Taxation of the Medical Device Industry for Healthcare Reform: An Ethical Analysis

Katherine Niehaus
Stanford University

Introduction

Since President Obama took office in 2009, Congress has vigorously debated the direction of healthcare reform policy. The basis of reform efforts has been to address the many flaws in the American healthcare system. Primary among these is America's status as the only country in the developed world that does not provide a governmental guarantee of minimal healthcare coverage. While expensive, high-quality, specialized treatments abound, the United States lags significantly behind its peer countries in standard health indicators such as infant mortality and average life expectancy. Despite these unimpressive rankings, the United States spends more on healthcare, at 15.3% of GDP, than any other developed nation (Barr, 2008). In broad terms, healthcare reform has attempted to address these problems by setting two goals: to make the current delivery of health services more efficient and to increase access to care.

Important measures to achieve the first goal have included reducing redundant care and increasing the use of information technology. A more contentious option, however, is providing increased access to care, which shifts the focus predominantly to health insurance reform. Proposed changes have included outlawing discrimination against citizens with pre-existing conditions, expanding Medicare coverage, offering healthcare subsidies to middle-income citizens, requiring small businesses to offer healthcare insurance, and requiring that almost all Americans not covered either buy health insurance or pay a fee (*The President's proposal*, 2010; Health care reform and you, 2009). As these changes are implemented over the next 10 years, clearly they will significantly transform the state of healthcare in America.

Besides the details of who should be covered under expanded health insurance, a central part of the reform effort has been to determine how the new expenditures, which are expected to total $940 billion over the coming 10 years, will be financed (Healthcare reform and you, 2009). The final bill includes taxes on high-priced insurance plans and on families earning more than $250,000 per year (Hitt & Adamy, 2010). The health insurance and pharmaceutical industries have also been targeted as a source for additional tax revenue over the next 10 years to help pay for

healthcare reform: the insurance industry will be subject to an $8 billion excise tax starting in 2014, which will increase in subsequent years, and the pharmaceutical industry will pay an annual fee of $2.5 billion starting in 2011, which will also increase in following years (What's in the bill, 2010; *The President's proposal*, 2010).

In addition, beginning in 2013, a 2.3% excise tax will be assessed on the medical device industry, to be collected over the ensuing 10 years (What's in the bill, 2010). This provision was introduced in September 2009 by Democratic Senator Max Baucus of Montana. In his original proposal, he called for an annual $4 billion excise tax on the medical device industry, with a total tax revenue of $40 billion over 10 years (The innovation tax, 2009). The tax would be based on the medical device manufacturers' share of US revenue (*The President's proposal*, 2010). Not surprisingly, the medical device tax proposal was met with heated opposition by both large and small companies in the medical device industry. AdvaMed, the lobbying organization for medical device manufacturers, eventually succeeded in lowering the total proposed tax to $20 billion, or $2 billion per year for 10 years.

Medical device manufacturers are companies that develop and sell devices such as imaging technologies, heart stents, glucose monitors, and defibrillators. The industry is characterized by a handful of large corporations that dominate the market in a wide range of devices, complemented by enterprising start-up companies that predominantly manufacture single devices. Large corporate players include St. Jude Medical and Medtronic, both based in Minnesota, and Boston Scientific, with headquarters in Boston. There were 1,247 venture-funded medical device start-ups in 2008, most working to commercialize technologies originating in medical centers or academic institutions (Ernst & Young, 2009). Over the past several years, the IPO market for medical device start-ups has become virtually non-existent, making acquisition by a larger company the predominant exit strategy for these small companies.

After their original conceptualization, novel medical devices face a long path to market. Following several years of development, a medical device must be approved by the Food and Drug Administration (FDA) before it may be sold in the United States. Depending on risks and degree of similarity to existing devices, new devices must meet certain requirements to demonstrate their safety. Upon FDA approval, the next major hurdle is to achieve approval for reimbursement by insurance companies. Without reimbursement, only a few patients will be able or willing to pay out-of-pocket for an expensive device or procedure.

Although healthcare reform has recently been passed in Congress, it is essential to examine whether its final measures can withstand ethical scrutiny. In particular, is the tax on the medical device industry, which will help pay for the expanded access to healthcare, an ethically defensible choice?

Viewpoint 1: Taxing the Medical Device Industry Is Not Justified

Taxing the medical device industry is not a sound policy choice when examined from a consequentialist ethical framework. Regardless of the benefits that may derive from a tax on the industry, these benefits do not justify the limitation on the rights of the medical device manufacturers that would result from a tax.

Most fundamentally, it may be argued that there is no right or societal interest, of any degree, in providing healthcare coverage for those who cannot afford it. From this viewpoint, any effort to limit liberties in the pursuit of honoring this right would be unjustified. A tax on the medical device industry for the purposes of funding healthcare reform, then, would be an unethical infringement on the rights of the medical device manufacturers.

Even if a protectable societal interest in providing healthcare were accepted, the negative consequences of a tax on the medical device industry would outweigh the societal benefits. Foremost among these negative consequences is the inhibition of innovation. A tax on the medical device industry could inhibit innovation in two ways: (1) large companies might be forced to cut research and development budgets, and (2) venture capitalists might no longer fund risky but promising start-up companies.

First, most medical device manufacturers have little market power, which means they have little control to increase prices in response to the tax that they would be forced to shoulder (Crann, 2009).[1] Instead, insurance companies and hospitals largely determine how much they will pay for a given device. Because the device companies cannot significantly influence prices, they will be left with smaller overall profits. While the profit margin for medical device companies has historically been large, the majority of these funds have been allocated toward investment in new technologies. Large medical device companies typically spend between 9 and 13 percent of their revenue on research and development (R&D).[2] Outside of the broad sectors of biotechnology, medical devices, and pharmaceuticals, this rate of spending on R&D is topped only by the software/Internet industry. The telecom, automotive, computer hardware, electronics, food, and consumer products industries, by contrast, each spend less than six percent of their revenue on R&D, on average (Dunn, 2005). While large medical device companies could assuredly put effort

[1] The validity of this statement is debatable; the alternative viewpoint that medical device companies do have significant market power is addressed shortly.

[2] In 2007, 2008, and 2009, Medtronic spent between 9 and 10 percent of its revenue on research and development (R&D) each year (Medtronic, Inc., 2009). Boston Scientific spent about 13 percent of its revenue on R&D each of these years (Boston Scientific Corporation, 2009), and St. Jude Medical spent about 12 percent of its revenue on R&D efforts (St. Jude Medical, 2009). Abbott Laboratories, which also manufactures many medical device products, spent about 9 percent of revenue on R&D efforts each of these years (Abbott Laboratories, 2009).

into increased efficiency, many have come to the conclusion that R&D spending will have to shrink (Crann, 2009). Thus, a tax will likely result in less innovative research and fewer development efforts by large firms.

Second, in the traditional venture capital funding model, venture capitalists will only invest in a company if they believe they can make a significant profit. This large profit margin is desired because most start-ups fail, and so a large return on investment is needed from those companies that do succeed. Medical device development already is an extremely time-intensive investment, usually requiring about 10 years to reach commercialization, in part because of FDA regulations. Moreover, even after a device has been brought to market, it takes considerable time for the company to make any actual profit. If such a company is already being taxed on its revenue before it is profitable, it will take even longer for venture capitalists to generate a return on their investment, and they will be much less likely to invest in new technologies that could have enormous life-saving potential. This is disadvantageous because innovation is one of the tools needed to provide more widespread care that is still of high quality. In other words, a tax on the industry could stifle the very innovation that could aid in the success of healthcare reform.

Additionally, a medical device tax would disproportionately affect those states with vibrant medical device industries, leading to a case of distributive injustice (Klobuchar, Bayh, Lugar, & Franken, 2009). An excise tax would force medical device companies, which are located predominantly in California, Minnesota, and Massachusetts, to cut back on jobs and lay off employees (Crann, 2009; Ernst & Young, 2009). Since the entire country will stand to benefit from expanded governmental health insurance coverage, it is not equitable that some states will be forced to shoulder more of this cost.

The estimation of overall harmful consequences for innovation and jobs is based on the presumption that medical device manufacturers have little market power to increase the prices of their products. However, even if medical device companies were able to demand higher prices, these higher prices would hinder the goal of increasing available low-cost healthcare; if medical device companies do have market power to increase device prices, they will pass most, if not all, of the cost of the tax to health insurance companies, who will pass the cost onto consumers through higher insurance premiums. In the end, such taxation will only serve to further drive up the cost of healthcare for consumers (The innovation tax, 2009).

Clearly, there are significant societal costs in taxing the medical device industry. In addition, targeted taxation on the medical device industry is based on the assumption that the industry will stand to gain from health reform because more patients will have access to their devices. However, it is more likely that reform will decrease the amount of reimbursement that medical device companies will receive. Indeed, there are projections that the medical device industry will lose $15 to $17 billion

over the next 10 years because of healthcare reform (Klobuchar, et al., 2009).

In conclusion, a tax on medical device companies is unethical because it forces the industry to shoulder a large burden of the cost of healthcare reform—reform that may actually harm the industry. Additionally, the negative consequences on innovation are too high, when innovation is exactly what is needed to provide high-quality, low-cost treatments.

Viewpoint 2: Taxing the Medical Device Industry Is Justified

However, convincing arguments may also be made that the tax on the industry is the most ethically defensible choice, and that it should be implemented. To illustrate this point of view, it must first be shown that taxation to fund expanded health insurance access is ethically justified, and it must also be shown that, in particular, the rights of the medical device industry may be trumped to realize the greater benefits brought about by a tax.

An argument often advanced for the necessity of healthcare insurance reform is that access to a minimum level of healthcare is a fundamental human right. As such, everyone should have access to affordable health insurance coverage. However, the presumption that healthcare is a fundamental human right is not immediately evident. While there are many viewpoints as to what constitutes a fundamental human right, here the definition of a human right as developed by Stanford Professor Robert McGinn will be adopted: human rights must be held by all societies at all times—they are rights granted by the nature of being human and are unalterable with the sociocultural context (McGinn, 2010). State-provided healthcare is a relatively recent societal phenomenon, made possible as societies have become more affluent. Given its dependence upon the current sociocultural regime, healthcare cannot be classified as a fundamental human right. However, this does not preclude healthcare from being a derivative moral right, taken from the moral right to life. If people have the right to live, then, assuming that the resources exist, this can be extended to mean that people have a right to the healthcare that will enable them to live longer and more fully. Indeed, it may be a protectable interest of society to provide a basic level of healthcare for all citizens, provided that the society has the means to do so.

A tax to fund healthcare reform, then, can be seen as an effort to correct a problem of distributive justice. While some Americans are unable to afford health insurance, others, by virtue of their personal wealth or lavish health insurance plans, have access to very high-quality care. Assuming that access to affordable health coverage is a protectable societal interest, this situation clearly is distributively unjust. Taxation could be used to re-allocate healthcare spending so that it is more equitably distributed.

There is a clear collective benefit to healthcare coverage, in that it provides citizens with the assurance that if they were to lose their job or

find themselves unable to pay for healthcare, they would still be able to have healthcare coverage. There is also a societal consensus that this is an important interest, with 55% of Americans believing that the federal government should guarantee health insurance for all citizens (Blendon, 2009). In cases such as these, in which there is a societal interest in extending the collective benefits of healthcare, it is justified to limit liberty in certain ways in order to realize these benefits.

The question then becomes whether the liberty limitation on the medical device industry, through taxation, is justified, given the societal interest in healthcare reform. A tax on the medical device industry clearly limits the liberty of these companies because they are no longer free to invest their revenues as they choose—instead, they are forced to provide some of their revenue to fund healthcare reform. Yet, in this case, taxation is justified for several reasons.

First, the medical device industry stands to gain from expanded healthcare coverage. With more people covered under insurance, more devices can be sold, and more revenue will be generated. Given that medical device companies will benefit from reform, it may be viewed as only fair that they shoulder some of the cost to moving toward this new system. In addition, the other industries most strongly affected by healthcare reform, such as the pharmaceutical industry and the health insurance industry, have also been forced to make concessions. It is only distributively just, then, that the medical device industry does so as well.

It may also be argued that the medical device industry is largely counterproductive in the quest for an affordable healthcare system. Many new devices, upon which millions of dollars have been spent, do not prove to be any more effective than existing alternatives. Often, they are worse. For example, new systems for robotic surgery for prostate cancer have been widely adopted throughout the country. These robotic systems are extremely costly, and to date there is no conclusive evidence that they provide improved outcomes for prostate cancer patients (Kolata, 2010). Yet, the new technology has been heavily marketed to patients and physicians, and now, at great expense, many prostate cancer patients are refusing to accept traditional surgery as an option.

Thus, even if the medical device industry does not actually benefit from expanded healthcare coverage, it is not necessarily a bad outcome if taxation brings about shrinkage of the industry. Many devices are unnecessary, costly, and only marginally improve care. Fewer new devices would prevent physicians from flocking to expensive devices simply because they are technologically advanced. Instead, large companies and venture capitalists would be forced to examine more closely the real benefits of developing a new device and bringing it to market.

Thus, taxation of the medical device industry has few negative societal consequences and allows the extension of health insurance access, which is regarded as an important societal interest. It is therefore justifiable to tax the industry to achieve the goals of healthcare reform.

Final Analysis: Taxation of the Medical Device Industry Is Not Justified in this Case

Despite the compelling arguments for a tax, in a final examination it becomes apparent that the strongest ethical case cannot favor the implementation of a tax on the medical device industry. Upon weighing the competing ethical stakes of the involved parties, it is found that there are less compromising ways to achieve the desired societal goals. In analyzing this debate, two major ethical dilemmas must be resolved: whether there is a right to affordable access to healthcare, and, if so, whether it is justified to tax the medical device industry to provide the required funding.

Is there a right to a minimum level of affordable healthcare? It has been established that access to healthcare cannot be justified as a fundamental human right. However, it may be viewed as a derivative moral right. Given a moral right to life, if society has the means to aid someone who is sick, it may be argued that this person has the right to receive the benefit of this aid. However, this leads to the difficult determination of what, exactly, is the minimum level of care that society is obligated to supply. If someone is sick and in their last weeks of life, is it society's obligation to provide this person with exorbitantly expensive life support so that they may live two more weeks? There is an opportunity cost to any societal resource spent on healthcare, and, taken to the extreme, a right to healthcare could lead to the dangerous result of all of society's resources being spent on health costs.

Given the current sociotechnological regime, then, it seems that a derived moral right to healthcare is not immediately evident. However, the lack of certainty surrounding the status of healthcare as a right does not imply that providing healthcare is not strongly in society's interest, or that it is not the moral course of action. Indeed, the current distributive inequity in access to healthcare,[3] combined with the United States' ability to improve this inequity, makes a compelling case for doing so. Additionally, expanded health insurance access, as elaborated upon previously, provides a safeguard for all citizens through the assurance that

[3] Of course, a factual question is important: Is the current system actually distributively unjust? Do many Americans lack health insurance coverage because they legitimately cannot afford it, or is it simply because they are young, have few health problems, and choose not to pay for it? While it is certainly the case that over a quarter of uninsured adults are young (age 18 to 29), 20 percent of all uninsured citizens are children (under 18). Additionally, 28.6% of uninsured adults earn less than $36,000 per year (Newport & Mendes, 2009). Clearly, for these children and low-income adults, the cost of health insurance is simply too prohibitive. Additionally, millions of Americans who have pre-existing conditions either cannot obtain coverage for their condition, or must pay hugely expensive rates for insurance coverage. At the same time, by virtue of their employment, some Americans have very lavish insurance coverage. The overall result in terms of access to healthcare is not equitable, and since it is based on factors largely out of one's control, it also is distributively unjust.

they will not lose their health insurance through a job change or sudden accident, or due to a pre-existing condition.

Healthcare access is not the same as health insurance. However, affordable access to health insurance dramatically improves one's ability to receive healthcare. Thus, given the societal interest in providing healthcare for those who cannot afford it, there is also a strong societal interest in providing health insurance because this is a means of ensuring at least a basic level of healthcare. In summary, increased access to health insurance is morally desirable. The question then becomes whether taxing the medical device industry as a way to approach this ideal is worth the benefits.

Taxing the medical device industry would likely result in negative outcomes for this sector, most notably inhibiting innovative progress and precipitating job loss. However, a key question is whether these outcomes are, in fact, even undesirable. Perhaps by decreasing innovation in the arena of high-priced devices targeted to small numbers of patients, resources such as venture capital and technically educated people can be reallocated toward solutions that will offer broader societal benefits—for instance, improvement in preventive public health measures could eliminate many problems that these devices aim to treat. Furthermore, many of the new devices currently being marketed have not been shown to be more effective than traditional means of care (Berenson, 2008; Meier, 2009). While a tax may inhibit innovation of high-risk, high-cost medical devices, this outcome is not necessarily a drawback.

The problem with this analysis is that a downsizing of the medical device industry does not mean that this specialized sector will be able to focus on more widespread preventive public health measures. Work in public health, for example, requires different skills than those of a medical device developer. Furthermore, medical devices such as defibrillators and stents benefit enormous numbers of people every year. While increased focus on public health and preventive health measures is desirable and necessary, this does not mean that the medical device industry is therefore undesirable and unnecessary; both fields of medicine complement each other. In other words, it is likely that loss of innovation and jobs in the medical device industry would have significant negative societal effects.

Even if some devices are unnecessarily advanced and costly, this problem can be fixed in more equitable ways than a blanket excise tax on the industry. The true reason that medical device companies have been able to thrive from selling expensive, highly specific devices is that insurance companies are willing to pay for them. If patients are forced to shoulder some of the cost of an expensive procedure or device, they will behave differently in their choice of care. This will not only help to rein in costs, but will also decrease demand for those expensive devices that provide only marginal improvements. The decrease in demand will cause only those companies that do not provide truly useful devices to leave the

industry. This outcome is much preferable to forcing the entire industry to shrink.

In addition, simply because there are beneficial outcomes from the tax does not immediately mean that the liberty of the medical device companies should be limited. This can be seen most clearly by delving into why the medical device industry itself should be targeted for taxation. It is argued that the industry will benefit from the reform efforts because more devices will be sold. However, if more people have access to care, they will likely live longer, and they will therefore use more electricity. By this logic, the electric companies should also be taxed. Clearly, there are so many industries that stand to gain from healthcare reform that it is inconsistent to target just a few. Furthermore, it is likely that the medical device industry will actually not benefit from reform, because while it may sell more devices, it may be forced to sell them at lower rates. The "fact" that the industry will benefit from reform is thus not a sufficient reason for taxation.

Singling out the medical device industry, along with a few others, is therefore distributively unjust. In addition, the medical device industry provides tremendous societal value; it has led to the creation of hundreds of devices that are now viewed as nearly essential for the practice of modern medicine. While the extension of healthcare coverage is justified through healthcare reform, taxation of the medical device industry is not the most ethical way to achieve this reform—more equitable methods should have been sought. For example, possible measures to fund reform could have included increasing tax rates for all Americans, given that healthcare reform is seen as a societal benefit that affects everyone. Patient co-payments and insurance premiums could also have been increased, which would have helped limit unnecessary spending. Furthermore, if certain industries are to be targeted, taxation of those goods and services that actually contribute to poor health, such as cigarette and fast foods, would be more ethically justified.

While the healthcare reform bill has now been passed into law, its provisions should not be blindly accepted without moral questioning. As concluded here, the final decisions of how to pay for healthcare expansion are not the most ethical solutions. Recognition and understanding of why this is the case can be used to inform future legislation in the healthcare arena.

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