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August 5, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0247, Food and Drug Administration Transparency Task Force, Public Meeting

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments to the FDA's Transparency Task Force. BIO applauds the FDA for convening this Task Force to advance the goals of President Obama's Transparency and Open Government initiative and we were pleased to participate at the June 24th public meeting. Clear, consistent and open communication with the public and regulated industry, conducted in a manner that balances the importance of protecting competitive commercial information, is a critical FDA function and essential for protecting and promoting the public health. BIO is pleased to offer the following recommendations to enhance transparency in FDA processes for communicating with the general public and interacting with regulated industry.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

I. BIO Supports Greater Transparency at FDA:

We are pleased to see the Agency's commitment to advancing the principles of transparency, consistency, and accountability by leveraging modern communication tools and re-evaluating Agency processes. Over the last 15 years, FDA has taken significant strides to enhance its openness and transparency, and that progress should be recognized. FDA currently is one of the most transparent regulatory agencies in the world and a significant amount of information related to drugs and biologics, such as approval letters, summary basis of approval, enforcement letters, advisory committee briefing materials, guidance documents, staff manuals, citizen petitions, and product safety information, is available on FDA's web site. FDA continues to make that information more easily accessible to the public. However, there is more that can be done to enhance transparency. Indeed, both FDA and industry have a shared responsibility after product approval to clearly and concisely communicate accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and clinical decision makers should be armed with the best available information to help assess the clinical benefits and risks of potential treatment options. In fact, drug and biologics manufacturers are making an unprecedented amount of clinical research data available under the FDAAA expansion of the National Library of Medicine's www.clinicaltrials.gov database.

As a first step in the Task Force's deliberations, we encourage the group to further identify deficiencies in FDA transparency and articulate the specific "problem statement" that needs to be remedied by any potential recommendations to the Commissioner. For example, when FDA takes regulatory or enforcement actions, the Agency may not always sufficiently explain to the public how it reaches its decisions, what scientific evidence these decisions are based upon, and how the agency reconciles incomplete or conflicting data. This can result in communication with the public and regulated industry that is neither timely, consistent, nor fully transparent. BIO looks forward to providing additional constructive feedback to the Transparency Task Force as the specific objectives of the initiative evolve.

II. FDA Can Enhance Communication with the General Public:

BIO believes ability to protect and promote the public health is adversely affected when the public loses trust in the Agency's credibility and capabilities, which in part can be a result of a basic misunderstanding of FDA's fundamental role and responsibilities. FDA can and should do more to clearly communicate the scientific basis for its regulatory actions in a manner that is understandable to the layperson. A key element in improving FDA transparency is an investment in FDA's public communications infrastructure.

The greatest single change that FDA can make to enhance transparency is to more clearly articulate the Agency's deliberative processes and to educate the public on how the agency conducts its work—including being forthright about the way it works with industry, how it balances risk and benefit, and where protection of confidential and/or undeveloped information is appropriate. We suggest that FDA host a series of "FDA 101" sessions to better educate the media and the general public on how FDA works and is organized, the scope of FDA's

jurisdiction, and how FDA conducts key activities such as human drug review. This could be done on a regular basis and posted to the FDA website.

We also recommend that FDA refine its procedures for crisis communication and for benefit-risk communication. We believe that FDA should strengthen the capabilities of its public affairs function to better communicate during times of crises and confusion, so that FDA can adequately explain the steps it is taking to evaluate conflicting or incomplete data to the media and the public. Indeed, FDA, industry, and the public benefit when FDA takes a proactive stance, anticipates the public's concerns, and stays ahead of an emerging safety issue. BIO was pleased to see FDA develop a strategic framework for risk communication, but we would like to see this high-level document translated into standard operating procedures that articulate clear expectations, defined practices, and established timelines for FDA communication of new safety information. BIO believes that FDA communications should be outcomes focused with clear advice for patients and healthcare providers on how to manage a risk, rather than just focusing on dissemination of facts or conclusions. Additionally, in the event of a safety issue or recall, we recommend that FDA notify the company involved well in advance of any external FDA communication so that the company may develop complementary communications to the public and healthcare providers, or work collaboratively with FDA to establish a joint communication plan. This type of coordination between FDA and sponsors will help to minimize the potential for conflicting information and provide multiple channels of communication to better inform patients and physicians.

It is also important to note that transparency alone will not enhance patient understanding of a product's benefit/risk profile or enhance medical outcomes unless the information is framed in meaningful context. For example, the public health is not necessarily advanced by communication of drug risks in the absence of a discussion of known benefits or the context of other commonly accepted risks, or by publication of analyses that have not been verified by quality systems to ensure accuracy of conclusions. We recognize that providing sufficient contextual information and corroboration as an element of the Agency's commitment to transparency will require adequate internal processes, resources, and infrastructure.

III. To Drive Biomedical Innovation, Trade Secrets and Confidential Commercial Information Should be Protected:

In our dialogue around FDA transparency, it is important to note that FDA's transparency and disclosure policies should support and be aligned with the market forces that help to drive biomedical innovation, particularly with respect to protection of trade secrets and confidential commercial information.

Much of the biotechnology industry's success in bringing novel medicines to market over the last 30 years is a direct result of the competitive nature of the industry. At any given time, several companies will be simultaneously racing to bring new products to market targeting the same disease or biological target. Throughout a product's lifecycle, firms will submit to FDA certain trade secret and confidential commercial information, such as manufacturing methods, processes, and formulations that may be necessary for FDA reviewers to evaluate the product's safety and

efficacy, with the understanding that this information will not be released to the public and competing firms.

Most of BIO's members are small, emerging biotech companies that rely on venture capital and investment funding to finance the 10-12 year clinical development pathway to bring a new drug or biologic to market. If FDA were to prematurely disclose confidential information, the result could undermine a company's competitive position and hinder its ability to raise capital to fund research into new treatments that will help patients in the future. For that and other reasons, trade secrets and confidential commercial information are strictly protected under FDA law and regulation.

However, BIO recognizes that restrictions on disclosing confidential commercial information may place FDA in a difficult situation when trying to communicate important public health information to the public and industry that may be based in part on confidential data. We would like to work with FDA and other stakeholders to explore mechanisms to enhance the effectiveness of FDA's public communications while continuing to protect confidential commercial information and preserving market incentives for innovation.

IV. FDA Should Improve Procedures for Interacting with Regulated Industry:

An additional area that deserves greater transparency and consistency is FDA's interaction with drug and biologics manufacturers at various stages across a product's life-cycle. To promote the advancement of new cures, we must reiterate the importance of FDA meeting and communicating with companies early in the development and review process. Despite financial support for FDA-sponsor meetings under PDUFA IV, our companies have been requesting these meetings but they have not been granted on a consistent basis. We hope to work with FDA to identify and minimize barriers to granting meeting requests. Additionally, in meetings with sponsors we encourage FDA to communicate recommendations clearly and precisely so that sponsors can more effectively consider the issues raised or act upon them.

Second, regulatory transparency and clear articulation of FDA's policies and expectations through development and timely publication of guidance documents can help to foster innovation. Yet it takes long periods of time—often several years—to finalize policy under FDA's guidance development process. The time-consuming and burdensome process also creates a disincentive for FDA to develop guidance in key areas where FDA direction is sorely needed. This creates significant uncertainty for sponsors, leaving companies to ascertain FDA policy by interpreting agency's regulatory decisions and enforcement actions, which is an inefficient way for industry to understand and meet the Agency's expectations. For our companies, this can be like driving down a highway without posted signs and trying to determine the speed limit by watching which cars get pulled over. Examples of guidances that have been delayed include those related to companion diagnostics, REMS, adaptive trial design, and non-inferiority trials. To optimize the use of guidances to educate stakeholders on the agency's policies, we ask FDA to review its guidance development process to ensure that adequate resources are provided to facilitate the timely issuance of guidance documents. In addition, we ask FDA to review its utilization of its guidance process to ensure that there is regulatory

transparency, consistency, and predictability to help stakeholders better understand the agency's expectations.

Finally, we note that FDA drug and biologics review processes can be inconsistent across different review divisions. For example, many review divisions appear to have differing informal criteria for meeting with sponsors, requesting clinical data, and interacting with sponsors during the review process. This can lead to difficulty anticipating FDA regulatory expectations and uncertainty for sponsors. We are pleased to see FDA managers implementing the Agency's Good Review Management Principles through the *21st Century Review Program* and establishing timelines and milestones for certain sponsor-FDA interactions. We encourage FDA to ensure that these important management reforms are fully implemented across all review divisions.

V. Conclusion:

We thank FDA again for the opportunity to provide comments to the Transparency Task Force. The biotechnology industry looks forward to working with the Agency and other stakeholders to realize greater transparency in FDA communications with the general public and in interactions with regulated industry.

Sincerely,

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Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)