

## **REMARKS**

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Thank you for that kind introduction.

At PhRMA – and throughout America’s pharmaceutical research and biotechnology sector – we often brag that the United States has the safest drug supply in the world.

With pride, we rightfully call our U.S. regulatory system the “gold standard” and we judge all other drug review and approval processes by how they measure-up against what we do here in America.

In our honest pride and confidence in the FDA and our drug approval process, it is sometimes easy to forget that one key reason the U.S. prescription drug supply is so good is the quality of the men and women – both in industry and in government – who make sure that the drug development, review and approval process works for patients and health care professionals.

In the end, the medicines we research and develop are only as good as the dedication to making sure that these medicines are not only safe and effective and meet the letter of the FDA’s regulations, but also that the medicines doctors prescribe and patients take have the stated quality and integrity.

So, when we speak about the “gold standard” we are really talking about you.

Every patient and every health care professional here in America and around the world who cares about quality of care, who cares about science and who cares about innovation and medical progress, owes you and your colleagues a big dose of appreciation for all that you do.

Now I want to talk today about a number of issues that I know you are particularly interested in – such as PhRMA’s revised Code on Professional Interactions, the matter of samples and our growing concern over the threat that counterfeiting poses to our pharmaceutical supply chain.

But before that, I think that it is appropriate to say just a few words about the elephant in the room today – health care reform, and the role that PhRMA is trying to play to achieve health care reform.

Throughout the long, on-going national debate over health care reform that has been taking place in this country, PhRMA and its member companies have worked and are working hard to be a positive force dedicated to helping to find solutions that make sense and that work for patients.

At the core of everything we are doing is a commitment to putting patients and meeting their health care needs at the top of our national health care agenda. At the same time, we are also working to both protect and strengthen our historic national commitment to rewarding innovation and risk taking that is so necessary if we are to continue expanding our scientific knowledge and creating the new medicines and treatments hoped for by every patient.

As makers of medicines, America's pharmaceutical research and biotechnology companies understand the important role that our products play in the lives and health of the millions of Americans who depend on them.

Today, millions of Americans do not have access to the medicines they need – whether because of inadequate insurance, the loss of insurance through the loss of a job or some other bar to obtaining quality health care. Our health care system is failing these vulnerable populations and its costs are dragging down our economy. We can and must do better.

We must do a better job of making sure that every patient has access to the care they need. We must do a better job of making sure that our health care system prevents what can be prevented and treats what can be treated. And, we must do a better job of inspiring and promoting new research and development of new cures and treatments that can help limit the human cost of chronic disease.

From the start of the national debate, PhRMA has worked to build broad coalitions with other key health care stakeholders – including patient groups, health care professionals, labor unions, business groups, and community leaders. Our aim has been to build consensus around common sense, pro-patient steps that can be taken to not just reduce health care costs and to bolster prevention and good health care practices.

PhRMA has long supported expanding private health insurance options as the best way to promote competition, choice and innovations. Specifically, we've called for providing individuals and families with real choices between competing private plans – with appropriate rules and consumer protections.

Specifically, PhRMA put out its Platform for a Healthy America calling for:

1. Covering the 12 million uninsured Americans already eligible but not enrolled in Medicaid and the State Children's Health Insurance Program (SCHIP);

2. Encouraging coverage for uninsured workers eligible for, but not yet enrolled in, employer-sponsored health coverage;
3. Expanding private health coverage;
4. Improving the healthcare safety net;
5. Promoting benefits that meet patients' needs; and,
6. Preserving consumer choice and enhancing competition through new pooling arrangements and insurance reform.

Together with our allies and other stakeholders, we have been diligently working for more than a year to advance bipartisan health care reform

A key part of these efforts is PhRMA's unprecedented, industry-wide pledge of \$80 billion dollars to help slow the rate of health care cost growth. This includes our commitment to help cut the cost of medicines to seniors who are in the contentious Medicare drug benefit donut hole in half.

Saving money during these difficult times is very important, as demonstrated by our \$80 billion commitment to health care reform. But you simply can't put a price tag on our commitment to improving and saving lives.

As to the proposals now before Congress, we applauded the House Energy and Commerce Committee for passing a bipartisan biosimilars amendment that strikes the appropriate balance between the desires for enhanced competition and preserves needed incentives for innovation. Such incentives are vital for ensuring the continued development of biologics that patients with complex diseases rely on today and will help to provide cures in the future.

Recently, the Senate HELP Committee also overwhelmingly agreed to support this important provision.

Unfortunately the totality of the House bill, while well intentioned, represents a step in the wrong direction in the health care reform debate.

Specifically, we oppose the House Tri-Committee bill because it undercuts the main goal of health care reform which is to help every American gain access to needed health care coverage and services. The House bill would effectively act as a tax increase by raising premiums for seniors in the popular Medicare prescription drug program, severely restrict patient access and choice and hurt an innovative sector that currently employs hundreds of thousands of workers across the United States.

The results could mean significant job losses in the middle of a recession. In addition, the legislation allows broad override of protections for Medicare and Medicaid beneficiaries by unelected officials with no chance for review.

Under the House proposal, we're concerned that the federal government will wind up rationing health care and dictating what medicines doctors can prescribe. This may well prevent patients from gaining access to the critically important medicines they need to fight diseases such as cancer, diabetes and heart disease.

What's more, even the Congressional Budget Office has said that government negotiation of Medicare Part D prices would save little, if any, money.

So, while we will continue working toward a comprehensive health care reform bill we can support, we will vigorously oppose legislation that hurts patients or the American economy.

Needless to say, this is a volatile time. The push is on to complete health care reform efforts even as I am speaking.

For our part, PhRMA and America's pharmaceutical research and biotechnology companies will continue working for reforms that both help patients get access to the medicines and the health care they need and that provides the incentives necessary to continue spurring on research and development into new and better treatments.

As you can see, we have a lot on our plate with health care reform. However, I do want to touch on a couple of issues that I know have a direct impact on everyone here today.

First – and as many of you are aware – PhRMA's revised Code on Interactions with Healthcare Professionals went into effect in January of this year.

We set out to revise and strengthen our Code last year as part of our ongoing efforts to pursue policies and practices that best serve the needs of patients and the healthcare community.

We have since reached out to the physician community, professional groups, non-PhRMA member companies and other healthcare stakeholders to explain how the Code has been enhanced to better ensure that pharmaceutical marketing practices comply with the highest ethical standards.

The feedback we received has been very positive, and we remain committed to engaging as many stakeholders as possible.

The voluntary Code builds on commitments already made in the 2002 version

and reaffirms that interactions between company representatives and healthcare professionals should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

Providing physicians with up-to-date, accurate information about the medicines they prescribe clearly improves patient care and advances health care in general. Pharmaceutical research companies that discover and develop new medicines are the most knowledgeable about their products and are in the best position to inform healthcare professionals about a wide range of topics related to these medicines, including new treatment options, appropriate dosing, emerging safety developments and potential interactions with other drugs.

Our updated Code fortified our companies' commitment to ensure their medicines are marketed in a manner that benefits patients and enhances the practice of medicine. It marked a renewed pledge to 'practice what we preach.'

To date, over 50 companies – including several non-PhRMA member companies – have committed to abide by the PhRMA Code. We hope all companies that interact with healthcare professionals will adopt these standards.

The PhRMA Code continues to allow the distribution of prescription drug samples that are heavily regulated by the FDA.

Samples help patients and health care professionals by making medicines available to patients who might not otherwise be able to afford them.

Manufacturer samples provided by a physician also enable patients to begin therapy immediately, without visiting a pharmacy and without having to purchase a full prescription.

Starting drug therapy immediately with a free product can be a cost-effective and time saving way to determine whether the medication is helpful for the patient's condition. If the patient experiences problems, or the physician decides that the drug is not working, the physician can change the prescription. The value to patients is best illustrated by the use of sample starter packets when a new drug is first introduced. Physicians who have not prescribed a drug before may want to give the patients a way to try a medication before they pay for a full prescription.

In short, we believe that samples play an important and beneficial role in the critical collaboration between doctors and their patients into the best and most effective therapy.

On the matter of post marketing studies of medicines, we were all gratified by the recent release of an FDA report detailing its findings on manufacturers'

completion of post-marketing studies.

The FDA report evaluated the completion of post marketing studies undertaken by medicine manufacturers and it underscores the deep commitment of America's pharmaceutical research and biotechnology companies to conduct on-going surveillance and study of FDA approved medicines.

America's biopharmaceutical companies lead the world in the discovery and development of new medicines, and the investment is clear -- \$65.2 billion dollars last year alone.

The recent FDA report confirms that America's biopharmaceutical companies are upholding agreements they make with the FDA – and with America's patients – and conducting trials that seek to improve our understanding of medicines that are on the market and not just those still in development.

Finally, I want to briefly address a matter of considerable and recurring concern for America's pharmaceutical research and biotechnology companies: the continuing threat posed by counterfeit pharmaceuticals.

It is hard to imagine any greater threat to our "gold standard" regulatory system. The worldwide proliferation of counterfeit medicines not only puts patients at risk, it helps to undermine the trust and confidence of both health care professionals and patients in the safety and efficacy of the medicines on which they rely.

And this counterfeit threat is very real and is growing.

Let me cite just a few examples.

The World Health Organization (WHO) reports that many countries in Africa and parts of Asia and Latin America have areas where more than 30% of medicines on sale may be counterfeit.

WHO reports that many countries in the former Soviet Union have counterfeit rates up to 20% percent.

It has been found that medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50 percent of cases.

WHO estimates that tens of thousands of patients around the world may be dying due to counterfeit HIV/AIDS, diabetes and tropical disease medicines.

FDA Commissioner Hamburg recently noted the growing increase in counterfeit medicine "Contaminated products from China and other problems with counterfeit drugs...are becoming a very serious global concern."

The number of FDA counterfeit cases has increased almost 10-fold since 2000.

FDA has issued several recalls and consumer alerts about the dangers of counterfeit drugs.

Globally, counterfeit medicine seizures rose 24% in 2007 according to the Pharmaceutical Security Institute (PSI). \$3 billion worth of counterfeit medicines were seized in 99 countries, including copies of 19 of the world's 25 best-selling drugs.

This litany of counterfeiting woes suggests something of the challenge we face as well as how critical it is that we do all we can to prevent counterfeit medicines from penetrating our own closed pharmaceutical supply system.

Americans have long trusted that the medicines they and their loved ones use meet the highest standards anywhere in the world.

Today, their trust in the system is not misplaced.

The regulatory system governing the development, approval, marketing and surveillance of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, this system has become increasingly comprehensive and robust over time.

Even with this regulatory system, however, there is evidence that new safeguards may be needed to help ensure that American consumers are adequately protected. In order to preserve the safety and integrity of our country's drug supply, Congress could consider several additional measures.

But, before enumerating those, I want to reiterate the importance of protecting and preserving the sanctity of the current U.S. drug supply chain. Our current system is by and large a "closed" distribution system. This closed distribution system was created by the PDMA – the Prescription Drug Marketing Act – enacted in 1987 and the reason we are here today. Congress passed the PDMA following investigations into counterfeit drugs that reached U.S. consumers.

Now, more than 20 years later, even with this closed distribution system, from time to time counterfeit and tainted products may surface, and the public health could be placed at risk.

These limited instances would, however, be greatly multiplied by the added complexities and burdens of an expanded international supply of unapproved drugs from various wholesalers and pharmacies in more than 30 foreign countries. In fact, the EU reported the seizure of a total of more than 8.9 million

medicinal products (articles) at EU customs borders in 2008. This was an increase of 118% over 2007.

This is just one of the reasons that Congress should reject proposals – such as those to legalize prescription drug importation – which would undo the PDMA and further strain and compromise the FDA’s ability to protect Americans from potentially dangerous counterfeit medicines.

In response to concerns regarding the rate and extent to which FDA is currently conducting inspections of foreign drug establishments, PhRMA supports the creation of a risk-based approach to help target and increase FDA inspections of facilities manufacturing approved products outside our borders. At the same time, we must not weaken our existing regulatory system – the strongest in the world -- by legalizing prescription drug importation.

We also support a strong, well funded FDA able to help assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients. As many have observed, the FDA is currently under funded and as a result it has become increasingly difficult for the Agency to meet its ever-expanding mandates. We believe that it is in the public’s interest that Congress should increase the appropriated resources needed for the FDA to carry out its vital mission.

The FDA’s responsibilities have consistently expanded over the years. However, appropriated funding has not kept pace to help the FDA meet it’s increasing regulatory responsibilities and demands on its attention.

In addition, we support the creation of FDA regional offices around the world, to facilitate the efficient targeting of limited FDA inspection resources using a risk-based approach.

Looking to the future, we must work hard to not repeat past mistakes by opening our prescription drug supply chain.

A key component to a strong U.S. supply chain is a strong, well-resourced FDA and a regulatory structure based on decision-making grounded in sound science. The PDMA exemplifies this regulatory approach and has helped protect American patients from counterfeit medicines. We should collectively look for ways to strengthen the PDMA and not undo it by opening up our borders to unapproved drugs from more than 30 countries.

A strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients.

Thank you.