The daily comedic dramas playing out in Washington threaten the economic viability of the United States and overlook many of this nation’s priorities, among which is a platform that encourages the continual development of innovative, safe, clinically beneficial, and cost-effective medical technologies.

This September issue of ORTHOPEDICS provides commentary on a framework that seeks to assure the above, and further includes a number of the hip and knee arthroplasty papers presented at the 27th Annual Current Concepts in Joint Replacement (CCJR) meeting, which embodies some of these advances.

A GATHERING STORM

In 2009, orthopedic products accounted for more than $37 billion in global sales with the United States enjoying 60% of this market. This, however, is a percentage that is being challenged by emerging technological bases in Asia, India, and Brazil where, in addition, manufacturing costs are significantly less than our own and product reliability is increasing. A quandary facing the United States is how this challenge will be met.

Over the past 4 decades, American exceptionalism in orthopedic product innovation has set the standard. However, the hurdles are not just keeping current with a foreign challenge but in optimizing the processes of regulation and reimbursement that are associated in bringing safe and effective orthopedic products to the public in a timely manner.

A NATIONAL STRATEGY

It is debilitating to corporations, both start-ups and established, who incur not only product development and manufacturing costs, but the add-ons imposed by surrogates knowledgeable in product approval pathways, agency application fees, product excise taxes, and liability protection, as well as the time lag between concept and product sale. The complexity of this process is inhibiting to innovation and a stumbling block to American competitiveness. Both the administrative and legislative branches of government should understand this and evolve a long-term national strategy that continually realigns itself through the expenditure of “smart dollars” to meet the challenge.

Regulation

Congressional, press, and citizen criticism of United States Food and Drug Administration (FDA) 510(k) product approvals where questionable safety and effectiveness was demonstrated has led to an independent Institute of Medicine review as well as an FDA internal audit of the process. While the latter suggests logical optimizations within the existing Congressional mandate, the former 227-page, just-completed report concludes that the current 510(k) process is insufficient to satisfactorily assure safety and effectiveness of moderate risk Class II medical devices. It recommends the implementation of a new medical device regulatory framework but falls short of providing the framework, which almost certainly will require a return to the legislative process. When considering the sheer volume of product clearances through the 510(k) route over the past 35 years, the process has well served the health and safety of the American public. The report, however, recognizes the limited resources the Agency has for carrying out its mandate. One thing remains certain: upheaving the 510(k) product approval process for a new and uncertain surrogate with draconian requirements will not increase the assurance of patient
safety, and most certainly will be a millstone that will deny any prospect of American product innovation going forward.

Funding Imperatives

At a time of fiscal conservatism, the government must strive to invest “smart dollars” in programs that assure American competitiveness in medical device innovation. This starts with the recognition that good ideas and entrepreneurial attitudes should be cultivated at the undergraduate and graduate levels. A multifaceted approach that encourages basic and translational technologies offering health care solutions as well as the business acumen and regulatory appreciations requisite in bringing safe and effective products to early market should be sought. Such enterprise should be recognized by the government.

The government should provide added dollar resources to the FDA to enable it to carry out the mandate of assuring the public health of the nation. In this regard, the 510(k) product approval pathway should be a work that is continually optimized rather than replaced. It must ensure that safe and effective products reach the American public in a timely manner while also recognizing its influence in maintaining the pipeline of American medical device innovation. There is little doubt that the Agency remains understaffed and underpaid for this daunting task. Added funding will assist the recruiting of the best and the brightest and continued improvement of existing medical products reporting, as well as provide for educational initiatives that serve to continually enhance the knowledge base of Agency members.

Beyond venture capital, there is a real-time need to assist medical device innovation from start-up enterprises with creative technologies, which all too often wither in today’s economic climate. Realistic government investments need to be made in corporations that offer translational technologies that go beyond the current Small Business Innovation and Research programs. Supporting such can ultimately lead to product returns that not only assist the shareholders but the health care of the nation, and directly ensure the maintenance of global competitiveness.

A redirection of a portion of the government funding that now supports National Institutes of Health basic medical research programs to include translational technologies that offer near-term product solutions for health care problems. This should also entail inclusion, in the grant review process, of individuals with track records in the practicum. The government should not hesitate in recognizing the challenges facing the United States as regards medical device innovation and acting in a way that encourages their development.

Reimbursement

The third hurdle of bringing a medical device to market lies in its ultimate reimbursement. This has roots in both the Centers for Medicare and Medicaid Services (CMS) and the private insurance sector. Too often, the role of the FDA in ensuring medical device product safety and effectiveness does not address the CMS requirement of necessity and benefit for the largest patient sector, which at the end of a long product approval process, can be frustrating, particularly when costly clinical trials are conducted. In September 2010, a Federal Register Notice announced the concept of Parallel Review of medical products by the FDA and CMS to assist the petitioner in realizing their end goals. This agency interaction needs to be encouraged and is of particular value to small companies with limited financial resources.

Insourcing

Maintaining global competitiveness lies in not only achieving the use of American-made medical devices at home and abroad, but seeking out particular regional health care needs that require safe and cost-effective innovative product solutions. The United States would do well to consider a presence in Asia, India, and Brazil where local needs are assessed and brought back for solution, manufacturing, and distribution abroad.

Oversight

The government should establish a National Oversight Advisory Board whose charge is to assure American exceptionalism in medical device innovation. Its membership should be drawn from the stakeholders inclusive of inventors, corporations, venture capitalists, surgeons, scientists, educators, patients, as well as representatives from the regulatory and reimbursement agencies. The broader the experience the more focused the national strategy.

EPilogue

A long-term national strategy that assures the continuous development of innovative, safe, clinically beneficial, and cost-effective medical products is in the national interest. It is a priority that the administrative and legislative branches of our government must recognize and not ignore. This should be assisted through the investment of “smart dollars” to ensure that we remain a nation where medical devices that meet contemporary and future global health needs are conceived through innovation, commercialized through entrepreneurial acumen, and manufactured with American know-how.

This September issue of ORTHOPEDICS contains an assemblage of contemporary commentaries on hip and knee arthroplasty derived from the Winter 2010 CCJR meeting. It is the hope that the reader will gain from the experiences of the contributors whose dedication to continuing orthopedic education is reflected on these pages.

Further reading and insight on the challenge to American leadership in medical devices may be found in a June 2011 White Paper entitled Value-Driven Engineering for US Global Competitiveness published by the Austen BioInnovation Institute in Akron. Download is available at http://www.abiakron.org/vde-home.