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President's Address

Good morning everyone, and thank you, Doug, for that gracious introduction.

It's a privilege to be here today to deliver the President's address for CBI's 9th Annual Pharmaceutical Compliance Congress. I had the chance in 2008 to address the 5th Annual Congress and I'm thrilled to be here again for many reasons, but there are three in particular that I'd like to discuss during my remarks this morning.

1. First, there are few things as important to me, to Pfizer, and to the innovative biopharmaceutical industry, as ensuring compliance and integrity in everything we do.
2. Second, when it comes to demonstrating a real commitment to compliance and integrity, I know that Pfizer and the industry has a lot to show for itself and to be proud of, even since I last addressed you just four years ago.
3. And third, while continued diligence and the passage of time are required to ensure the sustainability of our progress, I believe that we are ready to begin a serious discussion about what a world above and beyond today's compliance landscape might look like.

I'll address each of these points in turn over the next several minutes, closing with a challenge as to where we must quickly aspire to be.

[Point #1] -----

Few topics are as important to me, to Pfizer and to our industry as compliance and integrity in everything we do.

This is an obvious statement that anyone addressing you this morning would be expected to make, but it's important to be clear about what this really means, as, I believe, the future viability of our industry is at stake.

Most of us know that it didn't used to be like this. Rather than jockeying for position on annual "least admired industry lists," the pharmaceutical industry had for decades been widely admired and respected – and for good reason. I could go on at length with charts, statistics and other irrefutable evidence, demonstrating the incredible contributions the industry has made over the past 100 years toward the eradication, remission and relief of serious diseases:

- The dramatic improvements in both length and quality of life;
- The infant mortality reductions;
- The hope for patients with cancer, HIV, multiple sclerosis, heart disease, and many other diseases and conditions that were often virtual death sentences for our parents' generation; and
- The scientific discoveries that would otherwise go undiscovered which, after relatively brief periods of patent protection or regulatory exclusivity, become perpetual gifts for our children, their children and generations to come around the world.

As these examples and our history attest, the innovative biopharmaceutical industry has a noble purpose – simply put, to advance science and improve lives. The chance to build on and contribute to the fulfillment of this purpose is what first drew me from a pharmacy career into the industry nearly 30 years ago.

Today, however, our entire health care system is at a crossroads. As a society we face a multitude of complex and contentious legislative, policy, legal, fiscal and social

issues, here and abroad, whose outcome over the next several years will determine the future of health care for generations to come, and in turn, significantly impact the viability of the biopharmaceutical industry.

Whether our industry's future contributions will be able to match the remarkable accomplishments of its past, depends on several things, including:

1. A shared societal understanding of the dire need for continuous scientific advancement and discovery to address the enormous unmet medical need that remains and will inevitably emerge;
2. Recognition of the unique role that only the innovative biopharmaceutical industry can fill in addressing this need, without which many scientific discoveries will not advance, and many more will remain undiscovered altogether. This is not just a bad scenario for the industry, it's a devastating outcome for society; and
3. A legal, regulatory, business and health care policy environment that rationally encourages and supports the potential for the industry to be successful – now and longterm.

As of today, I question whether the momentum is very favorable for us on any of these three items. While I'm concerned, let me be clear: I believe strongly in the future of our industry. But like anything worth having, there is a lot of hard work ahead to secure that future. Without getting into the merits of any of the policy, legal or other issues to which I've alluded, I know that our industry has uniquely valuable ideas and contributions to make that can help to shape the right outcomes.

But our ideas will never be heard or considered if we are not at the table. The fight for that seat is tenuous these days, and it won't be secure until we have won the battle to clearly and convincingly demonstrate that as an industry we are a credible partner and a trusted voice.

So what to do about it?

We have to get ourselves off those “least admired lists.” We have to rewrite the headlines that have become all too common over the past 10 years. Headlines about the allegations, the investigations, the civil and criminal prosecutions, the settlements and the Corporate Integrity Agreements. These headlines have eclipsed the great work that we have done, have helped shape the public view of who we are and what we aim to do, and have firmly formed a widespread perception and opinion that we can’t be trusted.

We have to turn back the clock to a time when what we do – our noble purpose – was recognized, valued and admired. We were trusted before, and now we have to re-earn the trust of all our most important stakeholders – patients, their families and caregivers, physicians and the health care community at large, payers, state and federal legislators, regulators, our own colleagues, friends, families, neighbors and more.

Ensuring compliance and integrity in everything we do is the first and most important step to re-earning that trust. Without compliance and integrity at the core of our mission and operations, there can be no trust. Without trust, which is far more than mere compliance, the viability of our industry is in jeopardy.

[Point #2] -----

In demonstrating our compliance commitment, Pfizer and the industry have a lot to show for themselves and to be proud of.

As urgent, yet daunting a task as re-earning trust may seem to be, I’m encouraged in that much of the heavy lifting on some of the most fundamental and important steps has already taken place. Based on firsthand experience, this is certainly the case for Pfizer, but I also believe it to be so for much of the industry as well.

There’s something akin to a “12-step journey” required to really get one’s hands around this situation. For our industry there are four key steps:

1. To acknowledge that there is an issue;
2. To commit culturally to take it on;
3. To back up the cultural commitment with resources and a state-of-the-art compliance system; and
4. To prove it with a long-term sustained track-record of compliance.

I'm confident that the first step has been embraced by the entire industry — just look at how many people are in this banquet hall. I also know that at Pfizer, we're well through steps two and three, and are firmly committed to the fourth. I'm sure that many of the other companies present here today can say the same, and hope that very soon so will the entire industry.

As an industry I think we've come to appreciate that while we are businesses, we aren't just any business, nor do we want to be. We have that "noble purpose" I spoke of and we aren't just making widgets. The price of admission is high and we must accept that being held to a higher standard on many levels is simply part of the deal. While compliance is the essential starting point, our stakeholders expect far more. Understanding and embracing this reality, has helped us to acknowledge the situation and the issues we face.

Having done so, the response is obvious. Every effort is required to convincingly demonstrate the industry's commitment to compliance and integrity, and to dispel any potential for misperception. Let me be clear about what this means.

Our challenge isn't actual compliance. That's a given and there are many compelling legal reasons that demand and incent us on that front. Our ultimate challenge is to overcome the "presumption of noncompliance" that so often exists and has, to a certain extent, been fueled by our own mistakes. A deep hole has been dug over the past 10 or more years, fueled by more than a few self-inflicted wounds from across the industry. This "presumption" fuels an unacceptable misperception about our commitment to compliance in the minds of patients, their families, physicians and many health care professionals who come to believe that the industry cares more for profits than patients.

We have to overcome this “presumption of noncompliance” and get to where every stakeholder interaction starts with a hard-earned “benefit of the doubt,” an aspiration that I’ll return to later in my remarks.

Although the battle is far from over, the industry has responded. It has raised the bar.

Beginning with the 2002 issuance of the PhRMA Code on Interactions with Healthcare Professionals, which was further expanded in 2009, the industry has adopted numerous reforms that have significantly evolved industry practices regarding the marketing, sale and promotion of its pharmaceutical products. The 2009 expansion included a requirement that participating companies certify annually that they have implemented policies and procedures to assure compliance with the Code. Updated earlier this month, PhRMA’s website currently lists nearly 60 biopharmaceutical companies, including Pfizer, that have made this commitment.

With the most objectionable industry practices long eliminated, a wide range of additional industry-initiated voluntary reforms, new statutory mandates, and increasingly, the “de facto industry requirements” established with each newly-negotiated CIA, provide that remaining industry practices are or will soon be subject to transparency and disclosure measures, unprecedented in any other industry. Examples include PhRMA’s Principles on the Conduct of Clinical Trials and the Communication of Clinical Trial Results, or the Physician Payment Sunshine provisions of the 2010 Patient Protection and Affordable Care Act. Collectively, these and other measures ensure transparency of interactions with physicians and many other components of the health care community, whether related to the conduct of clinical trials or the publication of their results, support for unrestricted medical educational grants, independent investigator initiated research grants, charitable contributions, payments for consulting services, or, as in Pfizer’s case since early last year, even the cost of a few cups of coffee and a bagel.

Whether driven by the need to address actual compliance issues, to mitigate conflict of interest concerns, or simply to respond to reputation-based criticisms, the bottom line is

that today the practices at Pfizer and across much of the industry bear no resemblance to the practices that underlie most of the major government settlements announced over the past 10 years.

Unfortunately, there continues to be limited awareness among many of our stakeholders and the public at large about the extent of these changes. With every announcement of the latest government settlement, often lost is the fact that in many cases the conduct in question is several years old, pre-dating the impact of the many reforms that have already been made. Settlement announcements and the ensuing publicity often serve to reinforce perceptions that we are a rogue industry that puts profits over patients, and considers fines and settlements to be an expected cost of doing business.

To be sure, our work is far from finished, and no matter how robust the changes and reforms are to date, only the passage of time will prove their effectiveness and sustainability. Nevertheless, for meaningful progress to continue, more must be done to ensure that all industry stakeholders – supporters and critics alike – understand the changes already made and the related impact.

Beyond the industry-wide reforms, many companies have gone further. At Pfizer, we have of course learned many difficult lessons arising from our own government settlements and resulting Corporate Integrity Agreements. We have a deeply embedded commitment to a culture of compliance that permeates our entire organization; backed up by a comprehensive and innovative compliance program.

Buoyed by the launch several years ago of the “It’s Mine” campaign under the leadership of Pfizer’s Executive Committee and our Chief Compliance and Risk Officer Doug Lankler, our commitment to compliance has been driven throughout Pfizer to every colleague in the U.S. and around the world. Its message being the simple reality that compliance is not the responsibility of the legal or corporate compliance departments, but of each and every colleague at every level of the organization, from every discipline and function and in every country where we do business. The responsibility for compliance at Pfizer is “not theirs or yours, *It’s Mine*” goes the

campaign. While catchy, it's not just a mantra and a fancy lapel pin, but a philosophy and belief firmly embraced by all Pfizer colleagues. This campaign has permeated the organization, re-awakened the inherent nature and instincts we all had toward compliance and facilitates an ongoing, transparent and highly engaged dialogue across all quarters of the organization as to what compliance really is, how it's achieved and the critical role every colleague has to play.

The "It's Mine" campaign has also taught us that compliance is not a stand-alone goal. Although essential, compliance for compliance's sake, has limited utility. It is most valuable when integrated real-time as a conscious consideration into every decision we make. Doing so consistently results in better decision-making that not only ensures compliance, but optimizes the potential for legitimate business objectives to be achieved, and anticipates potential environmental or reputational issues that might exist.

We've backed up this culture of compliance with a tangible investment over the past several years in an extensive compliance infrastructure and innovative, industry-leading compliance systems. Since my last CBI address in 2008, some of the organizational enhancements Pfizer has made to further establish the oversight, accountability and effectiveness of our compliance operations, include:

- We've elevated our Chief Compliance Officer Doug Lankler and his Corporate Compliance organization to report directly to our CEO & Chairman of the BOD;
- We've implemented a tiered oversight structure that ensures accountability at all levels of the organization – from the Board of Directors down through our individual business units. This includes the Regulatory and Compliance Committee of the Board; an Executive Compliance Committee chaired by our CEO, that I am a member of; and the Specialty Care & Oncology Business Unit Compliance Committee that I chair;
- We've embedded Corporate Compliance colleagues within each of Pfizer's operating units, including my Business Unit, as well as our research and manufacturing operations; and

- We've created an office of the Ombudsman as another avenue for colleagues to confidentially raise compliance or other work-related issues.

We've also implemented several formal compliance system innovations that greatly enhance our ability to ensure the effectiveness of and adherence to our existing compliance policies, procedures and training programs. Two notable examples are:

- Our Risk Assessment & Mitigation Planning System, or "RAMP", a software-based application that requires proactive compliance risk assessments and mitigation planning for each Pfizer product supported by salesforce promotion; and
- Our Promotional Quality Assurance ("PQA") program, which for designated high-risk and other select products conducts quarterly reviews of emails, call notes and verbatims to proactively identify potential compliance-related issues.

As effective as we believe our efforts to be, no system is capable of guaranteeing 100-percent compliance, although that remains our goal. When instances of noncompliance do occur, our program is designed to ensure they will be isolated, nonsystemic events that occur despite a clear understanding of our policies and the consequences for non-adherence. We are diligent in our efforts to identify any instance of potential non-compliance as soon as possible. Through our PQA program, our long-standing open door policies, a well-publicized and anonymous compliance hotline, extensive HR requirements, our new Office of the Ombudsman and reports from third parties, including other biopharma companies, HCPs and government officials, we cast the net wide to capture any and all reports of actual, potential or even perceived compliance violations. Each is swiftly evaluated, thoroughly investigated and, when necessary, remediated up to and including termination. Root-cause evaluations determine whether modifications to our systems are needed.

With the addition of these and many other elements, Pfizer today has what we believe to be among the most comprehensive and effective Corporate Compliance programs in our industry, or any industry.

Within Pfizer we've often discussed the notion that industry-leading compliance can be a competitive advantage. I get that concept, but frankly I'd rather have our competitive advantage flow from the excellence of our scientific discovery capabilities, the quality of our clinical trial designs, the health outcomes achieved by the products we provide, or in the development of new, creative and valued ways to meet the needs of our customers.

While a competitive advantage based on a commitment to compliance and a sophisticated compliance system may yield certain benefits in the short term, in the long term, I believe we are far better served, as an industry, when all biopharma companies have an equal commitment to compliance and when we've all implemented effective compliance systems that are diligently maintained and continuously improved.

Our industry continues to be painted with a broad brush, with the lowest common denominator driving public perception and opinion. The announcement of every new government settlement, as devastating as it might be for the company in question, also triggers the "there they go again" sentiment, reinforcing the worst perceptions of our industry, and serving to set back hard-fought gains on our efforts to re-earn trust.

At Pfizer, we clearly are proud of our compliance commitment and program. I don't know if it's a competitive advantage or not, but if so I'll gladly give it up to raise the game of every company in our industry.

Like Pfizer, I know that many in the audience today are likewise proud of their own compliance programs and the enormous progress made in recent years. For any remaining outliers, it's time to up your game. If the culture and commitment to compliance within your organization is not where it could be – you have to get it there. Make your business leaders part of the process. Commit the resources to build the necessary infrastructure and implement the governance and oversight required to ensure long-term sustainability and effective results. Leverage the compliance best practices and innovative ideas that others have implemented. Reach out to them for help and advice; Pfizer is ready and willing to help in any way.

[Point #3] -----

Let me turn now to the third point that I wanted to address, which is whether we are ready to begin a serious discussion about what a world above and beyond today's compliance landscape might look like for the innovative biopharmaceutical industry.

I think we are. Let me try to explain.

I've spoken at length this morning about the measures taken by the industry in response to the compliance and trust crisis it has faced. I've acknowledged that we've all had to learn some tough and unfortunate lessons. I've acknowledged that there may still be outliers within the industry and that we all may not yet be at the shared level of commitment and effort required. Without diminishing the gravity of this very regrettable phase in our industry's history, I've cautioned that we also not forget how vital this industry, with its "noble purpose" is, and how much society needs for its future contributions to meet or exceed those of the past 100 years. Finally, I've acknowledged that our work is far from over. That as firm as our collective cultural commitment to compliance is, and as robust and effective as our compliance programs and systems may be, as an industry, we still have to complete Step #4 of our four-step recovery process - to prove it with a long-term sustained track record of compliance. In other words, only time will tell and our actions will speak louder than any words.

Let's assume for a moment that we do just that. Five or 10 years from now the data is in and we'll have knocked Step #4 out of the park. We'll have proven the claim that the innovative biopharmaceutical industry is committed to compliance and integrity and that any residual instances of noncompliance are merely the isolated acts of wayward employees who will be swiftly dealt with. Compliance and integrity will have become so ingrained in our respective cultures and businesses, that like breathing, they're achieved subconsciously and effortlessly. Then what?

Is it only then that we will have re-earned the trust of our stakeholders? Is it only then that we can ask patients, the health care community, regulators, other government

officials and legislators, and the public at large, to start giving us the “benefit of the doubt,” rather than the “presumption of noncompliance”? To begin to believe that we are committed to compliance, that we don’t regard the risk of massive government settlements to be a routine cost of doing business, and that we don’t put profits over patients! Is that when we can expect supporters and advocates for the industry, and its “noble purpose,” rather than critics and detractors? Is it only then that society will once again recognize the critical importance of the innovative pharmaceutical industry and the contributions it has the potential to make? Five or 10 years, maybe longer, does it have to take that long? Can society afford to wait that long? I don’t think so.

Earlier, in discussing my concerns about the long-term viability of the innovative biopharmaceutical industry, I identified three conditions that must exist to have any hope that the industry’s future contributions will match the remarkable accomplishments of its past. Let me repeat them again now. They are:

1. A shared societal understanding of the dire need for continuous scientific advancement and discovery to address the enormous unmet medical need that remains and will inevitably emerge;
2. Recognition of the unique role that only the innovative biopharmaceutical industry can fill in addressing this need, without which many scientific discoveries will not advance, and many more will remain undiscovered altogether. This is not just a bad scenario for the industry, it’s a devastating outcome for society; and
3. A legal, regulatory, business and health care policy environment that rationally encourages and supports the potential for the innovative biopharmaceutical industry to be successful – now and long term.

Considering the many complex and contentious legislative, policy, legal, fiscal and social issues presently at play in our society, here and abroad, that will impact the future of health care for generations to come, and in turn, the viability of the innovative biopharmaceutical industry, so long as the industry remains suspect and untrustworthy, the odds of securing any of these three conditions seemingly diminish each day.

The clock is ticking, society cannot afford for questions about the industry's commitment to compliance and integrity to continue any longer, much less five or 10 years. We need to be trusted now. So can we be?

Almost like a Subpart H drug seeking conditional approval, while we wait for the confirmatory long-term data to come in, do the industry's ongoing efforts to "re-earn" trust provide sufficient evidence that we mean it? A surrogate endpoint, if you will, to justify asking our stakeholders to begin to let go of the "presumption of noncompliance" and to start giving us the "benefit of the doubt"?

I sincerely hope and believe that the answer is yes. But if not, then I urge that we acknowledge what's at stake and commit that getting there is a goal we all must share – industry, patients, the health care community, payers, regulators, government entities and society at large. It's imperative that we take up the challenge to work urgently and pragmatically together to get to a world where compliance throughout our industry is a given, where trust has been "re-earned" and where the industry's contributions towards the eradication, remission and relief of serious diseases and conditions continue to benefit us, our families and generations to come.

Thank you for allowing me the privilege of being with you today. I truly value the chance to share my perspective and hope to join you again at future meetings.

Thank you.