# Jack Lewin, MD

The President and CEO of the Cardiovascular Research Foundation shares his views on the current impact of health care reform on the cardiovascular care community and shares predictions for the next 20 years of interventional cardiology.

**Do you think the Sunshine Act will cause a significant stifling effect on physician-industry relationships and hence innovation in the United States? Or do you think it will turn out to be a reasonable tool that was needed to keep conflicts of interest in check?**

The answer to this is complex. I think that the Sunshine Act will have somewhat of a chilling effect on the relationship between physicians and industry because both sides will be reluctant to have their activities perceived as potentially biased through industry funding. However, I think that over time, we will find our way through these concerns about reporting of financial exchanges to a more normalized relationship based on mutual respect and transparency, as well as on the important and long-standing relationship between industry and physician partnerships in promoting innovation. This relationship has also been key in promoting faster translation of scientific knowledge to better patient care through industry-sponsored education. Another positive element here has been industry's historic role in training physicians in the latest techniques and technologies. There is no doubt that bias has been created by industry funding. However, there has also been unbiased value, and we shouldn't forget that.

Over time, I also believe that the current provisions of the Sunshine Act will be modified to increase reporting threshold amounts to a more reasonable level. At this point, it's somewhat of an overreach that industry has to report something as trivial as a latte offered to a physician! The accounting of such small financial exchanges creates wasteful administrative costs without contributing much, if any, value in terms of bias transparency. That's why I think there will be improvements to the law, including raising the reporting threshold to something more reasonable (perhaps a minimum of $50) in the near future.

**What advice would you offer to physicians about managing partnerships with industry in order to allow scientific progress but maintain conflict-of-interest ethics and transparency?**

I would advise physicians to embrace transparency and not to try to gain something from industry through indirect means, such as an intermediary party, to avoid Sunshine Act reporting. In other words, just be transparent about where your funding sources come from and be proud of those relationships if you seek them. Explain the value of honorable educational or research-related industry relationships you've chosen during your career with your patients, colleagues, and the media.

**With the renewed examination of medical technology and regulation globally, do you see it becoming an arms race situation in which the United States will find it difficult to maintain its status as a leader in innovation, or will it be an effort of global cooperation to improve the health of patients worldwide?**

I think there's going to be increased global competition, regardless of the changing regulatory environment. That's inevitable and healthy, and we in the United States have to be aware of and prepare for it. The most important thing that we can do to promote our own history of innovation is to streamline the US Food and Drug Administration's (FDA) regulatory processes, as well as those of the Centers for Medicare & Medicaid Services (CMS), to both promote innovation and improve patient safety more effectively.

Currently, in the United States, we have a somewhat confused sense of the purpose of regulation. Regulation is in place largely to promote patient safety, as well as to ensure drug and device effectiveness. However, excessive caution and/or expectations about preventing complications and side effects (patient safety) in the United States has, to some extent, worked against innovation by increasing unnecessary regulatory hurdles, time to market, and regulatory costs as compared to other nations and regions. Even one major complication is seen as one too many by many consumer groups and the media. Rather than bashing the FDA, which to a very large extent is a victim of unrealistic public expectations and a gridlocked Congress in terms of receiving the resources it needs, we should support the agency into becoming a promoter of innovation for the future that expedites regulatory processes while simultaneously further improving patient safety. The FDA should someday (soon I hope) possess the resources in information technology and data analytics capabilities to track every patient who is taking a new drug or is the recipient of a new device or therapy in

*(Continued on page 64)*

(Continued from page 66)

order to detect even the most subtle side effects, complications, or even unexpected improvements in outcomes.

I believe the FDA needs more federal funding to do that kind of patient tracking and to engage in better scientific analysis and economic modeling related to new drugs and devices. There has to be more open access to electronic health records, registries, insurance, and other medical repositories of clinical data for the FDA and CMS to expedite the regulatory processes and allow responsible oversight of both agencies. These agencies need adequate resources for both scientific analysis and economic modeling of new drugs and devices. The political and economic environment related to drug and device innovation has already changed. Health reforms and new payment models are developing to counter the unsustainability of rising health care costs and are already having powerful effects on drug and device innovation. New higher-priced products that offer little clinical advantage over current therapeutics are no longer going to be viable. Tweaks and "me too" drugs and devices will not be able to be priced high enough to cover their research and development costs.

In other words, there is growing pressure on industry to be sure that they're developing new products that provide a societal return on investment in terms of "value," meaning better outcomes, lower costs, or both.

**Do you think there will be a change in the role of societies to bridge the gap between physicians and regulation?**

Certainly, we would welcome having professional societies join with the Cardiovascular Research Foundation and other interested groups to help the FDA and CMS secure adequate funding to promote innovation (and patient safety). This is an important issue that we need to promote together. Also, I think societies have to be careful not to be inappropriate conduits of industry funding to doctors, which can be seen as working in opposition to the principles of transparency in the Sunshine Act. Societies have an important role in educating physicians about the need to both streamline the regulatory processes in the United States and improve patient safety as the path to promoting more innovation in drug and device development.

**What new clinical trials designs are on the horizon and how will they improve our basis of knowledge on new techniques and technologies? What kinds of negative industry-sponsored trials are coming down the pipeline in an effort to increase transparency?**

In the past, negative or equivocal industry-sponsored trials were typically put on the shelf and not made publically available. Through the work of Harlan Krumholz, MD, at Yale and others, there's been a movement to promote open access to all research results, including those with negative outcomes. This would not only increase transparency, but prevent wasting time and resources in repeating studies that have already been done. I think that there will be a push on industry and academia to make sure that all future research endeavors, even if they're not published, are nonetheless available for other scientists and clinicians to evaluate and consider as they're planning new research or therapeutic approaches.

**With the focus of efficacy studies shifting from acute to more long-term outcomes to support reimbursement, will physicians need to record their experience and data on a more detailed individual level, and how will that impact daily clinical practice?**

The necessary shift to measuring outcomes over longer time frames will absolutely affect clinical practice, as well as hospital and physician reimbursement in "value-based" payment models. We physicians should become more interested in following our patients for many acute and all chronic conditions over multiple years to achieve better longer-term outcomes. Physicians need to be tracking over the longer-term for procedural outcomes and related complications, readmissions, quality of life measures, and functionality for their patients. And I think we're going to rely significantly in the future on patient-reported outcomes as well. Patient-reported outcomes may likely be a more accurate means of long-term clinical outcomes follow-up than traditional chart records offer.

**As hospital decisions on device coverage will fall more to scientific and administrative experts, and less on individual clinicians, how do you think physicians react? Do you think they will feel restricted in terms of operator preference or more secure because their treatments have the backing of their institution?**

Physicians are already feeling some of this shift of power away from them, and I think there is often a Kübler-Ross sequence of reactions. Doctors are first in denial that they can't always choose whichever device or drug they want, then they become angry and frustrated, but eventually, they reach acceptance that drug and device access and formularies need to be developed more scientifically, with consideration of costs as well as quality of care.

Also, from a cost-containment perspective, we need to look at what will produce the best outcomes at the most effective costs for society, patients, and a sustainable health care system. That's "value." The other factor here is that the

science is moving so fast that, quite frankly, we as individual physicians can't easily keep up with the current science in order to effectively evaluate which is the best drug or device to use for our individual patients. I think clinicians are gradually developing the understanding that participating in or supporting the value of newly emerging and increasingly effective formulary development committees that rely on health technology scientific assessments related to new drugs and devices will improve quality and reduce unnecessary costs over time. It is also likely that patients will be increasingly involved in decisions about which drug or device to use as payment reforms require patients to pay more out of pocket for the care they receive.

**How will the shift toward bundling payments be a positive force in quality of care and reimbursement?**

I think bundling will be a powerful tool as part of the transformation of payment and delivery systems in the health reform process. I think bundled payments, if properly constructed, can be a win-win-win situation for doctors, patients, and society. For example, currently, a cardiologist gets paid something in the ballpark of only $800 for an elective percutaneous coronary intervention (PCI; angioplasty and stenting) procedure; if you go back 10 years, that reimbursement might have been $3,500—the reimbursement for elective PCI has come down significantly. If you look at the overall costs related to PCI in the 90 days following the procedure, the bundled overall cost is roughly $30,000, of which perhaps about $17,000 is spent on the inpatient hospital care, and as noted, $800 is the cardiologist's acute procedure reimbursement. The remaining approximately $12,000 is spent in the postacute care period over the next 90 days.

The reality is that most patients don't incur $12,000 of postacute costs. It's the relative few patients who end up with complications (eg, stent thrombosis, arrhythmia, heart failure, etc.) that result in rehospitalization and/or an emergency department visit(s) where that other money is spent. So, this is where the major savings can also occur if complications and/or readmissions can be prevented. In bundled care models, whatever savings can be achieved (assuming quality of care and patient satisfaction are good), the clinicians keep perhaps 50% of what is saved. Thus, if a cardiovascular group/hospital system took the responsibility of cardiovascular-related postacute care of their patients for the 90 days posthospitalization, and they were able to prevent only 20% of readmissions or complications from occurring by focusing on those who might be most at risk, the individual patient reimbursement for the cardiologist jumps back up from $800 to $3,500 per patient, just by preventing one out of five complications or readmissions. The other 50% of the savings goes to the payer (Medicare or the insurance company). Because of this, payers are incentivized to help the doctors succeed in the bundled models.

In this model, society wins because the health care costs go down, patients win because we are preventing more complications, and doctors and hospitals win in terms of better reimbursement. Of course, there is a large number (possibly 40%–50%) of readmissions that will be very hard to prevent because, even with better medication adherence and coordinated care, complications still occur. But only a 20% or 30% reduction in complications from what we see today will allow significant savings, better overall outcomes, and an opportunity for higher reimbursement for physicians and hospitals.

**You seem to enjoy taking on the role of the prognosticator, so let me ask you, what do you predict will be the biggest change for those involved in cardiology care 20 years from now?**

I think science is on a roll, and we will be blown away by how much scientific and clinical progress will occur in the next 20 years. We can't even imagine some of the things that are about to happen. This isn't limited to pharmacology and devices, it's also through information technology that amazing things will happen. A lot of care—including some acute care—will shift to the home using new apps, mobile devices, virtual physician visits, and remote biomonitoring. The cardiologist of the future will need to find new ways to keep up with critical advancements in science. Specifically, genetics, genomics, and immunologic markers will have a hugely powerful role in both primary and secondary cardiovascular disease prevention. We will be able to identify patient populations who are more likely to benefit from personalized therapeutics. The patient will be the most important member of the care team because he or she will have more information and choices of care available to them than ever before. Patients will have access to reliable information to enable their choice of the best physicians and hospitals, as well as the most successful therapeutics—on a personalized basis—for themselves. The physician of tomorrow is going to have to be truly partnered with the patient in a way that we haven't been trained yet today to prepare for! ■

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