

**State of the Biotechnology Industry Address
The Honorable James C. Greenwood
BIO President & CEO
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Chicago, Illinois**

This was the opening slide for my talk in Atlanta last year.

We found ourselves then in the midst of a perfect storm of economic meltdown, political volatility and scientific challenge.

We knew that these challenges would bring significant change to our industry but that if we remained confident, we would emerge from these challenges better and stronger.

We have.

Let me tell you why I say that.

Biotech stocks have outperformed virtually every other index in the first quarter of this year and the Nasdaq Biotech Index has climbed back to a point even higher than it was when the market peaked in 2007.

The markets are coming back and biotech has come back faster and stronger.

The economic storm isn't over, but the winds are easing and the sun is beginning to shine.

When we met in Atlanta last year, the U.S. Congress had just started to debate healthcare reform.

Now it's the law of the land.

And in the process, our BIO staff and leadership and our member companies performed a couple of major legislative miracles.

Despite the ferocious opposition of the generic industry, the AARP, much of the popular media and powerful forces in Congress, we succeeded.

We placed into law the right kind of biosimilar legislation.

These new provisions protect patient safety and promote investment with twelve years of data exclusivity.

Winning this fight in Congress was tough.

But, we talked straight, we fought hard and we won the confidence of overwhelming majorities in both the House and the Senate.

We prevailed but, more importantly, our patients won.

There is an old Hindu saying: "When a man is healthy he has many dreams. When he is sick he has but one."

Had we lost this battle, millions would have lost their dreams.

They would have lost hope.

But now their hope is alive because, thanks to this new law, America's biotechnology companies will be able to continue to invest billions of dollars in innovative biologics research.

We will find cures for their cancers, their diabetes, their Parkinson's, their ALS, and the hundreds and hundreds of diseases that still have not been defeated by medicines.

And then, together, we pulled off another miracle.

The healthcare reform bill extracts big dollars from pharma and biotech companies that sell products to the government, from device manufacturers, and from insurance companies.

But our small biotech companies not only couldn't afford to contribute to the cost of the legislation, they were in many instances desperately in need of resources.

So, we worked with key members of Congress to include in the healthcare reform bill a billion dollars of refundable tax credits.

For countless of these emerging companies, this will mean the difference between failure and success and, once again, for patients still waiting for cures, it will determine the difference between despair and hope.

Not many observers thought we could get this done.

As Vice President Biden might say: this was a big...big deal.

But, we in biotechnology are used to pulling off big...big deals.

And saving lives is a big deal.

It is written in the Talmud that "Whoever destroys a soul, it is considered as if he destroyed an entire world. And whoever saves a life, it is considered as if he saved an entire world."

We save lots of lives...lives that mean the world to their loved ones.

We save 2.5 million children's lives every year with biotech immunizations.

We save millions from premature deaths from heart disease, AIDs and cancer.

Each one of these lives saved is a deeply personal story - stories about people like Lori.

As you can imagine, Lori was in shock when she found out that her breast cancer had spread throughout her body and metastasized into her liver.

She was told she had less than a 3 percent chance of survival - even for 5 years.

Recently she wrote me this note, "Today - ten years later, I'm alive and well because of Herceptin. I continue to receive this miracle-drug; designed & manufactured by Genentech. I'll be forever grateful! I'm grateful to the scientists, the funders, the doctors who administer it. I'm even grateful to the receptionist who answers the phone at Genentech! Now I can look forward to the second half of my life – thanks to biotechnology."

For many of our patients, we enter their lives at the very beginning.

In the United States the most common cause of pulmonary inflammation and pneumonia in infants is an infection called RSV.

Children with this condition are rushed to emergency rooms hundreds of thousands of times a year. Tragically, hundreds of them don't survive.

But today, Medimmune's product Synagis -- the first monoclonal antibody approved for an infectious disease -- has treated more than a million babies, dramatically reducing infant mortality.

No, the recent recession and policy hurdles have not diminished our passion to innovate.

Since our last International Convention, the FDA has approved 38 New Molecular Entities -- including, just last week, Dendreon's first-of-its-kind treatment for advanced prostate cancer.

We've seen approval of the first diagnostic blood test for ovarian cancer, a new cancer treatment from Celgene and Acorda's newly approved Ampyra product that enhances the ability of MS patients to walk.

And our pipeline continues to grow.

Think about how many lives will be touched by Human Genome Sciences' new lupus drug and by Vertex's hepatitis C product...and soon, by Amgen's treatment for osteoporosis.

For patients like Louise, this is personal.

She recently wrote, “The medicine that I am on has been 15 years in the process of development and I would like to say thank you to the people at Amgen; thank you for your knowledge and expertise in developing it ...I am grateful for the chance to be part of the process.”

Yes, we save lives, and yes we extend the length of lives, but sometimes we just add a little to the joy in people's lives.

Let me give you an example.

There is a heartbreaking fibrotic disease that causes a contraction of the fingers so that they stay permanently bent toward the palm. Ronald Reagan and Margaret Thatcher suffered from it as do millions worldwide. Surgical treatment frequently doesn't work.

But just this February the FDA approved Auxillium's drug that when injected breaks down the collagen that causes the fingers to clench.

This is Karen Mercaldo. For years this disease stopped her from playing her viola.

Then she was injected with Xiaflex. Now, once again, she is able to make her music.

We, the men and women of biotechnology hold in our imaginations the hopes of hundreds of millions—to be delivered from the brutal grip of disease.

We will not fail them.

But their hope will not only depend on our abilities as scientists and entrepreneurs, It also hangs on the willingness of public officials to understand the nature of biotech innovation and to stand with us and not against us.

Our critics often focus on the price tags for our products.

We understand that.

Healthcare is expensive and public and private payers must look for savings.

But we need to remind our critics that prescription drugs account for only 10 cents of every healthcare dollar. And we also need to point to the incalculable value that this small fraction of the health budget provides.

Too many Members of Congress fail to understand this. That's why not all of the provisions of the new healthcare reform legislation advance innovation.

When the government demands deeper discounts in Medicaid and deeper discounts in Medicare and imposes new fees on our innovative industry, it diverts resources away from critical medical research.

The government cannot continuously extract resources from the drug discovery enterprise and still expect us to discover new drugs.

And the government also has a responsibility not to diminish incentives for investment in the life sciences.

With very few exceptions private investors don't risk their capital with us because they share our aspirations. They do it because they expect a fair return on their investment.

And it's more than just the quality of our science and our business skills that drive investment to heal the world. It is also public policy.

Public policy sets reimbursement. Public policy determines how fairly and expeditiously our new product applications will be reviewed. Public policy impacts the value of our intellectual property. And public policy determines whether investors will put their dollars with us or put their dollars elsewhere.

That's why BIO's work to shape good public policy never ends.

With the healthcare legislation behind us, we will now focus intently to ensure that the act is appropriately implemented.

We will also now turn our attention to the new PDUFA reauthorization.

BIO will work to improve the FDA's performance and to insure that it has the resources it needs to move safe and effective products to the bedside as quickly as possible.

All of our science, all of our clinical work and all of the hope of our patients must, of course, ultimately come to the FDA for its assessment.

The very able and still underfunded FDA holds the fate of our patients in its hands.

The agency's processes must be clear, transparent, fair, rational and efficient, if our patients are to be well served.

And BIO will fight for appropriate public policy in the courts as well.

The recent decision in the *ACLU v. Myriad Genetics* case must be overturned.

Contrary to the rhetoric of our critics, we don't patent or own anyone's genes and we don't stifle research on genes.

We identify the functions of genes, and then isolate and purify them to diagnose and to treat disease.

No patent, no investment.

No investment, no treatment.

No treatment, no hope.

The choice is clear.

Public policy also determines whether our food and agricultural biotechnology companies can continue to feed a hungry world.

As the world's population grows from six billion to nine billion by 2030 the global food supply will have to double.

Think about that. We have to double the world's food production in just the next 20 years.

That's incredible.

And the vast majority of farmable land is already in production, so our future depends on increasing agricultural yields.

Thankfully, biotechnology is already unlocking dramatic productivity increases.

More than 14 million farmers are already growing biotech crops -- 93% of them in developing countries.

BIO will continue to work to ensure that the latest breakthroughs in agricultural biotech are expeditiously approved.

And public policy also plays a crucial role in enabling industrial biotechnology to fuel the world.

The same explosive demographics driving food demand are also pushing global energy requirements to increase by 50% in the next 15 years.

We cannot meet this demand in an environmentally acceptable way with fossil fuels.

Industrial biotech is helping to produce sustainable energy and reduce carbon emissions.

The next generation of biofuels production methods is just now emerging, driven by new tools like synthetic biology, and new approaches using algae.

We have come through the storm stronger and better on every continent—as well we must—because the challenges of disease, hunger and pollution are global.

And so is our biotechnology community.

Our biotech brothers and sisters here with us in Chicago this week come from Europe, Asia, Central, North and South America, Oceania and Africa.

We innovate together to create new insights, new science, new products and new hope.

Our companies compete globally, but our researchers advance the science as an interconnected global team.

And so should it be.

A sick child in any land breaks all of our hearts.

A hungry child is unacceptable anywhere.

And, if we have a chance to pass this planet on to our children's children, it will be because we have learned to save it together.

I believe that we will save an entire world.

We will heal the world, we will fuel the world, and we will feed the world.

And because all of you work so hard to do this every day allow me to say: Thank you.