

July 3, 2013

The Honorable Sylvia Mathews Burwell  
Director  
Office of Management and Budget  
243 Old Executive Office Building  
Washington, DC 20503

Re: Review of final rule for FDA's Unique Device Identification System

Dear Director Mathews Burwell,

As members of the Patient, Consumer, and Public Health Coalition, we urge the Office of Management and Budget to release the final Unique Device Identification (UDI) rule as soon as possible, and to ensure that the rule mandates a system that requires identifying information both on the packaging and the devices themselves.

Our Coalition includes organizations and individuals that represent patients, consumers, physicians, scientists, and researchers, and is dedicated to improving health care through the use of evidence-based medicine and works to ensure that the drugs and medical devices available to patients and consumers are safe and effective.

We are writing to you in the hopes that you will recognize that the OMB has a crucial public health role to play in expediting long-delayed release of this rule and ensuring that the final rule achieves its stated public health goals. Because the rule has been more than five years in the making, and in its proposed version remained under OMB scrutiny for 12 months, we wanted to express our concern that OMB release the final rule as soon as possible.

Currently, when implanted medical devices are found to be unsafe by the FDA and recalled by device makers, there is no way to ensure that affected patients and their doctors are informed. The owners of recalled cars have more information than patients with dangerously defective pacemakers. According to a 2011 report by the Government Accountability Office, when devices are recalled, medical device companies are able to locate fewer than half the defective devices.

Congress took action to address this problem six years ago. In 2007, it asked the FDA to promulgate regulations that would mandate a tracking system for medical devices. Unfortunately however, the UDI rule has encountered delays at every step of the process. FDA development of the proposed rule went on for nearly 4 years and the OMB review of the proposed rule lasted approximately a full year. When the FDA failed to promulgate regulations, Congress again in 2012 passed a law mandating release and implementation of the final UDI rule, and this time gave the FDA a firm timetable. On June 19, the FDA missed the Congressionally mandated deadline for the release of the final rule, which we understand is still under review at OMB. We strongly urge you to prioritize this review and expedite release of the final rule within the next month.

Implementation of the UDI system will strengthen two core components of the Food and Drug Administration's (FDA) device safety system: 1) the post-market safety surveillance of medical devices, and 2) medical device recalls. Patients, consumers, health care professionals, and device

manufacturers will be able to more accurately report adverse events to the FDA, and to determine if the problem is more likely due to a design flaw or to manufacturing problems that impacted specific devices made on particular days or weeks. This will also facilitate faster and more efficient and cost-effective device recalls.

But a tracking system cannot rely on identifying information on package materials alone. We also want to express our strong opposition to any effort to reduce costs by putting UDIs only on the packaging rather than on the devices. This would be a short-sighted savings measure because medical devices are often separated from their packaging before they are used by patients, and the packaging is often discarded. Therefore, it is essential that the UDI be on the device as well as the package, and that the UDI label on the package of any implanted devices be scanned into the patient's medical record. A UDI is essentially useless if it is only on packaging that has been lost or discarded, so only using the packaging would undermine the effectiveness of the entire UDI system.

The UDI rule will also result in significant cost savings across the healthcare system. An analysis by Drs. Eugene Schneller and Larry Smeltzer, Arizona State University's Carey School of Business, estimates that the increased efficiency and accuracy of a UDI system will save manufacturers, distributors and health care providers \$16 billion annually. Patients, consumers, and the healthcare delivery system will save money because the UDI system will enable the collection of data that will reduce the use of inferior or defective medical devices and remove defective devices from the market in a more timely manner.

We greatly appreciate your attention to this matter.

Sincerely,

Annie Appleseed Project  
Breast Cancer Action  
Center for Medical Consumers  
Connecticut Center for Patient Safety  
Consumers Union  
Jacobs Institute of Women's Health  
National Consumers League  
National Physicians Alliance  
National Research Center for Women & Families/ Cancer Prevention and Treatment Fund  
National Women's Health Network  
Our Bodies Ourselves  
Public Citizen  
Reproductive Health Technologies Project  
The TMJ Association, Ltd.  
Truth in Medicine Incorporated  
Union of Concerned Scientists  
WomenHeart: The National Coalition for Women with Heart Disease  
Woody Matters