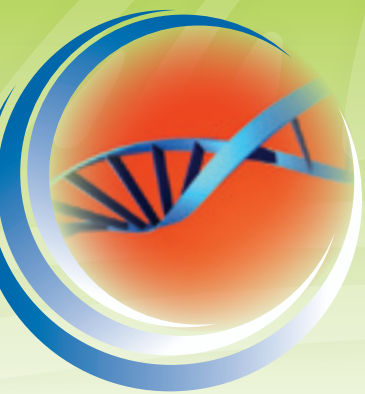


2009 LEGISLATIVE DAY FLY-IN

BIOTECHNOLOGY INDUSTRY ORGANIZATION

MARCH 31 - APRIL 1, 2009



HEALTHCARE



**FOOD AND
AGRICULTURE**



**INDUSTRIAL AND
ENVIRONMENTAL**



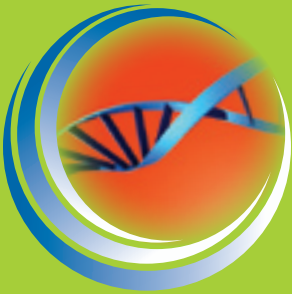
**INTELLECTUAL
PROPERTY**

BIOTECHNOLOGY INDUSTRY ORGANIZATION

2009 Legislative Day Priorities

March 31 – April 1, 2009

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For more information please contact Brent Del Monte, *Vice President of Federal Government Relations*, at 202.962.9200 or bdelmonte@bio.org.



HEALTHCARE

FOLLOW-ON BIOLOGICS

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

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.

The Food and Drug Administration (FDA) recently expressed concerns similar to those voiced by BIO, for example that clinical testing is fundamental for evaluating the safety and effectiveness of follow-on biologics, that it has not been determined how interchangeability can be established for complex proteins, and that sponsors developing innovative biotechnology products should be eligible for a significant period of market and/or data exclusivity to ensure continued innovation.

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 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. *BIO is asking for 14 years based on the following:*
 - Parity with small molecules
 - New molecular entities, on average, are marketed in the U.S. for 13.5 years before the entry of generic competition.
 - The breakeven point for a biologic occurs after it has been on the market between 12.9 and 16.2 years.
 - The patent term restoration under Hatch Waxman is 14 years.
 - 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. Thus, 14 years will provide a balance between providing the framework for research and develop new medicines and the pathway for lower-cost FOBs and maintain the competitive edge of the US biotech industry.
 - 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 down FDA’s review and approval of new therapies and cures,

many for currently 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.

ACCESS TO HEALTHCARE

Support Universal Access to Affordable, Sustainable, High-Quality Healthcare and Ensure the Fundamental Role of Innovation

BACKGROUND:

According to the U.S. Census Bureau, some 46 million Americans lack health insurance, most of them in working families. Current research indicates that the uninsured often delay medical care, decreasing their quality of life and shortening their life span. BIO supports universal access to affordable, high quality health care and believes that innovation plays a significant role in improving patient care. BIO is committed to working with other health care organizations, government agencies, the Congress, and the President to develop workable solutions for health reform.

BIO POSITION:

BIO supports universal access to affordable, sustainable, high-quality health care for all. Achieving universal access requires universal responsibility on the part of all stakeholders: individuals, employers, physicians, manufacturers, insurers, hospitals, and society as a whole. BIO believes that market-based reforms provide the best opportunity to achieve the goal of universal access while providing high quality care and incentives for the discovery and development of innovative improvements throughout the health care delivery system. BIO believes that innovation in health care, including health care solutions such as new therapies and diagnostics, has always been and will continue to be central to realizing our health and economic goals.

DISCUSSION POINTS & KEY PRINCIPLES:

BIO has identified the following issues as critical for policymakers' to address as they craft policies designed to improve access to health care services and coverage:

- **Ensure universal access to medically appropriate, innovative therapies and diagnostics.** Patients should have access to the most appropriate treatments regardless of cost. It is both the role of the patient and physician to choose the best treatment and use the benefits of innovation appropriately. BIO member companies are actively engaged in developing innovative pharmacogenomics, as well as personalized medical therapies and diagnostics to improve patient care. Proposals that limit access to these medical technologies can lead to potential delays in obtaining care or sub-optimal care, resulting in higher health costs and poor health outcomes. Through such means as Patient Assistance Programs (PAPs), many of BIO's members are meeting their responsibility to assist financially vulnerable patients in accessing needed therapies when cost is a barrier.
- **Implement market-based, consumer-oriented solutions to increase patient access to innovation.** BIO supports solutions that encourage and enable the private market to ensure that consumers and providers have a choice among affordable coverage options, while enhancing and continuing the discovery of new innovative therapies and their accessibility to those patients who need them the most. Fostering innovation is the best way to sustain the growth in value of the health care delivery system. Innovation, including new medical therapies, can help to ensure access to needed health care by reducing the burden of or even curing costly diseases, as well as keeping total societal costs down. Innovations in the way treatments are covered and paid for, such as diagnosis-based formulary design, can enhance access while reducing costs. These kinds of innovations can only occur within a market-based, consumer-oriented system. Incentives should be realigned, potentially through tax credits or vouchers, to ensure that individuals obtain insurance through their employer, existing public programs or individually. In addition, medical malpractice reform should be considered a critical element to enhancing the delivery of medicine.

- **Maximize participation in and support consumer-oriented reforms to existing public programs, especially Medicaid and SCHIP.** Providing education and information regarding the programs which many of the uninsured are currently eligible for, but are not enrolled in, is an essential step to ensure that existing solutions and programs are fully utilized by the most vulnerable individuals.
- **Enhance individual and employer responsibility in accessing health care coverage.** BIO and its members believe that individuals must take greater responsibility for their own health and obtaining health coverage. It is critical that all individuals be insured for the benefit of the entire health care system and have access to critical life-saving preventive care measures, such as immunizations, early detection and screening. Incentives should be provided to ensure that all eligible individuals participate in health plans where offered, either by employers or through the individual market. At the same time, employers, particularly small businesses, should have incentives to make providing health care to employees both affordable and efficient. BIO also believes that patients should have access to continuous health care coverage and supports policies that improve health insurance portability.
- **Strengthen our nation's health through increased access to preventive health measures.** Improvements to our health system are needed to ensure that all individuals have better, timelier access to care and therapies. Preventive health measures, such as screenings and immunizations, should be viewed as potential life-saving tools that will improve a patient's quality of life. Early detection is essential for the early intervention and successful treatment of disease, and all patients should have access to these services.
- **Embrace new technologies such as information technology that can improve the quality and delivery of health care.** The widespread adoption of secure and interoperable health information technology (health IT) has the potential to improve the quality of care while curbing the costs of health care.
- **Recognize that universal access is most likely to be achieved through the employment of a combination of many coordinated solutions.** In order to better understand the effectiveness and implications of different approaches, federal and state governments should examine and learn from state and private sector initiatives that have proposed or implemented universal health coverage reforms. These proposals aim to affordably expand and improve health coverage through a combination of solutions that may be applicable in other states or at the Federal level.

CAPITAL FORMATION TAX INCENTIVES

Urgent Capital Infusion into Emerging U.S. Biotechs is Necessary to Promote Continued Innovation and Foster Economic Competitiveness

BACKGROUND:

Emerging biotechnology companies have been profoundly impacted by the current financial market crisis which threatens to jeopardize U.S. biotechnology innovation and competitiveness. Emerging biotech companies fund research and development for a decade or more, on average, with investor capital in order to develop a new therapy for approval. Emerging companies constitute greater than 85% of the U.S. biotech industry and generally have 100 or fewer employees. Therefore, these companies are highly dependent on well-functioning capital markets to finance long term, capital-intensive research and development projects. These companies are especially vulnerable to the ongoing financial market crisis.

While many industries have seen a slowdown in available investor capital, biotech has seen a near-freeze. Access to the capital markets has come to a standstill, with no new initial public offerings and a very small number of secondary financings in 2008. As of January 2009, **roughly one-third of public U.S. biotech companies are operating with less than six months worth of operating cash remaining. This represents a jump of 90% more companies with less than 6 months cash on hand vs. 2007.** There has been a dramatic slowdown in private investments as well. This drain in financing has had a massive impact for

biotechs who must continue their research and development projects but are unable to raise capital from investors.

When confronted with these ongoing financing realities, emerging biotechs are faced with difficult choices in order to reduce their operating expenses, such as laying off employees, delaying or cancelling research projects, or even declaring bankruptcy. Ultimately, these companies with promising therapies may not be able to continue their work, delaying the availability of new treatment 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 in the U.S. Without new efforts to support America's biotech industry, the end result will be fewer high-paying, high-quality 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 new Administration consider legislative and regulatory policies that will improve the investment climate for American innovation and foster competitiveness of emerging biotechnology companies. Such legislation should include proposals that will shore-up companies' balance sheets and provide incentives to attract and retain investment in U.S. biotech companies.

CAPITAL FORMATION INCENTIVES FOR EMERGING BIOTECH COMPANIES:

BIO encourages Congress and the Administration to strongly consider: (1) provisions that will enable emerging companies to temporarily accelerate the use of their accumulated 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:

Accelerated Utilization of NOLs

- **Accelerate the Use of NOLs at a Discounted Rate With Proviso That All Proceeds Must Be Used For U.S.-based R&D.** This proposal would allow companies to continue research on new therapeutics and treatments for patients. These small businesses who lost money in 2008 and are currently impacted by the severe capital crunch would be able to elect a one-time advanced payment at a substantial discount of a portion of their accumulated NOLs. In exchange, such companies would permanently forgo the opportunity to use their NOLs at full value in the future. Further, all refunds would be required to be spent on U.S. R&D activities or else would be recaptured by the U.S. Treasury.
- **R&D Grant in Exchange of Discounted NOLs with Proviso That All Proceeds Must be Used for U.S.-Based R&D.** This proposal would allow small businesses to elect to receive a grant from the U.S. Treasury based upon a discounted percentage of their accumulated NOLs. In exchange, these companies would permanently forgo all accumulated NOLs attributed from R&D expenditures involved in the computation of the grant and 50% of all accumulated R&D tax credits. All grants must be reinvested in U.S. based R&D.

Investor Tax Incentives

- **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.

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.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act, which included a provision that devotes \$1.1 billion to comparative effectiveness research (CER). The legislation defines CER to focus on clinical benefit in the report language. Funding for CER is divided among the Agency for Healthcare Research Quality (AHRQ), the National Institutes of Health (NIH), and the Secretary of Health and Human Services (HHS). The legislation specifies that the funding must be spent in 18 months and creates a Federal Coordinating Council for CER, which is not permitted to make coverage or reimbursement decisions.

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, however, 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.

PARTNERSHIP TO IMPROVE PATIENT CARE (PIPC):

BIO is a member of the newly formed Partnership to Improve Patient Care (PIPC) and has a seat on its Steering Committee. PIPC is a coalition primarily comprised of patient and provider groups. The mission of PIPC is to raise awareness about the value of well-designed comparative effectiveness research, the important role of continued medical innovation as part of the solution to cost and quality challenges in healthcare, and the need to ensure that proposals to expand the government's role in CER are centered on patient and provider needs. PIPC aims to ensure that comparative effectiveness is focused on "clinical" effectiveness, and that any CER legislation preserves patient choice and innovation.

DISCUSSION POINTS & KEY PRINCIPLES:

The following are several issues decision-makers should consider in crafting policies related to comparative effectiveness and implementing the comparative effectiveness provisions in the stimulus legislation:

- **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.
- **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.**
- **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 spectra of 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.

NIH APPROPRIATIONS

Biomedical research funded by the NIH is critical to the advancement of health and medicine and has a strong positive impact on our nation’s economy.

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.

Congress deserves tremendous credit for swiftly addressing the global economic downturn through adoption of the American Recovery and Reinvestment Act, which includes an additional \$10 billion for the NIH for economic stimulus. This funding will not only provide much-needed near term benefits to our economy but also signals a welcome recommitment to invest in biomedical science that will assure a stronger economy and a better quality of life for all Americans in years to come.

It is absolutely essential that this be the first step in a long-term national commitment to stabilize medical research funding. The experience of the past decade demonstrates the problems caused by cyclical periods of rapid funding growth followed by periods of stagnation. 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, and is only able to fund one in ten meritorious research proposals, down from one in three in 2003.

Increases in NIH funding will put America's scientists to work immediately to find treatments and cures for diseases that touch far too many families across our nation. Alzheimer's, Heart disease, Parkinson's, Cancer, Diabetes are all diseases that afflict our aging population, resulting in significant economic costs and human suffering.

BIO POSITION:

BIO urges Congress to invest in our nation's biomedical research enterprise by supporting consistent growth in baseline NIH funding beginning in FY 2010. The success of biomedical research to improve technology, lower rising health care costs, and improve the health of all Americans requires that NIH funding be on a track of consistent sustainable growth in the range of 5-10% annually.

- **Stimulus funding for NIH should be the first step in making the investments necessary to improve our economy and to maintain our position in an increasingly competitive global economy.** Investment in biomedical research can create and save high paying jobs for researchers, technicians, and thousands of others who provide equipment, supplies, and services to laboratories.

- **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.** America's healthcare expenditures have been rising steadily for years and are predicted to become unsustainable over the next few decades. Technological innovation will be a key factor in addressing these rising healthcare costs.
- **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 diagnostics and treatments for many common and rare diseases that afflict our families and us.
- **Maintaining a strong publicly-funded NIH is important to America's scientific competitiveness.** America has always been the global leader in biomedical technology. However, lack of project funding hits young scientists and students the hardest, and over the past five years we have started to see some of the best and brightest young minds pursue 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:

The work of the Food and Drug Administration (FDA) touches every American in a very personal way – from ensuring the quality of the foods we serve our families to overseeing the medicines we give our children when they are sick - and BIO applauds the Congress for taking action in recent appropriations legislation to begin strengthening the FDA. We ask Congress to sustain an ongoing, multi-year commitment to restore the fiscal health of Agency and to fully modernize the FDA.

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. FDA should have the tools and resources necessary to effectively and efficiently preserve adequate standards for medical product quality.

BIO POSITION:

- **For FY10, BIO respectfully requests a total of \$2.4 billion for the Food and Drug Administration as part of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act, including an increase of \$83 million for the Human Drugs program and \$37 for the Biologics program.**
- **Reinforce FDA's Scientific Base:** FDA's scientific knowledge and expertise is essential for evaluating the safety and efficacy of medical products. However, recent assessments by Institute of Medicine, the Government Accountability Office, and the FDA's Science Board have concluded that chronic lack of federal funding in an era of
- **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. For FY10, BIO requests \$20 million for the Critical Path program.
- **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 and FY09 Consolidated Appropriations bills 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. 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

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 and sustained increases to the FDA's base appropriations.

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.

- **FDA Transparency and Accountability:** Additionally, BIO fully supports increased transparency in how new appropriated monies are spent, and clear communications from FDA about the public health benefits that have been achieved with the new funding.

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.

SBIR has always played 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.

The importance of SBIR funding for small biotechnology companies has never been more important as it is under the current economic conditions. While many industries have seen a slowdown in available investor capital, biotech has seen a near-freeze. As of January 2009, roughly one-third of public U.S. biotech companies are operating with less than six months worth of operating cash remaining. This represents a jump of

90% more companies with less than 6 months cash on hand vs. 2007. There has been a dramatic slowdown in private investments as well. This drain in financing has had a massive impact for biotechs who must continue their research and development projects but are unable to raise capital from investors. Reinstating eligibility for small biotech companies could help ensure that a generation of research and innovation is not lost.

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.

NON-INTERFERENCE

Oppose the Repeal of the Medicare Non-Interference Provision

BACKGROUND:

The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 established the “non-interference” provision, which ensures the market-based nature of Part D, which provides a prescription drug benefit to Medicare beneficiaries. Specifically, the provision prohibits the government from interfering in negotiations between private plans, pharmacies, and manufacturers, and from establishing a national formulary under Medicare Part D.

In 2007, the House passed legislation that would have repealed the non-interference clause and required the Secretary of Health and Human Services (HHS) to negotiate prices; however, the Senate did not pass this legislation. In addition, at the time, Senator Baucus offered a bill that would have repealed non-interference, but unlike the House version it gave HHS the discretion to negotiate prices.

BIO POSITION:

BIO is opposed to the removal of the non-interference clause. BIO supports market-based and consumer-oriented reforms to healthcare. Due to robust private competition, Medicare Part D is working well to generate lower costs for seniors and provide broader choice for enrollees. The 2009 average beneficiary monthly premium is 37% lower than originally projected when the benefit was established in 2003. Further, according to a recent survey, 92% of Medicare drug plan enrollees are satisfied with their plan. In addition, BIO supports negotiations, and true negotiations between private plans, pharmacies, and manufacturers have led to significant savings.

The Congressional Budget Office (CBO) has stated that in order to generate any real savings, the Secretary of HHS would have to restrict access to innovative therapies. The Secretary would have to use his public position as a bully pulpit, essentially bullying manufacturers to offer additional discounts or rebates. Therefore, the Secretary does not “negotiate”, but rather dictates drug prices through statutory price controls and restricted access.



FOOD & AGRICULTURE

AGRICULTURAL BIOTECHNOLOGY: INCREASED SUSTAINABILITY WITH SCIENCE BASED SOLUTIONS

Biotechnology Is Sustainable Agriculture

BACKGROUND:

Crops improved through biotechnology have been adopted by farmers in the United States and around the world at rates never before seen by any other advances in the history of agriculture. From the first significant commercial plantings in 1996, significant growth in each subsequent year has led to more than 309 million acres of biotech crops planted in 2008 in 25 countries¹. These crops are grown by 13.3 million farmers — 12.3 million of whom are small-scale farmers in 15 developing countries.

The reason for such impressive adoption rates is simple — agricultural biotechnology delivers significant and tangible benefits, all the way from farm to fork. Helping to provide for more sustainable agricultural production, the benefits include a reduction in the environmental impacts of agriculture, increased production on the same amount of acreage, improved food quality, and increased farmer incomes.

The 1990 Farm Bill defines sustainable agriculture as “An integrated system of plant and animal production practices having a site-specific application that will over the longer term:

- Satisfy human food and fiber needs;
- Enhance environmental quality and the natural resource base upon which the agriculture economy depends;
- Make the most efficient use of non-renewable resources and on-farm resources and integrate where appropriate, natural biological cycles and controls;
- Sustain the economic viability of farm operations;
- Enhance the quality of life for farmers and society as a whole.”

Source: USC Title 7, Section 3101

Agricultural biotechnology has helped enable large shifts in agronomic practices that have led to significant and widespread environmental benefits. No-till agriculture², in limited use prior to 1996, has been widely adopted due to the superior weed control from biotech crops that are able to tolerate herbicides with low environmental impacts. This has led to improved soil health and water retention, reduced runoff, and reduced greenhouse gas emissions from agriculture. Peer-reviewed scientific studies have repeatedly found biotech varieties to be much friendlier to the environment and more sustainable than other production systems.

BIO POSITION:

Biotechnology helps achieve plant and animal production practices that provide for more sustainable agricultural production.

¹ James, Clive. February 2009. *Global Status of Commercialized Biotech/GM Crops: 2008*. International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

² No-till agriculture seeks to conserve topsoil and moisture while reducing erosion by avoiding the use of plowing for weed control.

DISCUSSION POINTS:

Biotechnology supports the USDA definition of sustainability by:

- Enhancing crop production for sustainable food, feed, fiber and fuel supplies;
- Promoting resource conservation and energy efficiency;
- Reducing the environmental footprint of agriculture;
- Improving economic viability for farmers and communities; and
- Advancing product safety.

INCREASED PRODUCTIVITY

- Biotechnology contributes to increasing crop yields worldwide. Higher-yielding crops can help feed more people and boost incomes for poor farmers.
- Between 1996 and 2007, biotechnology contributed to corn yield increases of 33 percent and soybean yield increases of 17 percent.
- Yield increases are estimated to double by 2030 due to agricultural biotechnology.

ENVIRONMENTAL BENEFITS

- Pesticide applications have been reduced by 630 million pounds (1996-2006).
- No till farming increased by 35 percent (1996-2002).
- Fuel consumption savings equaled 551 million gallons (1996-2006).

ANIMAL BIOTECHNOLOGY

- Animal cloning and animal biotechnology provide solutions for public health through biomedical, food and environmental benefits.

**BIOTECHNOLOGY
PRODUCT LABELING**

Labeling: Mandatory labeling of products derived from biotechnology is misleading and not justified.

BACKGROUND:

U.S. food labeling requirements are appropriately science-based to give consumers meaningful information about the foods we buy and eat.

U.S. law limits affirmative labeling requirements for food to situations where there is a scientifically-valid and constitutionally-reasonable rationale for protecting the public, such as making nutrition information available to promote healthy food choices or warning about a common food allergen to protect susceptible populations.

Therefore, under current statutes and regulations of the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), changes to foods require labeling **only if the product has been significantly changed nutritionally or if there have been changes in other health-related characteristics of the food (allergenicity, toxicity, or composition).**

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 other 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 POSITION:

BIO supports the current law and regulations administered by FDA and USDA that require food labeling to be truthful and not misleading. Food labeling must also be consistent with U.S. international obligations.

DISCUSSION POINTS:

For foods derived from biotechnology, BIO supports FDA and USDA labeling policies including:

- No label is 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

Achieving the jobs and security potential of the Renewable Fuel Standard will require a major coordinated federal investment in advanced biofuels and biobased products

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. Of this, 21 billion gallons must come from cellulosic biomass or use other advanced biotechnologies. Advanced biofuels production under the RFS has the potential to create hundreds of thousands of new jobs, substantially reduce U.S. dependence on imported petroleum, and cut greenhouse gas emissions from the transportation sector.

The technology to begin commercial production of advanced biofuels is ready now, but the current economic crisis and low petroleum prices pose a serious threat to this emerging industry. To achieve the economic, energy security, and environmental potential of the RFS, a major coordinated federal investment in advanced biofuels and biobased products is needed.

BIO POSITION:

To realize the critical benefits mentioned above, a major federal investment in the entire value chain of advanced biofuels and biobased products commercialization is needed to move advanced biofuels and emerging biobased materials to market, including research, development, demonstration and deploy-

ment. Areas requiring major investment include but are not limited to: enzymes and fermentation organisms, feedstock development, collection, delivery and transportation of feedstocks and products, pre-processing technologies, alternative fuel distribution networks and vehicles, and biorefinery construction. A broad set of policies, including grants, loans, loan guarantees and tax incentives should be made available to assist a broad range of technology developers and business models.

We also must work towards advancing the concept of the biorefinery beyond biofuels. An integrated biorefinery uses renewable feedstocks and co-products to replace petroleum feedstocks to create several products, including fuels, chemicals, fibers and plastics. The modern biorefinery will aid in reducing our oil consumption and therefore our dependence on oil for products and fuels.

IN GENERAL:

The economic, energy security, and environmental potential of the Renewable Fuel Standard (RFS) is achievable with the help of biotechnology, but a major coordinated federal investment is needed.

Specific policies required to achieve these objectives are:

1) Inject Immediate Capital for Biorefinery Construction, Cellulosic Feedstock Development, and Fuel Delivery Infrastructure

- Boost funding and quickly issue loans and loan guarantees for biorefinery construction

- DOE Biorefinery Loan Guarantees (2009 Stimulus / 2005 EAct Sec. 1705)
- USDA Biorefinery Assistance Program (2008 Farm Bill Sec. 9003)
- Initiate demonstration projects throughout the country for the establishment, production, harvest, collection, storage and transportation of cellulosic feedstocks
 - Expedite Biomass Crop Assistance Program (BCAP) (2008 Farm Bill Sec. 9011)
- Major investment in fuel delivery infrastructure
 - Fund rail expansion, construction of blending facilities, E85 fuel pumps and flex fuel vehicles

2) Ensure Strong Market for Advanced Biofuels

- Maintain Renewable Fuels Standard (RFS) (2007 EISA Sec. 202)
- Address blend wall
 - Certify higher ethanol blends
- Extend cellulosic producer tax credit
 - Extend Section 40 Cellulosic Biofuel Production Tax Credit through 2017 (currently set to expire 12/31/2011)
- Fund DOE Reverse Auction for first 1 billion gallons of cellulosic biofuel
 - Authorized under 2005 EAct Sec. 942; NOPR public comment concluded Jan 2009

3) Incentivize the Full Range of Biorefinery Products

- Ensure renewable chemicals and biobased products facilities are eligible for biomass R&D and biorefinery grant/loan programs
 - Some programs, such as DOE Biorefinery Loan Guarantees are restricted to fuels only
- Create production tax credit for manufacture of advanced biobased chemicals and products
- Aggressively fund and implement USDA Biobased Markets Program (2008 Farm Bill Sec. 9002)

4) Aggressively Fund Ongoing RD&D to Maximize Economic Competitiveness, Sustainability and GHG benefits of Advanced Biofuels and Biobased Products

- Maintain Stimulus-Level Funding for Biomass and Biorefinery RD&D and Commercialization Through the DOE Bioenergy Program (2005 EAct Sec. 932)
 - Received \$800 million increase in 2009 Stimulus Bill, maintain this level through 2017
- USDA Biomass R&D Program (2008 Farm Bill Sec. 9008)
 - Match DOE R&D funding to ensure adequate cellulosic feedstock development
- Aggressively fund research to maximize the sustainability of biofuels and biobased products

DISCUSSION POINTS:

Direct Job Creation

The advanced biofuels industry has the potential to be an unparalleled jobs engine:

- Advanced biofuel production under the RFS would create over 800,000 new jobs through 2022 – potentially more than all other renewables and additional petroleum production combined.
 - Direct job creation from biorefineries producing advanced biofuels could reach 29,000 by 2012, 94,000 by 2016, and 190,000 by 2022.
 - Total job creation, accounting for economic multiplier effects, could reach 123,000 in 2012, 383,000 in 2016, and 807,000 by 2022.
 - Advanced biofuels production under the RFS could reduce U.S. petroleum imports by approximately \$5.5 billion in 2012, \$23 billion in 2016, and nearly \$70 billion by 2022.
- Advanced biofuels could generate more than \$20 billion in annual economic activity within a few years and as much as \$300 billion by 2030.
 - Direct annual contribution to U.S. economic growth will be felt quickly; it is estimated to rise to \$5.5 billion in 2012, \$17.4 billion in 2016, and \$37 billion by 2022.

- Taking into consideration the indirect and induced economic effects, the total economic output effect for the U.S. economy is estimated to be \$20.2 billion in 2012, \$64.2 billion in 2016, and \$148.7 billion in 2022.

Assisting Private Lending through market creation, production incentives and commercialization

The technology for cellulosic and other advanced biofuels is ready, but because of the downturn in the economy, developers are having severe trouble getting private capital:

- Over 30 advanced biofuels projects are currently underway or planned, but due to the difficult lending climate the country is facing, many projects are unable to move forward. A major injection of capital funding is required. Strong funding and rapid deployment of DOE and USDA biorefinery grant and loan guarantee programs is critical.
- A strong market for these next generation fuels is also required. Strong, continued support for the RFS, certification of higher ethanol blends, and production incentives for advanced biofuels will help ensure this market.
- The cellulosic biofuels tax credit, currently set to expire at the end of 2011, needs to be extended at least 5 years to encourage investment in production facilities that require up to 3 years to construct.
- In order to align federal regulatory requirements for making advanced biofuels projects “shovel-ready”, the industry needs streamlined permitting for advanced biorefineries.

Incentivize the Full Range of Biorefinery Products

To achieve the full potential of advanced biofuels, we must also invest in the full range of renewable chemicals and biobased products that will come from the biorefinery of the future:

- Renewable chemicals and biobased products should be made eligible for biomass R&D biorefinery grant/loan programs. These products – made from renewable biomass feedstocks instead of petroleum – are critical to the economic competitiveness of biorefineries, and deliver the same economic, energy security and greenhouse gas benefits as biofuels. They deserve federal support.

- A new production tax credit for manufacture of renewable chemicals and biobased materials would provide the market driver necessary to help these pioneering products compete with conventional petroleum-based alternatives in the early years.
- A strong USDA Biobased Markets Program is also needed to provide preferred federal procurement and a robust Biobased Labeling program.

Strong Funding for Ongoing RD&D Is Also Required

Ongoing research, development and demonstration is critical for the biofuels and biobased products industries to expedite innovation and technology advancement:

- Continued R&D on next generation feedstocks and conversion technologies is needed to ensure the continued advancement of biofuels and biobased materials production, and to maximize their economic competitiveness, sustainability and greenhouse gas benefits.

Climate/Greenhouse Gas Reduction

Ethanol production efficiency and environmental profile are improving rapidly:

- The cumulative total of avoided petroleum imports over the period 2010–2022 would exceed \$350 billion.
- Biomass for up to 90 billion gallons of advanced biofuels can be produced without displacing food or feed production.
- 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.

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



INTELLECTUAL PROPERTY

PATENT REFORM

Improve the U.S. Patent System, but Don't Weaken U.S. Innovation and Economic Growth

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 efficiency, objectivity, predictability, and transparency of the patent system. BIO believes that much of the needed reforms should take place at the front-end of the patent examination process within the United States Patent and Trademark Office (PTO).

IN GENERAL:

A strong patent system encourages collaborations that result in the 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 inventions.

Patents are key to biotechnology investment and product development. This is even more true in today's difficult economic climate. Because the majority of biotechnology companies have no products on the market, they leverage their patent assets to generate funding for their research and development activities. Despite the uncertainty of biotech innovation and the decades of capital-intensive investment and research efforts, the promise of biotechnology coupled with the hope of a return on the investment provided by patents attracts billions of dollars of investments every year. Without strong and predictable protections for biotech inventions, investors will shy away from investing in biotechnology, 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 PTO is reporting marked improvement in the quality of patents issued, demonstrating a more rigorous process of patent examination.¹ The PTO

¹ PTO Performance and Accountability Report for Fiscal Year 2007.

“allowance” rate has declined by about 40 percent since 1998.

- While any system will need to be modified over time, 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. For example:

- **Damages:** *Lucent v. Gateway*: this case is currently on appeal in the Court of Appeals for the Federal Circuit. It deals with the standards for calculating a reasonable royalty where the patented element is only a small part of the overall infringing product. The case will likely be decided this summer.
- **Business method patents:** The Federal Circuit, *In Re Bilski*, basically eliminated much-maligned patents on disembodied business methods.
- **Venue abuses:** The Federal Circuit in the *TS Tech* case recently compelled courts to start transferring more patent cases to other district courts in more appropriate locations.
- **Willful infringement:** Under the Federal Circuit’s *Seagate* decision, willfulness is now a much more circumscribed doctrine that is harder to establish in litigation.
- **Obviousness:** In *KSR*, the Supreme Court made it easier for the PTO to reject applications on combination inventions, and for defendants to prevail on an obviousness defense against asserted patents.
- **Licensor-licensee relationship:** In *Medimmune*, the Supreme Court provided new avenues under which businesses which are on the receiving end of aggressive licensing invitations can go to court. In *Quanta*, the Supreme Court constrained a patent owner’s ability to collect royalties from downstream users of its licensed invention.
- **Infringement liability for exported software:** In the *Microsoft v. AT&T* case, the Supreme Court eliminated infringement liability for exported software that is loaded on computers abroad.
- **Permanent injunctions and “hold-up” by “predatory” patent owners:** In the *eBay* case, the

Supreme Court made it harder for non-practicing patent holders to permanently enjoin infringers.

- BIO recognizes that there is room for improvement and there is much consensus about ways to further improve the patent system by making it less subjective and more predictable.
- However, The Patent Reform Act of 2009 goes *too far in some critical areas* –
 - It goes *too far* in attempting to change the law on damages. That legislation would have made it easier for competitors to infringe by decreasing royalty awards in many cases and thus would devalue patent assets.
 - It goes *too far* in creating an administrative review regime that would permit multiple challenges to a patent on a broad range of grounds throughout the life of the patent, creating unpredictability in patent rights and thus great uncertainty for investors.
 - It goes *too far* in restricting the ability of patent owners to sue infringers even when patent owners have a substantial nexus to the judicial jurisdiction selected for suit.
- The legislation does **not go far enough** with respect to inequitable conduct and best mode reform, as urged by the National Academies of Science 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.

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.

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.

BIO

1201 Maryland Avenue, SW
Suite 900
Washington, DC 20024
PHONE 202.962.9200
FAX 202.488.6301
www.bio.org



1201 Maryland Avenue, SW
Suite 900
Washington, DC 20024
PHONE 202.962.9200
FAX 202.488.6301
www.bio.org

