Statement of Michael Werner, Vice President for Bioethics
FDA Stakeholders Meeting
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Good morning. My name is Michael Werner. I am Vice President for Bioethics for the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies and academic institutions in all 50 states. More than 90 percent of our members are involved in finding new therapies for currently unmet medical needs like Alzheimer's, Parkinson's, various cancers, heart disease and diabetes.

Let me say first that our relationship with FDA is strictly professional. The biotech industry and FDA are not partners, not friends, not even colleagues. Our relationship is arm's length and we view it as one between scientific peers.

On behalf of BIO, thank you for the opportunity to speak this morning about the Prescription Drug User Fee Act (PDUFA). PDUFA III is of enormous importance to our companies – especially the small, emerging companies. Since the statute expires in October of 2002, it is appropriate to take the time now to assess its successes and shortcomings. BIO is in the process of evaluating PDUFA to identify what has worked and what hasn't, because a lot has changed since the statute was first passed in 1991.

The biotech industry barely existed back in 1991. Now we have an unprecedented number of potential new drugs in late-stage clinical development. BIO has set up committees of our members to gather the

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saved lives.

PDUFA has also demonstrated that if given the proper resources, the FDA can effectively administer review and approval programs regarding new drugs and biologics.

Despite these successes, BIO companies have identified some preliminary concerns with the current review and approval process:

- Despite a trend of reduced review and approval times over the years, reports indicate that for FY 2000, these times in fact, increased. This is a big concern for our members – particularly the smaller biotech companies. We need to understand why that happened.

- Although one of the purposes of PDUFA is to provide the biotech industry with a more predictable review process, there are some who believe that is not happening. Specifically, there are complaints of inconsistency throughout the agency. Consistency, predictability, and communication from the agency are critical – particularly to BIO's smallest companies. Some of our companies' very existence is threatened by confused or unclear actions at FDA.

- The lack of an FDA Commissioner remains a problem. Of course, a commissioner does not review applications. However, the agency needs a strong leader who can provide direction to the various departments, and who can fight for appropriate additional resources for the agency.

We hope to discuss these and other issues with policy makers over the coming months.

The PDUFA reauthorization debate also provides an opportunity for an even broader discussion about FDA resources. It is a given that our industry needs a talented, science-based FDA. Indeed, commercial acceptance of our products depends upon a rigorous and thorough review process. The FDA must maintain – and remain – the gold standard for the rest of the world. This will become even more essential in the coming years as our companies develop scientifically complex products designed to treat formerly intractable diseases. Simply put, we need to ensure that FDA has the resources it needs to do its job.

Although user fees provide one source of revenue, BIO has worked hard the last few years to help increase the appropriation to FDA from the Congress. We intend to do that again next year. Reduced appropriations from Congress will seriously impair this critical agency's abilities.

The biotech industry's strict, arm's length relationship has resulted in more than 100 biotech drugs and vaccines reaching patients. These medicines have now helped more than 270 million people worldwide.

In the coming years, we can – and must – do much more. Patients are depending on us. At BIO, we look forward to fruitful discussions with policy makers, patients, and the public to create a PDUFA program that ensures that we all get the drugs, biologics, and treatments that we need.

Thank you.