INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process
Board on Population Health and Public Health Practice

July 20, 2011

Jeffrey Shuren, MD, JD
Director, Center for Devices and
Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

I am writing in response to your January 21, 2011, letter to the Institute of Medicine (IOM) regarding seven recommendations proposed by the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). In your letter, you gave the IOM Committee on the Public-Health Effectiveness of the FDA's 510(k) Clearance Process an opportunity to provide feedback on the seven recommendations. CDRH's proposed recommendations are aimed at

1. Seeking greater authority to require postmarket surveillance studies as a condition of clearance for some devices.
2. Defining the scope and grounds for CDRH to exercise its authority to rescind a 510(k) clearance fully or partially.
3. Clarifying when a device should no longer be available for use as a predicate.
4. Developing guidance defining Class IIb devices for which clinical information, manufacturing information, or, potentially, additional evaluation in the postmarket setting would typically be necessary to support a determination of substantial equivalence.
5. Consolidating the concepts of "indications for use" and "intended use" into a single term, "intended use".
6. Pursuing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of a device.
7. Requiring each 510(k) submitter to keep at least one unit of the device that is under review available for CDRH to access on request.

Your letter and the release of *CDRH's 510(k) and Science Report Recommendations* came toward the end of the IOM committee's work. Because of time constraints, the committee was unable to study fully the seven recommendations referred to it. The committee did, however, address many of the broader issues related to those recommendations in its report, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*. That report responds to the IOM committee's statement of task, which was to review the 510(k) clearance process for medical devices and to answer two questions:

1. Does the current 510(k) clearance process protect patients optimally and promote innovation in support of public health?
2. If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) clearance process optimally?

CDRH's proposed recommendations 1–3 are related to FDA's postmarket authorities for medical devices. As stated in its report, the IOM committee found that the FDA has a broad array of tools available to address safety concerns in the postmarket period but that the agency does not use these tools extensively. The FDA has not adequately explained the limitations of the tools and why it has not used them more widely. As a result, the IOM committee recommended in its report that the FDA identify the limitations of its current regulatory tools and seek to address the limitations. The IOM committee supports the concept of allowing conditional clearance based on postmarket surveillance in appropriate cases and has suggested this option as a potential component of a modified de novo process.

CDRH's proposed recommendations 4–7 are related to FDA's authorities for the 510(k) program. The IOM committee's report concludes that the 510(k) process generally is not intended to evaluate the safety and effectiveness of medical devices and, furthermore, cannot be transformed into a premarket evaluation of safety and effectiveness. The report's recommendations are focused not on making improvements in the 510(k) process but rather on the steps needed to develop a more rational medical-device regulatory framework. The IOM committee does not believe that the FDA should use its sparse resources to modify the 510(k) clearance process. With regard specifically to CDRH's proposed recommendation 5, the IOM committee's report includes an extensive discussion of issues related to the lack of clarity in the phrases *intended use* and *indications for use*. It is not clear to the IOM committee how combining these regulatory phrases would lead to more consistency and transparency.

On behalf of the IOM's Committee on the Public-Health Effectiveness of the FDA's 510(k) Clearance Process, I thank you for your support of this study.

Sincerely,
David R. Challoner, MD
Chair, Committee on the Public-Health Effectiveness
of the FDA 510(k) Clearance Process