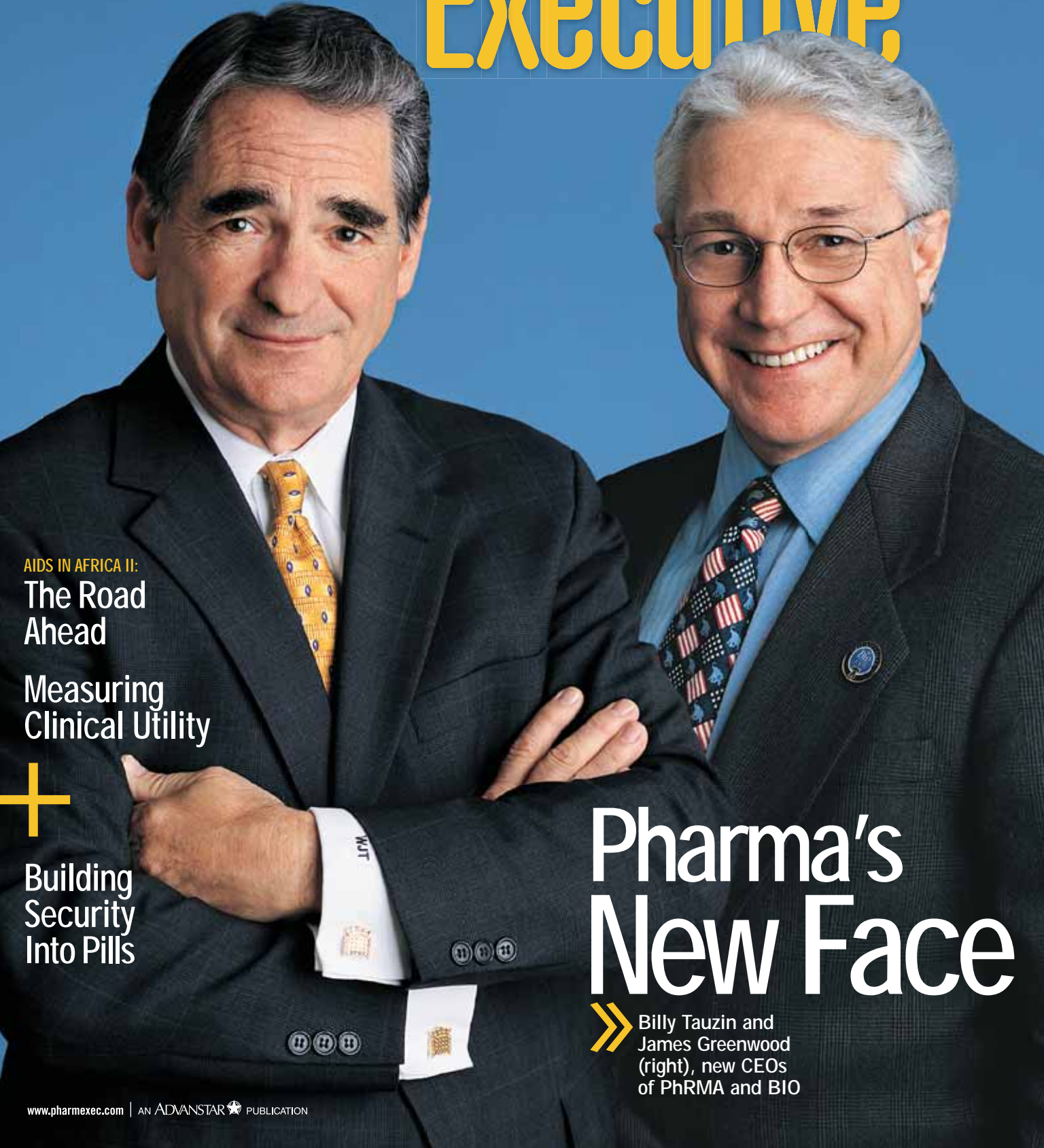


MARCH 2005

FOR GLOBAL BUSINESS AND MARKETING LEADERS

# Pharmaceutical Executive



AIDS IN AFRICA II:  
The Road  
Ahead

Measuring  
Clinical Utility



Building  
Security  
Into Pills

## Pharma's New Face

» Billy Tauzin and  
James Greenwood  
(right), new CEOs  
of PhRMA and BIO

BIO's new president left Congress for what he sees as a more influential role.

First order of business: Teach his former peers that biotech isn't just stem cells.

# James Greenwood

The Pharm Exec Interview

T

he day after President George W. Bush gave his State of the Union Address, James Greenwood had lunch with his longtime colleague, Billy Tauzin. It was a day that drove home the point that the pair had truly changed their lives when they retired from the House of Representatives to take the helms at the pharmaceutical industry's most influential advocacy organizations—Tauzin to become president and CEO of the Pharmaceutical Research and Manufacturers of

America (PhRMA) and Greenwood to take a similar role at the Biotechnology Industry Organization (BIO). “We agreed that there is a certain amount of withdrawal that happens, especially on a night like the State of the Union Address,” Greenwood says. “The last twelve of those I was in the room. This time I was on the sofa watching television. That’s different. But I came to BIO because I think that what is happening in biotechnology is the most transformational human activity of our time. It is an extraordinarily exciting place to be. Though it might seem counterintuitive to people, I believe I am going to be able to

BY JILL WECHSLER AND PATRICK CLINTON | PHOTOGRAPHY BY ADAM AUDEL



do more to shape public policy on healthcare, as well as agricultural and industrial policy, from here than I could have as a member of Congress.”

Greenwood follows in the footsteps of Carl B. Feldbaum, who served as president of the organization from its creation in 1993. He comes to office at a remarkable moment for the biotech industry: The same press release that announced his arrival also announced that the industry had received \$20 billion in investment the previous year, including a record \$5 billion in small, private biotech, and that during the same period, FDA had approved 32 therapies discovered, developed, or marketed by biotech companies.

Early in February, Greenwood sat down with Washington correspondent Jill Wechsler and editor-in-chief Patrick Clinton of *Pharmaceutical Executive*. What follows is an edited transcript of their conversation.

**Pharm Exec:** What are the most important things that you are going to be focusing on?

**James Greenwood:** Clearly right now there is a lot of focus on drug safety. In the wake of Vioxx, etcetera, there have been proposals to change the structure at the FDA for review of products post-market. That is understandable. The industry and the public policy makers should always be making sure we are doing the best we can to provide information to patients, healthcare providers, and physicians so

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make sure policy makers are cognizant of them, as well as the important intellectual property rights of our innovators.

Do you think there will be some kind of a compromise pathway developed in that area? There seems to be enormous pressure, and there also is a lot of advancement in the technology related to refining biotech production.

I think it's a little early to say at all where this goes. I think the FDA is moving cautiously, but they are moving. We have to be cognizant of that. And we have to help them follow the science. We are a cutting-edge scientific organization. So we need to make sure that all the scientific information is brought to bear.

Are you particularly concerned about the focus on pricing these days? Your members make some of the most expensive medicines in the world.

Here is the thing with pricing. Most of BIO's members, maybe three-quarters of them, don't have products for sale on the health side. For most of our members, capital formation is everything. They live by the degree to which angels and investment bankers and others are prepared to provide them with financing.

If the big companies like Amgen, Genentech, and Genzyme do not receive sufficient reimbursement for the products they sell, then the investors will go put their money into the next Blackberry. That is not good for finding new therapies for cancer, Alzheimer's, Parkinson's, and everything else. So there is a continuity, if you will, from the researcher with the thought in his or her head out to the big blockbuster product that has to be taken into consideration.

At the same time, I think the kids in the laboratories who are trying to cure these diseases would feel most gratified and most motivated to know that their products are available to the widest market—the children in India and Africa, too. I think the win-win is ultimately to pursue ways to manufacture these products less expensively, so makers can still achieve appropriate returns on investment, and the money is there to pay for the product. I think that is happening every minute of every day.

You don't have quite the same critical baggage that pharma is plagued with right now. Do you feel a need to maintain that distinction?

I don't think biotechnology or BIO needs to define itself as “not pharma.” I think we need to define ourselves based on what our companies are working on.

There is no simple definition of biotechnology that all of our members would agree to. To some extent, there is the large molecule–small molecule distinction. But many biotech companies do exclusively small-molecule research. To some extent, there is the large company–small company distinction. But, of course, Amgen is not going to be described as small, and it is a major biotech com-

## »James Greenwood



James Greenwood began his career as a social worker in Bucks County, Pennsylvania, after graduating from Dickinson College in 1973. He served in the Pennsylvania Legislature, and was elected to Congress in 1993 from the state's Eighth Congressional District. Greenwood specialized in health, environment, and children's issues. In Congress, he wrote legislation to promote pediatric labeling for pharmaceuticals, reform medical device review and approval, and expand research on traumatic brain injury. He served as chairman

of the Energy and Commerce Committee's Subcommittee on Oversight and Investigation. Greenwood left Congress in 2004, and in January 2005 assumed the position of president and CEO of the Biotechnology Industry Organization (BIO).

they can make intelligent decisions. Our challenge is to make sure that happens in a way that doesn't compromise our ability to get wonderful new products to patients. I told my staff that I want us to be at the intellectual front edge of that issue, and that's what we're doing.

Obviously reimbursement is always important for us. CMS [Centers for Medicare & Medicaid Services] is trying to understand the cost effectiveness of therapeutics. We have to make sure that it is done well. So we want to be—and will be—at the table for those discussions. As we all know, FDA is taking a look at the issue of follow-on biologics. That is a critical issue for the biotechnology community because making biologicals is different from making run-of-the-mill pharmaceuticals. So we need to understand the safety issues clearly and



pany. To some extent, there is kind of the spirited innovation and the desire to find new remedies for terrible diseases as opposed to the reiteration of an existing product. I think those distinctions cause us on a policy matter on one particular day to diverge from a pharma position and on another day to collaborate with pharma.

You are right that pharma has a lot of baggage right now, because they are big, because any time anyone is big and successful they have detractors. And employers, both private and public payers, are trying like mad to hold down costs. That's an issue that because the pharmaceutical industry is much more mature than the biotechnology industry, it's an issue that they have confronted before. But it certainly is one they are confronting more and more.

As you said earlier, very few of your members actually have products on the market. Do their interests in these issues, such as pricing and safety, do they tend to go together or do they tend to diverge? Do you have one organization or do you have two that you have to keep together?

Of course for our members without products, what they are most interested in receiving from BIO is help with capital. They gravitate to BIO to see if they can participate in either partnering meetings or venture capital meetings so that they can have access to resources. They are primarily focused on developing their products, getting their products into trial, and getting their products approved. They are not thinking much about that phase at the reimbursement levels.

But I think, as I said earlier, when they do think about it and they have the time and luxury to think about that, of course they know that if public policy and private sector insurance carriers make decisions that make it very rough to succeed, then it is going to hurt them, and it's just a matter of time. That doesn't impact them only when they get to the place where they have products on the shelves for sale. It can very well hurt them now when it comes time to attract investors. So I think those

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who are thinking over the horizon understand that they are all in the same boat.

When you were on the Hill, you saw a lot of pharma companies and biotech people come up, seeking to press their positions. Do you have some advice for companies regarding what they might do more effectively? I would say this: In the six months between the time that I announced I was withdrawing my candidacy and leaving the Congress and when I arrived here, as you might imagine, I had scores and scores of my colleagues coming up to me on the floor during votes or walking the halls saying, "Oh. You're leaving the Congress. We are going to miss you, Jim. Where are you going?" I would say, "I am going to be the president of BIO." Somewhat to my surprise and dismay, that drew a lot of blank stares.

It made me realize that members of the Congress, unless they are deeply involved in these biotech issues, do not necessarily know what BIO is. Second, when I would say that it is the trade association for biotechnology, the most common response was "Oh, stem cells." So I realized that was the extent that members even know what biotechnology really is; that is what they think of. Of course, only a very small percentage of our companies are engaged in stem cell research.

We have a big selling job to do and an educational job to do on the Hill. I think that's going to be some challenge. But I think it's going to be a lot of fun and a terrific opportunity, because when you tell the biotechnology story in Technicolor, if you will, it is such an astounding story. It is profound to talk about the extent to which we have been able to look inside our bodies, examine our own DNA, sequence the genome, and apply that in a revolutionary change in the way we do healthcare—and in the way we grow crops and feed hundreds of millions of mouths, and the opportunities to change the equation with regard to our energy demands to biofuels, and what biotechnology has to offer in terms of protecting us from bioterrorism.

That is a whale of a story. I think it's a fresh story. It's an exciting story. And it's all about the future. So I think we are going to have a good time in the course of this Congress, telling that story on the Hill. I think the more we tell that story in exciting ways, not just with another sheaf of paper, I think the better off we will be.

Besides going out and telling your story, are there some defensive things that you see coming up that make you really nervous?

On the defensive side, there are the genetically modified crops, which are under attack. Most Americans do not realize they are consuming them every day without problem. But there are radical organizations that are not scientific in their approach that are mounting attacks and actually bringing votes, arranging for ballots and referendums in California counties and so forth. So I think we are a little bit on the defensive on that issue. Again, we have to follow the science and explain to

the members of Congress and the public at large what this is really all about.

Certainly, the embryonic stem cell issue is highly controversial. That is an evolving issue every day. I just heard something yesterday about stem cells found in bone marrow, I think, and their ability to morph into other kinds of cells. But having carried the therapeutic cloning substitute to the Weldon Bill in the last two Congresses, I am acutely aware of how much disinformation there is about some of these stem cell issues. There are members of Congress who believe that biotech companies want to create embryo farms and that sort of thing, which is quite ridiculous.

**Is there a danger that the United States is going to lose out in maintaining its cutting edge position?**

Of course. When we have our conference in June, you will see pavilions there from dozens of countries. And they are not there to invite us to come to their beaches. They are there to invite companies to leave America and make their products in Asia and Europe and elsewhere and take jobs away. It is important that America maintain its prestige and its first-rate status in every aspect of biotechnology.

All of a sudden, both of the major advocacy organizations for the pharmaceutical industry are headed by recent former members of Congress. Of course, it has raised a certain amount of controversy—more when Congressman Tauzin was first talked about for PhRMA and less now when it is actually happening. It's clear what the industry gets from the so-called "revolving door." It's clear what you and Congressman Tauzin can get from it. What is the public-interest argument in favor of people going from Congress to organizations like BIO? Why is this a good thing for the public?

You look at someone like Billy Tauzin who has been thirty-seven years in public policy in public office. And you look at Jim Greenwood who has been twenty-seven years in public policy. I don't think you do that unless you are deeply committed to serving your community and the country and ultimately the world. That's why we both did this into our fifties from very young years of our lives.

If you look at our records, I think you would see in both instances very long records of commitment to trying to do just that. That is why I'm here.

You look at Billy Tauzin, and I'm sure you talked about his cancer. He has made some very tough deci-



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sions in his life about what medicines to take and what surgeries to undergo. He is deeply committed to the notion of putting patients in the driver's seat.

When I interviewed for this job, and the board of the search committee said they wanted BIO to become a world-class advocacy organization, I said to them, "After twenty-four years of being on the receiving end of that, I can tell you that I will bring to BIO the three secret tools of advocacy." And they all leaned forward and asked, "What are those?" And I said, "The truth, the truth, and the truth." One thing the public gets from us is that we know, from years of experience, that when people came to the Hill, if they couldn't give me the dead honest truth, I never listened to

them again. I don't expect anybody on the Hill or in the public to listen to me if I am not truthful with them at all times. So I think those people who are fair give us both time and watch what we do.

**You have quite an order ahead of you. Any specific changes in the organization to accomplish all this?**

I've just hired Scott Whitaker who is Tommy Thompson's chief of staff over at the Department of Health and Human Services to come on as executive vice president here. So he will be the number two guy here. And what he brings is the experience that comes from managing the second-largest department in the federal government next to defense, obviously the intimate knowledge of the workings of the FDA and CMS and NIH, plus he spent ten years in the Senate as a staffer. So he understands the legislative process. And I think he will be a real asset to our team, both in terms of coordinating our various departments so that they function well and also with our advocacy. ☺

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## Biotechnology Industry Organization

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BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.