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Insmed Incorporated

Energy and Commerce Committee

Subcommittee on Health Hearing

"Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States"

Wednesday May 2, 2007

Good morning Chairman Pallone, Chairman Dingell, Ranking Members Deal and Barton, and Members of the Health Subcommittee. Thank you for the opportunity to testify today.

I am Geoffrey Allan, President, CEO and Chairman of the Board of Insmed Incorporated. I testify before you this morning as Chairman of the Coalition for Biotechnology Innovation (CBI), and it gives me great pleasure to announce the launch of this newly formed organization to give a voice to small biotechnology companies that are being brought together by a shared interest in advancing innovation in the biotechnology industry. Our primary goal is to pass legislation in the 110th Congress that defines a practical, science-driven approval pathway for biogenerics. Collectively, members of CBI will stand together on the

key principle that timely approval and timely commercialization of biogenerics will create savings to publicly-financed health care programs, and will accelerate research and development of new and improved life-saving medications.

As a pharmacologist, I have spent 27 years in drug research and development at mature pharmaceutical companies in combination with my experience at an early-stage company like Insmed. I entered this field because I understand complex molecules, and I have dedicated my work at Insmed to helping patients with rare disorders. The scientific advancement in the biotechnology field has been tremendous, and as the CEO of a small biotechnology company whose goal is to provide therapeutic products for metabolic and endocrine disorders, it is my mission to utilize the scientific experiences and capabilities of our industry to bring medicines to patients where there is an unmet medical need. My goal is to extend our mission to include working with the backbone of the biotech industry the researchers, contract manufacturers, and like-minded small research and development companies to unleash our scientific expertise in developing biogenerics.

As I learned about Congress' interest and role in creating a biogenerics market, I felt compelled to contribute to the creation of a platform for our coalition to educate Congress about the burgeoning

interest among smaller biotechnology companies to compete in a biogenerics market. I believe we all agree that when a generic version or multiple versions of a therapy are available, competition will drive down overall cost of these life saving medicines. The development of biogenerics will create an explosion of both investment and innovation in the biologics market.

Innovation is at the core of biotechnology and solving the mysteries of disease is the goal of our industry. Unfortunately, protecting monopolies and the financial bottom line has had an impact on this mission. Our hope is Congress will allow the FDA to evaluate biogenerics on the basis of scientific facts and not the politics of the bottom line. In addition, small biotech companies often face financial hardship due to the high cost of development, but with the ability for small biotech to compete in the biogeneric market, they will have a source of revenue to invest into research and development of new and improved therapies.

In 2005 Insmed received FDA approval for the drug, IPLEX, to treat children with a rare growth disorder. IPLEX is a recombinant protein product that is similar in complexity to many of the recombinant protein products that are the topic of discussion regarding biogenerics.

We believe our experience with the development and approval of IPLEX has positioned us to successfully manufacture biogenerics. Insmed has developed the infrastructure for the manufacture, preclinical and clinical evaluation and approval of recombinant proteins that we now want to leverage for the development of generic recombinant proteins. We have the scientific and technical experience, the personnel, and the facilities to be able to produce safe and affordable generic biologics. I believe our experience with IPLEX is very illustrative of the scientific and technical issues confronting biogeneric drug developers, issues such as comparability testing and the nature of clinical data needed to support characterization of a biogeneric product. The same scientific approach we applied to the development and approval of IPLEX can be applied to the development of biogenerics.

I believe the scientific expertise and capability exist for many companies to manufacture safe and affordable biogeneric products. During the development of IPLEX, Insmed gained valuable experience in the manufacture and clinical development of recombinant protein products. We have developed expertise in all aspects of the manufacture of a protein product and in the many analytical assays that are used to structurally characterize proteins and ensure potency and purity. Insmed implemented several manufacturing changes during the development of IPLEX, including a change in the cell line used to

produce IPLEX. The impact of the manufacturing changes was assessed by comparability testing in which extensive analytical tests were used to determine if any changes to the product resulted.

Insmed also developed several clinical approaches to establish safety and efficacy during the development of IPLEX. These included pharmacokinetic studies to determine the level of product in the blood and how long it lasts and pharmacodynamic studies that were short-term to determine the effect of the product on a specific relevant clinical marker. Pharmacokinetic studies, and in some cases pharmacodynamic studies can also be useful to assess comparability. These short-term clinical studies were used together with several analytical tests to determine any potential differences in the product after a manufacturing change. Our experience with IPLEX also gave us expertise in longer-term clinical outcome studies and in assessment of immunogenicity, which measures potential antibodies to the IPLEX protein.

One might ask how our expertise in the production of one recombinant protein product would allow us to develop any generic protein. Although the manufacture of each product is unique they all share the same types of manufacturing processes and the same internal quality control systems are used to monitor these processes. The manufacturing procedures for different proteins have more in common

than they are dissimilar. For example, the same basic technologies and principles are applied to the fermentation, expression and purification of any recombinant protein product. We would not need information on the manufacturing methods used for the brand product but instead would use our expertise and tailor it to the specific generic protein of interest.

There is a similar ability to leverage one's knowledge regarding structural and analytical characterization of one protein to the development of a generic protein. While the types of analytical tests are tailored to each product there are well established batteries of tests that are common for proteins. One would not need the exact test methods or specifications set by the innovator company that were used to standardize the brand product. In fact, some of the tests used on the brand product may well be outdated. Since analytical technology has advanced considerably over the last 20 years, there is a real possibility that a generic protein drug will have a more robust characterization than its innovator product.

There is sometimes a misconception that the skill and expertise of generic manufacturers is less than that of brand manufacturers. I assure you that at Insmed, our personnel are highly skilled and have years of experience in manufacturing recombinant protein products. Many of our employees came from the brand industry and were involved

in the manufacture of the brand products that are now under consideration as biogenerics. We retain a highly skilled workforce.

Brand companies have been quick to point out that sometimes things can go wrong during a manufacture of a recombinant protein product. That is true and I do not know of any industry where occasional errors do not happen. However, it is critical to understand that there are safeguards that prevent any potential errors from ever affecting the safety of the product. Patient safety must be paramount. One of these safeguards is that every manufacturer must follow strict federal laws and make their product according to Good Manufacturing Practices, which mandates multiple internal controls and the establishment of precise product specifications. Further safeguards are provided by FDA in that the FDA thoroughly reviews the manufacturing process, the test methods and the quality and integrity of multiple batches before it would approve any product, whether brand or generic. The FDA also inspects the manufacturing facility before approval and at regular intervals after approval to assure the quality and integrity of the product, the manufacturing facility and compliance with good manufacturing processes. There is no reason to believe that a generic biologic would be of a lesser quality and less safe than a brand product. The FDA has only a single standard to approve safe and effective products.

You have heard that the science exists to allow for the safe production of biogenerics. I have told you that Insmed, like many other companies, currently has the expertise and capability to produce biogenerics. What is lacking at this time is legislation that provides the regulatory pathway. We need a pathway for biogenerics that gives the FDA authority and flexibility. The FDA can determine the scientific issues and the amount of data required for the approval of biogenerics on a case-by-case basis.

We expect the FDA to issue general guidance documents at some time regarding biogenerics, but guidance documents are not absolutely necessary. Furthermore, we would not wait for the issuance of guidance before submitting applications to the FDA. Insmed believes that close interaction and dialog with the FDA on a case by case basis would allow a more robust approval process than would result from a broad guidance system. At Insmed, we have shown that we can successfully work with the FDA and plan to continue to work closely with the FDA during the development of future biogeneric products.

In summary, we have seen that the science is there for biogenerics. The expertise and capability also exists for the manufacture of biogenerics. However, the regulatory pathway is not available and we are

asking you to support legislation that would create such a regulatory pathway. This would allow not only Insmed to make safe and affordable biogenerics available to the American public but would open the floodgates for all the small biotech firms with the drive, technology, and know how necessary to create a new and competitive biogenerics industry that will generate savings and new innovation for all.