

**Testimony**  
**of**  
**Peter Barton Hutt**  
**before the**  
**Committee on Health, Education, Labor, and Pensions**  
**United States Senate**  
**on**  
**S. 540**  
**The Medical Device Safety Act of 2009**  
**August 4, 2009**

Mr. Chairman and Members of the Committee, I am Peter Barton Hutt. I am a Senior Counsel at the Washington, D.C. law firm of Covington & Burling LLP and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on food and drug law during Winter Term for the past sixteen years. During 1971-1975 I served as Chief Counsel for the Food and Drug Administration (FDA). I appear before you today at the invitation of the Committee to present my personal views on Section 521 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which provides for national uniformity in the regulation of medical devices. Section 521 was enacted by Congress as part of the Medical Device Amendments of 1976.

### **Background**

During my tenure as Chief Counsel for FDA I was deeply involved with the development of medical device legislation. On my very first day at FDA in September 1971, FDA Commissioner Charles C. Edwards told me that FDA had been unable to obtain clearance by the Nixon Administration of the proposed medical device legislation that the agency needed, and delegated that task to me. I was successful, and the Administration's bill was introduced in December 14, 1971.<sup>1</sup> Commissioner Edwards then delegated to me the responsibility for development of FDA policy on the legislation and for negotiation of the statutory provisions with the House and Senate. By the time I left FDA in May 1975, the legislation had twice

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<sup>1</sup> H.R. 12316, 92d Cong., 1st Sess. (1971).

passed the Senate,<sup>2</sup> and the House bill<sup>3</sup> was largely in the form that was signed into law by President Ford as the Medical Device Amendments of 1976<sup>4</sup> on May 28, 1976.

The December 1971 Administration bill contained no provision addressing national uniformity. Nor did the successor Administration bill, introduced in March 1973.<sup>5</sup> In August 1973, however, Representative Paul G. Rogers (D-FL), Chair of the House Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, introduced medical device legislation that for the first time included a national uniformity provision.<sup>6</sup> On behalf of FDA, I strongly supported national uniformity in the requirements for medical devices because it strengthened the integrity, credibility, and primary jurisdiction of the agency. From then on, all medical device legislation considered in the House and Senate included some form of national uniformity requirement. The final version was enacted as Section 521 of the FD&C Act.<sup>7</sup> It is that provision that would be amended by S. 540 to make it inapplicable to decisions by judges and juries in product liability cases that are inconsistent with FDA decisions.

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<sup>2</sup> 120 Cong. Rec. (February 1, 1974); 121 Cong. Rec. (April 17, 1975).

<sup>3</sup> H.R. 5545, 94th Cong., 1st Sess. (1975).

<sup>4</sup> 90 Stat. 539 (1976).

<sup>5</sup> H.R. 6073, 93d Cong., 1st Sess. (1973).

<sup>6</sup> H.R. 9984, 93d Cong., 1st Sess., § 704 (1973).

<sup>7</sup> 21 U.S.C. 360k.

**The Risk-Based Regulatory System**  
**Enacted by Congress for Medical Devices**

Under the FD&C Act, as amended by the 1976 Amendments and subsequent legislation, FDA regulates medical devices according to three risk-based classifications. Class I medical devices are those simple devices for which general regulatory controls, that are applicable to all devices, are sufficient to assure safety and effectiveness. Class I devices include tongue depressors,<sup>8</sup> dental floss,<sup>9</sup> and surgical sponges.<sup>10</sup> Class II devices are those for which special controls, applicable to a particular class of device, are enough to ensure safety and effectiveness. Class II devices include vascular clamps<sup>11</sup> and powered wheelchairs.<sup>12</sup> Class III devices are those life-saving and life-sustaining devices for which general and special controls are not sufficient, and for which full premarket approval is necessary to assure safety and effectiveness. Class III devices include implantable pacemaker pulse generators,<sup>13</sup> cardiovascular stents, and artificial hearts.

Any Class I, II, or III device may lawfully be marketed if FDA clears a premarket notification (PMN) under Section 510(k) of the FD&C Act that demonstrates that the device is “substantially equivalent” to a marketed device that

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<sup>8</sup> 21 CFR 880.6230.

<sup>9</sup> 21 CFR 872.6390.

<sup>10</sup> 21 CFR 878.4014.

<sup>11</sup> 21 CFR 870.4450.

<sup>12</sup> 21 CFR 890.3860.

<sup>13</sup> 21 CFR 870.3610.

did not require FDA approval of a premarket approval (PMA) application.<sup>14</sup> The PMN process (commonly referred to as the 510(k) process) is a relatively simple procedure. A Class III device for which there is no marketed non-PMA substantially equivalent device, however, requires full premarket approval under Section 515 for both safety and effectiveness.<sup>15</sup> This is a much more lengthy, complex, and rigorous procedure.

### **Application of National Uniformity under Section 521 to the Medical Device Categories**

Section 521 provides that no State may impose a “requirement” on a medical device that is different from or in addition to a requirement imposed by FDA. The Supreme Court has interpreted and applied this national uniformity provision twice -- once with respect to devices marketed under Section 510(k) of the FD&C Act, and once with respect to PMA devices marketed under Section 515.

In *Medtronic, Inc. v. Lohr*,<sup>16</sup> the Court held in 1996 that an FDA determination that a Class I, II or III device is “substantially equivalent” to a pre-1976 device is not sufficient to invoke the requirement of national uniformity. The Court concluded that FDA did not make a sufficiently detailed and searching review of the new device and did not approve the device as safe and effective. Thus, a court

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<sup>14</sup> 21 U.S.C. 360; *see also* 21 U.S.C. 360c(i).

<sup>15</sup> 21 U.S.C. 360e.

<sup>16</sup> 518 U.S. 470 (1996).

decision in a product liability case that was inconsistent with an FDA decision was allowed to stand.

In the more recent case of *Riegel v. Medtronic, Inc.*,<sup>17</sup> the Court held in 2008 that a PMA device was subject to a comprehensive review by FDA under Section 515 and was explicitly determined by the agency to be safe and effective. Accordingly, the Court concluded that the national uniformity provisions of Section 721 apply. A court decision in a product liability case that was inconsistent with an FDA determination was therefore struck down.

### **Exemptions from National Uniformity**

Under Section 721, any State or city may petition FDA for an exemption from national uniformity. FDA may grant the exemption if the State or local requirement is more stringent than the FDA requirement, it is required by compelling local conditions, and it would not cause the device to violate any provision of the FD&C Act. FDA has in fact granted such exemptions.<sup>18</sup>

### **National Uniformity for PMA Medical Devices Reviewed and Explicitly Approved by FDA as Safe and Effective**

At issue today is the narrow question of whether devices approved by FDA under the rigorous standards of premarket approval (PMA devices) -- which comprise less than one-half of one percent of all the medical devices authorized by

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<sup>17</sup> \_\_\_ U.S. \_\_\_ (2008), 128 S.Ct 999.

<sup>18</sup> 21 C.F.R. part 808.

FDA for marketing since 1976<sup>19</sup> -- should continue to be protected under Section 521 from inconsistent and different standards set forth by judges and juries under State product liability law. It is important to understand that the bill under consideration -- S. 540 -- will affect only about one-half of one percent of all medical devices marketed in the United States. Only about two percent of all devices are Class III devices, and about 80 percent of those are marketed under the simplified Section 510(k) procedure. Thus, about 99.5 percent of devices come to market under the Section 510(k) process. Under the Supreme Court's *Lohr* decision, national uniformity does not arise from a finding of substantial equivalence under Section 510(k), even for a Class III device.

The half percent of devices that are the subject of full premarket review and approval under Section 515, however, represent cutting edge science. They are the new life-saving and life-sustaining devices that are critical to the public health. They are the highest priority devices -- those for which we should do everything we can to encourage investment in research and development.

It is those devices that are targeted by S. 540. The proposed legislation would allow judges and juries throughout the country not only to impose requirements that are inconsistent with FDA determinations, but that differ from one court to another. The result would be regulatory chaos.

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<sup>19</sup> GAO Report to Congress: *FDA Should Take Steps To Ensure That High-Risk Device Types Are Approved through the Most Stringent Review Process* at 1 (January 2009); *Lohr*, 518 U.S. at 479.

## The Rigor of the FDA PMA Process

The PMA process is scientifically rigorous and demanding. The Supreme Court has described it as follows:

Premarket approval is a “rigorous” process. *Lohr*, 518 US at 477. A manufacturer must submit what is typically a multivolume application. FDA, Device Advice-Premarket Approval (PMA) 18, <http://www.fda.gov/cdrh/devadvice/pma/printer.html>. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a “full statement” of the device's “components, ingredients, and properties and of the principle or principles of operation”; “a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device”; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1).. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(1)(G).

The FDA spends an average of 1,200 hours reviewing each application, *Lohr* at 477, and grants premarket approval only if it finds there is a “reasonable assurance” of the device's “safety and effectiveness,” § 360e(d). The agency must “weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. FDA, Center for Devices and Radiological Health, Summary of Safety and Probable Benefit 20 (2004), online at <http://www.fda.gov/cdrh/pdf/3/H030003b.pdf>.

The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and

effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B) and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).

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Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c)..

After premarket approval, the devices are subject to reporting requirements. § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. § 360e(e)(1); see also § 360h(e) (recall authority).<sup>20</sup>

**National Uniformity Should be Retained  
for Class III PMA Devices**

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National uniformity for FDA requirements of design and labeling for a Class III PMA medical device is the right policy for several reasons.

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<sup>20</sup> \_\_\_ U.S. at \_\_\_, 128 S.Ct at 1004-1005; *see also Lohr* at 477.

**First**, national uniformity in the regulation of Class III PMA devices is essential to preserve the jurisdiction and integrity of the FDA PMA process. In two 1973 cases that I took to the Supreme Court during my tenure as FDA Chief Counsel, the Court held that FDA has “primary jurisdiction” to decide matters that have been entrusted to its implementation.<sup>21</sup> S. 540 would strike at the very heart of this doctrine. If judges and juries can summarily disregard FDA decisions on Class III PMA devices, why should physicians, hospitals, or anyone else pay attention to them? S. 540 undermines the credibility and authority of the country’s most important public health agency.

**Second**, as the expert agency to which Congress delegated the responsibility for determining the safety and effectiveness of medical devices used throughout the country, FDA is in a better position to make the determinations of whether devices should be marketed than are the juries in diverse courts in the 50 States. As Justice Breyer stated during the oral argument for *Warner Lambert v. Kent*, “who would you rather have make the decision that this [product] is, on balance, going to save people or, on balance, is going to hurt people? An expert agency, on one hand, or 12 people pulled randomly for a jury role, who see before them only the people whom the [product] hurt and don’t see the people who need the [product] to cure them?”<sup>22</sup> It is no defense to say that FDA is not always perfect, or

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<sup>21</sup> *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652-654 (1973).

<sup>22</sup> Transcript of Oral Argument, *Warner Lambert v. Kent*, No. 06-1948, at 30-31 (February 25, 2008).

is understaffed. Although no agency is perfect, FDA's expert medical reviewers are far more qualified to determine the safety and effectiveness of life-saving Class III PMA medical products than are lay juries. And if FDA is underfunded -- something I have been saying for years<sup>23</sup> -- the solution is not to farm FDA's work out to juries, but rather to provide adequate funding for FDA. Congress has in fact responded to FDA's need for additional funds both by user fees and by an increase in appropriations from \$1.4 billion to \$2.3 billion since 2007.

**Third**, allowing juries in the 50 states to impose individualized standards would result in a chaotic system in which a manufacturer could avoid state court liability only by marketing different devices in each different state, and then on pain of violating federal requirements set forth by FDA in the PMA approval.

**Fourth**, product liability actions can have the effect of manufacturers seeking to label their products with additional or unsubstantiated warnings, which can result not only in underutilization of valuable treatments but in confusing both physicians and their patients. "Defensive labeling" by manufacturers helps no one.

**Fifth**, allowing claims to proceed against devices that comply with FDA requirements can result in devices being removed from the market that FDA has determined are, on balance -- and for the population for which they are intended -- more beneficial than harmful. And it can severely deter needed innovation. In this

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<sup>23</sup> Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 Administrative Law Review 431 (Spring 2008).

regard, it is important to focus not only those who may be harmed by approved devices, but also those who are helped by those same devices, and who might be harmed if the devices were removed from the market.

*Sixth*, product liability damage awards punish device manufacturers, but they do not contribute to safer devices. It is the inevitable adverse events that lead FDA and the manufacturer to correct deficiencies. By the time that a product liability lawsuit is brought and resolved, the defect has been found and corrected, and the safety issue has been resolved -- assuming, of course, that there is a defect that can be corrected and that the risk is not inherent in all uses of the device. Thus, the sole rationale for product liability lawsuits is to obtain adequate compensation for the injured patient.

*Seventh*, although compensation of injured parties must be achieved, it surely is not an answer to resort to the lottery system of jury trials, where some plaintiffs win big and others lose everything because of the vagaries of judges and juries. The goal of providing compensation can most appropriately be addressed through a statutory procedure that will not drive valuable products from the market, such as the National Childhood Vaccine Injury Act of 1986<sup>24</sup>. Unlike the product liability system, all patients injured by a PMA device would be fairly compensated, not just those who are fortunate to find a persuasive trial attorney and a sympathetic judge and jury.

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<sup>24</sup> 100 Stat. 3755 (1986).

*Finally*, we must keep in mind that national uniformity is a narrow doctrine. It does not apply to claims that a Class III PMA device *failed* to meet federal requirements -- for example, a claim that the device was negligently manufactured. If, for example, a manufacturer fails to meet the specifications for the strength or composition of the device set forth in the PMA approval, national uniformity would not affect the claim advanced by a plaintiff injured by this failure. And because less than one-half of one percent of devices enter the market through the PMA process, it applies only to a small category of devices.

Mr. Chairman, I appreciate the opportunity to present this testimony, and would be pleased to respond to any questions.