

# Congress of the United States

Washington, DC 20515

May 7, 2007

Commissioner Andrew C. Von Eschenbach  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Parklawn Building, Room 14-7  
Rockville, Maryland 20857-0002

Dear Commissioner von Eschenbach:

We are writing to express our strong interest in seeing the U.S. Food and Drug Administration (FDA) require a national unique device identification (UDI) system for medical devices as soon as possible. We have witnessed first-hand the multiple and varied product numbering and coding systems by visiting hospitals and other health care facilities in our districts. The officials who run these facilities have expressed to us their concern about the negative impact that these multiple coding systems have on our health care system. Our provider constituents overwhelmingly believe that a national UDI would improve patient safety, reduce medical errors, enhance device recall processes, and improve device adverse event reporting. We believe that our nation's health care system will benefit by having a defined UDI with a global nomenclature that complements the FDA National Drug Code system.

In May of 2005, several of us wrote the FDA to inquire about its intentions for plans to require the bar coding of medical devices. Since that letter was sent, the FDA and the Agency for Healthcare Research and Quality (AHRQ) have commented that an urgent need exists for a unique identifier for medical devices. At the FDA's recent public meeting on October 25, 2006 the Centers for Medicare and Medicaid Services (CMS) and the Department of Defense (DoD) also voiced support for UDI.

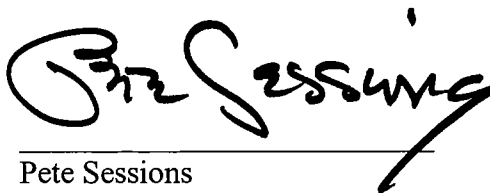
A national UDI standard has great potential for our entire health care system. It will benefit manufacturers and improve patient safety by reducing the potential for counterfeit products being used on a patient. Also, several of us have been working with health care organizations in our districts to promote electronic health records (EHRs) and Regional Health Information Organizations (RHIOs). A UDI standard would help contribute to the success of those electronic systems and improve patient care by providing appropriate health care providers with accurate information.

We appreciate the great effort that the FDA has put into the national UDI standard issue under your leadership. As technology continues to evolve, we believe that our health care system must have the appropriate standards to help facilitate that technology and enhance patient safety and improve health care efficiency.

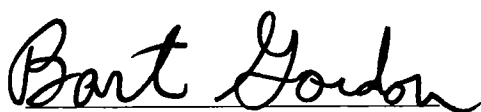
Sincerely,



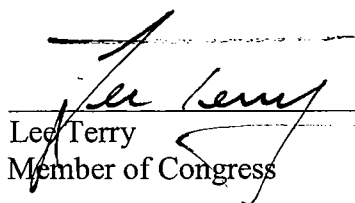
Mike Doyle  
Member of Congress



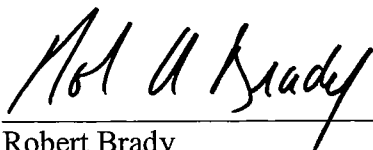
Pete Sessions  
Member of Congress



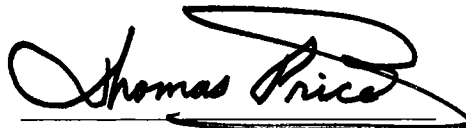
Bart Gordon  
Member of Congress



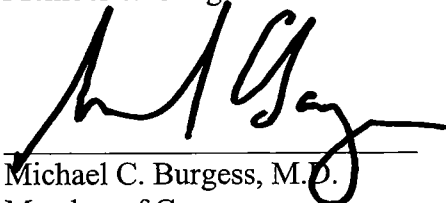
Lee Terry  
Member of Congress



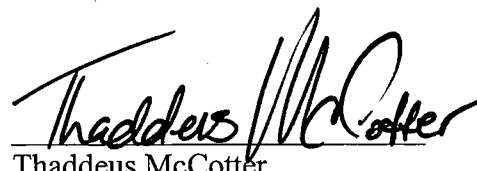
Robert Brady  
Member of Congress



Tom Price  
Member of Congress



Michael C. Burgess, M.D.  
Member of Congress



Thaddeus McCotter  
Member of Congress



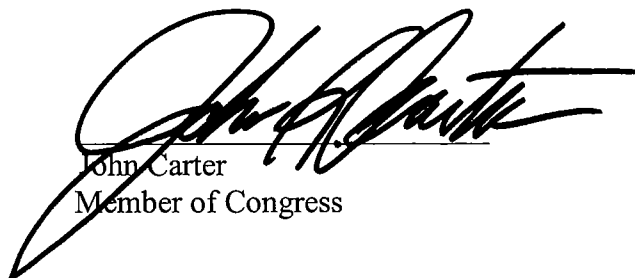
Bob Etheridge  
Member of Congress



Jason Altmire  
Member of Congress



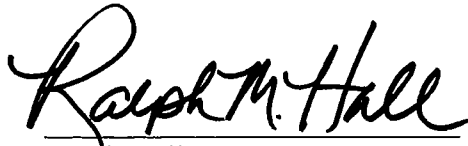
Todd Platts  
Member of Congress



John Carter  
Member of Congress



David Price  
Member of Congress



Ralph Hall  
Member of Congress



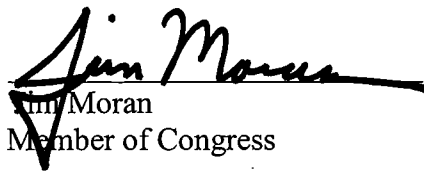
David Davis  
Member of Congress



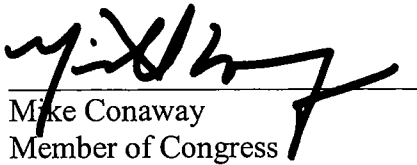
Stephanie Herseth  
Member of Congress



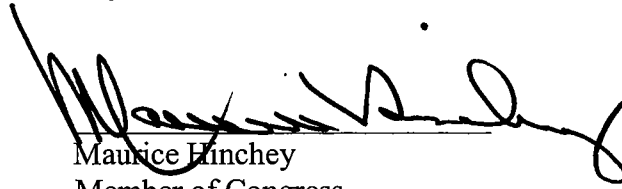
Linda Sanchez  
Member of Congress



Jim Moran  
Member of Congress



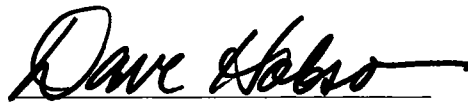
Mike Conaway  
Member of Congress



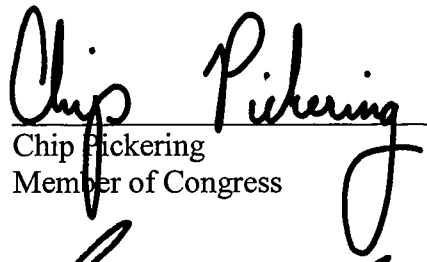
Maurice Hinchey  
Member of Congress



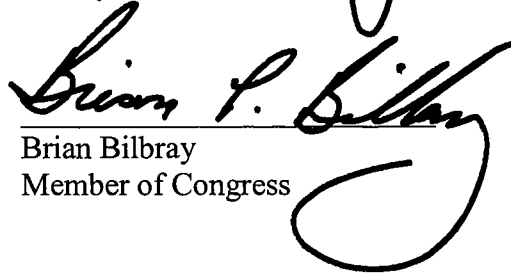
Silvestre Reyes  
Member of Congress




David Hobson  
Member of Congress

  
Chip Pickering  
Member of Congress

  
Diane Watson  
Member of Congress

  
Brian Bilbray  
Member of Congress

  
Michael Turner  
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