Substantially Unsafe

Medical Devices Pose Great Threat to Patients; Safeguards Must be Strengthened, Not Weakened

February 2012

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Acknowledgments

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Introduction

Regulation of medical devices—a $350 billion industry that includes such products as heart and brain stents, artificial hips and implantable defibrillators—is at a crossroads. With a major reauthorization bill up for debate, members of Congress already have introduced 14 bills[1] that aim to accelerate devices' path to the market, often by weakening measures intended to ensure patient safety.

The bills reflect industry's concerted lobbying campaign. In 2011, the medical device industry spent $33.3 million on lobbying, raising its total to $158.7 million since 2007. In just the third and fourth quarters of 2011, at least 225 industry lobbyists—including 107 who previously worked for the federal government—lobbied members of Congress or executive branch officials on issues relating to medical device regulation.

The campaign to weaken safeguards for medical devices comes despite a report released last summer by the prestigious Institute of Medicine (IOM), which concluded that the Food and Drug Administration (FDA) process used to clear at least 95 percent of moderate- and high-risk medical devices is so lacking in its ability to ensure safety that the IOM recommended that it be scuttled.[2] (The process is known as the 510(k) process, after the applicable section of the Food, Drug, and Cosmetic Act that was created under the Medical Device Amendments of 1976.) Even the process for approving the highest risk devices—called the premarket approval (PMA) process—fails to ensure that such devices are safe and effective.

Both processes are far less rigorous than those used to approve new drugs. For instance, both settle for a "reasonable assurance" that a proposed device is safe and effective,[3] whereas drug approvals require the higher standard of "substantial evidence" of effectiveness.[4]

For most new drugs, at least two well-designed, randomized, controlled, phase 3 clinical trials are required. In contrast, for most medical devices approved under the PMA process, only one controlled study is required by the FDA, and in many cases, the quality of the design of such studies is lower than that for most clinical trials for drugs (for example, many device studies are not randomized). Device manufacturers, meanwhile, have reduced incentives to ensure safety because the Supreme Court has created a civil liability shield for

[1] As Feb. 14, 2012.
[2] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 5 (National Academy of Sciences, 2011). (Brian Wolfman, former director of Public Citizen's Litigation Group, served on the committee that oversaw production of the IOM report.)
[3] 21 U.S.C. § 360e(d)(a)(1), http://bit.ly/yDn4L8.
[4] 21 U.S.C. § 355(d), http://1.usa.gov/ACBp8B.

most PMA-approved products. The 510(k) process does not even remotely incorporate the types of safeguards associated with the drug approval process.

This 510(k) process relies primarily on manufacturers' demonstrations that proposed products are "substantially equivalent" to devices already on the market (known as "predicate devices"). The purportedly similar proposed devices are often significantly different than their "predicates." For instance, in one example cited in this report, a device intended to diagnose tumors was cleared for sale without clinical testing based on its similarity to a predicate device used to test for illicit drugs.

Even in cases in which proposed devices are similar to existing devices, the public should take no solace. The 510(k) process imposes few requirements on manufacturers to prove that proposed products are safe and effective. Excepting one class of device, only 8 percent of submissions to the FDA under the 510(k) process are accompanied by any clinical testing data.[5]

This clearance process is especially dangerous because most of the products already on the market were themselves never tested to ensure that they are safe. Thus, a demonstration of a new product's substantial equivalence to an existing product proves little about safety. The Supreme Court articulated this shortcoming in a 1996 decision in which it wrote: "Substantial equivalence determinations provide little protection to the public … If the earlier device poses a severe risk or is ineffective, then the latter device may also be risky or ineffective."[6]

The use of substantial equivalence is intended to accelerate the timetable for a product to receive FDA clearance. Industry representatives argue that the current process is too slow, even with the heavy reliance on substantial equivalence.[7] As it happens, the FDA meets congressionally mandated goals of reviewing 90 percent of 510(k) submissions within 90 days and 98 percent within 150 days.[8] For permission to sell devices implanted in patients' bodies, 150 days hardly constitutes an excessive waiting time.

[5] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 108 (National Academy of Sciences, 2011).
[6] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), http://bit.ly/whHPIC.
[7] JOSH MAKOWER, ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION, A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES (NOVEMBER 2010). (Report produced with support from Medical Device Manufacturers Association (MDMA), National Venture Capital Association (NVCA), and multiple state medical industry organizations.)
[8] Food & Drug Administration Minutes from Negotiation Meeting on MDUFA III Reauthorization (March 7, 2011), http://1.usa.gov/zoOcTI.

The IOM report recommended that the FDA scuttle the 510(k) process and replace it "with an integrated premarket and post-market regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle."[9]

Relaxing review standards for medical devices, as proposed by recently introduced bills, would be exactly the wrong course of action, further weakening an inadequate system. The clearance and approval processes already are resulting in far too many untested, often dangerous, products entering the market and being implanted in patients. Recalls are rising. The average number of high-risk recalls for 2010 and 2011 (49.5), for instance, was more than double the average for the three preceding years (24). Recalls for moderate-risk devices also have doubled. Such recalls are almost always initiated by manufacturers, so a change in the presidential administration cannot be blamed.

Dangers posed by unsafe devices are magnified by the FDA's poor record of responding to problems after they emerge. The FDA has repeatedly acted too slowly and too timidly in response to clear evidence of dangers posed by devices on the market. Even when dangers compel a company to issue a recall, current law often allows manufacturers to satisfy the terms of the "recall" merely by sending out warning notices that their devices have shown a tendency to fail. In one example cited in this report, the FDA warned that an infusion pump was prone to failures that could cause "death and/or serious injury of patients."[10] Rather than order that the defective pumps be replaced, the recall notice merely advised providers "to have a backup pump available to mitigate any disruptions of infusions of life-sustaining drugs or fluids."[11]

Congress should reject the medical device industry's lobbying requests and follow the IOM's advice to devise a review process for medical devices that prioritizes patients' lives and health over companies' profits. It should also demand that the FDA make better use of its enforcement authority to minimize the damage caused by dangerous products that reach the market.

[9] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 8 (National Academy of Sciences, 2011).
[10] Food and Drug Administration, Baxter Healthcare Corp. Colleague Volumetric Infusion Pumps Class I Recall, (Sept. 19, 2005), http://1.usa.gov/wqIVPn.
[11] *Ibid.*

I. Medical Device Industry Has Used Lobbying and Campaign Contributions to Pursue a More Permissive Process.

The medical device industry used the third and fourth quarters of 2011 to press Congress and the FDA for relaxed rules that would allow it to get its products to market faster.

Enacted in 2002 and renewed in 2007, the MDUFA user-fee program requires the FDA to collect application fees from companies seeking clearance or approval to market new medical devices. In exchange, the FDA must meet a set of performance goals outlined by both parties. The 2002 and 2007 enactments of MDUFA did not substantially change the fundamental regulatory framework for medical devices

But the 2007 MDUFA reauthorization gave industry and other stakeholders the opportunity to make recommendations on the various aspects of the user-fee program prior to the 2012 reauthorization. For example, the speed of review times, number of FDA reviewers overseeing a device application, and industry application fees (called user fees) were put up for discussion. The 2012 reauthorization process also gives industry, other stakeholders and Congress an opportunity to seek changes to other parts of the medical device statute that are unrelated to the user-fee program.

As the FDA worked on its recommendations for MDUFA revision in the fall of 2011, members of Congress—under heavy influence from medical device industry lobbyists—introduced several bills aimed at easing the process for devices to reach the market. Specifically, the bills aim to accelerate approval times by such means as:

- further reducing the already weak standards for clearing and approving medical devices;
- raising the priority of promoting of medical innovation in relation to the FDA's core mission of protecting public safety;
- substantially weakening the "conflict of interest" prohibition for serving on the FDA advisory committee that oversees device approvals, allowing more people who have a financial interest in the medical devices under review by the committee to review applications;
- expanding the pool of third-party companies that can review a device application to include those that have financial relationships with the device industry;
- requiring the FDA to rule on third-party reviews of a device within 30 days or granting automatic approval of the device on the 31st day, which would result in the elimination of independent oversight by FDA officials for many devices; and

- prohibiting the FDA from disapproving the methods used in any type of clinical trial conducted by a medical device company, including clinical trials conducted on human subjects.

The FDA held a series of meetings with industry and consumer groups on how it should structure its recommendations to Congress for the MDUFA reauthorization bill. From 2011 through January 2012, industry representatives had 30 meetings with the FDA, while consumer groups had only 12 meetings.[12] Notes summarizing the meetings are a matter of public record. The requests made by industry were largely aimed at speeding up review times and reducing user fees for FDA clearance and approval of devices.

The medical device industry blanketed Congress, the White House, the FDA, and other executive branch agencies with visits from at least 225 registered lobbyists in the third and fourth quarters of 2011 in an effort weaken approval standards and speed up clearances for new devices. Of the 225 lobbyists, 107 (47 percent) previously held positions as congressional staff or in federal agencies. [See Table 1] The industry ramped up its lobbying efforts in the fourth quarter in anticipation of the congressional debate over device regulation. In the fourth quarter, 96 new lobbyists joined industry's campaign. Of the 53 companies that lobbied on the issue in the last two quarters of 2011, 23 entered the campaign in the fourth quarter.

Table 1: Number of Industry Lobbyists Working on Issues Concerning the Medical Device Approval Process (3rd & 4th Quarters 2011)

Number of Lobbyists Working on Device Regulatory Issues in the 3rd and 4th Quarters of 2011[13]	Number of Lobbyists with Past Federal Government Employment (Revolving Doors)	Percentage of Lobbyists with Revolving Doors Connections
225	107	47.5%

Source: Public Citizen analysis of Lobbying Disclosure Data provided by the secretary of the Senate Center for Responsive Politics data (www.opensecrets.org). [See search methodology in footnotes]

Additionally, at least 36 device industry lobbyists hosted campaign fundraisers for members of Congress in 2011. These 36 lobbyists held 40 separate fundraisers for 31 members of Congress. [See Table 2]

[12] Food and Drug Administration, MDUFA Meetings (Feb. 1, 2011), http://1.usa.gov/l5nZYy.

[13] The methodology for this research was to query the Senate Lobbying Disclosure Database for the key words: 510(k), MDUFA, Medical Device User Fee, Medical Device, H.R. 3209, H.R. 3203, H.R. 3230, H.R. 3205, H.R. 3211, H.R. 3208, H.R. 3206, H.R. 3214, H.R. 3207, H.R. 3204, S. 1972, S. 1943, S. 1865 and S. 1700.

Table 2: Fundraisers Held by Lobbyists for the Medical Device Industry on Behalf of Members of Congress in 2011

	Lobbyist	Clients	Beneficiary of Fundraiser
1.	Alex Vogel	National Venture Capital Assoc.	Sen. Bob Corker (R-Tenn.), Sen. Mike Crapo (R-Idaho), Rep. Tim Griffin (R-Ariz.)
2.	Andrew Whitman	Varian Medical Systems	Sen. Mike Crapo (R-Idaho)
3.	Aranthan Jones	Covidien	Rep. Sanford Bishop (D-Ga.)
4.	Barrett Thornhill	Varian Medical Systems	Sen. Mike Crapo (R-Idaho)
5.	Bob Brooks	Advamed	Sen. Dean Heller (R-Nev.), Rep. Kenny Marchant (R-Texas)
6.	Brenda Becker	Boston Scientific	Sen. Ron Johnson (R-Wis.)
7.	Bruce Mehlman	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Sen. Mike Crapo (R-Idaho)
8.	Chris Jones	C.R. Bard	Sen. David Vitter (R-La.),Rep. Kevin Yoder (R-Kan.)
9.	Courtney Johnson	Advamed, Boston Scientific, Edwards Lifesciences, Zimmer Inc.	Rep. Allyson Schwartz (D-Pa.)
10.	Darren Willcox	Medtronic	Sen. Pat Roberts (R-Kan.)
11.	Dave Boyer	Abiomed Inc.	Sen. Bob Corker (R-Tenn.), Sen. Pat Roberts (R-Kan.)
12.	David Castagnetti	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Rep. Anna Eshoo (D-Calif.), Rep. Bennie Thompson (D-Miss.). Sen. Debbie Stabenow (D-Mich.), Sen. Joe Manchin (D-W.Va.), Rep. Martin Heinrich (D-N.M.)
13.	David Thomas	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Rep. Bennie Thompson (D-Miss.), Rep. Dan Maffei (D-N.Y.), Rep. Martin Heinrich (D-N.M.)
14.	Dean Rosen	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Sen. Bob Corker (R-Tenn.), Sen. Mike Crapo (R-Idaho)
15.	Doug Badger	Medtronic	Sen. John Barrasso (R-Wyo.),
16.	Elise Pickering	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Sen. Mike Crapo (R-Idaho)
17.	Faith Cristol	Quest Diagnostics	Sen. Robert Menendez (D-N.J.)
18.	Jason Grove	Abbott Laboratories	Rep. James Jordan (R-Ohio)
19.	Jeffery Kimbell	Cyberonics	Sen. Bob Corker (R-Tenn.), Sen. Bob Corker (R-Tenn.), Rep. Joe Barton (R-Texas), Sen. Pat Roberts (R-Kan.)
20.	John Herzog	Cyberonics	Sen. Bob Corker (R-Tenn.), Sen. Pat Roberts (R-Kan.)
21.	John Weinfurter	International Assoc. of Medical Equipment Remarketers & Servicers	Rep. Jim McDermott (D-Wash.), Rep. Gwen Moore (D-Wis.), Rep. Stephen Lynch (D-Mass.)
22.	Jonathon Hoganson	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Rep. Bennie Thompson (D-Miss.), Rep. Martin Heinrich (D-N.M.)
23.	Kelly Bingel	National Venture Capital Assoc., American Clinical Laboratory Assoc.	Rep. Anna Eshoo (D-Calif.), Rep. Bennie Thompson (D-Miss.), Sen. Debbie Stabenow (D-Mich.), Sen. Joe Manchin (D-W.Va.), Rep. Martin Heinrich (D-N.M.)
24.	Kevin Brennan	Abbott Laboratories, Johnson & Johnson	Rep. Rosa DeLauro (D-Conn.)
25.	Kristen Morris	Abbott Laboratories	Rep. Tim Griffin (R-Ark.)
26.	Libby Greer	AdvaMed, Edwards Lifesciences	Rep. Terrycina Andrea Sewell (D-Ala.)
27.	Linda Tarplin	AdvaMed, Boston Scientific, National Electrical Manufacturers Assoc.	Sen. Orrin Hatch (R-Utah), Sen. Ron Johnson (R-Wis.), Sen. Rob Portman (R-Ohio)

	Lobbyist	Clients	Beneficiary of Fundraiser
28.	Lisa Kountoupes	National Electrical Manufacturers Assoc., AdvaMed	Sen. Amy Klobuchar (D-Minn.), Rep. Lois Capps (D-Calif.)
29.	Michael Lewan	Medtronic	Sen. Debbie Stabenow (D-Mich.)
30.	R. Bruce Josten	U.S. Chamber of Commerce	2011 Holiday Reception at U.S. Chamber of Commerce
31.	Raissa Downs	AdvaMed, Boston Scientific, National Electrical Manufacturers Assoc.	Sen. Orrin Hatch (R-Utah)
32.	Randall Gerard	Covidien, Quest Diagnostics, St. Jude	Sen. Dean Heller (R-Nev.), Sen. John Barrasso (R-Wyo.)
33.	Rolf Lundberg	U.S. Chamber of Commerce	2011 Holiday Reception at U.S. Chamber of Commerce
34.	Stephen Northrup	Covidien, Quest Diagnostics, St. Jude	Sen. Dean Heller (R-Nev.), Sen. John Barrasso (R-Wyo.), Rep. Kevin Yoder (R-Kan.)
35.	Thomas Donohue	U.S. Chamber of Commerce	2011 Holiday Reception at U.S. Chamber of Commerce
36.	Thomas Sparkman	Covidien	Sen. Dean Heller (R-Nev.), Sen. John Barrasso (R-Wyo.)

Source: Public Citizen analysis of the Sunlight Foundation's Political Party Time project and Lobbying disclosure data provided by the secretary of the Senate.

Overall, the industry spent $158.7 million on lobbying from 2007 through 2011.[14] [See Table 3]

Table 3: Medical Device Industry Lobbying, 2007-2011

Year	2007	2008	2009	2010	2011	2007-2011
Total	$27,783,181	$31,907,382	$33,222,131	$32,440,546	$33,337,195	$158,690,435

Source: Center for Responsive Politics (www.opensecrets.org)

Industry representatives who have proposed accelerating the clearance and approval processes say that doing so is necessary because the medical device industry is largely composed of small business start-ups that are suffering economic harms while they await FDA permission to sell their products. "The current regulatory environment is particularly challenging for start-up companies … because of their limited financial resources," a summary of an industry survey said.[15]

The size of companies seeking to market devices does not justify putting the public at risk. But small companies are not spearheading the lobbying campaign to weaken standards in any event. Instead, the record shows, large companies with big profits are invoking the alleged plight of small companies to win a more permissive process for themselves.

[14] Center for Responsive Politics (www.opensecrets.org). (Totals include spending for lobbying on all issues. However, many, if not a majority, of topics upon which industry lobbied concerned device regulation.)
[15] JOSH MAKOWER, ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION, A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES (November 2010). (Report produced with support from Medical Device Manufacturers Association (MDMA), National Venture Capital Association (NVCA), and multiple state medical industry organizations.)

Regardless of the number of small businesses in its ranks, the medical device industry has plenty of mature firms. Collectively, the U.S. device industry earned $12.4 billion in profits in 2010, a 57 percent increase over its $7.9 billion profits in 2009.[16] Additionally, a surge in investment in medical device development occurred in 2010.[17]

Five of the seven medical device companies spending the most on lobbying since 2007 are members of the Fortune 500. (This ranking does not include the industry's largest trade association, Advanced Medical Technology Association (AdvaMed), which ranked third in lobbying for the same time period.) The company that has spent the most on lobbying (Medtronic, at $18.7 million) ranks 158th in the Fortune 500. [See Table 4]

Table 4: Top 25 Device Organizations' Lobbying Expenditures, 2007 to 2011

Rank	Company	Lobbying Expenditures from 2007-2011
1.	Medtronic Inc.	$ 19,725,691
2.	Baxter International	$ 15,018,000
3.	Advanced Medical Technology Assoc.	$ 10,142,268
4.	Boston Scientific Corp.	$ 8,950,000
5.	Covidien Ltd.	$ 8,320,000
6.	Invacare Corp.	$ 4,889,250
7.	Edwards Lifesciences	$ 4,015,166
8.	Becton, Dickinson & Co.	$ 3,446,616
9.	Zimmer Inc.	$ 2,682,128
10.	Pacific Pulmonary Services	$ 2,650,000
11.	Kinetic Concepts	$ 2,625,000
12.	St Jude Medical	$ 2,595,000
13.	SCOOTER Store	$ 2,496,660
14.	Welch Allyn Inc.	$ 2,095,000
15.	Steris Corp.	$ 2,085,000
16.	Academy of Radiology Research	$ 1,865,000
17.	Varian Medical Systems	$ 1,850,000
18.	Medical Device Manufacturers Assoc.	$ 1,710,000
19.	Cook Group	$ 1,700,000
20.	Biomet Inc.	$ 1,630,000
21.	CCS Medical	$ 1,257,851
22.	Stryker Corp.	$ 1,236,287
23.	Pride Mobility Products	$ 1,215,000
24.	Accuray Inc.	$ 1,205,000
25.	Mobile Medical International Corp.	$ 1,165,000
	Total for top 25 firms	**$106,569,917**

Source: Center for Responsive Politics (www.opensecrets.org)

[16] ERNST & YOUNG, PULSE OF THE INDUSTRY: MEDICAL TECHNOLOGY REPORT 2011, 18 (September 2011), http://bit.ly/wmEWTW.
[17] *Id.* at 9.

The lobbying data in Table 4 includes only organizations that the Center for Responsive Politics classifies as representing the medical supplies industry. However, many very large, diversified companies that have medical device manufacturing divisions also are lobbying to speed up the FDA's clearance and approval process rules. These companies include:

- Siemens ($102.7 billion in 2010 revenue);
- Johnson & Johnson ($61.6 billion in 2010 revenue), which has acquired at least 35 device manufacturers since 1995;
- Novartis ($51.6 billion in 2010 revenue);
- Abbott Laboratories ($35.2 billion in 2010 revenue);
- Philips Holdings, a subsidiary of Royal Philips Electronics ($33.7 billion in 2010 revenue); and
- 3M ($26.7 billion in 2010 revenue).

The medical device industry also uses campaign contributions to increase its influence. For example, AdvaMed says its political action committee (PAC), which exists to distribute campaign contributions, is "the voice of Medical Technology and Innovation in Washington.[18] The device industry made more than $19.9 million in campaign contributions between the 2006 and 2012 election cycles. [See Tables 5 and 6]

Table 5: Medical Device Campaign Contributions, 2006-2012 Election Cycles

Year	2006	2008	2010	2012*	2006-2012
Total	$4,290,527	$6,822,333	$6,136,804	$2,667,958	$19,917,622

Source: Center for Responsive Politics (www.opensecrets.org)

*Data for the 2012 election cycle are partial.

[18] Advanced Medical Technology Association (AdvaMed*), Advocacy*, http://bit.ly/zM6Bp7. (Viewed February 14 2012.)

Table 6: Top 25 Contributing Medical Device Companies for Election Cycles 2006 to 2012

	Companies & Trade Associations	Campaign Contributions for Election Cycles 2006-2012*
1.	Medtronic Inc.	$1,527,955
2.	Boston Scientific Corp.	$1,279,590
3.	Invacare Corp.	$874,905
4.	Baxter International	$803,372
5.	C8 Medisensors	$738,661
6.	Pride Mobility Products	$693,300
7.	Advanced Medical Technology Assoc.	$683,479
8.	Medline Industries	$650,900
9.	Starkey Laboratories	$586,630
10.	Direct Supply Inc	$567,828
11.	A-Dec Inc	$547,150
12.	Scooter Store	$471,777
13.	Covidien Ltd	$427,198
14.	Novo Nordisk	$383,195
15.	Edwards Lifesciences	$368,827
16.	St Jude Medical	$338,637
17.	Becton, Dickinson & Co	$311,753
18.	Kinetic Concepts	$297,425
19.	CR Bard Inc.	$286,394
20.	Masimo Corp.	$230,080
21.	American Orthotic & Prosthetic Assoc.	$203,866
22.	Cook Group	$197,713
23.	Pacific Pulmonary Services	$196,950
24.	Stryker Corp.	$177,363
25.	Electrostim Medical Services Inc.	$175,500

Source: Center for Responsive Politics (www.opensecrets.org)

* Data for the 2012 election cycle are partial.

Members of the House who ended up sponsoring industry-friendly legislation and members on the Health Subcommittee of the House Energy and Commerce Committee, which has jurisdiction over the MDUFA reauthorization process, have received a disproportionate share of contributions. Sponsors of the 10 House bills have received nearly three times as much per election cycle as the average member of Congress since 2006. Health Subcommittee members have received more than twice as much as the average member. [See Table 7]

Table 7: Contributions from the Medical Device Industry to All House Members Vs. Contributions to Health Subcommittee Members and Bill Sponsors

Member of Congress	Average Amount Received in Each Election Cycle 06-12*
All Members	$4,281
Members of Energy and Commerce Committee, Health Subcommittee**	$9,726
Eight Sponsors of Medical Device Bills	$11,473

Source: Center for Responsive Politics (www.opensecrets.org)

*Totals represent average amount received per cycle by member. This methodology accounts for the number of election cycles in which each member has served since 2006.

**5 of the 27 subcommittee members are sponsors.

In addition to contributions directly from the industry, investors in medical device companies also have made significant campaign contributions.

For example, in 2011, Rep. Erik Paulsen (R-Minn.), who is either sponsoring or co-sponsoring all 10 of the industry-friendly House bills, received $74,000 from venture capitalists with a stake in device companies over the span of one month last spring.[19]

[19] Barry Meier and Janet Roberts, *Venture Capitalists Put Money on Easing Medical Device Rules*, NEW YORK TIMES, Oct. 25, 2011, http://nyti.ms/zsgWMX.

II. Increasing Recalls and Tragic Cases Show That the FDA Is Failing to Protect the Public from Dangerous Medical Devices.

Faulty medical devices are a major threat to patients. They can cause infection, inflammation, pain, injury, and death. Today's lax medical device clearance and approval processes allow manufacturers to rush medical devices to the market at the expense of safety.

A. Recalls for Medical Devices Are Rising.

An industry-funded report published in 2006 claimed that "serious device-related safety problems are extremely rare."[20] But the number of patient injuries and deaths shows otherwise. Every year, the FDA receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2,000 device-related deaths, according to an FDA consultant.[21]

The number of medical device recalls is rising. The number of recalls for moderate- and high-risk devices in fiscal year 2011 (1,201) more than doubled from 2007 (566). The number of recalls specifically for high-risk devices in fiscal year 2011 was also double that of 2007.[22] From 2006 through 2011, there were at least 171 high-risk recalls and 4,000 moderate- and high-risk recalls.[23] [See Table 8]

Table 8: Classifications of Recalls[24]

	Recall Classification	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011*	Total
Class I Recall	Recall poses high risk	26	14	32	49	50	171
Class II Recall	Recall poses moderate risk	540	710	677	751	1,151	3,829
	Total	566	724	709	800	1,201	4,000

Source: Federal Drug Administration
*FY11 numbers may change when FDA aggregates data.

[20] JOSH MAKOWER, ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION, A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES (November 2010). (Report produced with support from Medical Device Manufacturers Association (MDMA), National Venture Capital Association (NVCA), and multiple state medical industry organizations.)
[21] Hearing on FDA'S Drug And Device State Lawsuit Pre-emption before House Committee on Oversight and Government Reform, 110th Congress (2008).
[22] E-mail from Barbara Zimmerman, FDA's Center for Devices and Radiological Health Office of Device Evaluation, to Negah Mouzoon, Researcher at Public Citizen Congress Watch division, Nov. 18, 2011 (on file with author).
[23] *Id.*
[24] Generally, a recall can refer to different sizes or parts or a single device, from a single manufacturer or multiple manufacturers. The chart above accounts for what the FDA has categorized as "recall events," an agency grouping of related recalls.

The rising number of recalls has not been accompanied by an increase in the number of new product applications submitted to the FDA. [See Table 9] This suggests that the increase in recalls has been due to the decline in safety rather than an increase in the number of devices on the market.

Table 9: Number of Annual Device Submissions for Moderate and High Risk Devices

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Total:	3,966	3,747	3,933	4,191	3,989

Source: Food and Drug Administration, MDUFA Performance Reports (2010)

The FDA defines recalls as events that must "occur when a medical device is defective" or "when it could be a risk to health."[25] But recalls do not necessarily entail returning the products to the companies that made them. A recall may involve actions such as inspecting the device for problems, repairing or re-labeling the device, issuing notifications of a problem, or monitoring patients for health issues. Most recalls are initiated voluntarily by device manufacturers.[26]

The statistics on recalls do not tell the entire story. The case studies in the next section illustrate the tragic consequences of unsafe medical devices.

B. Case Studies of Six Recent High Profile Recalls Illustrate the Threat Posed By Dangerous Devices.

The six case studies below illustrate the potential harm to patients, from manufacturing errors or design flaws in medical devices.

Four of the six devices described below were believed to pose no more than a moderate potential risk and therefore received clearance under the 510(k) process, which rarely requires clinical testing. The other two devices were approved under the more rigorous premarket approval (PMA) process, which requires clinical testing of the device. In the cases below, the FDA either failed to prevent unsafe devices from reaching the market, failed to act promptly after evidence of serious harms came to light, or both.

i. Axxent Flexishield Mini Recall (Cleared Under the 510(k)Process)

The Axxent Flexishield Mini is a flexible pad composed of silicone rubber and tungsten that is inserted temporarily into breast incisions to shield healthy breast tissue from radiation exposure during a relatively new type of breast cancer radiation treatment called Intraoperative Radiation Therapy (IORT). IORT is administered to patients immediately after they have undergone a lumpectomy. It is faster than the traditional five-to-seven

[25] Food and Drug Administration, Medical Device Recalls (June 6, 2011), http://1.usa.gov/zOGiop.
[26] *Id.*

weeks of daily radiation therapy sessions. Once IORT therapy is used to treat breast tissue, the pad is removed.

The Axxent Flexishield Mini was initially manufactured by Xoft, which was subsequently acquired by iCad.

In 2010, routine mammograms revealed that 30 women who had undergone treatment with the Axxent Flexishield Mini were left with small particles of tungsten, a high-density metal, embedded in their breast tissue. The women were presented with a dilemma: they could undergo what would otherwise be an unnecessary and risky mastectomy to remove the affected breast tissue or simply live with the unknown dangers of having tungsten in their bodies.[27]

One woman's breast and surrounding tissues contained so much tungsten that her doctor recommended she undergo radical mastectomy. The operation removed one of her breasts and her underlying chest muscles, causing severe disfigurement.[28]

"I had this illusion, like most people do, that the FDA wouldn't allow this to happen," one of the affected patients said. "I definitely feel like a lab rat now."[29]

In 2009, the Axxent Flexishield Mini was cleared through the FDA's 510(k) process.[30] The predicate device for the Axxent Flexishield Mini was the Arplay Medical Lead Blocks,[31] a device with significantly different technological characteristics from the Axxent Flexishield Mini. More than a year later, the Flexishield Mini's manufacturer, iCad, recalled the device because of the problem with tungsten particles being released into the breasts of women who had been treated with it.[32]

The release of the tungsten particles apparently occurred because the Axxent Flexshield Mini devices were trimmed prior to insertion into the patients. This serious problem likely would have been detected prior to marketing if adequate preclinical and clinical testing had taken place.

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[27] Denise Grady, *Riddled With Metal by Mistake in a Study*, NEW YORK TIMES, March 21, 2011, http://nyti.ms/ygNqex.
[28] Interview with Jeff Milman, Dec. 1, 2011. (Milman, of Irvine, Calif. is the woman's attorney.)
[29] Denise Grady, *Riddled With Metal by Mistake in a Study*, NEW YORK TIMES, March 21, 2011. http://nyti.ms/ygNqex.
[30] Food and Drug Administration, June 2009 510(k) Clearances (July 9, 2009), http://1.usa.gov/wkuu7U.
[31] Food and Drug Administration, 510(k) Summary for the Axxent Flexishield Mini (June 23, 2009), http://1.usa.gov/wze1Z5.
[32] Denise Grady, *Riddled With Metal by Mistake in a Study*, NEW YORK TIMES, March 21, 2011. http://nyti.ms/ygNqex.

Few studies have examined the long-term effects of tungsten in the body. In 2005, a scientific study by the Uniformed Services University of the Health Sciences, in Bethesda, Md., examined the short-term effects of tungsten in rats. The study involved implanting rats with tungsten-alloy pellets. Researchers observed the formation of cancer clusters surrounding the pellets. The authors of the report suggested that cancer clusters are "part of a growing list of health concerns related to tungsten exposure."[33] If the effects shown on rats prove true for people, the use of the Axxent shield could end up causing cancer in people whose cancer it was meant to treat.

Further, the tungsten particles pose a significant long-term problem for the patients because they interfere with the screening tests (such as mammograms) used for periodic monitoring for recurrent breast cancer following treatment. The particles can easily be mistaken for calcifications during an X-ray or scan of breast tissue, and such calcifications can be a sign of recurrent breast cancer.[34]

On February 3, 2011, iCad sent a letter to all affected healthcare providers, notifying them that the Axxent Flexishield Mini was prone to shedding tungsten particles in women's breasts. The letter asked the providers to stop using the product and to return it to the manufacturer. Although iCad concluded that there is no evidence to suggest tungsten particles are toxic, the company still recommended urine and serum tests is to test for tungsten every 12 months.[35]

Beginning in February 2011, 15 of the women put at risk by the device filed complaints against iCad and Hoag Hospital, which conducted the experimental procedure.[36]

ii. Baxter Colleague Volumetric Infusion Pumps (CVIP) (Cleared Under the 510(k)Process)

Infusion pumps are medical devices that deliver controlled amounts of fluids, including nutrients and medication, intravenously into a patient's body. One such pump, the Colleague Volumetric Infusion Pump (CVIP), manufactured by Baxter Healthcare Corp., was implicated in numerous injuries and deaths, according to FDA data.[37]

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[33] John Kalinich, *et al.*, *Embedded Weapons-Grade Tungsten Alloy Shrapnel Rapidly Induces Metastatic High-Grade Rhabdomyosarcomas in F344 Rats*, 113 ENVIRONMENTAL HEALTH PERSPECTIVES 729, 729-734 (2005) (discussing carcinogenic potential of Tungsten-alloy).
[34] Denis Grady, *Breast Device Recall Made Most Severe*, NEW YORK TIMES, April 14, 2011, http://nyti.ms/egcZKR.
[35] Food and Drug Administration, iCad Axxent FlexiShield Mini Recall (April 14, 2011), http://1.usa.gov/A4HAKf .
[36] Interview with Jeff Milman, Dec. 1, 2011. (Milman, of Irvine, Calif. is the attorney for the women.)
[37] Public Citizen, Letter Condemning Delayed Recall of Defective Intravenous Infusion Pumps (March 12, 2009), http://bit.ly/wGKZQr.

The story of the CVIP provides a clear example of inadequacies in recall procedures and the failure of the FDA to promptly remove a dangerous medical device from the market once sufficient evidence showing that the device was unsafe had accumulated.

The Baxter CVIP was first cleared in 1996 through the 510(k) process.[38] CVIPs became a source of persistent safety problems almost from the moment they were put on the market.[39] For example, the pumps were prone to unexpectedly shut down or dispense the incorrect dose of medicine. In July 2004, Baxter issued its first recall in the form of a warning letter to healthcare providers, notifying them of ink deterioration of the pumps' keypads.[40]

Later in 2004, Baxter sent another urgent warning letter to providers, notifying them that the devices would exhibit false alarms and unexpected shutdowns.[41]

Problems also emerged because the "On/Off" key on the pumps' key pads was so close to the "Start" key that nurses often shut down the machines when they intended to begin drug therapy.[42]

In February 2005, problems with the pumps' batteries surfaced.[43] The FDA's recall notice said that such failures could lead to "interruption or prevention of therapy and the possible death and/or serious injury of patients."[44] Again, the FDA opted not to demand that the units be taken out of service but instead saddled hospitals with the responsibility of dealing with the problems. In its comments, the FDA wrote: "Baxter has advised health care institutions to have a backup pump available to mitigate any disruptions of infusions of life-sustaining drugs or fluids."[45]

In July 2005, Baxter issued another recall (again, in the form of an urgent letter), due to the CVIP's tendency to shut down inadvertently. In this recall, Baxter did not withdraw the device from the market, but advised providers to "review the event history of your pumps

[38] Baxter Company Profile, http://bit.ly/wBgswc.
[39] Food and Drug Administration, Questions and Answers About the Baxter Colleague Recall, Refund, and Replacement Action (Sept. 3, 2010), http://1.usa.gov/xpIsal.
[40] Food and Drug Administration, Class II Recall, Colleague CX Volumetric Infusion Pumps (July 20, 2004). http://1.usa.gov/y0kUsr.
[41] Food and Drug Administration, Class II Recall, Colleague CX Single Channel Volumetric Infusion Pump (Dec. 22, 2004), http://1.usa.gov/w2WVeq.
[42] Baxter Healthcare Corp., Urgent Device Correction Letter to Customer (March 15, 2005), http://bit.ly/wRsZqi.
[43] Baxter Healthcare Corp., Important Product Information (Feb. 25, 2005), http://bit.ly/wLb14B.
[44] Food and Drug Administration, Baxter Healthcare Corp. Colleague Volumetric Infusion Pumps Class I Recall, (Sept. 19, 2005), http://1.usa.gov/wqIVPn.
[45] *Id.*

and any pumps with a previous history of the aforementioned failure codes" to see if their pumps were covered by the recall. [46] Although Baxter's action was termed a "recall," the firm did not remove the affected devices from service.[47] Instead, the recall left the onus on the customer to identify defective devices and remove them from service.[48] The FDA's rules permit such actions under the heading of a "recall."

In October 2005, after problems with the pumps were linked to four deaths and 10 serious injuries, the FDA seized 6,000 CVIPs from Baxter's facilities in Illinois.[49]

Baxter discontinued the line of CVIPs in December 2005 and submitted to the FDA a modified pump design, which was cleared through the 510(k) process in 2007.[50] But Baxter did not remove the defective pumps that were still being used by hospitals and other healthcare facilities. The company issued another recall in 2006, referencing battery problems, false alarms, and interruptions to therapy, yet did not require the product to be removed from market.[51]

In 2006, the Baxter signed a consent decree for "condemnation and permanent injunction" with the FDA, which required the company to stop manufacturing and distributing all models of the CVIP until the company "corrected manufacturing deficiencies and until devices in use were brought into compliance."[52]

In 2007, a software irregularity began causing CVIPs to alarm, display an error code and stop working.[53] Separately, Baxter discovered that repair, test and inspection data sheets had been falsified, meaning that "pumps sent to be serviced, repaired, or corrected" may have been "returned without service being performed on them." Recalls for these shortcomings were issued.[54]

[46] Baxter Healthcare Corp, Urgent Product Recall Letter to Customer (July 20, 2005), http://bit.ly/wg0OdY.
[47] *Id.*
[48] *Id.*
[49] *Baxter: FDA Seizes Recalled Drug Pumps*, ASSOCIATED PRESS, Oct. 27, 2005, http://bit.ly/yl8M5j.
[50] Press Release, Baxter Healthcare Corp., Baxter Prepares to Upgrade COLLEAGUE Pumps in the U.S. (Feb. 27, 2007), http://bit.ly/AqNH9w; *Public Citizen Slams Baxter Infusion Pump Recall*, NEWSINFERNO, March 13, 2009, http://bit.ly/wrRhvk.
[51] Food and Drug Administration, Baxter Healthcare Corp. Colleague 3 and Colleague 3 Volumetric Infusion Pumps, Class I Recall (Jan. 31, 2006), http://1.usa.gov/zZCeBn.
[52] Press Release, Food and Drug Administration, FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps (May 3, 2010), http://1.usa.gov/d00CWe.
[53] Food and Drug Administration, Baxter Healthcare Corp. Upgraded Colleague Triple Channel Volumetric Infusion Pumps Class I Recall (June 20, 2010), http://1.usa.gov/ymjpjy.
[54] Food and Drug Administration, Baxter Healthcare Corp. Colleague and Flo-Gard Volumetric Infusion Pumps (Aug. 8, 2007), http://1.usa.gov/whxqXC.

In April 2010, the FDA finally demanded that Baxter withdraw all the CVIPs from the market, including more than 200,000 pumps that were in use.[55] The recall notice called for Baxter to complete the transition process by July 2012.[56]

The FDA's action came in response to what it deemed as an insufficient remediation plan proposed Baxter. The company's plan did not call for beginning the corrective actions until May 2012. "Baxter has failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague infusion pumps still in use," the FDA wrote.[57]

Despite the FDA's mandated recall in 2010, Baxter's infusion pumps continued to pose problems to patients, as seen in the company's issuance of another eight recall notices for remaining CVIPs on the market.[58]

iii. Medtronic's Sprint Fidelis Implantable Cardioverter-Defibrillator Leads (Approved Through the PMA Process)

In January 2006, Kelly Luisi was rushed to a San Diego emergency room because her Sprint Fidelis implantable cardioverter-defibrillator (ICD) began malfunctioning, resulting in the delivery of multiple inappropriate sudden electrical jolts to her heart.[59]

ICDs, like the Sprint Fidelis model that was manufactured by Medtronic Inc. and implanted in Luisi, are small devices inserted under a patient's collarbone and connected to the heart through a set of wires called leads. When a person's heart develops a life-threatening arrhythmia, the ICD is supposed to detect the abnormal heart rhythm and then send a therapeutic electric shock to the heart, which in turn prompts the heart to resume normal rhythmic beating. In a conscious patient, such shocks can be painful and potentially dangerous.

Medtronic's Sprint Fidelis ICD lead was based on Medronic's earlier Transvene Lead System, which was approved in 1993.[60] The Sprint Fidelis lead was never approved as a new device, which would require clinical testing.[61] Instead, it was approved as a

[55] Press Release, Food and Drug Administration FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps (May 3, 2010), http://1.usa.gov/d00CWe.
[56] *See* Questions and Answers About the Baxter Colleague Recall, Refund, and Replacement Action (Sept. 3, 2010), http://1.usa.gov/xpIsal.
[57] *Id.*
[58] Food and Drug Administration, Baxter Healthcare Corp, Colleague Volumetric Infusion Pump Recalls, Jan. 13, 2012, Jan. 11, 2012, Aug. 11, 2011, Aug. 8, 2011, July 19, 2011, July 13, 2011, May 19, 2011, Jan 21, 2011.
[59] Joshua Freed, *Heart Patients Sue Medtronic Over Device*, USA TODAY, Oct. 16, 2007, http://usat.ly/Avz36g.
[60] Food and Drug Administration Premarket Approval database, application for Medtronic Sprint Fidelis Lead Models 6949k 6948, 6931, 6930, http://1.usa.gov/yIq7bF. *See also* original PMA link in aforementioned source.
[61] *Id.*

modification to an existing PMA-approved device. The process for approving modifications is less stringent.[62]

Because of a defect in the Sprint Fidelis ICD lead, Luisi's ICD malfunctioned and repeatedly shocked her heart when she did not have an abnormal heart rhythm. She continued to receive multiple painful shocks as a representative from Medtronic looked on, unable to stop the device from going haywire.[63] Luisi survived the incident but had to undergo complicated surgery to remove the leads that scarred "her already fragile heart."[64]

In 2007, Bill Storms, from Delaware, Ohio, had to visit several emergency rooms before his malfunctioning ICD with Sprint Fidelis leads could be turned off. He said he received 138 unnecessary painful electrical shocks over a five-hour period.[65] The same year, Leonard Stavish experienced 47 shocks due to malfunctions with his Sprint Fidelis ICD.[66]

By January 2007, at least 599 reports of injuries associated with the Sprint Fidelis ICD leads had been filed with Medtronic.[67] By June, the number grew to more than 1,000.[68] On Oct. 15, 2007, Medtronic halted distribution of the device and issued a recall. Subsequent revelations indicate that Medtronic was aware of the product's defects months before it issued a recall.[69]

The Sprint Fidelis ICD leads are prone to developing fractures. When the device fractures, it can cause the ICD to suddenly malfunction and deliver multiple painful electric shocks.[70] The fractures in the leads also can prevent the ICD from delivering intended life-saving shocks in patients who develop ventricular tachycardia or fibrillation.

Although other manufacturers used similar types of ICD leads, Medtronic's Sprint Fidelis ICD leads apparently were more susceptible to degradation and fractures. According to a

[62] Food and Drug Administration, PMA Supplements and Amendments, http://1.usa.gov/z9aUey; Food and Drug Administration, PMA Supplements and Amendments, http://1.usa.gov/z9aUey. ("An applicant may make a change in a device after FDA's approval of the PMA without submitting a PMA supplement if (1) the change does not affect the device's safety or effectiveness.")
[63] Press Release, Lieff, Cabraser, Heimann, & Bernstein Attorneys at Law, Class Counsel Announce Patients File Class Action Lawsuits Against Medtronic for Manufacturing Faulty Defibrillator Lead Wires (Oct. 15, 2007), http://bit.ly/AsdW9g.
[64] Kelly Luisi, *et al*. v. Medtronic, Inc., CA. No. 0:07-4250, 22 (D. Minn. Oct. 15, 2007), http://bit.ly/zovmZ8.
[65] Sabrina Eaton, *Patients Injured by Faulty Medical Devices Want Laws to Hold Manufacturers Accountable*, CLEVELAND PLAIN DEALER, May 12, 2009, http://bit.ly/wA68va.
[66] Joshua Freed, *Heart Patients Sue Medtronic Over Device*, USA TODAY, Oct. 16, 2007, http://usat.ly/Avz36g.
[67] Letter Urging an Investigation of Medtronic Defibrillator Recall from Public Citizen's Health Research Group to Andrew von Eschenbach, M.D., FDA Commissioner, Food and Drug Administration (Oct. 16, 2007), http://bit.ly/xpoCyl.
[68] *Id*.
[69] *Id.*
[70] Medtronic, Potential Conductor Wire Fracture Advisory (October 2007), http://bit.ly/y5y6in.

study published in June 2009, the Sprint Fidelis ICD leads degraded at a greater rate than other contemporary ICD leads.[71]

More than 268,000 Sprint Fidelis ICD leads were implanted in patients worldwide. As of August 1, 2011, only half remain implanted. According to two studies, the ICDs that remain implanted will likely experience a 10 to 12 percent failure rate within three years and nearly 17 percent within five years[72]

Patients implanted with the recalled device filed thousands of lawsuits against the company alleging that Medtronic misrepresented the danger of the product, and minimized the likelihood that patients would need to have their ICD leads replaced.[73] In three of these plaintiffs, the Sprint Fidelis ICD leads malfunctioned, necessitating emergency life-saving surgeries to remove the device and implant a new lead.

But the lawsuits filed against Medtronic were blocked from being heard in court. In January 2009, New York U.S. District Court Judge Richard Kyle dismissed all personal injury and wrongful death lawsuits pertaining to the Medtronic ICD leads on the basis of a 2008 U.S. Supreme Court decision which concluded that federal law prohibited state civil actions against certain classes of FDA-approved medical devices.[74] The plaintiffs' lawyers appealed the decision on the basis that the manufacturer had given up its legal protections because it failed to adequately warn patients about the devices' defects.[75]

Before the judge ruled on the appeal, Medtronic announced it would pay a settlement to resolve existing lawsuits relating to the Sprint Fidelis ICD leads. Medtronic agreed to pay $268 million to settle the majority of cases that had already been filed against it. A federal

[71] *See* R.G. Hauser & David L. Hayes, *Increasing Hazard of Sprint Fidelis Implantable Cardioverter-defibrillator Lead Failure*, 6 HEART RHYTHM, 605, 605-610 (2009) (Discussing Medtronic Sprint Fidelis lead defibrillator failure rate in comparison to competing defibrillators).
[72] *See* P.F.H.M. van Dessel, *The Sprint Fidelis Lead Fracture Story: Time to Come to Our Senses?* 18 NETHERLANDS HEART JOURNAL 4, 4-6 (2010) (comparing the results of their study of Medtronic Sprint Fidelis Lead failure rates to Medtronic's similar study), http://bit.ly/A3F2tW; Thomas Lee, *Medtronic's Sprint Fidelis Settlement Leaves Some Patients Out in the Cold*, MINNPOST, Dec. 13, 2010, http://bit.ly/znCYpG; David Birnie, Ratika Parkash, Derek Exner, *et al.*, *Clinical Predictors of Fidelis Lead Failure: A Report from the Canadian Heart Rhythm Society Device Committee.* CIRCULATION. Published online Feb. 6, 2012
[73] Press Release, Class Counsel Announce Patients File Class Action Lawsuit Against Medtronic for Manufacturing Faulty Defibrillator Lead Wires, Oct. 15, 2007, http://bit.ly/xh0ZNN; Tom Lamb, *Sprint Fidelis Lead Wire Defect Litigation Comes to an Apparent Disappointing End*, DRUG INJURY WATCH, http://bit.ly/aGQm7y.
[74] Riegel v. Medtronic Inc., 552 U.S. 312 (2008), http://bit.ly/wv1xrN.
[75] Appeal from the United States District Court for the District of Minnesota, *Bryant, et al., v. Medtronic, Inc.*, No. 09-2290 (8th Circuit 2010).

appeals court subsequently ruled against the plaintiffs' right to proceed with their case, but the settlement stood.[76]

Despite the Sprint Fidelis ICD leads being implicated in more than 100 deaths, Medtronic acknowledged a possible implication of the lead in only 13 deaths and never admitted actual fault.[77] "The settlement is a compromise of disputed claims, and the parties have not admitted any liability or the validity of any defense in the litigation," the company said.[78]

Today, Medtronic estimates that about 143,000 active Sprint Fidelis ICD leads remain implanted in patients, who still face the possibility of being injured or killed by the products. Future victims, or their survivors, almost certainly will not be able to obtain legal remedies.[79]

The history of Medtronic's Sprint Fidelis ICD demonstrates the serious life-threatening harms that can occur even when a medical device is approved by the FDA under the PMA process without the necessary clinical testing to show that the device is safe and durable. In particular, more stringent premarket testing of the Sprint Fidelis ICD leads likely would have detected the defect that caused life-threatening ICD malfunctions in thousands of patients.

iv. Teleflex Medical's Hem-o-lok Ligating Clip (Cleared Under the 510(k) Process)

In 2008, 29-year-old Michael King stepped into the State University of New York Downstate Medical Center in Brooklyn, N.Y., to donate a kidney to his wife. The surgeon clamped off King's renal artery that supplied blood to the kidney being donated with a Hem-o-lok ligating clip. As King was recovering from surgery, his Hem-o-lok clip popped off, causing him to internally bleed to death in his hospital bed in front of his wife.[80] King was one of six donors to die as a result of malfunctions of the Hem-o-lok clip, which had been the target of a series of recalls since 2004.[81]

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[76] Press Release, Medtronic Inc., Medtronic Settles U.S. Lawsuits on Sprint Fidelis Family of Defibrillation Leads (Oct. 14, 2010), http://bit.ly/ydFRlB; Tom Lamb, *Sprint Fidelis Lead Wire Defect Litigation Comes to an Apparent Disappointing End*, DRUG INJURY WATCH, http://bit.ly/aGQm7y.

[77] *MassDevice Exclusive: Former Medtronic CEO Hawkins on the Sprint Fidelis Recall*, MASS DEVICE, Aug. 22, 2011, http://bit.ly/xA7L9K.

[78] Press Release, Medtronic Inc., Medtronic Settles U.S. Lawsuits on Sprint Fidelis Family of Defibrillation Leads (Oct. 14, 2010), http://bit.ly/ydFRlB.

[79] Thomas Lee, *Medtronic's Sprint Fidelis Settlement Leaves Some Patients Out in the Cold*, MINNPOST, Dec. 13, 2010, http://bit.ly/znCYpG.

[80] *No System Tracks Faulty Medical Devices in U.S.,* ASSOCIATED PRESS, Oct. 6, 2009, http://on.msnbc.com/xaV2im.

[81] Food and Drug Administration, Class II Recall, Hem-o-Lok SMX Legating Clips (Feb. 25, 2004), http://1.usa.gov/x6zFKH; Food and Drug Administration, FDA and HRSA Joint Safety Communication: Weck Hem-o-Lok Ligating Clips Contraindicated for Ligation of Renal Artery During Laparoscopic Living-Donor Nephrectomy (May 5, 2011), http://1.usa.gov/kwpD9n.

The Hem-o-lok ligating clip is a V-shaped surgical clip used by surgeons to clamp off blood vessels and other tissue structures during a variety of surgical procedures. One such use included clamping off the renal artery of a kidney being removed during a living donor operation so the patient would not bleed when the kidney was removed.

This Hem-o-lok clip was initially manufactured by Weck Closure Systems and later by Teleflex Medical. The device was cleared for marketing by the FDA under the 510(k) process in 1990.[82] The device did not undergo premarket clinical testing to evaluate its safety and effectiveness when used to ligate the renal artery in patients undergoing kidney donation.

Certain sizes of the clip were first recalled in 2004 for malformation and breakage.[83]

A year later, the clips were once again the subject of a recall notice, warning doctors that the company was aware of the product deficiencies due to manufacturing errors.[84] Yet, the clips were not removed from hospital shelves and returned to the manufacturer.

In April 2006, Teleflex Medical sent out another letter to doctors, warning them of the clips' trouble in closing properly when used for ligating renal arteries during kidney donation surgery.[85] Teleflex warned doctors that use of the clips was contraindicated during laparoscopic surgery because they could dislodge from the renal artery and lead to uncontrolled bleeding, causing death.[86] For non-laparoscopic open surgery to remove a kidney, the company recommended that surgeons use more than one clip to clamp off the renal artery.[87]

[82] Food and Drug Administration 510(k) Premarket Notification database, Hem-o-lok substantially equivalent (SE) decision (May 6, 1990).
[83] *See* Food and Drug Administration, Class II Recall Weck Hem-o-lok SMX Ligating Clips (Feb. 25, 2004), http://1.usa.gov/x6zFKH; Food and Drug Administration, Class III Recall Hem-o-lok Endo5 Ligation Clips (Oct. 22, 2004), http://1.usa.gov/AnRPCc.
[84] Food and Drug Administration, Class III Recall Weck Hem-o-lok Polymer Ligating Clips (Jan. 13, 2005), http://1.usa.gov/A3Vbiu.
[85] Food and Drug Administration, Class II Recall Weck Hem-o-lok Polymer Ligating Clips (June 9, 2006), http://1.usa.gov/AhLNHC.
[86] *Id.* and Food and Drug Administration, FDA and HRSA Joint Safety Communication: Weck Hem-o-Lok Ligating Clips Contraindicated for Ligation of Renal Artery During Laparoscopic Living-Donor Nephrectomy (May 5, 2011), http://1.usa.gov/kwpD9n.
[87] Food and Drug Administration, Class II Recall Weck Hem-o-lok Polymer Ligating Clips (June 9, 2006), http://1.usa.gov/AhLNHC.

Shortly thereafter, the FDA cited Teleflex Medical for manufacturing practice violations and for not having reported adverse events to the FDA when death and injury were related to the Hem-o-lok defects.[88]

Later in 2008, after 12 injuries and three deaths were associated with the clip's malfunction, the company finally expanded the recall to mandate that all clinicians "cease use and distribution and quarantine all affected product immediately."[89] The letter requested all affected products be returned to Teleflex Medical.

However, the recalls came too late for Michael King. His widow, Shelly Ann King, had sought a kidney transplant to forgo dialysis in order to permit her to try to have a baby with her husband.[90]

The story of the Hem-o-lok ligating clip provides a disturbing example of the failure of the FDA to ensure that a device has undergone appropriate clinical testing to ensure that the device is safe and effective prior to clearance for marketing. The story also demonstrates the failure of the agency to act promptly to protect public health by removing a dangerous medical device from the market once sufficient evidence has accumulated showing that the device was unsafe.

v. DePuy ASR XL Acetabular System (Cleared Under the 510(k) Process)

Today, many people cannot exercise, walk without a cane or stand up long enough to cook a meal due to serious problems resulting from a faulty, untested device implanted in their hips. On August 24, 2010, 93,000 patients worldwide were affected by a recall issued by DePuy Orthopaedic (DePuy), a subsidiary of Johnson & Johnson, for its line of Articular Surface Replacement (ASR) hip replacement systems.[91] Hip replacement systems are used to replace worn or damaged hip joints that limit mobility as a result from injury or disease.[92]

DePuy developed two types of hip replacement systems that incorporated novel features. One (the ASR XL Acetabular System) was used in total hip replacements. The other (the

[88] Warning Letter from FDA to Jeffrey P. Black, President & CEO, Teleflex Medical (July 20, 2006), http://1.usa.gov/AjPC1D.
[89] Food and Drug Administration, Class II Recall Hem-o-lok Polymer Ligating Clips (Sept. 16, 2008), http://1.usa.gov/w0uVQk; Safety Alert, Food and Drug Administration, FDA and HRSA Joint Safety Communication: Weck Hem-o-Lok Ligating Clips Contraindicated for Ligation of Renal Artery During Laparoscopic Living-Donor Nephrectomy (May 5, 2011), http://1.usa.gov/kwpD9n.
[90] *U.S. Has No Good System to Track Medical Implants*, ASSOCIATED PRESS, Oct. 9, 2009, http://bit.ly/yCIzp1.
[91] Greg Farrell, Alex Nussbaum and David Voreacos, *Johnson and Johnson's Bitter Pills*, BLOOMBERG BUSINESS WEEK, April 10,2011, at 71.
[92] National Health Service, http://bit.ly/xkXC9Q.

ASR Hip Resurfacing System) was used in partial hip replacements.[93] Only the former received permission to be marketed in the United States.

DePuy's metal-on-metal products were promoted as being tough, making them perfect for younger, physically active patients.[94]

In 2004, DePuy submitted its total hip replacement system (which is categorized as a high-risk, class III medical device) to the FDA for clearance under the 510(k) process.[95] This mechanism of review was permitted because of a loophole in FDA regulations that allows certain high-risk devices to bypass the PMA process. The FDA cleared the total hip replacement system without requiring clinical testing. The device entered the U.S. market in 2005.[96]

The company did not tell the FDA that the system included novel features. If the FDA had recognized this fact, it would have been obliged to require the product to be approved under the more stringent PMA process. Within two years of the FDA's approval of the total hip replacement system, 87 reports of adverse events associated with it had been submitted to the agency. By 2009, the number of adverse events reports had risen to 426.[97]

Separately, DePuy submitted its partial hip replacement system to the FDA for 510(k) clearance. In this case, the agency rejected the application. The FDA considered the partial hip replacement system's novel features—which were also included in the total hip replacement that was already cleared under the 510(k) process—as requiring the more stringent PMA approval.

Many studies have found that the total hip replacement system sheds metal fragments into the bone and surrounding tissue.[98] The metal debris then wears away the soft tissues surrounding the joint, leaving many patients with tissue inflammation, death of surrounding tissue, extreme pain and limited mobility.[99] The metal also leaches into the patient's blood stream. A study conducted by two private doctors found that ASR patients

[93] Greg Farrell, Alex Nussbaum and David Voreacos, *Johnson and Johnson's Bitter Pills*, BLOOMBERG BUSINESS WEEK, April 10, 2011, at 66.
[94] *Id.*
[95] Food and Drug Administration, *Depuy ASR Clearance* (Aug. 5, 2005), http://1.usa.gov/Aiiltq.
[96] Greg Farrell, Alex Nussbaum & David Voreacos, *Johnson and Johnson's Bitter Pills*, BLOOMBERG BUSINESS WEEK, April 10, 2011, at 70.
[97] *Id.*, at 71.
[98] Deborah Cohen, *Out of Joint: The Story of the ASR*, 342 BRITISH MEDICAL JOURNAL 115 (2011), http://bit.ly/ymlVOp.
[99] *Id.*

had elevated blood levels of cobalt and chromium from the metal contamination.[100] "There's so much metal, it's toxic to the tissues," a professor of medicine said.[101]

At the end of 2009, DePuy issued a recall for both ASR systems in Australia. The company claimed it was discontinuing the line for "commercial reasons," not safety issues.[102] Later, in August 2010, the company recalled the total hip replacement system in the United States.[103]

The device was supposed to last 15 to 20 years, but tended to fail after only four or five years, a law firm representing a client who had his hip device removed wrote.[104]

After the recall of the DePuy's total hip replacement system, a study presented in March 2011 at the British Hip Society Annual Conference reported that the device failed at a rate of 21 percent within four years and 49 percent within 6 years. In contrast, other devices fail at a rate of about 12 to 15 percent within five years.[105]

DePuy paid $84.7 million in 2007 to settle Justice Department charges that it made payments to doctors to entice them to use DePuy's hip and joint replacements.[106] The charges were dropped that year after the companies paid fines and agreed to stop compensating physicians except for legitimate consulting services.[107] In 2010, an investigative news report by a Connecticut television station alleged that, since 2009, DePuy had paid more than $80 million to doctors across the country to prescribe and promote its hip products, including its total hip implants.[108]

As of November 2011, approximately 4,100 lawsuits had been filed against DePuy, alleging injuries and damages suffered as a result of the defective DePuy ASR XL Acetabular System,

[100] Barry Meier, *The Implants Loophole*, NEW YORK TIMES, Dec. 16, 2010, http://nyti.ms/w1A6Kz.
[101] Greg Farrell, Alex Nussbaum & David Voreacos, *Johnson and Johnson's Bitter Pills*, BLOOMBERG BUSINESS. WEEK, April 10, 2011, at 66.
[102] Deborah Cohen, *Out of Joint: The Story of the ASR,* 342 BRITISH MEDICAL JOURNAL 115 (2011), http://bit.ly/ymlVOp.
[103] Colbach Law, Urgent Information Recall Notice from DePuy Orthopaedics to Clinicians (Aug. 24, 2010), http://bit.ly/yCTHbI.
[104] Press Release, Recalled DePuy ASR Hip Implant Lawsuits Filed by the Law Offices of John David Hart (Dec. 20, 2011).
[105] British Orthopaedic Association, Large Diameter Metal on Metal Bearing Total Hip Replacements (March 2011), http://bit.ly/xztRcF.
[106] U.S. Dept. of Justice, Settlement Agreement Between the United States and DePuy Orthopaedics Inc. (Sept. 27, 2007), http://1.usa.gov/xejM8D.
[107] *Id.*
[108] Peggy McCarthy, *DePuy, Scrutinized for Faulty Hip Parts, Paid Millions In Fees To Surgeons*, NEW HAVEN INDEPENDENT, Dec. 6, 2010, http://bit.ly/xqj9JR.

used for total hip replacement, according to a law firm that in December 2011 filed cases on behalf of two patients receiving the hip replacements.[109]

The story of DePuy's ASR XL Acetabular System demonstrates how a loophole in current FDA regulations allowed a high-risk, permanently implanted, class III medical device to be brought to market under the 510(k) clearance process without any premarket clinical testing, resulting in serious harms to thousands of patients.

vi. Guidant Ventak Prizm ICD (Approved Through the PMA Process)

During the summer of 2005, while riding his bicycle, Joshua Oukrop suffered a sudden cardiac arrest and suddenly dropped to the ground. Oukrop's ICD should have jolted his heart back into action. But the device failed and he died instantly.[110]

The ICD that had been implanted in Oukrop was part of Guidant's Ventak Prizm line, which FDA approved in 1997 under the PMA Process.[111] Two months after Oukrop's death, Guidant acknowledged that it had known for three years that the defibrillator had serious defects.[112]

By 2002, Guidant was aware that its Ventak Prizm model sometimes failed to activate when needed. It knew of at least two dozen cases in which the implantable defibrillator had short-circuited, but allegedly waited until 2005 to reveal the defect.[113]

On June 17, 2005, Guidant announced the recall of 26,000 of its Ventak Prizm ICDs. The number eventually grew to nearly 200,000 ICDs nationwide.[114] Guidant offered to cover the cost of replacement surgeries for affected patients. The company set aside $28 million to cover the cost of replacing the defective devices. [115]

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[109] Law Offices of John David Hart, Recalled DePuy ASR Hip Implant Lawsuits Filed by the Law Offices of John David Hart (Dec. 20, 2011), http://prn.to/z9Zf6c.
[110] Barry Meier, *Repeated Defect in Heart Devices Exposes a History of Problems*, NEW YORK TIMES, Oct. 20, 2005, http://nyti.ms/wighD0.
[111] Food and Drug Administration, PMA database, PMA approval of Ventak AV AICD System (July 18, 1997), http://1.usa.gov/zWMpTT.
[112] Barry Meier, *Repeated Defect in Heart Devices Exposes a History of Problems*, NEW YORK TIMES, Oct. 20, 2005, http://nyti.ms/wighD0.
[113] *Id.* and *Boston Scientific Pays $296 Million to Settle Fed's Guidant Inquiry*, REUTERS, Nov. 23, 2009.
[114] Robert G. Hauser, MD and Barry J. Maron, MD, *Lessons From the Failure and Recall of an Implantable Cardioverter-Defibrillator*, 112 AMERICAN HEART ASSOCIATION 2040, 2040-2042 (2005) (describing Guidant Recall of Ventak Prizm defibrillators), http://bit.ly/y83FvJ.
[115] Barry Meier and Andrew Sorkin, *Guidant Sues Johnson and Johnson for Completion of Merger*, NEW YORK TIMES, Nov. 8, 2005, http://nyti.ms/xfE2UW.

Also in 2005, several class action lawsuits were filed against Guidant, claiming that the company knew of the defects well in advance of the recall but delayed notifying physicians, patients and the general public.

Some of the lawsuits resulted in settlements, with the largest totaling $240 million and covering 8,500 claims. But in 2008, the Supreme Court blocked some of the lawsuits when it ruled that federal law barred most state law claims against device manufacturers if the device had received FDA approval.[116]

Eventually, 35 state attorneys general sued the company for marketing the unmodified device even after defect was discovered and corrected. Guidant settled the case in 2007 by paying $16.8 million and admitting no liability.[117]

In April 2010, Guidant pleaded guilty to misleading the FDA about the short-circuiting problems in three models of implantable ICDs: one model under the Ventak Prizm brand and two models under a separate product line.[118]

Guidant changed the design of the Ventak Prizm ICDs in 2002 to correct the short-circuiting problem, but continued to allow defective defibrillators it had already manufactured to be implanted in patients, according to the Justice Department charges. [119] A year later, Guidant reported the design changes to the FDA, but failed to fulfill a requirement to inform the agency that the change in design were in response to concerns about the product's safety.[120]

In culmination of those charges, a federal court in January 2011 ordered to pay a $296 million fine and to submit to the supervision of the U.S. Probation Office for three years for criminal violations relating to its interactions with the Food and Drug Administration (FDA), including "withholding information from the FDA regarding catastrophic failures in some of its lifesaving devices."[121]

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[116] *Boston Scientific Raises Guidant Settlement Cost*, ASSOCIATED PRESS, Nov. 20, 2007, http://bo.st/zpXUif; Riegel v. Medtronic Inc., 552 U.S. 312 (2008), http://bit.ly/wv1xrN.
[117] *States Settle with Heart Defibrillator Manufacturer*, THE SOUTHWEST TEXAS RECORD, Aug. 30, 2007, http://bit.ly/wu1HsN.
[118] U.S. Department of Justice Press Release, Medical Device Manufacturer Guidant Pleads Guilty for Not Reporting Defibrillator Safety Problems to FDA (Jan. 12, 2011), http://1.usa.gov/Ay6qPs.
[119] United States v. Guidant LLC, No. 10-mj-67, 4-5 (D. Minn. Jan. 4, 2011) (Government's position regarding sentencing).
[120] Press Release, U.S. Department of Justice, Medical Device Manufacturer Guidant Pleads Guilty for Not Reporting Defibrillator Safety Problems To FDA (Jan. 12, 2011), http://1.usa.gov/Ay6qPs.
[121] *Id.* (Guidant was acquired by Boston Scientific in 2006 and was a subsidiary of the company when this sentence was rendered.)

In a Texas product liability suit against Guidant, a former employee testified that the company had emphasized production speed over quality in manufacturing the ICDs. The employee said that the "devices in which flaws had been identified were assembled and shipped for implantation before all the known problems were resolved."[122]

The same lawsuit revealed that as many as 15 of every 10,000 Guidant defibrillators were prone to fail and, of those, one in ten could lead to death.[123] The Ventak Prizm ICD has been implicated in 13 deaths.[124]

The history of this device provides another disturbing example of the failure of the FDA to ensure that a high-risk medical device had undergone appropriate clinical testing to ensure that it was safe and effective. It further demonstrates the failure of the agency to act promptly to protect public health by removing a dangerous medical device from the market once sufficient evidence has accumulated showing that the device was unsafe.

[122] Avram Goldstein, *Guidant Put Speed Ahead of Quality, Ex-Worker Says (Update 2)*, BLOOMBERG NEWS, Jan. 13, 2006, http://bloom.bg/zfwaY0.
[123] *Guidant Defibrillator Failure Rate Revealed*, ASSOCIATED PRESS, Dec. 26, 2005, http://on.msnbc.com/AxVbtq.
[124] Janet Moore, *Guidant to Pay a Fine of $296M*, MINNEAPOLIS-STAR TRIBUNE, Jan. 12, 2011, http://bit.ly/zIRuq4.

III. The FDA Clearance and Approval Processes Are Riddled With Problems.

The processes for approving or clearing new medical devices for sale do not incorporate nearly the level of safeguards as those used to approve new drugs. The FDA review processes for devices are less rigorous than those for drugs because current statutes only require that there be a "reasonable assurance" that a proposed device is safe and effective,[125] whereas drug approvals require the higher standard of "substantial evidence" of effectiveness.[126]

In practice, for most new drugs applications, at least two well-designed, randomized, controlled, phase 3 clinical trials are required. In contrast, for most medical devices approved under the PMA process, only one controlled study is required by the FDA. In many cases, the quality of the design of such studies is lower than that for most clinical trials for drugs because many device studies are not randomized.

Worse, the system for clearing more than 95 percent of moderate- and high-risk devices (called the 510(k) process) fails to incorporate even the most basic safeguards. Very few products cleared through this process are subject to clinical testing. The vast majority are cleared for sale based on a mere demonstration that they are substantially equivalent to existing devices. Relying on substantial equivalence as a proxy for a determination of safety is inherently flawed. The FDA has amplified the dangers of relying on substantial equivalence by making a series of rulings that have permitted more devices to qualify as equivalent and, thus, to find their way to the market under the lenient 510(k) process.

Industry's core claim is that the FDA is taking too long to clear devices. But at least 95 percent of moderate- and high-risk devices are reviewed through the more lenient 510(k) process. The FDA says that it completes 90 percent of 510(k) analyses within 90 days and 98 percent of 510(k) analyses within 150 days.[127]

A. Incorrect Risk Classification of Medical Devices Has Permitted Dangerous Devices to Be Cleared Through a Lenient Process.

When Congress created the regulatory framework for medical devices in 1976, it established three classifications of devices. Class I devices represented those that posed the least risk. Class II was for moderate risk products. Class III (those that sustain or support life) was for the highest risk products.

[125] 21 U.S.C. § 360e(d)(a)(1), http://bit.ly/yDn4L8.
[126] 21 U.S.C. § 355(d), http://1.usa.gov/ACBp8B.
[127] Food & Drug Administration Minutes from Negotiation Meeting on MDUFA III Reauthorization (March 7, 2011), http://1.usa.gov/zoOcTI.

Congress permitted the lowest-risk devices to enter the market without review by the FDA provided that they conformed to general rules. Moderate risk devices would be cleared through the 510(k) process, which required a closer level of FDA scrutiny that stopped short of a full regulatory review. High-risk devices would be approved under the PMA process, which required clinical testing.

About 1 in 5 moderate and high-risk devices on the market are classified as high-risk. [See Table 10] But only 1 in 100 new moderate- or high-risk devices are approved by the PMA process, which is ostensibly for high-risk devices, according to recent FDA reports.[128] [See Table 11]

Table 10: Classifications of Devices on the Market

Device Class	Description of Class	% of Market	Review Process	Process Description
I	Low-risk. These devices are non-life sustaining, are the least complicated and their failure poses little risk.	47%	Exempt	Most Class III devices and a few Class II devices are exempt from the requirement of review. These devices must meet manufacturing standards under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have be registered with the FDA.
II	Moderate-Risk. These devices present more risk than those in Class I, but are non-life sustaining.	43%	510(k)	A 510(k) is a premarketing notification submission made to FDA to demonstrate that the device to be marketed is as safe and effective, and substantially equivalent to a legally marketed device that is not subject to premarket approval.
III	High-Risk. These devices sustain or support life. Their failure is life threatening.	10%	PMA	Premarket Approval (PMA) is the most stringent type of device review required by FDA. The manufacturer must provide "sufficient valid scientific evidence" to assure safety and effectiveness for the device's intended use before it is eligible to enter the market.

Source: Food and Drug Administration, http://1.usa.gov/yVLcVl.

[128] Elsewhere, the Government Accountability Office (GAO) reported that about 5 percent of moderate- and high-risk devices are approved through PMA. *See* U.S. GOVERNMENT ACCOUNTABILITY OFFICE, FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 9 (2009), http://1.usa.gov/yGXCXp.

Table 11: Number of Annual Device Submissions for Moderate to High Risk Devices

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	Total
Number of 510(k) submissions:	3,913	3,714	3,901	4,153	3,936	19,617
Number of PMA submissions:	56	37	33	41	49	216
Total Submissions:	3,966	3,747	3,933	4,191	3,989	19,833
Percentage of applications handled via PMA:	1.4%	1.0%	0.8%	1.0%	1.2%	1.1%

Sources: Food and Drug Administration, MDUFA Performance Reports (2009 & 2010)

B. The 510(k) Process Is Ridden with Shortcomings.

The 510(k) process, named after the applicable section of the Food, Drug, and Cosmetic Act that was created under the Medical Device Amendments of 1976, was intended as the clearance process for moderate-risk products. But the 510(k) process has become the pathway for many high-risk devices to gain entry into the marketplace, as well as nearly all moderate risk devices.

Several flaws in this process serve to provide industry with the path of least resistance to market its devices. This section describes several of the problems.

i. The FDA Has Failed to Complete the Review Process for Some Class III Devices.

When the Medical Device Amendments of 1976 were passed, more than 1,700 devices were already on the market.[129] Even for pre-amendment devices recognized as posing a high-risk and categorized as class III, Congress temporarily permitted these devices to be cleared under the less stringent 510(k) process intended for class II (moderate-risk) devices until the FDA published final regulations requiring them to go through the PMA process or reclassifying them into a lower class.[130]

But the FDA has yet to complete either of these steps for more than 20 types of class III devices that were on the market prior to the enactment of the Medical Device Amendments of 1976.[131] After this process languished for a decade and a half, the Safe Medical Devices Act of 1990 reiterated the requirement for the FDA to complete the regulatory process for either requiring these devices to go through the PMA process or reclassifying them into a

[129] Jonas Z. Hines, *et. al.*, *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 PLOS MED. 1 (2010), http://bit.ly/wTp46C0.
[130] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL ADDRESSEES, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS (2009), http://1.usa.gov/yGXCXp.
[131] Food and Drug Administration, Statement of William Maisel, M.D., Deputy Center Director for Science Center for Devices and Radiological Health, A Delicate Balance: FDA and the Reform of the Medical Device Approval Process (April 13, 2011), http://1.usa.gov/zndqXn.

lower class. But, 22 years hence, the agency still has yet to fulfill this mandate.[132] Of the original 140 pre-amendment class III devices the FDA was charged with evaluating in 1976, 26 had yet to undergo final regulatory action as of April 2011.[133]

As a result, proposed class III (high-risk) devices that are "substantially equivalent" to these 26 pre-amendment class III devices may continue to be cleared under 510(k). The clearance of the DePuy ASR XL Acetabular System for total hip replacement discussed in section II of this report is one example.

ii. Reliance on Substantial Equivalence Fails to Ensure Safety.

The 1976 law permitted future proposed devices to be cleared under the 510(k) process if applicants could demonstrate that the new device was "substantially equivalent" to a device already on the market (a predicate device). The 1976 law did not define the meaning of "substantial equivalence." However, in the 1990 Safe Medical Device Amendments, Congress defined substantial equivalence as follows:

> "Substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that [the FDA] by order has found that the device:
>
> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent contains information, including appropriate clinical or scientific data if deemed necessary by [the FDA] ..., that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.[134]

Aside from the results of many high-risk class III devices being permitted to be cleared inappropriately under the 510(k) process, the substantial equivalence test has other negative consequences. Most fundamentally, a mere demonstration of substantial equivalence to an existing product does not prove it is safe or effective.

The Supreme Court spelled out the logical flaw in relying on substantial equivalence in a 1996 ruling: "Substantial equivalence determinations provide little protection to the public … If the earlier device poses a severe risk or is ineffective, then the latter device may also be risky or ineffective."[135]

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[132] *Ibid.*
[133] *Ibid.*
[134] 21 USC § 360c(i).
[135] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), http://bit.ly/whHPIC.

An example of the failure of the 510(k) process was illustrated in the clearance of multiple synthetic surgical mesh devices used to repair pelvic organ prolapse (POP). POP involves bulging or descent of one or more of the pelvic organs, such as the bladder, rectum or uterus, into the vagina, sometimes past the opening of the vagina. This common condition is due to weakness in the connective tissue and muscles that surround and support the pelvic organs. Most women with POP have no symptoms. For symptomatic patients, treatment can involve surgical or non-surgical interventions. In surgical procedures, non-absorbable mesh often is implanted transvaginally (through incisions and punctures made through the wall of the vagina) with the intent of reinforcing the tissues around the pelvic organ that prolapsed, thereby increasing the longevity of the repairs.[136]

Over the past decade, multiple synthetic, non-absorbable surgical mesh products designed for transvaginal surgical repair of POP have been cleared by the FDA under the 510(k) process. Randomized, controlled studies done after these devices were cleared for marketing under the 510(k) process have shown that, while transvaginal POP repair with mesh appears to result in less prolapse being detected on pelvic examination following surgery in comparison to non-mesh repair procedures, the use of mesh does not provide any better outcomes in terms of relief of symptoms and quality of life measures, which ultimately are the clinically significant indicators for measuring treatment success for this condition.[137] Moreover, a review of the scientific literature demonstrates that use of the non-absorbable, synthetic mesh products for transvaginal surgical repair of POP leads to a high rate of serious complications, many of which require additional surgical intervention and some of which are not amenable to surgical correction and result in permanent, life-altering harm to women.[138]

Multiple mesh devices specifically designed for transvaginal POP repair were allowed by the FDA to come onto the U.S. market, based only on *in vitro* and animal-testing data and a determination of substantial equivalence to other surgical mesh products already on the market. Despite a lack of clinical data demonstrating that any of these invasive mesh devices was reasonably safe and effective for transvaginal repair of POP, the devices have been heavily promoted by industry and its well-compensated physician consultants. As a result, thousands of women have been seriously harmed, many permanently. Had appropriate premarket clinical trials, like those conducted in the postmarket period, been conducted before the FDA cleared these products for marketing under the 510(k) process, serious harms to these women could have been prevented.

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[136] Petition to Ban Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse from Public Citizen's Health Research Group to Dr. Margaret A. Hamburg, FDA Commissioner, and Dr. Jeffrey E. Shuren, Director of Center for Devices and Radiologic Health, Food and Drug Administration, 23 (Aug. 25, 2011), http://bit.ly/qtRggX.

[137] *Id.*

[138] *Id.*

iii. FDA Reduces Patient Protections by Interpreting "Same Intended Use" Too Permissively.

To establish substantial equivalence, a newly submitted device must fulfill the first criterion of having the "same intended use" as its comparable predicate device. The FDA has no congressionally mandated definition or list of criteria as to how a submitted device may prove to have the "same intended use." In many cases, a device's labeled intended use may not match its possible off-label use.

When assessing the intended use of a submitted device, the FDA must look to its reviewers to establish criteria on a case-by-case basis. In most instances, the agency uses a permissive interpretation. In the case of the Menaflex Collagen Scaffold (MCS), a device implanted during arthroscopic surgery of the knee to replace damaged medial meniscus cartilage and stimulate regrowth of cartilage tissue, the FDA cleared the device on the manufacturer's assertion that the MCS had the same intended use as several predicate devices when, in fact, its intended use was quite different.[139]

The controversy over the MCS's approval lay in the fact that the agency had originally assessed the device as posing a high risk (class III) and in need of PMA review and clinical study.[140] In 2003, the manufacturer, ReGen, originally conducted a two-year clinical study of the device only to conclude that the use of MCS had no clinical benefit.[141] Despite the data showing the device to be ineffective, the FDA allowed ReGen to re-submit the device under the 510(k) process.[142]

ReGen presented the device to the FDA as being substantially equivalent to surgical mesh predicates, including mesh used to repair rotator cuff tears in the shoulder and hernias. In December 2008, the FDA cleared the device under the 510(k) process. However, as one FDA reviewer pointed out, none of the predicate devices upon which this clearance was based is intended to be implanted in weight-bearing joints, such as the knee, or intended to facilitate the regrowth of joint cartilage.[143] Thus, because the intended use of the MCS was outside the scope of typical surgical mesh devices, the FDA displayed an inappropriately permissive interpretation of "same intended use" when clearing this device.

Also disturbing was the fact that the agency was aware of the negative results of the clinical study at the time of the 510(k) review, yet chose to ignore them and instead accepted the

[139] Press Release, Food and Drug Administration, FDA Determines Knee Device Should Not Have Been Cleared for Marketing (Oct. 14, 2010), http://1.usa.gov/bue4vS.
[140] Jonas Z. Hines, *et. al.*, *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 PLOS MED. 1 (2010), http://bit.ly/wTp46C0.
[141] *Id.*
[142] *Id.*
[143] *Id.*

company's absurd claim that clearance should be based upon "the function of this device as a surgical mesh … and not the clinical outcome."[144]

iv. FDA Puts Patients at Risk by Inappropriately Allowing for Disparate Technological Characteristics when Applying the Definition of Substantial Equivalence.

The second criterion for determining substantial equivalence depends on the device's technological characteristics. The technological characteristics of a new device, as compared to a predicate device, do not necessarily have to be similar, as long as they do not raise new questions of safety or effectiveness.[145] This aspect of the definition of same intended use has allowed 14 percent of devices cleared under the 510(k) process to be markedly different in technological characteristics than their predicates.[146]

In one example, as discussed above, the FDA cleared the Axxent Flexishield Mini, a pad used to block radiation from healthy beast tissue and redirect it to affected areas during IORT, despite its novel technological features.

The Axxent Flexishield Mini, manufactured by iCad, differed from its predicate device, Arplay Medical Lead Blocks, because the pad could easily be resized and reshaped by trimming the ends right before surgery, while its predicate did not have that characteristic.[147] Despite this major technological difference, the FDA cleared the Axxent Flexishield Mini for sale via the 510(k) process in 2009.[148] By allowing surgeons to trim the pads before surgery and place them into the breast tissue during surgery, the device released high-density tungsten particles into healthy breast tissue. The Arplay lead blocks, in contrast, were never intended to be reshaped or resized before or during the procedure, but were sold in a variety of shapes to customers.[149] Given the fundamental technological difference between the Axxent Flexishield Mini and the Arplay Medical Lead Blocks, the FDA should not have cleared the Axxent Flexishield Mini under the 510(k) process.

v. The FDA Has Allowed for "Predicate Creep" Through Incremental Change, Making a Mockery of Reliance on Substantial Equivalence.

Over time, manufacturers may submit a series of products for approval under the 510(k) process, with each product differing slightly from an earlier product, either in the

[144] Jonas Z. Hines, *et. al.*, *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 PLOS MED. 1 (2010), http://bit.ly/wTp46C0.
[145] *Id.*
[146] *Id.*
[147] Food and Drug Administration, 510(k) Summary for Axxent FlexiShield Mini (Feb. 17, 2009), http://1.usa.gov/wze1Z5; Food and Drug Administration, 510(k) Summary for Arplay Medical Lead Blocks (Jan. 5, 2001), http://1.usa.gov/wXwgu4.
[148] Food and Drug Administration, June 2009 510(k) Clearances (July 9, 2009), http://1.usa.gov/wkuu7U.
[149] Food and Drug Administration, Premarket Notification (Jan. 5, 2001), http://1.usa.gov/Axl5ox.

purported intended use or in technological features. Eventually, this allows the clearance of a device that is substantially dissimilar from the initially marketed product in a chain of sequentially cleared devices. This is called "predicate creep."

An example of this problem was the 2008 clearance of the Pathwork Tissue of Origin Test, which is a device that diagnoses tumors.

The device was cleared under the 510(k) process on the basis of its similarity to the BioPlex 2200 Medical Decision Support Software, a program cleared in 2005 that was used to diagnose autoimmune disorders. The BioPlex, in turn, had been cleared on the basis of its similarity to the Remedi HS Drug Profiling System, which is a diagnostic kit that tests for illicit drugs. Ultimately, the FDA's sequential substantial equivalence rulings created predicate creep and permitted it to clear a device for diagnosing tumors based on its similarity to a device that screens for illicit drug use.

vi. "Least Burdensome" Requirement Further Hamstrings the FDA.

In 1997, the Food and Drug Administration Modernization Act introduced a new concept to be applied to the 510(k) process. The statute required the FDA to determine whether a device met the "substantial equivalence" test using information gleaned by making the "least burdensome" requests of manufacturers. The IOM found that the least-burdensome clause has limited the FDA's ability to confirm that a device is safe and effective by restricting its ability to request additional data.[150]

The FDA asks only 8 percent of device manufacturers seeking clearance under 501(k) (excluding makers of in vitro devices) to provide clinical data.[151]

vii. Insufficient Use of Enforcement of "Special Controls" Ignores Congressional Mandates.

Devices approved under the 510(k) process may be subject to special controls, in addition to other requirements. Special controls include performance testing, clinical testing, special labeling, creation of patient registries, post-market surveillance. For example, the performance standards can require testing the performance of a device. Labeling standards can require special labels for installation, maintenance and operation of a device.

Although the FDA has the authority to require that many moderate-risk devices satisfy special controls standards, the agency rarely uses this tool. Of moderate-risk devices cleared in 2010, only 15 percent were subject to special controls.[152]

[150] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 269 (National Academy of Sciences, 2011)
[151] *Id.* at 108. (The majority of 510(k) submissions for *in vitro* diagnostic devices contain some type of clinical information.)

C. PMA Approval Process Is Not Rigorous Enough to Ensure Safety.

The PMA process is intended to assess the safety and effectiveness of high-risk devices, including life-sustaining devices such as pacemakers, heart valves and ICDs. (Notably, however, many high-risk devices are cleared through the 510(k) process, as discussed above.)

The PMA process requires manufacturers to submit "sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)."[153] As discussed above, this standard is much lower than the one required to approve a drug (for instance, requiring only "substantial evidence" of effectiveness). The approval of a new drug requires at least three phases of clinical testing, including at least two randomized, controlled, phase 3 clinical trials in most cases.

In contrast, a PMA application typically does not require more than one clinical trial, and that trial need not be as scientifically rigorous as would be required for a new drug. A study in the *Journal of the American Medicine Association*, for instance, found that PMA approval of cardiovascular devices by the FDA "is often based on studies that lack adequate strength and may be prone to bias."[154] The study examined clinical trial summaries for all 123 cardiovascular devices submitted for approval between 2000 and 2007. Only 5 percent had undergone two or more blinded, randomized clinical tests.[155]

The integrity of the PMA process is further compromised because, as with the 510(k) process, the FDA is obliged to fashion its requests for information in the "least burdensome" manner possible to the manufacturers from which the information is sought.[156]

[152] *Id.* at 50.
[153] Food and Drug Administration, Food and Drug Administration Section on Premarket Approval (Sept. 3, 2010), http://1.usa.gov/yxo3FS.
[154] Sanket S. Dhruva *et al*., *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices*, 302 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 2679, 2679-2685 (2009), http://bit.ly/xXvwlQ.
[155] *Id.*
[156] *See*, *e.g.*, Food and Drug Administration, The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry (Oct. 4, 2002), http://1.usa.gov/x6AOEw.

IV. Post-Approval Measures to Ensure Accountability for Devices Are Insufficient.

In addition to allowing far too many dangerous devices to reach the market, the FDA has proven inadequate at mitigating the damage from dangerous devices on the market after evidence of serious adverse events becomes apparent.

The current state of post-market surveillance is ineffective and wasteful. The agency primarily depends on manufacturers and users, such as hospitals, to report events of injury or death related to the use of their devices. Manufacturers, in turn, are often unable to locate patients implanted with dangerous devices because there is not an adequate system to track which patients have received their products.

The FDA has been criticized for making poor use of the data it receives from device manufacturers concerning recalled products. It lacks an internal system to analyze recall trends, which it might otherwise use in future decisions when reviewing a device for PMA approval or 510(k) clearance.

A. The FDA Gives Companies Too Much Discretion on Whether to Report Incidents.

Medical Device Reporting is a system in which manufacturers and healthcare facilities notify the FDA of instances in which a medical problem is associated with the use of a medical device. Under the Safe Medical Devices Act of 1990, hospitals and healthcare facilities are required by statute to file a medical device report to the FDA and the manufacturer if there is a suspected device-related death.[157] However, when there is a serious injury related to device use, facilities must only notify the manufacturer or, if the manufacturer is unknown, the FDA. [158]

When a manufacturer learns of an injury related to the use of its medical device, it is allowed to judge whether the evidence "reasonably suggests that a device has or may have caused or contributed to the death [or serious injury] of a patient."[159] If the manufacturer determines that the evidence does not reasonably suggest that the device caused or contributed to the adverse event, it does not need to report the incident to the FDA. Ceding the decision of culpability to manufacturers plainly ignores their inherent conflict of

[157] Food and Drug Administration, How to Report a Problem (Medical Devices) (June 18, 2011), http://1.usa.gov/HT4uK.
[158] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 115 (National Academy of Sciences, 2011).
[159] 21 C.F.R. § 803.50, http://1.usa.gov/wrzc1K (manufacturers) and 21 C.F.R. § 803.30, http://1.usa.gov/yGgLhM (user-facilities).

interest. Manufacturers wishing to downplay the dangers of their devices have an incentive to excuse themselves from admitting responsibility to the FDA and the public.

At times, manufacturers have chosen not to send reports to the FDA when the facts of an adverse reporting to them clearly warranted such disclosure. This occurred in the cases of Teleflex Medical's Hem-o-lok ligating clips and Guidant's Ventak Prizm ICDs (discussed in Section II). When the FDA reviewed the two companies' adverse event reports, it found many instances in which a device reasonably could have caused harm to a patient but in which the companies determined the device was not to blame.[160] Although user-facilities may have reported the adverse incidents to the FDA, both manufacturers withheld information that impeded the agency from taking appropriate action.

The statute also has had the effect of encouraging user-facilities (as opposed to manufacturers) to over-report adverse events. Perhaps to err on the side of caution, they tend to interpret the requirement for reporting device-related adverse events broadly. But the law does not require user-facility to furnish substantive information concerning the adverse events.[161] The combination of excess reports and incomplete information to evaluate them, hinders the FDA's ability to determine which adverse events were caused by dangerous devices. In contrast, in the case of drugs, user-facilities need clear evidence to support their filing; the drug must be the "primary suspect" for the report to be filed.[162]

B. The Current System Does Not Ensure a Method to Follow a Single Device from Recall to Patient.

The Safe Medical Devices Act of 1990 allowed the FDA to monitor products after clearance and track certain devices to the user.[163] But there is no reliable system in place for manufacturers to locate actual patients who have received their devices.

Most manufacturers trace products only to distributors or healthcare facilities. Facilities, in turn, are charged with contacting the patients. Because of complications in this process, warnings sometimes fail to reach the right doctors or patients in time.[164] For example, in

[160] *See* Warning Letter from FDA to Jeffrey P. Black, President & CEO, Teleflex Medical (July 20, 2006), http://1.usa.gov/AjPC1D; Press Release, U.S. Department of Justice, Medical Device Manufacturer Guidant Pleads Guilty for Not Reporting Defibrillator Safety Problems to FDA (Jan. 12, 2011), http://1.usa.gov/Ay6qPs.
[161] 21 C.F.R. § 803.50, http://1.usa.gov/wrzc1K.
[162] *See*, e.*g.*, Department of Health and Human Services Public Health Service Food and Drug Administration Center for Drug Evaluation and Research Office of Surveillance and Epidemiology, Pediatric Postmarketing Adverse Event Review of Ventolin HFA (Aug. 6, 2009), http://1.usa.gov/wCf5Xu.
[163] Food & Drug Administration, Section on Reporting Adverse Events (Medical Devices), http://1.usa.gov/y5WnZC.
[164] *No System Tracks Faulty Medical Devices in U.S.*, ASSOCIATED PRESS, Oct. 6, 2009, http://on.msnbc.com/xaV2im.

the case of its recalled hip implants, DePuy officials said they could not trace the implants to the specific patients who received them.[165]

C. The FDA Has Failed to Analyze Data on Failed Devices to Identify Problems.

The FDA has the ability to require "corrective action on problem devices and to prevent injury and death by alerting the public when potentially hazardous devices are discovered."[166]

However, according to an October 2009 finding by the Department of Health and Human Services inspector general, the FDA does not adequately use adverse event reporting to identify trends in problematic devices.[167]

The FDA does not have clear policies in place to determine whether a recall really worked. The data that the FDA collects is not systematically integrated or thoroughly analyzed for the purposes of tracking fundamental problems or developing a record of unsafe predicate devices for new device submissions.[168]

D. FDA Enforcement Is Lacking.

The FDA has been criticized for failing to take enforcement actions when evidence of unacceptable harm caused by a device becomes apparent or manufacturers violate the law. The IOM, for example, concluded: "When the FDA discovers violations of the law or products that pose unacceptable risks to consumers, it has a wide variety of authorities (or tools) available to try to remedy the situation and to sanction the violators. The committee found that the agency uses those authorities sparingly."[169]

Take, for example, the case of the Wingspan Stent System, intended to prevent new strokes in patients who have already have had them.[170] The device, manufactured by Stryker Medical, is a small wire mesh tube that is placed in narrowed brain arteries to increase blood flow to the brain in patients who have already suffered stroke. The device was approved in 2005 through the Humanitarian Device Exemption (HDE) process, which is an alternative means of approving a device intended to treat special conditions in a population

[165] Barry Meier, *The Implants Loophole*, NEW YORK TIMES, Dec. 16, 2010, http://nyti.ms/w1A6Kz.
[166] OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ADVERSE EVENT REPORTING FOR MEDICAL DEVICES 13 (2009), http://1.usa.gov/y6xLbL.
[167] *Id.*
[168] Sam Baker, *Report Faults FDA Oversight of Device Recalls*, THE HILL, June 6, 2011, http://bit.ly/AgtMTP.
[169] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 115 (National Academy of Sciences, 2011).
[170] Petition to FDA from Public Citizen's Health Research Group to Dr. Margaret A. Hamburg, FDA Commissioner, and Dr. Jeffrey E. Shuren, Director of Center for Devices and Radiologic Health, Food and Drug Administration 2 (Dec. 21, 2011), http://bit.ly/yNjP4Z.

of fewer than 4,000 individuals per year.[171] At the time of approval, there was no evidence that the device was more effective than treatment with medication alone, but there was an expectation that the device would improve outcomes in patients with narrowed brain arteries who were at high risk for subsequent strokes.[172]

Following the HDE approval for the Wingspan Stent System, a clinical trial funded by the National Institutes of Health showed that the rate of stroke or death within 30 days after treatment with the device in combination with aggressive medical therapy was more than double than for patients who received aggressive medical therapy alone.[173] The researchers terminated enrollment early based on safety concern, and because investigators determined that there was virtually no chance that a benefit from the stenting procedure would be shown if enrollment continued.[174] The message from the trial could not be clearer: the risks of the Wingspan Stent System outweigh any potential benefit to patients.

Despite overwhelming evidence that the Wingspan Stent System harms patients more than it benefits them, the FDA has yet to withdraw approval for the device and recall it from the market.[175] This failure has left patients at risk of serious, life-threatening harm.

E. The Courts Have Eviscerated Civil Justice Remedies.

The prospect of product-safety litigation should serve as a deterrent to selling unsafe or faulty products. But manufacturers enjoy an enormous liability shield.

The Medical Device Amendments of 1976 prohibit states from establishing or continuing in effect "any requirement" with respect to a medical device that is "different from, or in addition to" federal medical device requirements and that relates "to the safety or effectiveness of the device."[176]

In 2008, in *Riegel v. Medtronic*, the Supreme Court held that this provision of the 1976 Medical Device Amendments preempts most tort claims arising from allegedly defective devices if the device in question was approved under the PMA process.[177] The Court's ruling gave device makers immunity from most product liability claims. That is, if the FDA

[171] *Id.* at 3; Food and Drug Administration, Humanitarian Device Exemption Overview (Aug. 30, 2010), http://1.usa.gov/S1c1O.
[172] Marc Chimowitz, et al., *Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis*, 365 NEW ENGLAND JOURNAL OF MEDICINE, 993, 993-1003 (2011).
[173] *Id.*
[174] *Id.*
[175] Press Release, Public Citizen, Public Citizen and a Former FDA Official Call on FDA to Withdraw Approval of Wingspan Stent System Because Benefits Do Not Outweigh Risks (Dec. 21, 2011), http://bit.ly/sXPNuV.
[176] Riegel v. Medtronic Inc., 552 U.S. 312 (2008), http://bit.ly/wv1xrN.
[177] *Id.*

approves a dangerous or defective device through the PMA process, federal law generally bars consumers harmed by the device from seeking redress in court.

Riegel concerned a life-threatening incident in which Charles Riegel was forced to have emergency coronary bypass surgery as a result of a balloon catheter rupturing and blocking blood flow in his coronary artery. Riegel alleged that the device had been defectively designed and inadequately labeled. Because Medtronic had received PMA approval for the device, Medtronic argued that it was immune from liability. The Supreme Court ultimately agreed, and effectively placed all responsibility for device regulation in the hands of the FDA.

Both FDA regulation and state tort liability are essential tools for protecting patients. As they had before *Riegel*, tort suits can facilitate the discovery of flaws in devices on the market, which would, in turn, alert the FDA and the public of the dangers. Tort suits also encourage manufacturers to continue research and testing of their devices. Most importantly, because the federal law provides no means for patients to be compensated for injuries caused by defective and dangerous medical devices, state-law remedies, including the ability to seek compensation for medical expenses, pain and suffering, and lost wages, were their only form of redress.

In response to *Riegel*, members of Congress, including Rep. Henry Waxman (D-Calif.) and former Senator Ted Kennedy (D-Mass.) introduced the Medical Device Safety Act (MDSA) in 2008 and again in 2009 to clarify the law's meaning. The MDSA would have specifically amended the law to state that FDA regulations do not preempt actions for damages or the liability of responsible parties under state law, and would have restored patients' ability to hold manufacturers accountable in court.

V. Policy Prescriptions

The dangers and weaknesses of the existing systems for both premarket review and post-market surveillance of medical devices are readily apparent in the statistics on rising recalls and in the tragic case studies of people seriously harmed by medical devices. Premarket regulation of devices has repeatedly failed to prevent unsafe devices from reaching the market and injuring and killing patients. Further, devices unequivocally shown to be unsafe after receiving permission to be marketed have not been removed from the market in a timely manner by the agency. Congress and the FDA need to strengthen applicable statutes and policies for reviewing and monitoring devices.

A. Premarket Review Processes

Modify the 510(k) process (interim, short-term action). Recognizing that replacing the current 510(k) system will take several years, the following revisions to the process should be implemented immediately to improve the safety of medical devices:

- When a device cleared through the 510(k) process is recalled or removed from the market due to safety or effectiveness problems, it should automatically be removed from the list of devices that can serve as predicates for future devices reviewed under the 510(k) process.
- Manufacturers should be required to provide the FDA with information not just about the immediate predicate device on which a 510(k) clearance request is based, but about the full lineage of predicates.
- To facilitate efficient and effective tracking of the status of marketed devices that a manufacturer might use as a predicate for a proposed device, the FDA should be required to maintain an up-to-date and easily searchable database of eligible predicates.
- The FDA should be required to reevaluate the safety and effectiveness of devices that have already been cleared under the 510(k) process whenever a device that served as the predicate for those 510(k) clearances is withdrawn from the market due to safety or effectiveness problems. This reevaluation should include any device cleared under the 510(k) process that can be traced back through a chain of 510(k) clearances to the predicate device no longer on the market. This requirement should be imposed retroactively on all devices previously cleared under the 510(k) process.
- High-risk (class III) devices should be prohibited from receiving clearance under the 510(k) process.
- The FDA should be given authority to require postmarketing surveillance studies, including clinical studies, as a condition of clearance of a device under the 510(k) process.

Replace the 510(k) process (long-term action). Congress should mandate, in accordance with the Institute of Medicine's recommendation, that the FDA design a new medical device approval process to replace the 510(k) process. No future medical device premarket review system should rely on "substantial equivalence" to a device already on the market as evidence of safety and effectiveness. Instead, moderate- to high-risk devices—particularly those intended to be life-sustaining, life-supporting, or permanently implanted—should be subject to the same regulatory scrutiny as drugs. Review decisions should rely on "substantial evidence" to support a device's safety and effectiveness.

Revise the PMA process. The standard for approving any high-risk (class III) device under the PMA process should be changed to "substantial evidence" of safety and effectiveness from the current "reasonable assurance" that the device is safe and effective.[178] Device submissions reviewed under the PMA process should provide data from at least two well-designed, randomized, controlled, clinical trials conducted by qualified experts that can evaluate the true safety and effectiveness of that device. The current low standard threatens patient safety because it accepts data from poorly designed and uncontrolled clinical trials as acceptable evidence for establishing the safety and effectiveness of a device during the review process.

Drop the least-burdensome requirement. For all submissions, the requirement that the FDA evaluate devices in a manner that is "least burdensome" upon manufacturers should be eliminated. It is in the best interests of patients and device manufacturers alike for the FDA to make its judgments based on all necessary information. Not only does constraining the FDA to acting on incomplete information pose a threat to patients, but it ultimately leaves manufacturers in jeopardy, as well. Few would dispute that the industry and individual manufacturers stand their best chance to thrive if they avoid putting dangerous products on the market. Giving the FDA the best information to make decisions could spell the difference between a flaw being recognized before a product reaches the market or after it inflicts tragic consequences.

B. Post-Market Surveillance

Improve device tracking to patients. At present, when a device is recalled because it poses a hazard, no reliable system exists to locate affected patients because, unlike drugs and many other consumer products, medical devices in most cases are not given unique identifier codes that would allow for efficient and effective tracking. Under the current system, most companies only track devices to distributors or user-facilities. Without unique device identifiers, reliable tracking of devices to entities beyond the distributors and to patients is

[178] 21 U.S.C. § 360e(d)(a)(1), http://bit.ly/yDn4L8.

difficult, if not impossible. Currently, there are more efficient tracking systems in place for appliances, automobile parts and even pet food, than there are for medical devices. Under the Food and Drug Administration Amendments Act of 2007, Congress mandated that the FDA establish a unique identification system for medical devices.[179] In the almost five years since the Amendments became law, the FDA has failed to issue regulations implementing this system. Congress should set a deadline in the near future for the FDA to implement such regulations for all devices that pose a moderate- to high-risk to the patients intended to use them.

Improve adverse-event reporting. The FDA should require more thorough standards for reporting adverse events, similar to those used for pharmaceuticals. At present, manufacturers tend to under-report adverse events, and user-facilities tend to over-report, but with insufficient specificity. Mandatory higher quality reporting would give the FDA a better database of adverse event information to analyze.

FDA should use its authority to recall unsafe devices. At present, the FDA typically relies on manufacturers to initiate voluntary recalls when problems with devices are identified. As in the case of the Wingspan Stent System, the FDA often has failed to act in the face of convincing evidence that certain devices are unsafe. The agency should more promptly and frequently use its congressionally mandated authority to order recalls of medical devices when the agency deems them to compromise patient safety. Too often, the agency relies on device manufacturers to take action voluntarily, resulting in substantial delays in removing dangerous and ineffective devices from the market.

A recall should be a recall. When a manufacturer initiates a recall, the recall must mean the removal of the device from market. Communications to customers or user-facilities, like sending warning letters to hospitals, should not be classified as recalls.

Systematically analyze and track recalls. The FDA should be required to systematically collect and assess data regarding all medical device recalls, whether mandated by the agency or voluntarily implemented by manufacturers. As part of this analysis, the agency should determine whether recalls were implemented in an effective and timely manner in order to ensure patient safety. The FDA also should document the basis for any termination of a recall ordered by the agency. All such information regarding the analysis and tracking of recalls should be maintained in a publicly accessible database on the agency's Web site.

Restore patients' legal rights. Finally, Congress should pass legislation eliminating the provision in current law that preempts state civil court claims arising from defective devices approved by the FDA under the PMA process.

[179] 21 U.S.C. § 360I(f), http://bit.ly/zKT2eW.

Appendix: Lobbyists Working on Medical Device Regulatory Issues, 3rd and 4th Quarters, 2011

Name	Firm	Client	Revolving Door Position
Jane Adams	Johnson & Johnson Services, Inc.	Johnson & Johnson Services, Inc.	
Alex Vogel	Mehlman Wogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Chief Counsel for Senate Majority Leader Bill Frist (R-Tenn.)
Allen Thompson	Mehlman Vogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Staffer for Rep. Bennie Thompson (D-Miss.), House Homeland Security Committee Professional Staff
Allison Giles	The Cook Group	The Cook Group	Small Business Administration, Assistant Chief Counsel, Health Policy; Rep. Bill Thomas (R-Calif.), Legislative Assistant; House Ways & Means Committee, Professional Staff Member
Cara Bachenheimer	Invacare	Invacare	
Doug Badger	The Nickles Group LLP	Medtronic	Legislative Affairs for Social Security Administration, Chief of Staff of Sen. Don Nickles (R-Okla.); Deputy Assistant Secretary for Dept. of Health and Human Services
Daniele Baierlein	Podesta Group	Covidien	Legislative Assistant, Sen. Richard Durbin (R-Ill.)
Jessica Battaglia	Medtronic	Medtronic	Staff for Rep. Marion Berry (D-Ark.), John Lewis (D-Ga.), L.F. Payne (D-Va.), Norman Sisisky (D-Va.).
Madeleine Baudoin	Biocom	Biocom	
Brenda Becker	Boston Scientific	Boston Scientific	Assistant Secretary of Legislative Affairs, Department of Commerce, Assistant for Legislative Affairs, Vice President's Office
Michael Billet	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Kelly Bingel	Mehlman Vogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Communications Director for Blanche Lincoln, Chief of Staff for Sen. Blanche Lincoln (D-Ark.)
Ronald Bird	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Dan Boston	Health Policy Source, Inc.	Abbott Laboratories	Aid to Rep. Sue Kelly (R-N.Y., Rep. Joe Knollenberg (R-Mich.), Sen. Mitch McConnell (R-Ky.), Majority Counsel House Energy & Commerce Committee
Jennifer Bowman	American Clinical Laboratory Association	American Clinical Laboratory Association	Staff for Congressional Budget Office
Dave Boyer	Barbour Griffith & Rogers, LLC	Abiomed Inc.	Assistant Commissioner for Legislation, FDA, Special Assistant to the President, White House
Kevin Brennan	Foley Hoag LLP	Abbott Laboratories, Johnson & Johnson	
Bob Brooks	Alpine Group	The Advanced Medical Technology Association	Chief of Staff for Rep. Jay Dickey (R-Ark.), CoS for Rep. Jim McCrery (R-La.)
Cynthia Brown	Mehlman Vogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Chief of Staff to U.S. Representative Ron Kind (D-Wis.)
Brian Burns	Johnson & Johnson	Johnson & Johnson	

	Services, Inc.	Services, Inc.	
Megan Carr	3M Company	3M Company	
Paul Casasco	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Daniel Casserly	Novartis Corp.	Novartis Corp.	
David Castagnetti	Mehlman Vogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Chief of Staff for Norman Mineta (D-Calif.), Senior Staff Member, Edward Markey (D-Mass.), Chief of Staff, Max Baucus (D-Mont.)
Chis Cerone	Zimmer	Zimmer Inc.	
Kelly Childress	East End Group, LLC	Varian Medical Systems	Health Policy Advisor for Mike Rogers (R-Mich.)
Nicole Churchill	Policy Directions, Inc.	Bausch & Lomb	
Maggie Clarke	Kelley Drye & Warren LLP	Laboratory Corp. of America Holdings	
Julie Cohen	Johnson & Johnson Services, Inc.	Johnson & Johnson Services, Inc.	Staff Director for Senate Labor & Human Resources Subcommittee on Aging, Health Policy Adviser for Sen. Herb Kohl (D-Wis.)
Mark Coin	Baxter	Baxter	
Brian Connell	National Electrical Manufacturers Association	National Electrical Manufacturers Association	
Julie Corcoran	Bayer Corp.	Bayer Corp.	
Faith Cristol	Quest Diagnostics Inc.	Quest Diagnostics Inc.	Counsel for Sen. James M. Talent (R-Mo.)
Amy Jensen Cunniffee	Caris Lifesciences, Ltd.	Caris Life Sciences, Ltd.	Special Assistant for legislative Affairs, White House, Legislative Aide to Rep. Dennis Hastert (R-Ill.), Legislative Aide to Tom DeLay (R-Texas)
Rodger Currie	Foley Hoag LLP	DEKA Research and Development Corp.	Special Assistant to Sen. Edward Kennedy (D-Mass.); Professional Staff Member to House Ways & Means Committee, Counsel to House Energy & Commerce Committee
Kimberly Davis	Johnson & Johnson Services, Inc.	Johnson & Johnson Services, Inc.	Legislative Assistant for Sen. Barbara Boxer (D-Calif.)
Lori Denham	Kountoupes Consulting LLC	The Advanced Medical Technology Association, National Electrical Manufacturers Association	Legislative Director for Darlene Hooley (D-Ore.); Chief of Staff for Cal Dooley (D-Calif.)
Collette Desmarais	Mehlman Vogel Castagnetti	National Venture Capital Association	
Ronald F. Docksai	Bayer Corp.	Bayer Corp.	
Thomas Donohue	U.S. Chamber of Commerce	U.S. Chamber of Commerce	Deputy Assistant Postmaster General, US Postal Service
Nancy Dorn	General Electric Company (including subsidiaries)	General Electric Company (including subsidiaries)	Press assistant to Rep. Tom Loeffler (R-Texas); Staff for House Appropriations Committee.
Ashli Douglas	St. Jude Medical	St. Jude Medical	
Raissa Downs	Tarplin, Downs & Young	The Advanced Medical Technology Association, Boston Scientific, National Electrical Manufacturers Association	Health Policy Advisor for Sen. Mike Enzi (R-Wyo.); Principal Deputy Assistant Secretary of Legislation for Department of Health & Human Services
David Drake	Novartis Corp.	Novartis Corp.	
Jason DuBois	American Clinical Laboratory Association	American Clinical Laboratory Association	
Michelle Easton	Tarplin, Downs & Young LLC	The Advanced Medical Technology Association, Boston Scientific,	Chief Health Counsel for Senate Finance Committee, Legislative Director & Staff Director Sen. John Breaux (D-La.)

		National Electrical Manufacturers Association	
Ronald Eidshaug	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Ross Eisenberg	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
James Elkin	Novartis Corp.	Novartis Corp.	
Mark Esherick	Siemens Corp.	Siemens Corp.	
Thomas Evers	Abbott Laboratories	Abbott Laboratories	
Piran Farhadieh	St. Jude Medical	St. Jude Medical	
Chris Fetzer	Haake and Associates	MEDInstill, Inc.	Legislative Staff Member, Sen. Elizabeth Dole (R-N.C.)
David Fisher	National Electrical Manufacturers Association	National Electrical Manufacturers Association	Senior Health Policy Advisor for Senate Budget Committee
Jeff Forbes	Cauthen Frobes & Williams	The Advanced Medical Technology Association, Edwards Lifesciences	Legislative Affairs for White House, White House Deputy Director of Scheduling, Chief of Staff for Sen. Max Baucus (D-Mont.), Staff Director for Senate Finance Committee
John Ford	Abbott Laboratories	Abbott Laboratories	House Energy & Commerce Committee, Senior Democratic Health Counsel
Marc Freedman	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Jean Frick	Boston Scientific	Boston Scientific	
Whitney Gardiner	Covidien	Covidien	
Rosemary Garza	Medtronic	Medtronic	Senior Legislative Assistant for Rep. Charlie Gonzalez (D-Texas)
Elisabeth George	Philips Holding USA, Inc.	Philips Holding USA, Inc.	
Randall Gerard	Podesta Group	Covidien, Quest Diagnostics, St. Jude	Aide to Senate Commerce, Science & Transportation Committee
Todd Gillenwater	California Healthcare Institute	California Healthcare Institute	
Jennifer Gladieux	Health Policy Source, Inc.	Abbott Laboratories	
Erik Glavich	National Association of Manufacturers	National Association of Manufacturers	Legislative Assistant to Rep. Candice Miller (R-Mich.), Staff for House Oversight and Government Reform Committee
JoAnne Glisson	American Clinical Laboratory Association	American Clinical Laboratory Association	
Libby Greer	Cauthen Frobes & Williams	The Advanced Medical Technology Association, Edwards Lifesciences	Chief of Staff for Rep. Allen Boyd (D-Fla.)
Jason Grove	Abbott Laboratories	Abbott Laboratories	Legislative Assistant, Ralph Regula (D-Ohio)
Timothy Haake	Haake and Associates	MEDInstill, Inc.	
Rosemary Haas	Abbott Laboratories	Abbott Laboratories	
Sarah Haller	Novartis Corp.	Novartis Corp.	
James Hawkins	Alpine Group	The Advanced Medical Technology Association, Boston Scientific, Edwards Lifesciences, Zimmer Inc.	
Bradley Hayes	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Kristen Hedstrom	Boston Scientific	Boston Scientific	
Julie Hershey	Kountoupes Consulting LLC	The Advanced Medical Technology Association, National Electrical	Legislative Director for Rep. Joe Pitts (R-Pa.)

		Manufacturers Association	
John Herzog	Jeffrey J. Kimbell and Associates	Cyberonics	Health Aide, Sen. Lamar Alexander (R-Tenn.)
Adam Higgins	Ferguson Strategies LLC	C.R. Bard	Legislative Assistant for Rep. Mike Ferguson (R-N.J.)
Daniel Hillenbrand	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Keith Holman	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Stacey Hughes	The Nickles Group LLP	Medtronic	Staff for Senate Health, Education, Labor & Pensions Subcommittee on Aging, Legislative Assistant for Connie Mack, Senior Policy Advisor for Sen. Don Nickles (R-Okla.), Deputy Staff Director for Senate Budget Committee
Jimmy Jackson	Biocom	Biocom	
Lauryl Jackson	Johnson & Johnson Services, Inc.	Johnson & Johnson Services, Inc.	Senior Health Legislative Assistant for Rep. Bobby Rush (D-Ill.), Legislative Assistant for Donald Payne (D-N.J.)
Charles Jefferson	Barbour Griffith & Rogers, LLC	Abiomed Inc.	Chief of Staff for Mike Thompson (D-Calif.), Special Assistant for House Minority Leader, Dick Gephardt (R-Mo.)
Darrel Jodrey	Johnson & Johnson Services, Inc.	Johnson & Johnson Services, Inc.	
Courtney Johnson	Alpine Group	The Advanced Medical Technology Association, Boston Scientific, Zimmer Inc.	Staff House Energy & Commerce Committee
Randel Johnson	U.S. Chamber of Commerce	U.S. Chamber of Commerce	Republican Labor Counsel & Coordinator, House Education & the Workforce Committee
Jonathon Hoganson	Mehlman Vogel Castagnetti	National Venture Capital Association, American Clinical Laboratory Association	Legislative Director for Rep. Rahm Emanuel (D-Ill.)
Chris Jones	Ferguson Strategies LLC	C.R. Bard	Chief of Staff for Rep. Mike Ferguson (R-N.J.); Subcommittee Communications Director for House Government Reform Committee, Deputy Chief of Staff for David McIntosh (R-Ind.)
Aranthan Jones	Podesta Group	Covidien	Policy Director for Rep. James E. Clyburn (D-S.C.)
R. Bruce Josten	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Jack Kalavritinos	Covidien	Covidien	White House Liaison, Director of Intergovernmental Relations at Department of Health & Human Services
Katherine Mahoney	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Katherine Solon	Novartis Corp.	Novartis Corp.	
Andrew Kauders	Podesta Group	Covidien, Quest Diagnostics, St. Jude	Deputy Communications Director, White House Climate Change Task Force; Senior Advisor to Sen. Robert Menendez (D-N.J.); Executive Director to House Democratic Caucus; Deputy Secretary to EPA admin, Deputy Press Secretary to Department of Agriculture
Elizabeth Kegles	The Advanced Medical Technology Association	The Advanced Medical Technology Association	
Eleanor Kerr	Siemens Corp.	Siemens Corp.	Special Assistant for Department of Health and Human Services

Harold Kim	U.S. Chamber Institute for Legal Reform	U.S. Chamber Institute for Legal Reform	Deputy Chief Counsel to Sen. Arlen Specter (R-Pa.); Special Assistant to President Bush, Office of Legislative & Intergovernmental Affairs, Counsel to Senate Judiciary Committee
Paul Kim	Foley Hoag LLP	Abbott Laboratories, Johnson & Johnson, Medtronic	Counsel for Rep. Henry Waxman (D-Calif.), Deputy Staff Director for Senate Health, Education, Labor & Pensions Committee, Counsel for Sen. David Pryor (R-Ark.)
Jeffery Kimbell	Jeffrey J. Kimbell and Associates	Cyberonics	Member, Department of Health & Human Services
William Klinefelter	Kelley Drye & Warren LLP	Laboratory Corp. of America Holdings	
William C. Kolter	Biomet, Inc.	Biomet, Inc.	
Lisa Kountoupes	Kountoupes Consulting LLC	The Advanced Medical Technology Association, National Electrical Manufacturers Association	Assistant Director for OMB; Deputy Assistant for Executive Office of the President, Staff for Rep. John Dingel (D-Mich.); Special Assistant for Department of Energy
William Kovacs	U.S. Chamber of Commerce	U.S. Chamber of Commerce	
Page Kranbuhl	Stryker Corp.	Stryker Corp.	Health Policy Advisor for Senate Health, Education, Labor & Pensions Committee, Sen. Lamar Alexander (R-Tenn.)
Janet Lambert	Life Technologies Corp.	Life Technologies Corp.	Chief of Staff to Peter H. Kostmayer (D-Pa.)
W. Christopher Lamond	Thorn Run Partners	Medical Device Manufacturers Association	Legislative Correspondent for Sen. Fred Thompson (R-Tenn.), Systems Administrator for Senate Government Affairs Committee
Steve LaPierre	Boston Scientific	Boston Scientific	Legislative Affairs for Office of Personnel Management
Mark Leahey		Medical Device Manufacturers Association	
Elaine Leavenworth	Abbott Laboratories	Abbott Laboratories	
Tony Lee	Philips Holding USA, Inc.	Philips Holding USA, Inc.	
Dirksen Lehman	Edwards Lifesciences	Edwards Lifesciences	Special Assistant to President for Legislative Affairs, White House
Kelli Lester	Baxter	Baxter	
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Sources: Public Citizen analysis of lobbying disclosure data provided by the secretary of the Senate and Center for Responsive Politics (www.opensecrets.org).