

Examining the Sprint Fidelis Effect
on Medicare Costs

by

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SUMMARY

This white paper presents an actuarial analysis of the cost to the U.S. Medicare program due to Medtronic's defective Sprint Fidelis leads for pacemakers. Medicare will pay up to \$1 billion in additional claims as a direct result of the damage caused by Medtronic placing the defective Sprint Fidelis leads on the market. These expenses would be paid by the manufacturer had the U.S. Supreme Court, through the *Riegel v. Medtronic* decision, not provided complete immunity from liability to medical device manufacturers of Class III devices.

This examination of the cost of the Sprint Fidelis lead defect to Medicare is an example of the cost of this liability for Medicare, for a single defective medical device. There are many Class III products which have been put on the market and later found to be defective. The FDA website lists over 160 Class I medical device recalls for 2009. The actuarial analysis presented here uses indirect data to predict incurred to date and future costs for replacement of the defective Sprint Fidelis leads and the cost of increased monitoring of patients with the defective leads. The calculations show that for the 10 year period from January 2008 through December 2017, the cost to Medicare could exceed \$1 billion.

MEDICARE LIABILITY FOR THE SPRINT FIDELIS LEAD DEFECT

Implantation of a permanent cardiac pacemaker is the treatment of choice for several potentially fatal or health compromising heart conditions (Brunner, 2004). Leads are installed from the pacemaker to veins connecting to the heart, which provide the link between the heart and pacemaker. On October 15, 2007, the U.S. Food and Drug Administration (FDA) announced a Class I recall of the Sprint Fidelis Defibrillator Leads, manufactured from September 2004 through October 15, 2007, because these leads had an unacceptably high number of fractures. (FDA Homepage). A Class I recall

is the most serious type of recall and involves situations in which there is a reasonable probability that use of the product will cause serious injury or death.

Medicaid and Medicare have assumed the role of an injured patient and have recouped millions of dollars in damages from pharmaceutical companies for expenses paid by the government for medical care which was a direct result of side effects from prescription drugs. For example, in November, 2009, Utah announced that they reached a \$24 million settlement with Eli Lilly over “off-label” marketing of the drug Zyprexa to Utah Medicaid patients.

It is estimated that more than 85% of the patients receiving a pacemaker are 65 years or older. (Jahangir et al (1999)). Because the majority of the people to receive the Sprint Fidelis lead were covered by Medicare, the Medicare program has paid millions of dollars in claims to fix and monitor the problems caused by the defective leads. These expenses cannot be recovered through litigation, because of the Supreme Court’s 2008 ruling in *Riegel v. Medtronic, Inc.* which provides complete immunity from liability to manufacturers of medical devices which have been specifically approved by the FDA.¹ The decision in *Riegel v. Medtronic, Inc.* creates a very costly present and future liability for Medicare, Medicaid and private health insurance companies.

THE DEFECTIVE MEDTRONIC SPRINT FIDELIS LEAD

Medtronic released the Sprint Fidelis leads in September 2004. Pacemaker leads provide electrical conduits between the pacemaker and the heart, to allow the device to shock the heart back into a normal rhythm if it detects an abnormal heart rhythm. For any lead manufactured, there is a very small rate of failure over time due to cracking. Within the first year of their release, the Sprint Fidelis leads began failing at a higher rate than other leads. (Medtronic website, Nov. 2009 Lead performance update). Furthermore, an independent study found that the hazard of the Sprint Fidelis failure accelerated after the first year and continued to increase, progressively, over time. (R.G. Hauser, 2009).

There are several companies that make these leads and their failure rate appears to be about 0.58% per year. (See Hauser and Hayes, 2009). When the Sprint Fidelis lead

¹ *Riegel v. Medtronic, Inc.* (592 F. Supp. 2d at 1152.)

models (model numbers 6930, 6931, 6948, and 6949) were recalled, Medtronic stated that the leads had a 2.3% failure rate. (Medtronic website, 2007 Physician Advisory Letter). However, other studies find a higher failure rate of 3.75%, with increases every year. (See Hauser, 2009).

Failure of a lead results in random shocks to the heart muscle or loss of the functionality of the pacemaker. When a lead causes random shocks to the heart, a life-saving cardiac device turns into a torture device. Of greater concern is a defective lead failing to deliver a life saving shock when needed.

In October 2007, three years after their debut, Medtronic withdrew all Sprint Fidelis leads from the market. It is estimated that there were over 150,000 Sprint Fidelis leads in patients at the time the product was recalled (Hauser and Hayes, 2009). Because of the risks involved with invasive surgery to extract the defective leads, Medtronic advised that the leads be left in place and that patients with the leads be closely monitored, or alternatively, the leads be capped and replacement leads be installed.

Lead failure, or prospective failure, presents a number of complex health dilemmas. When a lead fails, it is necessary to either turn off the pacemaker to which it is connected, cap the lead and replace it with another lead, or explant (remove) the lead and replace it with another lead. Each of these is a costly procedure, and each procedure carries the risk of complications or even death. Removing the defective lead is especially difficult because leads become imbedded into the surrounding tissue after they are positioned into the veins connecting to the heart.

THE CONSEQUENCES OF *RIEGEL V. MEDTRONIC*

With the February 2008 U.S. Supreme Court decision, *Riegel v. Medtronic*, Americans lost their right to recover damages from manufacturers of defective Class III medical devices. A Class III device is any device which is used to support or sustain human life or for a use which is of substantial importance in preventing or impairment of human health. Marketing of these devices or modification of these devices requires FDA approval. In *Riegel*, the Supreme Court overturned 30 years of consumer protections by ruling that any Class III device approved under the FDA's premarket approval process

would receive complete immunity from state tort law claims, even if the manufacturer knew of potential dangers associated with the product.

The defective Sprint Fidelis lead provides a clear example of the financial burden to Medicare, as a result of the *Riegel* decision. Because the Sprint Fidelis leads were only a variation of the prior Medtronic lead model, the FDA did not require the extensive safety and effectiveness testing required of a new product. The application for a modified Medtronic pacemaker lead, which was to be called the Sprint Fidelis lead, was approved in 30 days, even though there was a significant change in how the wires in the lead were welded. (See Feder, Barnaby J., 2008).

There was an abnormally high incidence of lead failure in Sprint Fidelis leads within the first year of their use. Additionally, it has been discovered that the likelihood of failure of these leads increases as they age. If the current pattern continues, Medicare will likely experience over a billion dollars in expenses as a direct result of these defective Sprint Fidelis leads. This cost will be borne by the U.S. government, rather than recovered from Medtronic. Other defective Class III medical devices, such as pacemakers, infusion pumps, stents, joint replacements, and artificial heart valves, also enjoy complete immunity from liability – and when a defective product causes increased medical expenses, the cost of the damages will be paid by patients and their insurance carriers, rather than by the medical device manufacturers.

Not only does this court decision impose the burden of cost of defective products on the patients and their insurance providers, the decision seems incongruent to the Court's later holding in *Wyeth v. Levine*. In October 2008, less than a year after the *Riegel* decision, the Court held that federal law does *not* preempt state law in a personal injury action against a drug manufacturer for failing to include an appropriate warning label for an FDA-approved drug.

On May 12, 2009, David C. Vladeck, Professor of Law at Georgetown University, gave Congressional testimony in support of the Medical Device Safety Act, which would negate *Riegel*. He stated that, as the law now stands, the FDA's premarket approval of a device would require dismissal of any damages lawsuit for a defective device, "even if the device proves to be unsafe, even if the manufacturer is slow to warn doctors and patients of the defect, and even if the device's label fails to provide

physicians and patients with adequate information to assess the device's risks.” (Vladeck, 2009, p. 12). In his testimony, Vladeck also states that, currently, “manufacturers will have little economic incentive to swiftly recall defective devices, since they are immunized from liability in tort, and, at least during the prior Administration, virtually certain to face no enforcement sanction from FDA, which had withdrawn the regulatory cop from the beat.” (Vladeck, 2009, p. 23).

Medicare Cost Containment

Any discussion of cost containment for the Medicare program must address this current and future liability imposed by the court in *Riegel*. Affordable health care has become one of the primary political issues during the last few years. One component of the debate is the ability of the Medicare Trust Fund to remain solvent as the baby boomers begin to retire. It is currently predicted that Medicare will become insolvent in 2017. Proposals to alter benefits, reduce physician payments, and modify liability risks are just a few of the many suggestions that have been made to extend the time to insolvency.

One such proposal is that Medicare costs be constrained to grow no faster than the consumer price index and that Part C of Medicare, the Advantage plan, which was intended to operate like an HMO, operate at the same level of efficiency as other HMOs. Currently Medicare cost growth rate per beneficiary is 0.89% per year (compounded) more than the CPI. The Advantage program has annual costs that are 13% higher, on average, than patients in the standard Medicare fee for service program (MDEPAC, 2008). If these two conditions are met, the Medicare trust fund is predicted to remain solvent, past the year 2017. However, when Medicare is shouldering the cost liability for defective medical devices, these cost containment efforts will be far less effective.

ANALYSIS OF THE COST TO MEDICARE

The analysis presented here is an actuarial analysis of the cost incurred by Medicare, as a direct result of the defective Sprint Fidelis leads. The expected annual cost to the Medicare program is determined by the *additional* risk of failure over that of similar devices on the market multiplied by the expected cost of replacement or medical

remedy resulting from failure plus the cost resulting from additional utilization of medical services which result from the announcement of withdrawal of the device. Competing risks of death are included to adjust the pool of patients who die prior to failure of the leads.

There are additional costs to society and family for such failures that can not be identified by an in depth economic analysis wherein the economic impact of a recall of the device on the elderly cohort or the economy serving this cohort is evaluated. We stay focused simply on the costs to Medicare of the Sprint Fidelis problem and do not attempt a more extensive economic analysis.

Although there have been some fatalities associated with lead failure reported in the literature, the number of these is small. Additionally, the presence of any co-morbidities and risk factors for these deaths were not reported. Consequently, although it may seem reasonable to believe that implantation of a Sprint Fidelis lead increases the likelihood of death over what it would be for a different brand of implant, we assume that the mortality rate is the same across all brands and types of implants.

Data

One of the primary challenges in any actuarial analysis of health care cost is obtaining the relevant, reliable data. There are several sources of data that are readily available for analysis. The core pieces of data used for actuarial calculation of additional Medicare cost, resulting from the Sprint Fidelis defective lead are:

- A. The expected number of additional failures per year;
- B. The average cost paid by Medicare for health care resulting from each additional failure, and;
- C. The amount of health care services paid by Medicare for increased medical care for those with an implanted device that has not yet failed.

Federal Medicare records have reimbursed costs for Medicare eligible patients. To obtain the Medicare data necessary for addressing specific disease and procedure specific events requires possession of a finders list and justification for the request, because such requests will entail information such as social security numbers and specific

personal data for Medicare recipients.² For purposes of this paper, adequate indirect data are available to obtain an “order of magnitude” estimate of the cost to Medicare. We use such indirect data.

Excess Failures

In order to calculate estimates of expected failures and costs, we use data gathered from indirect sources other than directly from Medicare data. Medtronic presents up-to-date failure counts and failure data on their website (<http://www.medtronic.com/product-advisories/physician/sprint-fidelis/6949-LEAD-PERFORMANCE.htm>). Currently (November 2009) this site reports a cumulative failure using its CareLink PLUS system, of 7.2%. This represents the failures for the last four years. The average annual failure rate using these data is 1.85%. Vladeck (2009) reports a failure rate of 12% apparently over this same period of time resulting in an annual rate of 3.15%.

Hauser and Hayes (2009) determined the failure rate for Sprint Fidelis leads by examining data from a Multicenter Registry. Since under-reporting has been suspected in Medtronic’s database, this Multicenter Registry data base would seem to present more reliable data than the reporting mechanism employed by Medtronic. (Burton, 2010). The data used for their analysis covers the period from January 2004 to December 2008. A summary of the failure rate data is given in Table 1. The overall annual failure rate reported here is 3.75%. Faulknier et al (2010) reported on 426 Sprint Fidelis implants over this same period of time with a failure rate of 3.6% per year. Similar failure rates are reported by Farewell et al (2008) studying 480 Sprint Fidelis implants. Note that this data is not a representative sample from the U.S. population of pacemaker recipients. However, they do represent four different hospitals, under three different studies. Collectively, this data gives the most defensible estimate of failure rates of the devices.

² Justification usually requires a strong argument presenting how the government program will be enhanced or how the health of the elderly will be improved by granting the request.

Table 1
Failure Rates of Implantable Cardioverter-defibrillator Devices

Lead	Number Implanted	Implant Years*	Number of Failures	Failure Rate (% per year)
Sprint Fidelis	848	1,923	72	3.75%
All Others**	2,189	3,777	22	0.58%

*Number of implants multiplied by the number of years the implant is in place

** “All Others” includes Sprint Quattro Secure (Medtronic), Endotak Reliance G/SG (Guidant Corp.), Endotak Reliance (Guidant Corp.), and Riata (St. Jude Medical, Inc.).

As we see from Table 1, the rate of failure for the recalled Sprint Fidelis lead is considerably higher than for the other leads that were considered in the study. Researchers report that this difference was statistically significant (Hauser and Hayes, 2009).

This report will show two different failure rate scenarios to determine cost. The first scenario will use a 3.75% annual failure rate as the failure rate for the Sprint Fidelis, and assume that it is constant over time. The second scenario will use a failure rate that increases annually, as suggested by Hauser, Farewell, and Faulknier.

In Table 1 we take into account that there is an ambient (or background) rate of failure for all other leads of 0.58% per year. In other words, if the Sprint Fidelis lead were not on the market, a product from the list of Table 1 could have been used. These products have a failure rate of 0.58% per year, on the average. We assume that the failure rate in excess of 0.58% is the “normal” or background rate for lead failure. Excess risk of failure for the Sprint Fidelis lead is determined as the amount the observed failure rate exceeds this background rate.

To remove the background effect to calculate the excess number of failures, we build two multiple decrement tables, one with a failure rate of 3.75% and one with a failure rate of 0.58%. In both of these tables, the number of patients that are lost to death are removed using the assumed mortality rate (discussed below). We calculate the number of failures in a year by multiplying the failure rate of the device (either Sprint

Fidelis or a competitor) by the number of surviving patients who have not experienced a device failure. The differences in the number of failures in these two tables are the excess failures apportioned to the Sprint Fidelis problem. We will use these differences to calculate costs to the Medicare program.

A second issue of importance is that all three of the studies (Hauser, Farewell, and Faulknier) report a statistically significant increase in failure rate over time. This means that as the Sprint Fidelis lead ages, the likelihood of failure increases. No such increase in failure rate was observed in other leads. Table 2 gives the probability of failure as a function of time since implant from these three studies. Since the Sprint Fidelis implant has been followed for less than five years in these studies, it is difficult to assume that the increase in failure rates will persist. Consequently, in our analysis here we assume that the failure rate increases to 15% per year by year five and then holds constant. A second scenario for examining costs is to form the actuarial computations described above, but with an increasing rate of failure for the Sprint Fidelis device. The last column of Table 2 lists the failure rates we use for this scenario. These values are consistent with the failure rates observed in all three studies.

Table 2

Observed failure rates of Sprint Fidelis leads for Hauser (2009), Farewell (2008) and Faulknier (2010).
The last column lists the values used for the increasing failure rate scenario.

Age of Device	Hauser Report	Farewell Report	Faulknier Report	Assumed Increase
1 year	0.011	0.004	0.015	0.010
2 years	0.040	0.020	0.026	0.025
3 years	0.070	0.068	0.053	0.065
4 years	0.198	0.134	0.133	0.130

Number of Patients with Implanted Leads

Next we must determine the number of Medicare eligible patients who have the implanted leads. Mehrotra et al (2009) assume that there are approximately 175,000 patients alive with an implanted Sprint Fidelis lead at the time of recall. It is unclear

from their brief report if these were all in the U.S. and were all Medicare eligible. Researchers at the Garretson Firm Resolution Group (GFRG, 2009) determined that the number of patients who were eligible for Medicare benefits who had a Sprint Fidelis implant at time of recall was 130,130. We will use this as the number of patients.

Cost of Treatment for Failures

Once a failure has occurred, the cost of treatment depends on the type of treatment required. Some failures can be capped while others require explantation (extraction of the lead). With some lead failures, the pacemaker device must also be replaced whereas for others, only the leads require replacement. Co-morbidities (complicating health states and risk factors) associated with the client can greatly increase the cost of care. Depending on these factors and others determined by the physician, replacement can be done in the hospital on an outpatient basis (<24 hours in hospital) or requires inpatient care. Inpatient care greatly increases the costs of replacement. Consequently, the average cost for replacement depends on the proportion of the patients in each possible category of failure and treatment, along with types of co-morbidities. The proportion of patients in these various cost and treatment categories is referred to here as the “case mix.”

Mehrotra et al (2009) examined actual costs of treatment for 11 patients who underwent lead revision. The average cost depended on whether the lead was extracted (\$46,535) or abandoned (\$33,802). The difference was not statistically significant. Two concerns with the values reported by Mehrotra and colleagues are 1) it is unclear whether or not these were all inpatient or not, and 2) it is unstated how much of these costs were actually reimbursed by Medicare. If the procedure can be performed on an outpatient basis, the cost (and Medicare approved reimbursement) is significantly reduced.

GFRG (2009) used data gathered from a sample of 94 cases to determine that the case mix ratio, applied to the published Medicare reimbursement rates, resulted in an expected cost of about \$13,800 per failure, on the average. This number is adjusted for the difference in inpatient/outpatient care, replacement or not of the pacemaker device, and co-morbidities present. This number is accepted here as a reasonable cost per failure case.

Cost to Monitor

All recipients of the defective lead were notified, either by their doctor or by Medtronic, of the increased risk of failure of the implanted leads. Part of the notification entailed advice to patients that they have their leads checked by a physician. As a result, when considering increased costs to Medicare resulting from Medicare patients receiving the defective leads, the Medicare portion of the costs from increased monitoring must be included. Put in other words, there is an ongoing cost for any recipient of the defective lead, even if the lead does not fail. Because of the increased possibility of lead failure, there is an expected change in behavior of patients after a device recall has been issued, but prior to a failure of the device for the patient.

All recipients of a pacemaker have periodic performance checking (variously called interrogating or monitoring) of the device. Cost of checking the performance of the device depends on patient factors as well. Using the GFRG study, it is estimated to be approximately \$100 per check-up. It is possible that a doctor, knowing the increased rate of failure, would recommend more frequent check-ups for a patient with a Sprint Fidelis implant. Another possibility is that the patient may feel a need for more frequent monitoring, out of anxiety concerning the possibility of lead failure.

The Medtronic recall, which was sent to doctors and patients and posted on the Medtronic website, recommended that patients check with their physician regarding checking the device and to determine the frequency of checks. (<http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062377.htm>) Obviously, the additional number of times a device is checked for performance changes from patient to patient. We believe it is reasonable to assume that the additional number of times per year that the device is checked, because the patient has a Sprint Fidelis lead that is potentially defective, ranges from one to five additional times. This is assumed to represent the conservative (one additional monitoring per year) and liberal (5 additional monitorings per year).³ Medtronic gave no specific follow-up recommendation, beyond, “see your physician.” (<http://www.medtronic.com/product->

³ Five additional monitorings a year may not be a liberal estimate, as we have seen records where the physician recommended monthly patient monitorings.

[advisories/index.htm](#)). Recommendations in the 94 records suggest check-ups as frequent as once a quarter or even once a month were recommended by physicians.

Competing Mortality

Some of the patients will die before their device fails.⁴ Because we are considering the Medicare population that is primarily individuals over 65 years of age, the annual mortality rate is higher than for a younger population. For the population at large, the mortality rate for people 65 and older in the U.S. is slightly less than six percent. However, the cohort of individuals we are considering here have cardiovascular problems as evidenced by the need for the leads. Brunner et al (2003) followed a group of implant patients with an average age at implant of 72. They noted that over the 20 year period, the annual mortality rate for this group of patients was about 7.4% to 7.7%. Jahangir et al (1999) followed a group of older patients with an average age at implant of 85. The annual mortality rate, after the first year for these older old ranged from 12% to 14% per year. The actuarial analysis will use two mortality rates, 7.5% and 10%. The results based on 7.5% rate will reflect costs for a younger implant cohort that resembles that followed by Brunner and the results based on 10% will reflect an implant cohort that has more elderly individuals. Since the data on age distribution of Sprint Fidelis survivor implant patients are not available, these two scenarios will give a range of possible costs.

Excess Failures and Number of Patients Monitored

To calculate the cost to the Medicare program, as a direct result of Medicare patients having the defective Sprint Fidelis lead, we consider the additional expected number of patients having a failure multiplied by the cost of the failure. We add to this the number of patients having their device monitored times the additional number of monitorings.⁵ We have two scenarios to consider. In the first, we assume that the failure rate of the Sprint Fidelis leads is 3.75% per year. Table 3 gives the additional number of

⁴ Deaths of a few patients may actually be the result of the failure of the device as described by Hauser and Hayes. Although there is a significant familial loss for such deaths and a perceived social loss, there is little or no cost for death to the Medicare program over the regular cost of failure described above. Therefore, we do not add a cost for death.

⁵ Recall that we use the additional number of failures over the number that would have occurred at the ambient rate and the additional number of monitorings over what would have occurred under the ambient rate.

failures when the failure rate is 3.75% annually and the mortality rate is at 7.5% and 10% per year for the cohort.

Table 3

The additional number of failures when the mortality is 7.5% and 10% per year.

Year	7.5%		10%	
	Failures	Monitored	Failures	Monitored
2008	4125	115,490	4125	112,237
2009	3637	102,497	3534	96,804
2010	3206	90,966	3027	83,493
2011	2825	80,732	2592	72,013
2012	2489	71,650	2218	62,111
2013	2191	63,589	1898	53,571
2014	1929	56,435	1653	46,205
2015	1698	50,087	1387	39,852
2016	1494	44,452	1186	34,372
2017	1313	39,451	1013	29,646
2018	1154	35,013	865	25,569

We see from here, depending on the competing risk of mortality, the number of failures and the annual number of people to be monitored changes considerably. If the competing mortality is not included, the counts of failures and the number monitored will be too high.

In the second scenario, we assume that the failure rate of Sprint Fidelis leads follows the annual rate of increase shown in Table 2. Because data on lead failure is only available for five years, we will assume that the increase in failure rate caps in the fifth year at 15%. *Because data are not available, we cannot project a likely third scenario, where the rate of failure continues to increase, over time, and the resulting costs exceed our current estimates.* Table 4 gives the excess number of failures and the

number to be monitored assuming an increasing failure rate and the two different mortality rates (7.5% and 10%).

Note that the first row in Table 4 shows a decrease in the number of failures in the first year, relative to Table 3. This is because the failure rate for the first year for Table 4 assumes that the average implant patient has had the device for at least a year, as of January 1, 2008. Thus the failure rate in this case is 2.5% (see Table 2). The rate increases after 2008, as given in Table 2. Table 3, on the other hand, assumes a constant 3.75% failure rate, starting in January, 2008. The difference in the number of patients monitored in 2008 in Table 4 relative to the number shown in Table 3 is for the same reason.

Table 4

The additional number of failures when the mortality is 7.5% and 10% per year and when the rate of failure of the Sprint Fidelis increases over time. We assume that in 2008 the average age of an implant is 1 year.

Year	7.5%		10%	
	Failures	Monitored	Failures	Monitored
2008	2,499	117,117	2,499	113,863
2009	6,919	100,720	6,727	95,076
2010	12,456	80,073	11,756	73,208
2011	11,424	62,056	10,442	54,906
2012	8,770	48,093	7,753	41,179
2013	6,719	37,272	5,745	30,884
2014	5,135	28,886	4,247	23,163
2015	3,914	22,386	3,129	17,372
2016	2,974	17,349	2,297	13,029
2017	2,249	13,446	1,679	9,772

Because of the annual increase in failure rate assumed in Table 4, the number of failures is greatly increased. This decreases the number of individuals monitored because

we assume that when the failed device is fixed, it is not replaced by a second Sprint Fidelis lead, but with an alternative that has the ambient failure rate. The increased failure rate will increase the annual Medicare cost for replacing failed devices.

Actuarial Costs

We apply the cost of \$13,800 per failure for medical care and the cost of \$100 per monitor to the entries in Table 3. Table 5 gives the results for the 10% mortality for both one and five extra monitorings per year.

Table 5

Additional cost (in millions of 2009 dollars) to the Medicare program for failure of Sprint Fidelis and monitoring by year using an annual mortality rate of 10%. Failure rate of the Sprint Fidelis lead is assumed here to be a constant 3.75% per annum.

Year	Failure Cost	Monitoring		Cumulative Total	
		(1 extra)	(5 extra)	(1 extra)	(5 extra)
2008	56.93	11.22	56.12	68.15	113.04
2009	48.77	9.68	48.40	126.60	210.21
2010	41.77	8.35	41.75	176.92	293.73
2011	35.77	7.20	36.01	219.69	365.51
2012	30.61	6.21	31.06	256.51	427.17
2013	26.19	5.36	26.79	288.06	480.15
2014	22.40	4.62	23.10	315.14	525.65
2015	19.14	3.99	19.93	338.27	564.72
2016	16.37	3.44	17.19	358.07	598.27
2017	13.98	2.96	14.82	358.07	627.07
Ten Year Total	311.93	63.08	315.14		

If the mortality rate is less than 10% per year for those with pacemakers installed, then the figures given in Table 5 will be low. To determine how much they might go up with a lower mortality rate, we present the same results of Table 3 in Table 6 but with a mortality rate of 7.5%.

Table 6
 Additional cost (in millions of 2009 dollars) to the Medicare program for failure of Sprint Fidelis and monitoring by year using an annual mortality rate of 7.5%.

Year	Failure Cost	Monitoring		Cumulative Total	
		(1 extra)	(5 extra)	(1 extra)	(5 extra)
2008	56.92	11.54	57.74	68.46	114.66
2009	50.19	10.25	51.25	128.89	216.09
2010	44.24	9.10	45.48	182.22	305.76
2011	38.99	8.07	40.37	229.27	385.10
2012	34.35	7.17	35.83	271.43	455.26
2013	30.24	6.36	31.79	308.01	517.28
2014	26.62	5.64	28.22	340.27	572.11
2015	23.43	5.01	25.04	368.70	620.58
2016	20.62	4.45	22.23	393.75	663.41
2017	18.12	3.95	19.73	415.80	701.24
Ten Year Total	343.72	72.08	357.52		

When we assume that the failure rate of the Sprint Fidelis leads increases over time, we will have significantly more cost for failures and less monitoring costs. This is illustrated in Table 7 where we have used a mortality rate of 10% in an increasing failure rate given above. It is interesting to note that the cost of monitoring relative to the cost of failure is much lower in this scenario.

Table 7

Additional cost (in millions of 2009 dollars) to the Medicare program for failure of Sprint Fidelis and monitoring by year using an annual mortality rate of 10% and assuming that the failure rate increases.

Year	Failure Cost	Monitoring		Cumulative Total	
		(1 extra)	(5 extra)	(1 extra)	(5 extra)
2008	34.49	11.38	56.93	45.87	91.42
2009	92.83	9.51	47.54	148.21	231.79
2010	162.23	7.32	36.60	317.76	430.62
2011	144.10	5.49	27.45	467.35	602.18
2012	106.99	4.12	20.59	578.46	729.76
2013	79.28	3.09	15.44	660.83	824.48
2014	58.61	2.32	11.58	721.75	894.67
2015	43.18	1.74	8.69	766.67	946.53
2016	31.70	1.30	6.51	799.67	946.53
2017	23.17	.73	3.66	823.82	1,012.80
Ten Year Total	776.58	47.24	236.22		

Discussion

Looking at Table 5 and Table 6, we see that at the low end (10% mortality and one extra monitoring) the cost by 2017 to the Medicare program is estimated to be about \$375 million. At the upper end, with a mortality rate of 7.5% and five extra monitoring visits per year, by 2017 the Medicare expense will be \$1 billion. (See Table 7). Of course, these numbers are “order of magnitude” type estimates that are sensitive to the assumptions made in the actuarial computations.

Upon comparison of the second and fourth columns of Table 5 (or of Table 6), an intriguing picture arises. Namely, the \$500 per person, per year for the extra monitoring costs (column 4) results in an additional annual cost that exceeds the medical replacement costs (column 2). This means that the additional cost to monitor and provide peace of

mind for all the Sprint Fidelis patients who have not had a failure can exceed the costs of replacing leads for those who do have a failure. It is easy to overlook this group of people who have no failure but are recommended to have additional monitoring. If the health link program mentioned above is going to cost the Medicare program on the order of \$500 per person, per year, the total cost to the program for monitoring will exceed the cost of treating failures.

Table 7 gives significantly higher costs due to the assumption that the rate of failure of the Sprint Fidelis leads is increasing with age. The increased failure rate results in an increase in the number of devices that fail. If this assumption is correct, the Medicare program will pay over a billion dollars in excess health care costs in the next decade.

CONCLUSION

This examination of the cost to Medicare for the defective Sprint Fidelis lead shows how a single defective life supporting or life sustaining medical device can cost patients and their insurance companies hundreds of millions of dollars. Because of the Court decision in *Riegel*, the manufacturer of the device is protected from any responsibility to pay for the damage their defective device causes. People on Medicare are 65 or older and have more life supporting or life sustaining medical devices than the general population. This increases the likelihood that someone on Medicare will be the recipient of a defective device and thus increases the cost to Medicare to provide additional medical care, because of damage caused by the defective device. The Medicare program, in its struggle to remain solvent, can ill afford to assume this expense. The passage of the Medical Device Safety Act (MDSA), will give medical device manufacturers the responsibility to pay for their mistakes, assigning the cost of damages to the one who caused the damage.

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