Thank you, Bert (Weinstein), for that introduction. I’m pleased to be here this afternoon.

One of the most valuable assets any pharmaceutical company has is its reputation. The work we do is a public trust. We are researching, developing, and manufacturing drugs and vaccines that people rely on to prevent or treat disease in themselves or their families. The doctors who prescribe our products, the patients who use them, and the insurers who help pay for them, as well as the regulators who oversee us, all demand that we maintain the highest standards of ethics and integrity – just as we must demand the same of ourselves.

Our industry operates in a complex and dynamic environment. The demands of the market are more pressing than ever. Scientific discovery is taking us in remarkable new directions. And the political and regulatory climate poses real challenges. The landscape we must traverse every day is filled with more than its share of risks.

Evaluating and assessing those risks, and managing them successfully, is a major part of what we do every day. As I see it, there are two major categories of risk that require our careful and ongoing attention: strategic risks and regulatory and compliance risks.

The strategic risks we face include patent expirations, the ongoing challenge of discovering novel medicines that will provide true advances in patient care and provide value to our customers, and something economists call, “dynamic competition,” which simply means waking up one morning to find that one of your top-selling drugs is suddenly supplanted by a new therapeutic advance from a competitor. As all of you know, successfully meeting these risks requires long-range thinking, planning, and investment.

But in looking at the risks down the road, we must not ignore those that are right in front of us. The failure to manage the regulatory and compliance risks associated with such things as financial reporting, manufacturing quality, the appropriate conduct of clinical trials, and marketing and sales practices, can cause as much trouble as the failure to plan for the end of a patent on one of your most profitable drugs. In an industry as
highly regulated as ours is, not only must we effectively manage all these risks, we must do so within the boundaries set by laws and by regulations.

Of course, some risks are more directly manageable than others. When a drug is about to go off-patent, there’s not much you can do to prevent that. Instead, you try to manage that predictable risk by developing new drugs that meet real needs. Similarly, breakthrough scientific discoveries cannot be ordered up on the Internet from eureka.com – all you’ll find there are vacuum cleaners. So you manage that risk by investing in research and attracting the best scientific talent to your labs.

Clearly, managing strategic risks requires strategic thinking. Corporate leaders must have the foresight to develop plans to meet risks that may be far off in the future. But the same is true of the regulatory and compliance risks we face every day. It’s not enough to have the right tactics. You also have to have the right strategy. That strategy includes three major components: First, fully engaged leaders who consistently set the right tone; next, effective compliance structures and practices that include verification procedures; and, finally, a far-reaching “ethics ethic,” that emphasizes ethical behavior in every facet of business behavior.

When it comes to compliance and ethics, senior management sets the tone, not just with an occasional word, but in their every day deeds, as well. A company’s leaders must, at a minimum, exhibit their commitment to both the letter and the spirit of the laws and regulations that govern their company. And they must insist that the people who work for them, all the way down the line, do the same.

That’s why corporate leaders must model the highest possible standards of ethics and integrity in everything they do. They must do the right thing, even when no one is looking. Nothing will poison the well more effectively than a casual approach to ethics by senior management. The fear of getting caught may be a powerful motivator to some, but creating an atmosphere in which all people are expected to do what’s right in every aspect of their business life is an even more powerful tool.

But corporate leaders must do more than demand compliance and ethical behavior; we must also make certain our people know what is expected of them and we must equip them to achieve those expectations. People need to be trained about the rules and regulations that govern such key activities as manufacturing, marketing, clinical trials, stewardship, and financial controls. Knowing the rules is the foundation on which compliance is built.

Merck, like many of your companies, has long had structures in place to promote compliance. But several years ago, we decided we wanted to take our efforts to the next level, so we developed what we call our Compliance Charter. This written statement articulates Merck’s commitment to the highest standards of ethics and compliance, organizes our compliance functions around divisional lines, and provides for periodic reporting to the Management Committee and the Board. Through the Charter, we have
also established mandated compliance objectives and put in place clear measures of accountability.

To implement the provisions of our Charter, we depend on both our Corporate Compliance Committee and our Corporate Compliance Officer, Bert Weinstein. Bert and the Committee serve several key roles.

The first concerns the development and implementation of our divisional compliance functions throughout the company. We have deliberately given our divisions significant responsibility for managing and meeting compliance standards within their organizations. We believe that this divisional focus provides for more effective compliance throughout the Company for two major reasons. First, since each division has its own set of unique challenges, a “one-size-fits-all” approach might not fully capture all those needs. Second, the divisional focus allows for a rapid response to any potential problems that may arise.

Each division develops a compliance program tailored to its particular needs and circumstances. But to ensure that those programs meet our company-wide expectations, they receive assistance and guidance from the Corporate Compliance Officer and oversight and supervision from the Corporate Compliance Committee. This helps keep every divisions effort consistent with our overall goals.

The second key responsibility of the Corporate Compliance Officer and the Corporate Compliance Committee is to ensure that all company-wide compliance functions are linked. Because compliance cuts across several functional areas, including the Board’s Audit Committee, our Management Committee, and our Legal Department, we wanted one office whose sole mission and focus is compliance. That’s another part of what our Bert and the Committee do – keep our compliance efforts coordinated and moving in the same direction.

By overseeing compliance from the top and giving divisions responsibility for establishing and carrying out their own compliance procedures, we are drawing on the strengths of both areas of the company. We have established the benchmarks company-wide and provided mechanisms to ensure those benchmarks are met. But we have also given the various parts of the company the ability to meet those benchmarks in ways that make the most sense for them while meeting the highest standards of ethics and compliance.

Of course, because the stakes are so high, verification procedures are also important to promoting and ensuring compliance. “Trust but verify” wasn’t just good policy for nuclear arms agreements, it’s good policy for compliance efforts as well.

Quality assurance, the review of marketing materials by both legal and medical experts, and internal audits are some of the basic tools of any verification effort. To ensure compliance you need to actively reach into your organization. This is one area where you should never assume that no news is good news. By making sure that rules...
are being followed – by holding people accountable – you can help keep compliance efforts on track.

A formal compliance structure is just one part – a very important part – of any company’s efforts to meet those high standards of ethics and compliance. But as I said earlier, ensuring compliance alone is not sufficient. Because we are a public trust, we should aim higher. It’s not enough to just get by. We expect more of ourselves. We demand the highest standards of integrity and ethics of all our employees, in everything they do. The rules establish the minimum standard they are expected to meet – the foundation on which a truly ethical operation is built.

It is worth remembering that many troubled companies have, on the surface, followed the letter of the law and the rules. But while compliance is important, it is not always enough to protect your company. We cannot rely solely on rules-based systems. No set of rules, no matter how complete, can anticipate every eventuality. That’s why, at Merck, we are doing more.

In 1995, shortly after I joined Merck, we created our Office of Ethics. Some many wonder what this has to do with compliance, and I will admit there are those who think ethics is one of those “good corporate governance” things that may be nice to do, but isn’t truly necessary. I couldn’t disagree more – promoting ethics provides positive, practical benefits. Reinforcing the importance of ethics in anything we do helps promote compliance in everything we do.

Our Ethics Office is responsible for carrying out every aspect of our ethics policies, both here in the United States and abroad. The office has been headed since its founding by Jacqueline Brevard, a long-time Merck lawyer, who is today a nationally-recognized expert in this field.

When we established the Office of Ethics, I charged it with several important objectives:

First, develop one global code of conduct for every Merck employee in every office in every country in which we operate;

Second, develop the training needed to ensure that all Merck employees were not only familiar with the Code of Conduct, but know how to apply it in their work;

Third, establish fully staffed and supported confidential structures that our employees could use to ask questions about ethical dilemmas they faced, or report unethical or illegal behavior they knew or suspected was taking place without fear of retaliation;

Fourth develop a strategic communications plan, to ensure that all of our employees knew, not only what resources were available to them, but how to access those resources.
We also gave our new Office of Ethics independence within the company. Jacquie Brevard reports directly to me, and we meet at least once a quarter so she can share her informed perspectives on how the Company is functioning from an ethical standpoint.

It’s important to point out that when I decided to establish the ethics office, it wasn’t because I had any doubt about the integrity and ethics of Merck employees. Quite the contrary; Merck has a long history of adhering to the highest standards of conduct and behavior.

But one cannot rely on past performance, which is, after all, no guarantee of future results. And when companies, such as ours, are growing, adding new employees and expanding operations around the world, it’s important to ensure that every employee knows that meeting the highest ethical standards is not just a part of how we do business, it is at the heart of how we do business.

The first test our new Office faced was developing a global set of standards. Traditionally, companies have drafted standards of conduct designed just for use in the United States, and then have exported those codes to their overseas operations. Typically, such codes will cite chapter and verse of American laws against price-fixing or anti-competitive practices, for example, but they won’t address the values that underlie the laws.

For a company like Merck, with operations just about everywhere in the world, that doesn’t work. That is why Merck’s guide to Our Values and Standards deliberately does not read like an obscure legal document, it is written in everyday language that our employees can relate to.

Our code of conduct says such things as: “We compete fairly and honestly,” “We strive to maintain an environment free of harassment, where all employees are respected,” and “We may not buy or sell Merck securities, on the basis of non-public, material information.” Because they are based on the fundamental question of right and wrong, these standards can and do apply everywhere and to everyone. They also help bolster the specific of compliance training.

Of course, creating rigorous ethical standards is just the first step. Any company that’s serious about its standards has to make every effort to train their employees in what the standards mean to them on a day-to-day basis and how they apply to their business life.

At Merck, every new employee receives, as part of their orientation training, a section that covers our Values and Standards document and that gives employees all the information they need about the resources available to them through our Office of Ethics. Similarly, when employees move up the corporate ladder and become managers, for
example, our ethical standards are reinforced as part of the training they receive for their
new position.

In addition, we tailor our training to meet the needs of people holding different
jobs within the company. The real-world dilemmas a pharmaceutical sales rep will face
are different from those likely to confront someone who works in a research lab. Our
training takes that into account.

It’s also important that training offers more than just theory – it must provide
practical advice. Through our Ethics Awareness Workshops, we provide our employees
with practical advice that will help them recognize and then deal with a potential ethical
dilemma.

These workshops teach people how to apply our values and standards in the real
world. We recognize that when people are striving to succeed, they may be tempted to
take an occasional ethical shortcut. These workshops give our employees practical
advice on how to short-circuit that temptation.

Of course, no amount of training is ever sufficient to prepare people to meet every
ethical question they confront at work. There is plenty of gray area in ethics, and
sometimes certain ethical imperatives may appear to be in conflict. Most people who get
cought up in unethical behavior are not fundamentally bad. More often than not, they are
good people who are doing something unethical in the mistaken belief they are helping
the company. That is why it is crucial to give employees a place where they can turn for
guidance.

At Merck, we have several such mechanisms in place. Our Office of Ethics is
always available to provide advice, either by phone, email, fax, or even regular mail.

In addition, we have established what we call the Merck AdviceLine, a toll-free
number that employees can call to talk through an ethical dilemma they may be facing or
to report suspected or actual cases of unethical or illegal behavior. Callers to our
AdviceLine can remain anonymous – we do not want any employee who raises a
business practice issue at Merck to fear that they might lose their job or suffer retaliation.
We also let people know, that when it comes to promoting compliance and ethics, there is
no such thing as a dumb question.

A further resource is our Merck ombudsman program. All of our major locations
in the United States have an ombudsman on site, to whom people can turn. This is yet
another confidential alternative that people can use to help them navigate a potential
ethical minefield.

Of course, all of this effort is worth nothing if our employees don’t know it’s
available. An advice line that never rings isn’t doing any one any good. That’s why it’s
vitally important to effectively communicate information about the full scope of
resources available to support our commitment to the highest standards of ethics and integrity.

For example, we need to be sure that the phone numbers of our Office of Ethics and our AdviceLine are readily available, that employees know who their ombudsman is, that they know where to find a copy of our code of conduct, and that managers at every level reinforce the importance of ethics and compliance.

Of course, communicating the importance of ethical behavior requires much more than words alone. Actions always speak louder than words. That’s why we make ethical behavior, including treating others with dignity and respect, an integral part of performance reviews and advancement decisions.

Our commitment to ethics has served us well. We do not see it as a disadvantage; we find it gives us a competitive advantage. Dealing with people honestly and fairly, treating all those with whom you work (both inside and outside the company) with dignity and respect, meeting your commitments – those are the foundations on which strong business relationships are built.

I want to make one last point before I close and take any questions you may have. In the final analysis, it is the people – not the regulations – that run companies such as ours. When it comes to compliance and ethics, the measure of success is the sum total of countless business and ethical decisions that are made every day by employees, at every level of the company. That is why our firms must constantly focus on developing sound ethical judgment of their employees, just as we develop their technical or business skills.

All of us in this room share a common goal: ensuring that the medicines that America’s pharmaceutical companies provide are safe and effective, will provide real value to the patient, and will improve the quality of their health and their lives. By complying with our laws and regulations – and by going beyond – we will meet that goal in everything we do.

Thank you.