

Who speaks for small biotech?

The biotech industry's trade organizations need to better represent the concerns of their rank and file.

Biotech industry lobby organizations are not entirely representative of the biotech industry. Around 30% of the board of the US Biotechnology Industry Organization (BIO), for instance, comes from large multinational pharmaceutical, agrochemical or industrial processing firms—companies such as Pfizer, Schering-Plough, Johnson & Johnson or DSM; another 30% comes from big biotech—companies such as Genentech, Amgen, Genzyme or Biogen-Idec; the rest come from the smaller firms.

At EuropaBio, the European industry lobby, the mix of the board is even more skewed. Ten members come from large companies interested in 'white' or 'green' biotech (DSM, Degussa, Solvay, Novozymes, Danisco, Syngenta, Monsanto, BASF, DuPont, Bayer), four from the pharmaceutical side (Novartis, EMD Serono, GSK and Genzyme), plus three national industry associations. Only four small companies are represented.

What's largely missing in either body is a proportional representation of the thousands of nonmultinational, privately financed, not-for-profit-yet organizations that comprise >80% of the sector and still signify most of the hope for the future of the industry.

In some ways, the current power balance in BIO and EuropaBio is not surprising: it does represent the products that the industry has put on the market, the money it makes, the taxes it pays, and to some extent the people it employs. In any case, it is profitable companies that can best afford to provide resources to lobby organizations. It's almost inevitable, therefore, that the vast number of research-based young firms who depend on external finance from investors or who scratch out a living as part of the biotech supply chain will be underrepresented.

In this respect, BIO is set up to do a better job of promoting smaller companies than its European counterpart. Its 'Emerging Companies Section' has 45 members, representing investors and CEOs of firms that do not yet have major products approved and on the market. BIO's bylaws from 2003 even stipulate that 14 members of this Emerging Companies Section should be on its board of directors (49 members at present), and two should be appointed to the 13-member executive committee.

At EuropaBio, small company issues are often deemed the responsibility of the national associations, such as the UK's BioIndustry Association (BIA) or France Biotech. In some respects this makes sense, because EuropaBio is set up to tackle European-wide issues; and it is the national jurisdictions, rather than the European Commission, that tend to play a greater role in determining the financing and tax environment for startups.

Both organizations have undoubtedly gone to bat for small biotech in recent years. For example, BIO has undertaken a concerted effort to reverse a 2001 ruling that has made companies with >51% venture capital funding ineligible for the SBIR (small business innovation research) program. It has also recently presented testimony before the US Congress arguing that provisions in the Patent Reform Act of 2007 might harm small companies. In the past, it has campaigned for orphan drug and

R&D tax credits. And of course, BIO's partnering meetings and training programs are set up to help member firms find capital and strategic partners. Even so, at BIO 2007 in Boston, many of the concerns and issues that affect emerging companies seemed much less to the fore than in previous years (<http://invivoblog.blogspot.com/2007/05/bio-perspective-it-out-phrmas-phrma.html>).

On the other side of the Atlantic, EuropaBio has recently helped persuade the European Commission to introduce new State Aid rules that mean national bodies can offer a range of tax incentives to young innovative companies. It has argued for reduced fees at the European Medicines Evaluation Agency (EMA) and at the European Patent Office. What's more, the administrative structure of EuropaBio has been changed to ensure that small company issues are not filtered or watered down by its large company management structure. The Emerging Enterprise Council within EuropaBio provides a direct channel for the concerns and actions of small companies.

Despite these adjustments, much of what the industry lobbies deal with seems irrelevant to smaller firms. Both EuropaBio and to a lesser extent BIO are finding great resonance with federal and national governments for their 'white' biotech push. Governments have agreed to incentives for firms developing greener production processes, to targets for bioethanol and biodiesel. This is certainly close to the hearts of the past two EuropaBio chairmen, Feike Sijbesma of DSM and Hans Kast of BASF—and to newly elected chairman, Steen Riisgaard of Novozymes—but in Europe, at least, there is precious little white biotech in the small company segment.

The trade associations have also adopted a similar posture for biosimilars. The positions for which the industry lobbies have fought appear to protect the positions of firms with established protein drug products in the market, rather than encouraging challenge and renewal from more efficient processes. The lobbying efforts in biosimilars make great play of juxtaposing the 'innovators' with the follow-on producers of biologics. The fact is, though, many of these innovators innovated in what, by *present* standards, are fairly trivial ways; a spliced gene here, a serviceable production system there, a purification trick or two. In their day, these were significant steps forward, and were rightly rewarded. But patent expiry is usually taken as a strong indication that the novelty value has expired. However, the biosimilars legislation that the lobby organizations have sought says, in effect, that it is just as innovative to keep doing the same thing as it is to try new stuff. This is strange and troubling, and has removed a lot of the pressure to innovate further, leaving incumbent firms free to concentrate on maintaining their franchises.

BIO and EuropaBio need to do more to ensure they remain in touch with the needs of their members from small- and medium-sized enterprises. These are the firms responsible for the sector's future economic growth. And they are the lifeblood of biotech innovation that needs to be protected and nurtured. The voice of biotech's silent majority needs to be heard.