DIRECTORS ROUNDTABLE

WORLD RECOGNITION of DISTINGUISHED GENERAL COUNSEL

GUEST OF HONOR:

Cameron Findlay

Senior Vice President,
General Counsel and Secretary, Medtronic, Inc.

THE SPEAKERS

Cameron Findlay
Senior Vice President, General Counsel and Secretary, Medtronic, Inc.

Ginger Pigott
Shareholder & Vice Chair, Pharmaceutical, Medical Device & Health Care Litigation Group, Greenberg Traurig LLP

Martin Lueck
Chairman, Executive Board, Robins, Kaplan, Miller & Ciresi L.L.P.

Robert Cunningham
Partner, Baker & McKenzie LLP

Jodi Scott
Partner, Hogan Lovells US LLP

(The biographies of the speakers are presented at the end of this transcript. Further information about the Directors Roundtable can be found at our website, www.directorsroundtable.com.)

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 his leadership in the profession, we are honoring Cameron Findlay, General Counsel of Medtronic, with the leading global honor for General Counsel. His address will focus on key issues facing the General Counsel of an international medical devices corporation. The panelists' additional topics include governance; FDA compliance; international operations and taxation; and intellectual property, complex business, and product liability litigation.

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

Cameron Findlay

Senior Vice President, General Counsel and Secretary, Medtronic, Inc.

D. Cameron Findlay is Senior Vice President, General Counsel and Secretary of Medtronic, Inc., the world's largest medical device company. In this role, Cam leads Medtronic's 120-lawyer global legal department and its government affairs department and serves as a member of the Executive Committee.

Cam joined Medtronic after serving for six years as Executive Vice President and General Counsel of Aon Corporation, the world's largest insurance broker, with nearly $10 billion in annual revenues and 50,000 employees in 120 countries around the world. Before that, he served as Deputy Secretary at the U.S. Department of Labor in the administration of President George W. Bush. In that role, he was the number-two official and chief operating officer of a cabinet department with a $70 billion budget and nearly 20,000 employees. Before that, he was a partner at the international law firm of Sidley Austin LLP. Cam also has served in the White House in the administration of President George H.W. Bush as Deputy Assistant to the President and Counselor to the Chief of Staff, as a law clerk at the U.S. Supreme Court for Justice Antonin Scalia, and as a law clerk at the U.S. Court of Appeals for the D.C. Circuit for Judge Stephen Williams.

Cam received his bachelor's degree in political science *summa cum laude* from Northwestern University in 1982. He received a master's degree in philosophy, politics and economics with First Class Honors from Oxford University, where he was a Marshall Scholar, in 1984. He received his juris doctor *magna cum laude* from Harvard Law School in 1987.

Cam has been active in numerous philanthropic and professional organizations. He serves on the Board of Trustees of Northwestern University and on the Executive Committee of that Board, and on the Board of Directors of the Minnesota Orchestra. He is a member of the Council on Foreign Relations in New York City.

Medtronic

Medtronic is the world's largest medical technology company, offering an unprecedented breadth and depth of innovative therapies to fulfill our Mission of alleviating pain, restoring health, and extending life. Last year, more than nine million people benefited from our medical therapies, which treat cardiac and vascular diseases, diabetes, and neurological and musculoskeletal conditions.

With a global reach that extends to more than 140 countries, we have a deep understanding of many universal healthcare challenges. We're using our experience, extensive partnerships, and the passion of 46,000+ employees to help transform healthcare worldwide by improving outcomes, expanding access, and enhancing value.

JACK FRIEDMAN: Good morning. I'm Jack Friedman, Chairman of the Directors Roundtable. We are a civic group that does global programming for Boards of Directors and their advisors, which includes General Counsel. We've done 750 events in 23 years and have never charged for anyone to attend a program. It's truly a *pro bono* effort.

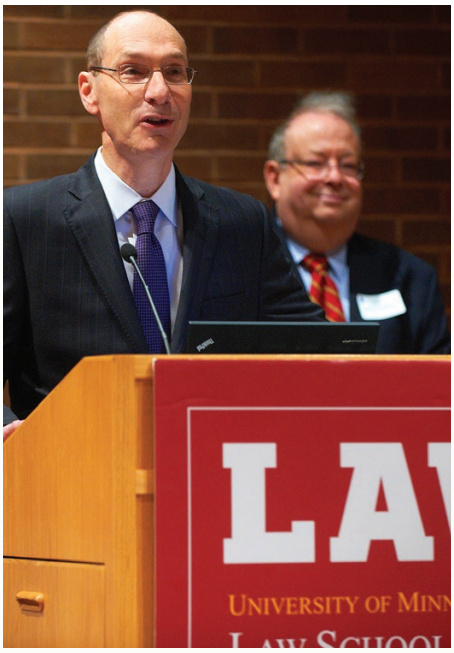
We will begin with opening remarks by our Guest of Honor and will then have the Distinguished Speakers introduce their respective topics. After that there will be a Roundtable discussion. A transcript of the event will be edited and then made available to approximately 150,000 leaders nationally and globally. In addition to the importance of this breakfast event, is the fact that what is said here will go out on an unprecedented basis.

First, I would like to introduce Dean David Wippman of the University of Minnesota Law School.

DEAN DAVID WIPPMAN: Thank you very much, Jack, and I want to thank you for your extraordinary efforts in organizing this morning's program. As the Dean of the Law School, it's my great pleasure to welcome all of you here — glad to see such a good turnout. I saw a few people still struggling to get into our parking lot. That's a perennial challenge, but we're working on it.

Today's program, as you know, was organized by the Directors Roundtable, in cooperation with the National Association of Corporate Directors' Minnesota chapter. The Directors Roundtable organizes the preeminent worldwide programming for corporate directors and their advisors. I know this is true because I read it on their website! If that's not enough to convince you, I think you only have to look at the panelists who are assembled here this morning, and our Guest of Honor. It's an extraordinarily distinguished group, and I'm sure you're going to have a very lively and wonderful set of presentations.

The Law School is delighted to be able to provide a forum for this morning's program.



We recently launched a corporate institute, with the goal of better connecting our students to the business community and helping prepare them for careers in law and business. So it's really a privilege for us to be able to host this morning's event.

I'm particularly pleased to see that the Guest of Honor is Cameron Findlay. I would love to be able to claim him as a graduate of this law school, but in this era of fact checking, I fear that Harvard and Northwestern might take exception to that!

CAMERON FINDLAY: Well, Harvard really would.

DEAN DAVID WIPPMAN: Well, Harvard might, but you're on the Board at Northwestern, right?

CAMERON FINDLAY: That's right.

DEAN DAVID WIPPMAN: We'll claim you anyway, because Cameron is a member of our Board of Advisors, so I can tell you, from personal experience, that you're in for a treat, and I don't think the Directors Roundtable could have made a better choice for its guests and Guest of Honor.

Again, let me thank Jack Friedman for this event. His *quid pro quo* for my offering these words of welcome was that I be brief and sit down, so I'm going to say "welcome" and sit down and enjoy the morning.

Thanks very much.

JACK FRIEDMAN: I'd like to make brief comments about our Guest of Honor. Cameron has a long service as General Counsel. He went to Harvard Law School; has worked at the White House; and was General Counsel at Aon. He's been with a law firm and is on the Board of Northwestern University.

He is the General Counsel of Medtronic, which is a world leader in medical devices and more broadly, in the healthcare field. There was a survey in 2000 of the world's top historians. They were asked for the greatest achievement of mankind in the Twentieth Century. They overwhelmingly voted for healthcare development leading to longer and healthier lives. I assume despite all the excitement with communication technology, that the impact of developments in healthcare is going to be the greatest single achievement of humanity during this century, too.

I would now like to read two emails that were sent to us regarding Cameron. The first is a congratulatory note from Martha Minow, the Dean of Harvard Law School. She said:

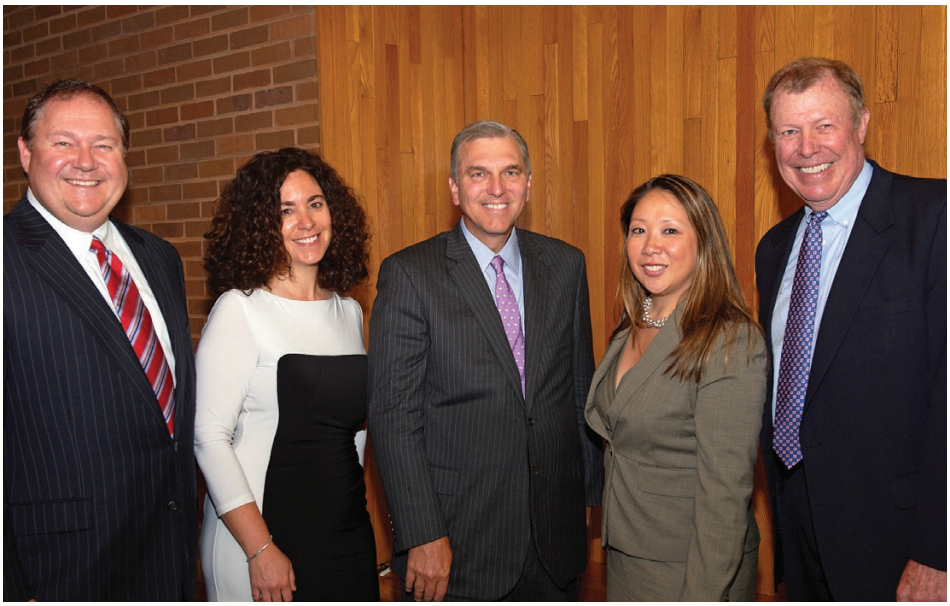
> "Cameron Findlay is a spectacular leader and counselor whose wisdom and clarity exemplifies the best of Harvard Law School and the legal profession. How terrific the Directors Roundtable is recognizing him."

The second is from Morton Shapiro, who is the President of Northwestern. It says:

> "Dear Cam, please accept my heartfelt congratulations for being recognized by the Directors Roundtable with their world recognition of distinguished General Counsel award. I endorse this well-deserved accolade given your extraordinary counsel

to Northwestern University as a member of our Board of Trustees and the Board of Visitors, and the Weinberg College of Arts and Sciences. I'm very impressed with all of the things you do. Your exemplary support of Northwestern's mission to provide a diverse academic community, delivering excellent teaching and innovative research, is much appreciated. Your professional contributions at the White House and at Aon and at Medtronic are broad and continue bringing distinction to your alma mater. On behalf of your Northwestern family, congratulations."

I'd like to have our Guest of Honor make his opening remarks. Then we'll move on with the other speakers in a Roundtable discussion and towards the end, we will bring in the audience. Thank you very much.



CAMERON FINDLAY: Thank you very much, Jack. Thanks to the Directors Roundtable and to the University of Minnesota for having us here today. I really have enjoyed getting to know David Wippman, who is the Dean here, and getting to know the law school. It's the second-best law school in the country with maroon and gold. Thanks, also, to these great law firms who are up here with me. Along with the 130 lawyers at Medtronic who make me look good every day, the outside law firms that are on the panel and in the audience are the ones who really do all the work. As I'll talk about, that's really a big part of a General Counsel's job. Essentially getting good people to work with him or her, and then sitting back and taking the credit! I really appreciate this recognition, and am honored to be with you all here today.

What I was asked to talk about is, "What does a General Counsel really do?" What's the role of a General Counsel in a big multinational corporation like Medtronic?

As I look around the audience, I feel a bit silly talking about this question, because the audience seems to be composed either of people who work for me and already know the answer, or people who are in law firms and already know it. But in truth, the role of a General Counsel has really changed a lot in the last twenty-five years or so. You think back to what a General Counsel did twenty-five years ago, and it really was principally to supervise outside counsel. As a result of Ben Heineman's pathbreaking work as General Counsel at GE, the job really has changed quite a bit. So I'm going to talk about what a General Counsel does today.

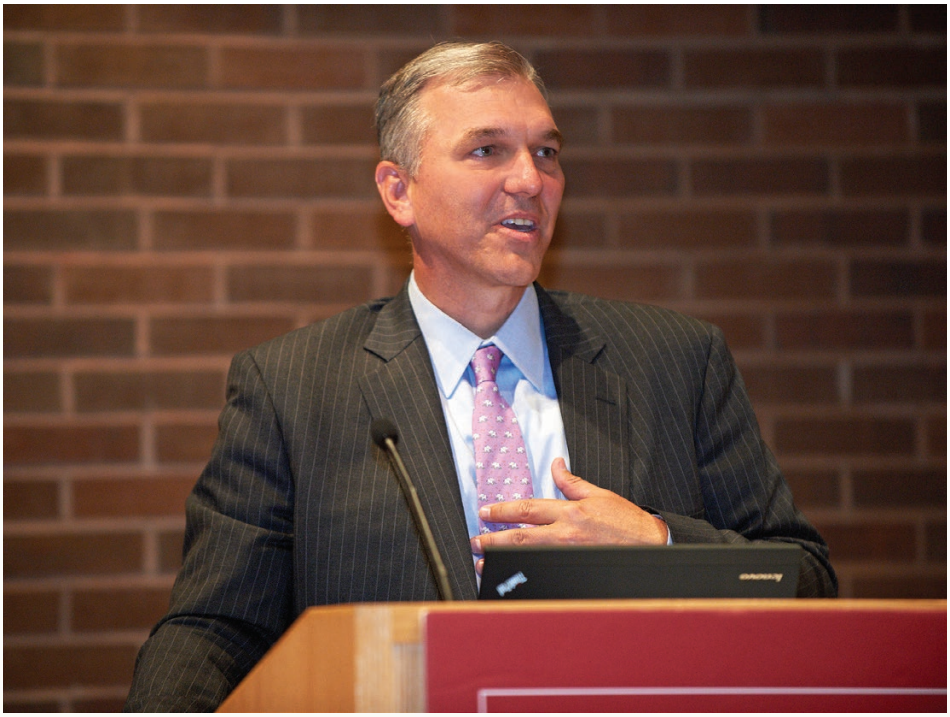
I've been a General Counsel now for ten years, as you heard, and I have been able to watch the latter part of this evolution.

So what does a General Counsel really do? I think popular culture offers some lessons to us here. You could go to *Michael Clayton*, and what the General Counsel did in that movie, when they had a really difficult product liability case, was arrange for the murder of some of the adverse witnesses. Or you could go to *No Way Out*, where the General Counsel used his position to cover up an affair by the Secretary of Defense. He then lured an IT expert to a gym and personally killed the expert who was about to uncover the affair. Then he actually threatened the Kevin Costner character with a gun before tragically turning the gun on himself. I do want to make clear that this sort of thing *rarely* happens.

Let me begin by giving you a little bit of background on Medtronic. A lot of you know Medtronic, so I won't spend too much time on that. I'll then talk about the job description for a big company General Counsel these days. Finally, the panel will then discuss the different topics in their areas of expertise.

So let's first look at Medtronic. You can see some of our products here. Medtronic is really a wonderful company to work for. The University of Minnesota actually had a role in its founding, because there was a snow storm on Halloween, 1957, and it shut down power throughout the region. Unfortunately, it caused the power to go out at the University of Minnesota hospital and, as a result, a child who was attached to a pacemaker that was plugged into the wall died. So the head of Cardiology at the hospital went to Earl Bakken, our founder, and said, "Could you invent a pacemaker that would run on a battery?" Our founder was a tinkerer; he went back to his garage and invented the first battery-powered pacemaker.

We're now the biggest stand-alone medical device company, with about 45,000 employees and $17 billion in revenues this year. It's a very profitable company, which, as I'll talk about, is a great thing for us, but also a challenge.



We have eight business units. I'm not going to list them all, but we make things like pacemakers, spinal devices, and insulin pumps for people with diabetes; we have a surgical technology business that makes everything from big diagnostic devices to shunts and other things used in surgery. We make stents and stent grafts. We make these science-fiction-like devices that stimulate the brain and eliminate tremors caused by Parkinson's. We make heart valves, including the one you see there, which is an absolutely fantastic device that is approved in Europe — not yet here. With this device, instead of having open heart surgery, the valves are put in with a catheter through the femoral artery, and you're out of the hospital in a day or two. So just think about what that will do for costs.

Medtronic has been changing quite a bit in the last five years, even, in the time I've been here. I'm not going to go through all these issues on the list, but in the old days, what we did, essentially, was to sell to doctors. Doctors would be the decision makers on what products to buy, even though they usually weren't the ones who were paying for the devices. Now, we are switching from going after doctors, focusing on what the product features are, to worrying about costs and generating evidence that our therapies work. We used to have to prove things to the FDA. Now we also have to prove things to the Department of Health & Human Services, payer insurance companies, and even to non-health-care agencies like the Department of Justice. We never had to deal with these other actors before. Our litigation portfolio has changed quite a bit too. It used to be just big IP litigation and employment litigation, and now we have big class actions. We now have all these government investigations. I saw a chart when I got to Medtronic that the amount of money we spent on outside investigations between 2006 and 2010 had gone up sixty-fold; which is an incredible rate of increase.

So that's a little bit of background on Medtronic. Now let's talk about the job description for a General Counsel. I would say there are really four roles that principally make up the job. The first is, for a place like Medtronic, where we've got 130 lawyers, 300 people in the Legal Department, being the CEO or the president of a big law firm or a big function, and that is not the same as practicing law, necessarily. The second thing is I have to spend a lot of time with our Board of Directors and our CEO and other senior management, giving them advice on legal and other issues. Sometimes, rarely, I get to actually pretend to be a lawyer. I'll also talk a little bit about whether a General Counsel is supposed to be the conscience of the company, because that has been a controversial topic over the last year or so.

First is the role as CEO of the legal department. When I said that the award really belongs to our 130 lawyers and our outside lawyers, it wasn't false modesty, because what a General Counsel does is manage this really big, complex organization that is a law department, and no General Counsel can do even a small fraction of the work him- or herself these days. So what do you do? You basically set strategic objectives; you set objectives for your individual direct reports; you get them the tools, IT and budgetary authority that they need to do their job; and then you oversee the performance. So, there is the role of being a manager of a big — in my case, 300-person — function that is in five or six locations in the U.S. and probably twenty locations outside the U.S.

So, just to give you a little background on the size of our organization, we have a Legal Department; we have the Compliance function outside the U.S.; and then we have Government Affairs, which is now a global function for us; and then we have things like Risk Management, which oversees our insurance programs, business continuity management, environmental health, and others. We have about 130 lawyers in eight U.S. locations and 20 outside the U.S. We are a hybrid, very complex, matrixed organization. So, we have lawyers who are centralized, who do litigation, M&A, employment law, regulatory advice, that type of thing. We have business unit lawyers who are co-located with their businesses. They do general business law for the specific business

units, and IP. We have geographic lawyers: one in the Czech Republic, one in Singapore, and three lawyers in Japan. So you have really three dimensions to our organization.

Like any other head of a big function or an organization, I set strategies and objectives, and then get good people to help me with it. We have our mission, and then we have our three strategies. The first and foremost is to attract and retain good talent to work for us. That involves everything from paying competitively to dealing with any employee issues that an organization has — somebody's unhappy or they want more responsibility or they don't like their boss — I spend a lot of my time on that type of thing.

The second is, in my view, to get the organization right in terms of focusing on the things our business units want us to focus on, and focus on the risks that are actually important for a company like us, and not take action that is high-risk.

The third thing that I've tried to do is to go around the country, see what's working in various legal departments, and take the best ideas on outside counsel management and other issues, and put them in place. We actually had a project called "Project Superior" that we started when I got here, and it was basically to put in place a lot of these best practices.

So I'll talk a little bit about each one of these.

As I said, really, for talent, we've got to pay our people. We want them to be appreciated. Lawyers tend to get a bad rap and we're thought of as the cops. I've always said that I never get invited to participate in NCAA brackets, because people think I'm going to blow the whistle on them! It's very important that I be the voice in the company to ensure that our people are respected and appreciated.

It goes without saying that if you're a legal organization, you are mainly a bunch of brains, and so you've got to treat every opening you have as an absolutely precious opportunity, and make sure you get it right when you fill it.

> "When I said that the award really belongs to our 130 lawyers and our outside lawyers, it wasn't false modesty, because what a General Counsel does is manage this really big, complex organization that is a law department, and no General Counsel can do even a small fraction of the work him- or herself these days." — *Cameron Findlay*

The second objective is to get our organization right. We spend a lot of time figuring out what functions we do that we don't do in-house. Our spending on outside counsel on investigations went up sixty-fold — why don't we bring some of that in-house. We need to focus on the big risks and not the little things that our clients might ask us to do, which is hard, since lawyers are trained to be very client-oriented. Sometimes we've got to say, "No, I'm not going to draft that letter for you; draft it yourself and I'll take a look at it."

Then we really have to work very hard to increase our teamwork and communication, and I have a weekly check-in with my direct reports. We do a quarterly off-site with direct reports. Annually, we either do a big, global meeting of all the top lawyers, or maybe just the U.S. lawyers.

We've tried to steal ideas from other legal departments. For us, I think that the biggest rock for us to break is dealing with outside counsel. That's where we spend all of our money. We haven't always spent it wisely. I don't mean "we" just at Medtronic, but "we in-house lawyers." There are a number of things we've been doing. We have been trying to cut down on the number of law firms we use. We've been trying to put in place a lot of alternative fee arrangements, because the hourly billing paradigm is not something that in-house lawyers consider to be the best way to compensate and incentivize outside lawyers. Sometimes you've got to do it, but we would rather have the certainty of alternative fee arrangements — fixed fees or something like that — or we also like to align the incentives with our incentives. I could give a whole speech on that. We've gotten our outside work to about 25% on alternative fee arrangements, not hourly billing.

We like to disaggregate the legal work for law firms. In the old days, you'd hand over a matter to a major law firm and you'd say, "just handle it." They would do everything. Their associates would review the documents; they would write the briefs; they'd check in with you for big decisions. But now we've basically said, "We don't mind paying six hundred bucks an hour for your top person to provide the judgment and advice that we need, but we don't want associates being paid $300 an hour to review documents." We can do that with contract lawyers, or perhaps even with Indian lawyers, which we've experimented with.

So we've got our outside spending down quite a bit in the last few years. We've tried to implement technology that helps us to do these other things. An eBilling system; all of our bills come in now electronically. It's not that they're coming in by email, but they come in with all the robust data in them, and we can slice and dice data and do reports by firm or by matter, or we can even do things like who uses more partners and who uses more associates. Then when we do our annual evaluations with law firms, we'll sit down and say, "We noticed that you are using partners considerably more than our other firms. Why do you think that is?" It

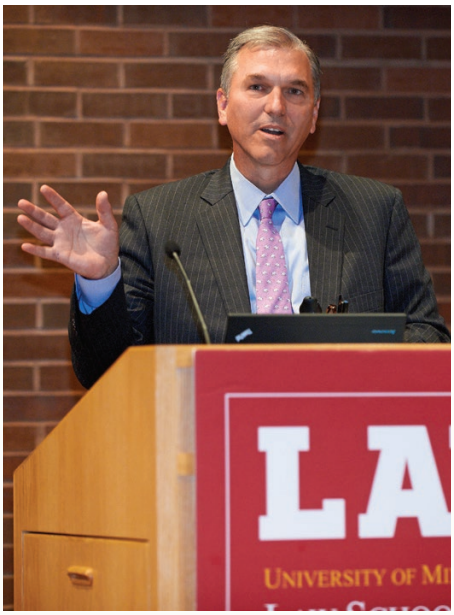
doesn't mean it's bad or good — sometimes it might be good — but it gives us some information to help figure things out.

We've tried to share best practices and information across the organization.

So, a year ago, we were delighted to be recognized by *Corporate Counsel* magazine. It was a really nice honor for us.

The second role is really to act as a consigliore to the CEO, to our Board, and management. Here, I would say, there are two pieces to it. The first is the formal piece. The formal piece is that the General Counsel is typically the secretary to the corporation, so I'm the principal point of contact for our Board of Directors, other than our CEO, who sits on the Board of Directors. I help put together the agenda; I attend meetings; I'm always asked questions at Board meetings. But the other part of this consigliore role is that General Counsels are viewed as not having agendas, more than perhaps business unit heads, and so every year, I'm encouraged by my CEO in my performance review, "We really want to hear from you on business issues and personnel issues and other issues like that." It's a part of the job that's really fun. Also, the people who sit on boards are enormously impressive. We have a fantastic board at Medtronic; I've learned a lot from just watching them in action. But I get to do that because a General Counsel is viewed as being a bit of a consigliore for the board.

I don't want to spend too much time on the issues that I counsel on, but the things that boards are talking about these days — they are obviously very concerned about government investigations. They look to the General Counsel to guide them through government investigations. We have an FCPA investigation. We always have a stable of healthcare law investigations or quality issues from the FDA or False Claims Act, off-label promotion, which is something the government's been very focused on.



We always have product safety issues, because our devices go in people's bodies. It's a huge responsibility we have, and so we've got to get quality and safety right. There are corporate governance issues, like majority voting for directors, or whether you should split the CEO position from the Chairman position. Executive comp is a very big issue these days, now that everybody gets "say on pay," and there are these outfits like ISS that opine on boards, on companies' compensation. Another issue is the board's role in risk management, and what is a company's role in terms of making political contributions. We've had shareholder proposals on many of these things in the last couple of years.

At times, I actually do get to be a lawyer.

As I mentioned before, prosecutors and legislators really have healthcare in their crosshairs. We've had a number of criminal and civil healthcare investigations by the federal government and by state AGs since I've been there. We've had some congressional investigations of our relationships with physicians and the safety of our products and we've had an antitrust investigation in a non-U.S. country.

From competitors, we are always getting IP lawsuits, and we have very strong help from our outside counsel on that.

We have healthcare regulators who are always looking at us. That's a picture of the head of the FDA, Peggy Hamburg. We *always* have quality as our number one job, and it's something that's very hard; the standards are very high. We have plaintiffs' lawyers out there, as well, and they have brought shareholder class actions, shareholder derivative suits, and ERISA class actions. We have a lot of product liability suits, and you're going to hear about that, because our products are in people who are often very ill, and sometimes someone has an adverse event that was not the result of our product; sometimes it is the result of our product. We have the typical employment and discrimination actions that a company has.

What is my role in these matters? Well, I don't try cases; I don't write briefs. Every once in a while, because I was an appellate lawyer at times, if I get a brief, I can't help myself and I start editing it, but that's not really what I'm supposed to be doing.

I don't write very many contracts; I sometimes will review them. I'm not a subject matter expert on healthcare law. I'm not an employment lawyer. I'm not an expert in any of these fields, and as you think about the role of a General Counsel these days, the reason you can see somebody like me come from Aon, which is a financial services company, to a place like Medtronic, is that there are skills in being a General Counsel that don't have anything to do with subject matter expertise.

So the last topic, which I thought I'd just pose as a question, is something that's become controversial in the last year or so, and that is the question "Is the General Counsel the conscience of a company? Does the General Counsel have a special role in ensuring that a company is ethical and follows the law and does the right thing?" Ben Heineman, whom I mentioned

before, was the General Counsel of GE, retired and is now associated with Harvard Law School. He wrote an article about the General Counsel having special responsibilities to be the conscience of the company. Then the General Counsel of IBM — a guy named Bob Weber — wrote an article saying "I fundamentally disagree. I'm not the conscience of the company; I'm an advocate for the company. I don't have any special training to be more ethical than others. And I reject the idea that I'm supposed to be the conscience."

I was with our panelists and I said I was going to raise this issue, and they said, "Well, what do you think?" I guess it's a wimpy way to put it, but I think there is something to be said for both sides. What I'd say is that I am not *uniquely* the conscience of the company; all of our senior businesspeople and all of the in-house lawyers and all the employees, really, have to act ethically and morally, and think about ethical issues.

The special role may be that we lawyers have, as part of our job, to think about ethical/legal issues all the time, so we may have a special role in being the issue spotter; we're not the judge, but we have to be somebody who says, "I think there might be a conflict of interest here," or, "I think that there may be a legal issue." I come out in the middle; I think we definitely have a special obligation of independence and objectivity, but we're not *the* conscience of the company.

That's all I had to say. Again, I really appreciate, Jack, being invited to do this. It was fun, as I put this together, to consider what a General Counsel does, and I'll be interested to hear what all of our panelists have to say about the issues I put up there. Thanks.

JACK FRIEDMAN: I'm going to ask Cam some questions before we move on to our next speaker.

First of all, a quick comment on the role of counsel. We once had an event with the General Counsel of Microsoft, and he told this story, "Try to imagine what it is like to be the General Counsel for Bill Gates, with how Bill's mind works." He said, "We were at Davos, and Bill Gates turns to me and says, 'You know footnote 67 of this recent Supreme Court case'" — it might have been some IP case — "he said, 'I really agree with it.'" The General Counsel is sitting there, thinking, "Footnote 67? What do I remember about footnote 67?" So, sometimes your bosses can be quite challenging in terms of how their minds are working.

> "Like any other head of a big function or an organization, I set strategies and objectives, and then get good people to help me with it. We have our mission, and then we have our three strategies. The first and foremost is to attract and retain good talent to work for us." — *Cameron Findlay*

Here's a question. You may have noticed on the news that Jim Comey was nominated to be the next head of the FBI — he was one of our General Counsel honorees when he was the General Counsel of Lockheed. He made a point which I'd like your comment on, because I think it was memorable. He said that small children have their antennae out, looking at how the parents actually conduct themselves, not just what they say. Are they honorable and how do they treat people, not just what they *tell* the children they should do. Children make ethical judgments on the model of what parents actually do. He said that being a boss is the same way. People who work for you as General Counsel, also have their antennae out, and they watch carefully to see what the boss *really* does — about treating people, making ethical decisions, and other issues.

CAMERON FINDLAY: Well, you're *not* going to get me to say, when there's twenty or twenty-five Medtronic lawyers in this audience, that they're really like my children!

JACK FRIEDMAN: The other thing I wanted to mention was that I saw you had clerked for Justice Scalia, and then you went to Oxford. Also, you were the Deputy Secretary of the Department of Labor at one point.

CAMERON FINDLAY: It's funny; I hadn't really thought about it until you asked me, but when I think back on what I did before I was a General Counsel, I was a lawyer in a big law firm. I love practicing law. I was at Sidley, what was then called Sidley & Austin, now Sidley Austin, and I loved having partners. I loved the intellectual aspects of the law; but what really taught me more about being a General Counsel, ironically, which is going back to what I talked about, was when I was Deputy Secretary, and I was a manager. I was in charge of the budget for our department, so that we formulated a budget with lots of help. Then we'd go to the Office of Management & Budget to present it to them, and we would negotiate back and forth. We also had something that started under the Clinton administration called the President's Management Counsel, and that really introduced management tools to the way governments run. So we had these red, green, and yellow charts for various projects that the government was working on. At that point, one of the big issues was to make government more electronically accessible. So a lot of these "something.govs" that exist now were being put in place while I was there. Because this was early 2000 — it's when the Internet had just started.

I'm not as good at project management as some of my colleagues are, but you learn how project management works, how you evaluate the problem, and how you set objectives; and you evaluate progress towards them. For those who would aspire to do this job, whether you can do it formally or

informally, learning management skills is really important. I wish I had time — I'd like to take a class in project management, or a mini-MBA. Law school and being in a law firm do not train you to do a lot of things that we do.

JACK FRIEDMAN: One more question and then we'll move on. In the Medtronic annual report it says, "Our mission is to contribute to human welfare by application of biomedical engineering and the research, design, manufacture and sale of instruments or appliances that alleviate pain, restore health and extend life." That is an awesome responsibility. Do you have any comments about it?

CAMERON FINDLAY: Those of us who work at Medtronic know that it's almost a uniquely mission-driven company. I'm told that our founder, Earl Bakken, when the company was bankrupt and he had to get a loan, and one of the banks here in town asked him to tell the bank just what the company does. He said, "We alleviate pain, restore health and extend life." It's a great mission to have, and we have something called a "mission medallion" ceremony for new employees. After someone has worked a certain amount of time at Medtronic, you go to a ceremony where you learn the history of the company and you get a little copper medallion that has our rising man symbol and also that mission around the edges, "alleviate pain, restore health and extend life."

One of the great things about working here is that you may meet somebody at a cocktail party, airport or social function, and say you work at Medtronic. They'll say, "Oh, I have a pacemaker of yours," or "my daughter has one of your insulin pumps," or "my dad has a stent or a heart valve" or another Medtronic product. It's really personal in a way that I don't think I have ever worked or will ever work again in a place like this, in that sense.

JACK FRIEDMAN: Thank you. Jodi Scott is our next speaker.

JODI SCOTT: I'm Jodi Scott with Hogan Lovells out in Denver, and I had the honor of working for Cam when I was in-house. Cam manages the large department of people, and I am the person who, when career counseling in law school came and told students that they should specialize, I was actually paying attention. As an FDA compliance lawyer I work on compliance and enforcement matters related to the FDA, but I also only work on medical devices, and mostly on the compliance side. I do very little pre-market work. I tend to focus on FDA inspections, advertising and promotion (I was heartened to know that Cam is very familiar with the indications!) — things like off-label promotion issues, warning letters, and consent decrees. Usually, these are things that people don't love to work on.

When I was in-house, I was the lawyer who would show up when an inspection didn't go fantastically, and I would get to say, "Hi! I'm from Corporate. I'm here to help." I don't get to say that any more, but usually when I show up in facilities, folks know that they've got a lot of work ahead of them.

I thought I would talk a little bit about the FDA compliance piece from a company standpoint, and also just from a business standpoint, based on what I see. I work a lot with large companies, usually after their inspection has not gone well. I think of it as my job to help them figure out what happened. Then work through with them how we are going to fix it, so hopefully we don't move to the next step, which is a step which involves a whole lot more lawyers; as well as warning letters, consent decrees, seizures, injunctions, and government investigations. I feel that if I do my job reasonably well and we stop the progression at a 483 inspection report, or possibly a warning letter, that I've actually done a good job.

I tend to work with a lot of really wonderful people in companies. Engineers and quality folks who truly are trying to get it right; they *really* want to do the right thing, but sometimes they need help getting there. The FDA will say, when they issue a company an unfortunate inspection notice, that they're here to help. But they don't necessarily have the benefit of seeing *all* of the hard work that goes into developing the products, manufacturing the products, and continuing to sustain them. They certainly don't see all the really hard, good work that goes into addressing inspection findings.

Companies get, and the folks that work for them get, that quality is very important; compliance is very important; it's also good for business; and they'd really like to do it right the first time. Once they're dealing with FDA on an enforcement matter, they truly want to get it corrected and do all the right things. But it's a lot of work. When these notices say that you've got fifteen business days to respond — and for a lot of these organizations, that's after you've been in three weeks of FDA inspections around the clock — they're already exhausted. At that point you have fifteen business days to respond, and oftentimes when you've completed a response, depending on how many things you have to respond to, it's linear inches of paper that you end up submitting to document. I consider that as the first opportunity you have to advocate for the company, and explain why what you've done is meeting the expectations of FDA; or, alternatively, where you recognize that there is opportunity for you to improve. It's your first opportunity to convince the government that you hear them, and you're going to fix it.

Hopefully that's where it ends; sometimes not. Once you submit your responses, the hard work starts. I see that as the time to plan what you're going to do to fix your situation. Once that goes in, there's just a ton of work that goes into actually fixing the issues that have been identified.

I see companies do wonderful work and they do it with an eye towards what it means to their patients and their customers. One of the best things about this industry is that people are really committed to the patients and the quality, and what it does to improve people's lives. That's one of the best things about being in the medical device industry and working with all these companies. I enjoy it, and they get that this is good for business; they get that it is good for patients. Frankly, they understand what's at stake, once you're in the mix of doing an enforcement, corrective action and plan that they never want to be doing it ever again!

JACK FRIEDMAN: Let's say you are talking to a new director of a medical device company. He or she is a smart business person, but doesn't really know some of the things about government regulations. You are asked the following questions: What is an FDA inspection? What do they inspect? Do they go out to a manufacturing plant?

Cam had mentioned that you have to get feedback. You want them to know that you take the inspection seriously about how the product is manufactured and actually works. So, obviously they look in the laboratories and manufacturing plant. What are the main components of an inspection?

JODI SCOTT: In an FDA inspection, the FDA usually sends out their investigators; they come to your facility — sometimes with prior notice, sometimes not.

JACK FRIEDMAN: Do they physically inspect the manufacturing facility?

JODI SCOTT: They will come to either your manufacturing facility, or where you designed your product, or where you're managing the post-market aspects of the product. They will actually come in and inspect. It's usually two components. If you've got a manufacturing line running, they will actually go down and see the line running and your operators doing whatever process you do there — assembling devices, building PCBA boards, whatever happens there. So they will actually observe the line, because it helps put in context all of your records. Then they sit and review your documents. They spend hours and hours reviewing files that you have gathered.

The thing about quality system FDA requirements is that the whole system is designed to record everything, and so there's certainly plenty for them to review, and there are certain places that they like to look, because those records are very rich with opportunities to find situations where you have, perhaps, not done as well as you could have, from a compliance standpoint.

So, it's largely a document review, but they also visually look at your inspection line.

JACK FRIEDMAN: They go in and talk to the workers?

JODI SCOTT: Yes, they will, and they'll talk to the operators on the line to see whether or not they know what they're doing, and whether they follow the procedure, and is the step that they're doing in compliance with that procedure. So they will actually talk to

operators and see what they can find. From an FDA standpoint, anything in your procedure, they consider it to be law, and can hold you to your requirements.

Now, in terms of what's happening to your product in the field, there's a lot of different ways that companies gather data on product performance. Many of them are mandated by FDA. Companies take that data and analyze it in a lot of different ways, because frankly, if your product is not performing the way you want it to in the field, as a company, don't you want to be the first one to know that? It gives the companies wonderful opportunities to make improvements, minimize risks to patients, deal with design issues that they know they can deal with, because there are these wonderful engineers who know how to address iteratively the different issues that come up.

So there is complaint data, adverse event data, and most companies are mining whatever publicly available data is out there that will give you a signal about something that may be occurring in your product, but also the issues that are identified by FDA.

JACK FRIEDMAN: Thank you very much. Our next speaker is Martin Lueck, the Chairman of the Executive Board of Robins, Kaplan, Miller & Ciresi L.L.P.

MARTIN LUECK: Just by way of introduction, I've been trying lawsuits for twenty-nine years, and much like Cam explained in his role moving from Aon to Medtronic, I bring a general skill set of being a trial lawyer, and in the context of the present-day trial system, I apply that to intellectual property cases. I've been trying patent cases for about twenty years; I was perfectly prepared for this by my undergraduate education, where I received a degree in playing the trumpet. [Audience laughter.]

What I'm going to talk about today is just three things that have changed a great deal in the landscape of the whole patent game, and how it affects the competitive

landscape, which is really what drives what people are interested in in Cam's world. I'm struck by the pace of change today, and yet what I'm going to do is relate it to principles that Sun Tzu, a general in China 2,500 years ago, laid out. There are some general principles that we can use to help navigate through these changes.

I look at things like Machiavelli and Sun Tzu, as first principles in conflict management, and in the intellectual property world, where you have head-to-head competition, particularly where companies are in two-competitor, or three-competitor markets. What that intellectual property is, and how strong it is, how it is utilized, often is determinative of who is the winner and who is the loser in the marketplace.

So I'll just start with the basic principle of what Sun Tzu was trying to do when he laid down these principles; I'm not going to read through it, but it basically gives you the idea that you have to have a strong conflict management program if you are going to succeed in competition with anyone.

There are three areas that I'll talk about before we get to the slide, where there have been a lot of changes in patent law in the last couple of years. One is in the way we establish priority in the United States. The second is where we choose to have the disputes resolved; the forum. And the third is really what is going to be the outcome in terms of winning and losing the balance of power, if you will, after a case of patent litigation has been resolved.

So going back to the first principles, Sun Tzu said, "The general who wins a battle makes many calculations in his temple before the battle is fought." This is an apt principle for looking at the recent changes through the America Invents Act, particularly relating to who is going to have priority in patent fights. Another way of thinking about it is any general who would go into battle would first have to raise an army. So it is in the competitive landscape today; you need to have intellectual property that protects your innovation and gives you the ability to use the innovation that you've invested in; you've invested scarce research and development dollars into these products; you want to make sure that you get the full benefit of that when it's rolled out into the marketplace.

So, just quickly, to run through what is the big change: in the past, the United States was really the only country which had a first to invent system. So we focused on the light bulb; the idea; the conception. If inventor "A" had that light bulb, we'll just track through how it worked; inventor "A" has the idea, then inventor "B." Inventor "A" lets a beaker he or she has reduced it to practice in their laboratory or the kitchen sink, as the case may be, and inventor "B" files before inventor "A"; the winner is inventor "A," because inventor "A" was the first to conceive.

Today, under the AIA, you have a different result. It is going to be the first to file, regardless of when someone conceived. So, there are a number of implications that come from this change, and the first overall implication is, if you are involved in the management of collecting the intellectual property of your organization, you need to be aware of the fact that you have to make some significant

changes to your in-house business process to make sure that you are capturing everything in a way that is going to be effective under the modern patent laws.

Under the "First to Invent" system, the policy is not to sit on invention. In the past, there might be good reasons to do that — develop the very best way of rolling the product out; a number of different considerations. Today, you can be, as you saw from my prior slides, penalized for doing so.

In the past, often broad applications were filed, and the inventions were divided up in a series of continuations and the like by the patent lawyers once it was filed. Today, much better, from a strategic standpoint, is to file discrete applications, and lots of them.

Finally, and this is an arcane point, but the law may have changed — we're not really certain — about what the effect of an early disclosure is. In the past, you had a year to make a public disclosure of your invention. Today, it seems to me there can be an argument that it's prior art as soon as it is disclosed; best to file for the patent before disclosing.

Sun Tzu, "In war, commanders attempt to shape the battlefield to their advantage by electing to fight a terrain of their own choosing." This principle was aptly applied by Julius Caesar when he managed to get the best ground when he was chasing Pompey to Alexandria. I think it's a better example, but we're not here for a history lesson, so I'll just apply this one.

What's changed? Well, if you look in the *Wall Street Journal* or the *New York Times* today, Samsung got an order excluding the Apple iPhone 4 and the 3G iPads from importation into the United States. It wasn't done in an Article 3 district court; it was done in the International Trade Commission.

Today, more than ever before, we have to choose where the fight is going to take place over the competitive landscape. So, different things have happened. For about ten years, the Eastern District of Texas was the forum of choice for virtually all patent litigation. Like many things, the pendulum swung; the Federal Circuit created some very restrictive rules on venue. You also had a decision in the *eBay* case, *eBay v. Merck*, which restricted the ability of Article 3 district courts to grant injunctions. Finally, as part of the AIA, you've had a lot of change in what you can do in the Patent Office. So today, there are a number of choices that one can make in terms of selecting a forum in which to fight, and they all have different features. I won't spend a whole lot of time on it, but as you can see, in the International Trade Commission, if you read the article about the Apple and Samsung fight, very fast, very effective, no money damages; only an injunction can result. If you're lined up and you're ready to go, you could bar importation if you're successful in proving infringement in defending the patent's validity.

So what's the back story on the Apple iPhone? It's a U.S. product, but the guts of the phone are brought in from China, right? So that's where the exclusion order will hit.

Interesting contour: the President of the United States has to sign off on exclusion orders, so I think there will be some interesting things that play out in the press as we watch this unfold.

JACK FRIEDMAN: One of the things I am always amazed at is the combined hourly billing rates of the Speakers here. All of these thousands of dollars per hour are available for free at this event.

MARTIN LUECK: Mine used to be $1,000 an hour until Cam took over, and now it's 75 bucks! So that's why I'm talking fast!

In the U.S. Patent Office, a very significant thing has happened, and that is, the ability to challenge a patent in what's called an IPR proceeding before there is any actual litigation. I don't have the statistics at my fingertips, but like reexamination, part of

the idea is to provide a speedy, inexpensive forum to get to an answer to create some certainty for business quickly. While there have been an enormous number of IPRs filed since this came online last September, the Patent Office is already very much behind. Let me just give you a couple of key features. You can basically go in and challenge the validity of a newly issued patent, and the Patent Office will conduct a trial on the validity and issue a decision. If it goes up to the Patent Trial & Appeal Board and you win — you win on validity; that is to say, you successfully challenged the claims of the patent — that's the end. That patent can no longer be assertive. If you lose, you are then in private litigation with the company whose patent you challenged, you may not raise those prior art defenses, or any that are related to it.

So, it is a big strategic decision to make. Many people feel that their chances are better in the Patent Office than they are with a judge and a jury; let's simply say that the balance, like Sun Tzu tells us, lies in analyzing each situation separately and making the best judgment that you can, if you are in a position to avail yourself of a Patent Office forum.

Finally, there are patent damages. So, Sun Tzu's principle, "In war, then, let your great object be victory, not lengthy campaigns." So, what does that mean? Well, if you are in a competitive situation, you need to look at what the end result is likely to be. You're not going to fight over nothing, not in this day and age of scrutiny that comes from the top down of every corporate legal department in the United States on the budget side. Like I said, with the pendulum swinging in other areas of patent law, it's certainly swung when it comes to patent damages. That really comes from a couple of judges around the country, but principally, the motivation has been insisting that damage awards are tied in some rational fashion to what the footprint of the invention is in the marketplace. So it puts a premium, if you will, on the way the trial lawyers frame the issues for resolution by the judge and jury. Some judges – I have a case right now in front of Judge Posner; he just tossed the other side's damage expert. He did this in the *Motorola* case, he did it in our case. Just another example of how much scrutiny there is on making certain that these damage models that are put forth to approximate the loss are tied in some realistic way to what the invention brings the marketplace.

I put three cases up here that have been reversed in the last seven years, big numbers. All reversed on the damages, all reversed on the notion that the damage theories that were advanced did not match what the invention truly brought to the expansion of the arts and the product in the marketplace.

So, I put two little points at the bottom: You need more sophisticated economic analysis, and you need less harmful evidence. The less harmful evidence, for those of you in the corporate world, really comes down to this: One of the things that we have seen over the last three years is wherever our statements about the value of particular technology, regardless of the context, the owner of that technology has been stuck with those statements in a very real and powerful way. The folks inside – you know, even in your FDA documents, sometimes – have to be aware that everything that is said about the value of a particular product *is* going to be used against the company in an enforcement action.

> "We need to focus on the big risks and not the little things that our clients might ask us to do, which is hard, since lawyers are trained to be very client-oriented. Sometimes we've got to say, 'No, I'm not going to draft that letter for you; draft it yourself and I'll take a look at it.'"
>
> – *Cameron Findlay*

At the bottom, I put the real principle: "The value of IP changes over time." It's dependent upon what the owner of the IP is doing; what use they are making of it in the marketplace; and it's dependent upon what the competitors are doing, and when their products are introduced; and you can see, in fields that are similar to what we're talking about here today, where you have FDA regulation, you can have many different entrance points into markets, depending on where in the world the products are getting approval. Under the United States patent laws, sometimes you can have extra-territorial impacts from the patent. You can have situations where products are made in the United States and sold elsewhere; you can have situations like the Apple/Samsung situation, where even though we associate it as a "U.S. product," some of it is coming from overseas and is subject to importation restrictions and the like.

So, the landscape has changed a great deal. I made all the main points, and Jack will probably now ask me some questions about things that are too granular for me to answer!

JACK FRIEDMAN: The lead article in today's *Wall Street Journal* is about Samsung's successful attack on part of Apple's patent position on phones. Taiwan is a huge supplier to Apple, not to Samsung and its Android. I am curious about the effect on chip manufacturing for Apple and whether the Taiwan stock market is affected. It's something that management itself better take seriously because it could be hit quite directly.

Ginger Pigott will introduce herself and her topic.

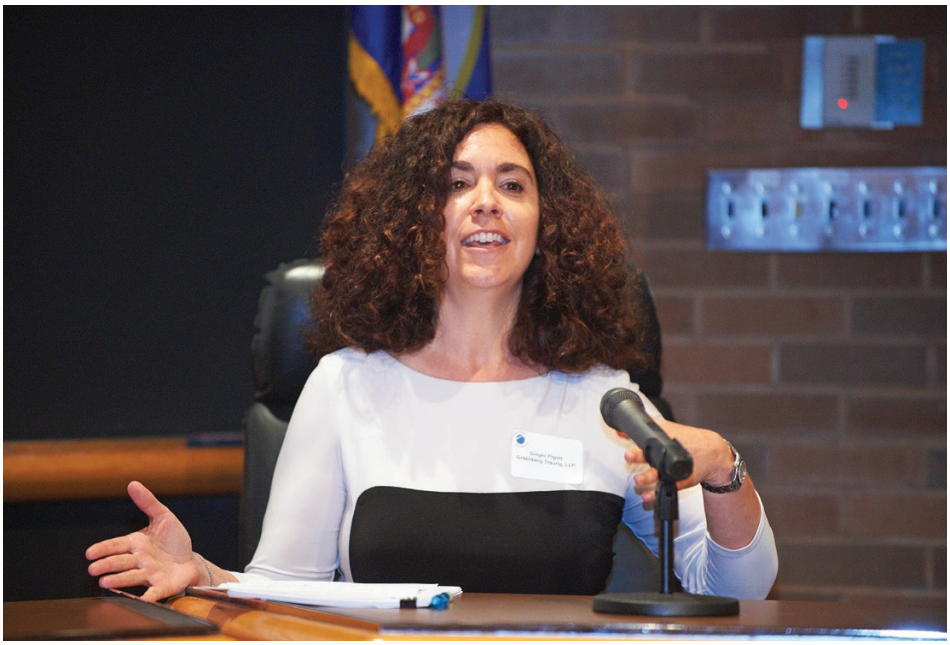
GINGER PIGOTT: Hi. I'm Ginger Pigott from Greenberg Traurig; I am your product liability panelist. One of the things that was interesting about this program was that Jack was bringing together people from a number of different specialties, and my background has been in product liability for over twenty years. Although I have defended a lot of different products, from foods to welding materials, 90% of my career has been spent working with medical device companies, pharmaceutical companies and nutraceutical companies (nutritional supplements). My interest came from a very personal place. I was given the opportunity to defend a company that had made a device implant that had been used in my mother. She had had a long history of different challenges. I found it so interesting to learn about what this company did, and how it handled adverse events. I learned a little bit more about the science and medicine. Product liability does give you the opportunity to become a bit of an expert in a lot of different areas. The reality is, for any company that manufactures a product, they're going to have product liability litigation – particularly a successful company. So, one of the things that an outside counsel perspective can bring is to help to provide insight into where the trends are.

There used to be this hesitation, or a temptation to ignore product liability. It was a reality; it was coming from a place where of course we're going to get these types of claims, but there wasn't necessarily the insight into where are the trends coming from, what are the various legal defenses that can work on our behalf. So, my topic for today is, in essence, to focus on my own specialty, which is in the medical device and pharmaceutical field, as a complement to the rest of the panel. I will talk about some of the various legal defenses that can be used to help to reduce, minimize or mitigate those inevitable product liability claims. I will also look at some of the ways that my colleagues' specialties impact the product liability litigation: the way that those inspections that Jodi was just talking about interplay with the onset of litigation; and the way that patents and patent litigation can impact product liability litigation. Then my colleague, Bob, will talk about tax, which implicates everything!

One of the areas that we often talk about is being proactive in identifying where the product liability claims are coming from, and how things going on in other fields, for example, might impact it.

Today, we provided you with our materials which relate to sales representative liability. This is a new area, where we are seeing what used to be traditional product liability claims. A claim that a product was either defective or malfunctioned in some way, that caused an injury to a patient, used to end up with negligence or a strict liability or maybe a breach of warranty claim. Now what you're seeing is that for certain categories of medical devices — for example, pre-market approved devices — there's preemption. The plaintiff's lawyer is asking himself, "How am I going to get this injured client of mine compensated in another way?" They're looking for novel theories; they're looking for a way around it.

I would like to talk today about preemption. How does preemption impact companies that make devices that don't get express



preemption, because they're not pre-market approved? Are they a pharmaceutical company with a branded product? Or maybe a pharmaceutical company with a generic product that gets a different preemption under *Mensing*?

There are a lot of different tools that as a product liability litigator, you have at the ready. How do those defenses help you, or do they help you when you have a novel claim like the sales representative liability?

Those are basically my areas. I don't have any philosophy to give you, but I am definitely interested in how our topics interrelate. In addition to talking about preemption — Comment k, for example, which most lawyers in here will know what I mean when I say "Comment k." In essence, what are the legal theories that help us defend these highly sophisticated devices that alleviate pain, restore health and extend life? I think I got the order right! I have this acronym, ARE, in my head.

But that's a very important point. It's interesting, because the perception of medical device and pharmaceutical companies is important. Being able to convey to a jury — in what I do, the corporate spirit is important, as well. At the same time, we have to be careful in product liability cases not to overstate certain positions, and so that's an area we can talk about, as well. That's my introduction to my topic, and I'm happy to discuss.

JACK FRIEDMAN: Just two general questions and I assume that juries tend to favor people who say they were injured. What is the present environment when dealing with product liability cases in the healthcare field? What is the difference between a jury trial, and just a judge making a ruling?

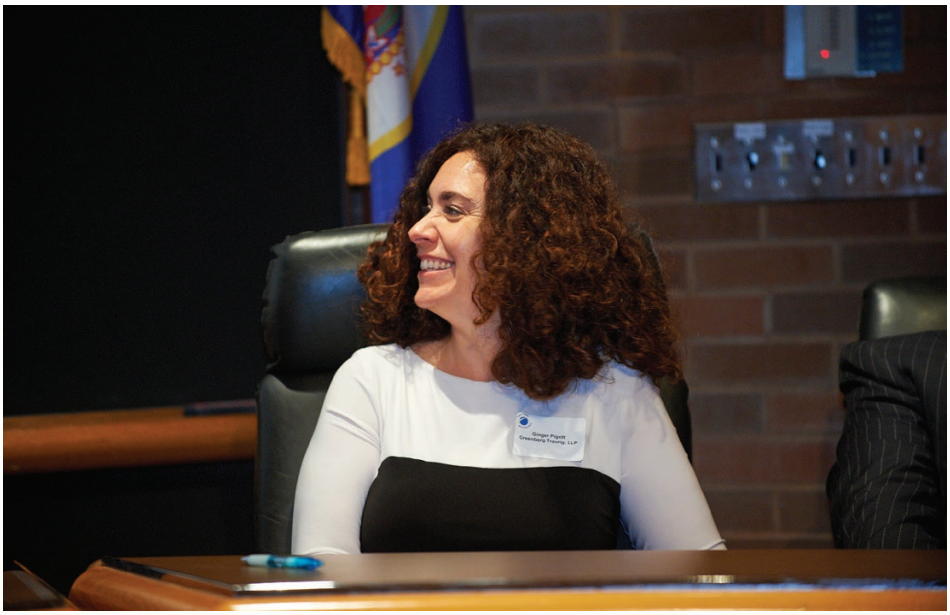
GINGER PIGOTT: The interesting thing with product liability claims is that they're typically filed in what the plaintiff perceives to be the most plaintiff-friendly venue they can find, and the goal for the person filing is to have a jury trial. They want to present their client, who probably has a sympathetic story, and they are hoping that a jury will think, "This person was hurt by a big multi-billion-dollar, multinational corporation." This is a major simplification but often close enough. Thus, one of the keys to a successful career in defending a big company is to try to win the case before

you get to the jury. You are very often able to utilize good legal defenses to explain to the judge why this shouldn't go to the jury in the first instance.

For example, if you have an express preemption defense, this may bar the claims altogether. In the Medical Device Amendments to the Food, Drug & Cosmetic Act, there is an express preemption provision, which basically states that no state shall enforce any law or allow any tort claim where the result would impose an obligation in addition to or different from what the FDA requires. The Supreme Court upheld this in the *Riegel v. Medtronic* case in particular and there are a long line of cases in support of preemption.

In fact, one of the things that I do when I first call and introduce myself to a lawyer who's brought a case against Medtronic, for example, is to invite them to do a search on all of the really good law relating to our express preemption defense, and they will see Medtronic's name throughout the successful wins.

But basically, what you're saying is that state law tort claims are, in essence, requirements that are different from or in addition to what the FDA requires when it approves the device — from its manufacturing, its design, its labeling, its instructions for use, whether or not there are other requirements that the company must comply with before a device is legally marketed in the United States or elsewhere. That covers any allegations. If I have a pacemaker and I make a claim that you should have designed it so that it plays the national anthem at night before I go to sleep, that would be, in essence, a requirement that the FDA did not allow us to do. The jury can decide, "She's right — her pacemaker really should play the national anthem for her before she goes to sleep," then Medtronic would be in a position where it would have to pay damages or do something that the FDA wouldn't have approved or didn't approve in this instance.



You are telling the judge that what the claim is actually saying is that they want to enforce a different design or a different warning or a different method of manufacturing than was otherwise approved.

That's a very simplistic case. Very often, what a plaintiff's lawyer will do, understanding the *Riegel* case and what happened in that instance and in the subsequent years since that decision came down, is to figure out a way to get around preemption. There is a very narrow window of opportunity in the *Riegel* decision, the U.S. Supreme Court left open, for what they call a "parallel claim." There has been a very robust legal analysis across the United States regarding what a parallel claim means, and what kinds of claims the plaintiff can bring that continues to evolve.

JACK FRIEDMAN: Does each individual injury have to stand on its own, versus a class action that says the company made a commercially bad product affecting a group?

GINGER PIGOTT: There is a distinction. In the product liability vein, you get mass torts. For example, if you sell a drug that's used to treat some cardiac illness, and the FDA and the company decide to recall the product. When the company takes it off the market, you can end up with thousands of people who are alleging different cardiac injuries as a result of having taken this drug. Those would be mass torts. They are not class actions because they are individualized claims. They're typically not certified as class actions, because each individual will have had a different prescribing history; they will have a different adverse event; they will have different issues that relate to causation.

Very often you will hear about mass torts and, in fact, I have some statistics on some of the areas that we're seeing currently with mass torts in various drugs and devices across the U.S. Metal-on-metal hip implants, for example, have been a hot trend, and many of the device makers who make those are seeing a continuing uptick in those cases. However, they're not a class action. So it's not, "I bought this sunscreen, and it said that it would protect me all day and be waterproof, and it didn't," and there's a class action.

People who "want my money back" versus "I want to be compensated for my sunburn." Those are different claims. My area is really related to someone alleging a personal injury of some sort.

JACK FRIEDMAN: I assume that public attitudes are reflected in the jury. Some people may go so far as to ask if you guys are trying to make people healthy, why don't you do it almost for free?

CAMERON FINDLAY: Joan Humes is our Head of Litigation, and she and I talk with our internal business colleagues all the time about how there's a disparity between the way we regard ourselves and the way that people who sit on juries regard us. We think that what we are about is to be alleviating pain, restoring health and extending life; we believe that we're a good company; we feel that we are mission-driven; we are trying to help people.

On the other hand, some people who sit on juries may see things differently regarding a company like ours.

They tend to think of companies as being venal and profit-driven, and they think companies will cut corners and lie and do unethical things in order to make money. As Ginger said, a huge tactical objective for every one of these cases is, first of all, we often admit fault ahead of time, or we'll offer to replace a product or compensate people without going to trial. But when we're in a case and we think that the suit's unjustified, our objective, really, is to avoid getting to a jury. So we have defenses like a medieval castle, we have a series of moats and defenses. One is at the motion to dismiss stage, where we have this preemption defense, which basically says a state tort suit can't survive a motion to dismiss. We get a lot of cases knocked out there. Then we get to the summary judgment stage, and we will argue on the facts that there's just no evidence that our product was defective or our product caused the injury. We try to get cases that we feel are unjustified knocked out at that point.

If we get to the jury, the balance of power is very decidedly in favor of the plaintiff, for the reasons you say. You've got someone who's injured, and often with a very sympathetic story. You've got this company that, at best, is very wealthy compared to the plaintiff, and at worst, might be viewed unfairly as a bad actor who will cut corners, lie, cheat and steal to avoid compensating people.

> "We've been trying to put in place a lot of alternative fee arrangements, because the hourly billing paradigm is not something that in-house lawyers consider to be the best way to compensate and incentivize outside lawyers."
>
> *– Cameron Findlay*

GINGER PIGOTT: Sometimes we actually do convince people, before we even have to respond to a complaint, that their claim will lose because of one of these defenses. Plaintiffs' lawyers who have a successful practice are smart, and they don't want to spend the money or the resources, and they have to have a difficult conversation to explain this with their client. One of the things that we have the opportunity to do sometimes is to meet with the person who's had one of our devices, or has used one of the products that one of my clients makes, and to have them understand a little bit better as to why they can still have an adverse outcome or be disappointed and not have the company be legally responsible.

JACK FRIEDMAN: I saw a situation recently, not product liability, where someone filed a class action before reading any documents and just sent a letter saying, "I've already filed a class action" before they even contacted the company. An attorney at a major law firm saw this and said, "Please let us take it on — we won't even charge," because the lawyer who defended these cases said, "I see this as a case against somebody who is ethically so obviously irresponsible that I can sue them for once."

CAMERON FINDLAY: Just one point I would like to add. Something that's interesting about working for a company like ours, it is mission-driven. The difference between the way we lawyers think of our jobs and board members think of theirs, is that there are a lot of discussions with senior management in our company and with our board that are just different from the way we lawyers think. We get a lawsuit, and we are trained to fight the lawsuit. That's what we do; we're trial lawyers or litigators. We want to win. We'll have senior executives at a place like Medtronic and board members that will say, "Is winning the right thing for a company like us?"

JACK FRIEDMAN: Thank you. I wanted to have Bob Cunningham of Baker & McKenzie make his presentation.

ROBERT CUNNINGHAM: Thank you. I'm with Baker & McKenzie in Chicago. I'm a tax lawyer! We haven't talked much about tax and Cam did not mention tax during his formal presentation. To get started, I'm wondering how many people here are lawyers or part of a legal department? [Most hands are raised.] Okay. How many of you are tax lawyers? [One hand is raised.]

Thanks, I am happy that you joined us today!

Tax plays an interesting and important role in the life and operation of a company, whether it is Medtronic or Boston Scientific or any other multinational corporation. I would like to spend a couple minutes giving you a little background regarding tax lawyers and what they do. (My area is international tax and thus my comments will focus on international tax.) First, while we deal with the General Counsel and the legal department, our primary contact is with the Vice President Tax and finance team. We are working with them to make certain that the tax rules of every country in which they

operate are properly applied and then to assist the company in responding to audits and other tax challenges to the company tax positions.

Now, tax is an interesting area, because you are dealing with cost and that cost can be quite significant for a company. For example, since tax has an impact on EPS; it has everyone's attention. As with any cost, careful planning can reduce that cost and make certain that the company pays no more tax than the laws require. It also is a challenging area in that the application of tax rules often is not a matter of black or white, but instead a matter of judgment as to how to apply those "gray" rules to the facts and goals of the company. In addition, this uncertainty can create some real questions within a company in terms of the strategies to adopt. In this regard, tax lawyers help to address these questions and at times evaluate the strategies being considered.

Now, taxes have received a lot of play in the press recently. I am sure most of you saw the articles about Tim Cook, who is the CEO of Apple, testifying before a committee of Congress. That testimony was all tax. Now, he was describing Apple's tax position and defending Apple's actions as correct within the current state of tax law. The reason for the discussion arises out of Apple's global tax planning. For many companies, tax counsel would work with a company with respect to this planning.

Tax counsel works with their clients principally in three, maybe four, areas. One area is helping companies to determine the appropriate legal structure to adopt to achieve their business objectives and to minimize properly the amount of tax that will be owed under that structure. Thus, tax counsel gets involved at the structuring level working with both tax and business people in recommending how to achieve the company's business objective. Tax counsel also will assist with determining what legal entities are appropriate and then with documenting the transaction properly.

Tax counsel gets actively involved with implementing many of the transactions entered into by companies, such as pre- and post-acquisition planning. Those areas are fun, because they require that all legal disciplines work together to achieve the optimum goals. I have been a partner with Baker & McKenzie for many years and with our lawyers, disciplines, and offices worldwide, we are able to involve all of them when you are putting together an international structure.

Tax counsel also gets involved in compliance, including dealing with tax returns and documentation requirements, with changing tax rules and their impact on existing structures and operations, and with audits and other challenges by taxing authorities around the world.

Tax counsel will work and get involved with the General Counsel and the legal department in the areas where a major transaction or strategy may be high on the IRS's radar or where the strategy may have a very significant EPS or other earnings impact. In those types of situations, tax counsel is likely to meet with the CFO and maybe the CEO regarding the tax rules in question. At certain times, tax counsel may meet with an audit committee or Board, because everybody wants to be certain that the company has correctly calibrated the planned strategy. The legal department will typically participate in those discussions.

If a significant tax controversy is on the horizon, tax counsel will work with the tax department, the General Counsel and the legal department. If there is tax litigation, the General Counsel may identify somebody in their group to participate as a member of the tax litigation team.

Tax counsel can provide services for and assistance to multinational corporations in all of these areas. This presentation is just a little picture of where the tax lawyer fits in this legal realm. It's a fun area, and as Ginger said, we touch everything.

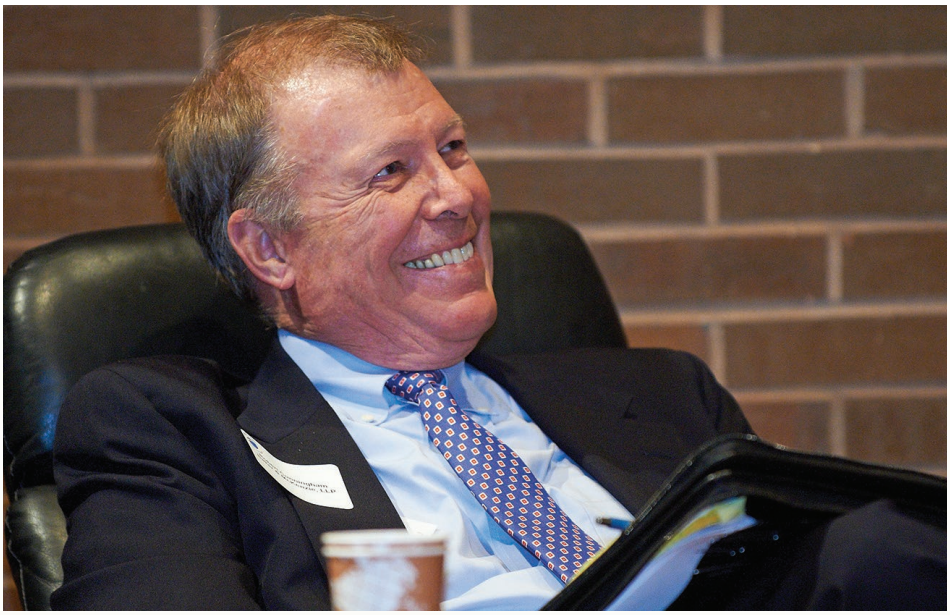
GINGER PIGOTT: Yes!

ROBERT CUNNINGHAM: You all have your own views of tax law, but I can say that on the multinational stage, it is a fascinating area that is receiving a lot of press at the moment, and it is likely to continue to receive a lot of press over the next five to ten years.

JACK FRIEDMAN: What are examples of some of the deals, M&A, investment financings, for example, here or abroad that you or Cam have been involved with?

CAMERON FINDLAY: Maybe I'll take it in two pieces, because first a tax piece and then Bob can speak with much greater precision on this, because I disagree with him that tax is fun. Maybe for tax lawyers, it's fun, but for the rest of us, it's complicated.

On the tax side, we do spend a lot of time working with outside counsel on structuring our corporate structure; that is, where IP is held and where manufacturing occurs and where various functions take place in order to minimize our tax liability. It's something that is made necessary by the terrible corporate tax system we have here in the United



States that, in my view, threatens to drive the great American companies out of the United States over the next decade or two. It's almost as if the tax system was created by a hostile power for that purpose.

Medtronic is an example. We have about $12 billion in cash that is held outside of the U.S., because if we bring it back in, it will essentially be taxed again. We earn it outside the U.S. and we pay tax on it outside the U.S. The U.S. is the only major country in the world that will tax income that was not earned in the U.S. as if it were earned in the U.S. So if we bring the cash back, we have to pay a 35% tax rate on income.

ROBERT CUNNINGHAM: Subject to certain credits.

CAMERON FINDLAY: Yes, subject to certain credits. So, on the tax side, we're always trying to do things which companies do to minimize their tax burden. He mentioned Apple. I don't know how carefully any of you watched this, and it was really fascinating. It's actually one of the few times that a CEO has gone before Congress and really shamed Congress. They thought they were going to bring the CEO of Apple and beat the table with, "You're a traitor to the United States because you don't bring this money back." He did a bit of Jiu-jitsu, and was able to put it back on them that they've created a tax system that causes any rational actor to do that.

So that's the tax side. We were talking, as we were doing our organizational meeting, on the acquisitions and investment side. Four years ago, when I got to the company, most of the deals we were looking at were venture capital companies that had created the best new technology. These companies were often here in Minnesota or California or Massachusetts. We would buy these startups as a way of doing R&D. We were always driving towards getting the next hot new technology. Now, when you look at the investments we are considering in our business development meetings, it's typically a foreign company. Here's a true example, we bought a company in China, for almost $800 million, called Kanghui. That is what is called a value-based orthopedics company. It's not the hottest technology company; it's not the newest thing. It actually copies things that we invented decades ago, but they have a very inexpensive manufacturing process. They've also got inroads into the Chinese market and other developing countries. We're doing a lot more deals like that. We're also looking at things in Brazil and Russia and India.

So it really is interesting. Our current CEO has been here two years, and he has two principal themes: one is globalization — we've got to be addressing the billions of people in the world who don't have healthcare. You're not going to sell a $25,000 implanted pacemaker/defibrillator in India or China, where that's a multiple of the average annual income. So you've got to come up with a way to have a $200 product, even if it doesn't have all the bells and whistles.

The second theme he's got is economic value, which is related. We have to think about designing products and marketing products, not just based on their therapeutic value or having the latest bells and whistles, but based on their value to what he calls the healthcare ecosystem.

So it's been really interesting. I haven't been there that long; it's been four years and it is an 180 degree turn in terms of the deals we're doing.

JACK FRIEDMAN: What would be some examples of how tax issues would come up in deciding how to structure the deal?

ROBERT CUNNINGHAM: Let me give you a brief outline of the various methods of doing business internationally and the tax consequences of those methods. The simplest example is that when a company starts out and wants to start selling product in the U.K. The company can merely sell to somebody, and the company is not going to be subject to tax in the U.K. The company can set up a branch, and be subject to tax on their sales income in that country at the same time that income is subject to tax in the States. Thereafter, the company will pay tax at the U.S. rate, after the credits.

In the progression of how a company can operate internationally, the company could set up a joint venture. Now, in a joint

venture, you're going to be giving away some of your income, and it may have a tax impact. The company could also be getting skills and contacts and information. Or the company could set up a subsidiary, in which case, it is going to be subject to tax in the foreign jurisdiction, but typically not subject to current tax in the States. There are fundamentally different tax consequences based upon how you set things up. Most international tax planning is dealing with some combination of these methods of doing business abroad.

Now, the issues that are on the front page — Apple and others — generally relate to setting up these operations so that income earned is subject to low-tax. Establishing operations in Ireland is one example of a low-tax strategy. This strategy has received a lot of press as Ireland has a 12% corporate tax. Typically, the company needs to establish or expand its manufacturing or similar operations outside the U.S. and those operations need to use the intangible property in their manufacturing and selling operations. Thus, it is necessary to transfer the intangible property to the Irish manufacturing company in the most tax-efficient manner. Once the manufacturing company has acquired rights to the appropriate intangible property, it can sell its products using those intangibles and earn the income that reflects the value of the intangibles that it owns. That is a basic strategy that multi-nationals have been using for over forty years and is clearly allowed in the U.S. tax rules. This strategy also is supported by the OECD and other international tax guidelines.

There have been a couple of current trends that should be mentioned. If you go back ten, twenty years, the international tax world was fairly stable. The BRIC countries all were encouraging multinational companies to invest in their jurisdictions. Their tax rules were generally very favorable to the investing multinational. But over the last five to ten years, these countries have started to revise their tax rules in response to the increased interest in their markets and business opportunities. Thus, they began to restructure their tax rules to make them more restrictive from the tax point of view. It is becoming more tax-expensive to invest and sell in those countries. Another trend was the expansion of internet business internationally, which changed the paradigm of how income is earned and where it gets taxed. Then the recession hit. When you put those three forces together you have very significant political pressures for changes in international tax rules. You are likely to see these changes played out in the press, in Congress and around the world over the next fifteen years. During that time, the tax world for companies trying to comply with tax rules, will be more uncertain than it has been and more difficult to manage.

> "We always have product safety issues, because our devices go in people's bodies. It's a huge responsibility we have, and so we've got to get quality and safety right."
>
> *– Cameron Findlay*

Now, I know that my answer goes beyond your question, but hopefully it puts some perspective on the role and position of tax counsel and tax planning today.

CAMERON FINDLAY: I would just add one thing that struck me. I said our tax system is so perverse, if the issue is that the IP is where the incomes are, and sometimes we can develop IP here and sell it to a subsidiary outside the U.S. at the correct value for a tax-advantage transfer. But an easier way to avoid that problem is to create the IP outside the U.S. So, move your R&D outside the U.S. You've got a system that is encouraging you to move your headquarters outside the U.S., to do research outside the U.S. You've got all this outside-U.S. cash that you can't use in the U.S. It's gotten bad enough now that Congress almost *has* to do something about it.

ROBERT CUNNINGHAM: We certainly hope so!

CAMERON FINDLAY: But when you see a hearing like that being called, there's not a lot of push from the populace standpoint to do something about it.

JACK FRIEDMAN: What is the impact of Obamacare on companies and customers?

GINGER PIGOTT: In twenty words or less.

CAMERON FINDLAY: I'd invite anybody else to chime in, but there are pluses and minuses for Medtronic. On the one hand we think we'll get some new customers, because more people will be covered by insurance. Now, of course, a company like ours is going to be less advantaged in that way than some other companies in healthcare, because many of our products, as you saw, are for people who are older, and so they're covered by Medicare anyway.

That's the positive side. On the negative side, we have a medical device tax that was a late addition to the Affordable Care Act, and it really wasn't based on any policy justification that holds water. It was because they needed money to fund the program, so they threw a medical device tax in, and it's 2.3% on our revenues. So, for us, it's going to be annually about $125 million, and you saw we just had to do a layoff. There were other causes, too, but certainly one of the motivating factors was we had a hole that was caused by the medical device tax.

Beyond that, the Affordable Care Act is really just one more manifestation of an issue we also see from insurance companies and in other countries around the world, which is that patients, governments, payers and doctors are demanding that we get more efficient and we make products that don't cost so much.

So the Affordable Care Act is just one example of that, because it will drive lower costs in a number of ways. There is this IPAB, which is supposed to come up with ways to cut costs. There are accountable care organizations and these holistic hospital/doctor partnerships. There are lots of ways in which costs will be driven down, and our prices probably will be affected. If Obamacare didn't exist, something else — insurers, CMS, hospital administrators, to name just a couple — probably would have had that same effect, and you just can't have the cost curve going the way it did.

So, it's something my current boss thinks about all the time, and challenges all of us to come up with solutions for, which is to figure out ways to make our products more cheaply and to add economic value, rather than just have the most technologically advanced products.

JACK FRIEDMAN: Medtronic is expanding and plans to expand more internationally. I know that's a big part of your activity. Are most of your customers outside the U.S.?

CAMERON FINDLAY: There's no question that the future for us is going to be outside the U.S. There will be greater growth outside the U.S.; that's why we have been looking at transactions in emerging markets, as we discussed earlier.

I even notice the trend toward globalization with law firms. The firm that I still think of as Hogan & Hartson a couple of years ago did a deal with Lovells, which is a U.K.-based, international law firm. Norton Rose and Fulbright & Jaworski have just consummated their merger. Greenberg Traurig is a very global law firm. Baker & McKenzie has been the epitome of a global law firm for a long time.

So we're seeing our vendors, the people that we buy our services from, trying to match up against us in terms of globalization. That doesn't mean that there won't be a role for a great IP trial firm, like Robins, Kaplan, or a great Minnesota firm, like Fredrikson & Byron, which has done work for us since our founding. But some of our firms are trying to become more global to match up with global companies like us.

JACK FRIEDMAN: I'll give you an example in the legal field. In the year 2000, I went through every major California-headquartered law firm, and counted up how many lawyers they had outside the U.S. There was one law firm which had sixty-five. Putting them aside, all of the other law firms in California put together had forty-five lawyers outside the United States. Now there are California law firms with hundreds of lawyers each outside the United States.

CAMERON FINDLAY: How many lawyers does Greenberg have outside the U.S.?

GINGER PIGOTT: We have thirty-six offices, now, with seven of those being outside the U.S., and I would say, of the 1,800 or 1,900 lawyers, we have about 200 attorneys in those offices (roughly 10%).

CAMERON FINDLAY: Yes. What about Skadden, David?

DEAN DAVID WIPPMAN: Well, I'd say probably a third.

CAMERON FINDLAY: A third, yes. So Skadden, Arps, which is a classic New York firm, has become this global law firm, and I think my old firm, Sidley — I don't know what the number is; it's probably a third now, too. I meet with law firms and they'll say, "We have a hundred lawyers in China."

JACK FRIEDMAN: When one does global litigation or a deal, there's various models of how a company works with the law firms. Is it more efficient having your people in a region coordinate with law firms in the region directly; or is it better for your headquarters to coordinate directly with the firms in each region?

CAMERON FINDLAY: I think it just depends so much on the specific matter. We just had a meeting last week with our senior legal team, where we talked about exactly this issue. There's tension, frankly, in our internal legal team, on how something should be handled. Okay, you have an FCPA case involving our spinal business in Germany. That is going to involve, for our company, our litigation investigations team, which is centrally located here and tends to run the FCPA stuff. It's also going to involve our German lawyers, and then our German lawyers report up through our chief European counsel in Switzerland. It's going to involve the business unit lawyer in Memphis, who's the chief counsel of our Spine business. Who decides what law firm to hire? Who decides strategic direction for the matter? Who decides how many witnesses will be interviewed? Who pays for it? Who does it get charged to — does it get charged to Spine? Does it get charged to the Geography? Is it paid for centrally? So, there's no one way to deal with issues when you have, as we do, a very matrixed organization.

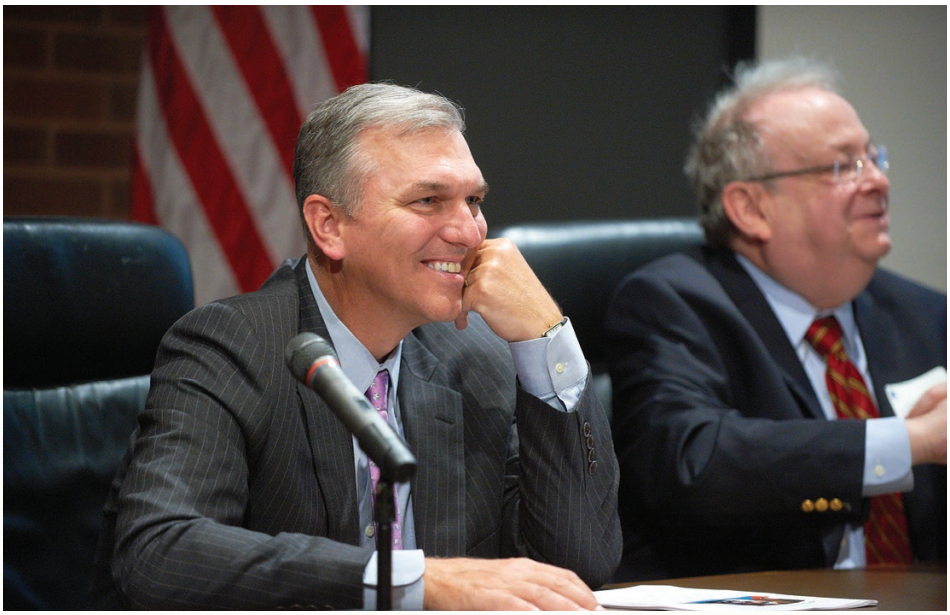
JACK FRIEDMAN: Are your department costs paid by specific business operating units?

CAMERON FINDLAY: Again, it's a complicated topic. We hold some corporately; we charge some things to the business units. There's a very complicated set of rules.

JACK FRIEDMAN: You mean the board doesn't just give you money?

CAMERON FINDLAY: Every company is different. Ours, we try to get the incentives right, but I'm not sure we do have them right. In our company, the business unit pays for the litigation, but if there's a big settlement, above a certain amount, the corporation may take the charge.

So, every corporation has a different way of doing it, and we try to get it right, but there's a lot of negotiation going on internally.



JACK FRIEDMAN: We have a few more minutes. Would anyone like to ask the panel a question?

[AUDIENCE MEMBER]: I was wondering about the allocation of work that you do. I heard you speak a little bit before the program about the idea of keeping significant instances of legal work in-house. Could you speak a little more about how to best outsource the functions of legal work? You've been doing it for quite a while, but it seems that it's also changed within the last couple of years. What have been some surprises that you had on the positive side of taking that approach, and then some challenges that were unanticipated?

CAMERON FINDLAY: We were talking before, so I'll repeat what I said that led to the question. I tend to think that you should have a presumption of doing legal work in-house, because it is typically less expensive, so long as you know the work's always going to be there and you're not going to have people sitting around and not doing anything. You should go outside if you have peaks and valleys in the amount of legal work, because you don't want to have a whole crew of litigators to handle the peaks. You also go outside when you need expertise, and there's certain expertise you don't need to keep in-house, like tax. We're not going to be doing a big tax restructuring all the time, but every once in a while, we'll go outside to do it. We need expertise on litigation, too, if it's a type of litigation that we haven't handled.

Then the third area, I would say, would be where you need independence or objectivity, such as an investigation. In many of these investigations, you have to have somebody who can go to the government. They're going to see the government for a lot of other clients, and the government knows the firm is on the hook and their integrity's on the hook. So when they tell the government, "I've looked, and there's nothing there," the government says, "Okay. Better be right, because you're going to be coming back to me for client 'B' sometime in the future."

You asked me about what has surprised me. Well, something that I didn't know much about before I got to Medtronic is intellectual property. I was just down in our Spine business a couple weeks ago. I've got to say that I had always wondered why we don't have an intellectual property law firm in-house rather than IP lawyers scattered around the businesses. But when I was hearing the IP lawyers talk about their interactions with the inventor and with the other people in the business, a light bulb went off. I thought, "We got it right by having the IP lawyers with the businesses, because they interact so much with the people who invent things."

In terms of challenges, a good legal department, if it has time and energy, ought to constantly be thinking about what do we do inside and what do we do outside. This inquiry ought to occur pretty often, because the nature of the risks you face changes every year.

You've got to get the balance right, and sometimes you need outside help to come in and help you see things you can't see, but really, we ought to get in the habit of doing it ourselves and we sometimes don't.

JODI SCOTT: I wanted to comment about that, having been inside and outside. I remember when I interviewed at Medtronic I kept saying, "What am I going to do every day?" They said, "You'll be able to build this job into what you really think it should be." Then two years down the road, I thought, "When am I going to go home? I've got so much work!" But it was good work; I really enjoyed it. The lawyers at Medtronic do a phenomenal job; they're great lawyers. They've got terrific projects and it is sophisticated legal work. There's an incredible amount of job satisfaction to being in the mix, and being point on issue. You get the benefit of having all that knowledge.

One of the things that I do miss now, being outside, is that I'm no longer the person who knows everything about that issue. I know part of it, but I don't know all the specifics: how did this person get involved, where are they coming from, and what are the objectives over here, and where are the issues that are going to come up if we don't deal with them? You don't get that when you're outside counsel, whereas when you're inside, you can't avoid it. I do miss that, not being in the mix that way.

JACK FRIEDMAN: But it pays better.

JODI SCOTT: Yes, it does!

JACK FRIEDMAN: There's an anecdote about a surgeon saying that he gives lectures all the time about healthy living, but he never has to worry that the lectures will make his practice obsolete. No matter how much they lecture people about healthy living, there's always work for surgeons.

Despite having an in-house legal team, there is always a place for outside counsel?

MARTIN LUECK: Well, I think, largely, if you just look at where things are at today and what the future holds, I think companies like Medtronic and so many others are going to continue to compete on that technological edge, and as long as they're doing that, they're going to be looking to protect their markets and their space so that they can get a return.

JACK FRIEDMAN: You mean, in an IP-driven world, it is the technology that counts?

MARTIN LUECK: That's basically what I'm saying.

JACK FRIEDMAN: There's another question from the audience.

[AUDIENCE MEMBER]: Did you get a chance to answer what was on your yellow sticky, what you were worried about?

CAMERON FINDLAY: Well, it's constantly amended. It's so easy in any in-house job, and particularly for a General Counsel, to come in in the morning and start answering emails, working on things that other people want you to work on. I keep my yellow sticky, because it has about ten things that I have to remember to come back to and force myself to come back to. Then I can call a colleague and ask, "What's going on in this matter? I haven't heard for a while."

So I never get through the list on my little yellow sticky, because once you get done with something, there's something else coming along. We have an in-house lawyer named John Eisenberg. He gave me a to-do list when I got there, and it turned out to be a great list, actually. He said we're too siloed, we need to hire this role or that, and so on and every one of those things pretty much turned out to be true. I have made progress on the Eisenberg list.

JACK FRIEDMAN: In closing, I have one last question. In the five minutes a month that you have free for personal time, what do you like to do?

CAMERON FINDLAY: I still love history and biography, so I try to read. In the old days I would get into bed and I would read for an hour before I went to bed. I could get through a book every week or so. Now, I fall asleep after two or three pages. I was recently reading a long book about Jerusalem, which I visited in January. I started the book in January, and I just now finished it. That led me to the revelation that if I keep at my current pace, given my life expectancy, I'm only going to read ten more books in my life. This is not a good thing.

JACK FRIEDMAN: It is always a pleasure to visit Minnesota. Thank you for having us here and thanks to our Guest of Honor and Distinguished Panelists.

Jodi Scott

Partner, Hogan Lovells US LLP

Hogan Lovells

Jodi Scott focuses her practice on assisting the medical device industry in navigating the complex requirements for achieving U.S. marketing authorization and maintaining compliance to the U.S. Food and Drug Administration's (FDA) quality system and other postmarket regulatory requirements. She has also spent considerable time developing and implementing strategies to manage FDA-initiated enforcement actions, such as the issuance of FDA Form 483s, untitled letters, Warning Letters, and consent degrees of permanent injunction. Additionally, Jodi assists companies in developing regulatory strategies and preparing product applications, including IDEs, 510(k)s, and PMAs; with compliance matters, including MDRs, recalls, and GMPs; in addressing regulatory due diligence issues; and with FDA training programs. Having been in industry, she counsels clients on risk management techniques for running a medtech business in today's heavily regulated environment.

Jodi has applied her healthcare background to build regulatory strategies for the development of medical devices, including ensuring clinical, quality, and regulatory compliance and providing guidance and assistance in the formation of policies and procedures related to FDA legal matters. Jodi is experienced in counseling medical device manufacturers on various FDA-related issues, such as satisfying FDA's requirements for importing and exporting medical devices through customs, evaluating FDA submission requirements, managing FDA inspections, responding to FDA enforcement actions, advertising and promoting medical devices in compliance with FDA's requirements, developing systems designed to mitigate the risks associated with the unapproved use of approved products (a.k.a. off-label uses), and developing policies and procedures designed to allow manufacturers to operate in compliance with FDA's complex QSR requirements.

Prior to joining Hogan Lovells, Jodi served for four years as senior FDA legal counsel and, subsequently, four years as principal FDA legal counsel for Medtronic, Inc., where she was instrumental in growing the company's corporate FDA legal practice to meet the needs of their business in an increasingly enforcement-minded environment.

Before joining Medtronic, Jodi was an associate with Hogan Lovells' legacy law firm, Hogan & Hartson. In this role, Jodi represented clients in negotiations with the FDA regarding clinical data requirements, clinical study design, and the necessary regulatory pathways to obtain U.S. marketing clearance/approval. Additionally, she worked with clients to prepare the necessary submissions and obtain clearance/approval. Her practice also included advising clients in addressing FDA enforcement actions and responding to FDA inquiries.

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- particular and distinctive strengths in the areas of government regulatory, litigation and arbitration, corporate, finance, and intellectual property; and
- access to a significant depth of knowledge and resource in many major industry sectors including hotels and leisure, telecommunications, media and technology, energy and natural resources, infrastructure, financial services, life sciences and healthcare, consumer, and real estate.

Our practice breadth, geographical reach, and industry knowledge provide us with insights into the issues that affect our clients most deeply and enable us to provide high-quality, business-oriented legal advice to assist them in achieving their commercial goals. We are distinguished by a highly collaborative culture which values the contribution of our diverse team both within Hogan Lovells and in the wider community. Our style is open, service-focused, and friendly. We believe that our commitment to client service, commerciality, and teamwork provides benefits to our clients and enhances effective business relationships.

Martin Lueck

Chairman, Executive Board, Robins, Kaplan, Miller & Ciresi L.L.P.

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

Nationally regarded as one of the top trial lawyers in the country, Martin R. Lueck has represented many Fortune 500 corporations in complex business disputes and patent litigation. In addition to serving as Chairman of the Board at Robins, Kaplan, Miller & Ciresi L.L.P., Mr. Lueck focuses his practice in the substantive areas of patent and intellectual property, antitrust, corporate litigation, construction, contracts, industrial catastrophe, property insurance coverage, fraud, and personal injury. He has represented corporations in the capacity of both plaintiffs and defendants.

Mr. Lueck is currently co-counsel for a class of approximately seven million U.S. merchants who accept Visa and MasterCard credit cards and debit cards for the purchase of goods and services. The case, *In re Payment Card Interchange Fee and Merchant Discount Litigation*, reached a $7.25 billion proposed antitrust settlement. The defendants included Visa and MasterCard, and major card-issuing banks such as JPMorgan Chase, Bank of America, Citibank, Wells Fargo, and Capital One. The settlement, which resolves the lawsuit, is believed to be the largest settlement of a private antitrust case in the 120-year history of the Sherman Act (15 U.S.C. §1 et seq.) and also includes important reforms of the payment card industry.

Mr. Lueck was counsel in *Omnicare Inc. v. UnitedHealth Group, Inc., et al.* (summary judgment); *Electromotive Division of General Motors Corporation v. Transportation Systems Division of General Electric Co., et al.* (summary judgment of invalidity affirmed by Federal Circuit); *Eolas Technologies, Inc. and The Regents of the University of California v. Microsoft Corporation* (jury verdict of $520.6 million, which later settled confidentially); *Fonar v. General Electric Co.* (jury verdict of $110.5 million); *Honeywell Inc. v. Victor Company of Japan and U.S. JVC Corp.* (jury verdict of $30 million); and *UNOCAL Corp. v. ARCO, Chevron, Exxon, Mobil, Shell and Texaco* (jury verdict of $69 million).

He is a Fellow in both the International Academy of Trial Lawyers and the American College of Trial Lawyers. In 2004, he was named one of Ten of the Nation's Top Litigators by *The National Law Journal*.

Robins, Kaplan, Miller & Ciresi L.L.P.

Celebrating 75 years of providing legal services, Robins, Kaplan, Miller & Ciresi L.L.P. is a national law firm of over 230 lawyers with offices in Atlanta, Boston, Los Angeles, Minneapolis, and Naples (FL). The firm is, first and foremost, experienced courtroom lawyers who know how to get results, whose focus is on winning at trial, even if the case may never get to trial. Each of the firm's clients has a story that deserves to be told. Robins, Kaplan, Miller & Ciresi's strength is in understanding that story and simply and convincingly conveying it to judges and juries. Throughout its 75 years in practice, the firm has represented some of the world's largest companies, most innovative start-ups, and individuals from virtually every industry and walk of life, both in and out of the courtroom.

It is the firm's fundamental belief that everyone should have equal access to the justice system, regardless of their personal or economic situation. Robins, Kaplan, Miller & Ciresi L.L.P. has been repeatedly recognized for *pro bono*, which makes up over 7% of total attorney billable time, and the extensive work done for the community through the firm's private foundations.

Robins, Kaplan, Miller & Ciresi L.L.P. has regularly received a top ranking for litigation from *Chambers USA* and was chosen as a "Go-To Law Firm" by *Corporate Counsel* and was named the "Minnesota Firm of the Year" and the Midwest "Intellectual Property Firm of the Year" by the inaugural *U.S. Benchmark Awards*. In addition, *Multicultural Law* ranked the firm as one of the top national law firms for diversity in 2012. *The American Lawyer* ranked the firm seventh in the country in the 2013 Pro Bono Survey, and twice named the firm to the A-List (2007 and 2004). rkmc.com

Ginger Pigott

Shareholder & Vice Chair, Pharmaceutical, Medical Device & Health Care Litigation Group, Greenberg Traurig LLP

Ginger Pigott focuses her practice on products liability litigation and commercial litigation. A particular focus of her practice lies in the defense of complex medical device and pharmaceutical products liability litigation, as well as counseling on pre-litigation issues that include document retention issues and best practices. She represents major corporations as part of national and regional counsel teams and on individual cases both in California and throughout the country. She is experienced in creating strategies for large litigation and document projects for geographically diverse clients on an international scale, as well as in developing alternative dispute resolution programs and preparing mass tort cases for trial.

Ginger has defended medical device products liability lawsuits involving a wide range of products, including spinal/biological devices, neurological devices, diabetes management devices, cardiovascular devices, implantable devices for various indications, cardiopulmonary bypass equipment, imaging equipment, as well as other external medical devices and related equipment. She is also experienced in defending products liability cases involving pharmaceutical drugs, nutraceuticals and biologics. In addition, Ginger has worked on a wide variety of other product liability matters, including welding products and consumables, airplanes, helicopters, rocket-propelled parachute systems, automobiles, soft drinks, and video games. In both product cases and commercial litigation matters, she has experience with various unfair competition allegations including those derived from Section 17200 Unfair Competition Law (UCL) and the Consumer Legal Remedies Act (CLRA). Prior to joining the firm, Ginger was a partner at a prominent, global law firm for more than 13 years.

Ginger received her J.D., with honors, from Loyola University Chicago School of Law, and her B.A., with honors, from the University of Michigan.

Greenberg Traurig LLP

Greenberg Traurig, LLP is an international, full-service law firm with approximately 1,750 attorneys serving clients from 36 offices in the United States, Latin America, Europe, the Middle East and Asia. In the U.S., the firm has more offices than any other among the Top 10 on *The National Law Journal's* 2012 NLJ 250.

GT provides integrated legal services for clients worldwide. We understand our clients' businesses and offer them a highly entrepreneurial approach to legal counsel. Our multidisciplinary team includes senior lawyers who have been the chief legal officers at major multinational companies and have spent years solving real-world problems in the business, political and legal environments of major commercial centers. We build teams around client needs, ensuring lean staffing, front-end planning and flexible billing, where appropriate. Our experience in more than 100 practice areas and our network of contacts throughout the world position us to help clients achieve their objectives both domestically and in the global marketplace. We provide our services with the dedication and responsiveness of a boutique firm and the breadth, depth, resources and operating efficiencies of one of the largest law firms in the United States.

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Robert Cunningham

Partner, Baker & McKenzie LLP

BAKER & McKENZIE

Practice description

Robert J. Cunningham has extensive experience as lead counsel in numerous state and federal income tax cases, including several intercompany pricing matters. In addition to his law practice, Mr. Cunningham is a frequent speaker in the areas of structuring international tax operations, U.S. taxation of international income and transfer pricing. He has been active in Firm management for years.

Practice focus

Mr. Cunningham's practice primarily involves advising multinational companies on international tax planning and transfer pricing. He also represents clients in local and international income tax controversies, both in the administrative and litigation levels.

Representative clients, cases or matters

G.D. Searle & Co. v. Commissioner, 88 T.C. 252 (1987)

The Perkin-Elmer Corp. v. Commissioner, 66 TCM (CCH) 634 (1993)

AMP, Inc. v. United States, 185 F.3d 1333 (Fed. Cir. 1999)

Medtronic, Inc. v. Commissioner, TC Docket No. 017488-08

Education and admission

Education

New York University School of Law (LL.M.) (1969)
New York University School of Law (J.D.) (1967)
University of Nebraska (B.A.) (1964)

Admission

Illinois ~ United States (1969)
New York ~ United States (1967)

Baker & McKenzie LLP

Founded in 1949, Baker & McKenzie advises many of the world's most dynamic and successful business organizations through more than 4,000 locally qualified lawyers and 6,000 professional staff in 74 offices in 46 countries. The Firm is known for its global perspective, deep understanding of the local language and culture of business, uncompromising commitment to excellence, and world-class fluency in its client service. We have more leading lawyers in more countries in the *Chambers Global Directory* than any other global Top 20 law firm. *Chambers* lists 23 of our practices in its global rankings of the world's leading practices. Baker & McKenzie understands the challenges of the global economy because we have had a global presence from the start. Since our founding, we have been advising leading multinational and domestic companies on the issues of an integrated global market. Nearly two thirds of our fees come from clients we serve in five countries or more and we serve more than 500 of the world's largest companies.