The Landscape

Not only an economic engine, a robust U.S. medical technology industry produces life-saving, life-enhancing treatments and cures for patients. Although the U.S. still dominates the global market, U.S. investment in R&D as a percentage of GDP is presently declining while other countries, including China, Brazil, and India, have increased their investment in this area. Within 10 years, China is expected to be on a par with the U.S. in R&D investment as a percentage of GDP [1]. Due in part to a cumbersome regulatory system (America's regulatory approval times rank 7th out of our top nine competitor nations), U.S.-based medical technology giants are increasingly looking abroad to capitalize on investing where the growth is most promising. For example, GE is moving its X-ray leadership team from the U.S. to China, and Siemens has manufactured imaging and ultrasound systems in India for more than 50 years. China's medical device market is expected to increase by 15% annually during the next five years to $43 billion by 2019; India's will grow by 23% during the same time to $11 billion annually [2]. Furthermore, emerging market countries are quickly taking the lead in developing lean, frugal, and reverse innovation that simplifies existing devices and processes. Therefore, maintaining U.S. dominance in the $350 billion global medical device industry will require a national response to product development, which will have significant impact not only on innovation and retaining and creating high-wage, high skill jobs, but also healthcare costs.

Value-driven Engineering

The Austen BioInnovation Institute in Akron (ABIA) led an academic, industry, and government collaboration to explore the effect of value-driven engineering (VdE) on the nation's global competitiveness. The *Safe Haven Summit on Value-Driven Engineering and U.S. Global Competitiveness* was held on March 10 and 11, 2011. Both industry and academic participants from institutions such as SEMATECH, Medtronic, Stanford and MIT, as well as thought leaders from the Ewing Marion Kauffman Foundation were in attendance. As a result of the Summit, a White Paper was written in which modifications in regulatory and reimbursement practices and recommendations for training the next generation of innovators were described [3]. In addition, a focus on Clinical Utility and Reduced Complexity and Healthcare System Cost reduction from design through development and manufacturing of medical devices and processes was included. This has been expressed in the following Value Equation:

$$\text{Value} = f\left(\frac{\text{Clinical Utility}}{\text{Complexity} \times \text{Cost}}\right)$$

"Clinical Utility" and "Reduced Complexity" (i.e., the time and effort required to perform a procedure correctly) are considered from the perspective of the end-user, and "Cost" is evaluated systemically. In healthcare, VdE represents an approach to developing new products that conform to the following principles:

1. Assurance of Quality- performance and delivery are never sacrificed for the sake of a "cheaper" or "less costly" version of a product or process;
2. Clinical utility driven by patient-centricity in demand, design, use, and function;
3. Reduced complexity in product design; and
4. Demonstrated cost savings and cost efficiency across the health system.

VdE is distinct from the value engineering principles employed by the Department of Defense's procurement office. As described in Public Law 104-106, Section 4306 [4], which requires the use of value engineering procedures and processes by each executive agency, value engineering analyzes the "functions of a program, project, system, product, item of equipment, building, facility, service, or supply of an executive agency, performed by qualified agency or contractor personnel, directed at improving performance, reliability, quality, safety, and life cycle costs". In value engineering, value is defined as the ratio of function to life cycle cost. VdE is distinct from value engineering as it defines value is a function of clinical utility and complexity at the end-user as well as cost to the overall system. Thus, VdE offers tremendous potential to bolster U.S. global competitiveness while concomitantly serving as a tool to bring healthcare costs in line with quality outcomes.

The following recommendations to advance VdE will be discussed individually:

1. Launch PAVE: Platform to Advance Value-driven Engineering
2. Adopt a regulatory framework to advance VdE product development
3. Train and Inspire the Next Generation of Engineers

Launch PAVE: Platform to Advance Value-driven Engineering (in response to questions 2 and 16)

The Platform to Advance Value-driven Engineering (PAVE) includes funding mechanisms, regulatory incentives, supports for cross sectors investments, and educational leadership that incorporates the principles of VdE and deploys the Value Equation as a core driver and test for VdE device product innovation. The PAVE framework is founded on the following pillars:

1. Demonstrated value, employing the Value Equation;
2. Patient-centricity, with community and customer engagement in product demand and design;
3. **Public-private engagement and investment, dependent upon innovative and budget-sensitive federal funding mechanisms, cross sector human and financial capital contributions**, **and collaboration across disciplines, bringing engineering into a close integrated working relationship with biology, medicine, clinical application and health system performance**; and
4. Educational focus requiring the adoption of new academic programs that train today and tomorrow's cadre of VdE engineers.

RECOMMENDATIONS:

- Launch and manage PAVE as a program of the Administration with the authority and capacity to assure cross-departmental coordination and optimization of pooled federal resources
- Adopt process mechanisms that embrace a "safe haven" environment for cross-sector, shared dialogue, while ensuring that best practices are fostered
- Assure input and engagement of experts, scientists, and the public, including those who may take advantage of downstream adoption and use VdE innovation
- Encourage development of funding mechanisms, regulatory reforms and federal support systems that are concrete and executable

Adopt a Regulatory Framework to Advance VdE Product Development (in response to questions 5, 13, and 15)

Involvement of the FDA in advancing VdE product development is crucial. One recommendation mentioned in the VdE White Paper, value-driven reimbursement, has recently been adopted:

the pilot program of parallel review by the FDA and CMS. Beyond value-driven reimbursement, the FDA might consider giving priority review of Investigational Device Exemption (IDE) submissions to new products that score high on the VdE value metric. This will not only permit faster clinical trial commencement, but also earlier clinical and design feedback to the product development team. **The FDA can and should adopt its iterative IDE process which, when fully implemented, will permit innovators utilizing VdE principles and processes to start IDE trials early and implement design and protocol iterations based on early clinical results without stopping the initial IDE and restarting**. Within the Premarket Approval (PMA) system, products meeting VdE criteria can be given "fast track" status using internal FDA processes, which does not require legislative action. In addition, the FDA can create internal and external support systems to assist VdE-based products in navigating the regulatory system. Some of these ideas can be incorporated into the recently announced CDRH innovation initiative. CDRH can train and deploy process experts or managers to guide the innovator and the submission through the process; ensure prompt attention to the submission; organize meetings with regulators and the sponsor and generally take accountability and responsibility for prompt review of a VdE-based submission.

RECOMMENDATIONS:

- **Create VdE Scoring metric. Within the Premarket Approval (PMA) system, allow products meeting VdE criteria to be given "fast track" priority status**
- Incent application of VdE principles for the development of medical devices
- Permit the introduction and utilization of computer simulation and modeling as a component in the design and development of VdE devices
- Identify specific medical device testing laboratories with expertise in both physical and computational evaluation of devices coming before the agency for 510(k), IDE, PMA, or humanitarian device approval to provide independent review and validation of a device's adherence to VdE criteria
- Continue to consider market incentives for VdE
- Include enhanced support for the VdE innovator
- Consider VdE principles in reimbursement

Train and Inspire the Next Generation of Engineers (in response to questions 1, 9, and 12)

Value-driven engineers need technical expertise to find feasible solutions to critical problems; however, this is not sufficient. They also need to understand human and societal needs as well as pragmatic aspects of manufacture, context, maintenance, and sustainability to produce solutions that are viable in their intended market or application. Innovation is rarely about technology in isolation.

Educating the next generation of value-driven engineers requires broadening the questions our students are taught to ask. From *Rising Above the Gathering Storm* to *Engineering the Future*, from *Wired to Care* to *Change by Design*, the need for empathetic and entrepreneurial engineers has been widely discussed. The world needs more T-shaped people – with breadth and depth – rather than solely deep – I-shaped – engineers. The challenge is how to educate them.

We learn what we practice. To produce value-driven engineers, we must create educational environments in which our students practice VdE. They must learn to ask their own questions, to set their own problems, to create responsive designs, obtain feedback, build, fail, try again, and persevere; interdisciplinarity and creativity are key. If we want graduates who engineer

value, we must provide our students with opportunities to practice VdE. They must communicate, work in teams, get their hands dirty, self-evaluate, plan, reassess. Only by being apprentice value-driven engineers will they obtain the requisite skills to become masters at this craft.

Fortunately, there are numerous successful examples of educational environments providing exactly this kind of experience, including ABIA; the Center for Bioengineering Innovation and Design program at Johns Hopkins University; the University of Kansas Institute for Advancing Medical Innovation; the Stanford Biodesign Program; the Health Sciences and Technology Program at MIT and Harvard and MIT's Deshpande Center; Olin College; and the NAE Grand Challenge Scholars Programs on many campuses. Identifying other successes and using them as models to share with others represents a first step in educating the next generation of value-driven engineers. It is not, however, sufficient to identify successful models and expect other institutions to emulate them. A long history of failure to widely transplant educational innovation – e.g., the Engineering Coalitions project – serves to underscore the context-sensitivity of education. Ultimately, successful educational innovation is owned by its practitioners and is fitted to the institutional needs and culture in which it thrives. Educational innovation must therefore be co-designed and co-created for its intended context. Thus, our recommendations substantially concern the building of communities (at the post-secondary and K-12 levels, as well as outside of academic institutions).

RECOMMENDATIONS:

- Employ challenge-driven innovation by sponsoring a **VdE Grand Challenge** to encourage innovative and VdE product solutions
- **Develop and offer patient-centered, problem oriented courses** (e.g., biodesign courses at ABIA, Stanford and Johns Hopkins)
- **Encourage entrepreneurship within the university setting** (e.g., ABIA's Women's Entrepreneurship Program)
- Create VdE Training Workshops designed to educate current and future professionals on medical device costs, barriers, streamlining processes, case studies
- National VdE Biannual Conference (April 2012) – gathering of multidisciplinary thought leaders from government, academia, industry, healthcare, venture capital, philanthropy and non-profit sectors, as well as medical device entrepreneurs to foster VdE principles

Conclusion

To sustain U.S. leadership in the $350 billion global medical device industry, an approach that leverages targeted public policy in tandem with private sector efforts is crucial. Deployment of VdE will have significant impact not only on innovation and retaining and creating high-wage, high skill jobs, but also healthcare costs by making the U.S. more competitive in the global market. Although these recommendations have focused on national challenges in health, VdE principles may also be applied to the nation's food, energy, and environment challenges.

References

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