September 22, 2011

Division of Documents Management, HFA-305
Food and Drug Administration,
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Request for Comments: [FDA-2011-N-0556]: Center for Devices and Radiological Health 510(k) Clearance Process; Institute of Medicine Report: “Medical Devices and the Public's Health, the FDA 510(k) Clearance Process at 35 Years;”

The National Organization for Rare Disorders (NORD), welcomes the opportunity to provide comments on the Institute of Medicine’s recent report, “Medical Devices and the Public’s health: The FDA 510(k) Clearance Process at 35 Years,” published on the IOM’s website (http://www.iom.edu). The National Organization for Rare Disorders represents approximately 30 million Americans who have one of nearly 7,000 rare diseases. NORD applauds the considerable effort invested in the recent Institute of Medicine (IoM) report.

Medical devices are very important to the health and well-being of people with rare diseases. Dr. Shuren, we have heard you say many times that a patient can leave a doctor’s office without a prescription, but not without coming into contact with a medical device. Many medical devices for people with rare diseases have been brought to market through the 510K process, including critical in vitro diagnostics for muscular dystrophy, cystic fibrosis and many rare infectious diseases.

The IOM clearly did a comprehensive job of examining the 510k process. Especially noteworthy is the recommendation in the report for the FDA to develop and implement a comprehensive strategy to collect, analyze and act on post-market performance information. An effective post-marketing surveillance system is essential to assure that medical devices are being used safely, and we urge CDRH to take appropriate steps to improve and advance the collection of data about devices that are being used in medical care.

Also valuable is the recommendation that FDA commission an assessment to determine the effect of its regulatory process on facilitating or inhibiting innovation. We in the rare disease community are wholly reliant on innovation; innovative medical products are central to our hope for new treatments.

At the same time, NORD advises prudent caution in considering the recommendation to replace the 510K process as a means by which medical devices are brought to market. Because the 510K process has proven itself a regulatory mechanism that has delivered to the marketplace tangible products of considerable value to people with rare diseases, NORD recommends that careful consideration be given to any efforts to create an alternative to the 510K process.
These are challenging times for the FDA and for medical care more generally. The FDA budget is not likely to grow in the immediate years ahead, which means you must be wise in how you spend your resources. We would be concerned if changes are made to the 510k process that increase the burden on the FDA in a manner that would slow down the introduction of products that will enhance patient care, even incrementally over existing products.

NORD commends the leadership of the FDA Center for Devices and Radiological Health for commissioning the IoM report and for examining the approval processes and the role they play in product innovation and better treatments for patients with rare diseases. We fully appreciate that these are challenging times and we at NORD look forward to continued collaboration as FDA approval processes are further refined.

Again, we greatly appreciate the opportunity to share our perspective about the IOM’s report, and the 510(k) Clearance Process generally. NORD looks forward to future opportunities to bring the concerns of patients with rare diseases to your attention in the hope of strengthening patient health through effective policy at the Center for Devices and Radiological Health. NORD is committed to working with the Center on this and other issues of mutual concern. Likewise, NORD welcomes and is prepared to answer any questions that you and your colleagues may have on the effect of CDRH policies and regulations on the rare disease community.

For additional information, please contact Diane Edquist Dorman, Vice President, Public Policy at ddorman@rarediseases.org or (202) 588-5700.

Sincerely,

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