We speak for small biotech

To the editor:

I would like to respond to your July editorial, "Who speaks for small biotech?"¹ As the chair of the Biotechnology Industry Organization's (BIO; Washington, DC) Emerging Companies Section Governing Body, I believe that it is easy to document BIO's deep and enduring commitment to the issues and needs of small biotech companies. Since its founding in 1993, BIO has consistently focused its resources to assist emerging companies in a variety of ways.

BIO represents more than 800 biotech companies. Eighty percent of these members do not yet have a marketed product and have fewer than 350 employees; the vast majority employs less than 100. The advocacy and service priorities of BIO's emerging companies are set by BIO's Emerging Companies Section Governing Body, whose mission is to ensure that issues of unique concern to small companies are brought forward and that the voice of small companies is fully heard on issues affecting the broader membership of BIO. This governing body, which includes >40 CEOs from companies in a wide range of therapeutic areas, is empowered to make decisions on behalf of the organization and has its own standing committees relating to health and regulatory policy and to capital formation policy.

BIO's emerging companies are well represented on the BIO board. They constitute >40% of BIO's Health Section Governing Body, which is the entity within BIO's governance structure that formally develops and sets BIO's positions on major healthcare issues.

BIO's advocacy agenda is often driven by its emerging companies. As you mention in your editorial, BIO has been at the forefront in urging the US Congress to restore eligibility for small venture-backed biotech companies to compete for small business

innovation research grants. BIO played a lead role in achieving a set of changes in the implementation of the Sarbanes-Oxley Act to reduce the compliance burden for small companies.

Even beyond issues specific to emerging companies, BIO's overall advocacy agenda is very relevant in ways that may not be readily apparent. For example, fair reimbursement of innovative biotech therapies may not seem important to a small company struggling to finance itself, but if established biotech companies with products on the market fail to provide a reasonable return on investment, how can we expect the capital markets to continue to support the higher risk funding of small companies working to develop the next generation of therapies?

Realizing that intellectual property is the key asset of emerging biotech companies, BIO has been actively working with Congress to shape the patent reform legislation, which passed the House and is pending in the Senate. Unfortunately, this legislation as currently drafted would make it easier and less expensive to infringe patents owing in particular to provisions relating to the apportionment of damages and the length of the post-grant review period. BIO is working with its state affiliate organizations and with member companies to educate Members of Congress about how devaluing intellectual property would make it all the more difficult for startup biotech companies to raise necessary capital. We are also currently involved in stakeholder negotiations with key Senators to try to improve the legislation.

BIO's position on biosimilars was approved last year by the BIO's Health Governing Body and the full board, both of which include significant representation by emerging biotech companies. BIO believes that there should be a pathway for the approval of biosimilars that

protects patient safety and achieves essentially the same outcome as provided by the Hatch-Waxman Act for generic pharmaceuticals with respect to continued incentives for innovation balanced with reduced prices for consumers and other payers. As biosimilars are 'similar', rather than exact, copies of the innovator product, the innovator's patent may not offer sufficient protection (as it does for the innovator pharmaceutical product under Hatch-Waxman). Therefore, to achieve incentives for innovation, a pathway for the approval of biosimilars needs to include 14 years of data exclusivity, a period comparable to that provided to innovator pharmaceuticals by Hatch-Waxman. This approach will help provide the continued incentive for innovation and help support the significant capital investment needed by emerging companies.

BIO's commitment to emerging companies pays dividends for its members beyond advocacy efforts. BIO hosts nine annual investor and business development meetings in which companies make presentations and engage in one-on-one meetings to attract either investors or partners. In 2007, 28,500 one-on-one meetings were held among 5,300 companies and 1,150 companies offered presentations.

Emerging biotech companies represent the future of the biotech industry, and BIO's mission is to be the champion of biotechnology and the advocate for its members—both large and small. BIO's track record clearly demonstrates that emerging company members are at the heart of all that BIO does.

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1. Anonymous. *Nat. Biotechnol.* **25**, 693 (2007).

To the editor:

Your editorial "Who speaks for small biotech?" published in the July issue¹ highlights the difficulty of engaging small and medium-sized