

# Elliot B. Sloane, Ph.D.

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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,

**MEDIQ/PRN Life Support Services, Inc. Pennsauken, NJ.**      **Jan, 1990 – Feb, 2000**

***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.

**ECRI (Emergency Care Research Institute) Plymouth Meeting, PA**      **May, 1975 – Jan, 1990**

**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 project**      **In his executive career prior to entering academia, Dr. Sloane was a successful team and**

**Highlights projects.**    **leader for global and strategic biomedical engineering and healthcare information system**

**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.

**HIMSS** Healthcare Information Management Systems Society, since 2001. Author, Annual Conference Session Chair, and Presenter, and Co-chair of IHE Strategic Development Committee.

**IEEE** Institute of Electrical and Electronic Engineers, since 1976

- Board of Directors, Engineering in Medicine and Biology Society, 2003-2006, and 2007-2009 terms.
- IEEE Standards Association Technical Sponsor for IEEE 11073x Medical Device Informatics Standards, since 2004.

**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
- Medical Device Nomenclature Task Force, Linkoping, Sweden (1988)
- Advanced Clinical Engineering Workshop faculty, Nepal & Havana (2001), Dominica & Cancun (2003)
- International Medical Error and Patient Safety Taxonomy Workshop and Taskforce. Geneva, Switzerland (2003)

**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/elliott.sloane](http://www.homepage.villanova.edu/elliott.sloane).

### Refereed Journal Articles

Dr. Vance Wilson, V. and Sloane, E. Winter 2007 Guest Editorial "Healthcare Information Systems" for the Special Issue on Healthcare Information Systems; *Information Systems Management* 23:2.

*International Journal of Networking and Virtual Organisations* - "Use of Coloured Petri Net models in planning, design, and simulation of intelligent wireless medical device networks for safe and flexible hospital capacity management" with Vijay Gehlot, Accepted for publication 8/29/2006, in production.

*Computer* - "Ensuring Patient Safety in Wireless Medical Device Networks" (35:4 (2006) pp. 32-38) Gehlot and Sloane

*IEEE Engineering in Medicine and Biology* - "Using a Decision Support System Tool for Healthcare Technology Assessments: Applying the Analytic Hierarchy Process to Improve the Quality of Capital Equipment Procurement Decisions." (23:3 (2004) pp. 42-55) Sloane

*Omega* - "Impact of process change on customer perception of waiting time - a field study" (32:1 (2004) pp. 77-83.) Luo, Liberatore, Nydick, Chung, and Sloane

*Journal of Computers and Operations Research* - "Using the analytic hierarchy process as a clinical engineering tool to facilitate an iterative, multidisciplinary, microeconomic health technology assessment" (30:10 (2003) pp. 1447-1465) Sloane, Liberatore, Nydick, Luo, and Chung

*Journal of Healthcare Information Management* - "Medical Decision Support Using the Analytic Hierarchy Process" (16:4 (2002) 38-43) with Liberatore, M. and Nydick, R.

*Biomedical Instrumentation and Technology* - "The Golden Age of Clinical Engineering: Digital Convergence and Information Technology Partnerships" (35:2 (2001) pp: 95-103)

*Journal of Clinical Engineering* - "Quality Management for a Nationwide Fleet of Rental Biomedical Equipment" 28:3 (2001) pp: 253-269.

### Refereed Conference Papers/Proceedings

- 1) "Executive Dashboard and Decision Support System for Reliable, Lean Global Military Medical Logistics Management" with Eric Rosow, Joe Adam, Dave Shine. Decisions Sciences Institute (DSI) 2006 Annual Conference. San Antonio, TX. 18-21 November, in production.
- 2) "JEDI – An Executive Dashboard and Decision Support System for Lean Global Military Medical Resource and Logistics Management" with Eric Rosow, Joe Adam, Dave Shine. Proceedings of the 28<sup>th</sup> Annual IEEE EMBS Annual Conference. New York, NY, 30 August – 3 September 2006, in production.
- 3) "Design and Development of a Prototype For An Inexpensive, Multi-Node Mobile, Palm-PDA-Based Wireless Clinical Information System Platform" with Nicholas O'Donoghue, Douglas Marzela, and Sarvesh Kulkarni. Proceedings of the Twelfth Americas Conference on Information Systems, Acapulco, Mexico August 04<sup>th</sup>-06<sup>th</sup> 2006. In production.
- 4) "A General-Purpose Safety and Performance Verification and Validation Toolkit (V2T) for Life-Critical Wireless Medical Device Networks (WMDN)" with Vijay Gehlot. Proceedings Of The Twelfth Americas Conference On Information Systems, Acapulco, Mexico August 04<sup>th</sup>-06<sup>th</sup> 2006. In production.
- 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 04<sup>th</sup>-06<sup>th</sup> 2006. In production.

- 6) "Safety First! Safe and Successful Wireless Medical Device Systems" with Todd Cooper. Healthcare Information Management Systems Society Annual Conference, San Diego, CA, 12-16 February, 2006.
- 7) "Conceptual Design and Resources for a General-Purpose Safety and Performance Verification and Validation Toolkit (V2T) for Life-Critical Wireless Medical Device Networks (WMDN)" with Rick Schrenker. Proceedings of the 27<sup>th</sup> Annual International Conference of the Engineering in Medicine and Biology Society, 2005. IEEE- EMBS 2005. Shanghai, China, 1-4 September 2005, pp: 178-181.
- 8) "Clinical Engineering Department Strategic Graphical Dashboard to Enhance Maintenance Planning and Asset Management" with Eric Rosow, et al. Proceedings of the 27<sup>th</sup> Annual International Conference of the Engineering in Medicine and Biology Society, 2005. IEEE- EMBS 2005. Shanghai, China, 1-4 September 2005, pp: 7107-7110.
- 9) "Ensuring Patient Safety by using Colored Petri Net Simulation in the Design of Heterogeneous, Multi-Vendor, Integrated, Life-Critical Wireless (802.x) Patient Care Device Networks" with Vijay Gehlot. Proceedings of the 27<sup>th</sup> Annual International Conference of the Engineering in Medicine and Biology Society, 2005. IEEE- EMBS 2005. Shanghai, China, 1-4 September 2005, pp: 162-165.
- 10) "Optimal Medical Equipment Maintenance Service Proposal Decision Support System Combining Activity Based Costing (ABC) and the Analytic Hierarchy Process (AHP)" with Leticia da Rocha and Jose Bassani. Proceedings of the 27<sup>th</sup> Annual International Conference of the Engineering in Medicine and Biology Society, 2005. IEEE- EMBS 2005. Shanghai, China, 1-4 September 2005, pp: 7103-7106.
- 11) "Quality of Service (QoS) in Healthcare Applications: Colored Petri Net Simulation for Design of Heterogeneous, Multi-Vendor, Integrated, Life-Critical Wireless (802.x) Patient Care Device Networks" AMCIS (Association of Information Systems) Annual Conference, Omaha, NB, August 11-14, 2005. <http://aisel.isworld.org/proceedings/amcis/2005/program.asp>
- 12) "Sun Tzu and the Art of Healing: Executive Dashboards and Data Mining for Business Intelligence in Integrated, Lean Military Supply Logistics for the 21st Century" AMCIS (Association of Information Systems) Annual Conference, Omaha, NB, August 11-14, 2005. <http://aisel.isworld.org/proceedings/amcis/2005/program.asp>
- 13) "Medical Equipment Maintenance Service Proposal Analysis Using the Analytic Hierarchy Process Tool" Proceedings of the Northeast Decision Sciences Institute (DSI) Annual Conference. Philadelphia, PA. March 30-April 1, 2005. With deRocha, L., and Bassani, J.
- 14) "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.
- 15) "Applications of the Petri net to simulate, test, and validate the performance and safety of complex, heterogeneous, multi-modality patient monitoring alarm systems" Conference Proceedings. 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Volume 2 (2004), pp: 3492 - 3495
- 16) "Clinical Engineering Use of Event-Driven Process Chain (EPC) to Develop Enterprise Models of Collaborative Information and Workflow for Re-Engineering the Operating Room" AMCIS (Association of Information Systems) Annual Conference, New York, NY, August 6-8, 2004. <http://aisel.isworld.org/proceedings/amcis/2004/program.asp>
- 17) "Application of the Petri net to Simulate and Validate Complex, Multi-Vendor, Heterogeneous Networks of Wireless Medical Device Systems" AMCIS (Association of Information Systems) Annual Conference, New York, NY, August 6-8, 2004. <http://aisel.isworld.org/proceedings/amcis/2004/program.asp>
- 18) "Case studies using graphically enhanced DSS to improve healthcare technology assessments and clinical decisions" Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Volume 4 (2003) pp:3636 - 3639. With Liberatore, M. and Nydick, R.
- 19) "Strategic dashboards for improved healthcare technology management decisions" Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Volume 4 (2003) pp:3634 - 3635. With Rosow, E. and Adam, J.
- 20) "Integration of heterogeneous military medical supplies and computerized equipment maintenance management (CMMS) databases and decision support systems" Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Volume 4 (2003) pp: 3628 - 3629. With Rosow, E. and Adam, J.
- 21) "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>
- 22)

- 23) "Improved Medical Decision Support Using the Analytic Hierarchy Process (AHP): Creating new Tools for Clinical Engineers, Health Systems Engineers, Clinicians, Insurers, and Administrators" Decision Sciences Institute Annual Conference, San Diego, CA. November 2002.
- 24) "An Analysis of the Medical Decision Support, Expert Systems, and Artificial Intelligence Literature" Decision Sciences Institute Annual Conference, San Diego, CA. November, 2002.
- 25) "Clinical Engineering Technology Assessment Decision Support: A case study using the analytic hierarchy process (AHP)" Proceedings of the 24th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Volume 3 (2002) pp: 1950-1951. With Liberatore, M., Nydick, R., Luo, W., Chung, Q.
- 26) Sloane, E., Liberatore, M., Nydick, R., Health Technology Assessments Using the Analytic Hierarchy Process. Association for the Advancement of Medical Instrumentation 18<sup>th</sup> Annual Conference. Minneapolis, MN. 1-4 June, 2002.
- 27) "Leadership in the Digital Convergence Revolution." Association for the Advancement of Medical Instrumentation (AAMI) 2001 17<sup>th</sup> Annual Conference. Baltimore, MD. 9-13 June, 2001.
- 28) Successful Collaboration Between Clinical Engineering and Information Technology Departments." Association for the Advancement of Medical Instrumentation (AAMI) 17<sup>th</sup> Annual Conference. Baltimore, MD. 9-13 June, 2001.
- 29) "Case Study: Using AHP to Select Neonatal Ventilators for Abington Memorial Hospital's Women's Health Facility." Association for the Advancement of Medical Instrumentation (AAMI) 17<sup>th</sup> Annual Conference, Baltimore, MD. 9-13 June, 2001. With Lewandowski, J., Liberatore, M., Nydick, R., Wack, D.
- 30) "Decision Support for Optimizing Health Technology Assessment." Institute for Operations Research and the Management Sciences (INFORMS) 2000 Annual Conference. San Antonio, TX, 5 November, 2000. With Liberatore, M., Nydick, R.

#### **Pedagogy-related conference and collegiate activities**

"Healthcare Information Systems Research and Career Opportunities in the Biomedical Engineering Field," lecture and panel. Annual Doctoral Student Seminar Series, IEEE EMBS 2006 Annual Conference. New York, NY, 30 August – 3 September 2006

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 Systems and Clinical Engineering Careers in the Biomedical Engineering Field," lecture and panel. Annual Doctoral Student Seminar Series, IEEE EMBS 2005 Annual Conference. Shanghai, China, 1-4 September 2005

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.

"Petri net simulation of wireless medical device alarm systems: Addressing an emerging critical safety issue in hospitals – Joint research between Compute Science and Business School" with Vijay Gehlot. Villanova Computer Science Colloquium Series, 25 April, 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.

Business Ethics Curriculum Study Group. Joint work-study mini-conference between Villanova's College of Commerce Finance and the College of Arts and Sciences. May, 2004.

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

#### **US Executive or Industry Education (Conferences and publications)**

- 1) "Achieving Successful Enterprise Interoperability Using IHE Profiles and Standards" HIMSS '07 (Health Information Management Systems Society) Annual Conference, New Orleans, LA. 25 February -1 March, 2007.

- 2) "Development of the US National Healthcare Information Network and Infrastructure" SIA (Service Industry Association) Executive Roundtable, Philadelphia, PA, September 14, 2006.
- 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.
- 5) "The 21st Century Mission for Clinical Engineering: Injecting Systems Thinking into the Healthcare Enterprise." AAMI (Association for the Advancement of Medical Instrumentation) Annual Conference. Washington, DC. 24-26 June, 2006.
- 6) "Successfully Creating and Managing Safe Wireless Patient Care Systems" with Todd Cooper. Medical Records Institute TEPR 2006 Annual Conference, Baltimore, MD, 21-24 May 2005.
- 7) "Healthcare IT Investments" Service Industry Association (SIA) Executive Summit, Las Vegas, NV, March 5-7, 2006.
- 8) "Creating and Managing Successful and Safe Wireless Medical Device and Information Networks." Delaware Valley HIMSS Regional CIO Conference, Doylestown, PA. April, 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 21<sup>st</sup> 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.
- 12) "Strategic Planning Summit for Convergence of Medical Devices and Medical Information Systems." Conference Chair, Keynote Speaker, and Moderator. Maryland Regional HIMSS Annual CIO Conference. Baltimore, MD. April 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.
- 14) "Successful Security Management Strategies for Integrated Biomedical and Information Systems" HIMSS National Annual CIO Summer Conference, Las Vegas, NV, June 15-15, 2004.
- 15) "Health Systems Engineering and National Medical Emergency Response" Drexel School of Biomedical Engineering Professional Colloquium Series, May 2004.
- 16) "Successful Project Management with Microsoft Project for Information and Medical Technology Projects." AAMI 20<sup>th</sup> Annual Conference, Boston, MA, June 5-7, 2004.
- 17) "Successful Strategic Planning for the Next Generation of Clinical Information Systems" HIMSS (Health Information Management Systems Society), Oregon Chapter Fall 2004 Annual CIO Meeting. Portland, OR , September. 30, 2004.
- 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
- 20) "Patient Safety and Medical Error Taxonomy Healthcare Industry Taskforce," World Health Organization. Geneva, SW October, 2003.
- 21) "Expanding the Clinical Engineering Toolbox: New Health Systems Engineering Tools for a New Century" ACCE Clinical Engineering Symposium, Long Beach, CA, 14 June 2003.
- 22) "Workshop on the Application of the AHP in Healthcare Technology Management," AAMI 19<sup>th</sup> Annual Conference, Long Beach , CA, June 2003 with Matt Liberatore.
- 23) "Successful Healthcare IT Leadership Strategies" Session Chair, Moderator, and Panelist. The CIO Forum, Valley Forge, PA, May, 2003.
- 24) "Current Developments in Medical Decision Support Systems" Regional HIMSS Annual CIO Conference, Atlanta, GA. November, 2002.

- 25) "Workshop on Decision Support Using the Analytic Hierarchy Process (AHP) in Healthcare" Decision Sciences Institute Annual Conference, San Diego, CA. November 2002, with Matt Liberatore and Robert Nydick.
- 26) "Successful Healthcare Provider Gap Analysis: CIO Compliance and the HIPAA Law" Sessions Chair, Moderator, and Panelist. The CIO Forum, Valley Forge, PA, May, 2002.
- 27) "E-Health: MIS Challenges and Opportunities in Healthcare" AITP-Montgomery County, PA. April, 2002.
- 28) "Leadership in the Digital Convergence Revolution" AAMI 17<sup>th</sup> Annual Conference, Long Beach , CA, 9-12 June 2001 Baltimore, MD. with John Glaser and Mike Malinia
- 29) "Managing Clinical Engineering and Information Technology – Point-Counterpoint" AAMI 17<sup>th</sup> Annual Conference, 9-12 June 2001 Baltimore, MD, with Ben Clark, LaDonna Shedor, Alan Lipschultz, and Leo Gilmore
- 30) "Update on the FDA Biomedical Service & Remarketing Standard" Healthtech 2000, Baltimore, MD, February, 2000.
- 31) "FDA Biomedical Service & Remarketing Standard and NPR" AAMI 16<sup>th</sup> Annual Conference, Washington, DC. June, 1999.

### **International Executive Education and Pedagogy**

PAHO Healthcare Technology and Clinical Information System Executive and Healthcare Industry Education Advisory Panel (2006)

PAHO Delegate and Presenter: "Emerging Trends in Healthcare Technologies" Bahamas National Healthcare Executives Conference, Nassau, February 4, 2005.

"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 (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.
- Central-Eastern Asia (WHO) ACEW; *Faculty Member* for the Computerized Maintenance Management Systems, Quality Management Programs, Life-Cycle Cost of Ownership Analytics, and Prevention and Management of Patient Injury and Death Incident modules. Kathmandu, Nepal, April 2001.
- Spanish Caribbean Community (PAHO) ACEW; *Workshop Leader and Faculty Member* for the Computerized Maintenance Management Systems, Quality Management Programs, Life-Cycle Cost of Ownership Analytics, and Prevention and Management of Patient Injury and Death Incident modules. Havana, Cuba, May 2001.
- English Caribbean Community (PAHO) ACEW; *Workshop Leader and Faculty Member* for the Computerized Maintenance Management Systems, Quality Management Programs, Life-Cycle Cost of Ownership Analytics, Executive Decision Systems, and Prevention and Management of Patient Injury and Death Incident modules. Cancun, Mexico, Cuba, July 2003.
- Latin American Community (PAHO) ACEW Workshop *Program Co-Leader and Faculty Member* for the Computerized Maintenance Management Systems, Quality Management Programs, Life-Cycle Cost of Ownership Analytics, Executive Decision Systems, and Prevention and Management of Patient Injury and Death Incident modules. Cancun, Mexico, Cuba, September 2003.

## **Academic Book Chapters:**

Chapter Editor: Information Systems. Clinical Engineering Handbook, JF Dyro, editor. Burlington, MA. Elsevier Academic Press, 2004

Section Author: Information Systems Management. Clinical Engineering Handbook, JF Dyro, editor. Burlington, MA. Elsevier Academic Press, 2004

## **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

*Information Systems Management* Guest Editor with Dr. Vance Wilson for the Winter 2007 Special Issue on Healthcare Information Systems; Volume 23, Issue 2.

## **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)
- 5) Board of Directors, IEEE Engineering in Medicine Society (2003-2006 and 2006-2009 terms).
- 6) Chair, IEEE Healthcare Information Systems Membership Development Board Committee (2005 & 2006)
- 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)

**10)** Advisory Board, Philadelphia Regional CIO Forum (2002-2006)

**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).
- 7) Voting Delegate, ANSI Healthcare Information Standards Standards Panel (HITSP), on behalf of US Department of Health and Human Services (2006 and 2007)

## **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. 25<sup>th</sup>, 26<sup>th</sup>, 27<sup>th</sup>, and 28<sup>th</sup> Annual Conferences. (2003-2007)
- 2) Conference Theme Co-Chair, Healthcare Information Systems. 26<sup>th</sup>, 27<sup>th</sup> and 28<sup>th</sup> Annual Conferences of the IEEE Engineering in Medicine and Biology Society. 2004 -2006.
- 3) Conference Theme Co-Chair, Biomedical Engineering Industry and Applications. 27<sup>th</sup> Annual Conference of the IEEE Engineering in Medicine and Biology Society. September 2005.
- 4) Session Co-Chair, Clinical Engineering. 25<sup>th</sup>, 26<sup>th</sup>, 27<sup>th</sup>, 28<sup>th</sup> Annual Conference of the IEEE Engineering in Medicine and Biology Society. September 2003-2006.
- 5) Session Co-Chair, Healthcare Information Systems. 26<sup>th</sup>, 27<sup>th</sup>, 28<sup>th</sup> Annual Conference of the IEEE Engineering in Medicine and Biology Society. September 2004-2006.
- 6) Conference Content Planning Committee. 26<sup>th</sup> Annual Conference of the IEEE Engineering in Medicine and Biology Society. Scottsdale, AZ, March, 2004.

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

- 1) SIGHealth Annual Conference Track Conference Planning Committee. 2003 – 2007.
- 2) Mini-track co-chair and paper reviewer for Integrating the Digital Healthcare Enterprise sessions. 2004-2007.
- 3) Session Co-Chair and paper reviewer for Integrating the Digital Healthcare Enterprise. Annual AMCIS (Americas Conference on Information Systems) Conferences. August 2004-2006.

**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
2.	"Evaluation: Oxygen Regulators"	Vol. 5:No. 10;	Aug. 1976
3.	"Evaluation: Oxygen Flowmeters"	Vol. 5:No. 10;	Aug. 1976
4.	"Evaluation: Oxygen Regulators"	Vol. 5:No. 12;	Oct. 1976
5.	"Evaluation: Oxygen/Flowmeter Combinations"	Vol. 6:No. 1;	Nov. 1976
6.	"Evaluation: Oxygen Masks"	Vol. 6:No. 7;	May 1977
7.	"Evaluation: Electrical Safety Analyzers"	Vol. 7:No. 2;	Dec. 1977
8.	"Evaluation: Battery-Powered Defibrillator/Monitors"	Vol. 7:No. 10;	Aug. 1978
9.	"Evaluation: Oxygen Gas-Powered Resuscitators"	Vol. 8:No. 2;	Dec. 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. "Hazard Report: MRL defibrillator monitor"
2. "Hazard Report: Sorenson shunt"
3. "Hazard Report: Razel infusion pump"
4. "Hazard Report: Robertshaw resuscitator" ("Pink Sheet", Nationwide Hazard Alert Bulletin)
5. "Hazard Report: Ohio Kreiselman resuscitator"
6. "Hazard Report: Instrutek electrical safety tester"
7. "Hazard Report: BD-Electrodyne defibrillator paddle connector"

### **Invited International Presentations and Lectures: 1984 – 1994**

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
6. 1989; "Medical Equipment Selection, Acquisition, and Safety/Reliability Management", World Health Organization (WHO) and Pan American Health Organization (PAHO) Conference on Medical Technology Management and Assessment for Caribbean Countries, - Port of Spain, Trinidad
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