

October 1, 2010

Mrs. Jane Earley
Director, Pharmaceuticals and Medical Devices
Office of Health and Consumer Goods
International Trade Administration
Department of Commerce
1401 Constitution Ave NW
Room 1015
Washington, DC 20230

Comments to the International Trade Administration: Vaccine production and additional planning for future possible pandemic influenza

Dear Mrs. Earley,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment the issue is vaccine production and additional planning for future possible pandemic influenza outbreaks. BIO represents more than 1,100 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 in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents most of the vaccine industry, which is devoted to discovering new preventive tools and ensuring patient access to them. BIO membership includes both current and future influenza vaccine developers and manufacturers who are investing in a broad range of technologies. These companies have worked closely with the public health community to support national and international pandemic preparedness efforts. Therefore, we continue to monitor those policies and activities that could both positively and negatively impact investment in influenza capacity and readiness for the next possible pandemic outbreak.

BIO members believe that the recent global response to the H1N1 pandemic has demonstrated how the existing system can provide an effective framework for addressing the challenges of a worldwide infectious disease outbreak. It is our hope that this recent experience will reinforce the effectiveness and importance of collaboration and cooperation in responding to these types of events.



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Educating the public on the importance of influenza immunization

BIO recommends that countries and NGO's be encouraged to allocate funds to broad educational programs directed to the public on the importance of both individual and community protection against seasonal influenza as a way to build stronger understanding of the role of vaccines in preventing influenza now and in the future. We believe that one of the most important roles of the global public health community in preparing for any future pandemic influenza outbreak is to invest in sustained, evidence-based educational activities for both health care providers and the general public.

During the 2009-10 H1N1 outbreak educational efforts related to mitigating strategies as well as the importance of receiving seasonal influenza immunizations helped limit the impact of the pandemic in many countries. However, confusion in the general population about the way seasonal and pandemic influenza is identified and how recommendations are made, coupled with a lack of understanding about the process for making the vaccines, caused many to question or delay receiving their immunizations. It is pivotal that governments, public health advocates and health educators use the periods between pandemic outbreaks to better inform the public about the importance of preventing seasonal influenza.

Vaccine manufacturers commitment to access

BIO believes that all participants in the global health care arena, including the vaccine developers, can help to improve the lives of those in the developing world by aiding in the prevention of infectious diseases. In our policy statement *Options for Increasing Access to medicines in the Developing World* (May 2010), BIO suggests that its members consider, as part of their specific company business strategies, a number of business options that may help expand access to key medicines and vaccines in developing countries. Members are encouraged to consider partnering arrangements, licensing agreements and various pricing strategies that could expand not only access to but research on vaccines that are designed for infectious diseases impacting developing nations.

BIO's members who have an interest in the development and manufacture of vaccines include a diverse mix of small biotechnology and large integrated biopharmaceutical companies, each with their own unique business model, approaches to R&D and commercialization of their products and varied scientific expertise. Regardless of these differences, each of these companies must in the end remain or become profitable in order to continue their investment in R&D and manufacturing activities. BIO's members believe that the goals of increasing access to vaccines and medicines, respecting

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intellectual property rights, and maintaining commercial viability are not mutually exclusive, rather they are mutually supportive.

Conclusion

BIO appreciates the opportunity to comment on issues related to global vaccine production and planning for future pandemic influenza outbreaks. We look forward to working with the Departments of State, Commerce and Health and Human Services along with others to address these critical issues in the future. We would appreciate any opportunity to meet with the various agency stakeholders in the near future to discuss industry's opinions on pandemic influenza preparedness in more detail. Please feel free to contact me at 202-962-6664 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

With Sincerest Regards,

A handwritten signature in black ink, appearing to read "Phyllis A. Arthur". The signature is fluid and cursive, with the first name being the most prominent.

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