

**BIOTECHNOLOGY INDUSTRY ORGANIZATION
STATEMENT IN OPPOSITION TO NORTH DAKOTA S. 2066****JANUARY 2013**

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology trade association. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. One of BIO's core missions is the promotion of a safe, innovative, and accessible market for biologic therapies in the United States. To that end, BIO believes that artificial barriers to access for biological products unnecessarily interfere with a physician's decision-making and a patient's access to necessary treatments. Accordingly, BIO opposes the proposal to subject certain cancer therapies to prior authorization measures under Senate Bill 2066.

Biologics are very complex medicines. Unlike traditional "small molecule" drugs, biologics are not chemically synthesized but, rather, are manufactured from living cells and tissues using a highly controlled and optimized process. Each resulting biologic therapy is complex and unique, and in many cases cannot be fully characterized by current analytical tools. As biologic science has evolved, scientists have been able to develop treatments to some of the rarest and most chronic diseases, many of which would have been untreatable in the past. Cancer therapy has benefited tremendously from these advancements in biologic science. Today we are able to treat multiple debilitating cancers, and in some cases send them into almost permanent remission as a result of advancements in biologic science.

In every case involving cancer treatment – or really any disease treatment for that matter – BIO believes that physicians are in the best position to decide on the course of therapy for their patients. Artificial barriers, like mandatory prior authorization, take some of that decision-making authority out of the physician's hands, thereby potentially limiting that physician's ability to engage in a course of treatment he or she feels is most suitable for an individual patient.

What is more is that early and accessible treatment with biologic therapies, while seemingly expensive in the short-run, can have a tremendous impact on long-term costs associated with disease progression. Giving physicians and patients the early, and accessible, option to utilize biologic therapies can slow or even stop disease progression and potentially eliminate, or at least significantly minimize, the long-term costs associated with aggressive disease evolution. For these reasons we strongly advocate for less, not more barriers to a patient's access to life-saving biologic therapies. Consequently, BIO opposes the prior authorization proposal contained in Senate Bill 2066.

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