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**Comments of the American Association of People with Disabilities (AAPD) to the U.S. Department Of Health and Human Services, Food and Drug Administration**

**In Re Docket Number: 2006N-0292 (71 FR 46233)**

**--Unique Device Identification (UDI) System**

November 6, 2006

The American Association of People with Disabilities (AAPD) AAPD is the largest national nonprofit cross-disability member organization in the United States, dedicated to ensuring political empowerment and economic self-sufficiency for the more than 51 million Americans with disabilities. AAPD works in coalition with other disability organizations for the full implementation and enforcement of disability nondiscrimination laws, particularly the Americans with Disabilities Act (ADA) of 1990 and the Rehabilitation Act of 1973, and other statutes.

**Comment on Specific UDI Issues for Medical Devices:**

The FDA invites comments about specific UDI issues for medical devices.

While a multitude of stakeholders and academics have offered a variety of opinions on the topic to date, the FDA has not formally decided whether or not to create and implement such a system, and if so, how and to what extent. Be it cochlear implants, insulin pumps, prosthetic limbs, or more commonplace medical devices like contact lenses or alcohol swabs, Americans with disabilities are most certainly critical users of the medical devices at issue for potential regulation and post-market surveillance, and as such, the concerns of the disability community must be heard during these preliminary days of planning.

AAPD supports policies which increase efficiency and consistent quality in the delivery of medical products and services aimed at producing optimal outcomes in the health, safety, and general well-being of Americans with disabilities. Further, we support those programs and initiatives which empower consumers to make informed medical decisions and that at all times uphold the integrity of consumer privacy.

AAPD acknowledges the potential consumer benefits of creating a UDI for medical devices, specifically with regard to improved medical accuracy. We recognize, however, that to the extent that such a system could generate direct or indirect linkages to a patient's medical records, a UDI necessarily implicates privacy concerns. Therefore, we urge the FDA to give preeminence to the integrity and confidentiality of the patient health record when weighing the pros and cons of developing a UDI, when choosing a technology to employ in the instance of deciding affirmatively to pursue such a system, and when regulating how such a system and any accompanying databases will be used.

As discourse continues to evolve around the development and implementation of a UDI for medical devices, regard for the concerns of the disability community – often high-use

consumers of medical devices and services – will help to ensure that *all* consumers' interests in privacy are represented equitably.

Respectfully,

A handwritten signature in black ink that reads "Andrew J. Imparato". The signature is written in a cursive style with a large initial 'A'.

Andrew J. Imparato  
President and CEO  
American Association of People with Disabilities

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