

**America's Health
Insurance Plans**

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November 8, 2006

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

Re: Unique Device Identification; Request for Comments
[Docket No. 2006N-0292]

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing in response to a Request for Comments on Unique Device Identification (UDI) published by the Food and Drug Administration (FDA) in the *Federal Register* on August 11, 2006 (71 Fed. Reg. 46233)

AHIP is the national trade association representing the private sector in health care. AHIP's nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans.

AHIP strongly supports efforts to more accurately identify and track medical devices and believes that such initiatives will improve health care quality and effectiveness and patient safety. As noted in a recent report to the FDA, the creation of a unique device identifier has the potential to reduce medical errors, facilitate recalls, improve reimbursement and inventory control, and reduce product counterfeiting.¹

Adopt a Unique Medical Device Identifier

The FDA should use its rulemaking authority to adopt a unique device identification system in a manner similar to the regulations for the bar coding of certain types of human drugs and biologics (21 C.F.R. Parts 201, 606, and 610). Each medical device should be assigned a universal product number (UPN) created by either by the Health Industry Business Communications Council or the GSI organization.

As part of the UDI final rule, the FDA should "harmonize" the process for the assignment of UPNs by these two organizations. A process should be created to require medical device manufacturers to assign a single, unique number to identify each medical device. In order to ensure patient safety and to enable tracking of a device to a specific patient, all singular device items should be tagged and not aggregated by lots (e.g., surgical sponges, tubing, etc.).

¹ *ERG Final Report: Unique Identification for Medical Devices*, March 22, 2006.

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Phase-In Adoption of Device Identifiers

While the use of an UPN should be required for all medical devices, the FDA may wish to consider appropriate and timely phase-in of the adoption of device identifiers. Initial efforts should focus on use of UPNs on Class III medical devices (which by definition pose a safety risk) with subsequent adoption on Class II and Class I devices. The highest priority for UPN use should be assigned to implantable medical devices which have the most inherent risk to a patient.

Use Device Identifiers in Reporting and Investigational Studies

The FDA should develop standards requiring the linking of medical device identifiers to adverse event reporting. The use of identifiers should also be required in all investigational and research studies involving medical devices. In addition, the FDA should take steps to incorporate the UPN into any databases that collect and maintain information about medical devices.

The FDA should also reach out to stakeholder groups involved in the collection and use of health information to encourage the use of device identifiers. This initiative should include the standards development organizations responsible for creating electronic health care transactions (ANSI X12, Health Level 7, National Uniform Claims Committee, and the National Uniform Billing Committee) as well as public and private bodies involved in the creation of standards for health information technology (Certification Commission for Health Information Technology and Health Information Technology Standards Panel).

We also strongly believe that health insurance plans should be included in the development and implementation of a UDI system. Health insurance plans serve as a nexus between patients, health care providers, and device manufacturers, and could assist the FDA in implementing an effective program to use UDNs in post-marketing reporting and investigational studies.

Promote Interoperability

The UDI system (including hardware and software) should be interoperable. For example, software should have standardized parameters and an open source code, allowing full access for software and hardware developers, thereby enhancing competition and constraining health care costs.

Creating a New Regulatory Approach

In addition, we would ask the FDA to consider its overall approach to the regulation of drugs, biologics, and medical devices. In particular, AHIP urges the FDA to adopt the recommendations included in our March 14, 2006 letter regarding the Medical Device User Fee

November 8, 2006

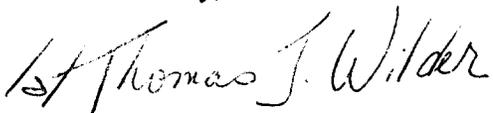
Page 3

Modernization Act of 2002. The comment letter, which is attached, outlined five recommendations to facilitate the transition to a more evidence-based, safe, and effective health care system:

- Require and adequately fund post-market studies of prescription drugs, biological products, and medical devices.
- Develop public-private partnerships to conduct post-marketing studies of drugs and devices.
- Provide early warning monitoring through linkages to the National Health Information Infrastructure.
- Establish procedures to track implanted medical devices.
- Encourage accountability for device failures.

AHIP believes the FDA has an important role in protecting patient safety and encouraging quality and cost-effective health care. We support the development and adoption of unique identifiers for medical devices and look forward to working with the FDA on this important initiative.

Sincerely,

A handwritten signature in cursive script that reads "Thomas J. Wilder".

Thomas J. Wilder
Vice President, Private Market Regulation

Attachment

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Insurance Plans**

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03/14/06 11:15 AM

March 14, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
United States Food and Drug Administration
Office of the Commissioner
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: The Medical Device User Fee Modernization Act of 2002 – Docket No. 02N-05341

Dear Dr. von Eschenbach:

I am writing on behalf of America's Health Insurance Plans (AHIP) representing 1,300 member companies providing health insurance coverage to more than 200 million Americans to provide comments on the Medical Device User Fee Modernization Act and to follow-up on previous discussions with your staff about collaborative initiatives to improve the safety and efficacy of pharmaceutical products and medical devices.

Our comments are designed to urge you to consider analyzing the long-term safety and effectiveness of prescription drugs, biological products, and medical devices as part of FDA's enforcement activity and to set aside funding for ongoing effectiveness analysis and comparisons across available treatments. We believe the agency has an important role to play in facilitating the transition to a more evidence-based, safe, and effective health care system and we are making five recommendations to help achieve these goals.

1. Require and Adequately Fund Post-Market Studies of Prescription Drugs, Biological Products, and Medical Devices

The FDA has committed significant resources to pre-market testing of prescription drugs, biological products, and medical devices through funding available under the Prescription Drug User Fee Act and the Medical Device User Fee Act. As the population ages and the number of individuals with multiple chronic diseases increases, it is critical that FDA expand its activities to include post-marketing surveillance that focuses on the long-term effects of drugs, biologics, and devices.

We believe that FDA should require manufacturers to conduct selected post-market studies of their products, including situations where safety concerns have not been raised, to determine if the drug, biologic, or device is safe, effective, and fulfilling its intended purpose. In addition, FDA should seek adequate support for its post-market surveillance activities through user fee funding. The Prescription Drug User Fee Act and the Medical Device User Fee Act provide critical resources to conduct cost-effective and efficient review of new prescription drugs, biological products, and medical devices. We support reauthorization of these two important laws, which are scheduled to expire next year, and urge the earmarking of specific user fee funds for both pre- and post-market studies of prescription drugs, biological products, and medical devices.



2. Develop Public-Private Partnerships to Conduct Post-Marketing Studies of Drugs and Devices

An overwhelming majority of Americans have their health care financed through or administered by health insurance plans. As a result, health insurance plans have comprehensive data sets that could be used in evaluating safety and effectiveness. We recommend that FDA work with health plans and other key stakeholders to design post-marketing studies that will draw upon these de-identified data. We would be delighted to bring together representatives of health plans and FDA staff to discuss this issue.

The Centers for Medicare & Medicaid Services (CMS) also can provide important information about drug, biologic, and device usage for older Americans and for the disabled. These data, coupled with information available from health insurance plans, could provide an expanded view of how prescription drugs, biological products, and devices impact patient outcomes.

We recommend that FDA work with CMS to establish appropriate protocols to utilize Medicare data in the development of post-marketing studies. We are available to participate in this dialogue to ensure that data sets available from health insurance plans can be integrated into data available from CMS.

3. Provider Early Warning Monitoring Through Linkages to the National Health Information Infrastructure

Health plans have taken a leading role in using information technology to improve health quality and care outcomes through activities such as electronic prescribing, creation of personal health records, and development of decision support tools for consumers and caregivers. These initiatives are part of a larger effort by the health care community to create an electronic "health information highway" to link physicians, hospitals, health plans, state and federal governments, and consumers.

We recommend that FDA consider ways to monitor drug and device safety through linkages with public and private health data systems. Such linkages will provide the tools to obtain early indications of potential problems with prescription drugs, biologics, and medical devices that impact patient safety.

4. Establish Procedures to Track Implanted Medical Devices

FDA's Center for Devices and Radiological Health (CDRH) recently published a report (*Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program*) discussing its process for post-market surveillance of medical devices. One important issue raised in the report is the lack of complete documentation in health care records at the time devices are implanted which results in an inability to monitor device performance. Unlike prescription drugs, which have a National Drug Code identifier, there is no currently reliable system to track medical devices.

We recommend FDA work with health plans, health care providers, standards organizations, and other stakeholders to establish procedures to track medical devices. This process should include the development of unique identifiers for medical devices that can be used for health reporting purposes and in the claims and payment process (such as the UB 04, HCFA 1500, and HIPAA 837 claim forms). In

March 14, 2006
Page 3



addition, a process should be developed to identify medical procedures that are performed as a result of device failures.

5. Encourage Accountability for Device Failures

Recent recalls of implantable defibrillators and pacemakers highlight the impact of device failures on patient safety and the cost of medical care. If device manufacturers are not held accountable for medical expenses associated with voluntary and involuntary device recalls, these costs are shifted to the public at large. We believe that manufacturers are responsible for all expenses related to a recall, including replacement costs, hospitalization, surgery, and other medical procedures to replace or repair the device. We recommend FDA use its existing authority to establish a process for medical device manufacturers to assume the cost of voluntary and involuntary device recalls. We have previously shared with FDA's General Counsel an analysis of this authority and would be happy to discuss this issue with you.

We believe the Food and Drug Administration plays an essential role in protecting patient safety and promoting quality health care for all Americans and we look forward to continuing our dialogue on how health plans can assist the FDA in this critical endeavor.

Sincerely,

A handwritten signature in black ink that reads "Karen Ignagni". The signature is written in a cursive, flowing style.

Karen Ignagni