DIRECTORS ROUNDTABLE

WORLD RECOGNITION of DISTINGUISHED GENERAL COUNSEL

GUEST OF HONOR:

David Scott

General Counsel
Amgen

THE SPEAKERS

David Scott
Senior Vice President, General Counsel & Secretary, Amgen

Meredith Manning
Partner, Hogan Lovells LLP

Charles Ruck
Partner, Latham & Watkins LLP

David Rosenbloom
Partner, McDermott Will & Emery

Michele Garvin
Partner, Ropes & Gray LLP

Francis "Frank" Aquila
Partner, Sullivan & Cromwell LLP

TO THE READER

General Counsel are more important than ever in history. Boards of Directors look increasingly to them to enhance financial and business strategy, compliance, and integrity of corporate operations. In recognition of our distinguished Guest of Honor's personal accomplishments in his career and of his leadership in the profession, we are honoring David Scott, General Counsel of Amgen, with the leading global honor for General Counsel. Amgen discovers, develops, manufactures and delivers innovative human therapeutics. His address will focus on the critical questions that challenge all of us in the health environment and new ways to think about counseling dilemmas. The panelists will discuss bringing medical innovations to market; uncertain government policies and enforcement; and emerging market opportunities and risks.

The Directors Roundtable is a civic group which organizes the preeminent worldwide programming for Directors and their advisors, including General Counsel.

Jack Friedman
Directors Roundtable
Chairman & Moderator

David J. Scott, J.D.

SVP, General Counsel and Secretary
Amgen Inc.

David J. Scott became senior vice president, General Counsel and secretary in March 2004. From May 1999 to February 2004, Scott served as senior vice president and General Counsel of Medtronic, Inc., a medical technology company, and also as secretary from January 2000. From December 1997 to April 1999, Scott served as General Counsel of London-based United Distillers & Vintners. From April 1996 to November 1997, Scott served as General Counsel of London-based International Distillers & Vintners.

Amgen Inc.

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A leader in biotechnology since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses.

Amgen pioneered the development of novel products based on advances in recombinant DNA and molecular biology, and launched the biotechnology industry's first blockbuster medicines. Today, as a Fortune 500 company serving millions of patients, Amgen continues to be an entrepreneurial, science-driven enterprise dedicated to helping people fight serious illness.

JACK FRIEDMAN: Welcome. This series of world honor for General Counsel over the years arose from Boards of Directors telling us that corporations never get credit for the good that they do. It's important to have programs that give executives, whether on the business side or the legal side, a forum to talk about what their companies are doing and what they are proud of. Also, it enables leadership to get to know about people that they have read about in the news, like our Guest of Honor. The transcript of this event is going to be sent out to about 150,000 people globally. What makes this the leading honor for General Counsel is not just the event itself, but also sharing it with leaders all over the world.

We could spend the whole morning giving the outstanding qualifications of the various speakers, but we have a tradition that less is best. So I will briefly introduce the speakers as their turn comes, and they will make their introductory remarks. Then we will go on to an extended Roundtable discussion among the panelists and invite comments or questions from the audience. At the end, the audience will be invited to come up to talk directly with the Distinguished Speakers.

Our Guest of Honor, David Scott, has the important responsibility of not only heading the legal department of Amgen from a traditional legal sense, but also advising the Board and top management, and working with government officials in matters of importance to Amgen. Geographically, his responsibilities are all over the world. He has had a distinguished career, including being General Counsel at Medtronic.

I would like to start the program by having David make his opening remarks. We thank him for accepting our invitation to receive this World Honor.

DAVID SCOTT: Jack, thanks for your kind words. I'll keep my father's admonition about speeches in mind — be brief, be clear, and be seated. I've already taken a third of that by sitting down for the presentation.

First, let me start with just a few words about Amgen to frame the discussion that will take place, for you. Amgen is the largest biotechnology company in the world. We make and sell complex medicines that help people suffering from grievous illnesses. The mission is a noble one, and it certainly fills our employees with tremendous pride and energy as they pursue their quest to help patients.

At the same time, it's incredibly daunting, the challenges that we face at Amgen and within the industry itself. Perhaps the best way to illustrate that is through just a little bit of data. Amgen was founded in 1980. Since 1980, 1,800 biotechnology companies have been founded around the world. Of those 1,800, about a dozen have made more money than they have spent. Eighteen hundred companies, only a dozen making a profit.

So let me discuss just a little bit why the challenge is so daunting. What Amgen, and companies like Amgen, set out to do is to discover important, innovative medicines, and most of those efforts — both at Amgen and around the world — end in failure, because this is a difficult task. So that's the first daunting challenge.

The second daunting challenge is: having discovered something, can you then protect it with powerful and reliable intellectual property? Obviously, the importance of that is that if you can't protect it, the chances are pretty good that despite spending years developing it, you're not going to get a return on your investment, because others will, in turn, benefit from your innovative efforts which you are unable to protect.

Then we have to demonstrate the medicine that we discover is both safe and effective, and that requires that we go to governments around the world and demonstrate, through clinical trial programs that, indeed, we are bringing something that is efficacious to patients, and we're bringing something that can be both efficacious and safe.

As if that weren't enough, you then have to demonstrate to governments and to other entities that pay for medicines — insurance carriers and the like — that the medicine has real value in a comparative sense versus other alternatives that might be available to physicians and patients in the market.

If you add up all of those daunting challenges, and then you look out to your shareholders, and you have to tell your

shareholders, "We hope you stick with us while we invest between a billion and two billion dollars in the development of innovative new medicines which we hope, in turn, will be of benefit to patients and will be paid for by patients and physicians serving patients, and by governments and carriers. So please stick with us while we make this investment and do all of this work, which typically takes anywhere from twelve years to fifteen years. So, trust us — we're going to deliver for you."

Then, how do you do all of that when the rules of the game are changing underfoot? So this is a very long-cycle business — twelve to fifteen years — and at the very same time, when you start this off, you think you understand certain rules of the game, and then halfway through, the rules change — including, for example, what is sufficient to qualify a drug for approval. As those rules change, you have to change as well, and you have to anticipate those changes.

On top of everything else, as you look around the world today and you look at what we would call the established economies — places like the United States and Europe — you realize that population growth and economic growth generally, in those established markets, has slowed dramatically — in some cases, to a standstill.

So you then look to other markets that perhaps show more growth and more opportunity — the emerging markets.

But the interesting thing in emerging markets is that governments are very much involved in the activities of medicine, not only in terms of providing it to their citizenry, but also making investments in companies that are developing those medicines locally.

So you have a host of difficulties in terms of how do you deal with those governments and those local companies and emerging markets that may have government investment within them, or may be influenced by government-related activity.

If you combine all of those obstacles, it would be certainly understandable if the folks in this room who are involved in this industry, or other folks who invest in this industry, are scratching their heads right now, wondering if perhaps there isn't a better line of work that they could get into, or a better investment to make.

But that is, nonetheless, the world we face, and we have a choice here: you can sit back and bay at the moon and lament your circumstances, or you can view this environment as a perfect environment for lawyers who see opportunities where others find difficulties. So, let's talk just a little bit about that, and then we'll use this panel to illustrate it.

So, capable lawyers with really sound legal judgment, who have a deep understanding of the business that they're in, can connect the dots between law and science and medicine and public policy in ways that few others can. Let me illustrate that.

I was a philosophy major, so it's unlikely that I'm going to be able to do much for the scientists at Amgen in trying to discover new medicines, many of which I can't pronounce. That's not where I'm going to be of much help. However, lawyers on my team who specialize in intellectual property work can be of enormous help, as they sit down with scientists early on and talk about development options for new medicines. Some of those development options may lend themselves to incredibly strong intellectual property protection; others may not. If the right options are picked from both the scientific point of view and from an intellectual property point of view, the chances are good that if that medicine is successful, the intellectual property that supports it will protect it for a sufficiently long period of time to secure a return on investment. There's a big role for sophisticated lawyers, who are also comfortable with the science, to play in helping choose the right paths forward here. Again, there is that intersection between law and science.

But there are other things that we can do, too. By thoroughly understanding the regulatory environment and the reimbursement environment, lawyers who are skilled in the art can help scientists, can help clinicians, can help people who are payment specialists, design clinical trial protocols that enhance the prospect of the drug upon approval for reimbursement purposes. So, a successful trial that is designed to deal with *all* of those issues will likely yield a medicine that will be profoundly successful in the market, provided the medicine does what it's supposed to do to help patients, because payment will be assured, because the evidence will have been demonstrated in advance of approval.

Those are the kinds of things that lawyers working with their business and scientific and medical colleagues can do to help navigate through this very difficult environment.

But more than that, while there's tremendous uncertainty in this environment, lawyers can help — working with government affairs professionals and with people in government — lawyers can help anticipate, as Wayne Gretzky used to say, where the puck is going to be, not where it is right

now. By doing that, even in a long-cycle business, a little bit of edge, in terms of anticipating the nature of the regulatory scheme that you're going to be subject to going forward — just a little bit of edge can be profoundly powerful and advantageous to a company like Amgen over those companies with which we compete.

With all of that in mind, what advice can I give lawyers and the business people who rely on lawyers, in terms of participating fully in this process, to deliver the greatest value? Well, I need to start with an admonition that a CEO that I worked for once gave me. He looked at me when I started as his General Counsel, and he said, "Look, David, I only want lawyers with one arm." I must have looked at him quizzically. He said, "Because I'm tired of lawyers saying 'on the one hand' and 'on the other hand.' So I want a one-armed lawyer, and I hope you're that lawyer." Of course, I was young at the time and I was thinking to myself, "I hope I'm that lawyer, too!"

So, here are a few suggestions from a one-armed lawyer. First, far too many lawyers are legends in their own mind, and for you lawyers in the room who don't recognize yourself, my suggestion would be, go look in the mirror just a little bit. I lower the average IQ of a conference room at Amgen that's full of scientists every time I step in it. So, again, I would urge a little humility in all of this.

Also, the language of lawyers can be profoundly off-putting. So, if you combine the language of lawyers with the more than occasional lack of humility, you have a perfect storm in terms of trying to decide exactly how much a lawyer's going to be of help here in this process. Business people out there are highly sensitive to this, so if you want to be one of those lawyers that is profoundly useful to business people and scientists and other colleagues, then be one of those lawyers that is humble and speaks *plainly* the important information that business people need to hear. Speak *plainly* and avoid all the legal language.

The second admonition I'd give to the lawyers in the room is to remember that "business" isn't a bad word. There are far too many lawyers who went to law school because they thought "business" was a bad word, and that's something to overcome quickly. Commit yourself to a deep understanding of the business fundamentals, and become a business counselor — not just a lawyer providing a few abstract words of legal advice. So, be a business counselor; be a business partner. Never forget that you may be the only lawyer in the room, and at the end of the day, if you don't give good legal advice, I wouldn't count on anybody else in the room to give good legal advice. But nonetheless, you need to be a good business counselor.

Lastly, your job is not just to raise alarms about risks. Don't just raise alarms about risks. There are too many lawyers who see risks in every business proposal and every business plan, without seeking to understand first the nature of the business plan and the objectives sought to be served by the plan. The industry we're in — my industry is *full* of risks. So be a good lawyer and identify the *important* ones. Then be a good business counselor and help your business colleagues and scientific colleagues learn how to seize great opportunity in the midst of risk, while mitigating the residual risk that runs with the business plan.

These challenges that I've described are, again, hugely difficult to overcome, and I would remind you where I started — 1,800 biotechnology companies started since Amgen was founded in 1980, and only twelve of them could be gauged to be a success. But I know a little bit about all twelve of those companies. I know a little bit about them and let me tell you what they all have in common. First, they all have brilliant science; they all have absolutely brilliant science. Second, they have incredibly powerful leaders who have done remarkable jobs. Third, they have very good lawyers who have been well-integrated into the business affairs of the company, so that they deliver profound value at that intersection between law, science, regulation and government rules.

So, with that as background, I think I've probably said enough, and we ought to turn to the real lawyers in the room; I'm just a little country lawyer, and so I'm here to learn with the rest of these folks.

JACK FRIEDMAN: For those of you who are too young to remember, during the Watergate hearings, one of the senators,

Sam Ervin of North Carolina, kept saying on national television, "I'm just a country lawyer from the South, from North Carolina" — he happened to be the former Chief Justice of the state Supreme Court. When a lawyer says, "I'm just a country lawyer," you'd better check around, because he's already somehow won the negotiations, because they're very clever. So, your modesty warned us in advance!

For those who are not necessarily knowledgeable about biotech, could you tell us how biotech overlaps with pharma in terms of scientific research to bring products for health?

DAVID SCOTT: Sure. So, pharmaceutical companies, for the most part, traditionally have made what we call "small molecule chemical pills." Biotechnology companies use biology and develop things like proteins and antibodies. These are biologic products that are actually alive, and the complexity of that is considerably more profound in terms of how you actually make them than a small molecule pharmaceutical company medicine. I don't say this to put anyone down, but I just say it to illustrate it. A small molecule chemical combination pill can be made by a sixth grader with a chemistry set that's properly equipped. A biologic is made by people with PhDs in biology, biochemistry or the like. Now, small molecules are equally difficult to *develop*, but once you've developed it, it's a chemical formula and it's relatively easy to put together. Not true for a biologic product.

But this line that you're describing used to be a fairly bright line. But now, most pharmaceutical companies also make biotechnology products, and hence, the industry has started to look more and more like a biopharmaceutical industry, which is actually the way I would characterize Amgen today — we also make small molecules.

JACK FRIEDMAN: What are some of the products and some of the illnesses that your products are focused on?

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DAVID SCOTT: We make a class of products called "filgrastim," and they help people who have undergone chemotherapy and have low white cell counts and are susceptible to potentially deadly infections. We make a product called "Enbrel," which treats psoriasis and rheumatoid arthritis; and a host of other products.

JACK FRIEDMAN: I wanted also to ask if you could give us in layman's vocabulary what are the basic steps in the development and approval process, so people have a sense of where you start and, if everything works out, where you end?

DAVID SCOTT: We start off by looking at diseases out there that are profound, that have substantial unmet medical need in terms of the treatment options that are available. Then we start looking at targets that we believe could address some of those diseases. Occasionally, we hit upon the right target to address with an appropriate molecular structure that we think can bring value to the treatment of that illness, and we will test that in animals first, and then gradually move it into people, and we go through a three-phase clinical development process, aptly named "phase one," "two" and "three."

The conclusion of this program would be a successful Phase Three program, which frequently involves the testing of the drug in thousands of patients, and that Phase Three program will have certain end points, and we believe that those end points that we have picked indicated that the drug is both safe and efficacious, if we meet those kinds of thresholds. If we're successful in Phase Three, we then will file a drug licensing application with the FDA in the U.S. or with EMA in Europe, and other regulatory agencies around the world, and seek government approval.

That process, from early discovery through to government application, on average takes something like twelve or thirteen years, and the ultimate approval and the marketing of the drug would take anywhere from twelve to fifteen years. So from ideation to launch is a period of time sufficient to have me start as a young man and end up as an old man.

JACK FRIEDMAN: Thank you very much. I would like to turn to our first Distinguished Panelist, Meredith Manning of Hogan Lovells. She will introduce her topic.

MEREDITH MANNING: Good morning, everybody. Thanks so much for having me.

Dave asked us all to come today to talk about the intersection of medicine, public policy and law, which is a challenging topic. I just want to start by saying that I think that Dave really embodies all of the skills that are needed to guide a major company through a very complex and changing area of law, and so, in that sense, he really is a model, and it's an honor to be here with him today.

The topic — medicine, public policy and law — and the issues of how public policy impacts companies like Amgen, *is* one that, when I was presented with this and asked to speak, reminded me of something that I heard when I started my career in the 1980s. I left college and went to work in Washington on Capitol Hill, where

I worked for the Energy & Commerce Committee. I was a lowly staffer who helped people think about policy ideas. We had discussions among staffers around the public policy scheme that the Energy & Commerce Committee was responsible for. It went like this: At Medicare and Medicaid, the two financing agencies, the government is essentially going to tell you what you can charge through financial payment schedules, *but* healthcare providers can do whatever they want; as long as the treatment being provided to patients is reasonable and necessary, it is paid for.

As Dave has pointed out, at FDA, the Food, Drug & Cosmetic Act creates *extensive* statutory and regulatory requirements for what companies must do in order to get to market. But once you get to market, there are no restrictions, necessarily, on what you can charge.

So that was an inadvertent policy scheme that was put into place in the 1960s. The Food, Drug & Cosmetic Act Amendments in 1962, established Phase One, Phase Two and Phase Three requirements, and then in 1965, Medicare and Medicaid were enacted, which essentially allowed for reimbursement of many more people.

So those kinds of policies really fueled huge amounts of innovation in the biotechnology and pharmaceutical industries, because markets were opened up, and providers were allowed to change treatment regimens and change the way that care was provided, as long as it was considered reasonable and necessary.

Now, of course, that's a little bit of an oversimplification, because there have been changes since then. We saw Medicare implement diagnostic-related groups in the '80s where there were treatments — it's oversimplifying to say "flat fees" — for hospital costs. We had enactment of generic drug approval pathways, which attempted to provide lower-cost alternatives to pharmaceutical

products in the '80s, as well. But that general framework has allowed for tremendous innovation.

So, today, after the passage of the Affordable Care Act, or "Obamacare"; the election in 2012, where it's become clear that the ACA will be implemented; and of course, after the Supreme Court's decision last summer, we are now at a threshold of trying to predict what the landscape might look like. We do have two federal agencies that establish public policy — the Food & Drug Administration, which is largely focused on science, and all of the scientific innovations that go into Phase One, Phase Two, Phase Three and approval; and then CMS, Centers for Medicare and Medicaid Services, which is focused now, almost increasingly or exclusively, on costs.

So how are those scientific innovations going to intersect with the cost constraints that are receiving tremendous attention now in Washington?

There is no question, as Dave mentioned, that the amount of information about the quantity of costs is going to explode for a number of reasons. The Europeans have required that information for a while. We are increasingly seeing CMS ask for and, indeed create, information about cost-effectiveness. The Affordable Care Act created a mechanism, a government-funded mechanism, to do research into patient outcomes and the quality of care. The Food & Drug Administration, as many people in the room know — one of my favorite topics — doesn't allow companies to talk about the results of that research. So you have a tremendous contradiction in policies between the two agencies that will have to be resolved.

Of course, we have what we would describe as the inadvertent results of policies that we are constantly struggling with in the healthcare field. The one that really calls attention to some of these themes is the New England Compounding Center issue that has dominated the news over the last several months.

I'll diverge for a few minutes and give everybody a little background. If you're not aware of it, the New England Compounding Center is a compounding pharmacy in New England that sold injectable steroid products as sterile drugs, without getting FDA's approval of its facilities or its products. It's allowed to do that under an exception to the Food, Drug & Cosmetic Act, which allows for traditional compounding by pharmacies, which allows changes to approved products to personalize them for individual needs. So, for example, cancer patients who can't swallow pills might ask a pharmacist to put an approved drug into a dermal patch for an alternate delivery mechanism. Some companies have used that exception to provide large-scale compounding services.

Now, why does this highlight the intersection between science on the FDA side and costs on the CMS side? For several years now, there has been a fairly loud policy discussion about whether or not CMS and insurers should pay for compounded drugs. That was largely a result of cost-containment efforts. Many people called for CMS to actively reimburse compounded products,

two in particular; the first being P17, which is used to reduce the likelihood of pre-term birth. It was an approved product which was introduced to the market when, after many years of being used by compounders, a company went out and got it approved. Then it charged a lot more than the compounders did, and nobody wanted to pay for it. So CMS decided, essentially, to pay for the compounded products, which made it extremely difficult, almost impossible, for the company that had developed the *approved* version to sell it.

Similarly, many compounding pharmacies began to compound Avastin, a well-known cancer drug, for use for age-related macular degeneration. Similarly, CMS did agree to pay for compounded Avastin. There were some tragic safety events that arose from that incident, and ultimately most physicians stopped using compounded Avastin for that reason.

So, today I think we have a situation around New England Compounding where the focus on costs has perhaps not kept up with patient quality demands. We've had a real crisis with the most recent numbers I saw being 36 deaths and over 500 injuries.

So, we do need to have a discussion about how, when you marry up science and cost considerations, we also protect the public in doing so. Certainly the folks here would agree that the way that we do that is by following the example of Amgen and other companies which have taken their regulatory responsibilities quite seriously.

JACK FRIEDMAN: Thank you. Later we're going to get back to a question which I will ask the whole panel. For Obamacare and going forward in the next few years, what are the changes coming down the pike? Our next speaker is David Rosenbloom of McDermott Will & Emery.

DAVID ROSENBLOOM: Thank you, Jack. I want to start from the notion that the title for today's discussion — Meeting the Challenge of Counseling at the Intersection of Medicine, Public Policy, and Law — captures well the challenge faced by all of you who are healthcare counselors. I don't think these challenges are unique to manufacturers — biotech or pharma. Lawyers who are counselors to payers and providers face these challenges as well.

What I want to talk about when I refer to "the Law," is the long arm of the law — what we used to call in high school, "Johnny Law". That's my life; that's my day-to-day work. My work is focused on government investigations, be they civil or criminal, and the lessons learned that I'd like to share today are lessons learned from working with companies where I saw good intentions and good advice on one problem were not enough to prevent the company from stumbling into yet another problem.

While I am flattered to be here today as part of honoring Dave, I need to say that none of these are lessons learned from Amgen! We're going to talk today about *other* companies. We're going to have the benefit of learning from the mistakes of others.

My premise is that the challenge of healthcare counseling is not simply that healthcare is heavily regulated, although that is true. Nuclear power is heavily regulated, too — I'm told it's the only area more regulated than healthcare — but clients seeking regulatory compliance in that area don't have nearly the challenges we see in health care. That is because in the nuclear power space, there generally is a clear set of rules to follow, and in general, people are able to follow those rules, absent acts of God.

The challenge of healthcare counseling is really that the regulation, by and large — or at least a major chunk of it, is regulation by prosecution. By that I mean it is regulation not by clearly stated prospective rules; but instead is regulation by rules that are created and applied in hindsight, on a case-by-case basis, through investigations, through conference room litigation, and very rarely,

through trial or appeal. The rules are enforced not by the regulators with whom they deal on the program side, but by prosecutors. Worst of all, the consequences of violating the interpretations of regulations announced through prosecution tend to be among the toughest consequences of all.

That is extremely frustrating for clients. You as counselors are telling clients to go 55, but you can't point them to any sign that says the speed limit is 55. You are talking to clients about how to avoid tomorrow's problem, and they want to tell you why they won't run into yesterday's problem. They're looking at the last case; while you are looking at the next case.

So, the challenge that I wanted to talk to you about today, the topic that I wanted to raise for discussion, is the challenge of helping clients understand how to play by the rules when the rules are not yet announced. I have in mind Dave's admonition that we as counselors should not just raise a problem and then walk out saying words to the effect of, "That's a tough one; let me know how you solve that." The absence of clear guidance is not a cause for either paralysis or recklessness.

My suggestion to you today is that it is an occasion for a different kind of counseling. It's a kind of counseling that helps the client understand the lack of bright line rules, and helps the client get a feel for when they are getting close to the line. My view is we help our clients only temporarily when we focus on the specific issue at hand; that is, when we talk about how some specific action will violate a specific rule. Inevitably, they will bump into a different rule when we are not around to help.

Each one of the specific issues is an opportunity for us to understand better their business challenges, and also is an opportunity for you to bring your colleagues on the business side into your decision-making, to help them understand better what you worry about, and to help them understand the enforcement environment and the context in which their decisions are being made.

So what are some of the things I like clients to know that I'm worrying about, that I want them to think about too? I like them to think about the fact that the people who make the rules and the people who enforce the rules are very different people. So when clients think of "the government," particularly in healthcare, they think of the regulators with whom they've met. When clients meet with regulators, the meetings have a different feel. The clients usually have brought their best and brightest people, often, to Washington, with well-thought-out, carefully prepared presentations. They've had discussions with people on the government side who are steeped in the history of regulation, and who understand the full framework of the rules, and who share with them a desire to work through the conflicting regulatory tensions of access to care and cost control. That's who most of our clients think about when they think about the government.

The enforcement people are very different, however. They come from a very different perspective. They have a very different view of our clients going into the first discussions, and going into their investigations. First and foremost, they often form first impressions of our clients based on the bad things they see from our clients' competitors. Ironically, this is probably the one point of agreement that we always start with between the government and our clients. Most clients I go to in healthcare tell me, either right at the outset or very early in the discussions, how bad their competitors are. "Everybody else is worse"; "everybody else is horrible." That is what I hear. And, by and large, the government is going to agree with you when you say that.

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When I raise the risks associated with client conduct, most clients want to talk to me about the willful wrongdoing they've seen by their competition. I am going to come back to this — I'll be a little bit of a broken record on this, because one of the most fundamental misunderstandings of clients, and therefore one of the most fundamental challenges for all of us as counselors to healthcare companies, is the relevance of the behavior of competitors.

When our clients look at a competitor, they see a bad player. When the government looks at a competitor, they often see a bad *game*, and so the government comes into these investigations assuming our clients are just like their competitors. In fairness to my friends in the government, history has shown that they are not entirely without some support for their views. The government has had a lot of success in walking its way through various industries and finding out that, in fact, competition tends to work like a funnel, and everybody tends to start doing what everybody else is doing. I guess a lot of clients went to their lawyers and said, "I want to do this because the competition is doing it," and thus, for example, the government has now prosecuted just about every implantable joint maker in America for doing pretty much the exact same things. The government recently went through a series of prosecutions for manufacturers of antipsychotic drugs. It was like watching somebody use a macro on a word processing program. They used the same investigative template and they saw the same behavior of others and they ended up charging each of the companies involved.

The second thing I want clients to understand about the perspective from the enforcement side of the government, is that the folks on the enforcement side have not met with your best and your brightest. They've probably met with your least happy, most disgruntled, most unsuccessful people. Those are the people from whom they have received their initial descriptions about your company. They've probably seen some poorly created documents, maybe hastily prepared emails. They've seen some bad acts. Some people do break rules. Now, one of the things you'll see in your materials we distributed is that the government repeatedly says, "We understand that no compliance program can prevent all misconduct. We understand that even the best compliance program will not prevent all criminal activity." I want you to know that's the most hollow promise made in the history of the world. It is worse than "the check is in the mail." They may understand that reality

at some theoretical level, but let me tell you that when they find out about wrongdoing, it's your burden to prove that the wrongdoing was an aberration. I have never had an initial meeting with the government where they said to me, "Look, we found all this misconduct, but let me tell you, we understand that you may have a good compliance program and that this could be aberrational." The working presumption is, "This is willful and approved, either explicitly or implicitly." That is the perception we deal with; that is the context of the decision-making.

The bottom line is that we begin to meet the challenges of counseling if we help our clients understand, that they are going to be making decisions in an area where we have regulation by prosecution, and we have prosecutions that will be done by people who bring a large dose of skepticism to the review of those actions. The prosecutors are not closed-minded – they will listen – but they're going to be skeptical and need evidence of our clients' good intent and their desire to comply with the relevant regulations.

If we can come to advising about decisions with this common understanding of the background, then it is easier for the clients to understand why counseling in the healthcare arena becomes more about a process and more of an approach than it is about the answer to any specific question.

When I am in counseling situations and I am with a client who is asking me to draw the line for them, as opposed to helping them develop an internal restraint when they sense the line is getting close, then I feel like I am not yet succeeding in helping the client as much as I can. If the client still wants to use me as "the goalie," by which I mean the client wants to see what they can get past us; what we will approve, then we haven't yet succeeded as healthcare counselors to clients who *do* want to comply. We haven't succeeded in helping them understand the fluidity of the environment, the unpredictability of where the rules will be over time, and the need to focus on a process that protects them and is able to adapt to those changes.

I'll try to mimic Dave and likewise to offer three suggestions for things in that process to focus on with clients.

The first suggestion is, we need to focus clients on the imperative of making decisions that not only help them achieve business success, but that also help them demonstrate that their commitment to compliance is as strong as their commitment to competition. Such a decision helps them demonstrate their uniqueness, why they're different from competitors.

What this means from a practical perspective is that when clients are considering different courses of action, they need to be thinking about documenting their good intent, creating the documents that are going to win the case instead of the ones that are going to lose the case. They need to document how they chose the less aggressive options. If there were five options on the table and three were more aggressive, how are we going to capture that moment of conservatism so people remember it three years from now?

When whistleblowers go to the government; they *always* remember the *less* aggressive approaches that were rejected. Somebody needs to institutionally recall the *more* aggressive approaches that were rejected. It's an important part of bringing the clients into the decision-making process, in my opinion, to remind them that we're measuring success in business success, of course, but we are measuring other success as well: compliance successes.

Second, and not surprisingly from what I've already said, I suggest that a big part of all counseling with clients is having them recognize the importance that the behavior of competitors is actually their biggest threat, and it's *not* a justification for taking additional risk. All of us who do healthcare counseling have been faced with clients who have said to us, "How is it possible you're telling me not to do this; Companies X, Y and Z are doing this. Why are you so timid?" Under those circumstances, we just have to help the clients understand that the fact that these other companies are doing aggressive things makes it *more* likely they will draw fire from the government – not less. The behavior of competitors cannot be the touchstone by which *you* are going to help that client draw its own lines. It is going to be a warning signal for you.

The third thing I would suggest you try to keep in context in these discussions is to get clients to recognize the importance of nurturing and listening to dissent. I have had many, many cases where a problem had been previously raised before the government brought it to the client. Oftentimes, the problem was brought by somebody who was viewed by many as "crazy," for lack of a better word, and that was why nobody wanted to look into the problem. I don't dispute the craziness of the messenger. But I do dispute that there is ever a good time to ignore dissent. If you silence dissent or ignore it, it leaves and it goes to the government, and it gets rich.

So you need to make sure you're helping your business clients listen to everybody they should listen to, not just who they want to listen to. Perhaps my Midwestern background makes that easier for me to say. In Illinois, we have a great example. We used to have a colorful gadfly who would protest out in front of the federal building about all sorts of crazy stuff: Everything from the Queen of England supposedly running the world, to the CIA supposedly running Coca Cola. Then one day he started complaining about Governor Otto Kerner being a crook. Nobody listened to him, but then he went to the government. And the government, as they usually do, listened to him. They don't care if the messenger is crazy; they want to know if there is evidence. And that is how Otto Kerner became the first of what has now become our long and infamous tradition in Illinois of convicted governors. There is a good lesson in there for all of us, not just elected officials. That case started with a crazy whistleblower that nobody wanted to listen to, but the government focused on the message, and not the messenger.

Dave started his talk with advice he learned in his youth. I'll go farther back — I'll go to the Greeks. The Greeks said character is destiny. In large part, what we do when we counsel with our clients is remind them that each decision not only has an aspect of business success or business failure, but it has an aspect of reflecting their character, reflecting that client's commitment to compliance success, as well as competition success.

> "By thoroughly understanding the regulatory environment and the reimbursement environment, lawyers who are skilled in the art can help scientists, can help clinicians, can help people who are payment specialists, design clinical trial protocols that enhance the prospect of the drug upon approval for reimbursement purposes." *David Scott*

So that's why, to just summarize, in meeting our counseling challenges, we would do well if we remind our clients that today's conduct *will* be judged against tomorrow's rules. If we remind them that every decision they make is an opportunity to document and demonstrate how they're harmonizing the challenges of competing with the challenges of compliance. If we remind them to be *worried* about competitors, not *comforted* by what competitors are doing, we are making great progress.

Michele is now going to talk about compliance programs, I share her view that effective compliance programs are absolutely essential and necessary to help support and reflect a culture of compliance. I also agree with Dave, who mentioned the strong leaders he has seen in the successful biotech companies. There is a connection between those two points. All cultures of compliance start with strong leadership. You, as counselors to those leaders, to the extent you can remind them of the fluidity of the environment in which they operate, and remind them to keep an eye on their best instincts, you really are the beginning of the success of any of those compliance programs.

So with that, I'll transition to Michele.

JACK FRIEDMAN: A few years ago, one of your predecessors in this honor made a comment that he knew his small children were always looking at the parents to see how they actually conducted themselves — not what they said — in order to learn proper behavior. He said that when you're in an executive position, it's the same way. Your employees have their antenna out, trying to size up what are the *real* ethical expectations of their boss. You can lecture all you want, but if your conduct is improper, they'll know that is the reality, not what you were saying to them in words. So, it's apropos of your comments.

DAVID SCOTT: I agree completely; a culture of compliance absolutely starts with strong leadership from the top.

JACK FRIEDMAN: Next, we are going to have Michele Garvin of Ropes & Gray speak about compliance.

MICHELE GARVIN: Thank you. I'm going to take this discussion down a notch, because I have been asked to talk about compliance, and compliance, while it may be about culture and values, is also a little bit about blocking and tackling. As I listened today I was counting the number of times so far that someone has said the word or used the phrase, "good compliance program," "compliance," "compliance is a good defense."

Frankly, for me, for an outside counselor, some of the most frequently asked and most difficult questions to answer come when management or the Board or a compliance committee says, "Is my compliance program working? Is it effective? Have I allocated enough resources to it? Is it good enough? Who owns the responsibility for a good compliance program? Is it the compliance department? Is it the law? Is it business?"

While we talk a lot about compliance, and we talk about values and culture — which are important — when you get down to, "Can I rely on my compliance program?" it's a very difficult question on which to engage.

Before talking about where the compliance program challenges are today, we should reflect on why the question of how effective is one's compliance program so difficult to answer. In part, it reflects a constantly evolving regulatory environment. Since the first draft of the anti-kickback safe harbor regulations came out (and I am old enough to go back to the first draft. I had to summarize it as a young associate) we have had two decades of voluntary compliance guidance for the healthcare industry, including clinical labs, hospitals, and for pharmaceutical manufacturers in 2003. We also have corporate integrity agreements that cut across every sector of the healthcare industry, in which the government establishes its criteria for effective compliance programs. However, it's only with the 2010 passage of the Affordable Care Act that compliance programs have been mandated for Medicare/Medicaid participating providers and suppliers.

Why is this important? Because while we have volumes and volumes of "guidance," in that guidance, the government explicitly states, "This is not a rule, these are not requirements, this is not a mandatory program." This guidance is really the government's statement of its views of the seven elements — essentially, have a compliance officer, policies, training, a means of identifying potentially non-compliant behavior, taking corrective action, and an effective line of communication about compliance concerns. We have the government telling us, "Here's what we think it means, now you can measure yourself against it." Where that really leaves us though, is with an expectation of needing to have effective compliance programs with no specific rules and requirements.

Moreover, embedded in all of the government's guidance is the notion of scalability; that a compliance program, and the resources that you dedicate to it, should be directly proportional to the amount of legal risk that you've identified, and the complexity of your organization. But nowhere in all of these guidance documents does it tell you how to assess that risk and how, then, to implement and allocate your compliance resources.

That leads quite reasonably to the conversation and the questions that I'm sure all of us have had with executive management and with Boards: What are compliance controls? How do we talk about them? How do we measure ourselves? You hear some people say, "It's the gold standard of compliance." Well, what does that really mean? Does it tell a company how many compliance FTEs it should have? The fact is, there are no GAAP equivalent rules for compliance standards; there is no uniform, external, universally accepted language to measure compliance program performance. Companies may share information and compare approaches across organizations, but there are no formal public reporting and disclosure mechanisms. While companies conduct internal benchmarking, it is along the lines of "my competitors are doing it." As Dave says, everybody's looking at "how many resources do my competitors have?" But that's based on informal discussions; there is no formal benchmarking. So, how then, do we know we're on the same page?

This lack of rules and standards and common language really means that companies have to look internally to define what's effective. In addition to the lack of uniform rules and standards, compliance guidance is continually evolving as the government is evolving in its focus. Through these decades, there has been a focus on programmatic elements, on process. Process counts; compliance programs are not expected to eliminate all potentially bad behavior. So the question traditionally has been, do you have the right processes in place? I would suggest that, in fact, we're now moving away from process as a point of emphasis. While programmatically, it's required, what we're seeing in healthcare compliance programs is really a movement to a Sarbanes Oxley (SOX)-like certification model of compliance.

By this, I mean an emphasis on management certifications and Board-level certifications. This approach fundamentally changes the way in which compliance interacts with the business. Essentially, the government's focus has changed from "process" to "results."

But because it's healthcare — and many can say SOX is complicated and finances are complicated — in healthcare, certifications are more difficult. They're broader and there are no clear standards. More people have to certify, and more certifiers means more sub-certifiers.

If you've looked at recent corporate integrity certification language, and here it's really getting to the nub of it, the government has said to us, in answering this question, "How do we know if we have an effective compliance program": "We can't tell you the answer to that. We don't know what works. Because, in fact, we don't know your business. While the elements may be the same for all healthcare

industries, they differ based on your enterprise." The government is looking at the company and saying, "If we don't know your business, we can't identify the legal risks, and we can't tell you how to mitigate them. So, instead of having a process and demonstrating that you have each of these seven elements, what we want you to do is to tell us that *you* believe you have an effective compliance program." For management, that means that they believe that the areas of their functional responsibilities, to the best of their knowledge, "Comply with law." This is the language in the 2012 corporate integrity agreements that have been coming out. It's a real shift from management saying, "If I become aware of something, I elevate it," to law or compliance, to, "I am certifying that my area of responsibility complies with law unless I expressly tell you otherwise." That is really significant for the healthcare industry, because it means we're changing what compliance has to do.

I'm going to give you a definition of an effective compliance program, and you'll note it doesn't mention the seven elements once. But picking up on Dave Scott's initial comments, it does talk about identification of important risks and integration with the business.

An effective compliance program is one in which compliance engages the business systematically to look at proposed operating and business plans and activities, identifies risks together, reaches consensus on the significance of the risk, and jointly develops an approach to mitigate the risk and reports on the effectiveness of that mitigation to the Board or executive management. That's a very different definition than, "We have seven elements in place and we can document each one." And, it creates a very significant challenge to "what do we do," as compliance lawyers, as compliance professionals.

This new compliance culture based on certification will be one of empowering the business managers to make these certifications. That means the business will be looking at tools, data, training, information on monitoring and auditing activities, and engagement in order to really say, "I understand where the risks reside, and we can agree on mitigation of that." I call a program developed with this approach an intelligent compliance program — it's not a compliance program that has been created *reactively* to two decades of government enforcement activity. We need to get out of that *reactive* mode and really say, "We're going to act in a proactive fashion."

> "First, far too many lawyers are legends in their own mind, and for you lawyers in the room who don't recognize yourselves, my suggestion would be, go look in the mirror just a little bit. I lower the average IQ of a conference room at Amgen that's full of scientists every time I step in it."
>
> *David Scott*

Now, this doesn't solve the lack of predictability that everybody's talked about — we still don't know what the rules are. But to Dave's point, if you're identifying the risks with business, you're documenting them, and you're saying, "We acknowledge them and these are our mitigation approaches." If later you're confronted with it, it's not a scramble to figure out what happened, why did it happen, what was occurring, because you can already proactively say, "Yes, we understand the risks associated with our business activities; we considered them; we documented it."

That sounds very straightforward and easy, and I would suggest that there are really two key components to this. I'll go back to the language of compliance, that too often we talk at or past each other. As lawyers, we may say "X, Y and Z" about the risk. Regarding Dave's point on language, we use complicated words, people nod, we all think we understand, and we both walk out of the room saying, "I told them what the risks are," and the business person says, "the lawyer told me it's okay to do it." So, have we really engaged in that discussion where we have a common understanding and alignment? Compliance, law and the business jointly own the risk assessment and the mitigation. But we can't talk past each other, and it can't be compartmentalized from or embodied in a declaration such as, "We've identified the risks; here they are — you deal with them."

The same is true for risk assessment. Risk assessment has historically been at two levels — one is the 100,000-foot, enterprise-wide risk assessment, where we say, "Antitrust is a problem. FCPA is a problem. Interactions with healthcare professionals and FDA approval are all risks or problems." At that level, it's really identifying abstract sources of risk, but it doesn't drive mitigation strategies. Or, alternatively, we've done it on a transaction-specific basis, where we have a proposed transaction, a proposed deal, a proposed arrangement, and we ask, "Is it okay?" We look at that in a vacuum without identifying all the aspects of operations contributing to particular risks in that product or transaction and looking at it systematically.

So the challenge is, where do you find the right level of elevation so you're getting a lens into business priorities and assessing risk at that level? That is really where compliance programs should be today. There aren't easy answers, and there aren't off-the-shelf solutions to it, because fundamentally, compliance is not something we do to the business; it's an engagement of business in that activity.

So, I go back to, "How do we know if we have an effective compliance program?" I would suggest that if we're asking a Board to certify that it has an effective compliance program, or if you're asking your managers to certify that their functional area complies with applicable FDA, healthcare and other laws, and they're saying, "Well, yes, except in this area where I have this problem." If they're willing to give those certifications, and they're comfortable and they're protected in that, then I would suggest to you, you have an effective compliance program. If they're *not* willing, or they're saying, "I have to certify; what does a certification imply? What if it's wrong?", then I think the question is, how can we better our resources to make the business people comfortable that they understand the risks and how to address and manage them.

JACK FRIEDMAN: Our final two panelists will be speaking on subjects such as dealmaking, international operations, FCPA, and disclosure. Before we do, I'd like to let anybody in the panel, including our Guest of Honor, speak about the compliance area.

As a layman, there are two ways I think of compliance for a company like Amgen. One is compliance that cuts across any public company. Second, what are the special compliance issues, laws, and challenges in biopharma that would not be the same for banks, manufacturing companies, oil companies or other industries? In biopharma, the phrase, "We have a great compliance program, and we're really sorry that ten people died; we did a great job" does not work well. Americans expect products to be safe and people shouldn't die, no matter what. So besides the legal requirement, there is the higher standard that the industry has as far as the public is concerned. Would anyone like to comment about some of the particular compliance issues in this field that are not found in other industries?

MEREDITH MANNING: Well, what you're talking about is the public safety obligation. Certainly, FDA has extensive regulations that require adverse event reporting and testing and development challenges. As we have highlighted, these can be extremely difficult, but also are quite comprehensive. Certainly, one of the challenges of being in the healthcare space is that you do have unexpected events that can occur, like the New England Compounding one which I was discussing earlier.

But there also is a baseline risk benefit calculation that goes into the government's evaluation of all products, and that does mean that in order to get the benefits of approved FDA products, you take an inherent, to some extent, amount of risk in taking those products. That is a risk that we try to manage, if you will, through the regulatory structure. I don't know if that answered your question.

JACK FRIEDMAN: I assume that you have to make a calculation regarding side effects. For example, these ads on television that say, "Our product is wonderful, but in rare cases..." and they list a chamber of horrors.

MEREDITH MANNING: That's the "important safety information."

JACK FRIEDMAN: Yes, they have this list of side effects that are rare, but are just absolutely unbelievable to hear. What room do you have legally? Do the courts let a jury use their opinion? Or does the court say, "Some health risk is intrinsic in the industry you're in," and the judge will make, as a matter of law, a judgment that "the compliance program followed the law and I'm not letting the jury scream at the company that they're bad people."

MICHELE GARVIN: I'm not going to answer your question; I'll let one of my colleagues. But I do want to re-frame it a little bit, about what I think is really interesting, in how you posed the question of what do the courts say, what does the jury say, from a healthcare regulatory compliance, particularly from an anti-kickback perspective. Really looking at the complicated relationships that exist between various actors in the healthcare field, and that is that the stick that the government carries is exclusion from the Medicare and Medicaid programs, which means that you

don't have a viable product if you don't have reimbursement. That stick means you often don't have the same type of opinions and law and reaction to it that you might find in other sectors. It really becomes a question of the government setting policy and rules and establishing future requirements through this exclusionary power that's unique.

JACK FRIEDMAN: Do you want to comment, Charles?

CHARLES RUCK: Only that the extent your question is about the unique challenges for biotech, they really tend to be not to the sales and marketing or other things that are similar across all drug or device manufacturers, but the focus of your question is more of manufacturing and safety and good manufacturing practices, and education of the regulator. Because it's not the division of biologics — this is Meredith's area more than mine — but the notion that you're dealing with, essentially, as David said, living organisms, the risks that that presents, and the understanding of the public to your product and how you're going to manufacture it, if biosimilars come along. Nobody really knows what the brand risk is, it's not hard to make a generic of a chemical compound. There's going to be people out there soon producing essentially generic versions of branded biologic drugs, and heaven knows whether they'll do a good or a bad job of that, and what that will do to the patients' — the consuming public's — tolerance for understanding the risks and benefits of biologics. Like all drugs, there's no such thing as a perfectly safe drug; all drugs have risks and benefits. That's the unique challenge for biotech as the innovators get big, is watching the biosimilar industry grow.

JACK FRIEDMAN: Do juries tend to feel that there is strict liability simply that the product was a cause? If you are seriously injured or there's death, juries may say, "I don't care what they did — even if it is one out of a million — you have to pay up."

> "...if you want to be one of those lawyers that is profoundly useful to business people and scientists and other colleagues, then be one of those lawyers that is humble and speaks plainly the important information that business people need to hear."
>
> *David Scott*

DAVID ROSENBLOOM: Well, I hate to do this, but there's nobody on this panel who's done more products liability cases than Dave!

DAVID SCOTT: Let's start from a different place. If I want to sell orange juice, or I want to sell Kleenex, or other consumer products, then all I need to do is put the capital together, and get the right people to help me make this, and get the right people to help me distribute it, and produce the right kind of advertising to interest consumers in buying it, and if I do a good job at those things, I'll be successful. Our business is completely different. In our business, if I want to sell a particular medicine, I first have to spend fifteen years developing the evidence that will be sufficient for the government to conclude that that medicine is worthy of approval. So I spend that fifteen years; I go through all kinds of machinations, and the rules frequently change in the middle of the game, and I do my best to adapt to all of that. Then eventually, the government approves my product, if I'm fortunate enough. But then the government says, "Now we're going to tell you what you can say to physicians who might wish to use this product with their patients, and we're going to tell you what you can say to patients, and we're going to tell you how you have to behave in the context of dealing with hospitals and the distribution chain and everything else." So, all of that has to have the government's *Good Housekeeping* seal of approval.

I actually don't object to all of that; that's part of the social bargain. The social bargain is that people who produce medicines that treat grievously ill people — the most vulnerable people in society — that folks who do that ought to have to go through a gauntlet of challenges before they can provide a lifesaving — or, if it's the wrong thing, a life-threatening — medicine, for patients. But what it creates is an entirely different kind of environment in which to think about compliance, and an entirely different kind of environment in which to think about how one goes about the investment calculus than if I'm selling Kleenex and orange juice.

JACK FRIEDMAN: What I left out of my comments, which I appreciate you filling in, is the fact that it's not just the point of the one in a million physical health risk. There is a vital educational component, including educating the patient on risk and proper usage, the doctor who is the one who counsels; and packaging and usage directions. If the patient knows there's a one in a million risk, at least the patient and their family are being involved in the decision process. That's an important element.

DAVID SCOTT: I'll respond to the product liability question, as well. Because of a misspent youth, I have a lot of experience in product liability matters.

First, Amgen has no product liability cases pending, and we serve millions of patients. We have no product liability cases pending, and during my time at Amgen, product liability has not been an issue for Amgen. What I have found historically with juries over thirty-five years of dealing with them is that with a jury, you have to pass an open book test. If you can lay out for a jury exactly what you've done to develop a drug or to develop a device that's helping address a serious unmet medical need, and if you can demonstrate to a jury that you have

been square about that, that you have lived up to your end of the social bargain, the juries will accept the notion that there is inherent risk in any drug or any device, or indeed, in any product. If there are appropriate warnings and the like, my experience has been that juries are respectful of that.

Where you get into serious problems in product liability matters in our industry is when you can't pass the open book test, when juries believe, because there is evidence there to support it, that you haven't comported yourself in a manner consistent with the social bargain. Then they will hold that against you and punish you, and I don't object to that notion. I think that that can be entirely appropriate.

JACK FRIEDMAN: I've just learned a lot and I thank you very much for your comments.

What do you see as some of the areas of regulation and law that might be considered for improvement? What would be some examples that the industry as a whole has been concerned about and would like to have reviewed?

DAVID SCOTT: Well, I think it goes back to something that Dave Rosenbloom was describing. In our business, the rules of the road with respect to engagement with, for example, healthcare professionals, are not well and clearly crafted by the government, either in the form of statute or regulation. There is a tremendous amount of ambiguity about the rules of the road and what they mean.

JACK FRIEDMAN: You mean working with the hospitals and doctors?

DAVID SCOTT: Sure, Dave's notion that you don't find road signs up that say "Speed Limit 55." You don't find road signs up that say "Yield the right of way." In our business, in those kinds of relationships, you don't have that clarity. Congress and the regulators choose not to provide that kind of clarity. That's their prerogative, and they choose not to provide it. So what it does is leave many of us to try and figure out the right course to take consistent with the social bargain that we've agreed to be in as a consequence of choosing to practice in an industry that offers you the opportunity to serve patients in need.

Like any business, sometimes you're not happy with the circumstances that you find yourself in, and you would crave greater clarity. In the absence of that clarity, we try to keep the social bargain in mind, and try to establish our rules of the road in a manner consistent with the way we think that well-meaning regulators would interpret our obligation.

JACK FRIEDMAN: Thank you. I'd like to turn now to Frank Aquila of Sullivan & Cromwell, who will introduce his topic.

FRANK AQUILA: Thank you, Jack. I'm going to talk about the Foreign Corrupt Practices Act, and this is a fitting topic for me to discuss at a session honoring Dave Scott.

Dave and I met the first week of January of 1987 — so roughly, soon to be 26 years ago — and we were on opposite sides of a transaction. It was a U.S. domestic acquisition, but it had some significant non-U.S. aspects. Shortly after the transaction was signed up, we learned that we had a "Mexican issue." Given the fact that both Dave and I were the then-youngest lawyers in the room, and given the way in which issues in emerging markets were dealt with in those days, we were tasked with solving the "Mexican issue." So Dave and I have been dealing with thorny, multinational issues for a long time.

Dave might want to characterize himself as "just a country lawyer" in the same way as Senator Sam Ervin did — they both, of course, were Ivy League law school graduates, I would note. In reality, although Dave has not grown up at either Amgen or in the healthcare industry, he has had a long history in both regulated industries and, most importantly for this topic, multinational industries.

When I think about Dave, I think about him as the quintessential 21st Century General Counsel, except that he was following today's "best practices" back in the last decade of the 20th Century.

What do I mean by that? Two things, really. One is Dave's 360-degree view, understanding of relevant issues; and the other is his truly global business perspective. These are two crucial elements to consider when you begin to consider a potential FCPA issue. Those of you who know me know that my area of expertise isn't the FCPA; it's mergers and acquisitions. However, the FCPA, a statute that was enacted in the early days of the Carter Administration as a reaction to Watergate, has really become quite significant over the last five years. I'm told by people both at the Justice Department and at the SEC that today, the FCPA is one of their highest priority enforcement areas, not only for U.S. companies operating outside of the U.S., but for non-U.S. companies as well.

Just since 2009, forty companies have resolved FCPA investigations with the U.S. government, and these settlements have led to $2 billion in fines. The poster boy, if you will, in FCPA is Siemens, which paid fines of roughly $1 billion — and that's not included in the $2 billion that I just mentioned — and their expenses in dealing with their FCPA investigation was another $1 billion. So this is an area where, whether you're in the healthcare sector or otherwise, if your business is global, you need to be focused on FCPA.

It is worth noting that while there are many statutes that are criticized for making the U.S. less competitive than our peer countries, that is not the case with respect to the FCPA. All 38 OECD countries today have anti-corruption statutes similar to the FCPA. So dealing with these issues is something that multinational companies are going to have to increasingly deal with, whether or not they have a U.S. nexus.

It is timely to discuss the FCPA, because just over two weeks ago, the Justice Department and the SEC published a 120-page book — *A Resource Guide to the U.S. Foreign Corrupt Practices Act* — that seeks to answer some of the most frequently asked questions regarding the U.S. FCPA. The Resource Guide was compiled and released because business people — U.S. and non-U.S. — have been looking for some guidance on many related questions for a long period of time. Is buying a cup of coffee for a government official an FCPA violation? What is a government official? While the *Resource Guide* does not have a lot of bright line tests and doesn't provide significant material, it does address some of the key areas of concern. I also believe that the *Resource Guide* is going to be helpful to companies in putting together FCPA programs. It's not the be-all and the end-all; but it is an important development.

One of the things to understand is that the United States Department of Justice and the United States Securities and Exchange Commission assert the position that they have global jurisdiction when it comes to the enforcement of the FCPA; not only with respect to the activities of U.S. companies, but also with respect to non-U.S. companies that are issuers of securities in the U.S. Essentially the FCPA is a very easy statute for the government to enforce, since the SEC and/or the DOJ simply instruct the company to conduct specific and intensive, multiyear investigations. As a consequence, Siemens and the other companies that have had FCPA problems, have had enormous costs. It's not just legal bills; it's accounting and other consultants' bills. The company goes into the SEC or the DOJ wanting to fully cooperate, and the government says, "We want to see every e-mail that any marketing or sales person has sent related to Indonesia in the last five years with words 'such and such', and we want you to interview all these employees," and all of that. So, it's very efficient and inexpensive for the regulators in Washington to enforce this statute.

One of the things that you should be aware of, particularly with respect to the healthcare sector — and healthcare is a little bit different than a lot of other industries — is the fact that in most parts of the world, doctors, hospitals, and other healthcare officials are, in fact, employed by the government. As a

consequence of that, this has been a concern for the healthcare industry for a long period of time. It is pretty clear that simply buying a cup of coffee, providing nominal value promotional material or samples will not, in and of itself, lead to an FCPA investigation, as long as it's in the normal course of business and there's no other particular payment. Nevertheless, it is something that's going to be looked at if there are other FCPA issues.

One of the things that has to be looked at very closely — and this is something that a lot of companies, both inside and outside the healthcare sector, are increasingly concerned about — and that is acquisitions, particularly in emerging markets. Now, typically, in acquisitions, we're used to being able to say to the seller, "Are you complying with law?" Usually they can tell you they *are* complying with law. Well, the fact is that a company that is sitting in Argentina or Malaysia or Taiwan, that is complying with local law and doing things the way that companies in those jurisdictions operate, owned by a non-local company, wouldn't necessarily have to comply with the FCPA or similar statutes. So that leads to the importance of due diligence in non-U.S. acquisition transactions.

Now, unlike a lot of other due diligence issues, you can say, "Well, if there is an asset that I really want, a business that I really want, I can go and acquire that business and after the fact, I'm going to put in my own compliance program; I'm going to put in my own systems; I'm going to put in my own accounting programs; and I'm going to be able to correct the problem." The only issue, though, is that the profitability, the ability to generate the revenue and profits, the ability to operate in the way in which they are, may only exist if they operate the way they are today. So, in effect, if they're making facilitating payments to government officials, that may be crucial to their ability to function.

So what does that mean? Does it mean that you simply do not make acquisitions in emerging markets? Obviously, given where the growth is in the world, and ninety percent of global growth is in the emerging markets, you really can't do that. So, we're going to have to face the fact that there are going to be acquisitions in markets where there will be FCPA challenges. The purpose of due diligence will be to attempt to answer two questions: Is this a company that, even when you fix the problem — if there is a problem — that you're still going to have a viable and profitable acquisition? Or is this a situation where even if you can fix it, you simply don't have a viable business?

I think in healthcare, unlike a lot of other sectors, you can find that, in reality, what you're buying is going to provide you with either an asset or a platform that may not be as profitable or worth as much in the hands of a U.S. or U.K. or other multinational company, but, nevertheless, it's going to be important.

I do want to highlight *some* of what we would consider to be the red flags that you should be looking for. One of the reasons you want to be aware of these red flags is that the SEC and the DOJ keep track. They have not said this publicly, but I think we all know this — they keep track of when

> "The social bargain is that people who produce medicines that treat grievously ill people — the most vulnerable people in society — that folks who do that ought to have to go through a gauntlet of challenges before they can provide a lifesaving — or, if it's the wrong thing, a life-threatening — medicine, for patients."
>
> *David Scott*

U.S. issuers make acquisitions in certain countries. You may acquire a company in Switzerland that has operations in countries that are problematic. So the SEC and the DOJ know, and very often will come to you three, six, nine, twelve months *after* an acquisition, and basically say, "Oh, tell us a little bit more about what went on there. Tell us a little bit about what you did to remediate the problems there."

What you want to be looking at is, are you in a problematic country, like Nigeria? Is this a company or an industry where there have been past accusations or a reputation for corruption? Is it an industry where you *have* to interact with government officials? Again, healthcare, in most parts of the world, you do have to interact with government officials at all levels. Are there government contracts and licenses? Are there any sort of special arrangements that are in place? What sort of payments for services are there? Very often what happens in certain countries is that you wind up hiring the law firm or accounting firm or consulting firm of the brother, nephew, or sister of the prime minister, or other official. So you need to look at all of those potential factors.

Just because a jurisdiction is what you would consider to be a western European-style country does not mean that some of these FCPA issues do not exist. As I said before, very often its activities at the subsidiary level, may very well, in the hands of the U.S. company or a U.S.-listed company, lead to an FCPA issue.

So I just want to leave you with one admonition, and that is that when you're in situations like this, you need to learn from people like Dave Scott and recognize that the world around us is a broad and evolving place. The practices that we have lived with and have served us well in the past don't necessarily serve us well in the future. To the extent that we can be sensitive to these issues going forward, whether they be in acquisitions or organic growth opportunities, the sooner we recognize them, the sooner we incorporate them into our compliance programs, the less likely it is that they're going to come back and be major issues that we're going to have to deal with.

JACK FRIEDMAN: Charles Ruck of Latham & Watkins will be speaking next.

CHARLES RUCK: Thanks very much. Dave, our firm's very proud of our thirty-year history with Amgen, and I wanted to make sure everybody in this room knew that Dave Scott hand-picked the people who are up in front of you talking about each of these topics. It's really a tribute to him. No one spent a lot of time talking about their bios, but each of these individuals are preeminent experts in their field. Dave calls on each of them to represent Amgen in various aspects, and we've all worked together on various things with Amgen, because Dave expects us to create teams of the best people in the country to work on things, and that's really a tribute to his leadership style. You should know that I am personally honored to be part of this group, and to be part of honoring you today, Dave.

I was asked, in part, to pull all of this together, to talk a little bit about the challenges of disclosure from a public company, because you've heard about the specific areas, the specific pitfalls and substantive expertise from the other speakers. The one thing that draws that all together is that as a public company, we're required on a periodic basis to update the market about what's going on, and that can be very, very difficult. Particularly, as the theme of the panel, when the ground is shifting under our feet and the rules and the regulations are changing, As Frank mentioned, we're just now getting interpretive guidance on decades-old legislation that's out there. That makes disclosure very, very difficult. We're asking what should we say about the rules and our compliance with them; when should we say it; do we know enough to say something now? We'd always have to be mindful that whatever we say may give rise to an obligation to update or change our disclosure over time, so we have to craft it very carefully.

The rules that the SEC gives us for what to say are actually not very helpful. We're number one in a periodic disclosure regime, which means we have to update the market once a quarter, and during the interim periods, we're only obligated to say things to the market under a *very* limited set of rules. Even the rules themselves about what to say on a periodic basis are guided by very broad principles: materiality, which we all learned as far back as law school just means, what would a reasonable person find important for their decision? That doesn't help you very much at the end of the day.

At the same time, you're held to an incredibly high standard in terms of disclosure, because whatever you say will be judged in 20/20 hindsight. So when the rules are shifting and the facts are shifting, you have to make a judgment call, but yet you have to make it knowing that when someone picks it up and reads it later, they're going to know *exactly* how the facts turned out, and *exactly* how the law turned out, which makes those judgments particularly difficult.

The information comes not only from very divergent sources — the business itself, plus the regulations and the different pitfalls we've talked about today — but the audience for your disclosure is wide and broad. The SEC is the one who dictates it, but the investors — hedge funds, etc. — are the ones who are clamoring for it. The FDA, the DOJ, they're looking at it in hindsight with respect to the types of enforcement actions we heard about today, and at the same time, your customers have a business of reading what you say, and wondering what it means that you have an enforcement action or investigation going on in a different area. So you're trying to balance a whole number of different constituencies when you develop your disclosure.

I thought it might be interesting to take one quick example, not from Amgen, but from a different company, that really highlights the tough calls that you have to make around disclosure. Let's take a drug company — not a biotech company, but a drug company — who is in the middle of a trial, and the doctors come together and they have the preliminary results of the trial. The first inclination would be, "All right, let's go out and disclose it." But what do the preliminary results of the trial mean? Oftentimes, you'll take the data from the trial and it'll take you 30, 60, 90 days to look at the data in all the different ways, and to determine the statistical significance of the information that comes out of it.

By the way, you never know, even with *that* information, whether the FDA will find the data to be sufficient to move your drug forward either to the next phase of trials or ultimately for approval, and so there's an interpretive aspect of it, as well.

You may have the information about the effectiveness of the drug, but underlying it may be side effects or the bad results of the trial. Even if it was effective, if it killed a few people, you're not going to get it through your trial, and you have to develop balanced disclosure.

The question in part is what do you disclose, and do you disclose it at that time? You may have a lot of pressure to disclose it, because the street knew the trial was coming to an end. The FDA is looking for the information; and at the same time, you don't have enough to tell the full story, and the market, if there's any truth, abhors a vacuum. You tell them half of what they want to know, they will assume all the rest is bad. That can result in a whole other

set of problems for you as a company. So I'm not going to give you an answer to that hypothetical today — only to indicate that the challenges are myriad.

I will end, being cognizant of time, with just a few quick principles that I've come to believe around the disclosure regime that we're in today. The first is, the most important thing for disclosure is not waiting until you have a crisis or you have an event to disclose, to think about what you need to say. The real benefit of the pressure relief valve for disclosure in one of those key situations is what you have said building up to that event. What have you warned the market about; what have you conditioned the market to believe; and if you've done a good job building up to that event, it will take a lot of pressure off the need to put out immediate information, and it will take the surprise out of the information.

That said, rarely have I heard a CEO or General Counsel afterwards saying, "I wish we hadn't disclosed that." Get the information out there into the market. You may have to deal with it, and it may have some gyrations settling into the market, but the *worst* situations I've ever been in, and Frank's nodding next to me, are when someone says, "You knew it but you didn't disclose? Why were you covering it up? What about that information didn't you want to tell people?" It makes people want to dig even harder. So get the information out there.

Keep all those audiences we talked about in mind. Sometimes the marketing department will want to get out some information with a positive spin, but you have to remember that the FDA is going to read that, too. For example; that prosecutors or plaintiffs' lawyers may read it back to you later in a context that you didn't want to hear it. At the same time, remember that whatever you say in those public disclosures gives rise to a need later to update it or to correct it if it was wrong, and you need to carefully craft whatever you say around those disclosure items at the time.

JACK FRIEDMAN: What is the outlook for biopharmacy in Washington after the election? I invite the panel to tell us what they think the big policy issues in Congress and the executive branch will be with the implementation of Obamacare. It can also include information from clients or people you talk to.

MEREDITH MANNING: I'll start briefly, to say that the slides that I provided tee up some of the key issues post-election with respect to implementation of the Affordable Care Act. There are a huge number of issues that HHS, in particular, will be grappling with. Now, I don't want to necessarily imply that all of those are going to be critical to the pharmaceutical or biotechnology industries, because those are largely aimed at expanding healthcare coverage for individuals. There are, however, a number of pieces of the ACA, or Obamacare, that are oriented toward shifting the landscape of the healthcare industry by doing research into patient outcomes by creating networks of healthcare providers that are incentivized to look at total treatment outcomes, as opposed to episodes of care. So those do have the potential in the long-term to perhaps shift the way that care has developed, which of course would influence the way that products are used.

In the shorter term, there are a number of critical policy decisions that the FDA will be making. Certainly the way that it implements the biosimilar statute will be extremely important for a number of players. Last year, Congress passed several statutes — as part of the User Fee Reauthorization — with several provisions designed to speed the way breakthrough therapies get to market. So, again, the way that FDA implements some of those could be very important and could potentially allow companies to get products approved a little faster.

FRANK AQUILA: I'll talk a little bit more broadly. As I was mentioning with respect to FCPA, government action sometimes can't really be seen immediately. The full impact is only recognized years later, sometimes decades later, and that's certainly true of a lot of the issues that are rattling around D.C. right now.

We all know that the biggest issue that has to be dealt with, whether it's before we go over the cliff or not, is how we're going to deal with entitlement reform and how

we're going to deal with tax reform. What is going to be crucial is to see what balance is reached, what brinkmanship is there. The hope has to be that, in fact, leadership in Congress and the President come together and come up with some agreement *before* Christmas. It's something that nobody particularly likes, but everybody accepts as necessary, or whether we, in fact, go over the cliff, and it's a game of brinkmanship that gets dealt with in the new Congress.

One of the things that I certainly — and I spend a lot of time in corporate boardrooms — am hearing from people in lots of different industries, is: "We know we're

going to pay more in taxes; we know that the deficit's probably going to go down; we know that interest rates are probably going to stay low for a little bit longer, and then they're going to start going up. The real question is, will this be a resolution that leads to longer-term growth; because let's face it — the only way we deal with the deficit is by increasing growth." If this simply reduces the deficit on paper but is an impediment to business activity, then it will be a Pyrrhic victory for both sides, or whatever side thinks they won. If in fact it allows economic growth to revive, then that will be a longer-term victory, not just for the economy, but for those who are unemployed and the country as a whole.

JACK FRIEDMAN: Anyone else with comments?

CHARLES RUCK: My sense, too, is that we're going to continue to see very much of an enforcement culture in Washington, D.C., whether it's insider trading, which hit the press with the SEC Michigan matter this last week, or on the FDA side, continuing to keep companies under corporate integrity agreements and the resolution of investigations. We're going to continue to see that theme clean up the excesses of the last period of our country's growth.

FRANK AQUILA: I couldn't agree more with Charles, in the sense that if you just watch the news — at least on the enforcement side — who is in power can lead to huge differences in how regulatory structures are built and the clarity of those regulations. When it comes down to the enforcement side, it tends to be — I'm not sure whether it's apolitical or bipartisan — but you might notice that every elected official you ever saw stand up said that there was no need for hard choices on Medicare, because they were going to find enough fraud, waste and abuse. Nobody actually has any data that I've ever seen to support the levels of fraud, waste and abuse that they're going to go find. But if you think about that as sort of a receivable, and what they're going to do to try to collect it, I would agree with Charles that the culture of enforcement — whether it's apolitical or bipartisan — will be continuing.

JACK FRIEDMAN: This is actually a true comment, not just an anecdote. Sometime in the 1930s, the head of Macy's said to the marketing staff regarding waste, "I know that half of our advertising budget is wasted, but I can't tell which half." So he approved the whole thing.

DAVID SCOTT: When you think about healthcare, in at least the United States, I like to think about it like a three-legged stool, and one leg of the stool is access, and that's what President Obama was trying to enhance. There's a certain salutary quality to saying that, "It would be great if everybody had access to medical care." But that's one leg of the stool. A second leg of the stool is the quality of that medical care, and the third leg of the stool is the cost of that medical care. Neither the quality nor the cost issues are addressed by the new healthcare act. So essentially what you're doing is increasing access without commensurate improvement in quality or cost, and that's a recipe for some serious issues which, in turn, play out in the cost of Medicare and Medicaid.

So, these are very difficult problems that Washington is going to have to solve, and historically, frankly, the biopharmaceutical industry has been the whipping boy for this sort of thing: "We'll just take it out of the drug companies." But when you actually sit down with people in Washington and say, "Are you interested in the data?"

The data says that less than ten percent of the total healthcare costs in this country is attributable to drugs. In fact, we've turned the corner on costs in that area. Probably in the next five years, it will be less than eight percent, and the reason for that is so many of the most popular drugs are going generic, so the overall cost of those drugs is way down, and probably in the course of the next five years, the trend line is something like ninety percent of all scripts written in this country will be for generic medications.

So that's not going to be the source of the solution. The source for the solution is going to be an awful lot harder, because it's going to have to go to the issue of quality. It's going to have to go to the issue of cost. It's going to have to address the grand irony of all — if you look at institutions that have reputations for delivering the highest quality of healthcare. These would be places like the Mayo Clinic and the Cleveland Clinic and Kaiser Permanente. There are some other examples for places that have a system and process designed to deliver the highest quality healthcare. There's a startling piece of data associated with those places, and that is that they're also the least expensive places in the country delivering that medical care.

So they have obviously addressed quality and cost in a unique kind of treatment philosophy way, so there is a model there. The question is whether or not anyone will pay attention to that and forge a new way forward. But I'd just be echoing what others have said — we're up for a very bumpy road here and a lot of hard work.

JACK FRIEDMAN: Are there any public policy or legal issues that might help accelerate the development of good products? Is there anything from the public sphere that could help private industry develop good products?

DAVID SCOTT: Well, I think we need to continue to work with the FDA and in Europe with EMA to come up with better, more sophisticated ways for viewing new drug applications. We need to do that together; we need to hold hands on that together. The extent that we can improve that process will expedite the delivery of really innovative products, and that will be certainly a benefit to patients who, in some cases, are really in desperate straits in terms of nearing the end of a period when drug therapy might actually be useful for them.

So, big challenges, but this is not something that industry can do alone; it's not something that the government can do alone, either. We're really going to have to work together as part of this social contract to figure out how best to address these issues. There are well-intentioned people in government, and there are well-intentioned people in the industry, who are committed to that process, but we need to see the fruits of those labors, and soon.

JACK FRIEDMAN: Apart from all the important information the Distinguished Speakers have given us, part of the program is to give people who don't already know David Scott a chance to know him better. So I'll wind up with a personal question. In the five minutes a month, or five minutes a year, that you have free, what do you like to do with your time?

DAVID SCOTT: I like to ski in chest-deep powder in the glades of Vail.

JACK FRIEDMAN: We have an athlete here! I would like to thank all the speakers for this wonderfully educational program.

Meredith Manning

Partner, Washington, D.C.
Hogan Lovells

Hogan Lovells

Meredith Manning is the Co-director of Hogan Lovells' pharmaceutical and biotechnology practice group. She primarily counsels companies in the pharmaceutical industry on an array of issues surrounding the U.S. Food and Drug Administration's (FDA) review, approval, and oversight of drug and biological products. She has broad experience addressing issues surrounding clinical trials, drug and biologic drug approval standards, and FDA compliance. She counsels clients concerning enforcement matters threatened or brought by the FDA and other regulatory bodies, including issues surrounding advertising and promotion of drugs and good manufacturing practices. This includes counseling companies about anticipated enforcement, responding to FDA inspectional observations, notices of violations and warning letters, and negotiating consents decrees with the FDA and the U.S. Department of Justice (DOJ).

Meredith has substantial government litigation experience, especially with respect to enforcement of the Federal Food, Drug and Cosmetic Act. She served as Assistant U.S. Attorney, Civil Division for the U.S. Attorney's Office in Washington, D.C., and was Associate Chief Counsel in the Office of the General Counsel at the FDA.

REPRESENTATIVE EXPERIENCE

Routinely assists major pharmaceutical and biotechnology companies in assessing their compliance programs and in reviewing and revising policies and procedures governing compliance with the FDA's rules and regulations.

Conducts internal investigations surrounding drug compliance practices such as assessments of promotional review committees, inquiries based on hotline complaints, and evaluations of the roles of medical and scientific personnel.

Represents companies and individuals with respect to current Good Manufacturing Practices and in cGMP enforcement matters brought by FDA in federal court.

Drafts comments to the FDA's administrative docket concerning pending policy issues, such as drug approval and REMS standards, drug advertising, and agency enforcement policy.

Assists companies in appealing FDA actions and decisions, such as FDA conduct and management of advisory committees and the issuance of complete response letters.

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David S. Rosenbloom

Partner,
McDermott Will & Emery LLP

McDermott Will & Emery

David S. Rosenbloom is a partner in the law firm of McDermott Will & Emery LLP and is based in the Firm's Chicago office. David focuses his practice on the areas of *qui tam* litigation, healthcare fraud and abuse compliance, internal investigations and complex commercial litigation. One of David's major areas of practice include defense of healthcare providers and manufacturers.

Prior to joining McDermott, David served in the United States Attorney's Office for the Northern District of Illinois for eight years, at the conclusion of which he held the position of Deputy Chief of the General Crimes Division. As an assistant U.S. attorney, David conducted and supervised numerous investigations concerning allegations of financial misconduct and fraud, including government program and health care fraud. David also successfully tried numerous federal jury trials involving a wide variety of matters, including financial crimes, securities fraud, public corruption and racketeering. As a defense lawyer, David has been lead counsel on jury trials for both individual and corporate defendants that resulted in acquittals.

David is a member of the state bars of Illinois, California and Colorado, as well as various United States District Courts and United States Courts of Appeals. David serves on the adjunct faculty at Northwestern University School of Law, where he teaches Trial Advocacy. David is ranked as a leading general commercial litigation lawyer and a leading white-collar crime and government lawyer in the 2009, 2010 and 2011 editions of *Chambers USA*. He was named "The Best of the Best USA 2009" by *Expert Guides*. The *Legal 500 United States 2010* and *2011* recognized David as a leading lawyer in the field of white-collar criminal defense litigation. In 2011, the United States Sentencing Commission appointed Dave to serve as a member of its Practitioners Advisory Group.

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McDermott has over 75 years of serving a broad range of client interests. Established in 1934 as a tax practice in Chicago, Illinois, McDermott has grown its core practices and offices around the globe. The expansion of our international platform has supported numerous cross-border transactions and litigation matters, while providing the experience necessary to offer corporate and commercial, international and domestic tax, labor and benefits, competition, intellectual property and regulatory counsel to clients across all industries. In the years to come, we will continue to expand geographically and enhance our existing practices and industry-focused strengths. We are committed to building from these strengths in order to best serve our clients and communities.

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Michele M. Garvin

Partner
Ropes & Gray

ROPES & GRAY

Partner Michele M. Garvin is the former chair of Ropes & Gray's Health Care group. A frequent speaker on health care issues and author of articles highlighting trends and opportunities in the field, Michele has practiced since 1987, representing a wide range of health care providers including academic medical centers and faculty practice plans, community hospitals, physician group practices, health maintenance organizations, insurers, prescription drug plans, and pharmaceutical manufacturers. She has a broad practice focusing on general regulatory compliance, governance issues, academic medical center and medical school relationships, corporate affiliations and acquisitions, clinical joint ventures, including electronic health records and physician integration strategies, as well as insurer/health plan matters, and third party reimbursement, including managed care contracting and pay-for-performance issues.

Currently, Michele is advising numerous clients on clinical integration and structuring of risk sharing arrangements with payors, including P4P contracts, quality incentives, and efficiency targets.

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Frank Aquila

Partner,
Sullivan & Cromwell LLP

SULLIVAN & CROMWELL LLP

Frank Aquila is co-head of Sullivan & Cromwell's General Practice Group, and in that role he has responsibility for 450 lawyers in 12 offices around the world. This group includes the Firm's corporate, financial institutions, securities, mergers & acquisitions, corporate governance, real estate, leveraged finance, private equity, project finance, restructuring and intellectual property transactional practices.

Mr. Aquila has a broad multidisciplinary practice that includes extensive experience in negotiated and unsolicited mergers and acquisitions; complex cross-border transactions; global joint ventures; private equity transactions; and corporate governance matters. He serves as a regular adviser to global leaders such as Amgen, Anheuser-Busch InBev, Avon, Diageo, International Airline Group and United Rentals.

Mr. Aquila has been repeatedly cited as one of the world's leading mergers and acquisitions lawyers. He has been recognized as one of a small number of lawyers ranked by *Chambers Global* in Band 1 (their top tier), as an *American Lawyer* "Dealmaker of the Year" and as a recipient of the Atlas Award as "Global M&A Lawyer of the Year." For his work in corporate governance, Mr. Aquila has been named by the National Association of Corporate Directors (NACD) to their "Directorship 100" — one of the 100 most influential people in corporate governance and inside the boardroom. He is also a two-time winner of the Burton Award for Legal Achievement (2005 and 2010). In 2009, Mr. Aquila was selected by the American Bar Association as a "Legal Rebel" — one of the profession's 50 leading innovators.

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Charles Ruck

Partner,
Latham & Watkins LLP

LATHAM & WATKINS LLP

Charles Ruck is a former member of Latham & Watkins' Executive Committee and currently serves as Chair of the firm's Strategic Client Initiative. Mr. Ruck's practice focuses on mergers and acquisitions, capital markets, and general corporate and securities matters. He serves as primary outside counsel to a number of public and privately held companies and he regularly represents Boards of Directors and special committees in complex corporate governance matters.

In the merger and acquisitions area, Mr. Ruck has worked on a variety of transactions, including:

- Public company mergers and tender offers
- Strategic acquisitions and divestitures involving earn-outs and CVRs
- Hostile takeovers
- Going private transactions

In the capital markets area, Mr. Ruck has handled numerous public and private offerings of both debt and equity securities, representing issuers and underwriters. Additionally, he regularly represents the nation's top investment banks in their capacities as financial advisors, underwriters and placement agents.

Mr. Ruck has been recognized in:

- *Law360* as a 2012 "MVP" in Mergers & Acquisitions
- The *Daily Journal* as one of the Top 100 Attorneys in California in 2008 and 2012
- *The New York Times* as one of an exclusive group of legal and financial professionals leading the next generation of corporate deal makers
- *Chambers USA* 2012 as one of the leading Mergers & Acquisition attorneys in Southern California
- *The Legal 500 U.S.* 2012 as a key partner for his Venture Capital and Emerging Companies expertise in life sciences
- One of the *Best Lawyers in America* as a recommended attorney in Mergers and Acquisitions law
- *California Lawyer* as Transactional "Attorney of the Year"

Mr. Ruck formerly served as a clerk to the Honorable David M. Ebel, on the U.S. Court of Appeals for the Tenth Circuit, and as negotiator for the U.S. Trade Representative at the World Trade Organization in Geneva, Switzerland.

Latham & Watkins LLP

Latham is dedicated to working with clients to help them achieve their business goals and overcome legal challenges anywhere in the world. From a global platform of 31 offices, the firm's lawyers help clients succeed.

Latham is committed to helping clients achieve their business strategies and providing outstanding legal services around the world. Clients depend on the firm's ability to find innovative solutions to complex business issues, and Latham's lawyers use the firm's experience and resources to help clients handle these challenges.

Latham's global platform is comprised of a single, integrated partnership focused on providing the most collaborative approach to client service. The firm offers:

- Deep experience in successful enterprise-transforming transactions and in defending bet-the-company controversies
- A solutions-based approach, providing innovative and sound commercial advice
- Optimally sized teams that provide cost-effective and high-quality services
- A culture geared toward establishing and nurturing long-term client relationships