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Thank you, Michael, for that kind introduction. And thank you all for giving me an opportunity to share with you my views on compliance and – most fundamentally – trust in our industry.

As compliance professionals, I'm sure you will agree that this is an important time to look at how we comply with healthcare laws and regulations.

Consider this: since January of 2009, the Justice Department has reached settlements totaling nine billion dollars against healthcare companies. These cases involved alleged false claims, fraud, and FDA violations.¹

As someone who decided more than 25 years ago to pursue a career in the pharmaceutical industry, I ask myself: what's going on? Why is this happening?

After all, our industry has made very important contributions to improve the health and well-being of people around the world. Our industry has discovered and developed hundreds of medicines and vaccines to treat or prevent diseases.² Procedures that were once common, like ulcer surgery, have been practically eliminated.³ The death rate from HIV/AIDS has fallen by more than 70% since 1995 because our industry discovered and developed highly effective antiretroviral treatments.⁴ Survival rates for cancer are increasing, thanks largely to new treatments from the pharmaceutical industry.⁵

So, pharma has done a lot of good. Yet, as many have observed, an industry that should be hailed as one of the greatest contributors to health in our society actually ranks among the lowest in public trust. In a recent Harris poll, only 11% of people said the pharmaceutical industry is generally honest and trustworthy.

So what went wrong?

The answer, I believe, is that, in some ways our industry lost its way, and failed to fully appreciate the evolving expectations of our stakeholders.

Before the first PhRMA Code was adopted in 2002, the industry worked with its customers in ways that are common in many industries in which business-to-business selling takes place. Yes, in the 90's and the early 2000s, we did take customers on trips, like many industries, and our customers enjoyed that. Yes, we did bring pads, pens, textbooks, medical models and other items to customer's offices. And, like in many industries, those "gifts" were appreciated.

We also increasingly relied on a competitive selling model based on sending in ever greater numbers of sales representatives to call on a single doctor. The focus was on reach and frequency – reach as many doctors as possible and provide them with our messages as often as possible.

This business model may still be OK for other industries, but we do not sell chocolate or cars. We bring life-altering and life-saving medicines to patients.

Society holds our interactions with our customers – healthcare providers and payers – to a higher standard. And it should. Society expects our business to be conducted openly and transparently and in a way that does not create even a perception of inappropriate influence.

To be fair, our industry has made significant changes in how we operate over the past several years. What our critics either are unaware of – or choose to ignore – is that our industry adopted the PhRMA Code almost ten years ago, which serves as a baseline for how we should work with healthcare providers and institutions. The industry then strengthened the code in 2009, making additional changes in areas such as meals, continuing medical education, support for educational and professional meetings, and the use of consultants and speakers, among other things.

I'm proud to say that many companies in PhRMA, like GSK, have taken actions that go beyond the code.

But negative perceptions remain. Some of this has to do with long-running government investigations, litigation over past practices, and the resulting news coverage that makes it look like we still take doctors on trips to exotic locations — which we don't. Some of it is because we haven't done enough to communicate what we do and don't do. Some of it is because industry bashing is good politics. Some of it is because we still make mistakes. No matter the reasons, at the end of the day, we must regain the public's trust in our industry.

So, what should we do?

Of course, we must comply with the laws and regulations that govern how we in the pharmaceutical industry are required to operate our business. That is not subject to debate or open to interpretation. It's a given.

But our customers need to understand – that beyond compliance – we operate from a core set of values that underpins every decision we make and every action we take. A values-based culture creates a framework and a mindset in which compliance with rules and regulations is not the ceiling, but the floor from which our organizations should operate.

Some of you may be wondering why I should be talking about values, when my own company has borne its share of allegations and has been in the news lately for settlements and legal charges. I'm here precisely because my company and the people I work with are not what are often portrayed publicly. The people I work with are dedicated to meeting the needs of our customers and those we serve based on our core values as a company.

And what are those values? There are four we strive to live by at GlaxoSmithKline:

- first, focus on the best interests of the patient,
- second, be transparent about our working relationships,
- third, operate with integrity
- and, fourth, respect those we work with and serve.

These values are not new to my company, and we don't always get it right. But, one of my goals in joining GSK two years ago was to ensure that if you stopped any GSK employee and asked them what the values of the company are, they could tell you without hesitation. Most importantly, my goal is to ensure our customers see those values in each of our employees.

It is my view that, as long as we continue to incorporate these values into our daily conduct and decision-making, we will meet the expectations society has for us, and we will be able to deliver value to our stakeholders in a values-based way.

Now, you may be thinking, that's fine – and it's great to talk about having a core set of values. But how do I, as someone who is responsible for compliance, make sure that a set of values is more than just a nice group of words or phrases? How can values make a difference to the business?

In my mind, three key elements make it happen: First, you have to be willing to break the mold and fundamentally change your approach to certain aspects of your business. Second, you must align your resources with your values. And, third, you must demonstrate leadership based on those values.

Let me address each of those points. First, breaking the mold. Times change, societal expectations evolve, and we have to continually re-examine how we conduct our business to ensure that our values are reflected in all our practices.

We also must ensure that our practices are aligned with the expectations of those we serve.

Let me give you a couple of examples of how we are breaking the mold at GSK to put our values into practice. I'll start with Focus on the Patient, which is the foundation of everything we do as a company. "Focus on the Patient" means we put the patients' interests at the heart of every decision we make.

Given evolving science, as we conduct clinical trials we obtain extensive information about our drugs. That information helps us better understand which patients may be helped by our medicines and which patients may not benefit from them.

Doctors don't need us to teach them how to practice medicine. But doctors do benefit from the very specific and extensive knowledge we have about our medicines and the conditions they treat. After all, it's hard for health care providers to stay current with all the information available about thousands of medicines – and the new ones coming to market.

When our GSK sales representatives talk with doctors, we require that they share the extensive knowledge they have about our drugs – including both who should, and importantly, who should not, take our medicines. This is something that my management team and I set as a fundamental requirement. Employees are trained to inform their customers when our products are not right for their

patients. That is just one example of delivering value to the physician that is in the best interest of the patient.

I rode with a sales representative a few days ago, and in every discussion we had with a physician, the sales representative repeated the label restrictions. In several cases, the doctor would refer to an off label use, and each time, our sales representative came back to the label. One physician said he heard us, he understood the label, but he still thought it would be appropriate to prescribe the medicine for that particular patient. And, that's fine. That's his job to determine the appropriate drug for the appropriate patient in his medical opinion. But it's our job to make sure that every physician clearly understands the approved information so they can make the right decisions for their patients.

To help ensure that the behavior of our representatives is consistent with our values, we've also decided to break the mold and change the way we provide incentive compensation to our sales representatives.

In the past, like other companies, we based the variable portion of the compensation for our sales force on the volume of prescriptions they obtained in their sales territory. That is no longer the case. We are now in the process of putting in place a new incentive compensation system in which individual sales representatives are not bonused on scripts, but on three factors: an assessment of their scientific and business knowledge; feedback from customers in their region, including demonstration of our values; and overall performance of the business unit they support.

Importantly, we're shifting our focus from obtaining the next script to providing the information and support our customers want and need. We may not be able to provide all our customers with everything they want, but what we do provide will be aligned with what they need to treat their patients better. As health care reform measures increasingly focus on improving the quality of health outcomes for patients, we believe this change will help healthcare providers in a way that is consistent with our values and delivers value to them and their patients.

I'd also like to talk about the values of transparency and integrity. Integrity is doing the right thing; transparency is being open about what we do. As I've said, some of the financial relationships and practices from previous years are no longer viewed as appropriate, and so we've changed them. Other practices that the public sometimes views as inappropriate are actually very important to good healthcare. For instance, we believe properly engaging doctors to share their knowledge with other physicians in peer-to-peer education programs helps them keep up with advances in medicine. Their knowledge and experience also helps GSK understand trends in the delivery of healthcare and the evolving needs of patients so that we can more effectively develop new medicines and vaccines.

Physicians should be fairly compensated for their time and expertise. Yet some patients, government officials, policy makers and even some in the medical community have questioned the integrity of these relationships. A recent Consumer Reports survey indicated that more than three-fourths of consumers

would be 'very' or 'somewhat' concerned about getting the best treatment or advice if their doctor were accepting drug-company money.⁷

This is where the value of transparency is important. In 2009, GSK began voluntarily posting our payments to US healthcare professionals for speaking and consulting services. To ensure that our interactions with physicians in these programs are appropriate, we've instituted a code on promotional practices. It specifies, among other things, the ways we can appropriately work with healthcare professionals, the types of information that we can provide them, where meetings can be conducted, and the fair market value rates at which we compensate them for their time and service.

GSK and other companies have increased our transparency in this area, yet by doing so, unfortunately, both the industry and physicians have been criticized in the media. We've also been criticized by some physicians who are unhappy that our strict guidelines mean they can't use their own slides in speaker programs. We make this restriction because we want to ensure that all the available information on our medicines – both benefits and risks – is presented in a fair and balanced way, and on label. But even if we get criticized for it, we should make sure we are doing the right thing and be open about what we are doing and why.

Continuing medical education is another area where we've broken the mold to ensure we are operating with integrity and transparency. We believe continuing medical education is absolutely essential to good healthcare. We also absolutely believe it must be provided based on sound science and independent of

commercial influence. Consistent with our values of integrity and transparency, we implemented a system where we limit grant applications to approximately 20 academic medical centers and national-level professional medical associations.

All CME providers we support must be directly accredited by a recognized accrediting body, and we now only fund CME by not-for-profit providers.

I've talked about focusing on the patient, transparency and integrity. Our fourth value is respect. We all know the golden rule: treat others as you would like to be treated. Let me give you an example of how we're putting that value into practice.

We market a drug that treats erectile dysfunction. This is a legitimate medical condition that affects the lives of many men. It is also a condition that many people are not comfortable speaking about. And it certainly is not a condition parents, aunts, uncles, and grandparents want to explain to children while watching a football game on Thanksgiving.

This is where respect comes in. While a practice may be perfectly legal and even acceptable according to industry codes, we have to respect the wishes of the society we serve. At GSK, we are very thoughtful about where we advertise our ED medicine. Our goal is to reach the patient where they are, rather than blanket the airwaves with general advertising. And we make every effort to avoid advertising in places that are easily accessible to children.

That brings me to how we can put resources behind our commitments to convert values and aspirations into action. Like any other aspect of business, producing results requires investment; in this case, investment in training, staffing, and systems or processes.

We all understand that training is essential if our employees are to comply with the laws and regulations that govern our business. Every employee must know what is allowed and what is not allowed.

But as compliance professionals, I don't have to tell you that not all situations are black and white, and we cannot write a policy for every possible situation. To address this, we've invested in a values-based approach to training for all employees that not only addresses real-world scenarios on relevant topics, but also provides them with skills building so they can make well-informed, ethical decisions, based on our values of transparency, respect, integrity and doing what is right for patients.

For managers, we've implemented mandatory training to help them more rapidly and effectively address, not only performance issues, but also behaviors that are inconsistent with our values. A parallel goal here is to drive home the accountability that comes with the manager role in our company.

We've placed a business ethics professional on our sales and marketing training team to seamlessly embed ethics and compliance principles into ongoing training and skills development. This is in addition to the traditional compliance education efforts in our Ethics and Compliance Department.

As I'm sure is the case in your organization, we work with lots of very smart people. When we conduct training, they not only want to know what to do, but they also want to understand the "why" behind laws, regulations and policies. So, we hold our management accountable for explaining "the why" and emphasize it in all our formal and informal communications. We also encourage employees to speak up and ask "why" if we have not sufficiently explained the rationale to them.

In addition to the "why," we also focus on the "how." As part of our performance management process, our employees have a values and integrity objective included in their annual performance plans. They are evaluated for not only "what" they do, but also "how" they do it. This enables us to incorporate a behavioral component into our performance evaluation process, further supporting our commitment to the company's values.

So, we've done a lot in the area of training. We've also invested heavily in staffing. We've embedded deputy compliance officers in each one of our business units. It's the job of these senior leaders to work with their business units to ensure that we are fostering a culture consistent with our values, implementing our training and education programs, and using our systems and processes to ensure we are operating and behaving as we should. In addition, our deputy compliance officers sit on the business unit leadership teams, and are

charged with establishing compliance controls and risk management programs specific to the business unit they support.

We've also made a significant investment in establishing 60 Integrity Champions who provide training and support so that we can further ingrain accountability for values and compliance throughout the business.

On the systems and process side, we've invested substantially to establish mechanisms for employees to report problems and raise issues. For instance, our GSK Integrity Helpline enables employees to raise issues and supports them in making informed, ethical decisions that are aligned with our values and policies. This is a useful resource if they feel uncomfortable talking with their managers, deputy compliance officers, Integrity Champions or legal or HR representatives.

All this work is moving our company beyond a compliance mindset to one that is values-based. We are helping our employees understand how our values support our business strategy and, most importantly, how they have a responsibility to guide us in always doing what's right for patients. And our employees get it. For instance, today our internal compliance helpline is used by employees less to report potential infractions and more to ask questions about how to make the right decisions for our company, which helps to avoid infractions in the first place.

All these efforts reflect my view that compliance belongs to everyone in the organization and isn't just owned by the compliance department.

Ultimately, you get returns from what you invest in and what you reward. Yet even with extensive training, and a culture that encourages and rewards values-based behavior, there will, unfortunately, be instances where individuals make mistakes or choose to do something they shouldn't do. And that is where you must have the systems and processes in place to address bad or inappropriate behavior. When we learn of behavior that is inconsistent with our values, we investigate and take disciplinary action, including dismissing employees when necessary.

So, investing resources in training, people and processes are important. But is it all about resources? Absolutely not. Which brings me to leadership – the final element I see as essential for making values fundamental to the culture of an organization and its daily practices.

All of the usual principles for leadership apply: we must set a clear vision, we must define a path forward and we must walk the talk. How do I, as a leader, do that? I'll give you an example. At every one of my staff meetings, the first item on our agenda is compliance with our values. I co-chair that discussion. It usually lasts well over an hour because my team is fully engaged and takes that as an opportunity to address any issues we need to tackle.

My leadership team has also developed "Integrity Plans" for each of their business units, which include specific action items they are taking to support and foster integrity.

But I believe the greatest imperative for us, as leaders, is to look forward and examine what more we can do to ensure our practices are in step with societal expectations.

Our customers are watching. A few months ago, I received an e-mail from one of our regional leaders, asking me to call a physician in California. That doctor had a conversation with one of our sales professionals about our values. She listened, but she was skeptical, so she asked our representative if she could talk to the President of the company to see if we were for real.

Well, I called this physician, who is a prominent expert in her field. This doctor told me she used to work with our industry, but had not for a while. I spent time explaining to her how we are putting our values in action. At the end of our conversation, she said that she believed we were the kind of company that she would like to work with because she believes we are truly patient focused. And she's right.

When our customers start telling us they see us differently, we have begun to shift our value in their eyes. They start to see our industry as a true and honest partner in making their patients better. I would like for all of our customers to say that. I would like for all our sales professionals to feel that.

For our industry to regain public trust, we must constantly examine how we interact with our customers, how we communicate with patients and providers, how we fund activities and how we share information. We also need to do a better job of informing those we serve about how we operate now – which is one

reason why I am here today. Yes, the past will continue to be reported as if it was the present, but we must communicate and demonstrate the changes we've made. And we will need others in healthcare to stand with us and embrace a values-based approach to all our interactions.

That's where your leadership is critical. As leaders, it is our responsibility to understand the needs and concerns of those we serve. As leaders, it is our responsibility to make sure we have the courage to break the mold. As leaders, it is our responsibility to back our aspirations and words with investment. As leaders, it is our responsibility to identify what still needs to change and make that change happen.

By doing these things, we can assure the public that our industry – an industry that has brought so much benefit to so many – is conducting its business with focus on the patient, with transparency, with integrity and with respect. In this way we will be worthy of trust.

Thank you.

- 1. Department of Justice, Office of Public Affairs, News Release, Tuesday, December 7, 2010.
- 2. PhRMA website, http://www.phrma.org/new-medicines-transforming-patient-care, January 6, 2011.
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- 4. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Health, Untied States, 2009 With Chartbook on Medical Technology (Hyattsville, MD: HHS, 2010).
- 5. J.M. Kremer, "COMET's Path, and the New Biologicals in Rheumatoid Arthritis," The Lancet 372, no. 9636 (2008); 347-348.
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