How Has the DES Market Changed?

Mark A. Turco, MD, FACC, an interventional cardiologist turned chief medical officer, offers a unique perspective regarding the pressures currently facing the DES market.

What are the economic forces that are currently shaping the drug-eluting stent (DES) market with regard to demand, supply, reimbursement, and cost of entry?

Dr. Turco: Within the United States, and for that matter globally, we are seeing once again a transformation in the medical device arena. These transformations are fairly common over the years and are very cyclic. What we're seeing now is a change toward a much more well-defined, evidence-based system that must demonstrate cost effectiveness to be successful.

The DES market is demonstrating a consolidation due to market forces. DES, in general, are under tremendous pricing pressures and, within the industry, market prices are declining. Also, there are pressures at the hospital level, physician level, and industry level to put a cost-effectiveness model to use—the idea of driving higher care at a lower cost to provide the best value.

I think as developers in the medical device field, we need to be conscious of this change and reduce production costs and increase efficiency so that we can bring quality technologies, which demonstrate safety and clinical effectiveness at a lower cost, to the market.

There is already evidence of this within the DES market in that there are DES products being offered in the emerging markets that are produced at a lower cost and gaining market share. I think we still have to see whether they meet the efficacy and safety standards that we have within the United States for our current and next generation of DES, but the fact is that these competitors do exist, and they do manufacture products at a lower cost.

Are the devices coming out of the emerging markets as separate and distinct products from what is currently available in the United States?

Dr. Turco: Yes, these are other companies within those markets that are producing DES technologies. They are not knockoffs, so to speak, of the current technologies; they are the company's own products, but they have been able to streamline production so that they are manufacturing devices at very efficient standards. The idea is to simplify technology.

That said, I think that these products need to be held to the same safety and efficacy standards that we currently hold for our products, such as Xience (Abbott Vascular, Santa Clara, CA), Taxus Liberté (Boston Scientific Corporation, Natick, MA), and Endeavor (Medtronic, Inc., Minneapolis, MN).

Recently, there has been a trend of private cardiology practices selling to hospitals. What effect does this have on the DES market?

Dr. Turco: Right now, hospitals are operating at very low operating margins. Recently, it was announced that the Centers for Medicare & Medicaid Services plan to implement Medicare cuts to hospitals and physicians throughout the United States—cuts that are even greater than where we are with current Medicare reimbursement. What we are seeing is that with physicians now being part of the hospitals, there is an overall cost-conscious type of approach to the product review committees that are bringing new products into the hospital. Whether physicians are still out in private practice or part of the hospital, the product review committees really are being cost-driven product review committees.

Although I don't think that for the DES market there is a specific impact from physicians now joining the hospitals, what we are seeing is that physicians' voices—whether they're employed by the hospital systems or in private practice—within the hospital product review committees are having less impact in decision making within a hospital system. Given the current economics of medicine, hospital administrators who are running these product review committees are looking at new technol ogy entrants in a much more cost-driven fashion.

This becomes particularly relevant if a physician wants a new technology or wants a new DES (due to some evidence-based advantages of one DES versus another). It used to be that was all that we needed to look at; now,

much more attention is paid to the questions, "What are we getting for that evidence-based difference" and "How does this translate into an economic advantage for the health care system?"

Does that change the way coronary stents are being purchased by hospitals?

Dr. Turco: Hospitals are placing tremendous pricing pressures on industry to lower costs. Product review committees within any particular hospital, which used to be physician driven, are now in many instances driven by the hospital administrators who are really looking at the cost drivers of new technologies coming into the hospital. The question is, by cutting costs at the hospital level, will we get economic return to the United States health care system, or will this affect future growth and drivers of the health care system that might have even greater impact on cost reductions? The ultimate goal for society is to offer the highest quality care at the lowest cost to not only the hospital but also to the patients who are number one in this process. We can't just look at one part of the system, we need to understand the whole process.

How frequently are those hospital administrators physicians themselves?

Dr. Turco: It is rare that hospital administrators are physicians. It would be great to have more physician administrators.

That leads us full circle back to the issue of the competitiveness within the DES space for market share and market price. Hospitals given cost constraints are looking for that $100 to $200 advantage, especially at higher-volume cath labs, which may lead to large savings and help them with the bottom line. There are those who would say, "Well, that's healthy competition, and that's great." At the same time, I would say that we need to ensure that we are not ultimately going to hurt innovation and transformation, which are critical to advancements in patient care.

If we have longer, more expensive regulatory paths including postmarket approval (PMA) demands that have significant cost, then how do we drive innovation without the ability to reinvest into the system? It gets into that whole time-to-market cycle, and if we don't have that money to reinvest into research and development, then how do we develop newer and innovative devices to help our patients?

If hospitals are increasingly using a cost-effectiveness basis to decide which DES to buy, could the result be fewer options of DES for patients?

Dr. Turco: I wouldn't say that right now patients are in any way being affected by the transformation of the marketplace. But the concern is, if we continue down this path, that we are not going to be that first-tier health care system and that the United States will very quickly lose out to our European and Asia-Pacific Rim colleagues because it will be easier for them to drive innovation. Medical device companies may choose to work outside of the United States for innovation because of the more user-friendly system, which may come back to have an impact on patients and health care in the United States.

Right now, it is difficult to say that patients are being affected if a hospital system decides to have just Xience on the shelf due to a lower sales price than Promus, because they are the same product, obviously. However, I think down the road, with resorbable stent technologies, resorbable polymers, or nonpolymer DES platforms coming onto the market, at that point, if an industry sponsor were to want a premium on those particular products, the question is, will there be enough differentiation between the earlier-generation DES with durable polymers to allow for a clear-cut cost-effectiveness benefit to a health care system?

I'm afraid at that point, physicians are going to be taken out of the mix, and economic decisions may be made. This change is not different from what we see many times from western European countries, but it will be a change for United States medicine.

The DES market is generally considered to be about $4 billion per year in the United States. Why are there only three companies interested in this very large market?

Dr. Turco: Well, it is an indication of how competitive the market is, but I think it speaks to the pricing issues of DES. Also, I think it speaks to the regulatory path that we have within the United States.

As you know, any DES coming to the market within the United States needs to go through an onerous and expensive PMA process through the US Food and Drug Administration (FDA) and needs to demonstrate the safety and efficacy component and endpoints that the FDA requires. Furthermore, large postmarket registries are needed after approval. That is quite different than what we see outside of the United States with the CE Mark process.

Also, within the United States, we are likely going through a revision of the 510(k) process, which used to be a process by which the FDA allowed devices to come to market once a medical device manufacturer showed that they were as safe and effective as a predicate device. There is talk about changing the 510(k) process for some devices, and although this is not related to DES because any new DES would need to go through a PMA process,

it is another example of how the regulatory onus within the United States is so great that it might limit the number of vendors that would want to do business in the United States. It's just very difficult for smaller competitive companies to come into the United States. Whereas the Europeans have a number of DES to choose from, within the United States, our physician community has limited choices of DES.

How will these factors affect innovation in the DES market, and can we now expect fewer new devices and fewer clinical studies?

Dr. Turco: I think the clinical requirements for the FDA with new medical devices are not going to become more lenient; they are likely going to have an increased onus. This might ultimately have an impact on innovation within the United States. If you move outside the world of DES and look at where we are with transcatheter valves, the Sapien valve (Edwards Lifesciences, Irvine, CA) has just recently undergone FDA panel review, yet the Sapien valve has been available outside of the United States for a number of years and is doing very well with regard to its safety and efficacy profile. The same goes for the CoreValve device (Medtronic, Inc.).

At some point, there will need to be a happy medium between being sure that within the United States we meet a certain bar that everybody is comfortable with regarding safety and efficacy, but that innovation is not hurt.

What role will health care reform play in shaping the DES market?

Dr. Turco: The health care system is going to need some transformation of itself. Again, it gets back to quality care at the lowest cost. What will become most important is that we continue to look at ways to prevent disease as a way to reduce health care costs.

One of the areas in which there are going to be challenges, and we are already seeing it, are workforce issues—the availability of specialists to provide specialty care in the face of increasing Medicare cuts and a more burdensome health care delivery system. That is a grave concern for patients, especially in remote areas.

Another area of concern is regarding the comparative and cost effectiveness within health care reform. Is that ultimately going to lead to some rationing of health care? I think we are all concerned with what may be coming down the pike—a more rationed approach. Physicians also need to look internally at the procedures we are doing and be sure that all of our procedures are appropriate and within guidelines. A recent article in the *Journal of the American Medical Association* from the American College of Cardiology database with regard to the appropriate use criteria applied to percutaneous coronary intervention for both elective and acute myocardial infarction catheterization showed that a percentage of elective catheterizations did not meet the appropriate use criteria. Evidence-based medicine must be followed, but at the same time, it is critical that we allow physicians to individualize care to their patients.

I think these are some of the big issues related to health care reform within the medical device space. Cost reduction needs to come by providing better care to keep our patients well. If we limit the ability to innovate, how can we find new treatments to obtain these goals? We have great opportunities to continue to bring transformational technologies to market. We went from the era of balloon angioplasty, to bare-metal stenting, to DES with a durable polymer, and are now moving toward resorbable polymers, nonpolymer platforms, and the drug-eluting balloon space. These are great transformations that are within the endovascular space that can only help patients, but we need to be very cautious of how some of these external drivers may affect innovation.

What factors do you think led to the Cordis Corporation (Bridgewater, NJ) decision to leave the DES market?

Dr. Turco: First, I think that Cordis and Johnson & Johnson (New Brunswick, NJ) are great innovators. They brought us the first bare-metal stent, and moved forward and brought the first DES to market. It's not always easy to be first, but clearly, their launch of the Cypher DES brought the field of interventional cardiology to a new level.

It is a very competitive space in which one needs to continue to iterate, and there are tremendous pricing pressures. I think that when they looked to their next-generation platform, they saw a long and expensive path to the United States market. I can only assume that at that point, they made a business decision that, given an extensive sales force and the costs associated with bringing a new platform to the competitive field that we are in, it just was not a good business strategy to continue.

I want to emphasize that this is my own personal opinion and speculation—I have no other insight, information, or knowledge, and it is sometimes wrong to speculate. But I see this as what I referred to previously as the transformation of the medical device field. We are transforming. We are becoming more compact and more consolidated due to cost pressures to bring technology to market. We will likely see increased consolidation during the next few years. This field has seen cycles of consolidation, and this may be one of those cycles.

As somebody who recently joined industry and is now in the medical device space, I see great opportunities for some of the medical device companies to move forward and look at strategies to strengthen portfolios, allowing for innovative devices and improved technologies to come to market to ultimately have a very positive impact on patient care.

It almost seems like a bit of a catch-22 because that portfolio acquisition process leads to more consolidation.

Dr. Turco: It does lead to more consolidation, and there are those who would say it leads to less competition. If you have less competition, you are going to have less pricing pressures because of the limited competition.

At the end of the day, it is up to us within the industry to be sure that we are efficient with our manufacturing processes and that we are able to reduce our production costs so that we can efficiently bring truly cost-effective, safe technologies to market that will have a very positive impact on patients. Physicians, hospitals, industry, regulators, and governmental bodies must all work together to maintain a "healthy" health care system. ■

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