November 9, 2006

Re: FDA NPR, Unique Device Identifiers

To Whom it May Concern:

My formal comments are that as proposed, the FDA’s UDI concept will not likely directly improve patient safety. The assignment of a UDI for each appropriate device and accessory will merely be a more uniform – and possibly duplicate – indication of serial numbers/lot numbers/batch numbers, etc. Any form of national registry of such numbers will not radically change the situation one bit, even if they are machine readable with bar-code or other technology. Ignoring for the moment that nearly half of healthcare is taking place OUTSIDE the hospital’s walls, in the event of a recall or accident, any individual hospital will still have to track down the device and all related accessories and supplies. Having managed a fleet of 500,000 medical devices, I can tell you from experience the proposed solution won’t help much, if at all.

The only way a UDI can significantly improve the patient safety and healthcare efficiency process is if the UDI is part of a fully-formed electronically-communicated and tracking framework, using wireless or wired methods. This will assist in tracking, electronic data capture, and, ultimately, billing and outcome analysis.

I also believe that a major omission in the current concept is the lack of commitment to a national nomenclature for devices, accessories, and supplies. Again, from three decades of experience, I can firmly assert that failure to make that commitment will render any UDI system virtually useless. Ignorance, illiteracy, mistakes, and creative marketing will all rapidly dismantle any non-standardized system the FDA mandates. It would be far better to simultaneously approve ECRI’s UMDNS and the European GMDNS as somewhat disparate but roughly parallel systems than to remain silent on the topic. US hospitals can ill afford to suddenly replace ECRI’s system, and ECRI itself deserves fairer treatment than to be forced to abandon three decades of seminal work that helped put this field within striking distance of achieving a major milestone like this.

I also believe that FDA MUST mandate a simple check-digit addition to either or both of the to the UMDNS and GMDNS codes to prevent dangerous transcription errors. Such a check digit is urgently needed, as it is the only way to protect patient-critical data in the event of inevitable information system failures, during which periods manual data capture will absolutely be required. In addition, I strongly recommend that UMDNS and GMDNS be required to provide a simple, lay-person nomenclature look-up to match their codes in order to really make it useful for reports and widespread deployment.

In addition, the FDA has an obligation to carefully consider the privacy and security aspects and requirements of any UDI system. Included in security must be the HIPAA-mandated dimensions of Confidentiality, Integrity, and Availability. If the FDA fails to include these factors into any systemic design, the system will NOT be adopted or supported at the hospital and clinician level. Furthermore, the FDA should probably place restrictions on its own use of such a system; open access for random data mining that threatens the privacy or security of hospitals, physicians,
nurses, or patients will not be tolerable or sustainable. Passive-aggressive tactics like simply exchanging external cases, accessories, cables, motherboards, or other components will make a sham of the whole exercise.

Lastly, I believe that the hospitals’ Clinical Engineering community, the American College of Clinical Engineering, the ACCE Healthcare Technology Foundation, and HIMSS should all be engaged in the final design of this system. Despite your present research partners’ good will, competence, and expertise, none of them do repairs and maintenance and they DO NOT run healthcare information system platforms in hospitals on a 24x7 basis. The FDA MUST have clear guidance from the individuals and organizations that use these tools daily in order to develop a viable system.

I would request by way of this letter that my comments during the public meeting be appended to this letter for consideration. For validation of my expertise, I am also including a copy of my CV on the following pages.

Sincerely,

Elliot B. Sloane, Ph.D.
Assistant Professor, Villanova DIT Department
Co-Chair IHE Strategic Development Committee
Co-Chair IHE Patient Care Device Domain
Career

Villanova University, Villanova School of Business, Villanova, PA May, 2000 - present

Assistant Professor of Decision and Information Technologies  eBusiness, Databases, Telecommunications, Biomedical Informatics, and Business Ethics for Executive MBA, MBA, and undergraduates. Research and publication in the Biomedical Informatics, Health Systems Engineering, and Decision Support fields.


Vice President, Operations, Clinical & Information Engineering, Quality/Regulatory Assurance

Major business segments included medical devices and pharmaceuticals. Largest US life-support technology distribution, rental, and repair company. $300 Million revenue, 20% EBITDA, with offices in over 100 cities in US. 1500 employees provided 365 day/24-hour services to 11,000 hospital, nursing, and home care customers. FDA-registered medical device manufacturer, and licensed for nationwide drug and surgical supply distribution.


Vice President, Operations (COO); Vice President, Information Systems (CIO) World-renowned medical device research, testing, database, publishing, education, and international consulting agency. Biomedical engineering, computer software and hardware development. President of NIST, ECRI’s for-profit subsidiary.

Education

Ph.D. 1999  Drexel University College of Information Science and Technology. (Human computer interaction)

M.S. 1982  Drexel University College of Electrical Engineering (Computer/Digital Design)

B.S. 1975  Cornell University College of Engineering (Electrical/Biomedical Engineering)

Industry Highlights

In his executive career prior to entering academia, Dr. Sloane was a successful team and leader for global and strategic biomedical engineering and healthcare information system projects.

He built a proven track record of reliable business program development and product/service delivery to in-house and outside customers, including:

- System design, development and implementation for information systems, biomedical /clinical engineering, research, management, finance, administration, manufacturing, publishing, and quality;
- Introduction and implementation of leading-edge information technologies, including PC/LAN business applications, SQL database, CD-ROM/WORM document scanning, OCR and archiving, working-group systems, Internet services, bar-coded asset tracking, and maintenance management; Technology acquisition, implementation management and consulting for information system, database, telecommunication, plant/facility, and health care/life-support technologies;
- Development, design, manufacturing and distribution experience for FDA-regulated medical devices and drugs (GMP, cGMP, CE, CSA, and UL compliance; ISO 9000 programs);
- New business development and merger/acquisition expertise, including international, corporate, government, and non-profit frameworks; Successful sales, marketing, and presentation roles, including international education, training, and writing. Extensive Board of Directors experience, including corporate, non-profit, and charitable organizations.

Affiliations

AAMI  Association for the Advancement of Medical Instrumentation

- Biomedical Engineering Management and Productivity Committee Co-Chair, since 1988

ACCE  American College of Clinical Engineering, since 1996.

- President, 2001/2002; Chair of Integrating the Healthcare Environment and Patient Safety Task Forces

ACCE Healthcare Technology Foundation, a 501(c)(3) educational foundation, since 2001.

- Founding Board Member, Chair of Finance and Budget Committee
AITP Association for Information Technology Professionals (formerly DPMA), since 1982.

- President, 1993 and 1997/98; Executive Vice President 2000-2002, Montgomery County, PA Chapter.

Ben Franklin Technology Center of Philadelphia - Biomedical Investments Reviewer since 1999.

Carelift International Medical relief & training for developing countries; Board of Directors, 1994-2005.


IEEE Institute of Electrical and Electronic Engineers, since 1976


National Institutes of Health ElderCare Biomedical Technology Grant Review Panel, since 2004.

WHO World Health Organization and Pan American Health Organization (PAHO)

- Clinical Engineering Advisor, 1988-present

Editorial

Biomedical Instrumentation Technology Journal, since 1990.

Boards

Technology for Respiratory Therapy, since 1990.

International Journal of Networks and Virtual Organizations, since 2006.

International Journal of Biomedical Engineering and Technology, since 2006.

For updates, see current information at Research and Presentations section of: www.homepage.villanova.edu/elliotsloane.

Refereed Journal Articles


Refereed Conference Papers/Proceedings


5) “Clinical/Biomedical Engineering Strategic Graphical Dashboard To Enhance Medical Device Maintenance And Asset Management” with Eric Rosow, Joe Adam, Dave Shine Proceedings Of The Twelfth Americas Conference On Information Systems, Acapulco, Mexico August 04th-06th 2006. In production.


15) "Integrating the Healthcare Enterprise - Alarm Integration and Interoperability for Patient Care Devices" HIMSS (Health Information Management Systems Society) Annual Conference, Dallas, TX, February 13-17, 2005.


22) "Case studies of graphically enhanced computer software to improve MIS and clinical decisions" with Liberatore and Nydick. AMCIS (Association of Information Systems) Annual Conference, Orlando, FL, August 4-6, 2003 http://aisel.isworld.org/proceedings/amcis/2003/program.asp


Pedagogy-related conference and collegiate activities


Inaugural Senior Undergraduate Course: Clinical Engineering for Biomedical Engineering Students. Summer 2006 Semester, Biomedical Engineering Department of the San Jose Medical School, Technologia de Monterrey, Mexico. June-July, 2006.


Healthcare Information Technology Curriculum Panel (Refereed Panel co-chair, Moderator, and Panelist); AMCIS (Association of Information Systems) Annual Conference. Omaha, NB, August 11-14, 2005.


Association of Information Technology Professionals (AITP) Montgomery County and Philadelphia Suburban Collegiate Liaison, Career, and Activity Advisor (2000-2006). Villanova University, Delaware Valley College, Gwynedd Mercy College, Penn State Abington Campus, Widener University

- Coordinator and advisor for annual AITP collegiate CIO curriculum committees for each Student Chapter
- Head of annual Student Chapter scholarship and collegiate conference grant committees
- Head of annual MIS Student’s Career Regional CIO Roundtables.


Clinical Engineering curriculum advisor, Drexel University School of Biomedical Engineering. 2001 and 2003.

US Executive or Industry Education (Conferences and publications)


3) “Clinical Engineers Working in the IHE Initiative” with Ray Zambuto. 24x7 Magazine, May 2000

4) “An Industry and Standards Perspective on FDA’s Unique Device Identifier NPR” Testimony to the Food and Drug Administration public meeting about the Notice of Proposed Rulemaking. 25 October, 2006, Gaithersburg, MD.


7) "Healthcare IT Investments" Service Industry Association (SIA) Executive Summit, Las Vegas, NV, March 5-7, 2006.


9) "Business Cases and “Warp Speed Ahead” to Patient Care Device Interoperability! Co-Presenter/Author with Ray Zambuto and Todd Cooper. HIMSS ’06 Annual Conference, San Diego, CA, 12-16 February 2006.

10) "Successful Integration of Medical Devices and Information Systems" AAMI 21st Annual Conference, May 2005, Tampa, FL.

11) "From Connectors to Care Records, Making the Link: Medical Device Interface Solutions," with Todd Cooper. Medical Records Institute TEPR 2005 Annual Conference, Salt Lake City, UT, 14-18 May 2005.


13) "Integrating the Healthcare Enterprise (IHE) Healthcare Industry Demonstration Showcase - Alarm Integration and Interoperability for Patient Care Devices" HIMSS ’05 Annual Conference, Dallas, TX, February 13-17, 2005.


18) "Philadelphia Regional Health Information Organizations and Shared Clinical Trial Information Systems" Drexel School of Biomedical Engineering and College of Medicine Panel, January 2004.

19) “Re-engineering the healthcare enterprise,” Colloquium of the Drexel College of Biomedical Engineering, October 2003


27) "E-Health: MIS Challenges and Opportunities in Healthcare” AITP-Montgomery County, PA. April, 2002.


29) “Managing Clinical Engineering and Information Technology – Point-Counterpoint” AAMI 17th Annual Conference, 9-12 June 2001 Baltimore, MD, with Ben Clark, LaDonna Shedor, Alan Lipschultz, and Leo Gilmore


International Executive Education and Pedagogy


“Information Technologies in Healthcare” via Internet 2 Live Telecast to the College of Medicine and Biomedical Engineering, TEC Univeristy of Monterrey, MX, 2003.

Clinical Engineering and Healthcare Information Technology Executive Faculty, World Health Organization (WHO) and Pan American Health Organization (PAHO) (2000-2006)

- Advanced Clinical Engineering Workshop (ACEW) Curriculum Committee, 2005. 5-day executive management leadership and education program for Ministry of Health officials, hospital administrators, physicians, nurses, and clinical engineers.
Academic Book Chapters:


Editorial Boards:

Biomedical Instrumentation Technology Journal, since 1990.
Technology for Respiratory Therapy, since 1990.
International Journal of Networks and Virtual Organizations, since 2006
International Journal of Biomedical Engineering and Technology, since 2006


Industry Awards:

American College of Clinical Engineering’s Thomas O’Dea Clinical Engineering Advocacy Award, June 2006.

University service activities

1) Lead faculty advisor for the Business Ethics Fortnight team that was jointly sponsored by the Commerce and Finance (C&F) Ethics Committee, the C&F Center for Principled Leadership, and the Arts and Science Ethics Program in 2003. Trained and traveled with the team to compete in our first national collegiate competition in April, 2004 at Loyola Marymount University (CA). Successfully invited to the final competition round, and went toe-to-toe with the Naval Academy for first place. Though they didn't win, the students made a very fine showing for our first outing. Supervised the second and third year teams (2005 and 2006) in their competitions at Loyola Marymount in this growing, competitive debate forum.

2) Villanova Center for Professional Ethics planning and advisory committee, College of Arts and Science, 2005 and 2006.

3) College of Commerce and Finance delegate to the Villanova University Who’s Who Committee, Fall 2005.

4) Active member of C&F Ethics Committee in 2003, 2004, 2005, & 2006. Addressed University Mission-related teaching in all C&F majors and also supported the MBA Ethics Debating team events.

5) Participant in Summer ’04 Business Ethics faculty workshop that was co-taught by Ethics and Business Ethics Program Staff. Worked on extending in-class business ethics training to improve the impact and quality of those efforts for Undergraduate and Graduate courses.

Recent professional/industry service activities

1) Co-Chair, HIMSS International Integrating the Healthcare Enterprise (IHE) Strategic Development Committee (Appointed October, 2006)

2) Co-Chair, ACCE Integrating the Healthcare Enterprise Strategic Patient Care Device Domain (Since 2004)

3) NIH Grant Review Committee, Biomedical engineering, medical informatics, and bioengineering , Elder care Technologies for the elderly (since 2003.)

4) Board of Directors, Association of Information Technology Professionals (since 1998)


7) Medical device and information systems IEEE/ISO/ANSI 11073 Standards Committee, Sponsor (Since 2004)

8) Board of Directors American College of Clinical Engineering (2001-2004)

9) Co-Founder and Board of Directors, ACCE Healthcare Technology Foundation. (Since 2004)
11) Investment Grant Biomedical Technology Advisory Committee (medical informatics and medical devices), Ben Franklin Technology Partnership (Since 2001)
Current society and industry organization activities

1) Board of Directors, ACCE Healthcare Technology Foundation.
2) Board of Directors, Association of Information Technology Professionals
3) Board of Directors, IEEE Engineering in Medicine Society (EMBS)
4) Co-chair, AAMI Clinical Engineering and Productivity Management Committee (1988-present)
5) Co-chair ACCE/HIMSS IHE Patient Care Devices Domain (2004-present)
6) Co-chair, Integrating the Healthcare Enterprise (IHE) International Strategic Development Committee, Healthcare Information Systems Society (HIMSS), Radiologic Society of North America (RSNA), and American College of Cardiology (ACC).

Recent conference/paper review chair activities (Note, this list is a selected subset, and is regularly updated)

Annual International Conference of the IEEE Engineering in Medicine and Biology Society

1) Conference Theme Co-Chair, Clinical Engineering. 25th, 26th, 27th, and 28th Annual Conferences. (2003-2007)

Annual International Conference of the Americas Conference on Information Systems (AMCIS)

Pre-Academic Career Publication, Research, and Executive Education Activities
(i.e., prior to joining Villanova University in May, 2000)

Publications and Software Systems: (1984 to present)

“Subacute Care: New Equipment, New Maintenance Concerns”, Nursing Homes Magazine, Vol. 44, No. 8, October 1995

“Rapid Serial Visual Presentation (RSVP) for Professional Tasks: A Trial Study of an Accelerated Reading Display for Citation Relevance Judgments by Domain Experts”, Elliot B. Sloane, Doctoral Dissertation accepted by Drexel University College of Information Science and Technology, July 1999

Health Devices Inspection and Preventive Maintenance System (Book), Contributing Author. ECRI, Plymouth Meeting, PA 1984

Health Devices Annual Sourcebook and Database, Software System Designer and Publisher. ECRI, Plymouth Meeting, PA 1984-1990

Health Devices Product Comparison Report System and Database, Software System Designer and Publisher. ECRI, Plymouth Meeting, PA 1984-1990

Hospital Equipment Control System (IBM PC Software and Book), Principal Software System Designer, Programmer, and Contributing Author. ECRI, Plymouth Meeting, PA 1987

Earlier Publications: Principal investigator and author of these issues of Health Devices Journal, Published by Emergency Care Research Institute (ECRI), Plymouth Meeting

1. "Primer on Medical Oxygen" Vol. 5: No. 10; Aug. 1976
5. "Evaluation: Oxygen/Flowmeter Combinations" Vol. 6: No. 1; Nov. 1976
6. "Evaluation: Oxygen Masks" Vol. 6: No. 7; May 1977
8. "Evaluation: Battery-Powered Defibrillator/Monitors" Vol. 7: No. 10; Aug. 1978
10. "Pulmonary Resuscitation with Artificial Airways" Vol. 8: No. 2; Dec. 1978
11. "Resuscitator Use and Abuse" Vol. 8: No. 2; Dec. 1978

Hazard and Accident Investigations and Publications (Principal Investigator): ECRI, 1975-1979

1. 1993; "FDA’s Safe Medical Device Act of 1990 Regulations for Medical Device Users", Annual Materials Managers Conference - South Carolina Hospital Association, Hilton Head, SC
2. 1993; "Impact of FDA’s Safe Medical Device Act of 1990 Medical Device Recall Policies", Annual Conference, AAMI, Boston, MA
3. 1992; Revised, updated, and presented above full-day Technology Assessment course at Annual Conference - AAMI, Anaheim, CA
4. 1991; "Medical Equipment Technology Assessment Strategies for the 90's", Course Director, full-day course at Annual Conference, - AAMI, Washington, DC
5. 1984; "AHA Arrhythmia Database Update", AAMI - Washington, DC
7. 1988; International Conference on Linking WHO Collaborating Center Medical Device Reliability Databases, World Health Organization - Dusseldorf, W. Germany
8. 1988; "International Medical Equipment Reliability Databases and Experience", World Congress of Medical Physics & Biomedical Engineering - San Antonio, TX
9. 1987; "International Medical Equipment Reliability Databases and Indexing", Annual Conference WHO/LINFO - Linkoping, Sweden
10. 1987; "The Development and History of Biomedical Engineering in the United States", Brazilian Clinical Engineering Conference - Rio de Janeiro, Brazil
11. 1986; AAMI Northeast Regional Conference - Equipment Control Program Albany, NY
12. 1984; 1) "Medical Equipment Reliability Databases" and 2) "National Medical Equipment Management Program", -Australia Dept. of Health Canberra, Australia
13. 1985; Annual Conference, AAMI - Panel, Equipment Control Programs Experts Roundtable - Chicago, IL
14. 1985; "Computerized Medical Equipment Registration", Australia Dept. of Health - Melbourne, Australia

Earliest Invited International Presentations and Lectures: 1975-1984
1. 1983; "AHA Arrhythmia Databases", Annual Conference Association for the Advancement of Medical Instrumentation (AAMI) - Los Angeles, CA
2. 1980; "Physician Automation", Podiatry Association - Philadelphia, PA
3. 1979; Northeast Regional Cardiology Conference - Hartford, CT
4. 1979; "Electrical Safety in Medical Devices", American Society of Cardiologists - Hershey, PA 1975; "Medical Device Safety", Respiratory Therapy Association Northeast Regional Conference -Philadelphia, PA
5. 1978; "Medical Equipment Hazards and Safety", Annual Conference of Emergency Physicians - Tarpon Springs, FL 1977; Committee member, Cardiopulmonary Resuscitation Conference, National Research Council, Committee on Resuscitation Washington, DC
6. 1978; "Biomedical Equipment Inspection and Preventative Maintenance", Ohio Hospital Association - Akron, OH
7. 1978; "Biomedical Equipment Maintenance Programs", Ohio Hospital Association - Columbus, OH