while leaving others free to brim over would require similar regulatory action on the part of New York State. But if Bloomberg is bent on appealing Tingling's ruling, it is time to start making a case with some muscle, which will require strong, active support from the medical and public health communities. If we can challenge the industries and businesses that profit by promoting bloated serving sizes, perhaps we can take on other corporate enterprises that similarly contaminate our social environment.

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From the Center for the History and Ethics of Public Health, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York.

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The Medical Device Excise Tax — Over before It Begins?

Daniel B. Kramer, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

In June 2012, the Supreme Court upheld critical provisions of the Affordable Care Act (ACA), which aims to expand health insurance to many of the 50 million currently uninsured Americans. With prospects dimming for legislative reversal of the entire law, the various stakeholders in the health care market are now focusing on its implementation. One of the numerous controversial elements to date has been the medical device excise tax, a 2.3% tax on domestic sales of medical devices, paid by the manufacturer, which went into effect in January 2013. Several categories of device sales are exempted, including purchases by government agencies and nonprofit institutions. Retail purchases of devices such as blood-glucose–monitoring equipment for use by individuals, as well as devices such as wheelchairs, hearing aids, eyeglasses, and contact lenses, are also excluded from taxation. All told, the excise tax is predicted to raise approximately $2 billion to $3 billion annually, from a medical device industry with estimated annual U.S. sales of more than $100 billion.[1]

Yet this source of funding for the ACA now faces an uncertain future, even as other key provisions of the law, such as state-run health insurance exchanges, slowly come to fruition. The U.S. Senate voted overwhelmingly on March 21, 2013, to repeal the excise tax in a nonbinding budget resolution, with 79 senators voting in favor of repeal and only 20 voting against. This bipartisan push followed months of intense lobbying from industry groups, which spent nearly $30 million in 2012 alone.[2] This raises several questions. Where did the excise tax come from? Why is it now in danger of repeal? And what would repeal mean for the ACA?

The ACA emerged in an economic and political environment in which major new spending proposals were usually paired with plans for offsetting revenue generation. To balance the primary public expense of the ACA — expansion of coverage through state Medicaid programs — several initiatives to limit spending were included in the law, such as decreased Medicare payments to physicians and hospitals, reduced subsidies to Medicare Advantage plans, and streamlining of pathways toward approval of follow-on biologics (i.e., new versions of existing biopharmaceuticals). At the same time, several new revenue streams were created, including the device excise tax, as well as taxes on high-cost health care plans and disbursements from health savings accounts. The device tax was therefore conceived as one of several strategies for balancing the overall expense

of the statute, which was estimated at $1 trillion over 10 years.[3] A key rationale for the device tax was that effectively broadening insurance coverage to tens of millions of additional Americans while emphasizing prevention, including appropriate use of medical imaging and other diagnostic tools, would translate to enhanced sales for many device companies. Moreover, the originally proposed excise tax was substantially pared down through negotiations between legislators and industry groups to the smaller version included in the final legislation.[1]

But since enactment of the ACA, the medical device industry has remained highly critical of the excise tax. AdvaMed, the industry's main lobbying group, predicted layoffs or off-shoring of jobs as a result of the impending tax and expressed fears about the future competitiveness of U.S. companies.[4] AdvaMed argued that small and medium-sized companies would bear the brunt of the tax out of proportion to their larger rivals, who typically have greater sales in international markets where the tax would not apply. AdvaMed also argued that the excise tax would impede innovation by increasing the average effective corporate tax rate for its members from 23% to 46%, thereby reducing the amount that medical device companies can spend on research and development; it suggested that the industry currently spends about $8 billion annually developing devices, although this figure has not been independently verified.[4]

Although some of these claims may prove valid, predictions regarding the tax's harmful effects on the device industry rest on several unproven assumptions. Decisions regarding layoffs are difficult to trace to single policy changes. With regard to off-shoring, it is unclear how the tax would provide an incentive to move production abroad, since it applies to domestic sales irrespective of the site of manufacture.[1] And since international sales remain unaffected by the tax, the competitiveness of U.S. companies abroad should not be impeded. In addition, individual companies' profits may be preserved by shifting costs to consumers, a tactic that will be aided by the expansion of insurance to millions of new patients.

The argument that the excise tax would harm innovation is perhaps the most difficult to prove or debunk, because the relationship between profits and innovation is not straightforward. Certainly, a company's revenue funds its research and development, but there is no evidence that a tax would affect these investments. According to one estimate based on company reports, average research-and-development expenditures by the 10 largest U.S. medical device companies amounted to 7 to 8% of sales revenue annually between 2007 and 2011.[5] In addition, many transformative innovations in the medical device market have not been driven by the types of companies that would pay the largest fraction of the tax revenue but instead originated in academic research centers, government-funded laboratories, or small companies supported by private venture capital. It is also possible that the device tax could help spur favorable innovation. Large medical device companies have sometimes been criticized for relying on small changes to existing product lines to drive revenue, but such changes may not be able to command so much of a pricing premium as health care dollars become increasingly limited. If a small tax made the industry more effective, enhanced competition could push more investment toward innovations that provide major advances in patient care and that consequently command higher pricing margins.

The uncertainty surrounding the medical device excise tax raises unsettling questions about other future efforts to tackle rising health care costs in the context of the ACA's expansion of health insurance. The legislation to repeal the tax was sponsored and supported by Democrats who also initially supported the ACA, from states such as Minnesota that are home to large medical device companies. No player in the health care arena that is currently entrenched in the patchwork U.S. system is likely to volunteer to receive payment reductions, new levies, or fewer choices in order to fund expanded coverage and other initiatives included in the ACA. Losing the revenue that would have been provided by the medical device excise tax would not by itself cause the ACA to crumble, but it would send a powerful signal to other groups and their lobbyists about the law's vulnerability to piecemeal erosion. Resolving the conflict over the device tax, then, may either strengthen the ACA and its laudable push toward universal health care or weaken both before progress really begins.

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From Harvard Medical School (D.B.K., A.S.K.); the Cardiovascular Institute, Beth Israel Deaconess Medical Center (D.B.K.); and the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital (A.S.K.) — all in Boston.

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