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Biotechnology Industry Organization  
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“Unleashing the Promise of Biotechnology to Cure Disease and Save Lives”  
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Today I'd like to tell you what we've been doing at BIO lately—we've been imagining.

We've been imagining not just how biotechnology can heal, fuel, and feed the world—but how we at BIO can make that happen sooner, rather than later.

And with that vision in mind, the BIO board and our staff have been hard at work for the past year constructing a comprehensive legislative proposal—BIO's first ever five year plan—that we're confident will accelerate our progress.

So today, I want to share with you some of the details, because we believe unleashing the promise of biotechnology can help us change the world.

And talk about changing the world, the other day I came across an article discussing vaccinations and the author mentioned his 15-year-old son asking him: “Dad, what's polio?”

Many of us here are old enough to remember a time when polio struck fear and caused suffering for millions.

Today, at least in the developed world, polio is something kids have to ask their parents to explain to them.

Imagine someday, our grandchildren asking us, “What was cancer?”

How great would that be?

That is the future that we in biotechnology envision and work towards every day.

To take cancer and aids and Alzheimer's and malaria and all the other deadly and feared diseases that still end millions of lives each year—and move them from the medical books to the history books.

Is there a reason that we shouldn't envision a time when children will ask their parents what it was like back when people went hungry or worried about climate change?

This is our vision, but we all know how much work it will take to get us there.

Think about it: screening millions of compounds for hits that might—but probably

won't—become leads can be monotonous.

But, there is always that hope that getting up in the morning and buttoning up that lab coat, day after day, and putting in the hours, might just lead to a new breakthrough drug.

The process of supplicating to yet another venture capital firm that might fund your start up company—but probably won't—and then, doing it over and over and over is grueling.

Clearly, there are easier and less insane ways to make a living.

But, the dream of changing a patient's life—maybe the lives of millions of patients—keeps you going.

Researchers at agricultural biotech companies certainly don't get results overnight either.

It takes years of effort to copy and modify genes, to insert them into plants and wait for them to grow to see if the desired trait is acquired—and it usually isn't.

But the prayer of a chance, that success in the lab could mean significantly more crops in farmers' fields, that could make the difference between life and death for millions of the world's hungry—that's what sustains those scientists.

And lord knows it's not easy to convert the cellulose in plant matter to sugars that can be fermented and converted to biofuels and bioplastics.

It takes a huge amount of scientific effort to construct enzymes to take apart plant matter that was meant to be very durable.

But, it is the dream that even though this next experiment probably won't work, it just might. And that could lead to the production of a new, affordable, clean-burning fuel that helps to save the world from overheating—it is that dream that keeps the bench scientist peering into her microscope day after day.

Every one of you is working on some part of this vision for the future. You're brainstorming, researching, and developing the biotech innovations that will transform our world.

It's what you do.

We at bio are not the scientists. We're not the entrepreneurs. We're not the investors.

We are your voice, your advocates to the policymakers and decision makers.

We work to create the right conditions so your work can go forward.

The video mentioned some of our recent accomplishments.

We fight in the political trenches for policies that support biotech innovation.

And we spend as much time fighting to stop bad policy, as we do advancing good policy.

But, despite all of our progress, let's face it: we are not getting the cures to patients, the crops to farmers and the fuels to consumers nearly as fast as we need to.

So, we at BIO have not just been imagining a better world through biotech innovation ... we've been busy constructing a plan to get us there ... and to get us there a lot faster!

And we know that the problem isn't that the people in biotechnology aren't up to the job.

For example: in May, the FDA approved two new drugs that completely eliminate the hepatitis C virus from patients; and that's not just a treatment, it's about as close to a cure as you can get for a disease that has been a death sentence for millions.

One of the new drugs is from Vertex, the other from Merck.

These medicines are protease inhibitors that block the enzyme that the virus uses to make copies of itself.

To develop them, scientists had to figure out the structure of the protease so they could then find the best binding configuration for the drug.

Now if biotech researchers can figure out all that—and can solve other problems just as complex—then why can't policy makers in every country figure out how to help us get these cures to patients faster?

Imagine if it didn't take 10 or 15 years to get a new medicine to patients.

Imagine if we didn't have companies laying off researchers and killing promising projects because investors just can't afford the risk of funding early stage companies?

Instead, what if when you went on a road show, the investors couldn't line up fast enough to give you money?

What if the FDA review of new product applications was actually coherent, transparent and predictable?

What if you could get your new drug or device approved in a timely way?

What a concept!

What if the EPA, the USDA and the FDA actually worked together to approve new biotech plant and animal products?

What a concept!

Imagine the difference it would make if every country's government made biotech innovation a national priority.

Is that too much to ask?

Last year, after our convention ended in Chicago, I decided that to truly unleash the pace of biotech innovation, we had to think bigger, bolder and more outside the box.

So, at BIO we started what we call our "big thinking project".

We asked biotech leaders, investors and patients across the country to give us their biggest and smartest ideas to radically change the policy environment.

And we said, "don't worry how controversial or how politically difficult it would be to accomplish—that's our job."

We have been imagining and designing the ideal environment that would enable biotech policy to keep up with biotech science.

We have spent the past year collecting ideas, thinking them through and hammering them into legislative and regulatory reforms that we will hand deliver to the Congress and to the president.

Can you imagine what it would be like if the president and members of Congress, Republicans and Democrats, put aside their political differences—and i know that's too much to imagine—but, what if they were to come to us and ask "What do you guys need?"

What resources and regulatory changes do you need so you can turn the science you have developed into the therapies, the crops and the fuels the world desperately needs?

We'd say: we need an FDA that is more interested in promoting new drugs than in postponing them.

We'd say: we need tax policy that encourages private investment in biotechnology companies.

We'd say: we need congress to get real about risk and benefit on behalf of patients who are running out of time.

And, we'd say: we need Congress and the President to understand that medical innovation doesn't begin and end at the NIH.

It takes place every day at small, medium, and large biotech companies who need government to work with them, and not against them.

So yes, we can imagine Congress and the president asking what we need — but we're not sitting by the phone waiting for them to call.

We have been going to the White House and to the Capitol and saying, "Look, our country has big, big problems to solve and we know how to help."

The United States is facing huge deficits—more than \$1 trillion this year, and we're already \$14 trillion in the hole—and you guys in Congress have to do better than just having a political food fight over it!

Congress knows that one of the biggest factors driving spending—and this is true all over the world—is the cost of government-funded healthcare.

Medicare is facing an unfunded liability of almost \$25 trillion over the next twenty years.

Our population is aging — just as it is in many developed countries.

Here in the U.S., the baby boom generation started turning 65 this year, making them eligible for Medicare.

In fact, in the U.S., ten thousand people turn 65 every day — and ten thousand more will turn 65 every day for the next twenty years.

There are 50 million Medicare beneficiaries today. There will be about 65 million by the end of this decade and more than 80 million by the end of the next.

The cost of caring for their cardiovascular disease, cancer, diabetes and Alzheimer's is unaffordable.

We have been telling members of Congress if you give us the chance, we can help you solve that problem.

Because you can't do it with price controls. And if you try, you will kill innovation.

The reason healthcare is expensive is not because doctors and hospitals and drugs are expensive.

Healthcare is expensive because cancer is expensive.

Diabetes is expensive.

Heart disease is expensive.

Alzheimer's is expensive.

What we need is less cancer. Less diabetes. Less heart disease. Less Alzheimer's.

What we need are fewer sick people.

Fewer sick people here in America and fewer sick people around the globe.

If we have fewer sick people, we'll spend fewer dollars on healthcare.

If we have fewer sick people, we'll have less suffering.

And that is precisely what biotechnology innovation delivers.

Instead of Congress fixating on the cost of innovative medicines, they should consider this: a new drug that could delay the onset of Alzheimer's by even five years, would save Medicare \$50 billion dollars a year.

Let me say that again: save Medicare \$50 billion dollars a year.

That's what biotechnology can do.

But, we could do so much more with the right policies.

So Congress, you can't control the federal budget without getting control of healthcare spending.

You can't control health spending without controlling chronic disease.

And to control chronic disease, you need much more, not less, biotechnology innovation.

But, for our industry to deliver on that promise, we need help with a few things.

Let's work together and fight the disease, not the cure.

We need to reengineer the economic model that drives biotech innovation.

And, we need to create a 21<sup>st</sup> century FDA.

We need to reengineer the economic model because biotech companies are different.

They have to survive on investor capital for long and rocky years before they make a dime.

Our tax code doesn't really recognize this. But, it should.

Our tax laws need to include incentives to encourage, **not** punish, more investment in biotech innovation.

That's why our plan includes eight new capital formation proposals including:

- A new 50% angel investor tax credit for companies with fewer than 500 employees;
- A new research and development partnership structure;
- A provision to make investments in small biotechs eligible for a reduced capital gains tax rate;
- Matching federal grants to venture capitalists that fund small innovative companies;
- New net operating loss provisions;
- Incentives for multinational companies to return overseas funds and invest them in small biotechs;
- A "patent box" providing reduced corporate rates on income derived from certain kinds of intellectual property.

Now, let's turn to the FDA.

The Congress has given the FDA neither the resources nor the authority to do its job.

The FDA review process has become too unpredictable, too time consuming and too expensive. Regulatory science hasn't kept up with the frontiers of innovation. And, the agency has been given too many conflicting missions — and not enough resources to perform them.

We have to change that.

Our plan has eleven new regulatory reform provisions including:

- Making the FDA an independent agency;
- Updating the FDA's mission statement to give the agency a clear mandate to encourage the development of innovative products;
- Providing greater continuity of leadership by giving the FDA commissioner a fixed term

of office that doesn't change over with every new presidential administration.

- Giving the agency a chief innovation officer to ensure that forward thinking, cutting-edge science is integrated into agency operations at all levels;
- Giving the agency new ways to bring in top-notch external scientific and medical advice and more input from patients.

And we also propose creating a progressive approval pathway so that even before final approval, patients can have earlier access to promising new therapies.

More investment in biotech research and a streamlined, predictable approval process will bring more new medicines to patients faster ... and keep them healthier at less cost.

We are also telling Congress and the White House that to balance the budget, we need more high-wage, tax-paying jobs.

Well, when you put biotechnology to work, you put people to work – lots of them.

So, our message to Congress and the president is: focus on how to incentivize biotechnology investments in medicines, agricultural products and advanced biofuels and watch us bring down the unemployment rate.

We've put together a comprehensive Biobased Economy Jobs and Development Act that would give a needed boost to dedicated energy crops, renewable chemicals, advanced biofuels and next generation bio-refineries.

We also need bold policy changes to advance agricultural biotechnology.

Unfortunately, the U.S. regulatory system for plant and animal biotechnology is fast becoming the greatest impediment to the development of safe and beneficial products.

Plant and animal biotechnology developers are no longer certain how long regulatory approval will take, which agency might also claim authority over a product, which data will be required, what the decision will be based upon and, especially, how susceptible a decision will be to a legal challenge.

Our plan calls on Congress to provide clear direction to the regulatory agencies to fix this mess.

These are the kinds of policies that will enable us to achieve the dreams we've imagined.

We **all** have a lot to be proud of...

Hundreds of biologic treatments and cures for deadly diseases;

Biotech crops feeding millions and creating new opportunities for poor farmers in developing countries;

Biofuels and bio-based products saving resources and reducing pollution.

Every day, our products reduce suffering, save lives, and provide hope and healing.

But for us, that's just not good enough.

If we really intend to leave our children a world with less disease, less hunger and less pollution, then we have to face the reality that our time is running out.

We have to do more.

We have to move faster.

We **can** innovate solutions to the world's most pressing challenges.

We want to do more.

We can do more.

That's why we're proposing **big** ideas.

Clearly, our ideas for unleashing the promise of biotechnology won't be easy to sell on Capitol hill.

But, the facts are on our side, and the science is on our side.

I need your help on this...

You have the passion and the knowledge to tell this story convincingly.

If every one of you adds your voice to our effort, we will move the policy makers to our side too, and when we do that we will move this world closer to the one we all have imagined.

Thank you.