One step forward, 2 steps back is a concerning assessment of future orthopedic technological developments as influenced by changes in medical device regulation, value-added product charges, and reimbursement, all within the framework of a continually evolving American health care system. Parsed further, are all of our contemporary technologies worth their candle in cost and clinical performance?

This annual September issue of ORTHOPEDICS opines on the above concerns intertwined with a number of hip and knee arthroplasty papers presented at the 26th Annual Current Concepts in Joint Replacement (CCJR) meeting.

PULLING ON THE REINS

Congressional and public citizen criticism that the United States Food and Drug Administration (FDA) has played “fast and loose” with 510(k) product approvals is a considerable overstatement of the reality. Rarely has a product claiming substantial equivalence to a predicate been approved that has not followed the existing filing requirements. Notwithstanding, an ongoing independent Institute of Medicine review as well as an FDA internal audit of the process has been mandated. The latter, just completed, has suggested changes that should not prove unfavorable to the medical device industry. Additional requirements inclusive of preexisting clinical studies and postapproval requirements to further support current benchtop and compatibility evaluations can only strengthen the process. One further addition should consider employing only predicate comparators that demonstrate long-term, clinically successful track records. None of the above is odious if it enhances device safety and effectiveness. Upending the 510(k) process by requiring extended clinical evaluations before approval would end orthopedic product innovation in the United States, as small technology-driven orthopedic companies could not afford to innovate while larger ones would be reluctant to risk the financial resources required in a rapidly changing product environment.

Charged with assuring the public health of the nation, the FDA operates under statutory mandate from Congress. In contrast to perceptions and recent criticism, the FDA remains understaffed and underpaid for this mandate. Personnel competency has also been challenged; but in reality, the FDA continually strengthens itself through onsite visitations and internal educational forums where outside orthopedic specialists provide information on contemporary clinical practices. One thing remains certain, up-heaving the product approval process would be akin to throwing out the baby with the bathwater.

THE ECONOMICS OF NEW AGE ARTHROPLASTY

The current paradigm, where medical device corporations continually strive to introduce next year’s model with bells and whistles to justify an increased product cost, is changing. The hospitals that buy these products are under reimbursement pressures where competitive bidding for the lowest system cost is gaining momentum. This has recently been compounded by value-added product charges that in aggregate will cost approximately $4 billion in excise taxes from this industry to assist paying for health care reform in the United States. The consequences are 2-fold: manufacturers will likely pass on added costs to their customers as well as limit their willingness to employ the best and the brightest to evolve new product technologies. There is
good reason to believe that generic implant systems will become increasingly attractive.

**ARE THEY WORTH THE CANDLE?**

Differentiating the hype from the hope in assessing evolving orthopedic technologies requires the tincture of time to determine clinical effectiveness and if reduction in the health care cost burden for joint arthroplasty procedures is realizable. Two examples follow.

Metal–metal articulations for both total and surface replacement hip systems have received excessive press coverage, most of it with a decidedly negative slant. Their advantages lie in the use of large femoral heads, which are a preferred solution for the young, active patient, reducing the potential for dislocation and wear. However, they have been associated with increased incidences of metal hypersensitive-like reactions leading to pain, pseudotumors, bone loss, and component loosening, requiring revision. This has led to the recent withdrawal of 1 surface replacement system from the marketplace and increased scrutiny by regulatory bodies. The British Medicines and Healthcare products Regulatory Agency recently issued a Medical Device Alert outlining assessment pathways for patients with metal–metal articulations while the American Academy of Orthopedic Surgeons (AAOS) has published a hip resurfacing technology review concluding that there is inadequate peer-reviewed literature on the topic. The increased cost of these hard-on-hard surfaces in the primary setting in the hope of improved patient function and device longevity is not realized when a subsequent short-term revision procedure is necessary. Clearly, this technology requires continued study in determining the influence of patient selection, component manufacturing, material, and surgical technique on outcome, and the overall cost benefit to the health care system.

It has long been felt that ensuring optimal alignment in total knee arthroplasty procedures is a requisite of an enduring outcome. While computer navigation has enhanced procedural accuracy by assisting the elimination of outliers, it has an associated learning curve and increased operative time, risk of fracture, and cost. Alternatively, rapid prototyping techniques based on preoperative magnetic resonance imaging and computed tomography to create custom cutting blocks and implants are truly patient specific. Concurrently, the use of robotic arms has filtered into the process to optimize component placement while minimizing bone resection. These technologies represent a first step in realizing the potential benefits of personalized medicine as it relates to joint arthroplasty with the hope of improved function and long-term outcome.

Overall, there is a determining question as to whether a health care delivery system should sustain the increased costs of unproven technologies in the hope that they represent long-term dollar savings. In essence, risk/benefit prognostications should be mandated as part of system changes, when in the end the system must sustain itself and not incur a runaway debt burden.

**USEFUL TOOLS?**

Tools to assess the effectiveness of advancing joint replacement technologies are also continuing to evolve. The AAOS and the orthopedic device industry have contributed resources for the development of an American Joint Replacement Registry. Registries accumulate both short- and long-term data on individual implant design performance where revision is an endpoint. This assists decisions on the effectiveness of particular designs, points to directions for future design development, and serves as an early clinical tripwire when systems prove inadequate. However, when using the data, it is incumbent to delve into the demographic variables that contribute to the revision endpoint for a particular design.

Also assisting a technology evaluation process is the FDA MedWatch products reporting program, which requires health care user facilities and manufacturers to promptly report adverse events involving medical devices. While reporting by orthopedic surgeons is voluntary, they provide the most relevant and useful clinical information to differentiate whether the device failed or the disease process intervened, causing the problem. A further shortcoming of the program is the absence of the total number of particular products being used clinically.

However, taken together, these resources can provide valuable short-term data on product performance and point to pathways for future device development.

**EPILOGUE**

One step forward, 2 steps back, began this editorial, which highlights orthopedic technology advances within an evolving American health care system where the fiscal realities will define their inclusion.

This September issue of ORTHOPEDICS contains an assemblage of further commentaries on contemporary topics relating to hip and knee arthroplasty in 2010. It is hoped that the reader will gain from the experiences of the contributors and their continuing dedication to orthopedic education.