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A Research-based Pharmaceutical Sector Built to Meet The Challenges of the 21st Century

Let me begin by stating the obvious: America's research-based pharmaceutical companies face significant challenges today and for the foreseeable future. At the same time, there are few industries in this country – or globally – that are as dynamic, that use and leverage emerging technologies better or that play as important a role in the lives of their customers as do America's research based pharmaceutical industry.

But the fact is there is one great problem that seriously challenges the ability of America's research based pharmaceutical companies to continue doing what they do better than any other entity on the globe: research and develop new cures and treatments.

In a word, it is "trust."

This is a great industry. It saves lives and contributes immensely to America's economy and technological leadership. It's an industry that should be both loved and admired.

It is not. Patients – while loving the products we make – are skeptical of the pharmaceutical industry. We must act now. The time to reverse the trend and restore public respect has come and we should have started years ago.

We have known about the problem of falling trust and public skepticism for far too long.

I am here today to say that everyone involved with this industry knows that the time for talk is over.

The industry's image problem is not intractable. Solutions exist. What's more, at both PhRMA and at our member companies, we are taking action to change the way that the public and policy makers think about this industry.

I've now had the pleasure – and challenge – of leading PhRMA for almost a year and a half.

I've been privileged to meet hundreds of the over 400,000 amazing men and women working in nearly every corner of the industry – from researchers to marketers; from those running the patient assistance programs to the men and women who make sure that medicines are packaged securely and safely.

I've seen dazzling technology being applied to the most important human problems: preventing disease, restoring health, curing disease and minimizing pain and suffering.

I've even had the privilege of personally thanking some of the thousands of dedicated men and women who worked for years to create the medicines and treatments that saved my own life.

Because I am not just an advocate for the pharmaceutical industry, I am also a cancer survivor.

I owe my life to my faith in God, the love and support of my family and to the miracle medicines made by the men and women of America's research-based pharmaceutical companies.

That is why I am saddened – as I know many of you are – to see the caricature that political

opportunists and misguided policy-makers paint of this life-saving, life-enhancing industry.

What should be viewed as a national treasure is belittled, derided and viewed skeptically.

Unfortunately, in both the short and long term, it is patients who are hurt by the doubts sown about this industry.

Until very recently, public confidence and trust in the industry had reached a dangerously low point.

Only 44 percent of consumers have a favorable view of the pharmaceutical industry;
Worse still, opinion leaders often have the most negative view;
One in three say their feelings toward the industry have gotten worse over the last year;
Press coverage is increasingly hostile – by four to one, those who have heard news about the pharmaceutical industry said that the news made them feel less favorable;
In fact, as late as last year, as much as 70 percent of the coverage in the dailies was negative.
And, as many of you know all too well, the situation appears dire:
The industry's public approval ratings are only slightly higher than those of personal injury lawyers;
Poor standing means weakening support with critical elected officials on every level and making us vulnerable to public policies that could hark our freedom to operate and our ability to successfully invest and be rewarded for our important research and development;
Our friends and allies – not those here today, fortunately – are battle weary and our adversaries are motivated.
But the news is not all bad.

Patients and physicians really do love and appreciate the medicines our industry makes.

Survey after survey shows that patients and health care professionals alike think highly of the medicines they use. For the most part, patients trust their prescribing physicians and understand that risks and benefits are always involved when taking any medicine

Unfortunately, the same patients who love individual medicines and even individual companies that has helped to save or maintain their lives, however, too often believe that the pharmaceutical industry has lost touch with their hopes, concerns and needs.

They fear that profits come before ending their suffering and some even believe that researchers and companies could suppress new cures or treatment if curing a disease would might end a lucrative income stream.

Somewhere along the way, too many patients and too many health care workers stopped seeing the pharmaceutical industry as we in the industry see ourselves.

Needless to say, we needed both actions and words to begin changing this toxic atmosphere.

Without acting, industry critics – whether acting intentionally or because they do not understand the long, costly years needed to create new medicines – will successfully chip away at this industry's freedom to operate and increase the risk of investing in new research and development until the biopharmaceutical industry in the United States begins to mirror the empty shell of the industry that once existed, for example, in Europe.

Their short term political victories, however, will ultimately have dire consequences for patients and for those like me who were in need of both hope and new cures and treatments to save their lives.

As a cancer survivor, this is not the future I envision.

The future I envision is one where newer, better cures and treatments continue to pour out of the research and development pipeline.

It is one where new technologies reduce the time and cost of bringing new medicines to patients.

It is a future where patients and physicians have access to the medicines they need when they need them.

It is a future where patients, healthcare professionals and the pharmaceutical industry work closely together to improve lives, health and hope.

I chose to work for PhRMA, and I am here today, because I believe we can together create this future.

Today, we are restoring patient and physician trust in America's research-based pharmaceutical companies.

I believe that the future of this industry holds the promise for patients of better health, disease prevention and new cures and treatments and because there is nothing more important than for this industry to fulfill this promise.

The key is our ability to communicate, advocate and educate patients, physicians, health policy makers and the general public about this industry and how it works and the works it does.

There are three challenges we have to address to fully win-back the trust and confidence of patients, health care professionals as well as health policy makers and the public. First, we must do better providing ACCESS to both care and information about our medicines, our industry and health care in general;

Second, we must be active in helping to develop new and better solutions to the real problems of COST and QUALITY health-care;

Third, we must continue to promote and environment that rewards and inspires INNOVATION.

These are difficult challenges. But, they are not intractable. And, we have already begun to build a credible record.

We have already taken steps at PhRMA and at our member companies to both rebuild this industry's reputation and secure its future.

The first, most important change needed to solve the industry's image problem has already occurred.

At PhRMA and at our member companies there is a renewed effort to see the world and the pharmaceutical business first and foremost through the eyes of patients.

This is not an entirely new way of seeing the world -- it is the heart of our industry's historic success and the heart of its business.

Anyone who has talked with and worked with the thousands of dedicated men and women working for American's research-based pharmaceutical companies knows that they have always tried to put patients first.

Anyone who knows PhRMA's member companies knows that they were each founded by men and women dedicated to patients, improving their health and preventing disease.

But somewhere along the way we stopped saying it and we stopped being seen to do it.

No longer.

At every company I've visited and every industry group I've addressed has dedicated themselves to reinvigorating the commitment to put patients first.

Because when we put the patient first in all of our words and actions, our business decisions, our policy goals and our research and development will all be driven by meeting the interests and needs of the patients who use the medicines PhRMA member companies make.

And when the interest of the industry is more fully aligned with the interests of patients and doctors – preventing disease, restoring health, healing and easing pain – the public will stand by the industry and those critics who attack us – whether through ignorance, opportunism and expediency – will NOT control the conversation and debate.

Of course, saying we stand with patients and that we see the world and our business through their eyes, must be – and is – backed up by our actions.

PhRMA and its member companies are now aggressively focusing on the problem of access to both our products and to information about our products.

Patients want and need access to the medicines the research-based pharmaceutical industry makes. If patients don't have access to these medicines, it defeats the whole purpose of the long and expensive development process.

A medicine that sits on the shelf helps no one.

Further, the concerns of many patients that the medicines we make will not be available to them play a significant role in the loss of trust that afflicts this industry.

That is why we have worked so hard to promote and educate patients about the importance and value of the new Medicare drug benefit.

Today, over 30 million Americans are enrolled for a benefit that is providing million, for the first time, with a drug benefit that reduces their drug costs and helps make sure that the medicines that they need are available when they need them.

Importantly, the Medicare drug benefit is giving beneficiaries real choices and flexibility. Patients can select from many plans the drug benefit program that best fits their individual needs and covers the medicines they need.

Helping patients select the right benefit for their need and navigate the sign-up process has been a priority not just for PhRMA and the pharmaceutical industry.

To help seniors and patients sign-up for the right drug benefit, PhRMA and our member companies are working as part of a network of over 70 public and private organizations that includes groups like the AMA, AARP, Pharmacists and the Chamber of Commerce – chaired by my good friend, former Senator John Breaux of Louisiana.

This isn't a political campaign or a public relations campaign...it is an education campaign.

The Medicare RxEducation Network was created with one purpose, to help organizations maximize their effectiveness at getting information about the new Medicare benefits to patients.

But, as the Medicare drug benefit is, we can and are doing more to make sure that patients get the medicines they need.

That's why in last April, we joined with public and private organizations, patient groups, health professional associations and community leaders at the national and local level and launched the Partnership for Prescription Assistance (PPA – www.pparx.org, 1-800-4PPA-NOW).

PPA is a one stop shop to match underinsured and uninsured patients with hundreds of private and public patient assistance programs. There are now over 470 programs participating – 150 of them sponsored by PhRMA member companies. More than 2,000 different prescription medicines are available from these programs for free or nearly free

depending on financial need or insurance coverage – this includes a wide array of generic drugs.

More than 60 national and local organizations are partnering with us to help tell patients about these programs include health care and patient advocates, medical professional societies, retail pharmacies, charities and community organization. We're getting help from the National Grange, the United Way campaign, Easter Seals, the NAACP, the National Urban League and many, many more.

Importantly, as we have joined with partners, not only do we in the industry understand better the concerns of patients and their communities, by working with us, seeing how we are helping patients get the medicines they need, our partners' favorable understanding of America's pharmaceutical companies is also growing.

Over 2 Million patients have now been matched to programs that can provide free or discounted medicines. And we expect this number to keep growing.

The PPA program is a hard, tangible example of this industry putting patient needs first, of working together and making sure that patients get the medicines they need.

It is responsive to patient concerns and it is changing how patients and their families view this industry.

And, while I am talking about responsiveness, let me talk for a moment about how we -- as an industry -- are responding to growing patient and public concerns over Direct to Consumer Advertising (DTC).

DTC advertising is proven to be very effective in raising patient awareness of disease and treatment options.

And, as importantly, DTC advertising is critical to raising public awareness of significant undiagnosed and under treated illness in this country.

The problem of un-diagnosed and un-treated disease is costly -- both to individual patients whose lives and livelihoods are interrupted or limited by disease and to society as a whole.

Let me cite just one example: the growing problem of diabetes. Diabetes is significantly under-diagnosed. Failure to treat it promptly leads to potentially tragic consequences for patients -- blindness, limb amputations and even death. It also costs us all as we -- as a society -- struggle to help patients cope with and pay for the preventable consequences of the disease.

Studies show that DTC helps heighten awareness of diseases like diabetes, heart disease stroke and other serious conditions. It gets patients into their doctor's offices to discuss undiagnosed conditions and to ask critical health questions. It promotes patients and doctors working together on real health care solutions -- from prevention to treatment.

But, it would be naïve to not acknowledge the fact that DTC advertising is also a lightning-rod in the health care debate in this country.

While individual patients find the information useful in discussions with their physicians, patients, physicians and consumers generally express unhappiness with DTC advertising.

We heard these concerns and recognized our obligation to act. It is an obligation that arises not only from self-interest, but also out of the profound understanding that the pharmaceutical manufacturing business -- a health business -- is not like any other.

We don't make cars or ice cream or high-fashion blue jeans. America's research-based pharmaceutical companies make medicines that can prevent, treat and even cure disease.

The way we advertise our products must reflect both the high public interest in our products and our respect for patients and their needs.

PhRMA Member companies, of course, already take their responsibility to fully comply with FDA advertising regulations very seriously. Every PhRMA member strives to create DTC ads that are accurate and not misleading; promoting claims supported by substantial evidence; and consistent with FDA approved labels.

But, we believe that we must and can go further. Patients and doctors expect us to do more than meet our legal obligations. More importantly, we know we can deliver messages that fundamentally educate patients and consumers and encourage them to seek guidance from their health care professionals.

In short, if we do our job right, not only will we make the FDA's work easier, we will be meeting the needs of patients for information and respecting their expectations.

DTC Guiding principles that have now been adopted by 28 PhRMA member companies!

Some of the key principles that go into effect in January include:

Companies should submit all new DTC television advertisements to the FDA before releasing them for broadcast;

DTC TV advertising that identifies a product by name should clearly state the health condition for which the medicine is intended to treat and the major risks associated with the medicine being advertised;

DTC advertisements should be designed to achieve a balanced presentation of the risks and benefits associated with an advertised prescription medicines – specifically, the risk and safety information in DTC advertising should be presented in understandable language, without distraction from the content and in a manner that supports the responsible dialogue between patient and health care professionals; and

Companies should spend an appropriate amount of time to educate health professionals about new medicines or new therapeutic indications before beginning the first DTC advertising campaign.

I am particularly proud that in creating these Guiding Principles, PhRMA and its member companies are ahead of the curve. We have listened to patients, we have acted to meet their concerns in a sensible and realistic way, and we have done so before industry critics could change the scope of the debate and force unneeded and even dangerous regulations on the industry – regulations that could, essentially, keep vital health information out of the hands of patients.

These steps – our PPA effort, our DTC Guiding Principles, our involvement in the network to help patients sign-up for the new Medicare drug benefit – are just a start.

And, importantly, we are making progress. You will recall I said that last year, around 70 percent of media coverage of the pharmaceutical industry was negative.

Recently, we've achieved almost 50/50 positive to negative coverage.

Of course, more must be done. The negative coverage number needs to continue to drop...but we are making a difference and we are changing how this industry is viewed and for the better.

The future confronting America's research-based pharmaceutical companies is daunting.

We must be vigilant to the threat that moves to allow imported medicines pose to patient safety and to our industry's ability to support the research and development necessary to develop new cures and treatments.

We must continue to fight against government-imposed price controls – especially because how government imposed price controls will hurt patients by curtailing and limiting the rewards available for innovating and creating new and better medicines.

We must continue seeking realistic solutions to help the millions of uninsured and under-insured Americans get the medicines they need.

We must work to promote tort and liability reform and promote the patient –centered medicine I've been talking about, rather than the lawyer-centered medicine that too often rules the day.

We must also work to protect and improve intellectual property protection so that the inherently long, difficult and risky process of creating new medicines and new health care technologies is rewarded. Needless to say, medical research and development is unlike designing new software or a new windshield wiper system for a car. The clock begins ticking on the intellectual property we develop well before that property can be sold and the investment recouped.

But, as I said at the beginning, first and foremost we can rebuild this industry's reputation by putting the needs of patients first.

This means making sure that America's research-based pharmaceutical companies can continue to do what they do best: preventing disease and creating new cures and treatments.

Because, in the end, if you put patients first, if you build a patient-centered health care system, than you will create a system that encourages and rewards research and development of new medicines.

Since 1990, America's research-based pharmaceutical companies have developed over 300 new medicines, vaccines and biologics and over 2000 more are in significantly advanced stages of development.

Many of these are medicines specifically targeting the most significant health care challenges we face in this country.

Take Diabetes for example. It afflicts more than 16 million Americans, more than half of them over age 60. But the threat of the disease now extends to the very young with doctors and nutritionists raising new warning about the growth of diabetes among school age children.

Old or young, what do they face? The possibility of heart disease, kidney failure, blindness, stroke and premature death. Right now, America's research-based pharmaceutical and biomedicine companies are working on 62 new treatments for both Type I and II diabetes.

Or, take Alzheimer's disease. One in 10 Americans over 65 has it – including nearly half of those over the age of 85. It could afflict 16 million patients by the middle of this century unless we find new tools to prevent it or even cure it. We are trying to do just that. The first generation of medicines is now on the market and as of last year, 22 promising medicines were significantly along in the development process.

And what about cancer? Our member companies are working on 400 drugs to combat cancer; more than 60 to treat breast cancer alone.

The list goes on and on. It includes new treatments for Parkinson's disease and stroke. It includes efforts to make sure that vaccines are created to meet emerging health threats and that those vaccines are available when needed.

But what it really means is that we are working towards a future where families that include someone suffering from cancer might not have endure what my wife and kids did – not to mention patients having to make the kinds of difficult, risky choices that I had to make trying to beat it.

Before I conclude, I want to stress that all of these potentially important medicines now in development are the result of risky investments made many years ago.

While the challenges then were different, many were certainly as formidable as those this industry today faces.

I especially want to urge you in the investor community to continue building and investing in the biopharmaceutical industry.

We have awakened and are tackling many of the difficult structural and perception issues that challenge this industry. And, as I have said we are beginning to have some real success.

Like the great ocean-going tankers that I could see in the Mississippi Delta when I was a child, turning the image of the pharmaceutical industry around will take time.

We're well into the pivot we needed to make to change directions and to set a new, better course for this industry.

But, while we are taking the steps necessary to re-engage this industry in creating and enhancing its role as a pro-patient health care industry, I hope that the venture capital community will continue making critical investments in start-up biotechnology companies.

That is where many of the medicines of the future will come from.

This biopharmaceutical industry has made a huge investment in research and development over the past 30 years. In 1980, that investment was only \$2 Billion dollars, last year – combined – over \$50 billion was invested in biopharmaceutical R&D.

That investment was made; those risks are being taken knowing that development of a new product can take a billion dollars and 12 to 15 years to bring to the market.

That \$50 billion investment was made because we have faith not only in this industry, but we also know that by using the technology and the knowledge we have created in the last 20 years, we can – and will – lead us to new and better treatments.

It was done knowing the risks are great but that the rewards – both economic and, as importantly, spiritual – can be great.

This is an industry that is daily innovating and creating new and better technology because of that investment.

Let me share with you two quick examples of how America's research-biopharmaceutical companies continue to lead the health care and medical revolution.

First there is Prevnar. Developed by Wyeth, it has been called one of "the most important advances in pediatric medicine." It has all but wiped-out invasive pneumococcal disease in young children and it is estimated that it prevented nearly 13,000 cases in young children in 2002 alone.

Then there is Gleevec, developed by Novartis.

Gleevec is a ground breaking discovery that dramatically improves how we treat chronic myeloid leukemia (CML) – a very painful and usually fatal disease.

Because of Gleevec, patients suffering from this cancer now have new hope – and believe me, when you are suffering from cancer, that is a very important part of the treatment.

In fact, the Gleevec clinical trials were so successful and convincing that the FDA approved it for treating CML only ten weeks after Novartis submitted the NDA.

Of course, the best part for someone like me -- a cancer survivor -- is that medicines like Gleevec and Prevnar are also the foundation for new discoveries and even more, new and better treatments.

These innovative medicines show that even though it takes between 10 and 15 years development time with an average R&D cost of that exceeds \$800 Million dollars, America's research-based biopharmaceutical companies remain on the cutting edge of medical science and technology, creating medicines that are not just saving lives but changing how medicine is practiced.

The future is full of promise and I urge you to continue helping to make this promise into reality.

I hope that you will join with us as we continue our work in Washington and in state capitols across the country to promote free market solutions to health care problems and fight proposals that would limit the free-market or otherwise cripple the economic and investment environment that reward research and development.

The lives of millions of Americans depend today, and will tomorrow, on a biopharmaceutical industry that is working to help them cure their disease, enabling them to live longer, healthier, more productive lives.

We must work together to make sure that policy makers, patients, physicians and the public understand that the solution to the health care problems we face in this country lie in encouraging innovation and using the power of the free market – not in creating a biopharmaceutical desert in this country to mirror the desert now existing in Europe.

Regaining our reputation and the public trust will take time and it will not be easy. But, at the very least, this critical effort reminds all of us, and daily, why we work in the pharmaceutical industry. It reminds us why this industry exists, and it thrills us with the future that can be.

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