

THE BIOTECHNOLOGY LEGISLATIVE AGENDA



HEALTHCARE



FOOD & AGRICULTURE



INDUSTRIAL & ENVIRONMENTAL



INTELLECTUAL PROPERTY



BIOTECHNOLOGY INDUSTRY ORGANIZATION

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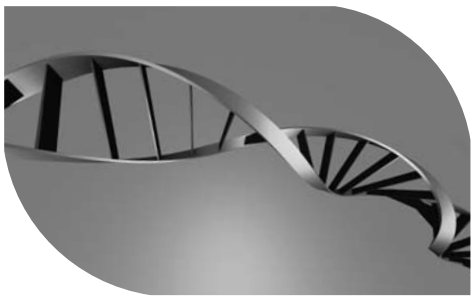
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HEALTHCARE

FOLLOW-ON BIOLOGICS

Patient Safety and Continued Innovation Must be the Focus of the Follow-On Biologics Debate

Cosponsor H.R. 1956, the Patient Protection and Innovative Biologic Medicines Act

Cosponsor H.R. 5629, the Pathway for Biosimilars Act

BACKGROUND:

Any statutory pathway for the approval of follow-on biologics must rigorously protect patient safety and preserve incentives to innovate in order to ensure that new pioneer biotechnology products continue to reach patients and physicians.

“Biologics” are complex medicines that are manufactured using living cells, and they are different from and far more complex than most small molecule chemical drugs. These products include many of the latest breakthrough medical therapies for serious and life-threatening illnesses, such as cancer, multiple sclerosis, diabetes, and HIV / AIDS, as well as many serious rare diseases. Due to their size and complexity, biologics generally cannot be scientifically characterized to the same degree as small molecule chemical drugs.

Follow-on biologics are not generic drugs. A generic drug is a product that is shown to be the same as an innovative drug and is generally designated as therapeutically equivalent to the innovator biologic. Unlike generic drugs, a follow-on biologic (or “biosimilar”) is a product that is similar to, but not the same as, the innovator drug. It is unlikely that follow-on biologics will provide cost savings even remotely close to the savings from generic drug products.

Because H.R. 1956, The Patient Protection and Innovative Biologic Medicines Act, and H.R. 5629, The

Pathway for Biosimilars Act, largely meet the principles explained below, BIO urges you to cosponsor these bills.

BIO'S POSITION:

As Congress explores the creation of a regulatory pathway for follow-on biologics, it is essential to follow certain key principles:

- **Ensure patient safety.** Patients should not have to accept greater risks or uncertainties in using a follow-on product than an innovator’s product.
 - Clinical trial evidence and data are fundamental for evaluating and demonstrating the safety and effectiveness of a follow-on biologic.
 - Follow-on biologics must be properly evaluated through post-marketing surveillance and post-marketing clinical studies as needed.
 - Follow-on biologics must be assigned a non-proprietary name readily distinguishable from that of the innovator’s product.
- **Recognize scientific differences between drugs and biologics.** Biologics are much more complex than small molecule chemical drugs.
 - The methods used to show that one chemical drug is the same as another are different from and insufficient for biologics. Further, the methods used by innovators to demonstrate continued safety and effectiveness after a manufacturing process change are insufficient to demonstrate safety and effectiveness of a follow-on biologic made by a different manufacturer using a different process.
- **Maintain the physician-patient relationship.** Small molecule generic drugs can be designated as therapeutically equivalent and may be dispensed interchangeably with innovator products without physician knowledge. In contrast, the Food and Drug Administration (FDA) has stated that it “has

not determined how interchangeability can be established for complex proteins.” Accordingly, Congress should ensure that patients are not given follow-on biologics unless expressly prescribed by a physician.

■ **Preserve incentives for innovation.**

In order to preserve incentives to research, develop and manufacture new innovative therapies and cures, as well as new indications for such products, any statutory pathway for follow-on biologics must:

- **Include 14 years of non-patent data exclusivity**, during which time follow-on manufacturers could not rely on FDA’s prior approval of pioneer biologics to support approval of their own products. Such data exclusivity is necessary because a follow-on biologic may be similar enough to a pioneer biologic for regulatory approval purposes but different enough to avoid the innovator’s patents. Thus, non-patent exclusivity is necessary to maintain effective market protection. Further, the fledgling nature of the biologics industry, its heavy dependence on access to significant amounts of high-cost public and private investment capital, and the high risks and costs involved in the development of new biologic medicines all warrant a substantial period of exclusivity.
 - **Respect intellectual property and other legal rights.** Follow-on biologic products should not be approved until after all protections, including data exclusivity and patent protections, are no longer available for the approved pioneer product.
 - **Provide adequate notice and process rights.** Any follow-on biologics regulatory pathway should ensure that any patent challenge involving the follow-on biologic product will be litigated prior to marketing approval of the follow-on product in order to protect the innovator’s intellectual property rights and avoid confusion in the medical, patient, and payer communities.
- **Ensure transparent statutory and regulatory processes.** Manufacturers of innovator products should be provided full and fair opportunities to engage Congress and other stakeholders in a meaningful public process. Establishing a balanced and rigorous statutory pathway for follow-on biologics requires deliberative evaluation of

numerous complex scientific, legal, intellectual property and economic issues. Further, any such pathway must require that FDA follow a transparent and public process in determining data requirements for the approval of specific follow-on biologics.

- **Continue to prioritize FDA review and approval of new therapies and cures.** Any applications for approval of follow-on biologics will raise novel and complex questions of science and law, requiring substantial time and additional resources to ensure a thorough regulatory review for safety, purity, and potency. In order to avoid slowing FDA’s review and approval of new therapies and cures, many for untreatable and serious diseases, Congress must ensure that workload associated with these new applications does not harm FDA’s ability to efficiently review new drugs and biologics, and that new treatments continue to have the highest review priority.

COMPARATIVE EFFECTIVENESS

Comparative Effectiveness Can Inform Patient-Centered Clinical Decision-Making but Should Not Deny Access to Appropriate Therapies

BACKGROUND:

Comparative effectiveness research generally refers to research comparing the relative clinical risks and benefits of various health care treatments for a given disease or condition. Currently, a variety of private institutions and government entities engage in this type of research. Congress is considering legislation that would create an entity to facilitate the production and dissemination of comparative effectiveness information.

BIO POSITION:

BIO strongly supports efforts to increase the availability of accurate, scientifically robust evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that,

together with a variety of other types of medical evidence, can contribute to improving health care delivery. BIO is concerned that comparative effectiveness information may be used strictly as a means to contain costs, rather than to improve health care quality by informing patient-centered clinical decision making.

KEY PRINCIPLES:

The following are several issues decision-makers should consider in crafting policies related to comparative effectiveness:

- **Comparative effectiveness information should inform clinical judgment and individual needs in medical decision-making.** The results of comparative effectiveness studies often illustrate the experience of the “average” patient on the “average” course of therapy. However, patients may respond differently to the same intervention in ways that cannot be anticipated—for example, the treatment may interact with medications they are taking, or known genetic characteristics may modify response to the treatment. In order to achieve the best possible outcomes, providers must have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient preferences and clinical circumstances. Imposing rigid practice guidelines that fail to recognize such variations among patients can interfere with the ability of providers to deliver the most appropriate care for each patient and lead to suboptimal outcomes and increased health care costs.
 - **Comparative effectiveness research should focus on the totality of the health care delivery system, and not just drugs and biologics.** Much of the interest in comparative effectiveness research to date has been narrowly focused on drugs, biologics, and medical devices. However, comparative effectiveness studies are most likely to improve health outcomes if they encompass all aspects of the health care delivery system. In addition to drugs, biologics, and medical devices, comparative effective research should equally examine preventative services, diagnostic tests, and medical procedures. Comparative effectiveness information that reflects the interactions among all of the various components of the health care system has the greatest potential to empower clinicians and patients to make more appropriate decisions
- when faced with “real world” clinical situations. In addition to comparing specific treatment interventions, research should also focus on how innovations in care delivery models, such as disease management programs, may produce better health outcomes.
- **The application of comparative effectiveness research should advance the goals of personalized medicine and encourage the development of targeted therapies.** Advancements in the development of innovative therapies are grounded in the ability of researchers to focus on the mechanisms of action that allow particular therapies to work in specific patient populations. Promoting innovation in personalized medicine requires clinicians to have the ability to make patient-centered treatment choices without conforming to inflexible standards or practice guidelines. In addition, many therapies targeting rare or “orphan” diseases, as well as severe, rapidly progressive, or life-threatening diseases, are not conducive to comparative effectiveness studies due to the vulnerabilities, small size, heterogeneity, and other characteristics of these patient populations. Government policies addressing comparative effectiveness should acknowledge these limitations, and not discourage innovation into unmet medical needs.
 - **If considering comparative effectiveness information in coverage and payment decision-making, payers should take into account the overall value of a treatment intervention and allow for individual patient variation, rather than just consider cost.** Too often, comparative effectiveness research is viewed by payers and policymakers primarily as an instrument to contain costs, rather than provide health care value by improving patient health outcomes. Comparative effectiveness information should be considered by payers as one of many factors encompassing the overall value of specific health care interventions. Payers should not use comparative effectiveness information to establish “one-size-fits-all” coverage and payment policies that ignore the variability among individual patients in treatment efficacy, safety, and tolerability of treatment interventions. The consequences of inappropriately applying comparative effectiveness research in this manner are exemplified in other countries, including the United Kingdom and Australia, where entire patient populations are

denied access to innovative, breakthrough therapies because they do not meet economic thresholds.

- Comparative effectiveness research should be conducted through an open and transparent process involving all stakeholders, starting from the research planning stage.** Different comparative effectiveness studies evaluating the same item or service can produce widely disparate results, depending on the methods and assumptions used in the analysis. To enhance the credibility and usefulness of any comparative effectiveness study, stakeholders should be afforded the opportunity to provide meaningful input into all steps of the study process, including the identification of priority areas to research, study design and research methods, and dissemination of results. Careful consideration should be given and rigorous standards applied to the research method selected, such as randomized controlled trials, observational studies, or data synthesis. In their final form, comparative effectiveness research studies should include a concise description of the research question, transparency as to inclusion or exclusion of evidence or clinical information, transparent analytical methods, discussion of limitations in the quality of the evidence and overall conclusions and recommendations for areas to further research or more fully develop evidence.
- Comparative effectiveness studies should capture all relevant aspects of diseases and their treatments using the highest possible standards of evidence.** Comparative effectiveness analyses often ignore many important aspects of treatment interventions that affect patients, or may not account for disease severities. For example, many of the unique benefits provided by drugs and biologics, such as increased safety and improved patient quality of life, are often not captured in comparative effectiveness analyses, or when evaluated do not reflect the use of well-validated methodologies. Increased worker productivity and savings to other parts of the health care system are also important benefits that may not be reflected in studies conducted with a narrow perspective. Risk-adjusted comparisons of treatment interventions

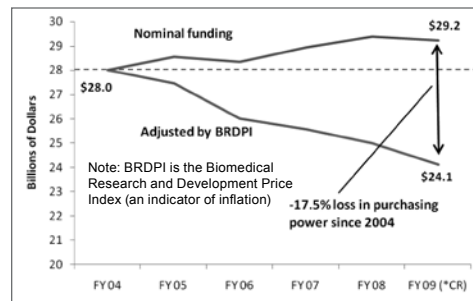
are also important to attempt to understand differences among patient subgroups in treatment efficacy, safety, tolerability, quality of life, and health economic outcomes.

NIH APPROPRIATIONS

Increased Funding for NIH Is Critical to the Advancement of Biomedical Discovery and Innovation

BACKGROUND:

The United States has historically been the foremost leader in the world for biomedical research and development. Breakthroughs in biomedicine and health over the past 50 years are largely due to the research and development that occurs within the biotechnology and pharmaceutical industries as well as the publicly-funded biomedical research enterprise centered at the National Institutes of Health (NIH). NIH supports basic research, which leads to discoveries at the molecular and cellular levels of disease, as well as translational and clinical research, which seeks to transform those discoveries into practical applications for new or improved treatment, diagnosis, and prevention. This research provides a critical foundation of knowledge and technologies that drive private biomedical investment and innovation.



Over the past five years the NIH budget has been flat or declining in real-dollar terms. Because funding has failed to keep pace with biomedical research inflation, NIH has lost more than 17.5% of its purchasing power since FY 2004.

Our nation now has an unprecedented capacity for research into emerging health opportunities and challenges, as well as an unprecedented demand for new healthcare solutions. As the Baby Boom generation ages, more and more people are suffering from chronic health conditions and it's becoming increasingly clear that without development of new health technologies, health care costs will continue to rise. The research infrastructure is in place but the NIH is simply unable to meet the growing demand for project grants, and many important well-designed research projects are going unfunded. Moreover, there is no

private sector alternative for much of the basic research that NIH supports. Adequate funding for NIH is necessary to sustain the public-private collaboration that is transforming biomedical discoveries into innovative treatments for patients.

BIO POSITION:

BIO urges Congress to support our nation's biomedical research enterprise by funding NIH at \$31.3 billion in FY 2009. This increase would set NIH funding on the track of sustainable growth that is necessary to realize our potential to improve technology, lower rising health care costs, and improve the health of all Americans.

- **Sufficient NIH funding is necessary to capitalize on new and unprecedented scientific opportunities in an era of genomic health and personalized medicine.** Research conducted and supported by NIH has led to advances in genomics, proteomics, and new biomedical technologies and tools that have the potential to bring us into an era of personalized, predictive, and preemptive medicine. It is becoming increasingly clear that one size does not fit all regarding therapies for complex diseases. The benefits (and risks) of different treatments and therapeutics are not equally shared by all patients. Research is needed to identify molecular determinants of susceptibility to particular health conditions as well as the benefits and risks of particular therapeutics and prevention techniques.
- **Biomedical research is the key to meeting the challenge of rising healthcare costs and an aging population.** Last year, the U.S. spent about \$7,100 per person for healthcare, yet we only invested \$95 per person in NIH-funded research that has the potential to lessen the burden of disease. Over 75% of healthcare expenditures today are associated with chronic and complex diseases. Research that leads to more effective treatment, prevention, and delayed onset of these diseases is the most effective means of reducing costs to individuals, companies, and the government.
- **Americans receive a significant return on our national investment in biomedical research.** Over the past 30 years, the United States has invested a cumulative total of \$44 per citizen per year at NIH. In return, American life expectancy has increased by more than six years, and NIH-funded discoveries have contributed to new and more effective diag-

nostics and treatments for heart disease, diabetes, cancer, and many other diseases.

- **Maintaining a strong publicly-funded NIH is important to America's global economic and scientific competitiveness.** NIH is the primary funding source for academic biomedical research throughout the country. Lack of project funding hits young scientists and students the hardest, and we risk losing our best and brightest young minds to opportunities overseas. Increased NIH support for development programs and independent research projects for young researchers ensures that the best students and young scientists remain in the United States.

FDA APPROPRIATIONS

Increased Funding for FDA Will Help Bring Novel Treatments to Patients and Promote U.S. Economic Competitiveness

BACKGROUND:

BIO supports a strong, fully-funded FDA with the resources necessary to keep pace with rapidly-evolving biomedical science and make sound regulatory decisions in a timely and efficient manner. For FY10, BIO respectfully requests an increase of \$75 million for FDA's human drug and biologics programs as part of a \$385 million increase for the agency as part of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act. This requested agency-wide increase includes \$125 million in new program funding, \$110 million to keep pace with mandatory inflationary increases, and \$150 million carried over from the FY08 Supplemental Appropriation and the FY09 Continuing Resolution for a total FDA budget authority of \$2.25 billion.

BIO member companies recognize that a reliable, science-driven regulatory environment fosters innovation, promotes economic competitiveness, and maintains high patient confidence in the integrity of their medicines. For people with devastating diseases and disabilities, roadblocks to getting new cures developed and approved can be a matter of life or death. Moreover, adequate FDA funding is an economic imperative as well as a public health priority. FDA regulates approximately \$1 trillion in consumer products, or 25 cents of every U.S. consumer dollar

spent, and it is critical to U.S. economic health and competitiveness that FDA has the tools and resources necessary to effectively and efficiently preserve adequate standards for medical product quality.

BIO POSITION:

Reinforce FDA's Scientific Base: FDA's scientific knowledge and expertise is essential for evaluating the safety and efficacy of medical products. However, a recent assessment by FDA's Science Board entitled *FDA Science Mission at Risk* concluded that chronic lack of federal funding in an era of increasing FDA global responsibility has undermined the agency's scientific base and jeopardized the agency's ability to accomplish its core public health mission. The vision of a 21st century FDA will not be realized in the absence of substantial increases to the FDA's base appropriations. Additional federal funding is critical to FDA's ability to recruit and retain the best and brightest scientists and medical reviewers, modernize the agency's information technology systems, and restore FDA's scientific capacity.

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- **Support the Critical Path and Restore Funding for the Reagan-Udall Foundation:** The FDA launched the Critical Path Initiative in 2004 to modernize the scientific process through which a potential human drug, biologic, or medical device is transformed from a discovery or "proof of concept" into a medical product. Through the application of modern regulatory tools and scientific approaches, problematic compounds can be identified and discarded earlier in clinical development while

safer, more effective, and more personalized medicines can be developed and reach patients without unnecessary delay. However, limited funding in past years has dramatically slowed its progress. For FY10, BIO requests \$12 million for the Critical Path program as part of the overall \$75 million increase for FDA's human drug and biologics programs.

Recognizing the urgency many patients face, Congress established the Reagan-Udall Foundation for the FDA in 2007 to advance the Critical Path program through private-public partnerships. Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress authorized FDA to transfer funding to the Foundation and also collect private funding. However, the FY08 Consolidated Appropriations bill subsequently restricted FDA's ability to transfer federal funding to the Foundation. BIO believes that this promising partnership is best served by a balanced commitment of both private and public funding sources and urges Congress to lift the restriction.

- **Bolster Import Safety and Global Responsibilities:** BIO also recognizes that the agency is under additional workload and stress due to the increasingly global nature of the modern economy and the persistent threat of counterfeit, adulterated, and diverted medical products. However, FDA funding has not kept pace with these new international responsibilities. Drugs and biologics are a small, yet important, element of the larger discussion around import safety and while America's drug supply is the safest in the world, there is more that FDA can do to further secure the supply chain. BIO is supportive of additional funding for post-market foreign inspections.
- **Modernize Drug Safety Activities:** In recent years, Congress has significantly increased FDA's statutory responsibilities but agency funding to implement these new laws has until recently remained flat. The most recent legislation, FDAAA, modernizes FDA's ability to properly evaluate the benefits and risks of medical products both before and after approval. This landmark legislation will not be successful if it is not accompanied by adequate appropriated funds to implement several key provisions such as the clinical trials databases and the electronic active post-market surveillance

system. The FDA's ability to operate a modern, scientifically-based safety surveillance program must be strengthened through a commitment to restoring FDA's base resources.

SBIR

Support SBIR Reform: Ensure Innovation is Brought to the Public

BACKGROUND:

The Small Business Administration (SBA) administers the Small Business Innovation Research (SBIR) program, through which 2.5 percent of all federal research and development grant monies are reserved for small business applicants. These funds provide critical seed money to new business innovators, including biotechnology companies. Small biotechnology companies with majority venture capital funding were eligible to compete for SBIR grants for more than 20 years after the program's inception in 1982. However the SBA ruled in 2003 that companies which receive a majority of funding from venture capital companies are no longer eligible to participate in the SBIR program.

BIO POSITION:

BIO recommends that legislation to reauthorize the SBIR program reinstate eligibility for small biotechnology companies which receive a majority of funding from multiple venture capital companies.

DISCUSSION POINTS:

- **As the world's leader in biotechnology, America has benefited greatly from the SBIR program which has been an essential component in the commercialization and economic development of the biotech industry.** However, the SBA's re-interpretation is preventing some of the most innovative biotech companies from participating in the SBIR program. SBIR plays a critical role in aiding small biotechnology companies in their early stage research to navigate through the "valley of death" where the concept is too high-risk for private market support. Without these funds, many companies will be forced to delay innovative research projects.
- **As a result of the re-interpretation, the SBIR applicant pool is shrinking and work on life-**

saving and life-enhancing technology is being postponed. Many companies are not applying for SBIR grants or are delaying grant submissions in the hope that this issue will be resolved. In 2007, the number of applications at the NIH dropped 21% since SBA's rule change and the number of applications by new small businesses is the lowest in a decade.

- **Patients will suffer if the new SBIR rules are not reversed.** On October 18, 2007, more than 50 patient groups—including the Leukemia & Lymphoma Society, the Juvenile Diabetes Research Foundation, and the Christopher & Dana Reeve Foundation—wrote to House and Senate leadership, urging them to restore SBIR eligibility for majority venture-backed companies in the upcoming reauthorization of the SBIR program.

CAPITAL FORMATION TAX INCENTIVES

Congressional Action Necessary to Encourage New Investment Capital into Emerging U.S. Biotech Companies to Promote Continued Innovation and Foster Economic Competitiveness

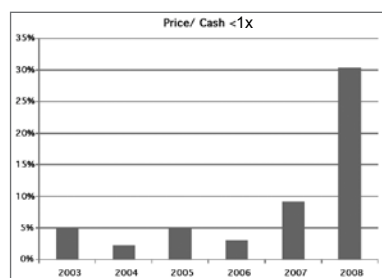
BACKGROUND:

Since August 2007, emerging biotechnology companies have been profoundly impacted by the current financial crisis, which could jeopardize U.S. biotechnology innovation and competitiveness.

It takes, on average, more than a decade and \$1 billion to develop a new molecule for approval. As a result, biotechnology companies go for years without revenue, instead relying on financing from investors. Emerging biotechnology companies—which are over 85% of the industry—are therefore highly dependent on well-functioning capital markets to finance their long term, capital-intensive research and development projects.

While many industries have seen a slowdown, biotech has seen a complete freeze. In 2008, access to the capital markets and new investment has come to a standstill: no new initial public offerings and a very small number of secondary financings. This drain in financing has had a massive impact: As of November 1, 2008, **99 companies are operating with less than six months worth of operating cash remaining (25% of**

all public U.S. biotech companies). Likewise, the number of companies which are presently valued at less than their cash on-hand has gone up nearly ten-fold over the past 24 months. There has been a dramatic slowdown in private investments as well. When confronted with these financing realities, emerging biotechnology companies are faced with difficult operating decisions, including postponing development of new therapies or laying off employees to reduce their operating expenses. Companies with promising therapies may not be able to continue their work, delaying the availability of new options for patients. In addition, the U.S. is at real risk of losing its



biotech competitive edge to the rest of the world. Foreign countries, including China and India, are making substantial investments in order to grow their

biotechnology industries. Even closer to home, Canada's favorable research and development (R&D) tax laws are enticing U.S. companies to spend significant amounts of their capital abroad instead of the United States. The end result will be fewer high-paying jobs in America, the U.S. may lose its global standing as a leader in biotech and a new and growing contributor to the U.S. economy will be weakened.

BIO POSITION:

At this critical point in time, it is imperative that Congress and the Administration consider legislative and regulatory policies that will improve the investment climate for, and competitiveness of, its emerging biotechnology companies. Such initiatives should be included as part of an economic stimulus package and tax reform legislation. Legislation should include proposals that will shore-up companies' balance sheets and provide incentives to attract and retain investment in our industry. Additionally, it is important that the SEC's capital market initiative includes provisions to ensure that biotech companies are not subject to market manipulation including illegal rumor-mongering or abusive naked short selling tactics, and that biotech companies are treated on a similar plane to those in other industries that have substantial risk.

CORPORATE AND INVESTMENT TAX INCENTIVES FOR EMERGING BIOTECH COMPANIES:

BIO encourages Congress to strongly consider: (1) provisions that will enable emerging companies to better utilize tax assets they have accumulated such as R&D tax credits and Net Operating Losses (NOLs) and (2) additional incentives for investors to invest and stay in the biotech industry. Some examples of potential capital formation initiatives include:

- **Extension and Expansion of the R&D/AMT in Lieu of Bonus Depreciation Provision:** Extend the R&D/AMT provision through 2009 and expand the provision to (1) allow NOLs along with R&D/AMT in lieu of other tax incentives (i.e., bonus depreciation and R&D tax credit); (2) allow all accumulated R&D and AMT credits to be refundable (not just pre-2006); (3) raise 6% the limit on the amount of refundable R&D and AMT credits; and (4) increase the \$30 million cap.
- **Allow Temporary Exchange of Discounted Net Operating Losses With Proviso That All Proceeds Must Be Used For Qualified R&D.** A temporary provision will allow companies to immediately strengthen their balance sheets. This legislation would allow companies to exchange net operating losses that have been discounted by the corporate tax rate, on the commitment that the funds received from the exchange must be used to support research and development of new therapies.
- **Suspension of §382 NOL Limitations Upon Substantial Change in Ownership:** Ensure §382 limitations on the use of NOLs are not triggered due to successive rounds of equity financings, or a business-driven merger of companies.
- **Capital Gains Rollover:** Allow deferral of capital gains on the sale of "small business" stock if held for longer than six months as long as the proceeds are reinvested in another "small business" company within 90 days.
- **Zero Capital Gains Rate for Small Businesses:** Allow 100% exclusion from taxes on sale of "small business" stock.
- **Capital Losses Offset Ordinary Income:** Allow a portion of capital losses from sale of "small business" stock to be used against ordinary income.



FOOD & AGRICULTURE

AGRICULTURAL BIOTECHNOLOGY: INCREASED SUSTAINABILITY WITH SCIENCE BASED SOLUTIONS

THE BENEFITS OF AGRICULTURAL BIOTECHNOLOGY:

For thousands of years, humans have improved the crops they grow through cross breeding, hybridization, mutagenesis and other methods to improve agricultural production and meet the needs of growing populations. Agricultural biotechnology is the newest technology to help enhance production and fight disease.

Since the commercialization of biotechnology in 1996, farmers have used this science to grow plants that yield more per acre while reducing production costs, are resistant to disease and pests, and benefit the environment. Foods from approved seeds derived from biotechnology are completely safe, and the environmental safety of commercialized products is not in question.

In the near future, new biotech crops will be resistant to environmental stresses such as drought, and crops that use soil nutrients more efficiently, will boost productivity in areas of the world with inadequate rainfall or poor soil.

Scientists are also looking to use biotechnology to fortify some food plants with higher nutritional content, produce pharmaceuticals in plants affordably and efficiently, and produce healthier and more productive farm animals.

Farmers are enthusiastically embracing this technology, especially corn, cotton and soybean varieties, according to United States Food and Drug Administration (USDA). This growing trend is expected to continue, especially at a time when the United States and the world are looking for science-based solutions for food and fuel security.

- In 2007, 282 million acres (114 million hectares) of biotech crops were planted in 23 countries by 12 million farmers.
- Ninety percent (11 million) are resource-poor farmers in 12 developing countries.

Agricultural biotechnology is already providing solutions for increasing global demand of food and fuel. Biotechnology is benefitting agriculture through:

- **Increased productivity**
 - Corn yield has increased more than 30 percent in the United States.
 - Soybean yield has increased 17 percent.
 - Biotech crops have the potential to increase productivity by at least another 25 percent worldwide.
- **Disease and pest resistance**
 - Pesticide applications have been reduced by 630 million pounds (1996-2006)
- **Environmental benefits**
 - No-till farming has increased by 35 percent (1996-2002)
 - Fuel consumption savings equaled 551 million gallons (1996-2006)
- **Animal Biotechnology**
 - Animal cloning and animal biotechnology have been proven to provide solutions for public health through biomedical, food and environmental benefits.

SCIENCE-BASED REGULATORY POLICY:

An important factor behind this country's leadership is the U.S. government's strong, science-based regulatory system for agricultural biotechnology. These regulations ensure that the production and use of biotech-derived crops and animals result in no significant adverse effects to human health and environment and that they are safe to enter into commerce. This system, encompassing the food safety and environmental regulations of the USDA, U.S. Environmental Protection Agency and U.S. Food and Drug Administration, has resulted in rigorous scientific review of products while providing a predictable regulatory environment that fosters scientific advancement and product innovation.

BIO supports regulatory programs, policies, and decisions that are based on sound science and that hold biotechnology-derived products to the highest standards of health and environmental safety. The marketplace will determine the commercial success of a product.

LABELING OF FOODS DERIVED FROM BIOTECHNOLOGY:

Labeling requirements should also be science-based to give consumers truthful information about the foods they buy and eat, without providing misleading information.

To require the labeling of foods that are indistinguishable from foods produced through traditional methods would mislead consumers by falsely implying differences where none exist. It also risks diverting attention from important safety and nutritional information.

Food companies have the right to voluntarily place claims on their products and often do so. However, federal law is very clear that the burden of truthfulness and non-misleading statements of the claim falls on the food company.

BIO supports the laws and regulations administered by FDA and USDA that require food labeling to be truthful and not misleading.

Specifically, BIO supports FDA and USDA labeling policies for food including:

- No label should be required if the food is substantially equivalent to its traditional counterpart.
- A label is required if the food is materially different from its traditional counterpart in nutritional or safety attributes.

Voluntary claims are allowed on food labels provided such labels are truthful, do not mislead consumers and are verifiable.



INDUSTRIAL & ENVIRONMENTAL

BIOFUELS

We Can Meet the Increased Renewable Fuel Standard in a Sustainable Way While Dramatically Reducing Greenhouse Gas Emissions Thanks to Advances in Biotechnology

BACKGROUND:

In 2007, an aggressive national Renewable Fuel Standard (RFS) was signed into law. The RFS will require 36 billion gallons of renewable fuels by 2022—5 times current production. Of this, 16 billion gallons must come from cellulosic biomass. These fuels can only be produced with the help of biotechnology. All new biofuels production must demonstrate superior lifecycle greenhouse gas (GHG) performance to petroleum alternatives. BIO's member companies are committed to the sustainable production of biofuels. Our industry can help biofuel producers meet the production goals in the RFS while substantially reducing greenhouse gas emissions thanks to recent advances in biotechnology.

BIO POSITION:

BIO supports the RFS and tax credits for advanced biofuels producers. Agricultural and industrial biotechnologies are the key enabling technologies that will allow the United States to reach the RFS through improved agricultural yields, environmentally-sensitive agronomic practices, advanced dedicated energy crops and revolutionary enzyme-based biofuels production technology to utilize cellulosic feedstocks. Biotech companies are developing new advanced biofuels to actually make hydrocarbons using agricultural feedstocks. The RFS is a good starting point and tax credits can help accelerate commercialization of advanced biofuels technologies.

The Renewable Fuel Standard is achievable with the help of biotechnology. Advances in feedstocks and

enzymatic technology will continue to increase not only the amount of biomass available on an acre of land, but also how much fuel can be produced from that same acre. Since agricultural biotechnology was introduced in 1996, corn crop yield has increased by 30 percent and is projected to increase another 20 percent by 2015. Switchgrass and other advanced dedicated energy crops will provide even greater per acre yields and environmental benefits.

Growing and producing biofuels reduces overall greenhouse gas/carbon emissions. Burning biofuels produces at least 28 percent less greenhouse gas than burning gasoline or diesel fuel. Improvements in agricultural and industrial biotechnology are making conventional ethanol production even more efficient and environmentally friendly. Agricultural biotechnology varieties allow for greater use of no-till farming while improvement in fractionation and enzyme technology are boosting ethanol yields to new highs. Growing use of biomass for heat and power generation at ethanol plants is reducing GHG emissions. Next generation biofuels, such as cellulosic ethanol, will reduce GHG emissions even further—by 86 percent or more over gasoline.

Water usage is an important element of the sustainability discussion for biofuels production. When compared to other industrial applications, the biofuels industry is a low water consumer and has the potential for significant water conservation as an industry. Ethanol plant designers are actively working on reducing water usage in new production facilities to make biorefinery water usage levels as low as possible. Wastewater can be recycled and used in the ethanol production process which can significantly further reduce the aggregate water use per plant.

The economic and societal benefits to local communities of a biorefinery will be significant. Job creation and economic growth due to the construction of biorefineries give local economies an opportunity to

rejuvenate and flourish in a way that has not been experienced in many parts of this country for several decades. The agricultural and industrial biotechnology industries are creating new products for these communities to produce and sell on a world-wide market.

DISCUSSION POINTS:

Meeting the RFS

The ethanol industry can and will achieve the production volumes established in the Energy Independence and Security Act of 2007:

- Over 12 billion gallons of ethanol capacity is either already installed or under construction.
- Six Department of Energy (DOE)-sponsored cellulosic ethanol demonstration biorefineries are moving forward and will be on-line in time to meet the first modest production requirement in 2010. Other projects are being planned. Commercially-ready cellulase enzymes are being introduced.

Land Use

Advances in agricultural biotechnology are combining greater yields with more environmentally sensitive agronomic practices:

- Per acre corn yield has increased 371 percent since 1944. Introduction of biotech varieties has helped increase yields 30 percent since 1996 alone. McKinsey & Co estimates that at this rate **the RFS would require little or no additional corn acres** to be planted.
- Biotech corn varieties and collection of agricultural residues allow for greater adoption of no-till farming which can increase sequestration of carbon 2 to 3-fold.
- The recent “Billion Ton Report” conducted by DOE and USDA found that the United States can displace over 30 percent of gasoline demand with biofuels without additional acreage.
- **Indirect land use changes are a function of land use policy. Sustainable biofuels production must go hand-in-hand with sustainable land use policy.**

Improving Greenhouse Gas Profile

Ethanol production efficiency and environmental profile are improving rapidly:

- The vast majority of research from academia, NGOs, and federal labs suggests that **biofuels have a positive and increasingly beneficial impact on climate.**

- New fractionation and enzyme technologies are further reducing energy inputs and delivering higher value co-products. New “no cook” enzymes substantially reduce biorefinery CO₂ emissions because no heat is needed to disassociate sugars from starch.
- Biorefineries are increasingly using renewable energy such as stover or manure to power their facilities, greatly reducing fossil fuel inputs. Cellulosic biorefineries are expected to require little or no fossil inputs and may even return power to the grid.

Dedicated Energy Crops

Switchgrass and other dedicated energy crops will provide even greater per acre yield and superior environmental benefits:

- Many dedicated energy crops grow well in poorer soils and can be planted on less productive land, building soil and sequestering carbon in the process.
- Many dedicated energy crops can be planted without tilling and can continuously sequester carbon even as above-ground biomass is harvested.
- Bioenergy crops can provide food/feed, fuels, and other high-value co-products from the same crop, making the highest possible use of the land.

Water Usage

The efficiency of water usage in biorefineries is improving and equals or surpasses energy savings of similar industrial processes:

- The National Academies estimates that consumptive water use by cellulosic ethanol biorefineries will be between 2 and 6 gallons of water for every gallon of biofuel.
- According to The Renewable Fuels Association, one gallon of gasoline currently requires 2.5 to 8 gallons of water to produce.
- 300 million gallons of water is used daily to produce U.S. newsprint, according to the National Renewable Energy Laboratory.
- According to the USDA, nearly nine out of ten acres of corn require no water other than natural rainfall and dedicated energy crops being researched for cellulosic ethanol production require far less water inputs to grow.

Economical and Societal Impacts

Construction of a biorefinery greatly impacts the economic growth of a local economy:

- Biorefinery construction and operation creates quality jobs and increases ancillary business development to significantly impact a local economy.
- A University of Missouri study shows that two 22-million gallon biorefineries add \$24 million and 1,815 jobs to the state's economy.
- Replacing a significant portion of current U.S. oil imports will result in keeping billions of dollars in the U.S. economy rather than sending it overseas and will aid in the security of our energy supply by producing additional domestic sources of transportation fuel.

CLIMATE CHANGE

Biotechnology Is Key to Combating Climate Change

BACKGROUND:

Biotechnology provides a powerful set of tools to address climate change. Biofuels and biobased products replace petroleum-based feedstocks with renewable biomass that circulates existing carbon dioxide (CO₂) instead of releasing additional fossil carbon into the atmosphere. Many next-generation energy crops work to sequester additional carbon in the soil as they grow. Advanced biotech manufacturing processes reduce inputs of heat and electricity, further reducing CO₂ emissions. And biotech researchers are even developing algae and other micro-organisms to remove existing CO₂ from the atmosphere. The 111th Congress is expected to address climate change through comprehensive cap-and-trade legislation on greenhouse gas emissions (GHG). A wide range of GHG mitigation technologies are likely to be explicitly incentivized under the cap and trade regime.

BIO POSITION:

Any comprehensive effort to address climate change should include strong incentives for biotechnologies that help reduce atmospheric GHG concentrations.



INTELLECTUAL PROPERTY

PATENT REFORM

Improve, Don't Kill, the U.S. Patent System

BACKGROUND:

Intellectual property is the lifeblood of the biotechnology industry. Strong patents are critical in ensuring a steady stream of capital to biotechnology companies developing innovative medicines, alternative energy sources, and insect-and-drought resistant crops.

BIO POSITION:

BIO supports a consensus-based approach to patent law reform, which would improve the patent system in ways that would benefit all sectors of the U.S. economy through enhancing patent quality and the objectivity, predictability, and transparency of the patent system.

IN GENERAL:

A strong patent system encourages research and development of innovative products and technologies. Patents are fundamental in spurring new and translatable research in universities and research organizations. Because patents require full disclosure of inventions, novel concepts, products and technologies are put into the public domain that can then be used as the subject of future research in universities and research organizations. This resulting research can then be developed into new and commercially-useful products and technologies through the transfer of patent rights. Weak patent rights would stifle further research, development, and commercialization of publicly- and privately-funded inventions.

Patents are key to biotechnology investment and product development. The majority of biotechnology companies have no products on the market, and thus their research and development activities are funded through massive amounts of investment, largely from

private capital. Despite the uncertainty of biotech innovation, the industry attracts billions of dollars in new investments each year based on the hope of a return on the investment from discoveries that will only be translated into actual commercial products after years, sometimes decades, of capital-intensive investment and research efforts. Without strong and predictable protections for validly patented materials, investors will shy away from investing in biotech innovation, degrading the ability to provide solutions to the most pressing medical, agricultural, industrial, and environmental challenges facing our nation and the world.

DISCUSSION POINTS:

The patent system is working, spurring American ingenuity and creativity across a broad spectrum of industries and technologies. Innovation is alive and well with record numbers of patents being applied for and granted over the past two decades.

- Despite the record number of new patent applications, the Patent and Trademark Office (PTO) is reporting marked improvement in the quality of patents issued, demonstrating a more rigorous process of patent examination.¹The PTO "allowance" rate has declined by 20 percent since 1998.
- While any system will, over time, need to be modified, the legal system governing patents has proven to be self-correcting. Over the past several years, the U.S. Supreme Court and the Federal Circuit have issued several major patent decisions that resolve many of the key legal complaints that have been raised about the current patent system.
- There is, however, room for improvement and there is much consensus about ways to further improve the patent system by making it less subjective and more predictable.

¹ PTO Performance and Accountability Report for Fiscal Year 2007

- However, the legislation being considered by the Senate, and which was considered in the House, goes *too far in some critical areas*—
 - It went *too far* in attempting to change the law on damages. The proposed legislation would make it easier for competitors to infringe by decreasing royalty awards in many cases and thus would devalue patent assets.
 - It went *too far* in creating a new administrative post-grant review system that would permit multiple challenges to a patent on a broad range of grounds throughout the life of the patent and without the protections under current law, creating unpredictability in patent rights and thus great uncertainty for investors.
 - It went *too far* in restricting the ability of patent owners to sue infringers even where patent owners have a substantial nexus to the judicial jurisdiction selected for suit.
- The legislation did **not go far enough** with respect to inequitable conduct and best mode reform, as urged by the National Academies report. Because of their highly subjective nature, these two aspects of patent law are often used to harass patent owners seeking to enforce their patents and serve to undermine efforts to enhance patent quality by chilling communication between applicants and the PTO. Yet the Senate bill simply codified the worst aspects of current inequitable conduct law and did nothing to fix the issues associated with the best mode requirement.

CONCLUSION:

BIO opposes provisions that weaken the ability of the patent holder to enforce his or her patent, or would otherwise undermine the predictability and thus undermine the value of patents. Patent rights are valuable only if they are predictable and can be enforced. The U.S. leads the world in biotechnology innovation and product development due to the strength and predictability of the U.S. patent system. It is critical that Congress first “do no harm” in its enthusiasm to reform a system that has made the U.S. the innovation engine of the world.

Specifically, BIO urges that any patent reform bill, at a minimum, meet the following criteria before being brought up for consideration:

- (1) The “second window” in any post-grant opposition system should either be eliminated entirely

or strictly limited in a manner consistent with the language as passed by the House of Representatives—that is, limiting the types of challenges that can be brought in any “second window” to only those based on objective evidence of prior patents or printed publications.

- (2) Any statutory language on the calculation of reasonable royalty damages should –
 - a. Preserve the discretion of courts and juries to apply any and all applicable factors and methodologies under current law;
 - b. Not direct courts or juries to engage in “prior art subtraction” or otherwise seek to separate out certain elements of a patent claim;
 - c. Not restrict the ability of courts or juries to use the value of the infringing product or process as a base for calculating a reasonable royalty.
- (3) The PTO Director should not be given any authority to promulgate substantive rules of patent law, including any restriction on the manner in which applicants may claim their inventions or seek continued examination of their applications.
- (4) The “applicant quality submissions” provision should either be eliminated or carefully restricted and pre-conditioned on meaningful reform of the “unenforceability doctrine,” as described below.
- (5) Any bill must contain major reforms of the current “unenforceability doctrine,” as recommended by the National Academies of Science and the PTO, under which application of this draconian penalty would be limited to patent applicants who deceive the PTO into allowing an invalid patent claim and where such deception was the cause for the claim’s issuance; and it must ensure that subjective determinations of “best mode” cannot be used to invalidate otherwise valid patents.
- (6) Any reforms to the statutory venue provisions should, at a minimum, permit patent owners to sue in districts in which the claimant has its principal place of business or has engaged in substantial research, development or manufacturing activities.

Finally, BIO urges that the Congress give a new Administration and a new PTO Director sufficient time to examine and implement various administrative reforms to reduce the patent application backlog and improve the efficiency of the patent examination system and the quality of issued patents, before imposing new burdens and requirements on the office.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

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