

**The Honorable Darlene Hooley**  
**Statement for MDUFMA Manager's Amendment**  
**Committee on Energy & Commerce**  
**Markup: FDA Bills (Thursday, June 21<sup>st</sup>)**

---

Thank you Mr. Chairman.

I once again want to express my appreciation to the Chairman, Mr. Pallone, and the majority and minority committee staffs for working with me to require FDA to promulgate regulations to establish a unique device identification (UDI) system for medical devices. The FDA has been working with stakeholders for many years to develop a UDI system. The manager's amendment will require the FDA to move forward with that process.

I believe the UDI language included in the manager's amendment will create an increased sense of purpose and urgency behind the FDA's efforts to implement this important system. The time to move forward with a UDI system is now and thankfully this amendment will help achieve that objective.

I want to also commend Mr. Doyle, Dr. Burgess, Mr. Hall, and the many stakeholders with whom I worked to get the UDI provision included in MDUFMA. In particular, Mr. Doyle has shown tremendous leadership on this issue. An extraordinarily diverse group of stakeholders has been working very hard to promote this important patient safety issue. The Coalition of stakeholders who supported our efforts to get UDI provisions in MDUFMA included the American Medical Association, the American Hospital Association, AARP, the American Heart Association, the National Rural Health Association, and many others. I believe the diversity of the stakeholders supporting this issue clearly indicates the importance of UDI to public health.

A UDI system will provide tremendous benefits to patients. Currently, most medical devices cannot be tracked or identified in any systemic fashion. A UDI will enable FDA to better pinpoint devices associated with adverse events and look for patterns across event reports. A more sophisticated reporting system will thus strengthen FDA's post-market surveillance capabilities. A UDI system will not only provide FDA with the tools to discover warning signs of a defective device earlier, thus potentially saving lives, but will also improve the agency's ability to promptly respond to device recalls. I believe our current system for notifying patients in the event of a recall is deficient. When defective medical devices are recalled, the absence of a standard identification system hinders the FDA's ability to notify patients. This amendment takes an important step toward improving the ability of the FDA, device manufacturers, and physicians to quickly and effectively communicate risk information to patients.

Over 600 medical devices are recalled each year. I am particularly concerned about Class I recalls, which the FDA characterizes as having a "reasonable chance" that the product will cause "serious health problems or death." Although many recalls do not present a serious health risk, the approximately 10 percent of recalls each year that do raise the most serious health concerns can be better managed by the FDA with the information provided by UDI. Quicker and

better ways of informing patients may save their lives and at a minimum help preserve their health.

The UDI system's potential will increase exponentially with the introduction of more advanced health information technology. After electronic medical records become standard, we may have the ability to measure the impact each medical device has on clinical outcomes. Comparative effectiveness studies may thus ultimately be possible to determine which devices work best. Although data with that level of sophistication may not be available in the short term, UDI opens up that possibility as health IT catches up with its promise.

Not only will patient health outcomes benefit if and when comparative data is available, but physicians and patients will have more information to help make cost effective treatment decisions. Moreover, supply chain efficiency will be greatly improved through implementation of UDI, which will result in further savings.

UDI is the key to unlocking those significant public health benefits and also sizable financial savings.

I look forward to seeing the FDA speed up its consideration of a UDI system for medical devices. I hope the FDA will now promptly promulgate rules to implement such a system.

Thank you Mr. Chairman.