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Department of Health and Human Services
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Via email to: HAIComments@hhs.gov

Re: FR Doc. E8-31195: HHS Action Plan to Prevent Healthcare-Associated Infections

To whom it may concern:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments on *The HHS Action Plan to Prevent Healthcare-Associated Infections* ("HHS Action Plan"). BIO applauds the U.S. Department of Health and Human Services, Office of Public Health and Science, for outlining the department's efforts to establish a comprehensive action plan for the prevention of healthcare associated infections (HAIs) including national benchmarks; recommended clinical practices; a coordinated research agenda; standardized measures to more accurately measure HAIs; infection control practices; and a national messaging plan.

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 technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Specifically related to HAIs, BIO represents companies that develop and manufacture the medical devices, molecular test systems, pharmaceuticals, and other products necessary for the diagnosis, surveillance, and administration of treatment of HAIs. For this reason, BIO companies will play a key role in the implementation of the HHS Action Plan.

HAIs are a critical worldwide health problem. They are one of the top ten leading causes of death in the United States. HAIs are also a leading complication in healthcare administered in U.S. hospitals,

and are a significant cause of morbidity and mortality. In addition, the financial implications of these infections impose significant excess healthcare costs each year. Reducing avoidable costs associated with healthcare acquired infections will help lower the costs of healthcare borne by Americans while at the same time, improving their quality of care.

BIO strongly supports an inclusive and transparent process in all phases of the development and implementation of the HHS Action Plan as the department seeks to collaborate with multiple stakeholders, including industry, to maximize reach and impact in order to effectively prevent HAIs. There is a strong need for government leadership in addressing HAIs as well as private sector involvement.

Overall BIO supports the HHS Action plan and its recommendations regarding best practices in infection control, including activities related to: HAI prevention targets, standardized measurement of infection rates, identification and management of colonized and infected individuals coupled with the implementation of proper hygiene and contact precautions to prevent transmission, appropriate treatment guidelines to decrease morbidity and mortality, and flexible approaches to implementation of infection control program(s) in healthcare facilities based on need or risk. BIO believes that advanced technologies, especially in the areas of diagnostic tests, safer medical devices, new antimicrobial drugs, surveillance systems, and vaccines, will play a key role in achieving these best practices.

BIO also believes that education, training and outreach to healthcare workers, the general public, and at-risk populations is an important component of a comprehensive HAI prevention strategy, and we strongly support the HHS Action plan in this area.

In particular, BIO encourages the department to work to ensure that the HHS Action plan addresses these key areas:

- Increased transparency and accountability in the healthcare system;
- Further evaluation of approaches for funding and reimbursement for HAI testing by third party payers, as well as ensuring access to needed therapies through a cautious approach in payment policies designed to encourage prevention of HAIs;
- Incentives for research and development of clinical infectious disease products, including, but not limited to, diagnostic tests, safer medical devices, new antimicrobial drugs, and vaccines;
- Sufficient funding and resources to implement HAI prevention strategies.

BIO encourages the Obama administration to make implementation of the plan a priority. This includes working internally and with Congress to provide appropriate funding and human resources, and to develop new legislative or regulatory authorities that may be needed to implement the plan. Leaders in the Administration and in Congress have made it clear that improving the quality of healthcare is essential for our nation in order to improve health outcomes and to reduce excess costs within our healthcare system. A comprehensive, target-oriented approach to reducing HAIs that recognizes the valuable role of diagnostic tests and innovative technologies in reducing HAIs will be a key move in this direction.

BIO is strongly committed to protecting patient safety, improving the quality of healthcare, and delivering best healthcare outcomes surrounding HAIs. We appreciate this opportunity to comment on *The HHS Action Plan to Prevent Healthcare-Associated Infections*. We would be pleased to provide further input or clarification of our comments, as needed.

Respectfully Submitted,

/S/

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