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HEARING:
REGULATORY REFORM SERIES #5
FDA MEDICAL DEVICE REGULATIONS:
IMPACT ON AMERICAN PATIENTS AND JOBS

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE COMMITTEE ON ENERGY AND COMMERCE

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Chairman Stearns, Ranking Member DeGette, and other distinguished members of the Subcommittee on Oversight and Investigations, I want to thank you for inviting me to participate in this important hearing. My name is Gregory Curfman, and I am a cardiologist and the executive editor of the *New England Journal of Medicine*.

For nearly 200 years, the *New England journal of Medicine* has been publishing research articles on new drugs and medical devices. Our publication is strongly committed to innovation in medical therapies. Vigorous innovation in medical products is critical to the health of our Nation, but we have learned that innovation in medical treatments does not come easily. While some new drugs and devices succeed, others unfortunately fail, in many cases owing to serious problems with safety. Much of our work at the *New England Journal of Medicine* is focused on ensuring that the efficacy, safety, and potential hazards of medical products are transparently presented in the articles we publish.

Innovation is essential to the future of our Nation's health, but innovative medical products cannot succeed unless they are both effective and safe. Proper procedures must be in place to ensure both the safety and effectiveness of new medical products before they are brought to market. Sensible quality assurance does not stifle innovation; it promotes it and avoids costly nightmare scenarios caused by flawed and potentially dangerous medical devices.

Patient safety is a national concern. Major stakeholders throughout our health care system agree that every step must be taken to ensure that medical interventions, used with the intention of improving patients' health, are as safe as possible. But every medical intervention has benefits and risks. Patient safety can be ensured only when novel drugs and devices are rigorously evaluated in regard to their efficacy and safety. As the Institute of Medicine has made clear,

medical devices and drugs need to be assessed for risks and benefits not just prior to marketing, but throughout their life cycles. (1)

Let me give two recent examples of innovative medical devices, one from the field of cardiology and the other from the field of orthopedic surgery, both of which were approved by the FDA by the 510(k) fast-track process, but which were later found to be defective even while they were being implanted in many thousands of patients.

The first example, from the field of cardiology, is the Sprint Fidelis implantable cardioverter-defibrillator lead, which was manufactured by Medtronic. This lead, which delivered an electric shock to the heart in order to halt potentially fatal heart rhythms, was approved by the FDA by the 510(k) process without clinical testing. The defibrillator lead received considerable hype as a major innovation in defibrillator technology. The company made the case that it was substantially equivalent to an existing lead that had undergone clinical safety testing and had been on the market for some time. The company also claimed that only minor modifications had been made to the original lead. However, soon after fast-track approval of the Sprint Fidelis, it became clear that the lead was prone to fracture, which resulted in inappropriate shocks in many patients and caused at least 13 deaths. The lead was eventually withdrawn in 2007, but only after it had been on the market for 3 years and had been implanted in over a quarter of a million patients worldwide. Thus, inadequate premarket testing and a fast track to FDA approval, in which corners were inappropriately cut, resulted in a devastating situation for patients.

It is also noteworthy that because of the U.S. Supreme Court's ruling in an important federal preemption case, *Riegel v. Medtronic* (2), the manufacturer could not be sued under state law by patients alleging harm from the Sprint Fidelis lead. Since the Supreme Court ruling in *Riegel*, thousands of lawsuits against medical-device manufacturers

have been tossed out of court by judges following the Court's decision in deeming such lawsuits to be preempted. (3) Such preemption, which removes any legal recourse for injured patients, defies logic in that it applies only to medical devices, not to drugs.

The second example, from the field of orthopedic surgery, is a type of artificial hip implant known as the metal-on-metal hip. Hip implants originally consisted of a metal ball inserted into a plastic cup. In newer models, which were widely hyped as a major technological innovation, the plastic was replaced with a metal alloy (the so-called "metal-on-metal" design). The new design, which, like the Sprint Fidelis lead was approved by the 510(k) fast-track process, did not undergo clinical testing, only bench testing. Not long after FDA approval, reports of and shedding of metallic debris and failure of the metal-on-metal implants began to surface, and upwards of tens of thousands of patients have thus far been adversely affected. Unfortunately, the bench testing of the device did not faithfully reproduce the wear-and-tear of real life. Thus, an apparently "minor" alteration in design – replacement of plastic with a metal alloy – resulted in nothing short of a public health nightmare.

These two examples vividly demonstrate that the glamor of innovation does not always work out well for patients. Innovation in medical devices must go hand-in-hand with a careful assessment their efficacy and safety. Such quality-control measures do not imperil innovation, they advance it.

In preparing this testimony, Mr. Chairman, I reviewed two recent reports on medical technology innovation and regulation, the first written by Joshua Makower and Aabed Meer (4), and the second issued by the California Healthcare Institute (5), a policy research and advocacy organization. As a medical journal editor, I conducted careful reviews of these reports and concluded that both are promotional pieces for the medical device industry and do not

represent rigorous research. Because of serious flaws in how these reports were generated, they could not survive peer review procedures at serious medical journals and would not be publishable in peer-reviewed publications.

Finally, Mr. Chairman, I would like to make a comment about the regulation of medical devices in the European Union, an issue that was discussed in both reports (4, 5). It was argued that because regulatory procedures are simpler (i.e., less rigorous) in the EU than in the US, devices get to market and to patients faster. In fact, the time lines to approval are only modestly shorter in the EU, and it is worrisome that in Europe the highest-risk devices (so-called class III devices) do not have to be shown to favorably affect clinical outcomes prior to approval (6). In contrast, when class III devices undergo premarket approval (PMA) in the US, there must be an evidence base showing not only that the device performs as it is supposed to, but also that it favorably affects clinical outcomes.

Mr. Chairman, I conclude by underscoring the high priority of innovation in medical devices to our Nation, but to be truly innovative medical devices must be shown to be effective and safe. Cutting corners in quality control will inevitably result in costly medical nightmares down the road.

Thank you, Mr. Chairman, for your attention.

1. Challenges for the FDA: the future of drug safety – workshop summary. Washington, DC: National Academies Press, 2007.
2. Riegel v. Medtronic, 552 U.S. 2 (2008).
3. Kyle RH. In re Medtronic, Inc. Sprint Fidelis lead products liability litigation. Multidistrict litigation no. 08-1905 (RHK/JSM). Memorandum opinion and order. U.S. District Court of Minnesota. January 5, 2009. (http://www.mnd.uscourts.gov/MDL-Fidelis/Orders/2009/090105-08md1905ord.pdf.)

4. Makower J, Meer A. FDA Impact on U.S. Medical Technology Innovation. A Survey of Over 200 Medical Technology Companies. November 2010.
5. Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry. California Healthcare Institute. The Boston Consulting Group. February 2011.
6. Cohen D, Billingsley M. Medical Devices: Europeans are left to their own devices. BMJ 2011;342:d2748 doi: 10.1136/bmj.d2748.