**PERSPECTIVE:**
Physician/Supply Chain Director

# Managing the Tough Choices Ahead

A physician with both clinical and supply chain expertise shares thoughts on how the Affordable Care Act and regulatory and reimbursement challenges could affect vascular practices.

*Sean Lyden, MD, is a vascular surgeon who specializes in aortic, carotid, and lower extremity disease therapies. He has practiced at the Cleveland Clinic since 2001 and has extensive experience in a variety of clinical studies, authoring more than 60 articles to date. In January 2010, while continuing his vascular practice, Dr. Lyden also took on the role of Medical Director for Clinical Supply Chain Management, serving not just the division of Vascular Surgery, but the entire Cleveland Clinic Health System. In this role, he was tasked with aligning and engaging physicians to work with supply chain to quickly and significantly cut operational expenses in the 3 years leading up to the present. He has closely followed the proceedings of the Affordable Care Act (ACA). With the ACA now in place and a variety of additional pressures on physicians, hospitals, and industry continuing to mount, we asked Dr. Lyden to share some of his impressions on the current landscapes of regulation, reimbursement, and innovation.*

### Which is the bigger barrier to future device innovation in the United States: the regulatory process before approval or the uncertainty regarding reimbursement?

It is a balance of both. The regulatory process stifles innovation, while reimbursement uncertainty has cut back investment by venture capital. Innovation is stifled because, the way the Code of Federal Regulations is written, companies have to propose something first, and the FDA can comment on it and then ask questions about the proposal. The voting to approve a product comes at the end of all the work. The FDA has very strict guidelines; it can't sit down and say to industry, "If you do these specific things with this outcome, we'll approve it." As written, the laws don't allow the FDA to do it that way.

At the beginning of the process, the companies are trying to figure out what would be acceptable. They submit a proposal to the FDA, and the approval either gets approved or denied. Because a lot of this involves evolving areas of treatment and the progressive understanding of diseases, the amount of data required or requested by the FDA as the collective knowledge advances is also always changing. If one company successfully gets a protocol approved, it does not necessarily enable another company to follow suit because the FDA might not approve the same protocol due to the accumulation of new knowledge.

In the vascular arena, we have seen less investment by venture capital. According to the MoneyTree Report from PricewaterhouseCoopers, venture capital funding in the Life Sciences sector, which includes the biotechnology and medical device industries, dropped 14% during 2012. I believe a large portion of this is due to the concerns over lack of reimbursement for new devices and procedures. It is more difficult for small startups to get money, even if they have a good idea, because companies aren't convinced they will see any return on their investment. Because the Centers for Medicare & Medicaid Services (CMS) determines reimbursement, and that process is separate from FDA approval, new devices and procedures are not reimbursed at the outset despite proof of safety and efficacy. CMS determines coverage policy by determining whether services are reasonable or necessary. This process is determined either as a national coverage decision or at the local carrier level. Local carrier medical review policies lead to nonuniform coverage decisions throughout the entire United States. For CMS to determine if a procedure is reasonable and necessary to drive a payment model change

and cover the procedure, it may require long-term outcomes or outcomes compared against existing procedures. These are almost never available at the time of FDA device approval.

### Are there any ways in which the regulatory and reimbursement forces can also foster innovation?

It could be possible, but I think it would take a paradigm shift from our government. The FDA is held in a pretty tough stance. People complain because it is difficult to get things approved, but as soon as there is a problem, they also hold the FDA accountable, especially with the legal environment in this country.

What none of our lawmakers do, and what we as physicians haven't pushed them to do, is say our system is broken. We have the FDA for device approvals, we have CMS determining the payments, but those two pathways are not connected at all. When something gets approved, there is no guarantee it will be paid for. We need to sit down at the table with the government, asking how to rewrite the Code of Federal Regulations such that those things are linked from the start. If a company is designing a device and if they prove it is safe and effective, it should be covered. This process should then require comparative studies against other approved similar devices to continue payment. The problem with our current process is there is little incentive to do comparative studies. If a device has reimbursement and it is shown to be less effective, it will go off the market. It's a big risk with little reward for already approved devices from a corporate side. The increased use of electronic medical records hopefully will allow physicians to gather and publish longitudinal comparative outcome data.

### What do you anticipate the effects of the latest "doctor fix" extension will be?

The doctor fix was enacted at the beginning of this year, avoiding a 27% reduction to physician payments. The doctor fix extension avoided an immediate impact that would have threatened the viability of many physician practices. We recently still received cuts to reimbursement when sequestration began on March 1, requiring $85.4 billion in nondirected cuts. Medicare reimbursement to physicians and hospitals was reduced by 2% due to this process this year. If budget cuts or increased revenue are not found, the sequestration process will reoccur yearly. The sustainable growth rate (SGR) formula is still in effect and will be required again in January 2014. A 2010 American Medical Association survey noted one in five physicians were restricting the number of Medicare patients in their practice. The top two reasons they gave for this restriction were Medicare payment rates are too low and the ongoing threat of future payment cuts, making Medicare an unreliable payer. I predict that we will continue to see an increasing number of physician practices opting totally out of Medicare or limiting the number of Medicare patients.

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### What are your thoughts on how the medical device tax will affect innovation in the US?

I think it will slow innovation. The IRS and the Treasury Department issued final regulations on December 5, 2012, and the payments are due quarterly, with the first payments due April 1, 2013. Most companies are just seeing the figures for how much this will mean to the bottom line. If I were running a company and facing this financial uncertainty, I would likely hold on to cash. Once three or four cycles of this payment have passed and companies have a good idea of what the device tax means to the bottom line, it will stabilize. But until they know how much it will affect their total statements for income and revenue, they clearly will not want to make major acquisitions or investments.

### How do you think the tax will affect physicians directly, both in the short and long term?

Physicians are required to obtain continuing medical education (CME) credits. The most common way for most physicians to obtain CME is by attending conferences. Conferences are very expensive to run, and a lot of the financial support today comes from the medical device industry. The device tax will force companies to cut back budgets, and conference support is likely to be reduced. I predict we will see some CME conferences disappear because companies won't be able to sponsor so many local, regional, and societal meetings. That will make things difficult for physicians because we're required to have continuing education and to keep up with current and developing technologies. These meetings are a great way to do that.

**In our February 2013 edition, you described the potential impact of the Affordable Care Act (ACA) and the device tax on endovascular aortic aneurysm repair. How do you think these forces will affect lower extremity revascularization?**

I think that what I predicted will not be just for EVAR, but for all vascular disease. Most of our peripheral vascular disease patients are older than 65 years of age and are Medicare beneficiaries. Medicare is likely to continue to try to reduce expenditures. We will continue to see bundling of our current procedural terminology codes and decreased reimbursement. We will be pushed to report and define outcomes without economic support to cover those costs. The reduction of venture capital, increase in medical excise taxes, and potential reduction in corporate revenues may lead to consolidation of device companies and slowing of innovation.

**What do you think the ACA will mean for clinical study going forward?**

The legislation is intended to help us look at outcomes and the overall cost of care, but it really doesn't provide guidance on how to make that happen. It will leave an open point for innovation and for people to try to define outcomes, to improve and share risk, but it doesn't really provide guidance to do that. There may be some new innovative players—from the payer side, the doctor side, and the device side—looking at ways to make that happen.

Perhaps there will be an interesting new concept that approaches the ACA in a way that no one else has thought of, similar to the Apple iPhone. This was something we didn't think we needed 10 years ago, yet a large percentage of the entire United States population is now walking around with one. An interesting entrepreneur could find a way to cut costs in clinical study and make money along the way. In terms of how and when the changes will occur, the ACA pushes for that to start to happen, but it doesn't really give guidance on how to do it.

**Even when well-designed, multicenter, randomized trials are undertaken, there are often debates as to what the data should mean for the future use of the techniques being evaluated. Different parties with unique biases can look at the exact same data and strongly voice opposing responses. How do you see the field dealing with a call for even more validation of current and future treatment options?**

In the next 5 to 10 years, we may start better utilizing electronic medical records. The problem is that, especially for the lower extremity, it is a diffuse disease pattern, and although trials may have similar results, it is difficult to ensure the patients are the same. It would be great if electronic medical record companies could partner with industry to capture real-world treatment and define what the patient population is in terms of their medical and their anatomic risk factors. By doing so, we could gather large datasets to look at how effective our treatments are. Such a system could capture both the inpatient and the outpatient encounter and provide longitudinal data to start studying outcomes in a more comprehensive fashion without spending the hundreds of thousands of dollars it takes to conduct a randomized clinical trial.

**How are reimbursements to hospitals and physicians changing with the implementation of the ACA?**

Almost 70% of physicians in the United States are no longer in private practice; they're employees of large groups or hospitals. They will be faced with the bottom line that, as part of their budget, has to be balanced, and less reimbursement will be provided to hospitals. Even 5 to 10 years ago, most physicians were in private practice or self-employed, and the decisions and choices as to which devices they used in the hospital did not affect their own personal income. There is becoming a more direct link of your expenditures to your income. As an employee of the hospital, we are now tied to the financial viability of that system. If a hospital is not profitable, we will share in that loss eventually. When the hospital is paying the physician salary and they go out of business, then the physician is out of a job.

As we see a reduction in revenues, the hospitals are forced to reduce costs. This can be done by a reduction of salaries, personnel, capital, or disposables. Most of us would prefer a reduction of disposables before salaries or personnel. Many hospitals are now beginning to ask physicians to make choices regarding the types of devices available to use for procedures. Consolidation of vendors can lead to better prices and a reduction in disposables spent.

**The ACA will affect different types of services differently, especially if you compare primary and specialty services. Do you have any impressions as to whether it will affect vascular specialties in disparate ways?**

According to CMS, the main goal of the ACA is to improve health care quality and slow spending growth in Medicare. Vascular specialists take care of an inordinate number of Medicare-eligible recipients—more than any other specialty. If spending is reduced by Medicare, vascular specialties are especially at risk. With

most other specialties, there is a better mix of private-pay patients to government-pay patients, which limits the effect of governmental cuts.

### What about within the vascular specialties, from one specialty to another?

I believe that practices that care primarily for peripheral vascular disease will be more affected than people who care for coronary vascular disease. There is a higher percentage of people under 65 who develop coronary disease as opposed to peripheral vascular disease, thereby affecting cardiology practices to a lesser extent. We are likely to see a bigger reduction in reimbursement for endovascular procedures as more codes continue to be bundled. Open surgical procedures are already bundled, so less reimbursement changes are likely in the short term. Vascular laboratory has come under scrutiny with recent pressure for cuts in reimbursement. Practices that have revenues driven by endovascular procedures and vascular ultrasonography will see the biggest impact.

### What are some of the ways that the Cleveland Clinic is preparing for or responding to the implementation of the ACA and the changes in reimbursement?

About 4 years ago, our CEO, Toby Cosgrove, MD, started telling us as physicians that this time was coming and that we needed to prepare. He saw it as an opportunity as opposed to a time of tightening; because we're a physician-run and a physician-led organization, we would look at every procedure we do, trying to find value to improve our outcomes. He has made us question how we spend money, how we get patients more efficiently through our hospital system, as well as how we try to keep them out of the hospital.

When he first said that to us, none of us was sure what he meant, and we thought he was a little crazy. Now he looks like a pretty important visionary, having said, essentially, that the train's left the station, and we see it as an opportunity to become a leader because we're not going to cut our outcomes, but we have to achieve them more efficiently, at a lesser cost. ■