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Surgical innovation and ethical dilemmas: A panel discussion

END RESULTS: WHY SO ELUSIVE STILL?

Dr. Isador Lieberman, Moderator: Let me begin this discussion with a 1910 quote from Ernest Codman, a general surgeon at Massachusetts General Hospital, who stated:

> In 1900 I became interested in what I called the "end result" idea, which was merely the commonsense notion that every hospital should follow every patient it treats long enough to determine whether or not the treatment has been successful, and then should inquire, "If not, why not?" with a view to preventing similar failure in the future.

My questions to the panel are: What has changed in the last 100 years? Are we documenting our end results? Have we gone wrong and, if so, where have we gone wrong?

Surgical training is now so oriented to operative techniques that residency programs have difficulty dealing with other important issues, such as evaluating outcomes.
—Dr. James Herndon

Dr. James Herndon: Although Codman's ideas in this area were not well received at the time, today we do have some "end result" ideas. We have outcomes data, but I would argue that they are far too limited and not to the level required in the 21st century. I have asked myself many times why the surgical profession has not focused on this issue more than it has. I agree with Dr. [Joseph] Fins' comments in his presentation [see previous article in this supplement] that it would be nice to have a bottom-up approach rather than a top-down approach, but I do not see a change until we as physicians step up to the plate and make a change.

Why haven't we? There are a number of reasons. The malpractice climate in the United States has been one major factor. Surgeons fear disclosure. The relationship between a surgeon and the patient is professional and private, and physicians do not want transparency—they do not want their patient or anyone to know that an adverse event or bad outcome has occurred.

Also, doctors, especially surgeons, are reluctant to use guidelines or follow protocols. I participated a number of years ago in an American Academy of Orthopaedic Surgeons project called MODEMS; it was an attempt to set up guidelines for orthopedic surgeons to manage back pain, shoulder pain, and other orthopedic conditions. By the time we finished we had accomplished nothing, because the protocols and guidelines were so extensive that almost any type of management for any patient would be compliant.

Additionally, hospitals in the United States have become more like for-profit businesses, with a focus on short-term profits and with short tenures for their chief executive officers (CEOs)—4 or 5 years, on

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Dr. Lieberman reported relationships with Merlot OrthopediX (management, founder, inventor, board member), Axiomed Spine Corp. (consultant, teacher/speaker, advisory committee member, inventor), Trans1 (consultant, teacher/speaker, advisory committee member, inventor), CrossTrees Medical (consultant, advisory committee member, inventor), Kyphon (consultant, advisory committee member, teacher/speaker), Mazor Surgical Technologies (consultant, advisory committee member, inventor), DePuy Spine (inventor), and Stryker Spine (inventor). **Dr. Herndon** reported relationships with the *Journal of Bone and Joint Surgery* (member of board of trustees), Revolution Health (employment), Dartmouth Medical Center (member of advisory committee), and the Bard Group (consultant). **Dr. Hahn** reported no financial interests or relationships that pose a potential conflict of interest with this article. **Dr. Fins** reported that he is an unfunded co-investigator of research on the use of deep brain stimulation in the minimally conscious state funded by Intelect Medical Inc. **Dr. Rezai** reported relationships with Medtronic (teacher/speaker, clinical trial funding) and Intelect Medical (ownership interest and consultant).

This article was developed from an audio transcript of a panel discussion. The transcript was edited by the *Cleveland Clinic Journal of Medicine* staff for clarity and conciseness, and was then reviewed and revised/approved by each of the panelists and the moderator.

average. With nearly 50% of US hospitals bordering on bankruptcy, they are not able or willing to invest in major patient safety protocols and guidelines because the CEOs do not see a short-term benefit to them. Witness the fact that only 15% of US hospitals have computerized physician order entry systems and electronic medical records. From what I have read, it takes about 5 years before a hospital recoups such investments from the resulting safety improvements and efficiencies.

These are some, but by no means all, of the reasons we do not have appropriate outcomes in all specialty fields. My plea is that physicians lead the effort to measure and report outcomes down the road.

Dr. Lieberman: Dr. Hahn, why do you think we have not kept up with Dr. Codman's premise from 100 years ago?

Dr. Joseph Hahn: We hold a yearly Medical Innovation Summit at the Cleveland Clinic, and what has emerged from many of those meetings is a lack of interest in paying for outcomes analyses. The providers, the government, and industry all say that they do not have the money for these analyses. So the first reason that Codman's premise has not been lived up to is that the source of funding remains undetermined. Second, most surgical innovations have been geared toward inventing devices to overcome very specific problems that arise during or following surgery rather than toward substantiating the worth of a procedure through collection of evidence. A third reason involves the pressure that investors place on industry to make money, which tends to lead to investments in getting products to market rather than outcomes research. With all of these factors and the pressures from so many directions, the surgical profession hasn't stepped back to thoroughly consider what we are doing to our patients and just how worthwhile it is.

As innovations develop, we have to ensure that the new technology is matched by the operator's skill.
—Dr. Joseph Fins

Dr. Lieberman: Who do you think should be paying for outcomes analyses?

Dr. Hahn: I think the government should. The role of government is to take care of its citizens. The Centers for Medicare and Medicaid Services (CMS) does its best with the information it has, but it admits that it pays for some procedures without knowing whether or not they are truly worthwhile. An example is the use of artificial discs in the cervical spine. I am sure that the artificial disc manufacturers made a case for their product to CMS by claiming it was associated with less pain and resulted in a superior outcome compared to fusion using bone from the hip, regardless of whether they had the scientific evidence to prove it.

Dr. Lieberman: Dr. Fins, would you like to weigh in on Codman's "end result" premise?

Dr. Joseph Fins: I would just point out that the history is not homogeneous. I have been involved in deep brain stimulation work, and the legacy of psychosurgery has been an egregious lack of outcomes studies, but now we do have outcomes studies and scales. For example, there is now the Yale-Brown Obsessive Compulsive Scale to rate the severity of symptoms in obsessive-compulsive disorder. In our deep brain stimulation study,[1] we are using a coma recovery scale, and the Food and Drug Administration's (FDA's) investigational device exemption (IDE) process requires us to produce outcomes data to protect potential subjects. It may be an example of neuropsychiatric exceptionalism that neurology and psychiatry are areas of increased focus while somatic therapies are somehow presumed to be okay.

Dr. Hahn: FDA may be requiring the outcomes data, but I have not heard that they are willing to pay for it.

Dr. Fins: You are correct.

Dr. Ali Rezai: Part of the problem is the translation of rapid scientific discoveries and technological advances into the field, and education has a role here. Surgeons' reluctance to integrate guidelines and outcomes measures into practice must be addressed very early in their training—in medical school—and then continued throughout residency and fellowship programs. The same early and continuing approach should be taken with respect to how to conduct and properly interpret a clinical trial.

Dr. Herndon: That is a good point. Surgical education programs have slipped a bit in the past 5 to 10 years, at least in orthopedics. With the reductions in residents' work hours and the fast pace of residency programs, our residents spend most of their time in the operating room, struggling to master the multitude of procedures in orthopedics. As a result, they are not discussing outcomes or adequately following patients long-term after surgery. I have a hard time getting our faculty to bring residents into their offices so that the residents can examine patients and see why they are operating on certain kinds of patients, as well as the

types of follow-up information that can and should be obtained from patients. Training today is so oriented to operative techniques that residencies have difficulty dealing with these other important issues.

WHO DEFINES THE INDICATIONS?

Dr. Lieberman: As new devices and new techniques emerge, who defines their indications? The inventor of the device, a government authority that may or may not have the medical background, patient advocacy groups, or the device manufacturer? And how should we regulate those indications?

Dr. Fins: I would echo Dr. Wilder Penfield's words, "No man alone." The orthopedic surgeon or neurosurgeon does not have to do this alone; it is really about teams. And those teams can and should include biostatisticians, recognizing that the biostatistician needs to fully understand what the surgeon is doing. There also has to be attention given to patients' individualistic outcomes. I recently met with some FDA staff and learned that the FDA is very interested in novel methodologies to better understand what counts as an outcome for individual patients. So I think indications should be guided by individualistic outcomes coupled with the surgical possibilities and with the rigorous biostatistical methods that are now evolving. A conference like this represents an opportunity to generalize the conversation and support more collaboration on indications going forward.

Dr. Rezai: Indications should be defined using a team-oriented approach. Part of the problem of psychosurgery in the past was that the surgeon was defining indications without collaborating with the psychiatrist. In my field of deep brain stimulation and brain pacemakers, everything we have done for the past 20 years—surgery for Parkinson's disease, depression, obsessive-compulsive disorder, traumatic brain injury, epilepsy—has involved working closely with neurologists, epileptologists, brain injury specialists, psychiatrists, and psychologists to agree on indications. These teams also need to have close partnerships with ethicists. Teamwork is a vital aspect of proper development of an indication.

Dr. Hahn: It has to be the clinicians who set forth the indications. Of course, that may be done by a team of clinicians, but as a surgeon I certainly do not want the manufacturers of an artificial disc telling me what they think the indications for an artificial disc are.

As for the role of patients, some of them are very well informed about their problem. I cannot tell you how many have shown up in my office with reprints of articles I have written. This is a trend that has really mushroomed over the past 10 years. But even though patients are catching up, they are still at a disadvantage. Patients are going to have a say, but it is still the clinicians whose role is to decide the indications and then provide patients with a risk-benefit analysis.

Dr. Herndon: I agree. Although patients are becoming more involved in the process, real shared decision-making has not yet happened in my field.

More broadly, I feel that our professional organizations have to become more actively involved in the process of defining indications. Otherwise, after the innovators develop a device or procedure that will significantly change the approach to a particular problem, it will enter the market at large without any critical assessment of the technology involved and without accounting for the learning curve for each individual surgeon.

It is important to try new technologies because the failure or complication rates may be reduced over time, but only if you evaluate the failures and then restrategize.
—Dr. Ali Rezai

Take the example of minimally invasive total hip replacement, which involves a 1-inch incision in the front of the hip and a 1-inch incision in the back of the hip. The learning curve for this procedure appears to be about 40 cases, based on the opinion of experts around the country. Yet when this minimally invasive approach emerged, every surgeon who had been performing total hip replacements wanted this new operation at his or her fingertips because patients were demanding it. Some surgeons adopted it too quickly, without adequate training. I know one distraught surgeon who abandoned the procedure because of numerous failures during his first 100 cases. He returned to the standard hip replacement approach.

Our profession cannot let this experience continue or proliferate. Yet the professional organizations in orthopedics have walked away from technology assessment because industry does not want it; technology assessment is not in industry's best interest. We have had a number of conflicts in our professional organizations when attempting to move technology assessment forward. It is also very expensive to do.

Finally, indications can sometimes be governed more by economics than by science. I was asked to

write a letter to the editor about two technologies for managing intertrochanteric fractures of the hip that were recently featured in the *Journal of Bone and Joint Surgery*.[2,3] One technology involves a compression screw that has been shown to be effective in outcomes studies. The other is an intramedullary nail that has not been well studied and has no proven benefit over the compression screw. In doing research for my letter,[4] I found that Medicare assigns more relative value units (RVUs) for the intramedullary nail than for the compression screw. In Boston, the total dollar difference in RVUs between the two is $300: the surgeon makes $1,500 for the procedure that involves the intramedullary nail versus $1,200 for using the compression screw. Not surprisingly, use of the intramedullary nail has been climbing rapidly in the United States without any evidence to justify its use over the other, less expensive technique.

CREDENTIALING: CAN IT KEEP PACE WITH INNOVATION?

Dr. Fins: I agree that surgical competence and regulation—self-regulation or professional regulation—are big issues. One of my greatest fears is that surgeons will do procedures they are not trained to do, and cause great harm as a result. We are hearing about this now with the resurgence of psychosurgery in China.

It strikes me as interesting that the field of neurosurgery is as yet undifferentiated and that there is no subspecialty certification in stereotactic neurosurgery. This is in contrast to invasive cardiology on the medical side, where physicians who do catheterizations and electrophysiologic studies have special additional training.

As innovations develop, we have to track qualifications and credentialing along the way. There should be provisions to grandfather surgeons in if they are in a post-training point in their career, but we have to ensure that the new technology is matched by the operator's skill. This is particularly pertinent in light of the concept of "surgical proximity"[5] and the importance of the individual operator; this is not comparable to just disseminating a new drug.

Dr. Lieberman: Who should do the credentialing? Should it be the government or our profession?

Dr. Fins: Recertification or credentialing should be by peers—the American College of Surgeons and the surgical boards. Of course, funders or payors may request an additional level of certification to do certain procedures, which I would endorse as a safety measure and to help ensure a minimal standard of care for innovative interventions.

Dr. Hahn: But it is not so simple. There is a blurring of surgical expertise once surgeons complete their training. Spine surgery used to be done by either neurosurgeons or orthopedic surgeons; now we have spine surgeons. What we neurosurgeons started to see with that change was that our neurosurgery trainees were being told they could not get on hospital staffs because they did not have credentials in spine surgery or, to take another example, in pediatric surgery. Well, the neurosurgery board made a conscious decision to not offer certificates of added qualification (CAQs). We challenged the hospitals in court and won. But the overriding message is that it is all about economics.

There is a learning curve for every operation, and learning on one's own, at the expense of patients, is not appropriate.
—Dr. James Herndon

Dr. Herndon: In orthopedics we now have two CAQs—one in hand surgery and one (starting in 2009) in sports medicine. The hand surgeons have not noticed any adverse effect because they do not generate as much revenue as the spine surgeons do. Most orthopedic surgeons start as general orthopedists and then change their practice characteristics as their practices mature. Over time they may focus on one particular area, such as arthroscopic knee surgery or total hip or knee replacement, which makes it difficult for them to pass a general orthopedic examination. Our board recognized this trend and developed oral and written board exams with case reviews concentrating on the surgeon's self-chosen specialty. We do not need the CAQs because they have been misused, and we as a profession have been letting others misuse them. Again, I think we need to get back to controlling the process ourselves.

Dr. Hahn: What do you do when a surgeon has finished training and then becomes interested in performing a new procedure developed since the time of his or her training? This can really be a challenge when the surgeon hears of a new procedure, goes and takes a 3-day training seminar on it, and comes back believing that he or she is ready to perform the procedure. I have had creative surgeons on staff who want to try a new procedure but have never done any cases, believing that the new technology alone will suffice. What we finally decided to do in these instances was

to put in place other staff to proctor these cases to ensure that no harm was coming to patients.

Dr. Herndon: I admire that approach, because we as a profession have to educate our colleagues about whatever new procedures they are about to use in their practice. There is a learning curve for every operation, and learning on one's own, at the expense of patients, is not appropriate. Should we have experienced colleagues work with surgeons on new procedures until they have performed the 40 or so cases necessary to be proficient? Should we send surgeons to other institutions to do their 40 cases under experienced supervision? I am not sure what the best approach is, but this is a question that a forum like this should begin to address.

HOW MUCH RISK IS ACCEPTABLE?

Dr. Lieberman: Let's build on this issue of credentialing by turning to the concept of risk. What is an acceptable level of risk with a new device? Is a 50% risk of an adverse outcome appropriate? What about 10%? And who determines the acceptable risk? The profession? The regulatory bodies? Patients?

Dr. Fins: Our expectation about risks in clinical practice should evolve from what was anticipated and actually observed in the clinical trial of an intervention. Adverse events should be envisioned prospectively in the design of a trial, with the magnitude of risks delineated in the protocol. Any unexpected risks that occur, even if small, could be a major reporting issue.

Beyond that, it is difficult to say what an acceptable level of risk is without a particularistic clinical trial. Whatever the risk of an intervention, the assessment of the risk must account for regional variation, variation among surgeons, and also systems issues.

The Institute of Medicine report, *To Err is Human*, attributed medical errors to faulty systems, processes, and conditions. So when we think about errors and risk, we have to consider more than just the individual operator. Just as *To Err is Human* analogized medical errors to airplane crashes, we might think of surgical retraining in the context of how pilots get retrained using flight simulators. If pilots have not flown a particular aircraft in a long time, they lose their flight certification for that type of craft and then must be retrained to operate it.

As surgical technology gets more advanced, specific, and nuanced, the discordance between one's training and the potential things one can do becomes greater. Paradoxically, innovation can at least potentially make situations more dangerous in that the operator may not be able to perform the task with the improved technology. For example, pilots who know how to fly a Cessna can fly another simply constructed plane, but if they attempt to fly a higher-technology aircraft, like an F-16, they have a greater risk of having a catastrophic event even though the F-16 flies better, faster, and higher.

Dr. Lieberman: But are you willing to identify a level of acceptable risk?

Dr. Fins: It is based on the patient's preference, after informed consent. An acceptable level of risk is the level that people are willing to accept. What I am concerned about is the variance around a known risk, whatever it may be, that is attributable to human errors that may be preventable through training or by solving systems problems.

Industry may try to convince us to use its innovations without our input, as opposed to working with us to identify a clinical problem and trying to solve it together.
—Dr. Joseph Hahn

Dr. Lieberman: Dr. Rezai, you place needles into the brain. Who should decide the risk of that action? You? The patient? And what do you feel is an acceptable risk level?

Dr. Rezai: It is a complex question, of course, and a number of variables come into play. Whether or not the patient's condition is life-threatening or disabling is a very important factor in the risk-benefit ratio. Regulatory guidance from the FDA is strong with respect to defining device-related adverse effects as serious or nonserious, and our peers, both surgeons and nonsurgeons, help to further dictate the risk and tolerability of a procedure and its alternatives. For example, in considering a surgical procedure, one must weigh its risk against the risks of medications to treat the disorder, such as side effects, the ease of medication adherence, and the number of emergency room visits that may result from adverse effects of the medications.

Determining acceptable risk rests fundamentally and first with the patient and then with the surgeon and his or her peers (surgeons and nonsurgeons) in conjunction with regulatory components and oversight. All of these factors contribute.

In my field of deep brain stimulation, the threshold for acceptable risk can be high since we see patients

with chronic conditions in whom all previous medication attempts have failed, many of whom are disabled, intractable to current therapies, and with a significant compromise of quality of life. Examples include wheelchair-dependent patients with severe Parkinson's disease, severely depressed patients who will not leave the house and have attempted suicide, and obsessive-compulsive disorder patients who need 10 hours just to take a shower. This type of intractability to current therapies and the suffering of patients and families with limited options and little hope influence assessments of procedural risk.

Dr. Hahn: Performing a controlled clinical trial of a surgical procedure is difficult at best. I recall a clinical trial in which patients with parkinsonism were to be randomized either to have stem cells implanted in their brain or to undergo a sham operation with no stem cells. Well, very few patients signed up for the trial because everyone wanted the stem cells. So, obtaining a large enough denominator to define the risk of, for example, hemorrhage from sticking a needle into a vessel is almost impossible.

Dr. Herndon: Except when there are risks of serious life-threatening events, I believe the patient is the one who makes the decision after having the risks fully explained to him or her. Surgeons are educated in a system in which we learn to accept complications. It is the risk of doing business. We have not learned very well how to differentiate a complication from an adverse event or an error. We must learn to do that. We live with complications every day. Those complications must be conveyed to patients so that they understand what they are about to undergo, what can happen, and what cannot happen. The patient is the ultimate decider, in my opinion.

Dr. Lieberman: That reminds me of something one of my mentors often said: "If you are going to run with the big dogs, expect to get bitten in the butt once in a while."

Investigators and innovators must use their roles to leverage industry resources to perhaps pay for some of the care that innovative devices make possible.

—Dr. Joseph Fins

ETHICAL DILEMMAS ARISING FROM NEW OPTIONS

Question from audience: In my specialty, we have a non-life-threatening condition with a well-established 25% recurrence rate after traditional surgery with sutures, and a 25% rate of reoperation. A device comes along and it improves the outcomes so that the recurrence rate declines to 10%, but along with the extra costs of doing the procedure with the device, there is also a complication rate of about 10% that requires reoperation with the device, and a few of those patients actually end up worse. Ethically, how should the clinician proceed in this situation? The old way, or the new way that improves outcomes but at a higher cost and risk?

Dr. Fins: Based on the size of the populations, is the difference in the combined rates of recurrence and complications between the traditional and new methods (25% vs 20%) statistically significant?

Response from questioner: The difference is probably not statistically significant.

Dr. Fins: Okay, so you are saying that the numbers are basically equal. That is the first consideration, but there is a nuance to one of the variables, and that is an improvement in quality of life with one of the treatments. Measuring its significance is subjective. A patient may place greater emphasis on quality of life than would somebody who is not a beneficiary of the operation. That is why I said before that biostatistical input that goes beyond crude measures of mortality or reoperation rates can be very helpful. The risk of reoperation may be one that the patient is willing to take for a chance at an improvement in quality of life.

There is a wonderful book by Howard Brody called *The Healer's Power*[6] in which he writes about the physician's power to frame a question so as to engineer outcomes. While that is not something that Brody endorses, he does endorse the use of the physician's power to guide patients using good informed consent, providing direction without being so determinative that patients feel compelled to choose the physician's recommendation. Patients should be able to decline your recommendation while still having the benefit of your counsel. And in a case like this, your counsel should include variables that may seem "softer" or more difficult to quantify than crude measures such as mortality or reoperation rates.

Dr. Rezai: You have to compare multiple outcomes between the two approaches—surgical time, recovery time, patient quality of life (as assessed by scales), family quality of life, time to return to work, etc. I think it is important to try new technologies because the failure rate or the complication rate may be reduced over time, but only if you evaluate the

failures and then restrategize. Only in doing so can you reduce risk, and if the benefit profile and the risk profile prove to be good, then the new technology should be pushed forward.

Dr. Herndon: If the volume of procedures performed by the surgeon is important with respect to outcomes with either one of these two procedures, that should be taken into account. Also, if a new procedure carries a higher complication rate than the traditional procedure, I think that more cohort studies from large centers are needed to gauge the true complication rate before the new technology enters the general market. Continued surveillance, such as with a postmarket registry of outcomes with these procedures, would also be helpful to make adjustments in the future if necessary.

Dr. Hahn: If you looked at the early experience of Medtronic with pacers, you would be amazed at the number of deaths and complications that occurred during the first 3 years. But we do not even think about that now.

CAN INNOVATION HAPPEN WITHOUT INCENTIVES?

Question from audience: Dr. Hahn alluded earlier to the influence of money. All of you on the panel are institutionally based, and you are used to practicing with colleagues. I would suggest that surgery today is really not an individual sport, but that is the way it is practiced in much of the nation. Would we be better off if we developed a system that removed us from direct financial influence? Can we get the money out of the equation so that people have motives other than direct personal gain?

Dr. Hahn: I went to an institutional review board (IRB) retreat that included, of course, some IRB members who were not clinicians. They asked the same question that you just did: Why would you even expect to get anything for what you invent? I think that is naïve. People who work hard and invent things deserve to reap a reward. The challenge lies in working with industry, which may try to convince us to use its innovations without our input, as opposed to working with us to identify a clinical problem and trying to solve it together. In that way, the end product and the logic behind its use will be better.

I will give you an example from when I was head of surgery here. A company made a voice-activated table that would obey the surgeon's commands, such as "left," "right," "up," or "down." I asked the representative why such a product was needed, and he responded that the surgeon wants to be in total control of the operating room. I told him we do not change the position of the table very often. After a 2-week trial, the table was a dud. He fired the entire group that was working on the project. It was a case of a company simply trying to come up with a product it could sell.

The opposite scenario is if I invent the latest and greatest stent for the carotids and I want to use it. The question becomes how to strike a balance: how to protect the patients while at the same time rewarding the inventor. Another challenge is that device companies want you to stay on their scientific advisory board and they will pay you for it.

We owe it to our patients to work on their problems. We also owe it to them to tell them when we are working with industry on a product and explain why we think it would work in their case, if we think it would.

—Dr. Joseph Hahn

These questions are a big concern, and we have spent a lot of time on these issues at Cleveland Clinic. In fact, we held our own conference on biomedical conflicts of interest in September 2006 with attendees from around the country to discuss the necessary firewalls for ensuring that data are not contaminated, that the surgeon-inventor does not fudge data so that his innovation will make it to the marketplace, etc. At that conference, a number of people spoke about Vioxx. I am a surgeon, and my take on the COX-2 inhibitors is that a lot of my patients take these drugs and think they are wonderful, but there are some problems and risks. What is wrong with explaining to patients the risks and complications of these drugs, making your own recommendation about their use (unless you are receiving money from their manufacturers, which you would need to disclose to patients), and then letting patients make their own informed decisions? Personally, I was on Bextra for 3 years and was furious when it was pulled from the market because nobody gave me a choice whether or not to continue using it.

Dr. Lieberman: Let's explore this concept a little deeper. We know that innovation is so important, but how do we encourage clinicians to innovate in this environment? Dr. Hahn, you served as chairman of CC Innovations, which is Cleveland Clinic's technology commercialization arm. What were some of the strategies you came across in that role?

Dr. Hahn: We look for creative staff. We tell them up front that we want them to come to Cleveland Clinic and invent things. Our mission is literally to work on problems and take solutions to our patients. The culture here is meant to be creative. As a part of that culture, we welcome working with industry, as opposed to industry thrusting its innovations on us.

We are averaging more than 200 invention disclosures per year. More than 500 of our staff are involved with various industrial partners, and we are not going to hide that. In fact, we are going to make it public. The thought is that we owe it to our patients to work on their problems. At the same time, we owe it to our patients to say when we are working with industry on a particular product and explain to them why we think it would work in their case, if we think it would. While doing so, we need to make it clear that we will be happy to refer them for a second opinion if they would like. If I have a patient who wants a second opinion, I will offer to make the phone call for them and get them in. I think that is an advantage of the model we have here.

The reality is that there are some procedures that can only be done by one surgeon here, a surgeon who may have helped develop the procedure or some technology involved in it. Are we going to tell that surgeon that he or she cannot perform the procedure on anyone? That does not make sense. So you need to have a management plan that puts in place firewalls to protect the data on that procedure from any possible contamination.

So yes, we do reward staff who are doing innovation, and we do work with industry, and we do tell our patients we are doing it, and we do build firewalls to protect the data.

Dr. Lieberman: How about the rest of the panel? What are your thoughts on providing incentives for innovation?

Dr. Fins: Money is a key issue. The way the landscape is now structured, collaborations with industry are part of the mix. Under the Bayh-Dole Act of 1980, institutions are granted intellectual property rights to ideas or inventions developed by their researchers, and then the institutions can enter into contracts with industry to move the innovations forward. If industry support of research were removed, we would have to double the budget of the National Institutes of Health to compensate.

On the other hand, industry support can sometimes prove to be a disincentive to innovation in that it may engineer certain kinds of research or deprive investigators of tools they may need to do more basic science types of research. It is an academic freedom issue. At a translational level, industry may be helpful and catalytic. But sometimes it pushes an investigator to work for a short-term innovative application at the expense of a more speculative, riskier innovation.

We need to acknowledge that industry collaborations are part and parcel of the universe and focus on working with industry to moderate its influences. At the same time, we must use our leverage on the investigative side of the equation to pursue academic freedom and to leverage industry resources to perhaps pay for some of the care that innovative devices make possible. For example, contracting agreements could be drawn up so that money came back to the populations that participated in a clinical trial, or to a community that otherwise may need the device but cannot afford it. I think we have to create some type of charitable impulse to moderate the excesses of the profits and use them for the common good.

Most innovators have it in their genes and in their blood. They can be taught to innovate, but they have to have the intrinsic curiosity and the creative mind to be an innovator.
—Dr. Ali Rezai

Dr. Herndon: I would like to touch on disclosure. The orthopedic implant industry has been required by law to disclose its relationships with orthopedic surgeons, including the amount of money that surgeons may be getting from industry. This requirement has had unintended consequences that underscore the importance of disclosure. First, some of the monetary awards, whether market-driven or not, are quite excessive. Second, reviewing the contracts for royalties has led to the discovery that many are not supported by patents or intellectual property rights. Third, these disclosures have revealed that certain surgeons who work at major US institutions, and who thus have an obligation to pay the institution some of the monies from their research, have not disclosed their relationships for years and have kept those monies solely for themselves. So this disclosure requirement has brought many things to light.

Dr. Rezai: As long as there is human disease and suffering, innovation will continue. It has in the past and it will in the future. Most innovators have it in their genes and in their blood. They can be taught to innovate, but they have to have the intrinsic curiosity and the creative mind to be an innovator. Institutional support of innovation is important, as is respect for

the process that must be followed, including transparency and disclosure. If you put all these together, then innovation can be facilitated.

IF TESTING MOVES OFFSHORE, CAN ETHICS FOLLOW?

Dr. Lieberman: I am going to paint a scenario on which I would like each panelist to briefly comment. New Device X is backed by a big vendor. It is a great device, but because of all the regulatory issues in the United States, it is taken to China or South America and is being implanted there, where the regulatory environment is much more lenient. Can we rationalize this practice? How is it possibly ethical?

Dr. Fins: I can answer in 5 seconds: we shouldn't do it.

Dr. Rezai: This is a reality we are facing with increasing rules and regulations in the United States. You have to engage the process, and it takes time. If you have colleagues who can follow clinical trials outside the United States, you can have the device tested outside and then bring it back to the United States. Unfortunately, the reality is that the regulatory process can be slow, so more testing will be done abroad, in my opinion.

Dr. Hahn: I disagree with Dr. Fins. This may be the only way to get the trials started, and we then are able to use some of the offshore data to approach the FDA for approval. I do not think that it is taking advantage of anybody; it is a way of getting things through the system.

Dr. Herndon: The door has been opened, and it is only going to increase. My only request would be that the investigators who do this function as they would here in the United States, under IRB controls and the other kinds of oversight that they would expect and demand of themselves in their own institutions.

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