PERSPECTIVE:
Medical Device Entrepreneur

Renewing the Spirit of Innovation in Vascular Medical Technologies

Startups, investors, and the role of government in the medical device market.

BY FRED KHOSRAVI

By its very nature, innovation is a complicated process fraught with risk. Innovation in a regulated industry, such as medical device manufacturing, is an even more prolonged, tangled, and meandering process. The medical device industry as a whole understands the need for and accepts the enforcement of regulations directed toward the protection of public health. Yet, when such regulations lack consistency and predictability, and enforcement is inefficient, the implications for medical device innovation are harsh.

The more unpredictable the approval process is for a medical technology, the less secure investors feel to risk backing such innovations. But this is not a simple problem that can be summarily addressed by the US Food and Drug Administration (FDA) relaxing its requirements. When it comes to ground-breaking medical technologies, which are supported by very little clinical evidence of safety and effectiveness, the regulators are naturally compelled to set a high bar until a reasonable body of clinical evidence is established.

CHALLENGES TO INNOVATION

In the last 35 years, the United States has become a global leader in medical device innovation, resulting in an explosion of technologies and leading to better health, increased longevity, reduced disability, and improved quality of life for patients. But this explosion has also meant that the FDA has had to review and approve a disproportionate number of novel devices with no known or appropriate predicates. Although the medical industry, by and large, is vigilantly focused on its mission to save lives, improve patient outcomes, and reduce the cost of health care, in the last 2 decades, we have all observed infrequent but serious examples of improprieties in the industry, raising the specter for more deliberate processes of approval and enforcement when it comes to new medical technologies and commercial practices. That said, the industry's overwhelming belief is that regulatory challenges and uncertainties of the approval process are the most significant factors contributing to the decrease in medical device investments, the reduced concentration in critical therapeutic areas, and a shifting of investment dollars in medical devices from the United States toward Europe and Asia.

THE EFFECT OF RECENT REGULATIONS ON INVESTORS

Investors' interests in the US domestic medical device industry have cooled off significantly in recent years. However, this is not an irreversible trend; they have cited increased predictability by the FDA in its decision-making processes and increased efficiency and speed in decision making as great steps in the right direction toward the potential revival of medical device investments, and thereby innovation.

In turn, the FDA has recognized that the existing global leadership of the United States in medical innovation is ours to lose and has implemented an outreach program focusing on developing a balanced approach to protecting and promoting the public health while at the same time maintaining our global leadership of this important segment of our economy. To do so, the FDA has intensified its efforts to reach out to the industry (large medical device companies, investors, and innovators) to better understand their concerns and to foster an environment of cooperation. Through these efforts, there seems to be active dialogue about whether it is reasonable or harmful to patients if the FDA attempted to zero out all the risk of a novel technology before it is approved. Other topics being debated are concepts such as allowing products that demonstrate the probable benefits outweighing probable risk to be approved and having a more robust system to track the performance of these products to ensure ongoing safety and effectiveness.

OTHER CHALLENGES

Regulatory issues are not the only challenges that medical device innovators have to contend with these days. A number of other factors impede the growth of medical device innovation in the United States. The contraction of the capital markets since 2007, and the most recent 2.3% medical device excise tax, included in the Affordable Care Act, have by no means been helpful to the cause of medical device innovation in this country.

The financial crisis that was set about in late 2007 has all but eliminated the initial public offering (IPO) market for medical device companies. When a medical technology successfully achieves the endpoints of improving outcomes and reducing the cost of procedures, access to the IPO markets is often regarded as vital to the survival of the startups. This is especially true for companies earning < $100 million in sales. For innovators, IPOs used to represent a key source of less expensive financing for their young companies. With that option having been all but eliminated, they are now forced into more expensive and punitive financing options, which creates another disincentive risk for medical technology innovators. For medical device investors, IPOs represented that element of certainty of exit and achieving a reasonable return on their investment, if their companies had to go the longer haul. According to data from PricewaterhouseCoopers, 116 early stage companies raised approximately $720 million in initial funding in 2007.[1] In just 4 years, that figure has decreased by more than 70% to 55 companies raising just $200 million. Some experts are concerned that the IPO market issue may not be a transitory trend, but rather a structural issue that could significantly cripple medical innovation.

As if innovation in this field is not hard enough already, the industry must now contend with the medical device tax. This tax was established based on a myth that health care reform creates a "windfall" for medical device companies. Supporters of the medical device excise tax claim that the nearly 30 million newly covered beneficiaries will use more medical devices, resulting in additional revenues for the industry. However, this assumption is highly questionable for several reasons. Past experience with near-universal health coverage in Massachusetts does not suggest a positive impact on medical device sales.[2] Most companies have experienced no noticeable increase in utilization from 2006 to 2011, when the state insurance mandate became effective in Massachusetts. Furthermore, most of the 30 million newly insured are younger individuals who are not typically medical device users. In fact, more than 80% of the uninsured are under the age of 45 years.

Although the medical device excise tax will have a negative impact on all companies, small medical device companies will face the largest burden. According to the Department of Commerce, 98% of medical technology companies have fewer than 500 employees.[3] Because the 2.3% excise tax is based on total revenue, not profits, many companies will see their entire margin evaporate. Many companies will owe more in taxes than they generate in profits. An Ernst & Young study found that the tax will increase the effective tax rate for the industry by 29%.[4] Unfortunately, companies are being forced to address the tax by lowering their costs, resulting in a significant shift in manufacturing and growth outside the United States. The Medical Device Manufacturing Association and other medical innovation advocacy organizations are engaged in an active outreach program urging the US Congress and Senate to repeal the medical device tax in its entirety.

ON THE BRIGHT SIDE

These important issues severely affect our leadership position in medical innovation, job creation, and access to life-saving treatments in the United States. With all that said and all the doom and gloom that is discussed every day in the United States regarding the medical device industry, large medical device companies are continuing to grow in the international markets, especially in emerging markets, and innovators continue to innovate. They find ways to persist and sustain the engine of medical device innovation in this country, but they also endeavor to create public-private partnerships that maintain the United States as the world's leader and a net exporter of medical technologies.

For US innovators, "necessity is the mother of invention." As a result, they continue striving and plowing through the exiting challenges to develop both the lion's share of the incremental evolutionary medical device innovations in the world as well as most, if not all, of the revolutionary first-time innovations that ameliorate the way medicine is practiced. This devoted and unyielding innovation culture must be nurtured by both public and private sectors in the United States.

In June 2010, a report by Dick Gephardt, the former US House Majority Leader and current Chairman of the Council for American Medical Innovation, noted, "investment in medical innovation is about health. As the United States implements historic health reform legislation, medical innovation should not be viewed only through the lens of cost containment, but rather be examined as a driver of substantial returns to personal and national economic health. Medical advances lengthen life, reduce disability, and improve productivity."[5] The report puts forward a series of recommendations for a renewed focus on the kinds of public-private partnerships and actions that made the United States the world leader in medical device innovations, such as:

- Committing to the appropriate funding of the FDA and sustained growth of that funding to reflect increases in the FDA's mandated jurisdiction and the growing complexity of life sciences;
- Adopting reimbursement policies that account for and encourage the diffusion of new medical technologies, as well as new standards and measurements in the implementation of health care reforms, which include evolution in standards of care, allow for consideration of individual patient needs, and avoid penalizing early adopters of new technologies;
- Strengthening the federal research and development tax credit by making it permanent, increasing it to levels that make it globally competitive, allowing partial refunds for emerging companies without income, and providing incentives to further public-private partnerships instead of instituting innovation-impeding policies like the medical device tax;
- Adopting tax and economic incentives to boost manufacturing, such as incentives for manufacturing resulting from medical innovation in the United States, and other export-related manufacturing incentives to encourage US-based production;
- Encouraging venture financing for emerging biomedical companies from formation through IPO by creating a federal-level angel investment tax credit and providing federal matching incentives to foster "fund-of-funds" equity capital pools.

CONCLUSION

With health care reform having become a national agenda, it is encouraging to see that the public and private sectors are once again striving to work together to find ways to maintain the United States as a leader in medical device innovation. Today, there is a growing sense of entrepreneurship in the life sciences space geared toward reducing the staggering health care costs that are contributing to the US budget deficit. These entrepreneurial endeavors will not only be vital for the domestic economy, but will also preserve the United States as the innovative powerhouse of the world. That said, this will only be possible if we lift up our nation's medical innovation ecosystem by maintaining a robust investment regimen in this space. To quote Hillary Clinton, " … change is certain. Progress is not. Progress depends on the choices we make today for tomorrow and on whether we meet our challenges and protect our values." ■

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