



January 15, 2004

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The Honorable George W. Bush
President of the United States
The White House
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Dear President Bush:

The United States is the world leader in biotechnology research and development. Maintaining that edge is important to the U.S. economy. As we face this new year, it is critical that we make certain the industry remains the world leader, bringing the benefits of biotechnology to those most in need. The Biotechnology Industry Organization (BIO) represents more than 1,000 biotechnology members engaged in research and product development for health care, agriculture, environmental protection, industrial applications and homeland defense.

As you noted last June in your speech to our annual convention, our industry is poised to protect our nation's security, provide food for the hungry, and cure disease. Each sector of our industry and application of biotechnology holds the promise of improving the human condition.

As president of BIO, I have prepared the following outline of our 2004 legislative priorities for the second session of the 108th Congress as well as regulatory matters before your Administration.

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As your Administration and the new Congress join forces to confront an array of economic, health, technology, security, energy and environmental challenges – many of them almost unimaginable when you took office three years ago – please consider the legislative and regulatory needs of a emerging biotechnology industry that will be essential to meeting those challenges in the coming years.

Medicare- BIO congratulates the Administration on the passage of the Medicare Prescription Drug, Improvement and Modernization Act (MPDIMA) of 2003. BIO supported passage of this historic legislation and looks forward to working with the Administration as it implements MPDIMA. One provision—section 303—in the bill is of immediate concern.

Congress sought to address concerns about reimbursement for prescription drugs administered in the physician office under section 303 of MPDIMA. Unfortunately, in 2004 there is a different reimbursement structure applied to some drugs and biologics for no rational reason. BIO believes that any reimbursement differentials for drugs and biologics administered by physicians should be based on policy grounds; what is best for the patient rather than payment differentials that may incentivize the use particular products based on reimbursement levels. This unfair policy should be corrected.

With regard to payment reform of Medicare Part B under MPDIMA, BIO appreciates Congress' efforts to implement a reimbursement system that accurately reflects the acquisition cost of drugs and biologics to providers. The key to the success or failure of this reimbursement methodology, however, will be whether or not Medicare beneficiaries continue to have access to important drugs and biologicals in the physician office. BIO is hopeful that physicians will find that the combination of improvements to the practice expense methodology for their reimbursement and the new “Average Sales Price” (ASP) or Wholesale Acquisition Cost (WAC) systems will prove to be adequate to ensure patient access.

Importation- Throughout the Congressional debate on so-called drug importation, BIO's first priority has been to maintain the safety of the US drug supply. We believe that no one would benefit if existing consumer safety standards were undermined by lax border controls.

BIO applauds the Administration and Congress for continuing to require certification from the Secretary of HHS before the new importation provisions enacted as a part of MPDIMA may take effect. As you know, under the certification requirement in an importation law passed by Congress in 2000, neither Secretary Thompson, nor Secretary Shalala before him, were able to certify the safety and savings to Congress. Continuing to require this certification will help to ensure that public health and safety are not jeopardized by the importation into the U.S. of, for example, counterfeit or adulterated pharmaceuticals.

BIO also strongly supports the exclusion from the importation provisions of controlled substances as well as biologics and other products that need to be carefully produced, stored, and shipped.

Appropriations- There are a number of appropriations issues of importance to BIO. Three priority areas include funding for FDA, NIH and the USDA/APHIS programs. With respect to the FDA, it is critical that Congress swiftly authorizes appropriations for the FDA. Increases in user fees authorized through the renewal of the Prescription Drug User Fee Act (PDUFA) were intended to bring FDA's approval process back to sound financial footing. Without continued and new appropriations, the FDA will be unable to advance many important initiatives agreed to as part of the PDUFA legislation and the accompanying "goals letter."

Also, as you are aware, the regulatory responsibility, review, and oversight for many biologic therapeutic products were recently transferred to the Center for Drug Evaluation and Research (CDER). While it is important that CDER have the staffing and financial resources to fulfill its new mission, it is imperative that the Center for Biologics Evaluation and Research (CBER) is funded at a level that allows its work to continue uninhibited. CBER maintains its responsibility to provide the regulatory review and oversight for vaccines, *in vitro* diagnostics,

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blood, blood components and related products, allergenics, gene therapy, and toxoids. BIO believes that it is vital that both CDER and CBER continue to be funded at appropriate levels.

At the USDA, the rapidly expanding role of the Biotechnology Regulatory Service within the agency requires critical funding support. Furthermore, the regulatory responsibility, review, and oversight for products of agricultural biotechnology must continue aggressively and unimpeded in the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

Intellectual Property- Strong, predictable and timely intellectual property protection is essential for the success of the biotechnology industry, particularly in light of the industry's need to generate hundreds of millions of dollars of investment capital over decades. For most biotech companies, their intellectual property serves as their key assets with which to generate investment and advance R&D.

We are concerned however, that the severely under-funded U.S. Patent and Trademark Office (PTO) may not be able to meet the demands of our industry's future innovation. One way to ensure that the PTO has the funding it needs to play its critical role in supporting America's research-based business sector is to urge Congress to eliminate the diversion of patent applicants' user fees to other programs. We also urge the PTO to discontinue its outdated practice of requiring separate applications for the same basic invention.

Recently, the Federal Trade Commission (FTC) published a report on competition and patent policy that details recommendations for patent reform many of which will require legislative action. Some of the FTC's recommendations would dramatically weaken patent protections in this country. We urge your administration to take into account the U.S. Government's appropriate stance on strong intellectual property protections in the TRIPS Agreement as you consider any future patent reform. Moreover, we point out that patent law reform will require substantial debate and input from all stakeholders and should be addressed through the appropriate Congressional committees.

Finally, effective patent protection is as important in the global marketplace as it is in this country. Any attempts to undermine U.S. law or worldwide standards for intellectual property protection – such as requiring compulsory licensing, enacting unreasonable patent disclosure requirements, or allowing countries to bypass valid patents entirely – have the potential to cause great harm to the biotechnology industry.

Capital Formation- There are nearly 1,500 biotechnology companies in the U.S. that have produced 187 FDA-approved products. Another 350 biotech drug products and vaccines are currently in clinical trials. On average, it takes these researchers more than 10 years and \$800 million to develop a new biotech therapy. The overwhelming majority of the firms engaged in this highly capital-intensive research are small to medium sized companies. These factors combine to create an industry structure that is relatively unique in our economic history.

This structure - as well as a natural outgrowth of economic circumstances - makes the biotech industry vulnerable to unintended consequences of tax policies originally designed to encourage research in more common industrial models. Specifically, current tax treatment of net operating loss carry forwards (NOLs) impairs, rather than fosters, biotechnology research in significant ways.

These rules could be improved through enactment of legislation to encourage further investment in this vital sector. On July 25, 2003, “The Biotechnology Future Investment Act of 2003” (H.R. 2968) was introduced in the House. Companion legislation, S. 1773, was introduced in the Senate on October 22, 2003.

SBIR- The Small Business Innovation Research (SBIR) program allocates a specific percentage of all federal research and development grant monies to small businesses. The program provides the critical "seed" money to entrepreneurs, spurring development and the creation of new jobs within the biotech industry. However, due to the Small Business Administration's (SBA) reinterpretation of the SBIR program's eligibility requirements, promising young biotech companies that have proved worthy of venture capital investment will no longer have access to these important SBIR grants.

Consistent with the program's emphasis on attracting venture capital investment to SBIR companies, the grants demonstrate the potential these biotech companies have to continue their research and create new jobs. Clearly, there is no justification for the SBA to suddenly change its interpretation of the SBIR eligibility standards that have a proven track record of serving the nation's most enterprising small firms so well.

Orphan Drug Tax Credit- In recognition of the 20 million Americans who suffer from one of over 5,000 rare diseases and medical disorders, the Congress enacted the Orphan Drug Tax Credit in 1983 in order to encourage biotechnology and pharmaceutical companies to develop therapies for rare diseases and conditions that affect 200,000 or fewer patients. The credit, which was made permanent in 1996, applies to 50% of qualified clinical trial expenses incurred with respect to designated orphan drugs. By reducing the costs of developing drugs for small patient populations, the credit allows companies to develop products that would otherwise be commercially unfeasible.

However, the Orphan Drug Tax Credit only applies to qualified clinical trial expenses that are incurred *after* the FDA officially designates the drug as an "orphan." Many companies, especially small biotech firms, must wait for orphan drug designation before initiating their clinical trials in order to obtain the full benefit of the credit and minimize the effective cost of developing the product. Starting clinical trials before orphan drug designation would make products available to patients earlier, but needlessly increases costs by denying the tax credit for otherwise eligible expenses. BIO applauds the Administration for including a correction to this problem in the FY2004 budget, as well as Rep. Kevin Brady (R-TX), whose legislation (H.R. 2931) addressing this issue was included in H.R. 1308, the "Tax Relief, Simplification, and Equity Act of 2003."

Stock Options- Most biotechnology companies utilize stock options to leverage tight payroll budgets and attract talent as these early-stage companies typically have little or no revenue until their first product is approved for sale. BIO opposes stock option expensing because it would force biotech companies to reduce the number of stock options issued to rank-and-file employees in order to

maintain growth in reported earnings or control losses. Further, many of the accounting options for expensing are inappropriate for valuing employee stock options issued by emerging companies with volatile stocks.

Homeland Security- BIO applauds the Administration and Congress for working towards enacting legislation that would facilitate the development and procurement of biodefense agents. In providing the necessary resources for government to prepare for, and combat acts of terrorism, one of the resources that will likely be sought is the innovation and technological insight of the biotechnology industry. Many of BIO's companies are at the forefront in developing products that could be called upon to head off a possible biological attack on the United States. In addition, our industry is uniquely poised to provide cutting edge technologies that can be developed for detection and prevention diagnostics. As we move forward, BIO strongly urges the Administration and Congress to enact Project Bioshield, and ensure liability protection for companies that work to develop and produce vaccines, therapeutics, and diagnostics to combat acts of terrorism. Without adequate liability protection, the fear of losing their economic viability will prevent most, if not all, biotechnology companies from developing and manufacturing these products.

Animal and Domestic Terrorism- In support of your Administration's commitment to fight all forms of terrorism, we strongly urge you to provide federal law enforcement with the necessary legal tools and financial support to stem the growing wave of terrorist violence -- lead by animal rights and environmental activists -- against the US biotechnology industry. Since spring of 2003, a number of biotechnology and pharmaceutical companies have come under attack from these eco-terrorists. Their campaigns, aided by the improved technology of the Internet, have gone well beyond harassment of scientists and corporate executives. Animal rights terrorists have engaged in bombings of research facilities, harassment of the children of biotech executives in their schools, and vandalism of personal property. Their campaign against biotechnology companies is strategic, specific, unrelenting and directed toward delivering economic, and sometimes physical, damage to companies engaged in innovation for life-threatening diseases such as cancer and cystic fibrosis. BIO believes that it is imperative for the Administration and Congress to take steps necessary to halt these activities.

Agricultural Biotechnology- The principal challenge facing agricultural biotechnology is to maintain and expand our ability to develop and export U.S. agricultural products worldwide.

Adventitious Presence - Freedom to operate is limited by numerous factors, but the principal obstacle is the absence of a rational U.S. policy regarding adventitious presence. In the absence of such a policy, industry must contend with a *de facto* tolerance threshold of zero. This is completely contrary to what is done with any other biological production system, and cannot be sustained or justified scientifically. But until U.S. regulatory authorities adopt a defensible, science-based approach such as that proposed by BIO, we can anticipate increasingly common and severe disruptions of U.S. agricultural exports.

Liability - The absence of both an AP policy and a mandatory food safety review process at FDA has led to increased liability issues for our industry. For example, a growing number of insurance companies are now excluding coverage of crops improved through the use of biotechnology for grain facilities and farmers. Until a rational policy is established for these issues, the situation will grow worse. This affects our member companies' freedom to operate both domestically and internationally.

International Trade - Internationally, there is minimal coordination and consistency in policy across federal agencies on issues ranging from the Biosafety Protocol, Codex Alimentarius, WTO and WIPO. Important international meetings will be taking place in 2004 and the United States needs to have well-articulated and coordinated policies on the issues important to our industry.

USDA Preferred Purchasing Program- BIO supports a strong implementation of Section 9002 of H.R. 2646, the Farm Security and Rural Investment Act of 2002. We strongly support a rule that provides for the success of real sustainable markets for these important products. A biobased product purchasing preference system should be an aid to market development; it should

not be a barrier through over analysis. We believe the department should consider taking an approach that incorporates three key elements. These elements include development of standard formulas for calculating biobased content, the development of biobased content label (somewhat like the new organic labeling system) for ease of product comparison, and, for the benefit of government and private purchasing managers, the publication of regularly updated product bulletins reporting the latest in biobased product availability.

Energy- BIO strongly supports passage of H.R. 6, the Energy Policy Act of 2003. Specifically we support the provisions relating to bioenergy contained in the Research and Development title (Title IX) and the Ethanol and Motor Fuels title (Title XV). Advances in biotechnology continue to expand uses into all sectors of the economy. One of the more recent applications is the production of energy and other products that reduce our dependence on foreign energy supplies, increase economic development in rural areas and help protect the environment. The bioenergy program is a program designed to advance technologies that will make biofuels competitive with gasoline or diesel fuel, with a particular emphasis on the advancement of enzyme-based processing systems and advanced biorefineries.

Liability- BIO appreciates the Administration's support for legislation to bring much needed reform to the current medical malpractice liability system. BIO's companies are at the forefront of efforts to develop improved drug delivery technology, new and more effective formulations, and new drug combinations that will offer significant opportunities to address unmet medical needs. Today America's biotechnology industry is the world leader in innovation and job creation in the biosciences. That innovation and US competitive edge is endangered by predatory litigation and frivolous lawsuits.

BIO looks forward to working with the Administration and Congress to enact a balanced federal policy to ensure that biotech companies are not held hostage to unfettered litigation, shifting resources from the biomedical bench to the judge's bench. Given the impact on patient access to medical care and the overall cost to biotech research and development cost, the time is now to pass strong medical malpractice liability reform.

Regenerative Medicines- Scientists continue to demonstrate the enormous potential of stem cell research. Advances in both adult and embryonic stem cell research could lead to therapies to treat a variety of diseases including cancer, diabetes, Alzheimer's disease and Parkinson's disease. While we are directly opposed to cloning for reproductive purposes, we strongly believe that use of nuclear transfer for research purposes (so-called "therapeutic cloning") must be allowed to continue.

Genetic Discrimination- Our nation is on the cusp of reaping the rewards from our significant investment in biomedical research. Using genetic information, biotech researchers will continue to learn about the causes and progression of disease and disability. However, if the public believes that genetic information will lead to denial of health insurance or other benefits, they will not seek these new diagnostics and treatments.

BIO supports federal legislation that would prohibit health insurers from denying insurance to individuals based on genetic information. At the same time, genomic research must advance. We are pleased you have announced your support for anti-discrimination legislation. BIO stands ready to work with you and the Congress to develop a proposal that will protect patients' rights while allowing important medical research to go forward.

Global Health- The developing world is facing a dramatic public health crisis as diseases such as HIV/AIDS, malaria, and tuberculosis are devastating the populations of many countries. Recent studies have concluded that biotechnology could dramatically improve health in these nations. BIO will work with the Administration and the Congress to develop policies that would provide incentives and resulting markets for companies to develop and distribute products to help cure and treat neglected diseases in the developing world.

Medicaid- BIO believes that the first priority of state Medicaid programs should be to continue to provide access to the full range of medically necessary treatments, without Medicaid officials requiring them to treat the patient with a less costly, less effective option. Programs that deny access to care are putting patients' lives at stake and are very likely violating federal law.

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Additionally, Medicaid rebates should support drug coverage. The Medicaid rebate program gives manufacturers a role in sharing state and federal Medicaid costs of providing drug coverage to the most needy citizens. Although we fully support this goal, we cannot support efforts that would undermine the program by requiring additional rebates as a mandatory “tax” that the state can use to provide discounts to citizens not eligible for Medicaid.

The Uninsured – Studies have shown that Americans who lack insurance coverage often delay seeking medical care. As a result, such individuals tend to be sicker and die at an earlier age than those with health coverage. This is a pressing national issue. America’s biotechnology companies are on the forefront of developing new and innovative treatment for unmet medical needs. We stand ready to work with your Administration and the Congress to explore workable approaches to providing more Americans with health coverage and access to the latest innovations in medical treatment.

We look forward to working with you, your Administration and the Congress in 2004 on these significant issues. If your staff has any questions, please contact me or Sharon Cohen, Vice President, Government Relations at (202)-962-9200.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl B. Feldbaum". The signature is fluid and cursive, with a long horizontal stroke at the end.

Carl B. Feldbaum
President
Biotechnology Industry Organization

CBF:sc
cc: U.S. Congress