GC
LEADERSHIP SERIES

# the evolving role of GENERAL COUNSEL

## Leadership in Challenging Times

A Roundtable Discussion

Keynote Speaker:

**Rupert Bondy**

Senior Vice President and General Counsel,
GlaxoSmithKline PLC

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# the PANELISTS

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*Partner, General Counsel, King & Spalding*

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*Partner, Dechert LLP*

**George S. Cary**
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**Arthur Makadon**
*Partner, Chairman, Ballard Spahr Andrews & Ingersoll, LLP*

**Jack Friedman**
*Moderator, Chairman, Directors Roundtable*

# TO THE READER:

The global Life Sciences industry has spawned medical advances that have saved or significantly improved the quality of countless lives. In the past, the world's poorest had no access or, at best, had to wait for the generic equivalent post-patent expiration. Thankfully, name brand drug innovators are making these patented medicines available to those who could otherwise not afford them through the WHO and other international assistance groups. This benevolence is only feasible when drug patents are honored and drug innovators are afforded the opportunity to recover the considerable research and development costs necessary to create them. Factor in competition, generic encroachment and an increasingly litigious corporate and consumer environment, and the business model which fosters these drug innovations is threatened.

In this, our most recent installment of the *GC Leadership Series*, we were honored to host a lively discussion featuring Rupert Bondy, Vice President and General Counsel of GlaxoSmithKline. Mr. Bondy's insights into the challenges faced by Pharmaceutical companies with respect to matters such as complying with multi-jurisdictional regulatory schema, protecting intellectual property in the wake of the Hatch Waxman Act, responding to negative public relations, and efficiently managing a large multinational legal function, were fascinating.

Also joining our panel was Chilton Varner, Esq., a partner at King & Spalding LLP, who focused on evolving tort liability. Next we heard from Steve Feirson, Esq. a partner at Dechert, LLP, who discussed securities class actions within the Life Sciences industry. Mr. Feirson was followed by George Cary, Esq., a partner at Cleary Gottlieb Steen & Hamilton, who had some very interesting comments on the intersection between Patent and Antitrust law. Finally, we heard from Arthur Makadon, Esq., Chairman of Ballard Spahr Andrews & Ingersoll, LLP who instead of covering a specific practice area, underscored the importance of choosing the right counsel — especially when faced with a Grand Jury subpoena.

Conducting business on a global scale challenges Directors, Officers and General Counsel to be knowledgeable of and comply with multiple legal and regulatory environments that are complex, and all too often conflicting or totally contradictory — making the role of General Counsel and the law firms that service them more critical than ever. We were fortunate to have the opportunity to spend time with all of our panelists. We learned a great deal from each of them — and trust you will too.

*—Brian Corrigan, Esq*
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***The National Law Journal***, an ALM publication, in partnership with **The Directors Roundtable**, a civic group which organizes events globally on issues relevant to corporate directors and their advisors, is pleased to present the latest in our **GC LEADERSHIP SERIES** examining the evolving role of General Counsel. We recently assembled several top attorneys who are counsel to multinational companies and invited them to comment on the legal challenges inherent in Global Business Ventures.

The text of the panelists' comments, edited for clarity and brevity, follows. The views expressed are those of the Roundtable participants and not necessarily the views of their firms or companies.

The Roundtable Discussion — held September 19, 2006 at The Union League Club in Philadelphia — was co-hosted by the marketing department of *The National Law Journal* and *The Directors Roundtable*. This custom publication is included as a special supplement to *The National Law Journal* and was produced independent of the *NLJ's* editorial staff.

***MR. FRIEDMAN:*** This morning we have four distinguished law firms represented. One partner from each firm will make a brief presentation about a topic that they specialize in. Then Mr. Bondy will speak.

Our first speaker is Chilton Davis Varner of King & Spalding. And without further ado, I'll just let her get started. Thank you.

***MS. VARNER:*** Thanks, Jack. I'm going to be talking this morning about tort liability, more commonly known as product liability. I think it was once a relative back-water of corporate law, but that's no longer the case. There are a number of reasons why. First, as recently as 1985, product liability was a courtroom affair, played out within the confines of the courthouse. Now it is being played out on many different playing fields. Examples: Product liability can affect regulatory affairs including the ability to sell your product to the government. It can affect media coverage, which can expand the number of cases there are and enhance the damages in those that are already filed. Congressional investigations can and sometimes do follow product liability claims. And Wall Street and stock price can be affected and sometimes intentionally manipulated by product liability claims. The bottom line of all of this is that corporate reputation can be tarnished and that is something taken very seriously in the board room.

Trend number two: Product liability litigation used to come in ones and twos. That, too, is no longer true. Plaintiffs have discovered the power of numbers. Nowhere is this proposition more dramatically illustrated than in the industry in which Rupert Bondy earns his living, the pharmaceutical industry. Remember that drugs were among the very last products to be swept up in design defect litigation. Until well into the 1980s most courts accepted the proposition that pharmaceutical drugs carried with them unavoidable side affects and they were reluctant to get into redoing the difficult weighing of risks and benefits that had already been done by the FDA. Well, that era is over.

Listen to these numbers, because I think they are striking in their illustration of this trend. In 2001 there were two point seven thousand product liability filings against pharma companies in federal court. In 2002 that rose to nine point five thousand; 2003, thirteen point three thousand; 2004, twenty-two point four thousand; and in 2005, a little daylight, with a slight dip to only seventeen thousand filings in federal court.

Now, those numbers are not cumulative, they are annual. So over a five year period the defense of an additional sixty five thousand pharmaceutical product liability filings was required. And that's only in federal court; the numbers are larger in state courts. So product liability certainly is no longer a "one off" affair. The name of the game is the aggregation of sufficient claims to acquire greater leverage.

Trend number three: Money talks. Major mass tort settlements in asbestos, Fen-Phen, and tobacco have funded additional litigation. Twenty years ago plaintiffs complained they needed special treatment and special dispensation in order to stay on the playing field with deep pocket corporate defendants. In fact, that hypothesis was one of the great drivers for the revolution in tort liability that produced so-called strict liability with lower evidentiary burdens for the plaintiff. Now plaintiffs have what Dickie Scruggs, one of the most well-known plaintiff's lawyers, calls, euphemistically, "staying power." That really is a euphemism for cash. That means, these days, power. Power in judicial elections, power in the courtroom, power in politics, including funding efforts against tort reform.

Trend number four: Discovery is a serious business

in tort liability. Individual plaintiffs ordinarily have very little to turn over in response to discovery requests. They have their medical records, for example in pharmaceutical cases, and in states where such evidence is admissible they can produce evidence of lost wages. But beyond that, there is often little else they have to produce.

Corporate defendants are quite different. They have filing cabinets and archives of documents. It's the way they communicate with each other within the corporation. So whereas in corporate business litigation there is the constraint of "whatever burdens you can impose on me in discovery I can impose the same on you," that constraint is notably absent in the tort liability field where discovery is, as one federal judge has termed it, "one way" discovery.

Trend number five: Networking connects. In product liability it seems the whole has been proven to be greater than the sum of its parts. In the 1980s, plaintiff's lawyers were known to have breast-beating competitions about who could get the biggest verdict and who could establish the biggest reputation. They now recognize the even greater value of sharing their information in clearing houses for deposition and trial testimony, documents, outlines of examination. Even trial-in-a-box packages are available for sale.

Trend number six: We are not immune from the effect of corporate scandals. Do not misunderstand me, corporations have never been particularly beloved by jurors. It's a little hard to fling your arms around something that's been referred to as a legal fiction. But current research shows that distrust has escalated in the wake of Enron, and Tyco, and Worldcom. And in product liability cases that sort of corporate distrust can be stimulated by a very sympathetic plaintiff.

I'll close with two "good news" trends. The first is that the Supreme Court's decision in *Daubert* has, in fact, brought scientific discourse in the courtroom much closer to that in the laboratory. The United States Supreme Court said in 1993 that before an expert's opinions could be brought to the jury, a judge would have to make a preliminary determination of their scientific reliability. If the judge determines that there is no scientifically reliable basis for that testimony, the judge may exclude the plaintiff's expert and normally the plaintiff will be unable to make his or her case. *Daubert* has been a great victory for good science. It also has been helpful to the defense of defendants who have scientific and technical defenses.

Trend number eight: More good news. We're going to talk now about a different trend line from that of pharmaceutical filings. Since the State Farm decision was handed down by the Supreme Court in 2003 saying that punitive damages needed to bear a reasonable relationship to compensatory damages, the trend line in damages awards has reversed. In 2002, the 100 largest verdicts, as reported by the National Law Journal, totaled 41 billion dollars. And those verdicts were driven by punitive damages. Then came State Farm and the trend line reversed, compared with that high water mark of forty one billion in 2002. The total one hundred biggest verdicts in 2003 were twenty billion; in 2004 eleven billion; and only (if one can say "only" before a word that starts with a B) eight point two billion dollars in 2005.

All of these trends mean that the stakes in tort liability are high indeed. The presence of tort liability on corporate board agendas is certainly justified. And we'll be talking as we go along about some practical pointers. But for now, I'll give it back to Jack.

***MR. FRIEDMAN:*** Thank you very much. Now I'd like to introduce Steve Feirson of Dechert.

***MR. FEIRSON:*** Thank you. I'm going to give you the

headline news version of securities class action litigation as it applies to the life science industry. It is and has been a growth industry over the last few years. The number of securities class action filings against life science companies is up one hundred percent in the past four years. When you take a look at why that is and why the filings against life science companies are currently occupying an ever larger percentage of the overall securities class action filings, you see a couple of things. One is that life science companies live in a highly regulated environment. For many years that regulation was used effectively by life science companies as a defense, in essence, relying upon the protection of the FDA or relevant state agency. It's now turned around to a large extent. In any instance when a life science company now runs into a problem with one of the regulatory agencies, there is potential for a securities class action litigation.

Back in 2004, the SEC and the FDA got together and reached an agreement to share information. In essence, what that has meant is that anytime the FDA sees a problem they pick up the phone and call the SEC and say hey, why don't you guys take a look at this, we think there is a problem. And, as a result of that, there has been increased SEC scrutiny. By far, the bigger factors are the sort of unique aspects of being in the life science business, especially in the pharmaceutical business. As Chilton pointed out, for a long time there was a notion in the courts that it was a tough business, that there were inherent risks in the products, and that the companies ought not to be punished if their products produced some side effects or didn't live up to expectations. Those days, as Chilton pointed out, are past, and they are past not only in the product liability area but in the securities area and I'll talk a little more about that later.

The other factor is that in the last couple of years, as the plaintiff's bar in the mass tort area is better and better funded, they have begun to share information and enter into other types of cooperative agreements with the plaintiffs' securities bar. And, as a result of that, what you see today in securities class action filings are much more detailed, much more colorful complaints. In the old days, what you would see, basically, was the run of the mill, typical out of the box, complaint which was very conclusory, had very generalized allegations, all of which made that particular complaint a much better target for an early motion to dismiss. Now, what you see are complaints that are complete with, quote, gory details, unquote, which the plaintiff's securities bar has gathered from the plaintiffs' mass tort bar, thus making it significantly more difficult to get rid of those complaints at an early stage.

What are the trends? Generally in the industry, as I mentioned, securities class action litigation against life science companies is up. And it's up even though securities litigation in 2005 in general was down. The number of class action cases — securities class action cases in 2005 generally was down about twenty-three percent. In the life science arena, it was up almost twenty percent.

Another trend is that large cap life science companies are increasingly targets for the plaintiff's securities bar. For a long time what you saw was that overwhelming majority of securities class action cases were filed against, for lack of a better phrase, start-up companies; companies that had one product in development, that certain statements had been made during the course of the clinical trials, or sometimes even before that, that wound up being overly optimistic. That's generally what you saw. That's not the case any longer. In 2005, twenty-five percent of the securities class action filings in the life science area were against life science companies that had market caps exceeding five billion dollars as compared to fifteen percent in '03.

An additional trend is you see more and more filings with respect to established products. Again, before you had incipient products which wound up being the trigger for these class action cases. Now, more established products, sometimes blockbuster products, wind up being the triggering event for massive class action securities litigation.

You are also seeing more and more specialized allegations with respect to the problem. So if we put to one side all the usual things that are generic to any large company, accounting irregularities, that sort of thing, and you focus on the life science industry, what you see is complaints being filed whose focus is the FDA approval process or in some cases the foreign regulatory process with the number of filings that focus on product efficacy increasing dramatically. It doesn't necessarily mean the product is harmful. It just means it doesn't work and as a result of not working the revenue stream goes down and you have class action litigation. You have the product safety class action litigation, which you all are familiar with. We're seeing more and more manufacturing process allegations in securities class action litigation against life science companies.

And one of the most interesting — I think one of the most interesting — trends recently is the appearance of suits targeting marketing practices of the big pharmaceutical companies. These cases target two things. The inducement part of marketing practices and secondly, the off-label use of marketing practices. Again, in the securities class action setting, what that means is the plaintiffs are alleging because of the inducements and/or because of the pushing of off-label use the revenue has been improperly inflated, therefore, inflating the price of the stock.

The last trend is that increasingly researchers are now being targeted as individual defendants in a lot of these cases. It used to be that the CEO was fair game, the CFO was fair game, but you rarely ever got any of the research personnel named as individual defendants. That's rapidly changing. When you talk to the plaintiff's lawyers, one of the reasons they say they are targeting those people is in the hope that those people will be better witnesses for the plaintiff's bar than the more sophisticated CEO and CFO.

These suits are obviously dangerous. They are dangerous for a number of reasons. And they are more dangerous today than they have been before. One is, as I mentioned previously, the information flow today is just much greater. The information flow that is in the hands of the plaintiff's lawyers prior to the time they even file the complaint is enormously greater than it was even four or five years ago.

And secondly, the exposure tends to be very large in these cases. The measure of damages tends to be, at least according to the plaintiff's bar, the loss in market

## *Chilton Davis Varner*

**has 30 years of courtroom experience as a trial lawyer defending corporations in product liability, business torts, contract and other commercial disputes. She has served as trial and appellate counsel for a number of the country's largest automotive, pharmaceutical and medical device manufacturers. She is experienced in mass tort litigation, class actions and MDL litigation, including the complex issues of discovery, attorney-client privilege and *Daubert* challenges to expert testimony that accompany such suits. She was appointed by Chief Justice Rehnquist to the Federal Civil Rules Advisory Committee in 2004, where she has participated in the Committee's recent drafting of amendments governing electronic discovery.**

**"Until well into the 1980s most courts accepted the proposition that pharmaceutical drugs carried with them unavoidable side affects and they were reluctant to get into redoing the difficult weighing of risks and benefits that had already been done by the FDA. Well, that era is over."**

cap after the disclosure of any event which, in theory, adversely impacts the revenue stream of the company. So, for example, big pharma generally has a lot of shares outstanding, so even if the stock price drops a mere dollar, if you multiply that times the number of shares outstanding, you come up with remarkably large, as Chilton called it, B-word numbers.

The other disturbing thing about these cases as they've started to develop is that to the extent the product is linked to the product liability arena, there is no need at the end of the day for the securities plaintiff's to show that there was anything actually wrong with the product. In other words, you've got a lot of product liability suits filed, folks like Chilton defend them vigorously and successfully, and it turns out the general consensus is that the product was okay. It had side effects but, by and large, it was okay. That doesn't mean that you're off the hook in the securities litigation arena because if the noise, as the district courts decision in the Bayer case called it, if the noise about the product adversely affects the revenue stream and or conflicts with prior statements by the company, you've got a securities law problem, even if at the end of the day — even if at the end of the day it turns out that the product is fine.

In closing, I would say that these trends are only accelerating. We would expect to see, as I said before, a lot more focus on the marketing practices aspect of phama life examined in the securities arena. In part that is so simply because it is juicy stuff. It appears to us that life science companies are going to have to live with this for at least the next four or five years until it sorts itself out. Thank you.

***MR. FRIEDMAN:*** Thank you. Next we have George Cary, a partner at Cleary Gottlieb.

***MR. CARY:*** Thanks, Jack. This program is particularly timely. General Counsel have assumed an increasingly important role in the crucial decisions facing major corporations. Nowhere is this more true than in the pharmaceutical industry. And if you don't believe me, all you have to do is look at today's newspaper. I brought a few with me: "Bristol chief forced to step down. Richard Willard, Bristol's general counsel was also asked to resign." This resignation was directly related to the topic that I'm going to discuss today: The interface between patent law and antitrust law, which is particularly important in industries like pharmaceuticals whose life blood is intellectual property. But the news is not all bad. Another headline reads: "A long shot becomes Pfizer's latest chief executive" about Pfizer's general counsel being promoted to the chief executive job. Both headlines illustrate, that for good or for bad, decisions made by the General Counsel materially affect the success of the corporation, not to mention the career of the GC.

The general counsel's role is central to a pharmaceutical company. Why is that the case? Because the lifeblood of a pharmaceutical company is patent protection for its products; and patent protection is the responsibility of the legal department. The environment for pharmaceutical patents is particularly treacherous these days. A pharmaceutical companies' profitability is not based on drivers such as supply chain or manufacturing which often determine the success of many industrial firms. While all those systems are world class at companies like GSK, the cost of goods delivered to the consumer is only a very, very small part of the total cost of producing a pharmaceutical product. The key to the pharmaceutical company's success is research and development. Developing new drugs costs hundreds of millions, if not billions of dollars. Out of thousands of products tried, one will be successful. And before they can prudently make these kinds of risky investments, pharmaceutical companies need assurances that the investment will be protected.

Generic companies can copy an innovator pharmaceutical company's innovation cheaply, simply, and quickly. Without patent protection, there will therefore be no return on the investment to drive further research and to create incentives for further investment. The Patent and Trademark Office looks at these patent applications carefully. The PTO has professionals skilled in the pharmaceutical arts to review pharmaceutical patent applications. The PTO takes months, and often years, to review these applications carefully before they will grant a patent. Given this level of scrutiny, the resulting patent has traditionally been presumed by the courts to be valid. In order to protect their investments, the pharmaceutical companies must patent every aspect of their innovation. Again, billions of dollars of shareholder money — money that belongs to people who own stock through pension funds and are looking forward to retirement or to parents saving to educate their children or for any of us saving for a rainy day — has been invested on the promise of this patent protection. It is the pharmaceutical company's fiduciary duty as the steward of the shareholders money to zealously protect these investments.

But in the pharmaceutical industry, patents have come under increasing attack by generic companies. Congress decided a few years ago that generic competition should be promoted. It did so by passing the Hatch-Waxman Act. Hatch-Waxman changed the patent landscape in a number of important respects. First it created huge incentives for the generic companies to challenge patents. These incentives amounted to hundreds of millions if not billions of dollars. And generic companies, obviously, took that up. Hatch-Waxman provided an incentive to be the first to challenge a patent. And this incentive, giving the generic company exclusivity for a period of time if they successfully challenged the patent, created a race among generic companies to challenge every patent on blockbuster drugs that they thought were the least bit vulnerable.

As more patents were subjected to the vagaries of litigation, even patents that initially were thought to be quite solid were occasionally struck down by the courts. Not unexpectedly, pharmaceutical companies became increasingly unwilling to roll the dice of litigation, and instead attempted to settle these patent lawsuits. Because generic companies have little downside in pursuing litigation (unlike patent defendants in other industries who are subject to damages for infringement), some generic companies were unwilling to settle without some compensation. Meanwhile, because the pharmaceutical companies had so much at stake, some were willing to reduce their litigation risk by making such payments. Several innovator companies settled patent litigation by agreeing to compensate generics in exchange for the generic company's agreement to acknowledge the validity of the patent and to stay off the market until those patents had expired.

The FTC, however, concluded that such settlement were nothing more than illegal agreements not to compete, and challenged several of them. The FTC characterized payments from the patent holders to generic challengers as the sharing of the monopoly profits available because the generic challenger agreed to stay off the market. BMS, Abbott, Wyeth and others signed consent decrees with the FTC agreeing not to engage in such settlements.

Pharmaceutical companies now had a dilemma: Do they litigate their patents at the risk of losing; do they give up on the patents rather than risk losing in court and being accused of attempting to monopolize the market through sham patent litigation; or do they settle with the generic challenger and face possible antitrust exposure as a result of the settlement?

One company challenged by the FTC, Schering Plough Corporation, decided to take on the FTC rather than signing a consent decree. After a lengthy trial before an administrative law judge and an appeal to the full Federal Trade Commission, the FTC reasserted its position that settlements which included anything of value in consideration for an agreement not to compete were anticompetitive and illegal. Schering appealed the FTC's decision to the Eleventh Circuit court of appeals, which reversed the FTC. The Eleventh Circuit held that as long as any exclusion of the generic product did not extend beyond the patent life, payment to the generic firm to stay out of the market did not violate the antitrust laws.

This history illustrates the kind of complex and subtle judgments that the general counsel of pharmaceutical companies are routinely called on to make: On the one hand, you have the FTC and private plaintiff's lawyers bringing class action law suits challenging these settlements. You have some courts of appeal which have decided based upon the facts before them that these settlements raise antitrust issues. On the other hand, the Eleventh Circuit and since then the Second Circuit have said that these agreements are perfectly legal. Making matters even more confusing, the FTC sought review by the US Supreme Court of the Schering. In an unprecedented response to The Courts request for its views, the Solicitor General of the United States with the concurrence of the Antitrust Division (which had previously brought its own reverse payment case) recommended that the Court not take the case, and took issue with the FTC's legal analysis under the antitrust laws. What does a general counsel do in this scenario? Does he aggressively vindicate his company's patent position at the risk of running afoul of the FTC and at the risk of private treble damage actions? Can he figure out another way to settle the patent cases without reverse payments, which may or may not succeed? Or does he litigate the patents at the risk of losing patent protection and facing subsequent antitrust exposure. As you can see, this is a very tough judgment call.

These are just some of the areas where general counsel have to make very subtle judgments in uncharted – or inconsistently charted -- legal territory. And the problem is compounded when one recognizes that just like the pharmaceutical industry, Antitrust regulation is now a global phenomenon. Given the illustration above of disagreement between our own two antitrust agencies, imagine

## STEVEN B. FEIRSON

has been a partner in the litigation department since 1983. He was, until recently, the chair of the financial services and securities litigation practice group and specializes in that area, as well as appellate practice. Mr. Feirson has been recognized as a leading securities litigation lawyer in the *2006 edition of Chambers USA*, a referral guide to leading lawyers in the United States based on the opinions of their peers and clients.

Mr. Feirson is a graduate of the University of Pennsylvania (B.A., 1972) and the University of Chicago Law School (J.D., 1975).

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## GEORGE S. CARY

**is a partner in the Washington, DC office of Cleary Gottlieb Steen & Hamilton LLP. His practice involves antitrust counseling and litigation. Before joining the firm in May 1998, Mr. Cary served as Deputy Director of the United States Federal Trade Commissions Bureau of Competition, responsible for merger enforcement. Prior to 1995, Mr. Cary was an antitrust and litigation partner at the Los Angeles firm of Irell & Manella.**

**Since joining Cleary Gottlieb, Mr. Cary has represented companies in many industry-transforming mergers and acquisitions. Among other matters, Mr. Cary represented The Dow Chemical Company in its acquisition of Union Carbide, the largest chemical industry merger in history; Time Warner in its merger with AOL, at the time the largest merger in history; SmithKline Beecham in its merger with Glaxo Wellcome, at the time the largest pharmaceutical merger; and Conoco, Inc. in its merger with Phillips Petroleum, creating the largest petroleum refining and marketing company in the U.S. In the high technology field, Mr. Cary represented Cable & Wireless, the buyer of the internet business required to be divested in the MCI/WorldCom transaction; and Northern Telecom in its acquisition of Bay Networks, among other matters.**

> **"Hatch Waxman provided an incentive to be the first to challenge a patent. And this incentive, giving the generic company exclusivity for a period of time if they successfully challenged the patent, created a race among generic companies to challenge every patent on blockbuster drugs that they thought were the least bit vulnerable."**

the perils when international regulators also become involved. The European Commission has a very aggressive antitrust enforcement program. There are also antitrust laws in every member state, not all of which are consistent. Having watched Rupert Bondy wrestle with these challenges, and having watched him avoid the pitfalls that can so easily result in liability for a company, I must say that Mr. Bondy is well deserving of the honor of this recognition this morning. Hopefully without tempting fate, perhaps I can cite to the fact that the Federal Trade Commission has yet to challenge one of GSK's settlements as evidence. Indeed, one of its settlements has been vindicated by one of the leading antitrust jurists in a private case brought by a bulk supplier of raw material. In that case, Judge Richard Posner credited GSK's settlement pro-competitive.

***MR. FRIEDMAN:*** Thank you. Our final panelist is Arthur Makadon of Ballard Spahr.

***MR. MAKADON:*** Thank you, Jack. In 1981, I coincidentally gave a talk to a similar group regarding the subject of White Collar Crime and in that talk I began as follows: "At some point in this decade — referring to the '80s — your corporation will probably receive a Federal Grand Jury Subpoena. Please, whatever you do, consult a lawyer who has seen at least one Grand Jury Subpoena before, because I will bet there is a good chance that your regular outside counsel has never seen one."

At the time, I was overstating, but not by much. The impetus for the talk was a recent experience I had had in the late '70s, an experience that is almost as instructive today as it was then. A federal agency undertook an investigation of a product that had been on the market for less than a year. During the time that the product was on the market, six deaths of persons using the product were reported to the company, but none of the deaths was brought to the attention of the appropriate federal agency. The labeling for the product did not refer to any serious side effects. The product was withdrawn from the market and the agency began an investigation. About eight or nine months later, after an exhaustive investigation, the agency referred the matter to the Department of Justice.

It was upon receipt of the referral letter that the General Counsel invited me to a meeting with him and the outside counsel who had handled the matter in front of the federal agency. I had been given materials in advance of the meeting. The meeting began with a very direct question by the General Counsel to me: "What is going to happen next?" While there is nothing quite like being put on the spot in that setting, I answered by saying that "the company would receive within three to six months an oppressive Federal Grand Jury Subpoena and a lengthy Grand Jury Investigation would ensue." At that point, the tension in the room became palpable. Outside counsel obviously had not prepared the General Counsel for this prospect and said that I was "dead wrong." He went on to add that never in the history of his law firm had any client been the subject or target of a Federal Grand Jury Investigation. When the Federal Grand Jury Subpoena arrived about four months later, I found myself with a new client and a fascinating representation.

While I do not think the forgoing example is a model for selecting counsel in "white collar" matters, I nonetheless think that the selection of counsel is the most important decision the General Counsel will make in a matter where the stakes almost always are very high. The General Counsel must feel comfortable with his or her choice and the only way to do that is to speak directly to the person in advance about his or her views generally, and his or her specific views regarding the particular investigation.

There is no formula for deciding whom would be the best lawyer in any given case. As I said, you must feel very comfortable with your choice. In this regard, I know that I would consider the following:

I would be wary of the lawyer who gives what sounds like stock advice. Fifteen years or so ago, it was fashionable for defense counsel to recommend fighting everything to the bitter end. Five years ago, potential defense counsel would say that it was of the utmost importance that you cooperate. The reason for this change had some basis in reality, but in fact not nearly so much a basis as warranted such inflexible views.

I should digress at this point to mention the issue of corporate cooperation in Federal investigations. This point has been the subject of a great deal of recent controversy and recently came to a head when officers of KPMG successfully challenged the position of KPMG not to indemnify them for the legal fees they incurred in a Justice Department investigation. Their right to be indemnified was upheld by a Federal Court and the Justice Department was taken to task for trying to coerce KPMG (by threatening prosecution) into not honoring its indemnification practices. While one can speak about the KPMG situation at great length, it is certainly open to question why KPMG even thought that the Justice Department would run the risk of putting another large accounting firm out of business given the criticism of the Arthur Andersen result.

In any event, the point here is that in choosing counsel one has to recognize that, at the outset, the most one can do is identify the key issues as they appear at that time and the initial strategy that will address those issues. One also has to acknowledge that what is vital at the outset may change and that counsel has to be flexible enough to see that change — often subtle — and adjust accordingly.

I also should note that there are lawyers who will always talk at length about their relationships with higher-ups at whatever agency or department is conducting the investigation. My advice is to stay away from those lawyers because a lawyer who talks about invoking higher-ups is almost certain to offend the people running the investigation. These are the people who you must be concerned with because in almost all circumstances they will determine the result.

But again, to reiterate, I think this is a very dangerous area. It is not going to become less

dangerous. Every decision you make can be second guessed. I think you have to feel very comfortable that you have the right representation. And the right representation is often a lawyer who will not have a formula at the outset because he or she will know that there is no formula for a successful result and that in all likelihood the result will depend on events not as yet even known.

***MR. FRIEDMAN:*** Thank you panelists, all four of you, for your comments. We will get back to them during the discussion period.

In introducing our Guest of Honor, I would like to just make some brief remarks.

The contribution of the pharmaceutical industry is simply unparalleled. There was a poll of many experts just before the millennium. They were asked what they felt was the greatest contribution to the wellbeing of humanity in the twentieth century. The overwhelming vote was the contribution of medicines. At the end of this century when a poll is taken it's quite likely that also the life sciences area will come out on top.

GlaxoSmithKline is very much appreciated both as an employer and in America and in the greater Philadelphia area.

Finally, I'd like to just make a personal comment about the friendship between the United States and the U.K.

In 2001, we had an event the day before 9/11. That morning I was having a conversation at Oxford with a very famous professor who's a renowned emeritus there and one of the subjects that came up was how the religions of the world were getting along so much better than they used to. And at around two o'clock I went back to the train station at Oxford and watched with amazement the sad vision of the planes hitting the buildings.

But what was striking was the extremely warm and sincere response of the average citizen in the U.K. in the days that followed. If you got into a taxi and the cab driver noted your accent, their concern was obvious and many offered whatever help they could. It was quite remarkable. And so without further ado, it is my great pleasure to recognize Mr. Rupert Bondy, Vice President and General Counsel of GlaxoSmithKline, for his numerous achievements. We are so fortunate to have him with us today. Welcome, Rupert.

***MR. BONDY:*** Thank you, Jack. And I'd like to thank everybody for showing up. I hope the breakfast was good. What I'd like to do is talk a little bit about GSK and why I'm proud to work for it. And then I'd like to talk about why GSK is a great place to be a lawyer. And then at the end I'd like to comment on some of the specific legal and governance issues and challenges that we face at the moment and that will pick up some of the remarks made by some of the other speakers on the panel.

I think most people in Philadelphia, or in the Philadelphia area know about GSK, but let me just remind you. We're the second largest research based pharmaceutical company in the world and our hundred and ten thousand employees are dedicated to the development of new and better medicines.

And picking up on what Jack said a moment ago, for all of us in this room, at some point in our lives, whether it be for ourselves, a family member, or a friend, having the right medicine to treat a health condition will be more important than having the right car, or T.V., or house, or vacation, or even dare I might say it, the right law firm. I do feel pride in being part of an industry dedicated to the discovery and development of new medicines. And I can't help but feel we are contributing to a higher and nobler purpose, saving lives and improving the quality of life for people across the globe. Within

## ARTHUR MAKADON

**is Chair of Ballard Spahr Andrews & Ingersoll, LLP. He also maintains an active litigation practice primarily focusing on white collar criminal matters and complex commercial matters. In recent years, his practice has included the representations of public officials and publicly traded corporations in grand jury matters and other government investigations; the defense of financial institutions for alleged violations under the securities and antitrust laws, ERISA, consumer protection laws; and the defense of a major accounting firm for alleged malpractice relating to the collapse of an insurance company. In addition, Mr. Makadon is engaged for appellate work throughout the country and in high profile matters generally. He also has counseled and represented corporations (and special committees) in connection with corporate governance issues. Before joining Ballard, Mr. Makadon served as law clerk to the Honorable Joseph S. Lord, III, Chief Judge for the United States District Court of the Eastern District of Pennsylvania and was Chief Assistant District Attorney for the City of Philadelphia.**

**"I think you have to feel very comfortable that you have the right representation. And the right representation is often a lawyer who will not have a formula at the outset because he or she will know that there is no formula for a successful result and that in all likelihood the result will depend on events not as yet even known."**

our industry I'm also particularly proud to be a part of GSK. We've got a long tradition of groundbreaking advances in medicine such as the launch of the first anti-retro viral drugs that revolutionized the treatment of AIDS. We also currently have one of the strongest portfolios of new medicines in development of any company in the industry. Indeed the best according to some external sources. And I'll talk in a minute about some of our most exciting projects. And we've also taken a leadership position on some of the key ethical and social issues facing the industry; in particular, how to enhance access to new and existing medicines in some of the poorest countries of the world, as well as some of the poorest patients in the rich countries such as the U.S.

So let me just mention some of our new drugs in the later stage of development. First, we're working on a vaccine for the prevention of cervical cancer, one of the leading causes of death for women across the world. This is very exciting. Vaccines have been around for a long time and for the prevention of many diseases, but not cancer. And while we're on the subject of vaccines, let me also mention a new vaccine called Rotarix that we're introducing in a number of countries that protects against rota-virus, a virus that leads to gastrointestinal illness and diarrhea. It's a leading cause of death in children in many developing countries. And it's a leading cause of hospitalization among children in developed countries including the U.S.

Moving back to cancer. We've recently presented exciting new data at the American Society for Clinical Oncology about a medicine in development called Tykerb. In fact, some of you may have seen our press release in the media coverage in the last couple of days that we've actually now made our application to the FDA to approve that drug. It's a drug that inhibits proteins that cause the growths of certain types of cancer including breast cancer. It's a highly targeted drug by contrast to traditional chemotherapy which damages many healthy as well as malignant cells. And we hope that Tykerb will represent a significant advance in the complex fight against cancer.

I want to move on to say a bit about diseases that principally affect the developing world because a commercial potential here is often limited by the poverty of these countries. Developing drugs that fight diseases affecting the poorest countries has become a relatively neglected area of research. But GSK is one of the leading companies committed to developing medicines for diseases in the developing world. And indeed we've got a specialist R & D unit, research and development unit, in Spain that focuses exclusively on these diseases, as well as doing research at our vaccines unit and other R&D sites around the world. In fact, we're the only company to be conducting research into all of the World Health Organization's, priority diseases: Malaria, TB, and AIDS.

We've also recognized that the prices charged for drugs in the developed world, which are necessary to fund innovations to discover new drugs for the future, may not be affordable for most people in the developing world. A good example is the AIDS epidemic, which so tragically afflicts so many countries in Sub-Saharan Africa and elsewhere.

We at GSK have been widely recognized for taking a leadership position in offering our anti-retro viral drugs at not for profit prices in these countries and for granting voluntary patent licenses to enable generic manufacturers to manufacture generic versions of our drugs.

Finally, before I leave the subject of the company as a whole, I do want to say a word about one of our philanthropic initiatives because I think it is so important and sometimes under-recognized. It's a program to donate sufficient quantities of one of our drugs, Albendazole, to eliminate a disease from the face of the earth, much like the world has done with small pox and is doing with polio. The disease is Lymphatic Filariasis, LF, also known as Elephantiasis. Caused by a parasite common throughout Africa, South Asia, and other tropical regions, LF manifests itself in a massive swelling of legs or groin. It's painful. It's disfiguring. It's disabling. It can be prevented by taking a couple of tablets, including our medicine, once a year for five years. After this the parasites are gone from the blood of infected people and can no longer be transmitted by mosquitoes. So the cycle of transmission is broken, eliminating the disease and preventing suffering for future generations.

As you can imagine, it's a huge undertaking. In Sri Lanka, for example, ten million people were treated in one single day with the help of fifty thousand volunteers. To date, we've donated over five hundred million tablets and by the end of this twenty year commitment we plan to donate a further five billion tablets.

So overall, I think we're a company with an important mission, which is doing the right thing in the right way and I am proud to be a part of it. It's also, for some of the reasons that some of the other panelists have given, a fulfilling and stimulating company in which to be lawyer. Sometimes too stimulating some people might say.

For better or worse, we operate in an industry where legal issues are at the heart of everything we do almost as much as scientific or commercial issues to the occasional frustration of some of my colleagues. First, we are understandably a highly regulated industry with complex laws and regulations governing every stage of a medicine's life cycle. From the conduct of clinical trials in animals and humans to the demonstration of safety and ethicacy through the manufacturing of the product to ensure that it complies with good manufacturing practices and meets the specifications approved of the FDA and equivalent agencies, to the way the way that approved medicines are promoted and marketed to physicians and other health care practitioners. And in some countries, like the U.S, promoted directly to the consumer. Pricing and reimbursement are also subject to complex rules and expert legal advice is needed every step of the way in this process.

Second, as George was mentioning, intellectual property, particularly patents and so-called data exclusivity are critical to our industry. The balance between incentivising innovation through intellectual property rights and creating a strong

generic industry to reduce prices after an appropriate period is an important public policy issue and is enshrined in the U.S. and other countries in a complex set of laws requiring expert knowledge from skilled lawyers, as George has talked a bit about that.

Third, our industry is quite transaction intensive with technology license agreements, manufacture agreements, merger and acquisition transactions, complex customer agreements. All of which are ultimately written and interpreted by us, the legal department.

And finally, as you've heard from several of our speakers, our industry has attracted, in my view, more than our fair share of litigation, particularly in the United States. We're seen as a deep pocket that's worth suing. And the loss of public confidence in business generally has more than manifested itself with regard to the pharmaceutical industry. There has been a perception as so-called big pharma, putting profits before patients and engaging in all kinds of improper conduct.

Most obviously, the pharmaceutical industry is subject to product liability litigation, as discussed by Chilton, and patent litigation. But there is now an industry in litigating sales, marketing, and pricing activities, and patent litigation and settlements can bring on further generation of litigation in the form of antitrust lawsuits.

All of this makes our industry, GSK included, a challenging, stimulating and very fulfilling environment in which to be a lawyer. Trying to resolve our legal issues with an eye to the bigger picture, serving the important mission to bringing new medications to people across the world and working with a range of talented and motivated people with a diversity of expertise from pure science, to clinical practice, to engineering, to marketing and other skills, makes our industry a fascinating one in which to work as lawyer. And GSK is a great place to be within that industry for the reasons I have given earlier on and also because of our culture as an institution and an employer, touched on by Jack.

We actually recently did an employee satisfaction survey of over twelve thousand of our managers using some standard questions that have also been presented to a lot of other respected companies inside and outside our industry. And the results, including for us inside the legal department, show that we led the industry on a number of levels of satisfaction. Indeed, GSK, the legal department included, led the survey in a kind of a catch-all question about overall satisfaction with GSK. So forgive me for making a brief plug, but I do think that the GSK legal department is a great place to work as a lawyer and I do think we have a great team here in the legal department, highly expert in their fields, highly motivated, passionate, generally fun to work with. I can see a number of them in the audience today.

Now, to finish off, I just want to touch on a couple of the legal issues and challenges that are important for us right now. And I'm going to start with civil justice reform in the U.S. covering some of the areas talked about particularly by Chilton, but also by Steve and Arthur. Now I know this may seem very tired, big business banging the drum in a totally self-serving way to cut back on the compensation process for injured claimants, but that's really not what we're asking for. Of course, companies who violate their duties should compensate those injured as a consequence. What's objectionable is when the legal process works in a highly inefficient, unpredictable and seemingly unjust way where the biggest winners seem to be the lawyers who retain an enormous proportion of the money flowing through the legal system.

When you read about states in which it's hard to

find an obstetrician in which to deliver your baby because the state tort system is so oppressive and the insurance premiums are so high, you do have to worry if that's a good thing. The risk of huge verdicts, not justified by the evidence can also lead companies to conduct business in a way that's more focused on litigation and defense strategy than what's really in the best interest of patients, customers, consumers and other stake holders.

Drug labeling decisions must be motivated by the necessity to inform prescribing physicians of the scientifically relevant risks and benefits associated with the drug and not by the desire to avoid litigation at all costs. Accordingly, GSK supports the recent FDA prescription drug labeling regulations which simplify and clarify drug labels and which express the FDA's position that certain state tort claims should be preempted when they conflict with an FDA approved label.

So while, of course, I feel that many aspects of the current tort system are unfair to the business sector, including GSK, I also feel that it's not in the public interest and that a clearer, simpler, fairer system which compensates the genuinely deserving but reduces the huge transaction costs, all of the defense legal costs and the huge amounts going to the plaintiff's bar, would be good for society and not just for business.

Second and finally, I want to talk about IP law. I mentioned earlier that intellectual property is the bedrock that enables us to invest in research for the future. I do also appreciate the public interest in making cheap copycat drugs available to consumers after a period of exclusivity for the inventor of the drug. In the U.S., as George has mentioned, Congress has attempted to find a balance between incentivising research and innovation on the one hand, and encouraging early generic drug manufacturing on the other hand. And this is set forth in the so-called Hatch-Waxman Act. The basic intent of the act is clear, but the implementation is very complicated. Research based companies have restored to them a portion of the patent term lost during the lengthy regulatory process that must be undertaken before approval On the other hand, generic companies are permitted to undertake otherwise infringing activities during the patent term so that they can market their drugs immediately on patent expiry and they are allowed to piggyback after a period of time on the pioneer company's clinical trial data.

Now, while the basic principles are clear, the devil is in the detail. There is a lot of complexity as to how the law works and often uncertainty. And George has touched on some of the dilemmas that that can

create for us day in and day out at GSK. There are many people who believe overall the balance struck by the Hatch-Waxman Law is tipped too far in favor of the generic industry, an industry that really didn't exist in any meaningful way before the introduction of the law in 1984.

The complexity surrounding the laws has resulted in both research based companies and generic companies being accused of gaming the system with consequent criticism and also follow-on litigation in the form of antitrust lawsuits. Given that a patent is actually a complex legal construct, and as I've learned a potentially fragile one, where any number of challenges can be made to the validity of the patent throughout the life of the patent; and given that the development and launch of a drug is based on a reasonable period of exclusivity after launch, you can see that some of the uncertainties and complexities of the current system are very difficult for a business to manage.

In my view, while the basic principles of Hatch-Waxman and patent law are sensible and reasonable, the current state of the law with such complexity and uncertainty and with what seems to be a continuous process of judicial and legislative hostility to the research based industry is not ultimately in the public interest. I think there should be a longer period of data exclusivity for research based companies to allow certainty and the return on the huge investment currently needed to develop and attain drug approval. This change to Hatch-Waxman law would inevitably require a balanced approach that is fair to both generic and research based companies and we would welcome this discussion.

Before I finish I do just want to agree with one comment Arthur made and that is that it's very important to get the right legal representation when you have complex legal issues to resolve. Indeed, I see it as one of our more important jobs as inside lawyers of the company to make the right choice on the outside firms that are going to represent us. That can make a huge difference to the outcome.

And I would just like to close with a thank you to the other members of our panel who've been selected, obviously, because we feel that they do give us the best possible representation on some of our most important matters. Thank you.

***MR. FRIEDMAN:*** Thank you. I'd like to continue with a question to all the speakers here. There was some talk of tort reform. Would any of you like to comment on some of the areas where the business and legal communities are interested in possible changes in the law — whether federal or state?

***MS. VARNER:*** Thanks. In the tort litigation area I think the next great push in terms of tort reform is going to be to cabin the reach of consumer fraud statutes. In the tort personal injury area, federal courts have been surprisingly resistant to certifying class actions. They found there simply were too many individual issues, individual medical histories, for example, in a pharmaceutical case that can provide alternative causation for the injuries that are claimed for the plaintiff. So over the last six or seven years (in federal court at least) I'm unaware of any certified class of personal injury claimants that's held up through appeal, other than perhaps settlement classes.

So in the tort area we've been reasonably successful in combating class certification. But if that door has been closed somewhat, the state legislatures have opened another loophole by passing consumer fraud statutes that are very consumer friendly and have low burdens of proof. I believe that the next push that we will see in terms of tort reform is a coalition between the U.S. Chamber and other entities that are interested in this area to try to tighten up the consumer fraud statutes.

The most notable victory in that regard has been the amendment of section 17-200 in California, which was amended by one of their prop votes to make it clear that claimants could not simply be private attorneys general who acted for the public in bringing consumer fraud statutes. They had to at least have bought the product, consumer fraud been exposed to the product, and been injured by the product. Those requirements do not exist in the consumer fraud statutes of some states and there they are a very powerful tool for plaintiffs.

***MR. FRIEDMAN:*** There has also been pressure regarding the Thompson memo. Would any of you care to comment?

***MR. MAKADON:*** Well, I think that was the subject of the head of the judiciary committee two days ago saying that the judiciary committee will not tolerate the Justice Department's requesting a waiver of attorney client privilege or taking into account whether a corporation waived the attorney client privilege in making the determination of whether to charge a corporation. I think the pendulum on that is going to swing drastically the other way and you'll see much more balance. It also makes perfect sense because it at least will allow the corporation to find out what happened. The corporation was placed in this ridiculous position of having to find out what happened internally and what went wrong and at the same time having to turn that information over to the government, thereby making it more difficult to find out what happened because your employees were less inclined, especially the employees that may have been on the fringes, were less inclined to cooperate.

***MR. FRIEDMAN:*** Rupert, during the brief discussion we had before the event you were mentioning that some of the rules in other countries may be different than here in the United States. What would be some of the differences?

***MR. BONDY:*** Well, the biggest difference and a very contentious topic for most legal departments in European companies is that the European Commission under European law does not recognize a privilege belonging to communications between a company and its inside lawyers. It only recognizes the privilege in communication with outside lawyers. That's very different from the United States, and also

## *Rupert Bondy*

**is the Senior Vice President & General Counsel, GlaxoSmithKline.**

**He began his career as a lawyer in private practice, with a focus on mergers and acquisitions. In 1989 he joined US law firm Morrison & Foerster, working in San Francisco, London and New York, and from 1994 he worked for UK law firm Lovells in London.**

**In 1995, Mr Bondy joined SmithKline Beecham as Senior Counsel for Corporate and subsequently assumed additional responsibility for the Corporate Secretarial group and for legal support to Worldwide Supply Operations. He was appointed as the head of the Corporate Legal and Secretarial group at SmithKline Beecham in 1998.**

**At GlaxoSmithKline, Mr Bondy most recently served as head of Legal Operations, Global Manufacturing & Supply and Corporate. He was appointed to his current position in June 2001.**

**Born in 1961, Mr Bondy graduated from Cambridge University in 1983. He then spent a year as a Harkness Fellow in jurisprudence at Harvard University. After qualifying at the English Bar, he spent a further year as a teaching fellow at Stanford Law School, where he also earned a masters in law degree.**

**Mr Bondy is a member of the English Bar and the California Bar.**

**"Developing drugs that fight diseases affecting the poorest countries has become a relatively neglected area of research. But GSK is one of the leading companies committed to developing medicines for diseases in the developing world...In fact, we're the only company to be conducting research into all of the World Health Organization's priority diseases: Malaria, TB, and AIDS."**

from most individual European countries where there is a privilege recognized for internal counsel just as there is for external counsel.

***MR. FRIEDMAN:*** You mentioned that you had a hundred and ten thousand employees around the world, which means that you have to conform to an unbelievable number of national labor laws. One of the issues that's been coming up more and more is in the area of reconciling privacy issues. What is the nature of the difference between employee rights in the E.U. versus in the U.S.? And how do companies try to reconcile that?

***MR. BONDY:*** Well, I can't give you chapter and verse, but there are some conflicts which can be complex for a company that operates on a global basis and tries to have global standards. So coming out of Sarbanes Oxley and other developments in the United States, there is obviously a stronger and stronger interest in momentum behind compliance hotlines, the ability to report allegations of misconduct on an anonymous basis and that can conflict with some European data privacy laws, which creates a dilemma for the company if it is subject to conflicting rules and we've had to do the best we can to take a kind of basic structure that we operate for the company globally, including in the United States, and then customize it in order to accommodate and particular legal requirements in particular countries. So I can't give you a lot more chapter and verse than that, but it's part of the complexity of being a global company in a world where sometimes you are faced with conflicting legal demands.

***MR. FRIEDMAN:*** The general principle in the United States is that a company should be very carefully if it's doing an investigation about alleged illegal conduct of an employee. It should be very careful before makes any sort of formal contact with the employee. You have to get your ducks in a row and so forth.

I was told that the French just passed a law that says that if someone is the subject of an allegation they have to be told about it within seventy-two hours. So the company is forced to throw it into a formal confrontation before they really have had a chance to do much of an investigation. American companies that operate in France are troubled because they don't want to be in that position.

Moving on, Rupert how do you as a general counsel deal with your outside law firms in terms of giving business?

***MR. BONDY:*** Yes, well, it's a very important subject and it's one of the most important parts of our jobs. On the one hand, the legal risks that we face are very significant. Our exposures are very significant. And as I said earlier, it's a very important part of our job to get the best possible legal representation. It's an important choice we make, which outside firm to instruct and we're looking for the best. The greatest wisdom, the

greatest strategic sense, the greatest advocacy skills. A number of different competencies required that, I think, if you get it right can really help the company and make a huge difference. So we want to get the most expert and the best possible lawyers to advise us on these matters for the company where the stakes are really huge. Combined with the fact that equally huge these days are the huge legal fees that we pay because legal issues, challenges, litigation, are exploding and the amount of money that we spend on legal fees is a nontrivial amount of money and another part of our job is to manage that spend in a sensible and structured way rather than well, whatever you want to charge us, charge us and whatever you want us to pay, we'll pay. So we're constantly trying to strike a balance or integrate all those elements into a program that provides the best value for us and provides world class legal service on the matters that require it, but on a basis where we are getting value for money and spending that money wisely. And like many other big companies we have a program in which to have structured relationships with law firms and to try to some extent to cut down on the number of law firms that we use because it's not efficient for us to be dealing with many, many thousands of firms, but at the same time, to recognize that you need different skills on different matters and you get that from different law firms. So we try to have an integrated program that strikes a balance between those various different factors and I hope we do a reasonable job. There's also a constant theme of people trying to get away from the billable hour. What's the best alternative? Some of the alternatives don't seem very satisfactory either. So, I think, as with many things in life, it's a matter of judgment and balance and constantly working at it and if there is a magic solution I'm absolutely dying to here it.

***MR. FEIRSON:*** To follow up on something Rupert just said, and one of the things I think we look for is the active participation of the lawyers in the company. There is an enormous amount of expertise and frequently in the subject matter — in the subject matter area more expertise resident for the in house people rather than in the lawyers outside. And if there ever was a day where the lawyers in the company suddenly handed over a file to outside lawyers that day has long passed. And I think it's our experience that the partnership aspect of the relationship sort of goes beyond the sort of financial part of the relationship but it's the part of actually getting the work done and achieving results. The give and take between the people outside and the people inside to try to come to the best solution and the best answer for the client is something which is good for both sides and, frankly, for the individual lawyers I think it enormously enhances the experience and the pleasure of practicing law.

***MS. VARNER:*** I think that proactive risk management is no longer just a "best practice," it's really a necessity in the environment that Rupert has described so vividly in which litigation is a constant for a company like GSK. And I think that successful outside lawyers are being called on increasingly to be participants and partners in that proactive risk management. That includes lessons learned from litigation, and there certainly is no litigation from which there are not a number of lessons to be learned.

***MR. FRIEDMAN:*** Sometimes very painful ones.

***MS. VARNER:*** Some very painful, and it means staying in touch with management, briefing management, briefing middle management on issues as basic as the creation of documents and litigation holds. All of those things, I think, are more and more the product of a partnership between inside and outside counsel.

I think GSK, as is true of many firms, has looked to a smaller and smaller group of firms to assist it. That is not uncommon and I think there are real advantages to a smaller group of firms, including a better understanding of the companies that they represent and, hence, a better platform from which to provide proactive risk management. I also think that it eases your administrative burdens in terms of cost effectiveness. All companies are struggling to conserve cost while at the same time preserving aggressive legal defenses to the cases that confront them.

It's going to be interesting to see what effect the new electronic discovery amendments to the federal rules are going to have. They now loom closer and closer and will become effective in December of this year. That whole area is one in which the cost of litigation has been starkly framed. It's the reason the amendments were debated for three years before they were submitted. It's the reason that some six hundred people provided comments on something that's usually regarded as a rather dusty topic, the federal rules of civil procedure. But corporate America in particular has spoken and spoken loudly that the cost of discovery, which already represents well over fifty percent of the total cost of litigation, is going to be exponentially increased by electronic discovery. Some framework had to be provided for it. But I do believe that both inside and outside counsel in most good companies are working more and more closely together to try and manage risk.

***MR. CARY:*** Following up on what Chilton said, I think she's put her finger on something that's very important. The risk management calculus. It's not simply a matter of how much risk do you want to take, but also of which risk do you want to take. For example, If you have a patent risk on the one hand, and an antitrust risk on the other, the company has to make a judgment first as to which risk is more important to it as reducing one risk may elevate the other. Only by working with a company over months or years and participating as those decisions get made can a counselor know precisely how the company trades off different types of risk, and what level of risk in each category it is comfortable with. Communicating these decisions to the relevant regulatory agencies and getting their feedback on these judgments then allows the counselor to recalibrate the risks with additional information and to better counsel the company on the next decision. This iterative process greatly increases the level of sophistication that can be brought to the analysis and that the company requires. Consistency in the approach taken is also very important. Explaining a consistent position to a regulatory agency when new issues arise is a lot different than going in with a position that is very different from that the company took on the last transaction, even if that position is perfectly defensible in its own right. Working with a company to understand where they want to position themselves with respect to different types of risk and quantum of risk is critical.

***MR. FRIEDMAN:*** What are some of the insights and advice that an attorney might share with a general counsel regarding the implementation of a compliance program?

***MR. CARY:*** I'm not sure that there is any real secret. The standard approach is to educate everyone as to what those risks are, educating everyone as to what the principles are. This should not stop at the top levels. Lower level employees potentially could create bigger problems in industries where they have more control over prices than they might in pharmaceuticals given how prices are determined in the pharmaceutical industry. But clearly all employees who deal with customers, with pricing, or with competition should understand their obligations under the antitrust laws.

***MR. BONDY:*** Well, I think there are three aspects I'd touch on. First of all, you do need a structured compliance program to include all the traditional elements including proper policies and training and communication and monitoring and auditing and there has been more and more of that over the years and it can seem bureaucratic, but it's simply a necessity when you're getting out to very large numbers of people like very large sales forces as pharmaceutical companies have. So you need to have all the nitty gritty of a comprehensive compliance program.

Secondly, you need to have a message of doing the right thing. In other words, it's not just about how narrowly you can squeeze yourself into the box that the rules allow you, but you have to have a bigger picture of how will this be seen, how are society standards and expectations evolving. While this may look okay technically today, in light of society's evolving standards, in three years time is a regulator or a prosecutor going to take a different view and you have to get people into having that mindset.

And thirdly, while you can't do things just from the top down, actually the top down messages are extremely important. There has to be a very strong message from the top that we mean this, this is important, you must follow the rules and we must have a culture of ethical behavior.

***MR. FRIEDMAN:*** At one of our events a general counsel who used to be the deputy attorney general of the United States made the — he's now general counsel — said that although the senior executives of a company are grown up and are not children, some of the rules you use within your own family are relevant and that the non-verbal example plays an important role. He observed that just as a child who sees his or her parent receive too much change at the grocery store and promptly give it back, the non-verbal message i.e. leading by example, is just as important in the corporate world.

***MR. CARY:*** I think the major difference is rather than reporting to the board, the current tendency is to explain in more detail to the board. To walk through the

analysis that leads to the conclusion. To let them understand in much more nuanced detail what the various options are and why a particular road is being followed, and quite candidly what the repercussions of following that road could be, but what the repercussions of following a different road might be. I think that level of detailed analysis was not conducted at boards ten years ago and I think it's increasingly being done today so that everyone understands that there is no risk free solution to these difficult problems that companies are facing today.

***MR. FEIRSON:*** And I think that George is right. I think that we spent a lot more time talking about downsides and risks than we ever did before.

***MR. FRIEDMAN:*** Downsizing risks –

***MR. FEIRSON:*** Downsizing risks for certain alternative courses of action.

***MR. FRIEDMAN:*** You mean laying out alternatives for them.

***MR. FEIRSON:*** As George said, I think you go through the thought process of why you come to where you've come to. But as you do that you spend a significantly greater amount of your time talking about the sort of up sides and down sides of the alternatives where, at least in my experience, ten years ago you spent a lot of time saying, this is why we think this is the right course of action. You didn't spend a whole lot of time talking about the course of action if you weren't recommending them. And you didn't spend a ton of time talking about the risks of the courses of action you were talking about. It's a much more fulsome discussion, much more balance and in some ways much less comfortable for the board.

***MR. CARY:*** Can I just make one other point going back to the discussion of attorney client privilege: The uncertainty that exists not only in Europe, but also in the United States is a very serious problem. On the one hand, Sarbanes Oxley and good corporate government standards put a premium on a board of directors and senior management really taking responsibility for major decisions and being able to justify the decisions they make. To do this they need candid and objective information at a detailed level. And as we have described, the information has to focus and highlight the risks inherent in alternative courses of conduct. None of this can happen if there is a constant concern that candid discussion points could later be disclosed in litigation, taken out of context, and used to demonstrate that the company acted inappropriately in accepting those risks. And nowhere is this more of an issue than in the patent /antitrust context where going in the board needs to have a very good understanding as to the strength of its patent position. If there is a risk that three sentences out of a twenty page report which talk about the possible problems with a patent will be presented to a jury in a suit alleging that the patent was litigated in bad faith, there will be a chilling of information delivered to the Board. Such a result is very dangerous and inconsistent with good corporate governance. We need to develop a process whereby judges can serve as gatekeepers to allow limited waivers of attorney client privilege when appropriate to prove the company's good faith in enforcing patents without the risk that all attorney client communications end up before the jury.

***MR. FRIEDMAN:*** Isn't it possible that board members are sometimes overwhelmed with the amount of information they are presented with and might adopt the attitude of "thank you very much for the presentation but I don't know what to do about it."

***MR. FEIRSON:*** I don't' know about the others but the board members that I've come into contact with these days don't seem to adopt that attitude.

They're much more interactive and to George's point, I mean, the last couple of board meetings I've gotten the same kind of question at each one and that's securities litigation. Yeah, yeah, I hear you about why we're going to win. Tell me what the best argument is on the other side. Tell me what I should be afraid of and if you can't answer that question honestly for fear that it's going to get played back later in the director's deposition, you've got a big problem.

***MR. FRIEDMAN:*** Rupert?

***MR. BONDY:*** Well, I think, first of all, it's a fact of life that the boards are just spending more time than ever before and certainly than ten years ago on legal issues and governance. And partly that's because Sarbanes Oxley, et cetera, just require a more formal process and partly it's because legal issues can represent a bigger exposure and it's part of the board's job in managing the company to manage those exposures. And it can be difficult to know what level of information to give. But boards can only act on the information that they have, so you're trying to strike a balance with an audience that may not be an expert in a particular field of law but you need to give them enough so that they have, at a high level, a balanced and informed view of what the key issues are. And, actually, one of the tests for me of a good outside law firm is that if they can't explain in a succinct and clear fashion to me or to the board what the key issues are, then how are they going to do in front of a judge or in front of a jury. So you are just trying to make a judgment all the time about what is the key information. And I think boards understand and take very seriously that it is their duty to have enough information on which to make an informed decision or assessment. So you have to try to give the clearest, most balanced, most succinct, most comprehensive view of what the issues are and to have the expert outside lawyer give the view on an area where he or she knows far more about the law than I can ever know. And also maybe give a view on how a judge or jury would react to this information or this evidence. That's important and that's very helpful for the board to hear directly from the horse's mouth.

***MR. FRIEDMAN:*** If all the important risks were presented to a board in a thorough manner, they never would have time to even read the piles of documents that they are now getting. How do board members possibly keep up with all the important matters that you want them to know about much less all the business that the operating units want them to know about?

***MR. BONDY:*** Well, I think it's gotten harder, but you have to do the best you can. And I don't think it's helpful to the board to give them a hundred page paper on a particular topic so that in the future you can say the key point is on page fifty-seven in paragraph three. So what you have to do is make constant judgments — about what is the right information and what is the key information. We have to do the best we can. And that's why good analytical skills are such a premium and good communication skills are at such a premium.

***MR. FRIEDMAN:*** Because I know in the U.K. the law is that the CEO and the position of chairman are separated by law, I think.

***MR. BONDY:*** Not by law as such, but it's considered best practice and under the Listing Rules if your shares are listed on the London Stock Exchange you have to -- if you don't separate the roles of chairman and chief executive you have to explain why.

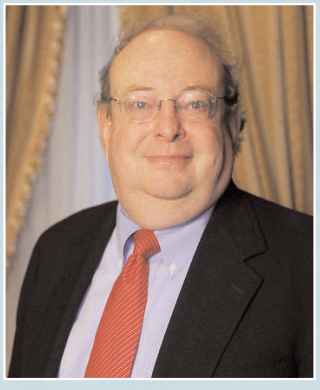
***MR. FRIEDMAN:*** For large companies in the U.K., what is considered the standard number of meetings a board should have?

***MR. BONDY:*** I'm not sure if there is a significant difference in the amount of time spent by U.S. boards versus U.K. boards. And I'm obviously much more familiar with U.K. boards than, for example, European companies.

***MR. FRIEDMAN:*** Right.

***MR. BONDY:*** What I will say is for both U.S. and U.K. companies is that people spent more time on board meetings now than ten years ago. If you look at how long an audit committee takes at the average company now compared to ten years ago it's

## JACK FRIEDMAN



Jack Friedman, Chair of the Directors Roundtable, is an executive and attorney active in diverse business and financial matters.

He has appeared on ABC, CBS, NBC, CNN and PBS, authored numerous business articles in the *Wall street Journal*, *Barron's* and the *New York Times*.

Mr. Friedman has served as an adjunct faculty member of Finance at Columbia University, NYU, US (Berkley), and UCLA. He received his MBA in Finance and Economics from Harvard Business School and a J.D. from the UCLA School of Law.

dramatically different. Audit committees meet for far longer now than they used to.

***MR. FRIEDMAN:*** With the big new publicity regarding executive compensation, is there a difference between the U.S. and the U.K.?

***MR. BONDY:*** To understand the compensation structure at GSK you need simply look at our annual report, in which, we have very detailed disclosure of our compensation. I think that in the U.K. there was a much bigger focus and much more pressure on executive compensation some years ago. Before we saw that same pressure in the U.S., although I think the US is now catching up.

At GSK, if you read our annual report, you'll see that we have a very, I think, thorough — an objective process for setting executive compensation particularly at the top level of the company, the corporate executive team. And for some elements of our compensation we compare ourselves to a peer group, and not just a peer group of U.K. companies, it's a peer group of our key competitors in the global pharmaceutical industry. So it's a number of pharmaceutical companies, including U.S. ones.

***MR. FRIEDMAN:*** Arthur, I'd like to wind up this section on the governance area. A lot of governance rules are all nice when everyone is getting along in the board room. But when there are allegations of serious wrongdoing people feel that they have to start watching out for themselves. Before the event I had asked you about whether the insurance companies are really paying on the D&O policies. You were also talking about indemnity.

***MR. MAKADON:*** There is no particular difference today from ten years ago. Most states permit, indeed, some mandate, indemnification of expenses, including legal fees, of officers, directors and employees incurred in matters arising out of their employment (that is an oversimplification, but it is sufficient for present purposes). As I stated earlier, the Justice Department has recently shown some skepticism of this arrangement, but I think that issue probably is behind us and that the general provisions that have prevailed for many years will continue to prevail.

***MR. FRIEDMAN:*** We have mentioned the SEC, Justice Department and so forth. Given the fact that we're right over the border from Delaware, I'd like to ask whether there is any sense of the Delaware courts in terms of defining duties or liability or changing anything recently? They say they are not changing what they are doing since Enron.

***MR. MAKADON:*** The only thing I know that's different about the Delaware court system today is that the bankruptcy courts appear far less busy.

***MR. FRIEDMAN:*** Let me thank everyone. Rupert, let me thank you very much. It gives us both perspective, what you do, the company, and what it's like running an international legal department and the achievements that you've accomplished. Thank you. ■

GlaxoSmithKline (GSK) is a world leading research-based pharmaceutical company with a powerful combination of skills and resources that provides a platform for delivering strong growth in today's rapidly changing healthcare environment. GSK's mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

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GSK has a leadership position in anti-infectives, respiratory and vaccines and has a growing portfolio of oncology products. The company also has a Consumer Healthcare portfolio comprising over-the-counter (OTC) medicines, oral care products and nutritional healthcare drinks, all of which are among the market leaders.

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