study points out, there will also be "[i]nflated price variability across states as tort costs and regulatory cost vary," with prices of remaining medical devices increasing to cover higher tort and regulatory costs.[63]

For those supporters of the MDSA who claim that the FDA is not properly carrying out its duties to protect the public because it is underfunded, the correct response "is not to declare open season for unrestrained regulation by judges and juries (who lack the FDA's expertise and broad public-health perspective) but for the Congress to fund the FDA adequately and to conduct effective oversight of its management and performance."[64] President Obama's budget request for FY 2010 is already

59. *Id*. at 9 (citations omitted).

60. *Id*. at 13–14 (citations omitted).

61. Statement of Dr. Randall Lutter, *supra* note 18, at 6–7. The manufacturers of the DPT vaccine dropped from 7 to 2; of the measles vaccine from 6 to 1; and of the polio vaccine from 3 to 1. The vaccine law is codified at 42 U.S.C. § 300aa-1 *et seq.*

62. BERNDT AND TRUSHEIM, *supra* note 24, at 21 (citations omitted).

63. *Id*. at 6.

requesting a 19 percent budget increase for the FDA. It also includes a major initiative called "Safer Medical Products" that will spend $166.4 million to improve the safety of drugs, medical devices, vaccines, and other medical products.[65] Whether that increase is actually necessary for the FDA to properly perform its function is unclear, but the fact that the President asked for such a large increase demonstrates that the political support is there to remedy any real problems that may exist in the FDA's regulation of medical devices and other medical products.

Conclusion

The chaos and confusion caused by subjecting manufacturers of medical devices to the varying and conflicting rules generated by individual verdicts rendered by nonmedical experts would severely damage America's health system. The passage of the MDSA would injure the health and well-being of the public by eliminating innovative medical devices or substantially increasing their costs. It would eliminate jobs in an important sector of the nation's economy and increase the government's cost of providing health care through federal insurance programs.

The current regulatory structure that provides federal preemption only when the FDA has completed a full safety and efficacy review of medical devices not only protects individual patients, but ensures that medical devices are made available to the public as a whole and not eliminated because of liability risks incurred by a small number of individuals who suffer adverse reactions from their use. The MDSA would favor "litigious trial lawyers over sick patients" and its "passage would amount to serious legislative malpractice."[66] Congress should reject policies that undermine the FDA's regulatory authority and thereby protect the American public from abusive tort litigation that would decrease their quality of life.

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64. Statement of Richard M. Cooper, *supra* note 41, at 14.

65. Press Release, The U.S. Food and Drug Administration, President's FY 2010 Budget for FDA Invests Substantially in Food and Medical Product Safety (May 7, 2009) *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm152276.htm.

66. Editorial, *Patients in the Crossfire*, THE WASHINGTON TIMES, May 14, 2009, at A18.