WORLD RECOGNITION of DISTINGUISHED GENERAL COUNSEL

GUEST OF HONOR:

Greg Boss
Executive Vice President Legal and Group General Counsel, CSL Limited
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THE SPEAKERS

Greg Boss
Executive Vice President
Legal and Group General Counsel,
CSL Limited

Robert Baron
Partner, Ballard Spahr LLP

Stuart Langbein
Partner, Hogan Lovells U.S. LLP

Kevin Arquit
Partner, Simpson Thacher & Bartlett LLP

Jeff Barker
Executive Director,
Cushman & Wakefield

(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 increasingly look 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 and passion for ethical leadership, we are honoring Greg Boss, Group General Counsel of CSL Limited, with the leading global honor for General Counsel. CSL is a leading global biopharmaceutical and specialty biotherapeutics company headquartered in Australia, with major operations in the United States and more than 17,000 employees conducting business in over 60 countries. CSL marks its 100th anniversary in 2016. Mr. Boss addressed key challenges facing the General Counsel of an international pharmaceutical business and discussed how he and his team help the company deliver on its promises to patients, partners, and shareholders in an ever-changing global economy. Panelists discussed intellectual property; government regulations including the FDA and Medicare; risk management; antitrust; and operating a national system of plasma collection centers.

The Directors Roundtable is a civic group which organizes the preeminent worldwide programming for Directors and their advisors, including General Counsel. Join us on social media for the latest news for Directors on corporate governance and other important VIP issues.

Jack Friedman
Directors Roundtable Chairman & Moderator

Summer 2016
Greg Boss
Executive Vice President Legal and Group General Counsel

Greg is responsible for worldwide legal operations for all CSL Limited Group companies. CSL is a global biotechnology firm with business operations in 60 countries, and Greg has served as Group General Counsel since 2009. He is a member of the Executive Global Leadership Group, and he serves as Secretary to the Board’s Audit and Risk Management Committee.

Greg first joined CSL in 2001, serving as U.S. General Counsel for CSL's U.S. sales and distribution business, ZLB Bioplasma. In this capacity, he was instrumental in the company’s acquisition and integration of competitor Aventis Behring, and upon the integration of the two companies in 2004, Greg assumed the General Counsel position for the combined business.

In January 2009, Greg was appointed to the role of Group General Counsel for CSL Limited, an Australian Stock Exchange listed company headquartered in Melbourne, Australia. Greg is based in King of Prussia, Pennsylvania, and oversees legal operations globally. In addition, Greg is responsible for Risk Management, Compliance, and Corporate Communications.

Prior to joining CSL, Greg served as Vice President and Senior Counsel for CB Richard Ellis International, a global real estate and financial services firm. Before that, he worked 10 years in private practice, focusing on corporate and securities law, mergers and acquisitions, corporate finance, and commercial transactions.

Greg received his Juris Doctor degree from the University of Southern California in 1987 and his bachelor's degree, cum laude, in Finance and Business Economics from the University of Southern California School of Business in 1983.

Delivering on promises is what we do at CSL. Starting a century ago, we made a promise to save lives and protect the health of people who were stricken with a range of serious and chronic medical conditions. Today, as a leading global biotherapeutics company with operations in more than 60 nations and over 17,000 employees, that same promise has never been stronger.

CSL focuses its world-class research and development, high-quality manufacturing, and patient-centered management to develop and deliver innovative biotherapies to treat disorders such as hemophilia and primary immune deficiencies, and vaccines to prevent influenza. Our therapies are also used in cardiac surgery, organ transplantation and burn treatment.

Our 1,100 dedicated R&D experts focus on solving patients’ unmet needs every day. CSL collaborates and supports patient and biomedical communities by improving access to therapies, advancing scientific knowledge, supporting future medical researchers, and engaging our staff in the support of local communities.

We understand the very unique challenges faced by people stricken with life-threatening medical conditions because of our long experience, deep knowledge and laser focus on preventing and treating serious diseases. We deliver innovations that patients and providers want. And we are just getting started. Today, our future has never looked brighter.
JACK FRIEDMAN: I want to welcome everyone. I’m Jack Friedman, Chairman of the Directors Roundtable. We are a civic group that has done 800 events globally at no cost to the audience. Our goal is to organize the finest programming for Directors and their advisors in different industries, topics, and locations.

This morning, we have the privilege of presenting the world’s leading honor for General Counsel to Greg Boss of CSL Limited. The purpose of this particular series is that Directors have told us that their companies are rarely acknowledged for the good they do. We decided to create a serious discussion on a global platform about business and what companies do that they are proud of. There will be a transcript of the program, made available globally to more than 100,000 leaders, including the vast majority of the in-house counsel in the world.

I am now going to introduce the Distinguished Panelists. Robert Baron of Ballard Spahr; Stuart Langbein of Hogan Lovells; Kevin Arquit of Simpson, Thacher & Bartlett; and Jeff Barker of Cushman & Wakefield. Each will introduce his own special topic after Greg’s presentation.

As a special acknowledgement to Greg I will read a letter from the dean of Greg’s law school, USC School of Law.

Dear Greg:

Congratulations on receiving the World Recognition of Distinguished General Counsel from the Directors Roundtable. This well-deserved honor is a testament to your career as a General Counsel and your notable contributions. Your accomplishments and passion for ethical leadership is a fine reflection on your alma mater. We at the Gould School of Law wish you continued success.

Here is your copy from the Office of Andrew Guzman, Dean, and Carl Mason Franklin, Chair of Law and Professor of Law and Political Science.

GREG BOSS: Thank you.

JACK FRIEDMAN: Without further ado, I would like to have our Guest of Honor make his opening remarks. Then we will move onto different topics with some questions and interactive panel discussion. Let’s welcome Greg. [APPLAUSE]

GREG BOSS: Good morning, and thank you, Jack, and thank you to the Directors Roundtable for the opportunity to be here. I truly appreciate the honor, and I’m humbled by the recognition. I’d also like to thank all of you for attending. I see many friends out there, so thank you.

I’ve never been mistaken for a dynamic speaker, I’ll tell you that, but we’ve assembled an all-star panel to ensure a lively discussion today.

I also see several CSL colleagues in the audience, and thank you for attending. My CSL colleagues also deserve to be recognized for the company’s achievements over the last few years. I’d like to particularly acknowledge our CEO and Managing Director in the front row, Paul Perreault. [APPLAUSE] He told me today that this is his second day back in Philadelphia in 60 days, so thanks for spending it with us.

As with any CEO-General Counsel relationship, without the CEO’s trust and support, no General Counsel can be successful.

Now, Jack’s already introduced the panelists, but I’d like to specifically thank each one, not only for participating today, but also for their support of CSL, and for me professionally, over the years. Each of our panelists has been a longtime legal partner with CSL, and without their support, I wouldn’t be here today.

Finally, I’d like to specifically acknowledge Rob Baron and his Ballard Spahr colleagues for hosting us today. As I said, Ballard, like the rest of the panel, and Rob, in particular, have been longtime partners with CSL. But it’s fitting that we’re in these offices today,
because over 12 years ago, CSL commenced due diligence in these offices, on this floor on an acquisition that would transform our company. That was back in the days of a paper data room, and we sat in one of the conference rooms and thumbed our way through paper.

CSL ultimately succeeded in completing that deal, which was the acquisition of Aventis Behring. We combined two then-struggling plasma products businesses, saving both businesses, and generating an entity with sufficient scale that effectively kick-started 12 years of growth. We’re very proud of those achievements, but that acquisition didn’t come without legal challenges. We were involved in “bet-the-company” litigation and were operating under an FDA consent decree; but one thing was for certain: during that time we never compromised on our commitment to our patients, our commitment to our employees, and our commitment to conducting an ethical business.

Now, Paul has joked from time to time that CSL is the biggest company that no one’s ever heard of. I have to say, oftentimes that seems quite true. In my 15 years with CSL, and the last seven as Global General Counsel, I’ve operated comfortably under the radar. I must admit it is a bit awkward being up here, speaking to all of you today about an honor of which I’m truly proud, but it’s good to get out of your comfort zone occasionally and take considered risks.

One of the responsibilities that I have at CSL, in addition to the legal work, is oversight of corporate communications. I’m told that one of my strengths is that I don’t think like a lawyer. [LAUGHTER]

Now, I think that’s a compliment — at least that’s what I tell myself!

CSL is a global specialty biotherapeutics company that has more than 17,000 employees and operates in more than 60 countries. For me, today is recognition of CSL’s global workforce and the achievements we’ve all worked together. Each of our employees works every day as if someone’s life depends on it. In our industry, that’s true; lives do depend on what we do. We develop and deliver life-saving medicines to people with serious and chronic medical conditions.

When we get the question at CSL — “What do you do?” — we say, “We deliver on our promises to those in need.” It’s really a powerful commitment for us, and a powerful message.

This year, 2016, marks CSL’s centenary celebration. This is our 100th anniversary delivering life-saving therapies to those in critical need. There is no better time for me to talk about the role of the General Counsel at CSL and in the global pharmaceutical industry in general. As General Counsel, my role includes certain non-legal functions, like risk management, compliance and communications; but today, I’m going to primarily focus on the intersection of the legal and compliance functions. I believe they represent the foundation of ethical performance, which we are all duty-bound to deliver.

First, I want to share a little bit more about CSL, who we are, and how the legal department can help a global organization live out its corporate values. CSL has a long and storied history in Australia. The Australian government founded CSL in 1916 to ensure its people had a consistent and reliable supply of important medicines, including vaccines and anti-venoms. One early achievement of the company was the delivery of vaccine to protect the Australian people against the outbreak of Spanish flu following World War I. Now, remember, Australia’s a long way away from all of us, and getting medicine there was an early challenge. Also, Australia is home to more deadly snakes and other deadly species than anywhere else in the world.

In the early 1990s, CSL was privatized and later publicly listed on the Australian stock exchange. Its initial share price was $2.43 Australian, and that delivered a whopping $299 million in market capitalization. At that time, the Australian dollar was worth about 75¢ U.S. Through a series of smart acquisitions — one of which I mentioned earlier — and strong organic growth, today, CSL generates more than $6 billion U.S. in annual revenue, and operates in more than 60 countries.

CSL Behring is our biotherapeutics business. This is the business I mentioned earlier that started with due diligence in these offices. The global headquarters for this business is in King of Prussia, just up the road. This business accounts for the majority of our global operations, and drives about 90% of our global revenue. Half of that revenue comes directly from the U.S.

This part of the business operates under what has been self-described as a vein-to-vein business model. Through our CSL Plasma operations, we collect human plasma, which is the liquid part of blood, with a network of over 140 plasma collection centers in the U.S. and Europe. We have plasma collection centers in the U.S. in over 30 states, including two here in the Philadelphia area. Our plasma donors are as much a part of the CSL family as our employees and our patients. As we like to say, CSL Plasma delivers the fuel that feeds the engine, and each plasma donor plays an important role in saving people’s lives.
We take the plasma that we collect, fractionate it into proteins — essentially our finished product — and infuse it back into patients, depending on their need. Again, our therapies are generally non-discretionary and for people with critical illnesses. Some of the illnesses that we treat are primary immune deficiency, hemophilia, and other rare clotting factor deficiencies, including von Willebrand disease, alpha-1 antitrypsin deficiency, and hereditary angioedema.

Now, complementing this core plasma products business, we also have a robust recombinant protein manufacturing business, which serves some of the same illnesses. Somewhat more mainstream, we have an influenza vaccines business. In fact, we are the second largest producer of influenza vaccine in the world. That business operates under the name “Seqirus.” We also have a world-class R&D organization made up of more than 1,100 experts globally. We actually have more scientists than salespeople.

While CSL was founded for the isolated population of Australia, in order to succeed and deliver long-term sustainability, the company had to globalize. We’ve done that successfully. I’m happy to say that I’ve experienced much of CSL’s key growth and expansion over the last 15 years, and this has really been a General Counsel’s dream.

Since our initial public listing in 1994, we’ve delivered a compound annual growth rate of approximately 24% per year in net profit. If you do the math, that’s a pretty good investment. Of course, a good legal department can’t take all the credit for this extraordinary growth. [LAUGHTER]

I believe our success over the past 100 years is due, in large part, to our global commitment to our corporate values: integrity, innovation, collaboration, superior performance, and patient focus. At CSL, we like to say, “Our employees operate with a unique CSL DNA.” Now, every company may claim a unique DNA, but at CSL, I truly believe that our workforce operates with a passion that doesn’t exist at other companies.

Still, if you ask me to define the CSL DNA, I can only refer back to my law school days at the wonderful Gould School of Law, and Justice Potter Stewart’s famous line, “I may not be able to define it, but I know it when I see it.”

People are a company’s best asset, and employee engagement and creating a desired culture are critical to ensuring an organization’s continued success. That’s certainly easier said than done. It remains universally clear that employees, shareholders, and other stakeholders prefer to be associated with organizations that are highly credible and have earned a strong and positive reputation. At CSL, our reputation is that of a trusted biotechnology leader that operates successfully and responsibly in the global marketplace and delivers on our promises.

Our core values guide us in the decisions, behaviors and actions that we take in our daily work, and they ensure our commitment to compliance. At CSL, each of us is accountable for understanding and complying with our company values, and we stress diligence in detecting and preventing unethical conduct. Each employee at CSL is responsible, and deserves credit for, contributing to our global reputation. Notably, in the last two years, we’ve earned a “best place to work” award in four countries — Switzerland, Australia, Germany, and Italy. Paul and I are still working on the U.S. [LAUGHER]

As CSL builds on our successes and navigates emerging challenges, we are expanding our employee base, on average, 10% per year. Now, that’s an exciting number these days, but it comes with challenges. I’d like to share three best practices that I believe in, to ensure ethical employee engagement in a high-stakes, fast-changing global pharmaceutical industry.

First: Know what you’re committed to. Internalize the company’s values, and understand why these values matter. For me, this means remembering what’s on the line. As I said before, our medicines are not really discretionary; they serve people with critical illnesses. People’s lives depend on us.

Second: Ensure everyone you work with shares this commitment. Our greatest resource is our people, and conducting business in more than 60 countries means we need to rely on our global teams to live out our values. This includes third-party contractors as well as employees. We often say that if you want to work with CSL, pay attention to the patient. We encourage our employees to get involved with patient organizations appropriately. People from all over our organization volunteer at local walks, bike rides, golf tournaments, and other events in support of a wide variety of patient support organizations, such as the Immune Deficiency Foundation, the Alpha1 Foundation, and national and regional Hemophilia Foundations. This is all part of the CSL DNA.

When we get the question at CSL — ‘What do you do?’ — we say, ‘We deliver on our promises to those in need.’ It’s really a powerful commitment for us, and a powerful message. This year, 2016, marks CSL’s centenary celebration. This is our 100th anniversary delivering lifesaving therapies to those in critical need.

— Greg Boss
Third: Know where you can win, without compromising your values. It’s critical for everyone across the organization, including the operating lines and especially the attorneys, to understand where our core capabilities and competencies are, and how they line up to our values. This not only helps us make decisions on where to invest our resources, but it also ensures that we keep our values front and center every day. At CSL, our innovations respond to human needs, not necessarily market size. We have some products that treat as few as 300 patients in the U.S., and we call that a big win.

Applying these principles to the legal function at CSL, it is routine for our business colleagues to seek out our legal team for counsel on various business questions that may not necessarily require a legal answer. I see these opportunities as key examples of where the legal team can add its best value.

Now, I’m putting aside the trivial matters that we, from time to time, are asked to get involved in. Generally, as attorneys, we must always think of ourselves as strategic business partners first, who approach matters with the company’s key business objectives in mind. In doing so, we certainly bring a legal expertise to the equation, but we can do more than simple legal problem-solving.

As an aside, I attended a legal conference in London earlier this week. I heard one of my colleagues describe his legal function as the “lubricant” for the business. Now, I don’t think I’d go that far. [LAUGHTER]

I’m proud to say, at CSL, my legal colleagues are just as passionate about ensuring patients’ access to medicines, as they are to defending our intellectual property or other legal positions.

Now, as you’ll all appreciate, the more successful an organization becomes, the bigger challenges they face. This is especially true in the pharmaceutical industry, and it’s certainly true for CSL. From regulatory changes to payer austerity measures to IP protection, the environment’s constantly changing, and we need to be able to adapt without losing our way.

The role of the General Counsel is to help advise and guide the organization through challenging environments, while staying true to our values and delivering our promises to patients, partners, and stakeholders. I’m proud to say that the legal team at CSL plays a pivotal role in helping to create a culture where people are encouraged and empowered to live out our values, while still meeting the challenges of navigating a complex, diverse and evolving business.

One example of our industry under pressure is from the pharmaceutical payers as they grapple with rising costs and shrinking budgets. Government spending on healthcare remains an issue that grabs headlines on a daily basis, including today. While the cost of medicine is often portrayed as driving up healthcare costs, medicines are not the main driver of the increase in healthcare spend in the United States. In fact, medicines account for only a small — and shrinking — percentage of healthcare spending growth. According to the Pharmaceutical Research & Manufacturers Association of America, in the U.S., only nine cents of every dollar spent on healthcare comes from prescription drug costs.

Now, you wouldn’t know this based on recent, albeit limited, high-profile events and publicity, but this is a challenge for the pharmaceutical industry overall. At CSL, our team advises the organization on how to best interact with payers, including governments, to help them and other stakeholders understand how their policies impact patients. One initiative of which CSL is particularly proud is a collaborative effort with the Australian government to support Australia’s Medical Research Future Fund. This is a public private endeavor that will eventually generate a capital value in excess of $20 billion Australian, with the annual interest benefit from that fund going to support medical research grants.

Now, CSL has suggested that to help maximize the economic returns from the fund, it should ensure a significant number of the grants go towards supporting translational research, moving discoveries from the laboratory into practical application to best improve people’s health.

I would like to move to one other key challenge in the industry today, and that is the digitization of healthcare. This involves interactions with patients via digital channels, and collecting and stewarding patient data. The rise of digital and social information channels puts more information and decision-making in the patient’s hands directly. As a result, I see a paradigm shift in the industry from doing for patients to doing with patients. Delivery of healthcare is much more collaborative now, and this shift is especially true in the rare disease community, where patients are often well-educated on their conditions even before they arrive in a physician’s office.

You’ve all heard the phrase, “There’s an app for that.” Well, that’s becoming especially true in the healthcare industry. However, where there’s an app for that, there’s also a lawyer for that. [LAUGHTER]

That’s because the digitization of healthcare data represents a significant legal, regulatory and cybersecurity challenge. Anyone can engage the right external or internal counsel
to advise them in this area, but what’s really important is that our industry seeks solutions that include a focus on the patient.

If you remember, I said earlier that patient focus is one of our core values, and at CSL, we call our approach “patient centricity.” It means putting ourselves in their shoes and understanding how they want to address their medical needs. At CSL, we work closely with patient advocacy communities to find ways to raise awareness of rare disease and encourage the right conversation with healthcare professionals to prompt early diagnosis and timely treatment.

I’d like to take a few moments to share with you a story about Jacob, an energetic young man who is stricken with a serious primary immune deficiency disease. Hopefully, you’ll see what it means to CSL and his family to see patient centricity.

[VIDEO PRESENTATION]

MOM: Mostly, our life revolves around our kid’s scores. Jacob actually decided this year once he got to high school that he wanted to swim and dive. The thing that’s so cool for me with that is that with all of his health issues, swimming was never an option for him. His life was pretty much medical treatments, hospitalizations, and doctors’ offices. We had to really limit him being in public, because we were so afraid that he was going to catch something from somebody.

JACOB: My name is Jacob Richards. I’m from Grand Rapids, Michigan. I am in ninth grade at Grand Rapids High School. I play soccer all year around. Right now, I am swimming and diving on the high school team, and I have a primary immune deficiency.

MOM: Primary immunodeficiency is when there’s a part of the immune system that you’re born with, that we all have, that Jacob was born without. So part of his immune system is not functioning; he doesn’t have it; he never will. Jacob was diagnosed when he was right around five years old, and what led to my diagnosis finally was I had been sick for so long, both as a child and as an adult, that I knew to go straight to Jacob’s specialist and ask them to test me. That led to my being diagnosed with a primary immunodeficiency, about two years ago.

JACOB: As a young child, I was constantly getting sick and in the hospital.

MOM: When he started school in kindergarten, he had 65 absences in his kindergarten year.

JACOB: The doctor just kept saying, “No, it’s just a normal infection,” but my mom knew that it was something much more, and so she kept pushing for a diagnosis.

MOM: When we finally got a diagnosis, I literally wept tears of joy, because finally, we can get support. We can move on now. We can start our life, because we now know what it is, and we can start to help him.

Jacob self-infuses once a week with Hizentra, and he’s been doing that for years.

JACOB: When I was six, I decided that it was time for me to do the Hizentra infusions on my own, for more of a feeling like I was in control of my body.

MOM: Hizentra has been so convenient for our lifestyle. We’re running to sports all the time; we are so busy.

JACOB: It’s important for me to individualize my therapy, because I can adjust the time that I take it to fit my personal schedule.

MOM: That’s a big thing when you’re a patient, to feel like, “I’m doing this; this is my treatment, and I’m in charge of it.” I love that.

CSL Behring delivers on its promise to patients with primary immunodeficiency by always putting the patients first. I’ve been to their company; I’ve met their people. I have never seen a company more driven by us.

JACOB: Thank you so much for helping not only me, but my mom and thousands of other people with the same disease.

MOM: If I had every employee of CSL Behring in a room right now, and I could speak to every single one of them, I would say, “Thank you for making us a priority, to make our lives better, to listen to what we have to say.” I mean, who does that? CSL does that. I would just say, “Thank you so much for everything you do for the P.I. patients. Thank you.”

GREG BOSS: No legal presentation should be without a disclaimer, so that’s why that’s included. [LAUGHTER]

Seriously, now you know why I, and all of my CSL colleagues, really love our job. We really like serving the patients.

In closing, I hope I’ve left you with a few ideas of how a legal organization can help the broader organization deliver on its promise and operate ethically in the global marketplace. No matter where someone sits within CSL, our work is driven by our passion for making a difference in the lives of people like Jacob who rely on us to deliver life-saving therapies. When we say we are going to do something, we do it. That’s our commitment, and it reflects the importance of our values in achieving our business success.

Thank you all very much. [APPLAUSE]

JACK FRIEDMAN: Thank you. That was very moving, and I appreciated you bringing the film to share.
At the end of the twentieth century, great intellectual historians from around the world were asked what they considered to be the greatest achievement of mankind in the century. Overwhelmingly, the vote was “medicine.” Probably at the end of the twenty-first century, when there’s another survey done, it’s likely that it will be the same answer.

Could you tell us about how you work with the business side, and how you organize your work with outside law firms to handle the legal function on a global basis?

GREG BOSS: Since we have a broad global footprint in the business, we structure the legal group geographically, but we have also developed strong functional support teams. Where we have global functions, we have dedicated legal teams that support those functions, whether they operate in the U.S., Australia or Europe. It’s a combination of both, but the intent is to deliver legal services in a very collaborative and proactive way as a business partner.

We view our legal team as much a part of the business strategy as we do simply legal resources. That’s worked well for us.

In terms of interactions with the Board, we have a largely Australian Board, and they can be, from time to time, fairly operationally involved. There’s not necessarily a lot of direct linkage with the broader legal team, but as far as I’m concerned, my interactions with the Board are regular and consistent, and they’re quite interested in certain legal issues that come up on a regular basis.

JACK FRIEDMAN: Are there some differences that may be of interest to the global business community in the business and regulatory environment, values, or politics for a company that has its global headquarters in Australia?

GREG BOSS: That’s a twofold answer. From a strictly corporate oversight and Board governance perspective, the governance principles in Australia are largely the same as in the U.S. in terms of director responsibilities and liabilities. For directors, there’s a little more proactive director liability litigation in Australia, but it hasn’t risen to the class action level like you’ve seen in the U.S. There is a movement in Australia to adopt more of the U.S. class action standard, and directors are very concerned about that in Australia, but the governance principles are largely the same.

Since 90% of our operations and global revenue are driven outside of Australia in the northern hemisphere, we do operate consistently under U.S. and European governance standards. There are very strict FCPA, U.K. Bribery Act governance principles that we abide by. So we adopt a dual standard, where we recognize our Australian stock exchange principles and guidelines by which we operate the corporate company, but we consider global regulatory standards just as much.

JACK FRIEDMAN: You mentioned that you have plasma collection centers in different countries. Could you tell us about your research efforts, and how you work with other groups or universities?

GREG BOSS: As a scientifically based pharmaceutical company, we start with research, which is the driver of all of our future growth. In terms of plasma collection, we’ve done quite a bit of research in the collection of plasma, and the processes for plasma and identifying donors that minimize risk. This helps us collect the best types of plasma from the most productive donors. Then we use that to improve our manufacturing methodologies.

Most of our collected plasma comes from the U.S. The U.S. is the gold standard in plasma, so out of our 140 collection centers, more than 125 are in the U.S. We rely on U.S. plasma for most of our operations.

JACK FRIEDMAN: I would like to continue with the other speakers. Our next speaker is Kevin Arquit of Simpson Thacher.

KEVIN ARQUIT: Thank you. Greg, you started your remarks by saying, with characteristic modesty, you felt a little bit out of your comfort zone. After hearing you, I doubt there’s a single person in this room that believes that to be the case. But, frankly, that’s a phrase I’ve put on the sidelines for a little while, because the last time I heard it, it was Ryan Lochte explaining his activities in a men’s room in a Rio de Janeiro service station. [LAUGHTER]

But just real quick, working with Greg — and we’ve done it for years — is terrific. I know all of us up here would agree with it. You have General Counsels that come in all stripes, and you have clients that come with all levels of risk adversity. I do antitrust, and in antitrust matters, you’re going to have good days, and you’re going to have bad days. It’s just part of it. Greg demands absolute perfection in terms of result, but in getting there, he doesn’t have these ups and downs that I find so difficult. When the General Counsel gets caught up in the emotion of the executives that he or she is reporting to, and taking a lot of heat, it sometimes gets transferred down to the lawyers in the law firm. Greg somehow doesn’t do that, and he lets us do our job. As I say, there’s no allowance on compromising on quality, but to just be able to deal with somebody who is as even-keeled as that is just a huge, huge improvement, and it lets you get your job done.
With that, I’ll turn to my subject, which is to talk a little bit about how Washington looks at the pharmaceutical industry these days, in terms of antitrust enforcement. I’ve got about five, seven minutes here, so I’m going to be quick and limited. Antitrust basically breaks down into mergers and transactions on the one side, and then conduct on the other — things like price-fixing, division of territories, and agreements among competitors. I’m going to leave that off and talk about the transactional side in the time that I have.

If you stay in touch with the business publications, you certainly know that this is a very aggressive time in Washington. Consider the transactions that have been blocked recently — Halliburton–Baker Hughes, Comcast–Time Warner, Office Depot–Staples (although the government did allow, right before that, the Office Depot–Office Max transaction), and they go on. Now they’re challenging Anthem–Cigna, and they’re also challenging Aetna–Humana.

It will be really fun to watch this one that was announced the other day of Bayer acquiring Monsanto. I can’t imagine how long that’s going to go on for.

But in this environment, if you are number one and you want to merge with number two, you’re going to have some real issues with the government.

Now, that’s generally speaking. It is an almost historically aggressive time. Back in the sixties, the government used to challenge mergers basically just on concentration; it was that simple. Things have become much more advanced since then. The government relies on economic theory. They have to have a coherent story of how a transaction will result in market power which, for common purposes, means that the resulting entity will be so large that it will have market power. This gives the company the ability to raise prices above competitive levels, either by itself or in some sort of tacit coordination with other players in the industry.

But tough as it’s been for companies generally, for whatever reasons, the government is particularly aggressive in the pharmaceutical industry. Typically in a given year, there are between 1,500 and 2,000 transactions reports to the government. It’s called the HSR [Hart-Scott-Rodino] process. But the reason these transactions are reported before the merger is it gives the government a chance to get involved and to try to deal with something before it’s occurred. It’s not trying to be Humpty Dumpty after the egg has been cracked. Most large transactions are subject to this filing.

There are 1,500 to 2,000 transactions, typically, a year. In the last couple of years, it’s been increasing and getting higher. But of that number, about 6.6% of the total that are filed involve pharmaceutical companies — and this includes every industry: energy, entertainment, transportation, manufacturing, you name it. When you look at the actual enforcement actions that are brought by the government, just take 2015. Even though pharma is only 6% of the filings, over one-third of the challenges have been in the pharmaceutical industry. If you add medical devices to it, it’s 55%. Well over half of all transactions challenged by the government in the last year, and the trend has been moving this, is in pharma or pharma-related industries.

Now, when I say the government challenges a transaction, I don’t mean that it necessarily gets stopped; that means that they impose themselves into the transaction. If they don’t block it, they will force conditions, such as divestiture of assets that they think are overlapping and could lead to a competitive problem.

In 2016, they’re very active again. Just a couple days ago, they mentioned another matter involving Mylan where they’re going to have to divest a few businesses before they can continue on with their transaction.

Let me mention a couple of these very fast, so that you get the idea of what they’re doing. Usually, pharmaceutical mergers are ones that ultimately get through the government for the simple reason that pharma companies, large pharma, typically have a range of products. If you’re a one-product company and the government has a problem with it, your deal’s going to get blocked; there’s no fix. When you’ve got lots of different products, the government will come in and say, “On A, B, and C, we want to see a divestiture or some other relief, and if you do that, you can get on with the rest of your transaction.” Again, single-product companies don’t have that luxury. Even the other companies have to make a determination whether so many holes have been put in their transaction that what’s left is a piece of Swiss cheese and that it’s not worth doing.

But just to give what I think is the best example over the last year, would be the Teva–Allergan case. The government there picked out 79 overlaps of finished generic products, where they’re making the merging parties divest the assets of one of those businesses in order for the merger to continue. That’s why anything that’s ever happened before. They also manufacture the API, the active pharmaceutical ingredient, and they’re requiring them to enter into long-term agreements there, as well. But the point really is that that’s a huge number of divestitures to have to live with.
There are others, but there’s no reason to go into all those again, because our time is limited, although I’m glad to answer questions about any pharma merger over the last few years.

It’s one thing to challenge a merger when you’ve got an actual horizontal overlap. Remember, your concern is that the concentration or the market share of the remaining firm is going to be so high that it gives you power in the marketplace to behave anti-competitively. That you can raise prices or somehow otherwise injure consumers, lower quality, without the rest of the marketplace adequately disciplining you. It’s typically a market share analysis in the first instance.

Now, what the government has done recently is they have brought cases where the present market share of one of the parties, with respect to the product in question, is zero. You might say, “How can they do that? What’s the overlap?” In the pharma industry, it’s often easier than in other industries to tell where other people are in terms of their R&D, because of the pipeline at the FDA. The government has dusted off this doctrine known as “actual and potential competition.” They’re saying that if two parties are merging, and one of them makes the product as a dominant manufacturer and they’re buying a company that’s not presently making, or even gotten FDA clearance to supply the product, that if they’re going to start making it within the foreseeable future, we’re going to act like they’re a player in the market now, and they have forced divestitures on that basis. That’s what they did in Synergy–Steris, the number two and three sterilization companies. Basically, before pharmaceutical products go out, they have to be sterilized, and these are the two companies that do most of it.

But the problem was, Synergy isn’t even yet in the business of so-called gamma radiation, which is one method of sterilization. What the government said was, “We see what’s coming down the pipeline, and we think that within the next year, you’re going to get your product approved, and so you have to divest a business.” Now, think of the inconsistency here for a minute. If Synergy had entered the market two years ago and it had acquired a 1% share, the government would never challenge the transaction, because they’re actual competitors. A combination of any percentage with 1% isn’t going to get people’s attention. But here, where they haven’t entered the market, and they’ve got zero percent, the government says, “That’s potential competition; you’ve got to divest; you’ve to divest the assets of one of those companies.”

That’s a big development. But keep in mind that in all these cases I’ve talked about so far, what the government did was they pushed, pushed, pushed, and then they got a consent agreement with the companies, meaning that the companies agreed to these certain divestitures.

You don’t have to do that. The FTC and the DOJ are not the ones who are the final arbiters; federal courts do it. So if you want, you can say, “That’s just the same as a district attorney accusing a defendant of some action, the equivalent of an indictment, but we’re going to take you to court.” That’s exactly what has happened recently with the STERIS case. There was an earlier one where the government settled out with Pfizer–Hospira, a potential competition case, but the parties agreed to give up the assets.

In this case, with the sterilization, the companies said, “No, we’re not doing that. We haven’t gotten clearance for this, and frankly, we don’t know if we’d ever get clearance for it, so we’re taking you to court.” The FTC says, “Look, you are going to get in this market — we all know it — and the only reason you’re not entering it is that with the merger agreement having been announced, you no longer want to spend the money on developing this product that your buyer already has. As a result of that, your saving of money is going to keep an independent competitor from coming into the market, so, therefore, you’ve got to divest the technology.” They said, “No! That’s not what happened. For four months after this…}
merger was announced, we continued looking to develop the product, and the reason we didn't end up commercializing it has nothing to do with this merger; it has to do with the fact that it didn't meet our internal hurdle rates. We didn't have a single customer who had signed up to buy it, because we want that assured supply before we make those kinds of capital investments. It would have used up our entire discretionary budget for the year, had we gone forward with it. The FTC says, "Yes, we hear that, but you created all those documents after the merger was announced. Those have no credibility."

They took it to court. The judge said, "I don't even know if the potential competition doctrine is legitimate — the Supreme Court has dumped on it but never said it doesn't exist — but I'm going to assume, for purposes of argument, it exists. But you simply haven't shown that this company probably would have otherwise entered this market." The judge found against the FTC.

Now, I don't think it will stop them, because 90% of the cases are resolved through consent agreements, and the simple reason for it is the federal government holds the cards. When you're entering into a transaction, you have to worry about the possibility of other bidders. If your transaction drags out, because you've got antitrust risk, forget it — it's not a clean bid for the board of directors of the seller to look at.

Secondly, during that period of uncertainty, especially if you go to court, the sellers are hanging and drying. Their employees are leaving; the people out in the marketplace, maybe even the buying companies, are saying, "Why do you want to do business with them? They're not even going to exist here in another year; we're going to own them. Where are the guys you ought to be doing business with?" It's a terrible place for a seller to be. They can't let this stuff hang out there like that.

Then financing agreements fall through. As a result, most of the time, theoretically, companies have the ability to challenge this in federal court, but as a practical matter, they just can't do it. Particularly in the pharma industry, the government always knows they've got that leverage, but in the pharma industry, they can push and get divestitures of certain products, and still have the deal go through so that they don't take the hit when they've blocked a deal completely.

It's a difficult situation, and one that, as long as this kind of administration's policies continue, is going to be mean that pharma investigations are very complicated, because it's not just a question about price; it's a question about looking at pipelines, innovation, research, and all those things.

I do believe that the legal department at CSL is accountable to help the global organization live out its corporate values in an ethical and compliant way, in order to achieve sustainable success.

-- Greg Boss

In listening to Greg's opening remarks, I am reminded of something that he and his legal team impress upon us — their outside counsel — so often. While they expect us to provide terrific, tough, cost-effective advice and legal work, we must always remember that the ultimate purpose of our work is to help the patients who rely on CSL's therapies. When you're a litigator like I am, it's easy to think in terms of wins and losses or beating the other side. Certainly, we're all competitive. We like to win and do well, and we like to protect our clients' assets. But what Greg and the CSL legal team and management remind us is that good legal advice needs to solve the problem for both CSL and for its patients. For example, we once represented CSL in a significant dispute over the supply of an important therapy. As trial approached, we felt very confident that we would win, which would have led to a significant damages verdict. Then an opportunity presented in which the parties could resolve their differences via a new deal that would ensure a more dependable, long-term supply of therapies to patients. It was a very good legal and business result, and also a great outcome for patients who would benefit from a more dependable supply of these important therapies.

The lesson to remember is this: our clients' mission must become our own. For CSL, it's about solving problems for patients and it's something that underpins every representation we handle for them. It's a lesson we've taken to heart, and it's made us better lawyers. Thank you, Greg.

I'm a litigator and I do a lot of patent, licensing, and other IP litigation in the life sciences space. I am here this morning to talk about the intellectual property issues facing the life sciences industry. Now, I can't make up the story I am about to tell.
I wake up this morning, thinking about this discussion, and how to start my portion of it. And while I’m thinking, I grab my phone to scan the day’s headlines. At the top of the legal news is the following headline: “IP Fears Keep Life Sciences and Healthcare GCs Up at Night!”

GREG BOSS: I slept fine last night! [LAUGHTER]

ROBERT BARON: I thought for you it would be USC football that would keep you up at night!

GREG BOSS: Oh! [LAUGHTER]

ROBERT BARON: This headline is not really a surprise. Pharma is an innovation industry. Obviously, as Greg said, research and development is the key to creating new therapies, better therapies, better ways to make those therapies, and better ways to allow doctors and patient to determine when those therapies are needed. All of that involves IP. This is an always-changing legal regime, and it is not limited to one country. As Greg said, CSL serves patients around the world. They have facilities around the world. So you have to think about things globally — although obviously, the U.S. is a very big market.

Interestingly, in the U.S., as some of you may know, patent litigation is down, but not for the life sciences. In part, that’s because of generic litigation, which is now moving from Hatch-Waxman traditional pharma to the bio-similars. Also, there is more and more patent litigation between competitors — not branded vs. generic, but between different branded competitors in the same space. It might be in the district court. It might be via new administrative trials before an agency within the Patent Office called the “Patent Trial and Appeal Board,” which allows for very specialized and fast litigation procedures to challenge patents. The challenge may be before the ITC, or obviously in courts and tribunals in other countries.

It’s interesting that patent litigation is maintaining its pace in the pharma space. That’s going to continue.

There are a couple of trends I will point out, and I’ll speak broadly because I know there are a lot of other people with interesting things to say, and we want to get to a dialogue. In terms of the general trends we’re seeing, particularly in life sciences and patent litigation, patent litigation is down not because people got nicer or cared less about IP, but because the procedures have changed. The law has changed in two particularly important ways: One, there are more and more challenges before this Patent Trial and Appeal Board I mentioned, in actions called inter partes review proceedings. In these proceedings, a party can bring suit solely to seek a ruling that a patent is invalid. The advantage for a patent challenger is, first, that the burden required to show that a patent should be invalidated is lower than in district court. Second, these actions happen quickly, with final decisions rendered within 18 months. Third, discovery is limited, so the proceeding is more cost-effective than district court litigation. These proceedings have mostly been in the computer software space, but they are happening more and more in the pharma and biotech industry. We’re seeing competitors do it as part of pre-existing litigation, sometimes even before litigation, because they want to clear out patents they’re nervous about before the launch of a product. Sometimes we see it in new and bizarre ways in the life sciences industry, such as when hedge funds short-sell single-product pharma companies and then attack the patent surrounding the one product that pharma company provides, seeking to cash out on their short position. That’s certainly not about innovation and it’s not done for the patients, but that’s what is happening.

These procedures are much more effective at invalidating patents than doing it through the district courts. The industry is trying to get some reform, and the life sciences industry is trying to increase some of the standards to make that a little more challenging to do. But this new litigation is something that’s reducing the amount of patent litigation in the courts.

The other way the law has changed is that the Supreme Court has — in the last couple of years — really limited, as a gateway issue for district court judges, whether something is patentable at all, which used to really not be an issue that you’d litigate much. Parties sued for patent infringement are now winning early motions to dismiss the case on the grounds that the patent covers subject matter — like a law of nature or an abstract idea — that is not patentable. You see it both in the software industry and also more and more in the life sciences industry, particularly the diagnostics area, where things that were thought to be protected and highly invested in methods to diagnose genetic mutations that could relate to a disorder or a disease state, are being deemed laws of nature that aren’t patentable. Therefore, the methods to identify those correlations and treat them are sometimes found not patentable. We’ve seen this in litigation, and our team has been involved in a lot of those cases.

That’s bringing down the litigation, but it’s always going to be there, and it’s steady with life sciences.
JACK FRIEDMAN: Thank you. One of the overwhelming topics for decades in the litigation field is how the cost of litigation keeps increasing. Articles have been written for 20 years now about the cost of eDiscovery and new technology, with everything computerized. What is the chance of anything expediting business litigation, and reducing costs?

ROBERT BARON: It’s a good question. For a long time, one of the most expensive things about litigation — and not just patent litigation, but any kind of complex commercial litigation, or antitrust litigation — is dealing with the extensive amount of electronic information. What we call “eDiscovery” is what makes litigation so expensive. It really began in the nineties, when the business world began relying on email as the principal way to communicate. The vastness of the data — where it was kept and how to preserve it — was such a cumbersome process that judges who were, at that time, in their sixties and seventies and not familiar with eDiscovery, did not have a tolerant reaction to hearing, “We really didn’t mean to lose something. It’s just that we are in 60 countries and we bought 20 companies in the last 10 years, and it’s hard to know where all the servers are, and people come and go all the time.” The judges were thinking, “Isn’t it just a couple of boxes of documents?” They didn’t get it. There were some really bad decisions. I don’t think that they appreciated the cost, and the burden beyond cost, of collecting all of that electronic data.

For a company like CSL, where Greg and I have handled complex litigation, it’s a challenge to collect documents from people and custodians all over the world, because not only do you have to do that, you also have so many different privacy laws, for example, in Germany versus in the United States.

More recently, judges and the bench have begun to appreciate the dilemma, and their perspectives have changed. Also, at the end of 2015, the Federal Rules of Civil Procedure were amended specifically to deal with this issue. The amendments limited what is relevant and discoverable. They changed the rules so that sanctions needed to be connected to bad faith; and I think the judges now are starting to get it. What we’re seeing now is judges really trying to limit discovery, because they think it has taken over the trial process. No one is getting to a just result because of the enormity of the burden and cost to collect and review electronic evidence. Companies were deciding to settle cases, not on the merits, but because they didn’t want to pay to collect all the email. Judges are getting fed up with that, too.

So I do see a turn. As I said, there are also these Administrative Proceedings, these IPRs, and they have almost no discovery — very, very limited discovery. So it’s a relatively inexpensive way to invalidate a patent.

JACK FRIEDMAN: What choices are available to the General Counsel or outside counsel advising a company on email and social media policy?

GREG BOSS: It’s a factor of the real world; it is what it is. People say dumb things when they talk, when they send emails, when they write letters from time to time. It happens, and short of banning electronic communications, it’s just something you have to live with.

We try to counsel our workforce, but with 17,000 people, it’s difficult. We try to counsel them on the appropriate use of email and social media. We don’t try to hide content or anything like that, but you just have to train people to use discretion in how they communicate, just like you would for any other means. It’s just that in the electronic world, everything’s saved forever.

KEVIN ARQUIT: If someone says they had lunch with a competitor, you don’t like it, but it’s not the end of the world. Actually, there are procedures that the Justice Department has in antitrust if something rises to the level that it might be criminal, because cartels are
inherently unstable. They have a program, not because they like people to come in and rat, but it's their way of destabilizing a cartel. The first one who comes in and discloses that there's a conspiracy, that company can get complete amnesty, and they typically can keep the executives out of jail. If you're the second one, and even by 10 or 15 minutes, you don't get that same right. There are differing levels. The answer to the judge saying, “What did you do when you found this employee did this – did you take some decisive action?” you can’t just say, “This is a good guy or woman and they won’t do it again.” You really have to have a policy in place that you stick to. If you do, at least at the Justice Department level, when they go to prosecute, they take it into account. There are these so-called “sentencing factors,” and there’s an offset if you have a good compliance policy and you can establish that this wasn’t company policy.

JACK FRIEDMAN: What would be corrective action besides reprimanding someone for writing something that was adverse to the company?

KEVIN ARQUIT: If it’s substantively wrong, and you can prove that, you just deal with it with a reprimand or some other penalty. But if somebody did have lunch and they did raise the issue of prices, even if it didn’t get to the point of stabilizing it that can lead to a government action. You’ve got to do things like demote them, fire them or deny them their bonus. You’ve really got to show that you’re serious about it, because otherwise, the government won’t believe you’ve gone to all this work to have a great compliance program. You’ve done all this work to get people not to engage in this behavior. When somebody does, they can put the company at risk for hundreds of millions of dollars. You’ve got to use the person as an example so that other people understand you’re for real.

JACK FRIEDMAN: Thank you very much. Our next speaker is Stuart Langbein of Hogan Lovells.

STUART LANGBEIN: Good morning, everyone. Again, my name is Stuart Langbein; I’m a partner in the Health Group at Hogan Lovells, and Greg, we’re delighted to be participating in this achievement and recognition of you, which is very well earned. We also appreciate the ability to work with CSL Behring. Having worked with the company for decades now, we share the desire to facilitate getting products to patients. That’s what it’s all about, and we can’t play a direct role, but we like to think that we can facilitate, even in a very indirect role. So we appreciate that. If a mark of a person is the people that he or she leads, you should get full marks. We work with a number of people on your staff and have terrific relationships with them, and we really appreciate them. I’m not just saying that because you had the wisdom to hire someone from Hogan Lovells. [LAUGHTER]

I want to talk about a few of those, at least on the Medicare side. Costs – that big 29%, almost a third, if you can do lawyer math – that is what drives initiatives like in the President’s budget, reducing the potential to reduce payments for Medicare Part B drugs. Part B is a part of the program that pays for medical benefit drugs, not the prescriptions that you get from a drugstore, but even if it’s not a significant part of the pool. When you think about that amount of money, and you think about some of the PR headlines associated with the pharmaceutical industry for situations like EpiPen, for example, that makes those dollars a target.

Just to give you a little bit more of a sense of that $300 billion, about $250 billion is paid for by different insurers, and about $50 billion is paid out-of-pocket. So breaking that down a little bit further, about 43% of the prescription drug costs are paid by private insurers. That’s a lot of spend. But Medicare is also a significant amount. It’s about 29% of the dollars. That’s why you see a lot of movement on the Medicare side with regard to payments for prescription drugs. Medicaid and state healthcare programs represent about 9%. There are a lot of pressures.
Another area in the drug pricing space that is going to be more challenging for drug companies is this notion of transparency in prescription drug costs. There is a federal bill that was just put out there, and then a number of states have bills aimed at forcing manufacturers to be more transparent about how they’re setting prices and what the production costs are. That really has not been in the bailiwick of the Medicare program. They’ve always taken what the prices are; they’ve not really said, “We want an analysis of your production and research and development costs.” But that’s some of what’s being talked about now. Also transparency in price changes, especially price increases.

Another theme — I mentioned it in the Medicare space, but you see this a lot in the commercial spaces, as well is by the commercial payers, which I said has a significant chunk of the dollars for prescription drug costs. They’re looking for ways that they can shift drug costs both to manufacturers and to patients, to save themselves some money. That’s all about formularies and cost-sharing and tiering. Again, these are shifting landscapes that companies like CSL Behring have to deal with, whether bringing new products to market or just dealing with their existing products.

Those were just a couple of the things that I wanted to talk about. There are also, and we’ve seen this with CSL Behring, initiatives that the company wants to undertake to ensure that patients continue to have access. Especially for a company like CSL Behring, where you have patients — smaller populations — often with chronic conditions, with an absolute need for the product. The company, in different ways, tries to really facilitate that, but there are impacts of even trying to undertake those efforts. When you think about the pricing structures, there are a number of different federal programs that regulate and require reporting of pricing and rebates. What companies may do to ensure a certain population has access to products, maybe at a reduced price, can have ramifications for the government’s payments for other patient populations and the broader patient set.

It is a very complex minefield to deal with, and it’s not going to get any better. It’s going to get even more regulated. As Congress enacts statutes, one of the things that I’ve seen in my days is enactments are getting more quickly put together from Congress, leaving a lot more ambiguity, leaving a lot more room for the government to push their own agenda. That is also challenging for manufacturers.

I want to make sure that I’m leaving time for the other panelists here, so I’ll end there, but I’d be happy to take questions as we go along.

JACK FRIEDMAN: Greg?

GREG BOSS: My initial comment, briefly, on that, is that the government — especially in the U.S. — seems to be more of an activist regulator than anything else. That’s a little troubling from my perspective. That some of this legislation that gets put together hastily is addressed for activist reasons or to address a very narrow, one-off type issue or matter. They’re using it to tick the box for the next election. “Look what I’ve done. I’ve introduced this legislation which has no practical effect but it’s really coming down hard on the pharma companies.”

JACK FRIEDMAN: Congressman Oxley of Sarbanes-Oxley was asked why some of that legislation was well-crafted and thoughtful and other parts were disorganized. He said that he and Sarbanes had worked very carefully on the bill. But when Worldcom hit, the bill was being debated on the House floor. All of a sudden congressmen from both parties were running in to his office asking for amendments to introduce immediately.

What are some of the big issues now with implementing the Affordable Care Act?
STUART LANGBEIN: On that score, probably the biggest development will be the election result. If the Republicans take the White House, there will certainly be more of a move for a “repeal of the ACA.” Frankly, I think even those on the Republican side on the Hill have come to realize that there is no such thing as a total repeal of the Affordable Care Act (ACA). The reason is what happened as a result of the ACA, many individuals have received health insurance. If you scrap ACA altogether, what are you going to do with those patients? No one has a good answer to that question.

Republicans probably wouldn’t admit it, but they have practical hurdles getting to a repeal. What you will see if the Republicans take the White House is a scaling back. But they’re going to have to figure out how to scale it back. How are they going to pursue a real repeal or a semblance of a repeal? There isn’t a good mechanism in place yet, but it’s all about where do you want to take the issue. That hasn’t been developed yet.

What’s interesting to me is I don’t know if some of the insurance pullout from the exchanges is timed relevant to the election. It’s positioning and it’s setting a marker that isn’t more than a negotiating ploy, such as “we want better terms to stay in the exchanges,” and setting the marker for the next administration. Even if it’s a Democratic administration the position may be, “We expect that the exchanges will still be out there, but if you want us to participate, things have to change and we need improvements.”

Some of that may be levers; some of it may be political, displaying aggravation with the current administration. It’s an entirely political dynamic in addition to a business dynamic, but I think where it goes is going to be driven, in large part, by who the next president is.

JACK FRIEDMAN: I want to now turn to Jeff Barker, who is an Executive Director at Cushman & Wakefield. I asked him to talk about real estate assets and strategic decisions that the company might deal with at a Board and General Counsel level.

JEFF BARKER: As the only non-lawyer on this panel, I’m sure you’re as surprised as I was by the close 4–1 decision as to who gets to go last. [LAUGHTER]

First of all, on behalf of Cushman & Wakefield, we’d like to congratulate Greg Wakefield, who is an Executive Director here today. This dramatic growth has been most significant over the last couple of years thanks to strong leadership at CSL.

Since that initial lease in 1995, CSL has more than tripled their space in this marketplace, which further reinforces why we are here today. This dramatic growth has been most significant over the last couple of years thanks to strong leadership at CSL.

As Jack said, I thought I’d talk about the importance of strategic planning in real estate. Clearly, CSL has matched a very successful business strategy with a real estate strategy in order to accommodate the growth we just talked about. In order to build a real estate strategy, it’s important to adopt a process that aligns company goals with the real estate criteria so that we develop a repeatable framework for decision-making.

What is a strategy? Simply put, it’s an integrated externally oriented plan that guides how a business will achieve its objectives. There are a couple of steps to the process: set your objectives; reveal the actions required to achieve those objectives; and align employees’ resources against those actions.

In most industries we deal with, one of the core challenges is that real estate is a long-term commitment vs. the more short-term nature of business decisions. A strategy is essential to getting this right, but shockingly, by a recent survey by the Real Estate Executive Board revealed that only 18% of companies surveyed actually had a comprehensive real estate strategy. In this survey, 95% of the companies utilized an operating plan, which is not the same as a strategy. Typically an operating plan is more a set of broad goals without an underlying road map on how to achieve them.

We would suggest four steps in order to build a strategy. One, obviously define the company’s missions and goals. It’s important here that the stakeholders push their thinking to ensure that the full potential of the company both today and in the future are included in those goals.

Next, translate the goals into specific real estate criteria, such as cost — not that that’s ever impacted a real estate decision [LAUGHTER] — access to labor; access to clients; visibility; risk, as my friends to my right were talking about; transportation and workplace design. That’s a good example of what CSL went through just a few years ago, with the redo of their space: dramatic expansion and a complete renovation. Prior to that, I would describe your space as very traditional Pharma — large perimeter offices and large high-walled interior cubes. It was a beautiful, very expensive, gorgeous space — but they have now taken a very different approach.
We’ve seen companies go to a very high-density office environment, take people out of offices and move everybody into smaller workstations and call it “collaborative.” When it is actually more of a cost-saving approach.

CSL did something we felt was a little bit different. With a non-traditional approach, they eliminated perimeter offices, possibly reduced the size of offices, reduced the size of workstations but put them along the exterior, lowered walls and included standup desks. Instead of crunching or increasing the density, they basically changed how their people worked. Smaller individual workplaces but created more collaborative areas. They added a tremendous gym and a great cafeteria, and other collaboration areas. Their overall density didn’t change, but the work environment did. All the feedback we’ve heard is it’s been extremely well-received as opposed to just taking everybody and crunching them into a smaller space to achieve efficiencies.

Next, we have to weigh each of the criteria according to relative importance. This assures that current and future options are evaluated on what matters most to the company’s mission and not subject to bias and preconceptions.

Make decisions based on a transparent, quantitative, and qualitative analysis. This ensures that the merits of any scenario can be examined using a comprehensive set of criteria.

In summary, an effective real estate strategy must adopt to changing internal and external forces. As previously noted, the nature of our business is long-term vs. the more short-term business cycles.

A properly developed strategy ensures its survival by allowing new criteria to be evaluated using the same goal and criteria that were in the weighting framework. The strength of a strategy in the face of potentially sensitive and contentious matters is its defensible, informed, data-supported decision-making process.

The influence on real estate on a company’s success is often underestimated and misunderstood. Historically, real estate — considering the significance of it to your employees and bottom line — is often relegated to a secondary position. However, we think it’s an incredible opportunity to recast real estate as an important foundation of a company’s success by instituting the strategy we discussed. Companies that invest in the upfront time and energy, along with the proper framework, will get results in cost-savings; improved employee experience, as we’ve seen at CSL; long-term ability to better compete, adapt, and ultimately thrive.

JACK FRIEDMAN: Thank you very much. [APPLAUSE]

GREG BOSS: Just a comment. At CSL, we’ve thrown several strategies at Jeff over the years. The first was to reduce the amount of space into one building, and we crammed ourselves into one. Just as we did that, we told him, “We’re going to start expanding at 10% per year, so start growing our space.” It was a little schizophrenic for us, but it’s worked out.

I wanted to emphasize the employee part of a strategy, because we’re trying to attract a younger workforce, and they value things like gyms and common areas, open space and collaborative space. It is really important. We’ve expanded in King of Prussia; we’ve expanded in the New Jersey area; we’re expanding in Boston. All of those are very different markets in terms of the labor pool that we’re trying to attract. It’s very important what your employees want.
On our plasma collection side, we’re expanding by 20 new centers every year on average. Where we locate those centers is a very strategic decision, because it’s essentially the foundation for the supply of our most important raw material. It’s more than just where we can put up a quick collection center. We look at demographics, and although it’s not a retail business, we look at retail demographics, to make sure that where we put a center is going to give us the best amount of plasma collection capabilities that we can possibly have, because that’s really important to sustainability for our business.

JACK FRIEDMAN: Do you pay people for plasma?

GREG BOSS: Yes, it depends. In Australia, we have plasma donations that are associated with the Australian Red Cross. In the U.S., we do compensate people for their time. Our plasma donors are an integral part of our business, and we believe we’ve developed a very close working relationship with them. They come to us, we give them compensation for their time, and they come back time and time again.

JACK FRIEDMAN: Can people pay to store their own plasma?

GREG BOSS: We store it! [LAUGHTER]

If they stored it, as you can imagine, we wouldn’t simply buy a bag of plasma off the street from someone! [LAUGHTER]

JACK FRIEDMAN: You have a very important, intimate product that you’re dealing with, that has to do with the body. How do you make sure it’s pure?

GREG BOSS: There are very strict guidelines in terms of the collection process and the storage requirements. When we collect plasma, there are FDA guidelines that are very strict in terms of how we do that and what we do with the plasma after. Referring to the “intimate” part, yes, we feel as close to our plasma donors as we do to our patients. They’re really a part of the family.

JACK FRIEDMAN: I would like to invite the audience to ask any questions they may have. Here is someone with a question.

[AUDIENCE MEMBER]: I have a question for Mr. Arquit. In the tons of mergers, why are there so many consents and reports of actions in pharma as opposed to all the other industries? What is the FTC’s track record on pharma consents?

KEVIN ARQUIT: What do you mean by track record?

[AUDIENCE MEMBER]: Have they been successful?

KEVIN ARQUIT: Typically, the consents are more likely to be worthwhile in circumstances where an entire business is transferred. A lot of time in the pharma area, the buyer of the assets will have some of the assets already for other operations they’re already engaged in — whether it’s manufacturing the capsule or some other part that applies — and there are economies of scope, so that the buyer, to the extent that they can integrate that equipment to take the new active ingredient they’re buying and turn it into a tablet, can be very successful.

But I think that the reason that there are so many more pharma consents is because people will enter into transactions where they know that with some of the products, it may be a 2:1 that would normally be challenged, but they go into it knowing that they’re going to have to divest those, but realizing that sometimes you can go into the government right at the very outset and say, “To get this done quicker, we’re willing to give up A, B and C businesses,” and you hope that government stops there and you don’t have to keep going.

The pharma consents can be more collaborative when people are realistic about what they’re going to have to give up and they don’t fight it. We’ve worked on things with supermarkets and so on, where the gray line about which regions you have to give them up in is grayer; but if you go in, even in those kinds of things, and say, “These are the things we have to give up,” and even look for the buyers ahead of time, you save yourself a lot of time. But in single-product companies, it’s all or nothing. Then there are the deals that I don’t know why they get tried. I mean, NASDAQ and the New York Stock Exchange — what were they thinking? Or AT&T–T-Mobile. I don’t know who would advise them; I don’t know if anybody advised them. But there’s just no chance. I don’t understand how these were the subject of arbitrage-kind of buys and sells, because you can take an intro course in Antitrust and you know these things aren’t going through. But I think a lot of it is CEO or top management-driven, and boards that just think everybody else is subject to something that they’re not, so they try things that are really impossible at the outset. That’s why it’s important to have a good General Counsel — because a lot of people’s incentives are to announce and do these deals, right? The outside professionals are going to make money; there’s a chance the company’s going to get a lot of positive press about it; and lots of good reasons. But you’ve got to think through how the
customers are going to react; how other transactions in this space are going forward. You’ve got to look at the whole picture before you make these determinations.

I must say these couple that were announced in the last few days, given the climate in Washington, I don’t know what to think. Halliburton–Baker Hughes is another one. With the number of overlapping products, entry is impossible to get into — oil infrastructure, wells — I mean, who’s going to enter that? You’re going from two to one? I mean, who possibly thinks these deals are going to get through? But they do, and they sit around for a year and a half; people, the service providers, make a lot of money, and then they abandon them and the CEO makes some comment about the unreasonableness of the public servants in Washington. They can be plenty unreasonable, but I’m just saying in those deals, those are not examples of them.

JACK FRIEDMAN: Isn’t one of the things that a GC will do to help the management people who may not understand the implications of some decision, is to bring in a second opinion, like one of the expert law firms?

GREG BOSS: Yes, obviously we do get external second opinions in any significant transaction. We have done that, but I’ve been fortunate at CSL in being able to provide external advice directly to management and to the Board, and at least I’ve had enough credibility that they’ve relied on me and not necessarily directly on external counsel so much.

We haven’t had the requirement to actually bring in external counsel as a validation, if you will. We’ve got a pretty collaborative and interactive management team and we just haven’t had to go that far.

KEVIN ARQUIT: Jack, in our world, first of all, there is a false empiricism to it. The decision can be as arbitrary as which group within the agency gets the transaction. The other thing is a lot of law firms that do this regularly won’t take on the work of the second opinion. They’re annoyed they weren’t hired to do the primary work, and for $30 or $40,000, they’re not going to put the firm’s name on the line about whether a deal’s going to get through or not. I’m not saying it should be that way; I’m just saying that there’s a certain hubris that keeps some from doing that.

JACK FRIEDMAN: We had a speaker say this really happens. Someone will walk in and say, “I was told to come to you before we launch a major website for a new product line.” And he said, “When are you launching?” The guy says, “In an hour.”

GREG BOSS: Yes, obviously that happens; I don’t think anyone in this room, at least from the legal perspective, hasn’t had somebody come to them and say, “By the way, we need an answer in an hour.” Generally at CSL, we have established a very positive collaborative working relationship between our legal teams and the business, but the scenario you described does occur from time to time, where people don’t think about what they’re doing. We had a deal last year where it was a licensing transaction, and we were ready to sign, and all of a sudden — and this was an exclusive IP license — someone says, “What about the HSR [Hart-Scott-Rodino] filing? How are we going to deal with that?” Nobody had come to a legal person to talk about that until the deal was basically ready to sign.

Those are one-offs. It happens and it is unfortunate. We try to manage it, but it certainly happens.

JACK FRIEDMAN: If you have a climate of cooperation, you must really work hard to explain that lawyers are their friends.

GREG BOSS: We’re working on it! That’s one of the reasons we have tried to go, at CSL, at least partially into global functional legal support teams, so there’s more alignment with core global functions and legal teams. When there are cross-border transactions, it’s not somebody in the U.S. trying to deal with a German issue or something like that.

JACK FRIEDMAN: Thank you.

ROBERT BARON: Just to add quickly, Greg has been good at teaching his internal and external counsel the importance
of talking straight and talking like a business partner. Greg reminds us that we are talking to busy people, so speak straight; speak plain; don’t speak in jargon; and if it’s not a dead-stop “no,” explain the problem in terms of risk profile. Don’t give clients an octopus’ set of choices. Just say, “Yes, you can do that, but it’s high-risk, and these are the consequences that you have to weigh.” That’s something a businessperson can appreciate, because it’s translated into a risk profile which, in some way, is what the business person is doing all the time.

The team here at Ballard has learned a lot from Greg and his team. That kind of lesson reminds us day-to-day, to speak plainly.

JACK FRIEDMAN: I have a question for Stuart. One of the similar barriers is that a lot of businesspeople would think, “The government, those regulators, are stupid, or bad, or they’re politicians and we don’t like them; we don’t want to listen to them.” I’d assume that you have also the problem of trying to educate clients to be understanding of the regulator point of view.

STUART LANGBEIN: Yes, that’s exactly right. In the healthcare space, we have a number of clients who really underestimate the perceptiveness and the level of knowledge about the industry that the government officials have. One of the things that we try to bring to our clients is an understanding of the perspective that the government regulators will have on a certain issue. I worked for the Centers for Medicare and Medicaid Services; a number of my colleagues have worked in the General Counsel’s Office for the Department of Health & Human Services. One of the things, both from that experience and then dealing with these programs for years, if you’re attuned to it, you can start to figure out why they’re looking at it a certain way; why they’re not going to be really interested in doing what a company may be asking. But then — and this was mentioned earlier — you want to understand, in advising a client, what’s their goal; what are they trying to pursue — because there may be other ways that you can shift the dialogue somewhat so that it’ll be more in the bailiwick of what a regulator can be comfortable with.

Yes, if you assume that they don’t know anything, that’s a recipe for disaster. Whether it’s the company or you acting on behalf of the company, you’re not going to be a good advocate for your client’s position. That’s a very important thing.

I’ve been doing this for longer than I ever thought I would, but it takes time to develop that understanding. We work with a lot of associates coming up and one of the things that I try and emphasize is to be aware of not just what the regulation or what the law says, but, “What’s the underlying policy?” What is the government trying to achieve? If you’re thinking about that as you’re dealing with issues, that’s going to enhance your knowledge base and help you think a little bit more like the regulator is thinking, and help you develop a better advocacy strategy, whether for that issue or going forward.

JACK FRIEDMAN: Any other questions from the audience now?

[AUDIENCE MEMBER]: What are some of the ethical issues involved at the corporate level for deciding what medical conditions to go after in terms of research and dissemination, especially where the profit motive has to be a consideration, but other factors might also warrant attention?

GREG BOSS: Each company may address that differently. At CSL, as I mentioned, we’re driven by human need or our patients’ needs. If there is a market for something, whether it’s a large market or a small market, and we have the capability, science, and expertise, it’s an area that will be considered. Certainly, there are always competing strengths in an R&D portfolio. We have a number of competing strong products, and it’s more about our capabilities for delivering a successful product to the market than it is necessarily about profit, although I won’t disagree that you can’t launch something that’s not profitable. It won’t be sustainable.

But certainly, our initial motivation is determining human need or patient need, and then economics is a second.

Recently, we have collaborated on an Ebola virus research product that won’t ever generate any economic return for us, but we felt it was
our obligation to contribute to that research spearheaded by the Gates Foundation. We don’t know whether there will ever be a profitable market for that, but we did contribute some of our capabilities to that research, just because it was a good, ethical obligation.

Some of the other ethical issues we face, which may not necessarily be in the research area, are the areas to which we deliver product? We believe we have a global obligation to deliver product to those in need. Sometimes that means delivering product into either dangerous regions or into regions where there might be U.S. sanctions. We have to get appropriate licenses from the U.S. government in order to deliver product into those regions.

Again, it’s part of our obligation as a global pharmaceutical company to deliver product where it is needed, and whether it’s in a dangerous region or whether there needs to be some extra regulatory hurdles that consume time, energy and resources in order to do it. We do believe that there is that commitment at CSL to deliver.

JACK FRIEDMAN: Thank you. Jeff, we talked about at the board level, when companies are dealing with assets like real estate. What are types of people in large companies that you work with?

JEFF BARKER: It’s really driven by the size of the company. A very large company will have a dedicated real estate department. In many cases, on the outsourcing mode, companies like Cushman & Wakefield will have a head of real estate. We’ll have people who are in their offices that are in charge of transactional management people who will run real estate for them as third-party providers. As you get smaller, different-sized companies, it falls to very different people. At one point, when we first started working with Greg, you really were running the real estate, back in 2004.

GREG BOSS: I was the one that had to downsize everything into one building. [LAUGHTER]

JEFF BARKER: Now they’ve been growing rapidly, they give it to somebody else because it’s more fun to do it now!

JACK FRIEDMAN: I’d like to thank Greg for honoring us by spending his time with us and letting us have you as our guest. Thank you very much.
Robert Baron is a partner in the Litigation and Intellectual Property Departments, and the former Vice Chair of the Intellectual Property Department. He prosecutes and defends cases at the trial and appellate levels involving patent, copyright, trademark, and trade dress infringement; the theft of trade secrets; breaches of contract; licensing disputes; the breakdown of commercial acquisitions and related investments; unfair competition; partnership disputes; and business terminations.

Mr. Baron has litigated and tried cases, including injunction actions, before state and federal courts and arbitration panels throughout the country. He represents pharmaceutical and biotech companies, software developers, chemical companies, financial institutions, manufacturers, aerospace companies, publishers, universities, retailers, franchise systems and distributors, accounting firms, real estate funds and partnerships, and charitable organizations.

Chambers USA: America’s Leading Lawyers for Business, a directory built primarily on client and peer interviews, has named Mr. Baron a leader in the field of intellectual property law every year since 2012. Chambers notes that clients praise Mr. Baron as a “brilliant strategist who anticipates future issues and navigates around them.” IAM Patent 1000–The World’s Leading Patent Professionals, one of the world’s most extensive guides to leading private practice patent professionals, has ranked him as a leading patent litigator annually since 2013, citing him as an “extraordinarily successful litigator.” In addition, Managing Intellectual Property magazine recognizes him as one of the “IP Stars” in Pennsylvania since 2013, this year referencing both his patent and trademark work for clients. He also has been named a “Pennsylvania Super Lawyer” from 2004 through 2016 for both Intellectual Property and Business Litigation.

Mr. Baron served as the Chair of the Business Litigation Committee of the Philadelphia Bar Association. He serves as a Judge Pro Tem for the Commerce Litigation Division of the Philadelphia County Court of Common Pleas to assist the court when asked in the management of settlement discussions and mediations.

Mr. Baron writes and speaks nationally on a variety of intellectual property and litigation topics. In addition, he is active in his community, serving on the boards of a number of nonprofit organizations.

Ballard Spahr LLP is a national firm of more than 500 lawyers in 14 offices across the country. Our attorneys provide counseling and advocacy in more than 40 areas within intellectual property, litigation, business and finance, real estate, and public finance. We represent a diverse cross-section of clients that range from large public companies and privately held corporations to government agencies and nonprofit organizations. Our practices span the life sciences and technology, energy, health care, and other sectors that are driving innovation and growth in today’s marketplace.

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Stuart Langbein brings a passion for healthcare to his office each day. He is renowned for his leadership in facilitating the market viability of new medical technologies, and knows how to develop and implement strategies that secure their coverage, coding, and reimbursement.

When clients work with Stuart, they quickly learn about the importance of being proactive. That’s especially critical for organizations with new medical technologies; Stuart is often advising them long before they’re granted Food and Drug Administration approval.

Stuart routinely works with a cross-section of medical technology organizations, including pharmaceutical, biological, and medical device companies; trade associations, and academic medical centers. He continues to build on his prior experience at the Centers for Medicare & Medicaid Services, as well as on his long-term relationships with many agency officials.

Stuart is a longstanding volunteer for the JDRF, an international organization focused on a cure for diabetes. He coordinates the Hogan Lovells Walk to Cure Diabetes team, and works on national government advocacy issues related to diabetes.

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Kevin Arquit is regularly recognized as one of the world’s top antitrust attorneys. In 2015, he was one of 50 lawyers named to the “Lawdragon 500: The Legends” list for being recognized on the Lawdragon 500 Leading Lawyers in America list each of the ten years it has been published (2005–2015). Lawdragon wrote that Kevin is “One of the most accomplished antitrust lawyers ever, and a model for public service and professionalism.” For the past eight years, he has consistently been ranked by Chambers USA and Chambers Global as a leading lawyer in his field and “one of the great antitrust lawyers in the country.” The Legal 500 recently named him a leading practitioner in his field for the eighth consecutive year (2007–2014). The 2013 and 2014 editions of Euromoney’s Benchmark Litigation identified him as a “Litigation Star” both nationally and locally, in New York, for antitrust litigation. Law360 has named him on its list of the “10 Most Admired Competition Attorneys.” In March 2010, he was named by the National Law Journal as one of the “Decade’s Most Influential Lawyers,” a list of 40 attorneys selected by the editors for legal work considered influential for pushing the profession, industry or practice area substantially forward. In 2012, and previously in 2008, he was named on The BTI “Client Service All-Star Team for Law Firms.” He received the inaugural award for “The Chambers Shield of Excellence for Antitrust” in 2006 and similarly the “Global Competition Lawyer of the Year” by The International Who’s Who of Business Lawyers. Kevin has been ranked among the Chambers Global list of “Global 100 Lawyers.” Both PLC Competition Law and Global Counsel 3000 have also rated him as the leading individual competition/antitrust lawyer in New York. In 2014, The American Lawyer named Simpson Thacher the “Antitrust Litigation Department of the Year,” the first year it recognized firms in this category.

Kevin is Chairman of the Board of GenerationOn, a nonprofit organization dedicated to service learning among children. He is also on the Board of the Points of Light Foundation and the Board of the United States Ski and Snowboard Foundation (U.S. Ski Team).

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Since joining Cushman & Wakefield in 1979, Jeffrey W. Barker has been responsible for commercial office leasing and land sales in the suburban Philadelphia marketplace. He has developed extensive experience in both exclusive tenant and agency representation, including involvement in several of the largest exclusive tenant representation and land acquisition assignments completed in the Philadelphia area. He has been responsible for leasing and sales in the Delaware Valley in excess of 6,000,000 square feet since 1995.

Some of the major transactions in which he has been involved include the sale of a 1,200,000 square foot headquarters and centralized research facility on 300 acres for Aventis Pharmaceuticals; 260,000 square foot lease to The Hartford Fire Insurance Company on behalf of Argent Ventures; a 125,000 square foot build-to-suit for XL America; a 112,000 square foot lease to Astra-Merck on behalf of a major Pennsylvania based Pension Fund, a 200,000 square foot lease for CSL Behring; 240,000 square feet of leases and 170,000 square feet of sales for The Manufacturers Life Insurance Company of Canada; 80,000 square feet of leases and a 311 acre land sale for Pfizer, Inc.; 225,000 square feet of leases and an 160 acre land sale to Sterling Drug, Inc., for a 1 million square foot centralized research center; and numerous other assignments for clients such as Ceridian Corporation, Pharmanet, and Hewlett-Packard Company.

Community Leadership
In addition to involvement in the Pennsylvania and Philadelphia Board of Realtors, he has served on the Board of Directors for the Philadelphia Scholastic Rowing Association, the Planned Giving Committee of St. Joseph’s Preparatory School, is a former volunteer at The Children’s Hospital of Philadelphia, and former Secretary for the Board of Education of St. Margaret’s School, as well as the athletic director for the St. Margaret Youth Ministry CYO. He currently serves on the Handmaids of the Sacred Hearts of Jesus Board and he has traveled to El Salvador nine times with Project FIAT.

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