

BIOTECHNOLOGY INDUSTRY ORGANIZATION POLICY STATEMENT: Options for Increasing Access to Medicines in the Developing World

Biotechnology plays a critical role in saving lives and improving the quality of life for millions of people throughout the world. It provides useful tools for combating disease, hunger, climate change, and other environmental impacts. The Biotechnology Industry Organization (BIO) is committed to addressing these global challenges. BIO represents biotechnology companies, academic institutions, state biotechnology centers, venture capital firms, and related organizations throughout the United States and in 30 countries.

In the area of healthcare, BIO's members recognize the significant unmet health needs that are prevalent in the developing world. While many of our hundreds of members are taking, or have taken, individual steps to address this global challenge,¹ they recognize that more can and should be done. The public health concerns in this area are two-fold: developing products for diseases that disproportionately affect people in the developing world, while also increasing access to such products as well as the existing range of medicines commonly utilized in the developed world.

BIO's members with an interest in healthcare include a diverse mix of innovative small biotechnology companies, large integrated pharmaceutical companies, top-tier research institutions, and biotech investment firms – each with its own different expertise and experiences that can be used to address these unmet needs. Each biotechnology company also has its own unique business model, with varying approaches to R&D and commercialization depending on the products at issue and the markets for them. At the heart of these business models, however, is respect for strong intellectual property rights. Further, each company must in the end remain – or become – profitable to be able to continue its investment in R&D activities and make products broadly available. BIO's members believe that the goals of increasing access to medicines, respecting intellectual property rights, and maintaining commercial viability are not mutually exclusive, rather they are mutually supportive.

BIO's members also recognize that many of the problems with access to medicines in the developing world are caused by factors outside the control of individual stakeholders, such as lack of adequate manufacturing, delivery and public health infrastructure, trade and tariff barriers, regulatory obstacles, lack of market incentives, local corruption, diversion of supply to more lucrative markets, and a chronic underinvestment in health in national budgets. Nonetheless, BIO believes that all participants in this complex arena – including BIO's healthcare members – can help improve the lives of those suffering in the developing world from preventable or treatable conditions.

With these considerations in mind, some or all of the following approaches are options that BIO's healthcare members should consider as part of their individual strategies to help increase

¹ See Global Health Progress <http://www.globalhealthprogress.org>, Health Partnerships Developing World <http://ifpma.org/healthpartnerships/index.php?id=1995>, BioVentures for Global Health <http://www.bvgh.org/linkclick.aspx?fileticket=867bPGw-kYo%3d&tabid=79>, Partnering for Global Health <http://www.bvgh.org/What-We-Do/Partnership-Creation/Partnering-for-Global-Health/PGH-2008.aspx>

access to medicines in the developing world, to the extent consistent with a company's own business model and all applicable laws and regulations.²

When entering into license agreements, explore creative strategies that help to expand access to medicines in the developing world.

Many biotechnology companies in-license inventions from universities, non-profit entities, or commercial partners. Others serve as the licensor in such transactions. When negotiating such licensing agreements, BIO's members should explore with their partners opportunities to expand access to resulting medicines in the developing world. For example, companies may seek out licensees or licensors in the developing world, or from other non-traditional sources. Also, companies might consider geographic limitations, sublicensing arrangements, and alternative royalty payments and incentives designed to facilitate greater access in the developing world.

While researching and developing products, work to identify compounds or technologies that can have useful applications in the developing world.

There are times when products made for the developed world for the treatment of a particular condition can have other useful applications for diseases that afflict the developing world. Other times, research and development efforts yield compounds or technologies that have no market in the developed world, but have promise for addressing unmet needs in the developing world. In such situations, BIO's members should consider approaches to help further R&D and ultimately the availability of these technologies in the developing world. For example, companies may consider pooling their intellectual property so that their inventions would be made available to interested parties in ways specifically designed to facilitate, and reduce cost and transaction barriers, to research and development of useful products or particular applications for the developing world.³ Alternatively, they could seek out licensees in the commercial or non-governmental organization (NGO) global arenas to further such R&D efforts aimed at the developing world.

Where practicable, participate in partnerships that develop medicines and medical technologies for the developing world.

Biotechnology companies may have medical inventions that, for one reason or another, are not commercially viable or useful on their own. These inventions may, however, be useful for the developing world when utilized in combination with other available technologies or products. In such situations, BIO's members should consider partnering with other commercial entities or participating in public-private partnerships (PPP) with governmental or non-governmental organizations to further such efforts. Information about PPPs is available on the NIH's website (<http://ppp.od.nih.gov>) and the BIO Ventures for Global Health website (<http://www.bvgh.org>). Many of BIO's members and other stakeholders also participate in the recurring Partnering for Global Health meeting, which is co-hosted by BIO and BIO Ventures for Global Health and

² Note that the links cited in this document are only for the purpose of providing examples.

³ One example of such patent pool information is available at <http://www.bvgh.org/News/Global-Health-R-D-News.aspx>

serves as a vital forum for the development of such partnerships. For more information, visit the event website at <http://pgh.bio.org/opencms/pgh/2010>.

When doing clinical trials, take into consideration the needs of people living in developing countries.

BIO's members support including populations that have previously been underrepresented in clinical research whenever possible and appropriate. This approach provides increased access to experimental treatments, including those that may provide benefit, and also helps ensure the collection of comprehensive clinical information. BIO's members adhere to universal ethical standards regarding the conduct of clinical trials and to their specific provisions regarding potentially vulnerable populations living in developing countries.

When commercializing medical products, explore individualized strategies that will help improve the affordability of medicines in the developing world.

BIO's members recognize that the financial resources of most people living in the developing world are extremely limited, and that governmental budgets in these nations are similarly limited. As a result, many of BIO's members already have company-specific programs in place to provide free or low-cost access to their medical products in such countries.⁴ BIO's members should also explore various individualized strategies that are consistent with their particular business model and could help improve the affordability of medicines in the developing world. Consistent with applicable laws and regulations, companies might consider, for example, donating supplies to certain governmental or non-governmental organizations, exploring tiered-pricing approaches that include special humanitarian pricing (at-cost/low-cost), engage in capacity-building with local partners, or licensing to generic companies or other non-traditional partners for production or distribution in certain countries.

Where practical, explore ways to overcome non-price barriers that hinder access to medicines and medical technologies in the developing world.

While there is much focus on the issue of price of medicines and medical technologies in the developing world, often there are other – larger – barriers that hinder access, as described above. BIO's member companies should explore ways to overcome these barriers to facilitate access to medicines and related technologies for people living in the developing world.

Share individual experiences and approaches broadly to advance the goals of enhanced access in the developing world.

There are many individual efforts that are being, or have been, taken by BIO's members to help improve access to medicines in the developing world. Consistent with applicable laws and regulations, BIO's members should broadly share their individual experiences in this area, in order to foster greater industry involvement in similar efforts and to spread knowledge about successes and challenges with varying approaches.

⁴ See footnote 1, *supra*.