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**Statement of Rita F. Redberg, MD, MSc.
Subcommittee on Health
House Committee on Energy and Commerce
July 15, 2011**

Dear Congressman Waxman,

Thank you for the opportunity to review the Makower Report, which was cited in a recent Congressional hearing on medical devices. I am Rita Redberg, MD, MSc, Professor of Medicine and full time Faculty Member in the Division of Cardiology at the University of California, San Francisco Medical Center. I am Director of our Women's Cardiovascular Service. I am also the chief editor of the *Archives of Internal Medicine*, one of the most preeminent peer-reviewed journals of scientific research in general internal medicine, and have served on the Editorial Board of several other journals. The Archives of Internal Medicine receives over 2500 submissions annually, so I have extensive experience in medical article reviews. Much of my own research has concerned the appropriate and optimal use of medical technology in patient care, and the journal frequently publishes articles related to use of medical devices. My review of this report represents my professional opinion and does not reflect the official position or policy of my institution, or any journal or association with which I am affiliated.

There are several serious methodological issues with the Makower report that render its findings scientifically invalid. Firstly, in order to do a survey it is essential to have a random sample of a large population, or a high response rate of the target population, otherwise selection bias is present. The Makower report has neither. On page 18, he states that there are "more than 16,000 medical device companies" and of the total, 4, 776 are medical device manufacturers. He surveys a selected group of venture capitalists, and members of the Medical Devices Manufacturers Association. Even in this select group of over 750 medical device companies, the response rate is about 20%. Ironically, Makower states that he is doing this survey to disprove the perception that complaints about the FDA are just from a "vocal minority", but this report seems to be exactly that.

In addition, to the selection bias and unacceptably low response rate, there are additional issues of conflict of interest - present for the authors, funders and survey respondents. All of them are medical device companies or venture capitalists, whose livelihood depends on fast approval of medical devices. It is understandable that their focus and priorities are on rapid approval as time relates directly to costs and their bottom line, but there are other crucial considerations, such as safety and effectiveness of devices to ensure patient benefit. The perspectives of other interested

parties, such as patient groups whose lives are seriously harmed by the approval of unsafe and/or ineffective devices, or physicians who care for such patients, or the FDA are not represented.

Additionally, the report cites a presentation by Ralph Hall, entitled “Using Recall Data to Assess the 510(k) Process” at the Institute of Medicine’s July 2010 meeting, to claim that the FDA “does an exceptional job of protecting patients.” However, this talk by Professor Hall, who is the CEO of a start-up medical device company and counsels device companies, is not published in any peer-reviewed medical journal and has important inaccuracies. In brief, he argues that the percentage of FDA-approved medical devices, which are recalled by the FDA, is a very small percentage of those that are submitted for FDA approval.¹ However, this analysis uses the incorrect denominator of device submissions – one which is much larger than the correct denominator, the number of devices cleared by the FDA. Only the devices cleared accurately represents the true proportion of devices which can be recalled. The Makower report misses this important distinction by stating that Hall’s results were of devices that were “cleared/approved,” when, in fact, they were of submitted devices.

Another example to illustrate the inherent bias in the Makower report is with regard to the findings on transparency. He states that 85% of respondents found European Union (EU) processes to be transparent versus just 27% for the FDA. This EU statistic is incongruous with findings of a recent investigation by the British Medical Journal into medical device recalls in the United Kingdom which found that there was no transparency about recalls; the authors were unable to find information about the specific approval process for recalled devices or the risk of harms from those devices from the United Kingdom’s Medicines and Healthcare Products Regulatory Agency.² They even contacted the manufacturers, but only 2% provided any clinical data. The Notified Bodies, which are responsible for device approval in the EU, refused to provide that information as they stated it was confidential. This peer-reviewed research suggests that the Makower Report’s statistic for the EU is inaccurate, likely related to the problems in survey methods and selection bias. What was not addressed in the Makower report that would be helpful in comparing the US and the EU is to include outcomes data – how many patients are benefiting from use of devices, and how many are suffering adverse events and/or recalls. The metric of time to approval is of interest to companies because it directly relates to the cost to the companies of device development, but is of no relevance to patients.

Regarding economics, the Makower Report states that current FDA processes are causing innovators and medical device companies to relocate internationally, sending important tax revenue and jobs away and, therefore, hurting the U.S. economy. However, this argument is faulty because approving unproven and unsafe devices actually hurts the economy by allowing limited healthcare dollars to be spent on expensive devices that do not help patients, which leads to higher health insurance premiums which can lead to economic difficulties and bankruptcies for many small businesses. Technology is the leading correctable cause of rising health care costs. Further, when patients are harmed from unsafe devices, they are unable to work, which presents additional costs. Certainly medical devices have provided important advances to patients, but this evidence of benefit, must be demonstrated, not assumed and studies take time. It would be negligent to use these devices without evidence of benefit in patients, particularly high-risk devices which are often permanently implanted.

The Makower report is helpful in identifying areas that could be improved by the FDA, such as decreased staff turnover. Such turnover, likely related to inadequate funding leads to avoidable and frustrating delays in device review. As FDA Commissioner Hamburg recently stated, “Our

resources are outstripped by our responsibilities...there is a continuing need for expansion of investment.”³ Providing the FDA with more funding and increased resources would likely help to alleviate these difficulties and reduce time to approval without shortchanging the time needed for clinical trials. The calls for consistency in the approval process are important and would help the FDA, as well as the companies.

For all of the limitations above, this study would not be accepted at a peer-reviewed medical journal.

Sincerely,

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¹ Hall R. Using Recall Data to Assess the 510(k) Process. Public Health Effectiveness of the FDA 510(k) Clearance Process: Institute of Medicine, Washington, D.C., July 2010.

² Thompson M, Heneghan C, Billingsley M, Cohen D. Medical device recalls and transparency in the UK. *BMJ* 2011;342:d2973.

³ Okie S. Reviving the FDA. *N Engl J Med* 2010;363:1492-1494.