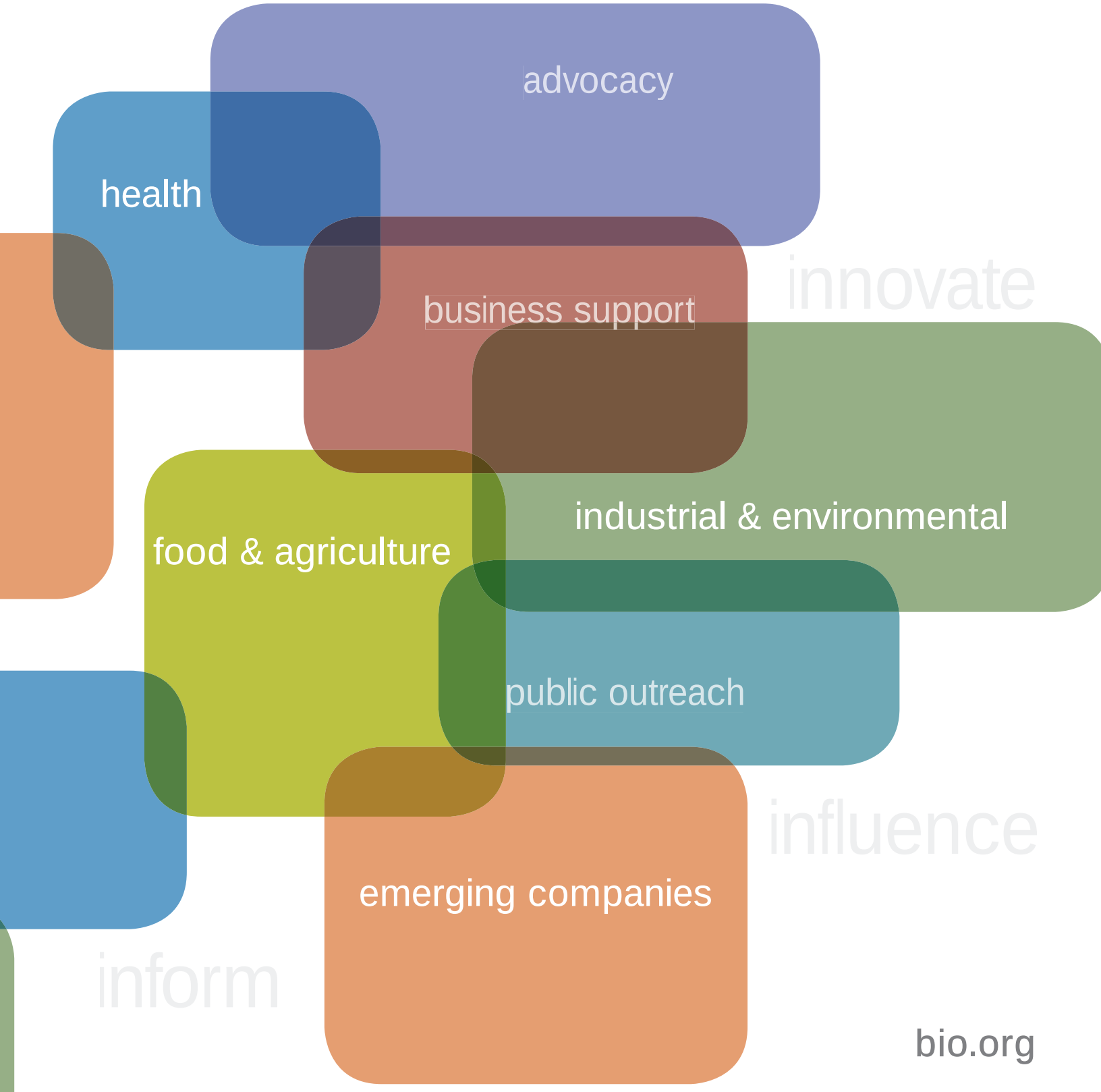
2007–2008 Milestones

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION



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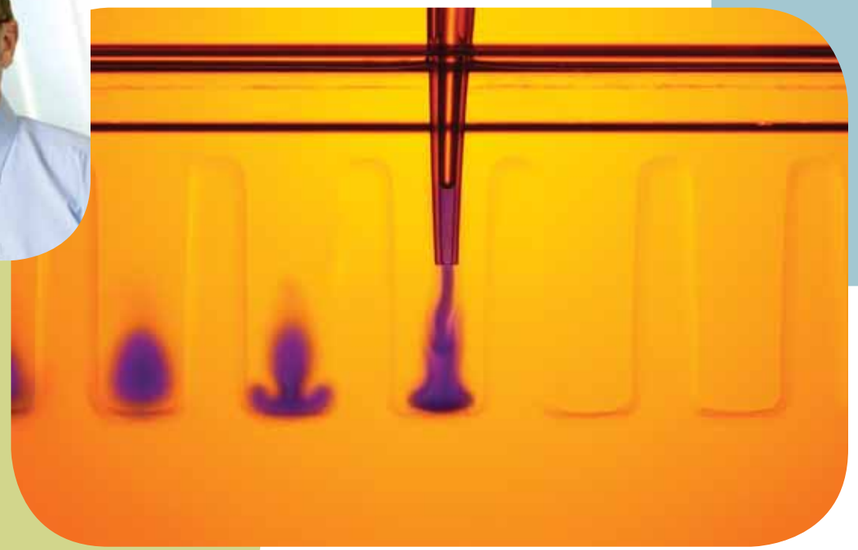


Today, the biotechnology industry is enjoying more success and influence than ever before.

Our industry's innovations continue to improve the lives of people worldwide, and the advancement of these innovations is supported by the work of BIO. But these are challenging times. Our continued success is not assured, and we must neither rest on past accomplishments nor retreat from new challenges.

At last year's BIO International Convention, I sketched a bold vision of what I believed the industry must achieve: *Greater access to our innovative medicines, at lower prices. Improvements in drug safety, ultimately at lower cost. The continued advancement of the agricultural revolution. The growth of renewable energy with low or near-zero carbon footprints. And a cleaner environment.* The industry—and BIO—witnessed major strides toward achieving these lofty goals over the past year and are today on a trajectory to make even greater advancements in the year to come. And there is still much to do.

Thanks in no small part to BIO's world-class advocacy team, major FDA legislation passed that provides resources to strengthen post-market safety. We made the case against raising Medicaid rebates and hastily enacting poorly-reasoned comparative effectiveness legislation, and we pressed for major energy legislation that tripled the mandate for renewable biofuels.

Our tenacity on the regulatory front was rewarded by FDA's long-awaited risk assessment finding that food derived from cloned animals is safe—a major step forward for this technology.

The coming year will bring even more opportunities for BIO to showcase the importance of biotechnology on a number of vital issues. Lawmakers are taking up key efforts affecting our industry, such as patent reform and follow-on biologics legislation. Come next January, a new administration will take over the White House and will undoubtedly bring a new perspective and new ideas to the troubled American health care system.

Whatever happens, change is certain, and BIO will be ready for it. BIO has an outstanding record of delivering the message of biotech innovation to federal and state policymakers across the country. But now it's time to bring that message to a much broader public and to raise and to deepen the impact of that messaging.

A BIO-sponsored public opinion survey found that while 78 percent of voters considered curing diseases as a top national issue, only 45 percent had a favorable opinion of the biotechnology companies on the forefront of this effort. However, nearly twice that number—86 percent—voiced favorable opinions of biotech after being told about the industry's pioneering approaches to treating disease, creating alternative energy sources and combating worldwide hunger and malnutrition. So, why this disconnect? And more importantly, what will BIO do about it?

The work of biotechnology companies is incredibly challenging. With such challenge, there are inevitable disappointments. Unfortunately, we often hear more about setbacks than progress; such is the unfortunate zeitgeist of the online age, where the negative and conspiratorial more readily dominate attention than the hopeful and true. This is far more than a public relations issue. It is clear that unless we proactively and compellingly present the facts about the benefits and potentials of biotechnology, vital innovations could be held back by public misinformation.

BIO must also convey our industry's values—including our commitment to access—and our industry's importance to growing a 21st-century economy. Good people, working at companies committed to the common good, characterize our industry. Greedy executives working for ruthless corporations are largely a creation of popular fiction, providing a magical explanation for unfulfilled needs. The more difficult reality is that, by and large, our companies and their leaders are working diligently, trying to solve complex problems. We don't succeed all the time, and we make mistakes. But when we do succeed, we deliver on the hope for improving our world.

That is why the Board of Directors and Section Governing Bodies have asked BIO to implement the first ever, wide-scale, far-reaching communications campaign explaining and promoting the biotechnology industry. The goal: to tell our stories and thereby build new networks of our supporters, allies and friends. Sound ambitious? You bet it is. It's incredibly ambitious, and it will be the work of years to come. But as the only organization encompassing every application of our industry's innovations, BIO stands proudly as the most prominent and powerful standard bearer for innovation across biotechnology.

BIO will work with the Board, Governing Bodies, outside experts and communications professionals within our member companies to achieve this crucial objective. We are up to the challenge and I urge you to get involved in this campaign, not because it's the story of BIO, but because it's the story of us all—our companies, our breakthroughs, and the billions of people whose lives will be transformed in a brighter future that only the innovations of biotechnology can bring.

Sincerely,

Joshua Boger, Ph.D.
Chairman, Biotechnology Industry Organization
President & CEO, Vertex Pharmaceuticals Incorporated

"Whatever happens, change is certain, and BIO will be ready for it. BIO has an outstanding record of delivering the message of biotech innovation to federal and state policymakers across the country. But now it's time to bring that message to a much broader public and to raise and to deepen the impact of that messaging."

The national election of 2008 ushers our nation to an historic crossroads that will present new challenges and opportunities for our industry.

With control of both the Congress and the White House at stake—and with health care, food and fuel among the most pressing issues of concern for the voters—the biotechnology industry is guaranteed to face a new policy landscape come January.

Maintaining a favorable business and policy climate for biotech innovation is the core of BIO's mission as an organization. We have built a world-class advocacy team that is recognized as one of the most effective in Washington, as well as at the state and local levels. This *2007-2008 Milestones* details BIO's advocacy efforts and other activities during the past year. As you will read, we scored some significant victories, such as the inclusion of the new renewable fuel standard in the Energy Independence and Security Act of 2007 and the completion of the FDA final risk assessment on the safety of foods from cloned animals. We also advanced sound policy alternatives for patent reform and the development of a regulatory pathway for follow-on biologics.

BIO's ongoing challenge is to more effectively educate policymakers and the public about the profound value and potential of biotech innovation.

The American public demands more effective, more affordable and more accessible health care. Elected leaders and candidates are responding with a broad range of proposals. Unfortunately, many of the ideas put forward are focused not on innovation, but on regulating our way to a better health care system, through price controls and other restrictive measures.

BIO member companies have pioneered hundreds of life-saving therapies, vaccines and diagnostics that have saved and enhanced millions of lives worldwide. What is too often overlooked is that innovative drugs also produce real health care savings by speeding patient recovery and reducing the need for expensive surgeries and lengthy hospital stays. One study found that the economic benefit of new drugs is almost nine times their estimated cost.

"...our companies routinely face opposition from activists, the media and policymakers—often coupled with calls for regulation, controls and even bans on innovative new technologies. Again, BIO and our members must be ready to engage critics, correct inaccurate or misleading information, and explain our work in a way that engages, informs and inspires the public."

When policymakers turn their attention to reforming health care, BIO will be at the table to make the case for innovation, not regulation, as the best path forward. Our health biotechnology member companies have hundreds of new therapies, vaccines and diagnostics in the pipeline, while new technologies like gene silencing and regenerative medicine promise even greater advances in our ability to predict, preempt and prevent disease.

Biotech innovation can continue to create such life-saving products—or shortsighted price controls intended to secure cheaper drugs today can destroy the hope for better cures tomorrow. For those of us who work every day in the biotech industry, the right choice is clear. We must all work together to share that clarity with the American public and our elected leaders.

The choice between innovation and regulation extends beyond health biotechnology. The industrial and environmental biotechnology sector is opening doors to new innovations and products that will revolutionize every aspect of our lives: industrial manufacturing, production of chemicals and consumer goods, environmental protection, and meeting our energy needs in a way that reduces our reliance on fossil fuels. The goal of creating a biobased economy founded on biobased plastics, renewable consumer products and sustainable production of advanced biofuels inspires the work of many BIO member companies.

Likewise, BIO members working to develop next generation biotech crops, animal biotechnology and other advances have a vision of providing food, fiber and fuel to meet the needs of a growing world population.

Yet, in both of these areas, our companies routinely face opposition from activists, the media and policymakers—often coupled with calls for regulation, controls and even bans on innovative new technologies. Again, BIO and our members must be ready to engage critics, correct inaccurate or misleading information, and explain our work in a way that engages, informs and inspires the public.

The common theme here is our need to do a better job sharing the biotech story with the public. For those of us engaged in this industry every day, the benefits of our work and the value of our products may be obvious. Yet, we often forget that the vast majority of people don't think about biomedicines until they or a loved one falls ill; may only know about biotech crops in the context of a negative news story planted by hostile activists; and are not familiar with the economics or technology of advanced biofuel production.

We must not be dismissive of legitimate fears and concerns, nor perpetually defensive about the latest crisis or controversy stirred up by opponents of biotech innovation. That is why we are excited to launch the far-reaching communications campaign that Chairman Boger describes in his message to you.

When I accepted this job in January of 2005, my primary direction from our Board of Directors was to develop a world-class advocacy team. Over the past three years, BIO has built highly effective working relationships with regulators and elected officials. Now the time has come to expand our communications to a broader audience. In the coming years, we must, and will, work to win the trust and confidence of the broader public.

Along with BIO's outstanding professional staff, I am proud to serve the many talented and dedicated individuals who make up the biotech industry. Through your work, you are creating a better future for all of us—a world increasingly free of disease, hunger and pollution. We look forward to supporting and advancing your vision in the coming year.

Sincerely,

James Greenwood
President & CEO
Biotechnology Industry Organization

cross-cutting issues

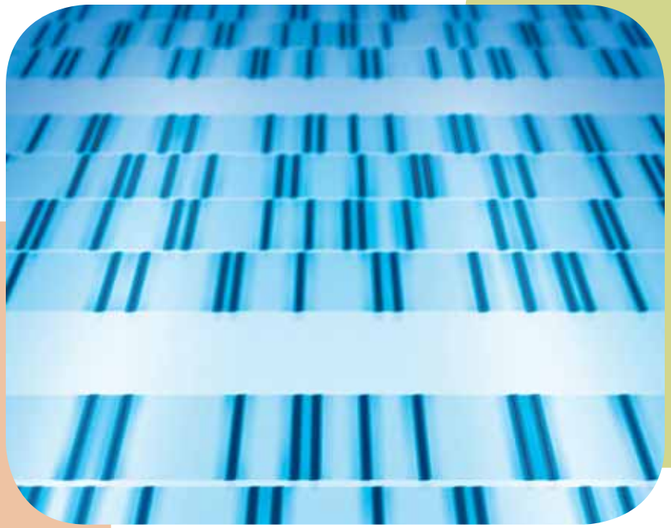
BIO's four governing body boards—Emerging Companies, Food & Agriculture, Health and Industrial & Environmental—focus on issues pertinent to their Section's and are authorized to address and make respective policy decisions on behalf of BIO. However, some issues affect all BIO member organizations regardless of the Section to which they belong. These topics—referred to as "cross-cutting issues"—are deliberated and decided upon by the BIO Board of Directors.

Intellectual property

Recognizing that a strong and predictable patent system—domestically and internationally—is a driver for continued biotech innovation, BIO has deployed our world-class advocacy team to respond vigorously to legislative, regulatory and judicial action that could potentially weaken biotech patents. We have been active in the U.S. patent reform debate for the last several years, and have advocated aggressively to reduce patent backlogs and increase government support for the U.S. Patent and Trademark Office (USPTO). Internationally, BIO represents biotechnology interests in discussions on patent law harmonization within the World Intellectual Property Organization (WIPO) and in WIPO's Intergovernmental Committee on Folklore, Traditional Knowledge and Genetic Resources. We have also been an active participant in intellectual property (IP) issues at the World Trade Organization (WTO), the World Health Organization (WHO) and the Convention on Biological Diversity (CBD).

Bioethics

BIO is committed to the socially responsible use of biotechnology to improve and save lives, raise the quality and availability of food, and protect our environment. At the same time, we are intensely aware of the ethical questions these new applications can raise. Therefore, we are working to increase public acceptance of biotechnology and promote dialogue about its ethical considerations. To this end, the BIO Board of Directors adopted a Statement of Ethical Principles, and is continually refining an industry-wide vision of measures to ensure that biotechnology is not abused, but responsibly harnessed for the benefit of humankind. Additionally, the BIO Board-level Committee on Bioethics enables industry executives to participate in policy, strategy and planning discussions regarding bioethics issues that touch all sectors of the industry: human health, food and agriculture, and industrial and environmental. These discussions help inform and influence our policymaking.



Government and academic research

Biotechnology innovation could not exist without the contributions of government and academic researchers. We strongly advocate for government agencies supporting science, such as the National Institutes of Health (NIH). In turn, these agencies support academic researchers with grants and other aids to innovation. In 2007, BIO continued our steadfast advocacy for uninterrupted and increased support for today's scientific endeavors that may potentially become tomorrow's treatments and cures.

The following progress report provides an overview of our work on patent reform and other intellectual property issues, as well as our recent bioethics activities and efforts to support government-sponsored research over the past year. We also invite you to explore these issues in more depth at bio.org, where you will find Congressional testimony, regulatory comments, press statements and many other materials.

Progress Report

Safeguard and advance intellectual property protections, domestically and internationally

Objective

Advocate for international intellectual property agreements and foreign national laws that provide strong IP protections for BIO members.

progress

WHO is considering a public health plan that, if adopted, would affect the intellectual property framework of many medicines, vaccines and diagnostics. The draft plan recommends several approaches for enhancing access that would actually serve to undermine incentives for research and development of such products, including:

- Requiring patent applications to disclose the source of a biological material, and evidence of informed consent to use the material and benefit-sharing with the owner.
- Expanding a nation's right to force compulsory licensing of products or patents to competitors.
- Establishing mandatory patent pools that would *require* companies to cross-license related patents.
- Creating research use exemptions mandating free access to patented technologies and tools that may be used in product development.

We continue to oppose this draft plan, which would not only allow—but encourage—WHO member states to pass laws endangering the integrity of intellectual property associated with biotech inventions. Where patents are available, the plan would make it difficult to enforce such patents. A further cause for concern is that the draft plan calls for weakening the intellectual property of all medical products and technologies—not just those related to infectious diseases disproportionately affecting poorer nations, which has been WHO's historic area of focus.

Without the ability to adequately protect biotech inventions, companies would be unable to generate the necessary investment to shepherd needed treatments from early research to commercialization. In addition, weakened enforcement rights would devalue existing patents, removing incentives for further investment in high-risk biotech ventures.

As part of our opposition to these well-intentioned—but misguided—proposals, BIO has highlighted industry concerns by filing comments with WHO. We recommended practical, market-based solutions, including advanced market commitments, public-private partnerships and collaborations. We spearheaded a letter from 13 international biotechnology trade associations, and communicated our positions and recommendations to the U.S. government and other relevant countries. At press time, negotiations are ongoing and are expected to be completed in spring of 2008.

cross-cutting issues

Objective
Articulate the critical role of intellectual property protections for biotechnology in patent reform efforts.

progress

At press time, the Patent Reform Act of 2007 (S. 1145) is under consideration in Congress. The bill, as originally drafted, contained provisions that would weaken the predictability, value, and enforceability of validly-issued patents. Some of the proposed reforms pose serious negative consequences for continued innovation and American technological leadership in a competitive global economy. We have fought these provisions, which have included:

- Expanded apportionment of damages.
- A new, indefinite and broad post-grant opposition process.
- Enhanced rulemaking authority for USPTO.
- Excessive venue restrictions.
- Burdensome and expensive mandatory search and analysis requirements.

In addition, the bill codifies the current inequitable conduct doctrine rather than enacting broadly supported reforms to enhance patent quality and eliminate litigation abuse of the doctrine—which has been called a “plague” by the top U.S. patent court.

Although BIO believes patent reform is a worthwhile goal, we do not support the present patent reform bill in its current form, and are working to ensure changes that will safeguard the intellectual property of America’s biotechnology innovators. We continue to work with members of Congress and their staffs, publish papers in support of our positions, and coordinate our efforts with other groups that share our concerns. Our supporters include more than 400 health organizations, universities and other industries and groups that signed on to a letter opposing the bill in fall of 2007.

The U.S. House of Representatives narrowly passed its own version of patent reform legislation, H.R. 1908, in September 2007, which BIO opposed.

Objective
Continue to oppose the present form of USPTO-proposed rules on claims, continuations, and information disclosure statements and minimize negative impact of possible further rule revisions.

progress

When it comes to patents, biotechnology inventions are unlike other products. A researcher or company often begins the patenting process with the discovery of a gene or other molecule of interest and gradually adds claims that successively cover that molecule for use in a diagnostic, then a therapy, and so on.

In August 2007, USPTO issued several new rules harmful to biotech patents, which would limit the number of claims and continuation applications that can be filed. BIO filed extensive comments with USPTO opposing these rules and seeking to change them. In the fall of 2007, we filed an amicus brief in support of GlaxoSmithKline’s lawsuit to stop their implementation by USPTO. A U.S. District Court recently granted GSK a permanent injunction, barring USPTO enforcement of these rules; the federal government has appealed.

We also commented on USPTO’s proposed rules on information disclosure, deposits of biological materials, and alternative claiming of inventions. Our comments and letters are posted on the intellectual property section of bio.org.

Objective
Launch a public relations campaign to educate policymakers on the importance of intellectual property protection for biotechnology innovations.

accomplished

BIO placed position advertisements, op-ed articles and other public materials in targeted publications. BIO’s communications team also responded to breaking news on intellectual property issues on a continuing basis.

Objective
Support the efforts of the BioJudiciary Project and other non-profit organizations to educate the judiciary on the intersection of biotechnology and patent law.

accomplished

The 2007 BIO International Convention included a BioJudiciary Project booth to disseminate educational materials on biotechnology and patent law. We are working with the BioJudiciary Project to develop an educational seminar for the courts and laypersons about the intersection between biotechnology and the law.

Objective
Further refine BIO’s framework for access and benefit sharing by developing a Model Material Transfer Agreement for accessing genetic materials in other countries—such as those with rain forests and other biodiversity harbors—as an alternative to mandatory patent disclosure requirements.

accomplished

We completed a model transfer agreement (available at bio.org) and presented it at public forums, including the Convention on Biological Diversity working group meeting.

Objective
Complete and communicate the results of BIO-sponsored IP studies relating to the role of patents in the development of innovative therapies.

accomplished

BIO published several papers on patent issues (available at bio.org), including:

- *The Tragedy of the Anticommons.*
- *The Economic Implications of Patent Reform: The Deficiencies and Costs of Proposals Regarding the Apportionment of Damages, Post-Grant Opposition and Inequitable Conduct.*
- *Proposed Patent Reform Legislation: Limitations of Empirical Data Used to Inform the Public Policy Debate.*

Foster a dialogue about ethics and biotechnology advancement

Objective
Identify, analyze and promote policies that address the ethical questions facing companies and society to enable BIO to respond in a timely manner.

accomplished

We engaged the priority topic of “Access and Innovation” by analyzing ways to improve access to innovative medicines, while continuing innovation for the unmet medical needs of current and future generations. The BIO Board-level Bioethics Committee identified the following ethical

questions as central to the discussion about access and innovation:

- Is there a moral obligation to provide access to new medicines?
- If so, what are the sources, nature, and extent of that moral obligation?
- On whom does that obligation fall?
- Is the obligation satisfied by a health care system that would assure access?
- Do biotechnology firms creating new medicines have an ethical obligation to foster access to their products in the absence of a health care system that assures access?
- What is the source and extent of any such special obligation?
- What is industry's obligation to innovate?

We also identified the ethical questions related to synthetic biology in response to an announcement that a team of scientists created the first synthetic bacterial genome. The question of whether synthetic biology crosses moral boundaries by "creating artificial life" was identified as central to the discussion, along with questions related to dangerous dual use of the technology. These discussions of synthetic biology will continue in 2008.

Objective

Facilitate a dialogue among industry leaders of the ethical considerations surrounding biotechnology innovations, access to medicines, development and commercialization of products, potential conflicts of interest arising in the research environment, and other priority issues.

accomplished

The BIO Board-level Bioethics Committee invited leading bioethics experts to address ethical and economic considerations related to the topic of "Access and Innovation." At each meeting, the Committee heard presentations from outside bioethicists and other experts including: Tom Murray, president of the Hastings Center; Kathryn A. Phillips Ph.D., professor of health economics and health services research at the University of California, San Francisco; Alan Buchanan, professor of philosophy and public policy at Duke University; and Patricia M. Danzon, Celia Moh Professor in the health care department at the University of Pennsylvania's Wharton School.

BIO publishes the *Bioethics Newsletter* to inform member companies of the latest developments in such areas as human subject research protections, clinical trial transparency, research misconduct, conflicts of interest, the non-therapeutic use of biotechnology, gene therapy, physician/industry relationships, animal biotechnology, and biotech-enhanced food crops.

Objective

Seek enactment of legislation facilitating stem cell research and prohibiting genetic discrimination.

progress

Our staff have attended discussions, held panels on stem cell research, and participated in numerous Congressional meetings to urge enactment of legislation related to stem cell research and genetic discrimination.

Promote investment in government and academic research

Objective

Advocate for relevant increases in NIH funding and engage in policy debates about other NIH reforms.

progress

In recent years, the NIH budget has stagnated even as research costs continue to rise. We joined other research advocates in urging a 6.7 percent increase in NIH appropriations to $30.8 billion for FY 2008. The agency received $29.3 billion in budget authority—a 1.1 percent increase—as part of the final FY 2008 omnibus appropriations bill signed by the President. NIH received this small increase despite most domestic programs being flat-funded. However, the primary indicator of inflationary costs associated with biomedical research was 3.8 percent for FY 2008. Thus, marking the fifth consecutive year that NIH funding failed to keep pace with inflation.

Our efforts to boost NIH funding included a letter to Speaker of the House Nancy Pelosi (D-CA) and the House Appropriations Committee leadership signed by our California affiliates. We also organized a Congressional briefing on the value of NIH-supported research and co-sponsored advertisements in media outlets targeting Members of Congress and their staff.

Objective

Continue to engage in government and university initiatives to ensure appropriate incentives are reflected to promote innovation.

progress

The academic discovery of a method to manufacture human proteins in bacterial cells created the biotechnology industry more than 30 years ago. Today, the industry continues to rely on academic research to fill the early stage of the product pipeline. Biotechnology companies frequently license intellectual property from academic researchers under the technology transfer rules of the 1980 Bayh-Dole Act.

Bayh-Dole set some of the most important policies of the biotech era, and BIO is a staunch supporter. As the Act approaches its 30th anniversary, Congress is expressing interest in assessing its impact and considering changes to it. In the second half of 2008, we filed strongly supportive comments with the Senate Judiciary Committee and the House Science and Technology Committee. We are also considering funding a National Academy of Sciences study on Bayh-Dole.

Alliance Development: uniting advocates and biotechnology innovators

In 2007, we strengthened our alliance development team by adding new staff and increasing our activities.

BIO reaches out to health and patient organizations, groups representing farmers and food manufacturers, environmental organizations, university and academic centers, and others with a stake in biotechnology. In health care alone, BIO has cultivated relationships with more than 300 organizations. Recently, we have stepped up our services to these groups, hosting both informational briefings and social events, with a goal of developing more continuity in these relationships.

A creative risks-and-rewards tutorial in the form of a poker tournament may well have been the highlight of the year. Yet, our Alliance Development team can be counted on to organize compelling events year-round involving health organizations, universities and research groups. Alliance Development events over the past year have included:

- Advocacy briefings on the Prescription Drug User Fee Act, follow-on biologics, Medicare formularies, industry funding, use of drug compendia in Medicare, comparative effectiveness, patent reform and World Health Organization guidelines on patents.
- Congressional staff briefings on osteoporosis, obesity, lung cancer and the 25th anniversary of the Orphan Drug Act.
- Day-long workshops on biotechnology (the Biotech Primer), clinical trials and venture philanthropy.
- A roundtable in which BIO joined 12 health advocacy groups to discuss messages on the research continuum and the need for innovation.

emerging companies

Throughout 2007, BIO's Emerging Companies Section (ECS) continued working for the success of small biotechnology firms, many of them operating on a modest budget.

Because 90 percent of BIO's research and development (R&D) members are small companies, ECS is dedicated to ensuring that the next generation of biotech pioneers will flourish in a financial and public policy climate that supports—and rewards—innovation.

With most biotech products requiring more than 15 years and $1 billion to develop, our efforts to secure capital for small member companies in 2007 were crucial to their continued success. The year-end results were impressive: biotech companies garnered $26 billion in new investments.[1*]

Our longstanding initiatives to promote partnering for our members also paid off in 2007. Last year, biotechnology companies struck 417 new partnerships with pharmaceutical companies and 473 deals with fellow biotech firms, while the industry saw 126 mergers and acquisitions during the same period.

In addition to connecting emerging companies to investors and partners, ECS acts as the industry's advocate in Washington. We made our voice heard on a variety of policy issues in 2007. We worked to ensure that legislative efforts on taxation and small business federal grant-making will allow our members to continue their innovative work without unwarranted regulatory barriers.

The biotechnology industry has never been stronger, and we are taking proactive steps to help preserve and foster that strength through the current economic turbulence.

The following progress report details our recent efforts on behalf of our members, particularly small companies. We also invite you to explore these issues in more depth at bio.org, where you will find Congressional testimony, regulatory comments, press statements and many other materials.

1* *Sources of industry financial information:* Signals Magazine *and* BioWorld

Progress Report

Advance the interest of emerging companies in capital formation and financial services policy

Objective

Create and maintain incentives and increase investment in emerging biotechnology firms through financing policy and tax reform.

progress

Tax reform legislation with provisions that favor emerging biotechnology was introduced in July 2007 by U.S. Reps. Allyson Schwartz (D-PA) and Kevin Brady (R-TX). The bill, the American Life Sciences Competitiveness Act of 2007 (H.R. 3264), would modernize numerous elements of the federal tax code to ensure that America's biotechnology companies can continue to raise the funding necessary to bring new therapies to market.

In particular, the legislation:

- Reforms net operation loss rules.
- Improves the R&D tax credit.
- Modernizes the orphan drug credit.
- Encourages the development of new bio-defense and pandemic flu countermeasures.
- Promotes long-term investment in small life sciences companies struggling to raise research capital.

In February 2008, the Home Ownership, Manufacturing and Economic Growth Act (HOME, S. 12) was introduced in the U.S. Senate. It would provide tax relief for biotechnology companies by allowing the use of accumulated R&D tax credits and Alternative Minimum Tax (AMT) credits in lieu of bonus depreciation. Specifically, the HOME Act would enable companies without federal tax liability to increase their capital investments by claiming some portion of their unused R&D and AMT tax credits. We will continue working to advance R&D and AMT acceleration provisions this year.

Increase availability of federal grants for emerging companies

Objective

Advocate for and develop venues to increase government funding for emerging biotech firms.

progress

Over the last 20 years, the Small Business Innovation Research (SBIR) Program has awarded grants to hundreds of biotech companies to help them explore cutting-edge science. However, a 2003 interpretation of the SBIR law excluded companies in which venture capital firms have a majority stake. Because biotechnology is capital intensive and most often requires venture capital funding, many otherwise qualified companies have been excluded from the program. With the restoration of SBIR eligibility for these firms a top priority, we pursued legislation in both the House and Senate simultaneously, as well as engaging with the U.S. Small Business Administration (SBA).

emerging companies

In the House, we were successful in having legislation introduced that would reauthorize the SBIR program. This bill (H.R. 5819), allowing majority venture-backed small biotech companies to compete for SBIR grants, was overwhelmingly passed by the House in April 2008 by a vote of 368–43. H.R. 5819 was referred to the Senate Committee on Small Business & Entrepreneurship (SBE). The Senate is expected to introduce and act on a SBIR reauthorization bill later this year.

BIO has established a strong relationship with SBE and its counterpart in the House, as we work toward a solution on SBIR. Our staff and member company executives participated in a SBE roundtable on the issue in October 2007.

Our best opportunity for reform is imminent. The SBIR program must be reauthorized before it expires on September 30, 2008, and we are working with both the House and Senate to include SBIR grant eligibility reform in reauthorization legislation.

Objective

Oppose attempts to change the tax treatment of venture capital profits from investments in biotechnology companies.

accomplished

In June 2007, U.S. Rep. Sander Levin (D-MI) introduced a bill to treat the income received by partners providing investment management services to a partnership as ordinary, as opposed to capital income. Primarily targeting hedge fund managers, the bill would also raise the tax rate on venture capital investment profits from 15 percent to 35 percent. Although the bill's introduction received media coverage, the legislation did not advance.

The idea resurfaced late in 2007 when some in Congress sought to alleviate the burden from AMT by raising taxes on investment managers. Recognizing the vital role played by venture capitalists in funding start-up biotech companies, we fought hard against the measure, which failed to attract the necessary 60 votes needed in the Senate for consideration.

Advocate for the removal of burdensome financial reporting regulations

Objective

Ensure that reforms to Sarbanes-Oxley lead to reduced costs of compliance and take into account biotech companies' size and risk.

accomplished

Since passage of the Sarbanes-Oxley Accounting Reform Act in 2002, we have argued that rules implementing Section 404, which covers internal controls, should include provisions that reflect the needs and resources of small, publicly traded companies. The cost of compliance with Section 404 can reach $1 million per year—a substantial cost for a small company and one that can make the difference between a research project moving forward or collecting dust.

On the regulatory front, BIO has worked with the U.S. Securities and Exchange Commission and the Public Company Accounting Oversight Board to press both agencies to adopt modified rules that provide relief from Section 404. We have succeeded in persuading both to adopt new standards. This guidance helps provide more of a risk- and scale-oriented approach than prior rules. Unfortunately, this guidance does not go far enough and lacks a definition of a "small company."

BIO President & CEO Jim Greenwood praised the regulatory steps "to get on the right track" in June 2007 testimony to the House Small Business Committee, saying that "[t]he stakes for getting this right could not be higher." Greenwood stressed that without a solid definition of a "small company," auditors lack a clear tool to help them scale audits properly.

Legislative relief may be on the way with the HOME Act (S. 12); we have endorsed the bill. In addition to providing tax relief, S. 12 would make explicit the definition of a small public company as one "with a market capitalization of approximately $700 million or less, with reported annual revenue of approximately $250 million or less."

Influence health care policy to reflect the concerns of small companies

Objective

Ensure health care policy development reflects emerging company concerns, especially for policies which have a disproportionate impact on smaller firms, or policies in which small companies have a different view from large firms.

progress

ECS has added new health policy staff and is aggressively working with our Health Section on policy development and advocacy for specific priorities. For 2008, the top priority is addressing the needs of first-time filers—companies submitting their first U.S. Food and Drug Administration (FDA) applications for product approval.

The move is motivated in part by the results of a 2006 Booz Allen Hamilton report, which found that only 33 percent of first-time applications from small biotech companies were approved within the first cycle of FDA evaluation (10 months under Prescription Drug User Fee Act). By comparison, 64 percent of applications from large pharmaceutical companies—and 86 percent from large biotech companies—were approved during the first cycle.

A recent BIO survey of ECS member company executives found that enhanced communications with FDA is considered the most important factor in improving the experience of first-time filers. The executives called for earlier and more frequent consultations with FDA, including informal meetings. FDA communications need to provide information that clarifies process requirements; outlines the agency's concerns and the severity of those concerns; and states their expectations of first-time filers.

In February 2008, ECS Governing Body members opened a dialogue with FDA by meeting with senior officials to discuss first-time filer issues. The discussion explored how small companies can improve their interactions with FDA and how FDA can improve or update its practices so as to raise first-time filer approval rates in first-cycle reviews.

food & agriculture

Agricultural biotechnology is booming thanks to surging worldwide demand for biotech products, hard-won regulatory gains in the United States and elsewhere and industry-led advances in environmental stewardship.

In 2007, global use of biotech crops continued to climb, with a record 282 million acres in production in 23 countries—a 12 percent increase from 2006. More than half of those acres are in the United States, where biotech crops are vital to global commodities, including soybeans (with 91 percent biotech content), cotton (87 percent) and corn (73 percent). The developing world also continues to aggressively adopt biotech crops; 11 million resource-poor farmers in 12 countries grew hardier, higher-yield biotech crops in 2007, an increase of 18 percent from 2006[1*].

Biotech crop and animal research has also made stunning advances. The corn genome was sequenced, along with rice and *Arabidopsis*. Researchers are developing plants requiring less fertilizer (thus resulting in less fertilizer runoff), while disease-resistant eggplant and papaya varieties are being perfected. Crops that enhance conversion to biofuels and that use water and nitrogen more efficiently are just around the corner. And trees that are cold-tolerant are in field trials, along with plants that can produce human pharmaceutical products more efficiently and cost effectively. Researchers are producing disease-resistant animals, such as cattle resistant to a disease that can transfer to humans—bovine spongiform encephalopathy or "mad cow disease"—and chickens resistant to avian influenza. Recently, biotech animals were developed that will serve as models for study of human cystic fibrosis.

Biotechnology innovation has also brought significant environmental benefits to agriculture. No-till agriculture, in limited use prior to 1996, has been widely adopted due to weed-resistant biotech crops. The resulting decrease in tilling has enabled farmers to stem soil erosion and use less fuel—in turn lowering greenhouse gas emissions. Targeted, lower-impact biotech pesticides and herbicides continue to reduce the amount of chemicals needed to feed a growing world as well.

Over the past year, significant actions on the regulatory front were also achieved. The U.S. Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA) issued policies on the low-level presence of unauthorized agricultural biotechnology products. USDA issued its long-awaited programmatic draft Environmental Impact Statement to initiate the formal rulemaking process to revise its regulations. Additionally, the U.S. Food and Drug Administration (FDA) released its final risk assessment on animal cloning after an exhaustive review of more than 700 scientific studies—ultimately recognizing that meat and milk products from animal clones and their offspring are as safe as conventionally produced foods.

Whether through the initiation of its new quality management program, *Excellence Through Stewardship*℠, or securing several important regulatory victories, we have worked proactively on many fronts crucial to Food & Agriculture Section members and the continued success of their companies. The following progress report details BIO's efforts on behalf of our members over the past year. We also invite you to explore these issues in more depth at bio.org.

[1*] *Sources of industry information: International Service for the Acquisition of Agri-biotech Applications and the U.S. Department of Agriculture National Agricultural Statistics Service*

Progress Report

Improve global low-level presence and risk-assessment policies

Objective

Advocate for the U.S. Department of Agriculture and the U.S. Environmental Protection Agency to issue policies on low-level presence to serve as a global model.

accomplished

In the spring of 2007, USDA and EPA announced their interim policy and final guidance for low-level presence (LLP, also called adventitious presence), which is the unintentional and incidental commingling of an unauthorized event at low levels in commercial crops. The U.S. Food and Drug Administration previously announced its early food safety assessment for LLP in 2006. The United States' science-based policies on LLP and the guidelines of the Codex Alimentarius Commission (CAC), the international food standards body (see below), provide science-based models for governments worldwide.

Objective

Influence the development of a CAC low-level presence policy and a risk-assessment process for biotech plants.

progress

CAC is an international entity created by the United Nations and the World Health Organization to protect the health of consumers, ensure fair trade practices and promote international harmonization of food standards.

In recent years, CAC has focused on biotechnology through its *Ad Hoc* Intergovernmental Task Force on Food Derived from Biotechnology. The task force completed a draft LLP risk-assessment guideline in September 2007—one year ahead of schedule. The group also agreed

to develop an online database to facilitate expedited safety assessments of biotech-derived plant material. BIO advocated for the guidelines and supports their adoption, which is expected in mid-2008.

(Note: The CAC task force also drafted an animal biotech guideline—see discussion on page 19.)

Advocate for successful implementation of the Cartagena Protocol on Biosafety

Objective

Promote industry positions in Protocol negotiations on:

- ☐ Risk assessment.
- ☐ Liability and redress.
- ☐ Capacity building.
- ☐ Regulatory requirements for approvals.
- ☐ A central source of information on regulatory decisions and laws.

progress

The Cartagena Protocol on Biosafety is a supplement to the international Convention on Biological Diversity intended "to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology." Goals of the Protocol include establishing an advance informed agreement procedure on biotech imports and a Biosafety Clearing-House of information.

In 2007 and early 2008, BIO and the Global Industry Coalition (GIC) led industry representation at the Protocol's working group on liability and redress. The industry had a strong and influential presence, which resulted in agreement in March 2008 on draft text that contains BIO-supported options. Several key parties, including Japan, Paraguay, New Zealand and the European Commission, supported positions advocated by the industry—an outcome in large part due to coordinated advocacy of GIC. In May 2008, during major negotiations on a range of issues related to implementation of the Protocol, BIO and GIC again realized progress on industry priorities with a final decision consistent with industry positions.

Promote science-based animal biotechnology policies

Objective

Advance finalization of the FDA risk assessment on the safety of livestock cloning.

accomplished

In January 2008, FDA issued a long-awaited risk assessment affirming that foods from livestock clones and their offspring are as safe to eat as foods from any livestock. FDA's extensive review of more than 700 scientific research studies conducted over the past 30 years has determined that foods from animal clones and their offspring are equivalent to foods from other livestock. These findings are consistent with two reports by the National Academy of Sciences. USDA indicated that it would work with the biotech and food industries to ensure the smooth introduction of food products from cloned animals to the marketplace, though it requested technology providers continue their voluntary moratorium on doing so in the short term.

The biotech community recorded a major state-level victory in 2007, when California Gov. Arnold Schwarzenegger, slated to speak at the 2008 BIO convention, vetoed a cloned-animal labeling bill. The California Farm Bureau Federation, cattlemen and grocery manufacturers worked proactively and in close cooperation with BIO and our members to defeat the bill.

As of press time, labeling bills for foods with a link to cloning had been introduced in more than a dozen states in response to FDA's January 2008 determination that these foods are safe to eat. BIO has worked with state affiliate organizations and stakeholders to educate legislators and block these bills, which lack a scientific basis.

BIO created a new Animal Cloning Coalition in support of cloning technology. For the past 18 months, BIO has facilitated meetings between more than 20 organizations from across the food industry to discuss supply chain management and the need to improve public awareness about cloning technology. Coalition participants include farm bureaus, cattlemen, dairy producers, pork producers, food retailers, grocery manufacturers, technology providers and meat and dairy suppliers.

A new supply chain management program for cloned animals introduced by two BIO members was developed through the collective work of the coalition. A survey of food retailers was conducted and a consumer tool kit was developed. Information is available at clonesafety.org. The work of the coalition continues in 2008, as cloning is slowly being adopted during the seamless and orderly transition period led by USDA.

Objective

Establish a regulatory process for all genetically engineered animals, including those used for food, non-food and human pharmaceutical applications.

progress

In September 2007, the CAC *Ad Hoc* Intergovernmental Task Force on Food Derived from Biotechnology approved a guideline for food safety risk assessment for genetically engi-

food & agriculture

neered animals. The task force agreed to move the guidelines forward for adoption by CAC in 2008. This new international guideline sets a global precedent of unified support of the rapidly emerging animal biotechnology industry.

Domestically, BIO advocated for publication of a rigorous, science-based and coordinated regulatory process between FDA and USDA. When published, the draft guidance will be the first domestic regulatory guidance for genetically engineered animals and their products. Publication of the guidance will assist the industry by bolstering both investor and public confidence.

Enhance plant biotechnology stewardship

Objectives

- ☐ Improve and gain consistency in industry best practices and stewardship.
- ☐ Implement a proactive communications plan to promote industry stewardship activities and programs.

accomplished

BIO launched the *Excellence Through Stewardship*℠ program in July 2007. The program's three main components are:

- ☐ Adoption of quality management principles and management practices for maintaining plant product integrity.
- ☐ Publication of a Quality Management Program Guide for BIO member companies and others involved in agricultural biotechnology research and development for use in understanding and implementing their own best practices.
- ☐ Adoption of an independent, third-party stewardship audit program designed to verify implementation of stewardship programs and confirm quality management systems and compliance with certain principles and management practices.

BIO encourages participation in the stewardship program for all companies and institutions involved in research, development and/or commercial activities for plant biotech products including, but not limited to, commodity crops, specialty crops, energy crops, perennials, ornamentals, plant-made pharmaceuticals and plant-made industrials. Program details are available at ExcellenceThroughStewardship.org.

Advance improved biotechnology regulations

Objective

Advocate for publication of USDA's Programmatic Environmental Impact Statement (EIS) in support of revised agricultural biotechnology regulations.

accomplished

Biotechnology is changing, and that means regulations need to change as well. BIO has encouraged USDA to update its rules to adapt to such new technologies as non-food feedstocks for biofuels and plant-made pharmaceuticals. Biotechnology has also expanded from commodity crops like corn and soybeans to perennials such as grasses and trees.

In January 2004, USDA announced intentions to update and strengthen biotechnology regulations, with the first step being issuance of an EIS. More than three years later, USDA published the draft EIS in July 2007. BIO strongly supported publication of EIS, as well as many of the major changes it proposed, including a tiered permitting system based on potential environmental risk. Our comprehensive comments are available at bio.org.

EIS is the first step toward changing critical Part 340 regulations of USDA's Animal and Plant Health Inspection Service. Part 340 refers to USDA regulations for biotechnology, first promulgated in 1987 (7 CFR 340) under the authority of the Federal Plant Pest Act and the Plant Quarantine Act.

Improve state and local preemption environment

Objectives

- ☐ Support proactive legislation, regulation and dialogue to complement agricultural biotechnology at the state and local levels, including local preemption bills, coexistence discussions and economic development plans.
- ☐ Defend against non-science-based restrictions on agricultural biotechnology at the state and local levels.

progress

Our state and local advocacy was remarkably successful in dealing with more than 100 anti-biotech agricultural bills at the state level in 2007. Only Minnesota passed restrictive legislation on research involving wild rice.

Positive developments included the passage of state preemption legislation in Wyoming and Puerto Rico. This legislation overrides or preempts any local law addressing agricultural biotechnology and helps assure consistency.

In California, a new law promotes coexistence with organic farming, which BIO supports. We have also been successful at building biotech caucuses in state legislatures around the nation.

By the end of 2007, vital health applications of biotechnology burst onto the market, and a BIO-sponsored survey showed that the American public overwhelmingly recognized their value.

Cutting-edge advances in stem cell research, personalized medicine and gene sequencing laid the groundwork for the next generation of medical breakthroughs. And we continued to safeguard the policy and financial environment that makes biotechnology innovation possible.

Our industry could not ask for a better ally than the very people we serve. A survey commissioned by BIO in 2007 revealed that about four out of five U.S. voters had a favorable view of biotech health applications and backed greater public support for them.

Seventy-eight percent of voters ranked curing diseases such as cancer and HIV/AIDS as a top priority for public policy—ahead of improving the economy and fighting terrorism, and 80 percent said full Medicare and Medicaid coverage of biotech products was a positive development. Clearly, the public recognizes the importance of biotechnology and wants greater access to the fruits it bears.

And the industry is not letting them down. The past year has brought a number of breakthroughs to patients, ranging from treatments for rare genetic disorders and critically needed vaccines to life-saving diagnostics. Some of 2007's advances include the first vaccine approved for avian flu, the first-ever treatment for a group of debilitating genetic disorders and several new cancer treatments and tests. A list of highlights is in the box below.

Selected 2007 breakthroughs

- ACAM2000, a new smallpox vaccine.
- Arcalyst, the first-ever treatment for Cryopyrin-Associated Periodic Syndrome, a group of genetic autoimmune disorders.
- Avastin, a previously approved cancer drug, now cleared for metastatic breast cancer.
- GenesSearch BLN Assay, a test for signs of metastatic breast cancer during lumpectomy or mastectomy, allowing doctors to remove cancerous tissue immediately without a second surgery.
- H5N1 Vaccine, the first vaccine approved for avian flu.
- Kuvan, a treatment for the genetic disease phenylketonuria.
- LC Detect, a new blood test for detecting early lung cancer.
- Letairis, a new drug for pulmonary arterial hypertension.
- Nexavar, a previously approved cancer drug, now cleared as the first FDA-approved drug for liver cancer.
- Somatuline Depot, a major advance for acromegaly, a rare and devastating pituitary disorder.
- Tasigna, a second-generation version of Gleevec that binds more tightly to the target protein.

The year 2007 brought crucial earlier-stage advances as well, most notably the November announcement that two groups of scientists had genetically reprogrammed human skin cells to create cells identical to embryonic stem cells. Progress was made with adult stem cells as well, with London researchers transforming bone-marrow stem cells into human heart-valve tissue. With the dedicated efforts of a biotechnology industry allowed to develop pioneering new treatments in an environment that fosters innovation, this technique could progress to clinical trials within the next three to five years.

Personalized medicine also marched forward. New tests are available to help doctors properly dose the widely used blood thinner warfarin, and to test patients of Asian descent for possible side effects of a drug for epilepsy and other nervous-system disorders (people of Asian heritage have been shown to have a higher risk of severe side-effects associated with this drug). In October, the American Society for Clinical Oncology (ASCO) added several new useful clinical markers to its breast cancer guidelines, including Onco*type* DX, which predicts the likelihood of breast cancer recurrence and helps doctors and patients make decisions about chemotherapy.

Technologies for gene sequencing and analysis advanced at top speed in 2007. Three million single-nucleotide polymorphisms in the genetic code were identified, and since then more discoveries are bringing the "holy grail" of the $1,000 genome sequence closer to reality.

The following report details our victories and progress on a host of issues vital to preserving and expanding innovation in health care biotechnology. We also invite you to explore these issues in more depth at bio.org, where you will find Congressional testimony, regulatory comments, press statements and many other materials.

Progress Report

Improve the performance of the U.S. Food and Drug Administration (FDA)

Objectives

- Enhance the ability of BIO members to receive timely approval of safe and effective biopharmaceuticals and therapies; increase public confidence in drug safety.
- Achieve appropriate resources to meet these goals from appropriations and user fees.
- Support consistent, transparent and predictable regulatory practices and strong, stable leadership at FDA.

Efficient drug reviews

Achieve timely enactment of the Prescription Drug User Fee Act (PDUFA) legislation consistent with BIO's PDUFA principles.

accomplished

A top priority in 2007-2008 was to ensure reauthorization of PDUFA. First enacted in 1992, PDUFA sets certain five-year goals and policies for the agency, including FDA performance goals for review times. On September 27, 2007, President Bush signed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which reauthorizes PDUFA.

Under the new PDUFA provisions, FDA will begin communicating target dates for planned review milestones—such as labeling and post-marketing commitment discussions—to increase the transparency and quality of the review process. FDA must also continue to meet the current goals for review times (ten months for regular applications, six months for priority reviews).

Regulatory predictability

Work with FDA leadership to identify trends and obstacles to consistent, transparent, and predictable FDA product reviews; anticipate regulatory challenges that may be posed by novel therapies and work collaboratively with FDA to design strategies to ensure efficient drug review.

accomplished

Because drug development and FDA filings may be especially challenging for small, young companies, BIO made improving the process for first-time filers a priority. We hosted a meeting between Emerging Companies Section Governing Body members and FDA review management staff to discuss problems with first-time applications, from both the FDA's and industry's perspectives, and develop solutions.

Throughout the year, our scientific and regulatory working groups also met with FDA staff to discuss specific topics, such as the Critical Path Initiative, the development of products in a particular therapeutic area (e.g. oncology) or the regulatory requirements in specific review areas (e.g. preclinical safety assessment).

Drug safety

Develop and promote a framework for private-public collaboration relating to drug safety. Oppose legislation that does not contribute to enhanced drug safety programs or that would otherwise hinder regulatory review.

accomplished

The Food and Drug Administration Amendments Act provides FDA with substantial resources for enhancing and modernizing the FDA Drug Safety System. BIO and our allies successfully included provisions in FDAAA that would also establish a private-public partnership to conduct active post-market surveillance through the analysis of electronic population-based medical databases, such as those maintained by major insurers.

In addition, FDAAA creates a Risk Evaluation and Mitigation Strategy (REMS) process. Under this process, when FDA determines that REMS is necessary to ensure that a drug's benefits outweigh its risks, sponsors may propose REMS for FDA approval. To foster regulatory clarity and predictability, BIO successfully incorporated language in FDAAA to help clarify when a REMS is appropriate and ensure that the agency weighs both benefits and risks.

FDA appropriations

Continue to lead the Alliance for a Stronger FDA's efforts to garner substantial appropriated resources for human drug review activities, as well as funding for the Critical Path Initiative.

accomplished

BIO and other coalition members continue to advocate in favor of increased appropriations for FDA. For 2008, FDA received a 10 percent increase in appropriations, including an additional $38 million for its drug review center (the Center for Drug Evaluation and Research, or CDER) and $11 million for its biologics review center (the Center for Biologics Evaluation and Research, or CBER).

Critical Path

Work with FDA to advance the development and regulatory acceptance of tools—biomarkers, new clinical trial designs—that make drug development better and faster, and ensure that the Critical Path Initiative receives funding through appropriations.

accomplished

The Critical Path Initiative is FDA's effort to strengthen and modernize the medical development process. Congress appropriated $7.1 million for FDA's Critical Path Initiative for FY 2008—a win for BIO. We also worked closely with FDA and other stakeholders on a number of Critical Path Initiative projects and related activities, including:

- ☐ An FDA/industry meeting to evaluate and discuss ways to foster the Critical Path Initiative.
- ☐ An educational briefing on the Critical Path Initiative for 19 patient groups, with presentations by FDA and the Parkinson's Action Network.
- ☐ Membership on the Biomarkers Consortium Executive Committee. We also developed a document outlining ways to improve the Consortium's Intellectual Property/Data Sharing policy.
- ☐ BIO is considering joining the steering committee of the Clinical Trials Transformation Initiative (CTTI), a public-private partnership founded by FDA and Duke University to identify practices that, through broad adoption, will increase the quality and efficiency of clinical trials.

Enhance patient access to innovative therapies

Objectives

- ☐ Advocate for policies and develop strategies for expanded coverage, timely coding decisions and appropriate reimbursement that fosters innovation.
- ☐ Conduct analyses and effectively communicate the value of innovation.
- ☐ Oppose initiatives that restrict patient access to innovative therapies or that harm innovation.

Access to innovative therapies under Medicare

Oppose legislative proposals that would limit Medicare patient access to innovative drugs and biologics and harm future innovation.

accomplished

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a prescription drug program called Part D, which allows beneficiaries to enroll in drug coverage offered by competing private plans. Since taking effect in 2006, the program has been highly successful in delivering prescription savings and increased choices to seniors who previously lacked coverage, and in providing security for all seniors against catastrophic drug costs.

In January 2007, however, the U.S. House of Representatives passed legislation to strike the "non-interference" clause that forbids the federal government from interfering with private sector negotiations and establishing price controls under Part D. The U.S. Senate considered a similar measure later in the year, which failed on a procedural vote. These bills would have undermined the current success of Part D by limiting the choice of therapies available to beneficiaries on a national basis. BIO supports the current struc-

ture of the Part D program, and believes in reducing costs through marketplace competition and informed beneficiary choices rather than government price controls.

Based on this rationale, we have advocated against repealing the non-interference clause and other government proposals that would inappropriately limit Medicare patient access and deter future innovation.

Medicare: coverage and reimbursement issues

Interact with the Centers for Medicare and Medicaid Services (CMS) and other stakeholders on highly technical coverage and reimbursement issues that can affect patient access to innovative therapies.

accomplished

Our Health team monitors proposed CMS regulations and is proactive in anticipating possible policy shifts that could affect patient access to biotech products under Medicare, Medicaid and other government health programs.

In 2007, we worked on issues, including:

- ☐ CMS' formulary guidance for 2008 and other policy changes to Part D.
- ☐ The drug compendia used to make Medicare Part B coverage decisions for anti-cancer therapies.
- ☐ Problems with the coding assignment process for Medicare coverage, especially for biologics and other single-source products.
- ☐ Medicare policy on covering products used in clinical trials.
- ☐ A proposal to cut Medicare reimbursement for drugs in the hospital outpatient setting.
- ☐ Federal drug price reporting requirements for manufacturers under Medicare and Medicaid.

Comparative effectiveness

Develop appropriate quality measurements and support quality and evidence-based medicine initiatives that focus on improving clinical decision making and patient outcomes rather than restricting patient access.

accomplished

Congress and federal agencies have expressed interest in head-to-head studies comparing approved therapies to determine which are most effective. BIO supports evidence-based policies that improve clinical decision making, and opposes measures that are focused narrowly on containing costs and may limit treatment options available to physicians and patients. To support the appropriate application of comparative effectiveness research, BIO has:

- ☐ Developed Board-approved principles on comparative effectiveness research.
- ☐ Released an educational white paper on comparative effectiveness.
- ☐ Hosted a briefing for patient groups on the patient-access implications of government sponsored comparative effectiveness research.
- ☐ Submitted comments to the Agency for Healthcare Research and Quality (AHRQ) on its draft guide to conducting comparative effectiveness reviews.
- ☐ Worked with Congress and other stakeholders to ensure that comparative effectiveness initiatives help improve clinical decision making and preserve patient access to valuable treatment options.

Value of biotech products

Complete and communicate the results of BIO-sponsored value studies that relate to innovative therapies and needed investment for the development of these therapies.

accomplished

BIO released a Milliman, Inc. report; its projections suggest the cost of new innovative therapies will not create large cost burdens on the health care system by 2011. By then, the cost for all FDA-approved biotech therapies (existing and new) will probably be about 6 percent of total private commercial payer costs—an increase of only 1 percent from 2006.

We also finalized a return-on-investment study that documented the high financial risks that biotechnology firms face, as well as their extreme sensitivity to policy shocks that can affect industry profitability. In addition, we hosted a briefing for Congressional staff on the value of the newest biotech innovations in treating cancer.

Ensure that follow-on biologics policies protect patient safety and promote biomedical innovation

Objectives

- ☐ Engage strategically in regulatory and legislative advocacy consistent with BIO's follow-on biologics (FOBs) policy.
- ☐ Conduct analysis, develop materials and educate stakeholders—including policymakers and media—regarding the scientific, policy, economic, legal and intellectual property issues associated with consideration of a regulatory pathway for follow-on biologics.
- ☐ Ensure that naming and labeling for FOBs are science-based and protect patient safety.

Education

Effectively engage and educate policymakers regarding the legal, regulatory and scientific differences between FOBs and generic drugs. Develop high-quality, one-stop resource materials to educate policymakers about the scientific and regulatory issues associated with consideration of FOBs.

accomplished

In a number of fora, BIO has described the complexity of biologics and how they differ from small molecule drugs, as well as their inherent heterogeneity and dependence on specific manufacturer processes that cannot be duplicated exactly by other manufacturers. Our member company CEOs have testified at Congressional hearings, and we have met with FDA officials and Congressional staff frequently on these issues.

To educate policymakers and opinion leaders, BIO has also:

- Developed BIO Principles on Follow-On Biologics.
- Worked with the American Association of Universities to gain its support for 14 years of data exclusivity and other key intellectual property provisions.
- Worked with patient groups to gain their support for BIO principles on interchangeability and data exclusivity.
- Developed a Web site to house fact sheets, background information, BIO studies, press releases and a bibliography on FOBs (bio.org/fobs).

Legislation

Oppose legislation that contains provisions that harm or inhibit biomedical innovation or that would establish a regulatory framework that would harm patient safety.

progress

BIO worked with member companies, patient groups, and certain U.S. Senators and Representatives and their staff to ensure the passage of legislation that includes appropriate protections for patient safety and sufficient incentives for innovation. At press time, two bills have been introduced in the House and one in the Senate that align with many, although not all, of the BIO Principles on Follow-On Biologics. We will continue advocating for legislation that meets all of our Principles, including that patients are not given FOBs unless expressly prescribed by a physician, and a substantial data exclusivity period for pioneer biotechnology products to ensure continued innovation.

Promote development and use of research tools, molecular diagnostics and personalized therapies

Objectives

- Identify and advocate for pathways and policies that promote the development and utilization of research tools and molecular diagnostics (RTMD) to enable the discovery and development of innovative therapies.
- Advocate for policies that foster the development and acceptance of personalized medicine.

Regulation

Seek a consensus position within BIO and advocate externally on appropriate models for regulatory oversight, including the role of FDA, as it relates to relevant in vitro diagnostics.

progress

BIO commented on FDA's revised draft guidance on in vitro diagnostic multivariate index assays. We recommended an open process as FDA undertakes to regulate these products.

We also submitted comments on a draft report on oversight of genetic testing issued by the U.S. Health and Human Services Secretary's Advisory Committee on Genomics, Health, and Society. The report presents recommendations to coordinate genetic testing oversight among Health and Human Services agencies to develop new and enhanced partnerships with the private sector. BIO comments stressed the following points:

- Regulatory review of any test should be based on the risk the test could pose to the health and safety of the patient. All high-risk tests should be subject to FDA regulation.
- BIO would actively participate in an open stakeholder forum convened by relevant federal agencies to develop a risk-based, flexible and transparent model for the regulation of all advanced diagnostics.
- A genetic test registry is needed to provide information about the spectrum of tests offered and their analytical and clinical validity, which should increase confidence in the tests and help physicians and patients make decisions. We believe registration should be mandatory for certain moderate- to high-risk categories of tests.

Funding

Advocate for relevant increases in NIH funding and engage in policy debates about other NIH reforms. Identify opportunities to influence significant programs that provide funding for RTMD development and procurement.

progress

We advocated for strong funding for federal biomedical research programs, including NIH and the Biomedical Advanced Research and Development Authority (BARDA). Please see Cross-Cutting Section, p.10 of this report for more details.

Other RTMD issues

progress

BIO developed a working draft of principles to guide policy development and advocacy on priority issues for RTMD companies, including biomedical research funding and collaboration, intellectual property, regulation, and reimbursement. We are monitoring and responding to issues that affect the realization of personalized medicine, and in 2008, plan to develop BIO Principles on Personalized Medicine.

Advocate for policies that foster vaccine innovation and promote pandemic and bio-defense preparedness

Objective

Identify, create and promote opportunities for BIO members to enhance the infrastructure and capabilities to provide innovative treatments and therapies necessary to address naturally occurring diseases and public health threats posed by a global pandemic or bioterrorism.

BARDA appropriations

Advocate for appropriations for the recently enacted Biodefense Advanced Research and Development Authority (BARDA).

progress

BARDA was authorized and created by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA). BARDA is intended to support the advanced research and development of critically needed medical countermeasures against

biological, chemical, nuclear and radiological threats to the nation, as well as naturally occurring threats such as pandemic influenza. BIO was a key supporter of BARDA and PAHPA.

We advocated for $500 million in BARDA appropriations for FY 2008, but due to the challenging appropriations environment, only $102 million was funded this year—bringing total appropriations to $201 million. This is far below the authorized level of $1.07 billion. Consequently, for FY 2009, BIO, along with other key stakeholders, is advocating for $850 million in funding for BARDA.

Public health emergency medical countermeasures enterprise (PHEMCE) strategy and implementation

Advocate for timely issuance and execution of the U.S. Department of Health and Human Services (HHS) PHEMCE Strategy and Implementation Plan.

accomplished

BIO was actively engaged with HHS in advocating for clear and transparent strategies and plans for the development and procurement of medical countermeasures. We were also invited to present on behalf of the industry at several stakeholder fora hosted by HHS. Many of BIO's advocacy positions were incorporated into the department's PHEMCE Strategy and Implementation Plan.

Outreach

Reach out to the public and to policymakers on the value of vaccines and pandemic-preparedness products. Inform BIO members about pertinent literature and studies.

accomplished

We hosted a session on vaccines at the 2007 BIO International Convention and have more events planned for the 2008 convention in San Diego.

In addition, BIO has fostered dialogue with the American Medical Association (AMA), the Infectious Diseases Society of America (IDSA) and the Association of State and Territorial Health Officeholders (ASTHO).

World Health Organization

BIO kept our members abreast of developments in this field. We reported on Congressional briefings on Advance Market Commitments (AMCs), and distributed reports from BIO Ventures for Global Health, open-access academic studies, and synopses of discussions at the Clinton Foundation, the American Enterprise Institute and other fora.

We are currently engaged in discussions with the National Vaccine Program Office (NVPO) as it develops a vaccine-financing workshop in the second quarter of 2008. BIO is the primary industry organization engaged with NVPO, representing a wide range of vaccine manufacturers.

Improve the international environment for biomedical innovation

Objectives

- ☐ Strive to reduce obstacles and eliminate standards that hinder or delay product approval and utilization in foreign markets.
- ☐ Promote the positive economic impact that the biotechnology industry has on local, national and regional economies.

Regulatory harmonization

Ensure that BIO members are represented in activities of the International Conference on Harmonization (ICH) that relate to biotechnology.

accomplished

ICH brings together representatives of regulatory agencies and medical product industries to harmonize requirements for development and approval in the United States, Europe and Japan. We worked with sister trade associations EuropaBio and the Japanese Health Sciences Foundation to ensure biotech representation in ICH activities, such as the Quality Roundtable and several safety and multidisciplinary topics.

Free trade

Advocate to ensure that free trade agreements promote the ability of the biotechnology industry to facilitate access to medicines in foreign markets.

progress

BIO worked with the Office of the U.S. Trade Representative, the U.S. Department of Commerce and other agencies to address issues in the Korean Free Trade Agreement. We also met with Congressional staff and provided comments on the Peruvian Free Trade Agreement.

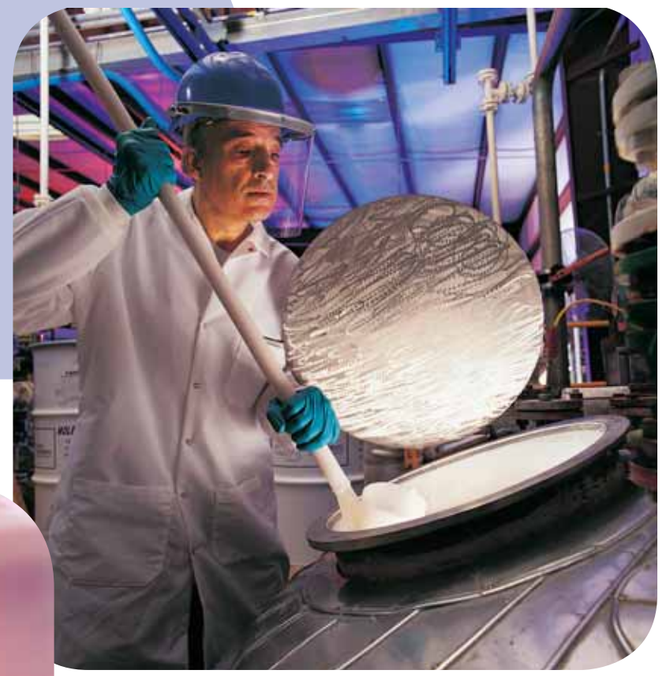
Other international activities

progress

BIO is increasingly active in international fora. We have recently:

- ☐ Advocated on behalf of the biotechnology industry in bilateral negotiations with foreign trade partners, including the U.S.-China Strategic Economic Dialogue and U.S.-China talks on a Memorandum of Understanding for pharmaceutical safety issues.
- ☐ Formed an International Health Policy Working Group.
- ☐ Participated in the Transatlantic Administrative Simplification Workshop with U.S. and European Union (EU) regulators to set priorities and develop a roadmap for U.S.-EU harmonization.

industrial & environmental



As one of the newest applications of biotechnology, industrial and environmental (I&E) biotech took enormous strides in 2007, catching up with the more established industry areas of Health and Food & Agriculture.

BIO has worked over the past year to open new markets and knock down barriers to innovation as our members' I&E breakthroughs continued to streamline manufacturing processes, reduce pollution and create clean, sustainable energy.

The I&E Section at BIO is also very active in demonstrating the use of industrial biotech for producing pharmaceutical and fine chemicals; renewable chemicals; bioplastics; food ingredients, flavorings and fragrances; and many other commercial applications in the manufacturing sector.

I&E biotech innovators have responded to the dual demands for food and energy solutions with unique approaches that leverage agricultural wastes as environmentally friendly energy sources. Farmers are now closer to being able to grow crops with both food and fuel applications thanks to these evolving processes. As part of our ongoing advocacy on behalf of members, BIO reached out to policymakers and legislators to highlight these benefits in a report called *Achieving Sustainable Production of Agricultural Biomass for Biorefinery Feedstock*.

BIO members made significant progress toward creating sustainable mass-market advanced biofuels in 2007. For example, Gevo Inc. modified *E. coli* bacteria to produce biobutanol, while Genencor, a division of Danisco A/S, and Mascoma Corporation made important advances in converting cellulosic biomass to usable fuel. LS9, Inc. moved last year to commercialize a biotech method for producing gasoline-like hydrocarbon biofuels from renewable resources, with a pilot plant slated to begin production in 2008.

Now more than ever, energy independence and sustainability is a top priority for government, business and consumers alike. But creating innovative new solutions to intractable energy problems requires sizable capital and a regulatory environment that rewards innovation. BIO was instrumental in securing billions of dollars in government support for I&E biotech in 2007, as well as advocating for policies that expand I&E markets and encourage biotech breakthroughs through reasonable regulation and market incentives.

The achievements of the BIO I&E Section on behalf of our members are detailed in the following progress report. We also invite you to explore these issues in more depth at bio.org, where you will find Congressional testimony, regulatory comments, press statements and many other materials.

Progress Report

Increase federal funding of bioenergy initiatives

Objective

Build on successful passage in 2005 of a $1 billion spending authorization by Congress for bioenergy construction and R&D projects to ensure adequate appropriations.

accomplished

The Energy Policy Act of 2005 authorized more than $1 billion in incentives for bioenergy. BIO has followed up with advocacy to ensure those initiatives are fully funded. Our success is reflected in several recent funding announcements:

- In February 2007, the U.S. Department of Energy (DOE) awarded $385 million in grants—including many to BIO members—for the construction of the country's first commercial scale cellulosic biorefineries.
- In January 2008, DOE awarded $114 million for four additional pilot scale biorefineries to demonstrate emerging biofuels technologies. BIO members are partners in two of these biorefineries
- And in February 2008, DOE added $34 million in funding for additional research and development of improved enzymes for production of advanced biofuels. All four grants were awarded to BIO member companies.

BIO successfully increased the authorized funding for core biomass R&D in the Energy Independence and Security Act of 2007 (EISA), which was signed into law by President Bush on December 17, 2007. The law increases funding for technologies that use biomass to make useful products, including green plastics made from corn sugars. The biomass program also includes biorefinery grants, which were boosted by 50 percent to nearly $400 million for FY 2009. Additionally, the new law increases the number of DOE Bioenergy Research Centers from three to seven and provides grants for cellulosic biomass transportation infrastructure.

industrial & environmental

Objective

Develop policy initiatives for inclusion in new energy bills.

accomplished

The I&E Section successfully advocated for a stronger renewable fuel standard (RFS) in EISA. RFS calls for annual production by 2022 of 36 billion gallons of biofuels, an amount equal to one-fifth of U.S. gasoline supplies. The bulk of that production—21 billion gallons—must be cellulosic ethanol or other advanced biofuels.

The I&E Section pushed hard for RFS, which could add as much as $170 billion to the U.S. economy in advanced technology development, biofuel production and infrastructure construction.

Objective

Seek agricultural appropriations for unfunded bioenergy sections in the 2002 Farm Bill.

progress

In March 2008, the U.S. Department of Agriculture (USDA) issued $18 million in grants for biomass research, development and demonstration grants. BIO member companies are partners in several of these.

Advocate for Farm Bill policy initiatives to improve industrial biotechnology

Objective

Advocate for Farm Bill policy options that will accelerate the commercialization of next generation biofuels and biobased products.

accomplished

In May 2008, Congress passed a comprehensive Farm Bill that provides over $1 billion in programs and incentives advocated by BIO, including:

- Cellulosic biofuels tax incentives. We advocated for a tax credit to apply to all cellulosic biofuels production, regardless of fuel type or production capacity. The final version of the tax credit—$1.01 per gallon—addresses all of our concerns and will provide a strong market pull for these next generation fuels.
- The USDA BioPreferred Program. The last major farm legislation in 2002 created a biobased purchasing mandate for the federal government. However, that mandate did not include biobased chemical intermediates and their derivatives. We worked for several months to persuade Senators to designate these products for the program in the 2007 Farm Bill. The final bill includes these products, as well as single-source products, and doubles funding for the program through 2012.
- Biomass Crop Assistance Program. We worked with House and Senate staff to create a program to help farmers plant, harvest and transport next generation energy crops for biorefineries, and to remove excessive restrictions on feedstock eligibility and harvesting conditions.
- R&D investment and biorefinery demonstration incentives. The Farm Bill includes $320 million in grants and loan guarantees for pilot, demonstration and commercial biorefineries. It also provides $120 million for the Biomass R&D Program and $300 million through the Commodity Credit Corporation bioenergy program to help biorefineries purchase feedstocks for advanced biofuels and biobased products.

Promote bioenergy legislation at the state level

Objective

Work with BIO's State Government Relations team to promote bioenergy and biobased products legislation in the state legislatures, and generate support for the I&E Section's national agenda.

progress

The I&E Section worked with the Governors' Ethanol Coalition to explore state-level initiatives, as well as to support EISA. Sound implementation of EISA, which determines the federal government's appropriation priorities to support biorefining, is a top focus of many states as they compete to grow biorefining and biofuel clusters. The coalition and BIO both support full funding for cellulosic biofuels initiatives and efforts to create a market for perennial, dedicated energy crops such as switchgrass.

The Section also worked with BIO's State Government Relations team to brief the biotech community in North Carolina, Hawaii, Kansas, Arkansas and Michigan on bioenergy.

Raise the profile of I&E biotechnology and the I&E Section

Objective

Increase coverage of I&E technologies in the mainstream media and maintain positive public opinion.

accomplished

The I&E Section launched a public relations committee and worked with public relations firms to develop story ideas for mainstream media and promote the World Congress on Industrial Biotechology & Bioprocessing and the Pacific Rim Summit on Industrial Biotechnology & Bioenergy. Major biofuels stories ran in *Fortune*, *The New York Times*, *The Washington Post* and many other news outlets. The Section also conducted a press briefing at the 2007 BIO International Convention.

The trade press is also integral to our work. The I&E Section worked with the editor of *Industrial Biotechnology* to ensure BIO member companies and conferences were covered. Subscriptions for the *Industrial Biotech Innovation Report*, a weekly newsletter published with the American Chemical Society, continued to grow.

Objective

Grow I&E Section membership.

accomplished

In the last 18 months, the number of BIO's I&E members has more than doubled, representing our growing advocacy strength and, perhaps, the growing public, scientific and financial interest in the I&E industry. New members include: Shell Group; Mascoma Corporation; Codon Devices; Allylix, Inc; LiveFuels, Inc; and LS9 Inc. In addition, BIO member Diversa merged with Celunol and the new company—Verenium Corporation—joined.

Bio International Convention
The Global Event for Biotechnology

As the world's premier biotechnology organization, BIO hosts the industry's most prestigious and well-attended events.

We organize more than a dozen conferences and activities throughout the year, bringing together industry partners and investors for events ranging from the BIO International Convention to professional development conferences for human resources and business development executives.

The BIO International Convention: another record year

The BIO International Convention is our flagship event and the world's largest gathering of the biotechnology community. The 2007 Convention in Boston was our biggest ever, drawing more than 22,000 participants representing 48 states and 64 countries, nearly 15 percent increase in attendance from the previous year.

Event highlights included keynote addresses from Michael J. Fox, founder of the Michael J. Fox Foundation for Parkinson's Research, and Her Majesty Queen Noor of Jordan. Fox, who appeared before a packed room, urged the biotechnology industry to continue to accelerate the translation of basic science into improved therapies for patients. Queen Noor discussed the opportunities presented by biotechnology to address global health and poverty.

The accompanying BIO Exhibition featured the largest gathering of biotech exhibitors in our history, with more than 2,100 organizations and 60 country and regional pavilions representing every aspect of the biotechnology industry.

While the convention has more than doubled in size since 2000, we know the value of intimate gatherings in nurturing business opportunities and making important connections. The convention now hosts many niche gatherings in sessions, lounge areas and the BIO Exhibition for attendees to meet, exchange ideas and further business interest. Additionally, BIO provides convention attendees with a free event planning tool—myBIO personal portal—that allows each attendee to arrange appointments and to create personal schedules in advance of the convention.

The 2008 BIO International Convention is scheduled to be held June 17-20 in San Diego, and in 2009 we move to Atlanta. Check bio.org in the coming months for information on 2009 registration, session applications, exhibits and more.

Investor & Innovator Conferences: growing the industry

Our suite of investor and innovator conferences have continued to grow under the guidance of our Emerging Companies Section (ECS), attracting hundreds of companies and hosting thousands of one-on-one meetings among attendees in 2007. These events are valuable opportunities for biotech firms to connect with potential partners and the most influential and well-funded investors in the industry.

BIO CEO & Investor Conference

Our flagship investor conference is held in New York City every February, exploring financial and therapeutic trends, while featuring presentations from the world's leading biotech companies. Most participating companies are publicly traded. The meeting attracts the industry's top investors; some 2,000 biotechnology executives and investors attended the event in 2007.

BIO Investor Forum

Held in San Francisco, our fall BIO Investor Forum is a west coast counterpart to the BIO CEO & Investor Conference. The meeting showcases more than 200 late-stage private and emerging public companies to investors from leading banks and private investors. The 2007 BIO Investor Forum attracted more than 1,200 investors, industry executives and journalists.

BIO National Venture Conference

In 2008, we hosted the National Venture Conference in Boston. This popular event matches small companies with venture capitalists.

BIO Business Forum

Bio Business Forum
Partnering for Growth

Held in conjunction with the BIO International Convention, the BIO Business Forum is the world's largest business development event. In 2007, the BIO Business Forum hosted more than 6,000 attendees from 1,500 companies and arranged some 12,000 one-on-one partnering meetings.

BIO-Europe & BIO-Europe Spring

Launched in 1995, BIO-Europe is the longest-running ECS event. Historically held in November, attendance has grown steadily and today tops 2,000. BIO-Europe has become the largest European stand-alone partnering event, with more than 2,200 attendees and 8,000 one-on-one meetings. The 2007 conference was held in Hamburg, Germany.

In 2007, at the request of the biotech community, we added a second BIO-Europe meeting that takes place in the spring. The inaugural event, held in Milan, Italy, brought together international decision makers from all sectors of biotechnology and featured one-on-one meetings, company presentations, panel discussions and an exhibition.

BIO-Asia

With the importance of Asian markets increasing in the global economy, it's no surprise that attendance at the BIO-Asia Conference is growing fast—more than 170 percent since the inaugural conference in 2004. This elite meeting is held each winter in Tokyo and introduces U.S. and European clinical-stage drug development companies to Asian biopharmaceutical companies, as well as providing partnering opportunities for participants.

BIO-Windhover

BIO hosts this annual winter/spring event with Windhover Information, a leading biotech publishing company. Launched in 2002, BIO-Windhover has become the preferred U.S.-based partnering event for top-level pharmaceutical and biotechnology business development executives and CEOs.

Industrial & Environmental Events: take center stage in 2007

With public attention focused on developing alternative energy sources and protecting the environment, our Industrial & Environmental Section has developed and organized conferences to help educate the public, policymakers and investors on the latest breakthroughs.

World Congress on Industrial Biotechnology & Bioprocessing

In March 2007, we hosted the fourth annual World Congress in Orlando, Florida, where keynote speakers included top venture capitalist Vinod Khosla and prominent biotechnology industry business consultant Dr. Jens Riese of McKinsey & Co. Both said that the biofuels industry is poised for exceptional growth and that ethanol from cellulose appears to be the most promising alternative fuel over the long-term.

Pacific Rim Summit on Industrial Biotechnology & Bioenergy

In its second year, the November 2007 Pacific Rim Summit gathered nearly 350 biotechnology and bioenergy business executives, researchers and government officials in Honolulu to review progress in developing the bioenergy industry.

The summit, jointly hosted by BIO, the American Chemical Society and the state of Hawaii, featured more than 100 presentations from researchers and scientists on biotechnology applications in energy, marine biotechnology, fine chemicals and biobased products.

Human Resources Conference: helping staff a growing industry

The annual BIO Human Resources Conference is one of our longest-running and most popular conferences. Nearly 300 HR professionals attend the annual event to learn about trends in compensation, retention, employment, recruitment; and to focus on career and business development in their profession. The conference also features an overview of trends in the industry from biotechnology executives and experts.

The November 2007 event was held in Boston with sessions covering topics that included:

- Talent Development: A Key Business Driver
- Start-Up or Upstart? How HR Can Help Set the Stage for Growth and Success
- The Coaching Conundrum
- Strategic Compensation: How to Leverage Your Total Rewards Program in Today's Marketplace
- Creating a Competitive Advantage Through Your Organization's Culture
- Working Effectively With Board Members
- Latest HR Legal Developments Facing the Biotechnology Employer

The 2008 BIO HR Conference is scheduled to be held in San Diego, October 26–28. Check the events calendar on bio.org for details.

finances & membership

The Biotechnology Industry Organization (BIO) is a non-profit organization dedicated to providing advocacy and business services to the biotechnology industry.

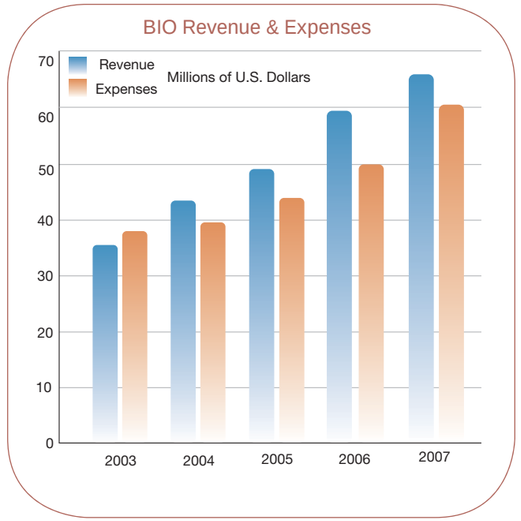
Our revenue sources include: membership dues; event fees; sponsorship of events; advertising in BIO publications and on the bio.org Web site; Bio Business Solutions℠ income; and interest and investment income.

BIO revenue increased approximately 12 percent to reach $66 million in 2007. In addition to increased membership dues and event revenue, we earned approximately $4 million in interest and investment income.

In 2007, in our effort to continue to improve and increase our member services, we hired additional staff, moved our offices and increased our public relations activities—resulting in a 20% increase in our expenses.

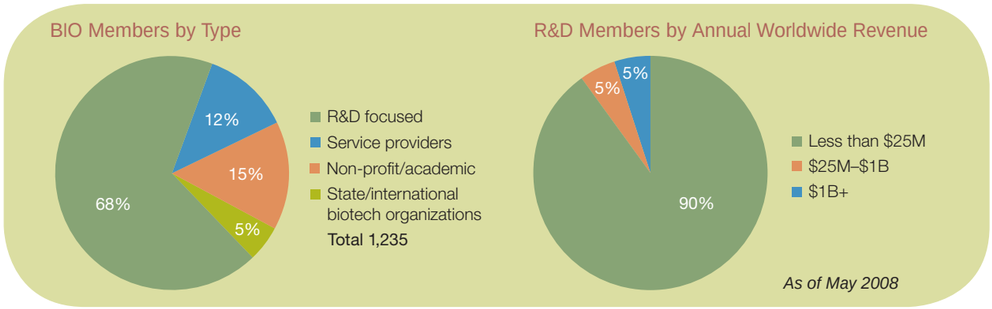
We relocated our Washington, DC headquarters in April 2007 to 1201 Maryland Ave, SW. As such, we experienced one-time costs associated with leasehold improvements and additional office furniture and equipment that will be amortized over the useful lives of the improvements and furniture and equipment. The Maryland Avenue location provides us with 50 percent more office space, which better accommodates our current staff and provides for future growth. While our rent has increased, it is now financially predictable and mitigates expense risks beyond 2010.

We also experienced significant increases in public relations and media expenses to support our advocacy activities in the Washington, DC metropolitan area. Additionally, funds were used to develop the initial phase of a branding campaign that will launch in the fall of 2008.



Membership

In 2007, our membership grew by over 100 organizations—reaching more than 1,200 members. The number of R&D-focused member companies continued to climb and today accounts for almost 70% of our membership.



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