



**PRESIDENT OBAMA,
THE 111TH CONGRESS,
AND BIOTECHNOLOGY:**

**WORKING TOGETHER TODAY
TO ENSURE A HEALTHY TOMORROW**



A Massachusetts Biotechnology Council White Paper

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**A MESSAGE FROM MASSACHUSETTS BIOTECHNOLOGY COUNCIL
PRESIDENT AND CEO ROBERT COUGHLIN**

As President Obama and the 111th Congress set out on an historic mission to find remedies for these troubled times, they are not alone. Among others, the biotechnology community – including members of the Massachusetts Biotechnology Council – is right there as well, continuing to do its part for a healthier, cleaner, safer, more prosperous nation and planet.

By its nature, biotechnology is about getting to the root of and solving difficult problems in novel and innovative ways. As a life science, biotechnology operates down to the molecular level, where causes of disease are generally found so they can be treated. As a business, biotechnology has made a difference by applying its breakthrough science to address vast unmet medical needs and other complex challenges.

Biotechnology brings problem solving to the contemporary policy arena, also. In the health care reform discussion, for example, we will make a strong case for the value biotechnology adds to the health care equation. Our cutting edge products improve the length and quality of life, enable patients to avoid extended stays in medical facilities, and can result in significant cost savings. These are all key considerations, as lawmakers seek to expand health care coverage in ways that both promote quality and are fiscally sustainable.

Listed at the conclusion of this paper are biotechnology's accomplishments to date, the fruits of its first generation. While the numbers are impressive by themselves - hundreds of biotech products already approved, thousands more in the pipeline – we must also realize that these aggregate statistics actually represent individual patients and their loved ones who have benefited from biotechnology.

Accordingly, the patients who rely upon the great work our member companies engage in on a daily basis must be in the forefront in all our endeavors. The ongoing needs of individuals struggling with disease are so important that we are making the patient community the prime focus of our organizational efforts in 2009. We are mindful that we share this focus with our leaders in Washington, and we are compelled to work together on the behalf and for ultimate benefit of the patient population.

There are a number of synergies that should ease this task. President Barack Obama and the new Congress were swept into office by lifting hopes and promising change. Hope for change provides a source of courage for patients and inspiration for biotechnology workers each day as they face their respective challenges in seeking cures. Joining together, the President, Congress and members of the biotechnology community can set change in motion, and help put hope into action.

Thank you for reading on to what we trust is a clear roadmap for reaching desirable public policy destinations successfully together.



Robert K. Coughlin – President & CEO
Massachusetts Biotechnology Council

FEDERAL POLICY AND THE BIOTECHNOLOGY INDUSTRY - AN INTRODUCTION

Government leaders in the United States have long held an avid interest in biotechnology, and with good reason. By harnessing breakthroughs in advanced biology and chemistry to innovative processes for developing and manufacturing products, biotechnology is positioned to deliver solutions for problems policy makers engage in every day, such as disease, hunger, pollution and the energy crisis.

There are other compelling reasons why Washington should care about biotechnology:

- *It is one of the few major industrial sectors that our nation presently dominates, with three-quarters of global biotech research and investment and more than half its manufacturing occurring in the United States.*
- US biotech revenues constitute 76% of global biotech revenues. (\$48 b of \$63 b)
- The average annual salary in the biotech industry is \$72K, 86% higher than the average US private sector wage
- The US biosciences community (public and private) employs 1.2 million people directly and another 5.8 million indirectly.

Biotechnology in turn is intently interested in government. From the laboratory bench to the patient bedside, biotechnology is heavily regulated by and closely interacts with government each step of the way, as the sector undertakes the long arduous task of commercializing basic academic research.

Because biotechnology is a sector that is involved with the health and well-being of humans and other living things, we recognize that government has an appropriate role to play in the oversight of our industry. Indeed, this industry is unique in that it has consistently called for stronger and more sensible authority and increased funding for its lead regulator, the Food and Drug Administration (FDA). We all benefit from a system committed to the rigorous, science-based review and timely approval of cutting-edge products that are safe, effective, and address unmet medical and/or other socio-economic needs.

On the other hand, there are no benefits from laws and regulations that discourage and stifle innovation, make it difficult for scientists to pursue discovery, impede companies' ability to raise the massive amounts of capital needed to commercialize promising research, preclude patient access to state-of-the art therapies or that otherwise detract from biotechnology's ability to perform and meet its maximum potential.

Fortunately, this is a sector that was built with the help of visionary public policies, factors still widely recognized and understood more than a quarter of a century after biotechnology's birth. From the groundbreaking Bayh–Dole Act to the doubling of the National Institutes of Health's (NIH) budget, from passage of the Orphan Drug Act to creation of the Medicare Part D drug benefit, the best policies have sought both to promote innovation and to share as widely as possible the fruits of American scientific ingenuity and commercial enterprise.

Let us continue to journey together down avenues of hope and innovation, guided by humane and visionary leaders committed to sound public policy. We look forward to working with President Obama, the 111th Congress, their staffs, the American people and all other stakeholders to realize our mutual goals for the common good.

THE MBC FEDERAL AGENDA: SUMMARY OF IMPACT ISSUES

The following section outlines key impact issues affecting the biotechnology and life sciences sectors and offers a brief description of our position on each. In their resolution, all issues listed here hold great potential to influence – either positively or negatively - the climate necessary for our members and others in biotechnology nationwide to achieve success. That climate, in turn, determines whether our members and our colleagues across the country can help promote the public good by bringing new innovative products to patients safely, expeditiously, and equitably.

The MBC impact issues agenda, while comprehensive, is listed here in no absolute order of priority, as given the diversity of the biotechnology sector certain issues will have a different resonance for different segments of our membership. The biotechnology sector is actually an amalgam of organizations, among them universities, teaching hospitals, small to mid-sized companies spun out of academic settings, and large-cap companies that are global leaders in biotechnology R&D and biopharmaceutical manufacturing. The issues agenda reflects that diversity, and may be incomplete. The MBC is committed to advocating for all of our members and their interests equally.

There are a number of common threads running throughout the MBC impact issues agenda. Notably, all have to do with innovation and progress in one way or another. All ultimately affect patients, their families and communities, and quality of life. For those who have placed faith and hope in a brighter future – from patients and pensioners to society as a whole – the stakes are high and so are expectations that biotechnology can continue to succeed.

The MBC 2009 – 2010 federal policy agenda encompasses the following principles and positions:

HEALTH CARE REFORM

- We support reforms of our current health care system that ensure efficient and effective delivery of quality health care and that provide affordable medical care to all Americans. To succeed, a reformed system should embrace and make accessible innovative medical technologies, incorporate best practices such as chronic disease management, and overhaul outdated payment methods. Biotechnology, whose products add great value to health care in cost-effective ways, must be an integral part of any new federal system, a system that should build upon models that may include the Massachusetts Health Care Reform Act as well as SCHIP and Medicaid expansions that are not financed through biopharmaceutical price controls.

BIOSIMILARS

- The MBC supports creation of an abbreviated regulatory pathway for approval of biosimilars (also referred to as follow-on biologics), so long as the enabling legislation prioritizes patient safety and continues to give pioneering biopharmaceutical companies incentive to risk developing novel products through strong protection of their intellectual property and marketing rights. These fundamental principles have been upheld and articulated in legislation reported by Senator Kennedy's Health, Education, Labor and Pensions (HELP) Committee and in the bipartisan Eshoo – Barton bill on the House side during the 110th Congress.

SUPPORT FOR STEM CELL RESEARCH

- We have long been an advocate for embryonic stem cell (ESC) research, and have led successful efforts to pass pro-stem legislation in the Commonwealth of Massachusetts. Accordingly, we support efforts to lift restrictions on federal funding for research on embryonic stem cell lines created after August 9, 2001. We further support President Obama's intention to lift the current ban on research funding through executive order, which will allow all qualified scientists to participate in this important field under rigorous ethical guidelines proposed by the National Research Council.

DRUG IMPORTATION

- Holding a position consistent with that of HHS Secretaries under both Democratic and Republican administrations, we strongly oppose importation of pharmaceuticals from foreign countries. Importation from impossible to regulate foreign sources – already under new scrutiny following issues with heparin, melamine, pet food, toys and produce - is totally inconsistent with efforts to heighten the safety margins of our own "closed" domestic drug system, which Congress created with the Prescription Drug Marketing Act. Importation proposals have also been rendered irrelevant by dramatically increased access afforded by Medicare Part D and patient assistance programs, to an extent that the City of Boston, to cite one example, recently ended an importation program because of lack of consumer interest and participation.

SBIR ELIGIBILITY

- We support reinstating eligibility for Small Business Innovation Research (SBIR) grants to companies whose ownership by multiple venture capital companies may exceed 51%, a policy goal overwhelmingly endorsed by both the full House and the Senate Small Business Committee in 2008. Even with venture capital support small biotechnology companies are generally desperate for additional capital, and SBIR helps fill particular funding gaps, including those facing companies with promising early-stage technologies caught between proof of concept and commercialization, the so-called "Valley of Death."

NIH FUNDING INCREASE

- We support increased funding for National Institutes of Health (NIH) research initiatives, with a short-term goal of keeping pace with inflation and a longer term goal of making sure research already supported by NIH and discoveries emanating from such research can be sustained and built upon. The five year doubling of the NIH budget with bipartisan support (circa 1998 – 2003) was a great policy achievement and has led to a continued escalation of biomedical discovery and knowledge. These advances are threatened by flat funding levels that have eroded research dollars through inflation.

STRENGTHENING FDA

- The Food and Drug Administration's total appropriations are currently less than the agency's actual cost of doing business. As recommended by the agency's own impartial Science Board, we support a significant, permanent increase to the appropriation for the Food and Drug Administration (FDA), which is confronted with an aging work force, additional new mandates, and an explosion of new products requiring review and regulation. This requires enormous new resources. Congress has begun to provide the FDA with some of the resources it urgently needs,

adding in FY 2008, FY 2009 and FY 2008 supplemental appropriations more growth than FDA received in the 5 previous fiscal years combined. The MBC supports the Alliance for a Stronger FDA's call that FDA's appropriated budget for FY 2010 be \$2.25 billion

MEDICARE AND NON-INTERFERENCE

- The Medicare Part D drug benefit's strong success has been driven by marketplace competition, and we support the continued "non-interference" policy toward government oversight of Part D pricing or other government mandates that would reduce prices without demonstrated cost-savings and positive health outcomes. Private sector competition and negotiation under Part D has produced significant savings for beneficiaries and taxpayers and expanded choices for patients and their doctors, making government price controls unnecessary and undesirable.

PATENT REFORM

- The U.S. patent system is strong, and while reforms are clearly necessary - patent law has not been significantly updated for half a century – they should not be achieved at the expense of large segments of the innovation economy. We support consensus legislation to achieve meaningful patent reform. We will continue to oppose legislation that would undermine strong patent protections, make patent infringement easier and less punitive, or otherwise put at risk the increasing economic development that has been spurred by technology transfer of university-based patents to start-up companies across the spectrum of technological innovation.

TAX CODE: MAKING R&D CREDITS PERMANENT, REFUNDABLE

- We support making the federal R&D credit permanent in the interests of good tax policy and business planning, and refundable, so that companies amassing credits through significant investment but lacking tax liability against which to apply credits can still gain benefit from positive economic behavior. Tax policy can be a form of capital formation for cash strapped biotechnology companies, especially in times of tight credit, as Congress acknowledged in the recent housing stimulus bill that allowed companies not taking the depreciation allowance to monetize R&D credits. It has been a goal of the biotechnology industry for many years to let our "pre-profitable" companies turn earned but unusable tax credits into capital for reinvestment.

MBC IMPACT ISSUES AGENDA BACKGROUND PAPERS



HEALTH CARE REFORM

We strongly support expanded, affordable coverage for all Americans. We have actively supported the Massachusetts reforms, SCHIP and Medicaid expansions that are not financed through price controls that would negatively impact the development and dissemination of biotechnology therapies.

As Senator Kennedy has pointed out, however, expanding coverage to those who need it is but half the battle. We need to ensure that health care provided to the newly covered as well as to all Americans is of the highest quality and designed to be delivered in a cost effective manner that takes maximum advantage of state-of-the-art medical technologies and management practices.

Biopharmaceuticals are a relative health care bargain, making up barely 10% of all health care spending in the U.S. Our members will be fully involved in the health care reform discussion and are prepared to make the case that biotechnology must be an integral part of the nation's health care coverage system, based on the value biotechnology products add to health care outcomes, particularly when compared to other treatments and therapies. Biotechnology is very much part of the solution to our health care coverage, cost, and outcomes issues.

We share Senator Kennedy's belief that systemic reforms are needed to improve quality and to overhaul archaic payment systems. As President Obama's health advisor Professor David Cutler has pointed out, 30 - 40% of our nation's health care resources are wasted outright, including money spent on inefficient or substandard care. There are substantial savings to gain in health care from eliminating inefficiencies, utilizing best practices, and applying what we already know works. For example, improving compliance for medications used to treat chronic conditions is a critical, often overlooked priority.

This is also true for many of our innovative, single source products, such as cancer therapies that show clear survival benefits, or chronic disease treatments that keep beneficiaries out of hospitals, where the vast amount of health care expenses are incurred. Our membership has a great deal of experience with chronic disease management and other initiatives that will be at the heart of quality improvement.

Additionally, there is a dire need to address how the Congressional Budget Office (CBO) scores health care. Health reform is at risk if CBO's analytical foundation fails to capture productivity gains, long term gains in morbidity and mortality, and reductions in disability due to medical innovation. This is a critical policy and political challenge. New medicines help keep people healthy, productive, employed, and out of hospitals and nursing homes, factors that need to be reflected in government health care policy design and decision making



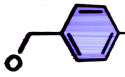
Our industry's success is dependent on continued innovation and a strong record of patient safety. If Congress creates an approval pathway for follow-on products that undermines patient safety and fails to maintain adequate incentives for innovation, we will not be able to continue developing the high-quality, life-saving medicines on which we are all counting. The three key principles that the Massachusetts biotechnology community believes are essential for an abbreviated pathway are:

1. Assuring that biosimilars are safe and effective.
2. Providing adequate incentives for investment in research and development of new biotechnology medicines, and providing strong protection of intellectual property rights.
3. Establishing a clearly defined and efficient pathway for approval of biosimilars after appropriate periods of data protection have expired.

The 110th Congress enacted bipartisan drug safety legislation, as part of the Food and Drug Administration Revitalization Act, and it would be incongruous if Congress limited the safety standards for biosimilar products, which are among the most complex products regulated by the FDA. Comparative clinical studies, in actual patients, are essential to detect risks that cannot be detected through chemical and physical assays, animal studies, and limited studies in healthy subjects. Clinical studies are the only way to understand whether small differences in products or in their manufacture will be clinically meaningful for patients.

The final legislation must also include an adequate period of data exclusivity and strong patent protections for innovator products. A substantial period of data protection is needed to ensure that manufacturers will have sufficient incentives to risk \$1.2 billion or more on preclinical and clinical studies, over a period of a decade or longer, with no guarantee of success. Unlike small molecules, patents for biotechnology products are not adequate by themselves to assure a substantial period of exclusivity. If the data protection period for biologics is less than the optimal effective patent life established in Hatch-Waxman for drugs (i.e., up to 14 years) then it will skew investment options away from biotechnology. The European Union biosimilars framework provides a period of up to eleven years of data exclusivity. The Senate HELP committee report and Eshoo – Barton bill essentially give biologics the same marketing protections Hatch – Waxman has historically afforded small molecule drugs. Furthermore, the legislation must include provisions to protect the intellectual property rights of innovator products and procedures to resolve patent-related disputes prior to marketing approval of the follow-on product. Any regulatory pathway should respect existing trade secret protections for innovator's data and not permit the use of the protected data to approve follow-on products.

Interchangeability is one of the most important public health issues associated with the approval and use of biosimilars. If patients are switched from one product to another (as is done with small-molecule generic drugs), there is a real risk of adverse events (including immunogenicity), lack of efficacy, and other detrimental effects. The FDA needs to develop scientific consensus on the definition of interchangeability to distinguish such products from those that are not "substitutable" or "therapeutically equivalent," but which may be interchangeable in that under a physician's supervision they could be used to treat the same disease or condition in the same patient. FDA must also develop scientific consensus on the data required to demonstrate that biological products can be safely substituted for one another at provider or pharmacist discretion.

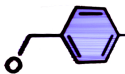


SUPPORT FOR STEM CELL RESEARCH

Human embryonic stem cells have great potential for treating a wide variety of diseases and health conditions and for providing new insights into human development and disease. We support President Obama's plan to reverse by executive order the Bush administration's ban on federal funding for embryonic stem cell research on cell lines created after August 9, 2001, thus allowing all qualified scientists to participate in this important field in accord with the rigorous ethical guidelines proposed by the National Research Council.

Our nation's top scientists agree that embryonic stem cell research has the potential to lead to cures and treatments for many of our society's most devastating diseases and disabilities such as cancer, diabetes, ALS, Parkinson's disease, Alzheimer's disease, and spinal cord injury. Embryonic stem cell research will further the development of cell-based therapies by leading to greater scientific understanding of cell differentiation – the process by which our cells become specialized to perform certain functions – and proliferation – the process where cells expand, or multiply for controlled use as a therapeutic. That's because these cells are pluripotent, which means they can be turned into any other of the body's cell types.

We have consistently supported a strong ethical framework for this research. We support NIH efforts to fund other methods to attempt to derive stem cells without using embryos, as these techniques are deemed by some scientists to hold promise.



DRUG IMPORTATION

As a policy proposal, importation of pharmaceuticals from sources abroad – largely driven by efforts to access cheaper drug prices imposed by foreign governments – has been around for nearly a decade. Over that time, concerns about the safety of imported goods have not abated but rather sharply increased, given recent experiences with heparin, melamine, pet food, toys and produce emanating from foreign producers. At the same time, the original rationale behind calls for importation no longer exists, as creation of Medicare Part D and expansion of pharmaceutical patient assistance programs have made safe, affordable drugs widely available to our nation's seniors and other populations in need and at risk. The City of Boston, to cite one example, just ended its once highly publicized importation program for retirees because of lack of consumer interest and participation.

In addition to safety and other concerns regarding importation, the CBO reported in a 2004 study that lower prices overseas would not translate into large savings for domestic consumers.

Holding a position consistent with that of Health and Human Services (HHS) Secretaries under both Democratic and Republican administrations, we oppose importation of pharmaceuticals from foreign countries, including modern industrial nations. A policy of drug importation would be totally inconsistent with efforts to heighten the safety margins of our "closed" domestic drug system, which Congress created with the Prescription Drug Marketing Act.

In 2007, the Senate voted to continue requiring the administration to certify the safety and effectiveness of drugs before they can be imported. Speaking on the issue, Senator Michael Enzi, ranking member of the HELP Committee, said the requirement for a safety certification was essential to protect the public. "Under both Democratic and Republican administrations, secretaries of Health and Human Services have declined to certify that foreign drugs — like those allowed under the Dorgan

Foreign Drug Act — are safe for American consumers. They realized, as I do, that close enough isn't good enough," Enzi said.

Drug standards and regulations vary from country to country and the FDA is responsible only for those marketed and sold inside the United States. Joseph McCallion, a consumer safety officer in the FDA's Office of Regulatory Affairs, summed it up this way: "If you buy drugs that come from outside the U.S., the FDA doesn't know what you're getting, which means safety can't be assured."

Based on safety concerns, we also opposed re-importation of drugs with U.S. origins. The Medicine Equity and Drug Safety Act (MEDS), enacted in 2000, would have allowed prescription drugs manufactured in the United States and exported to certain foreign countries to be re-imported from those countries for sale to American consumers. One provision required that the HHS Secretary determine whether adequate safety could be maintained and whether costs could be reduced significantly. Both Secretary Tommy Thompson and his predecessor, Donna Shalala, concluded that these conditions could not be guaranteed. "Once an FDA-approved prescription drug is exported for sale in another country, it is no longer subject to U.S. requirements and it can no longer be monitored by U.S. regulators," Thompson wrote to one of the bill's sponsors.

SBIR ELIGIBILITY

On July 30, 2008, the Senate Small Business Committee – chaired by John Kerry of Massachusetts – approved legislation that will allow companies with majority venture capital fund ownership to compete for a portion of SBIR dollars, including NIH funding. Such companies have been totally barred from SBIR participation since 2003. The Senate action followed House passage of language even more favorable to biotechnology companies.

SBIR grants had been an essential source of early stage funding until 2003, when a rules changed prohibited companies with 51% or more venture fund ownership from program participation. Knowing that most early stage biotechnology companies rely heavily on venture funding, MBC has been working to overturn that ruling ever since, advocating for the industry position on Capitol Hill, discussing the issue in depth with members of the state's Congressional delegation, and undertaking an intensive member-driven informational outreach campaign.

Under the Senate Small Business Committee version approved July 30, majority venture backed companies would be eligible to compete for a pool of dollars equivalent to 18% of NIH's total SBIR budget, 8% at all other federal agencies. The House set no such limits, and we will work to increase the venture company carve-out in subsequent legislation.

NIH FUNDING INCREASE

Over the past five years the NIH budget has been declining in real-dollar terms. Because funding has failed to keep pace with biomedical research inflation, NIH has lost nearly 15% of its purchasing power since FY 2004.

MBC supports a 15% increase in NIH appropriations over the next four years. This will allow NIH to recover in spending power losses it has suffered over the past five years. We will work with Congress to establish a long-term funding regimen that is rational, responsible, and sustainable.

Some members of the 110th Congress asked what the American people and taxpayers get in return for the funding NIH already receives. It was a legitimate inquiry for which there are quantifiable, affirming answers. **It is clear that many advances in biomedical research, improved public health care outcomes, economic development related to the biomedical sector, and other measurable achievements can be attributed to research funded by NIH. While new medicines are almost exclusively discovered and developed by biopharmaceutical companies, our global leading industry often depends on NIH funded extramural research for the fundamental knowledge and tools necessary to make these discoveries possible.**

Some of the benefits of NIH-sponsored medical research include:

- Through competitively awarded research grants, NIH funding drives fundamental scientific discovery in the life sciences, trains each successive generation of scientists, and launches the careers of our best researchers.
- Roughly 80% of all NIH funding is distributed to research institutions across the country to enable thousands of research projects, clinical work, and vital infrastructure support.
- NIH funding accounts for roughly one third of all the biomedical research funding in the US.
- Thanks in part to the total NIH investment of approximately \$44 per year, per American, the projected death toll from coronary heart disease has declined by over 50%.
- Research both at NIH and extramurally enabling early detection of cancer has dramatically improved survival rates.
- Advances made at NIH in understanding and treating cardiovascular disease has led to vastly improved prevention techniques involving cholesterol reduction, and discoveries in thrombolytic (clot-busting) therapies for heart attack and stroke.
- Alzheimer's disease alone is expected to cost the US government \$1 trillion over the life of the baby boom generation; NIH funded research may help in the creation of treatments and possibly cures.
- NIH funded research is the foundation on which the US biotechnology industry has been built, and the US biotechnology industry is the clear world leader.
- The link between and the importance of this economic activity and NIH funding and grants are easy to see – nearly every biotech company is located near a research center supported by NIH funds.



STRENGTHENING FDA

Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research (CDER), told Congress last spring that the FDA is an underfunded, 20th-century domestic agency struggling to protect American consumers in a globalized, 21st-century world. While there have been some increases in public funds for the FDA over time, the agency's funding has not kept pace with its growing responsibilities. In recent years, the FDA's responsibilities have expanded to include more counterterrorism activities, pandemic disease preparation, food safety activities, and increased drug safety surveillance. The FDA's total appropriations are currently less than the agency's actual cost of doing business.

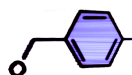
Additionally, there are concerns that FDA's growing reliance on industry user fees for operational purposes undermines the agency's regulatory credibility and creates barriers to smaller companies which must struggle to meet the ever increasing fee structure.

Yet despite being forced to address an ever-increasing array of issues and revolutionary food and medical advancements with tightening resources, the FDA continues to set the global "gold standard" for regulatory science and consumer protection. The MBC agrees with the FDA Science Board recommendation and supports efforts to provide FDA with significant additional public resources so that the agency may reliably fulfill its mission of guaranteeing the safety, efficacy and security of the products it regulates.

Thankfully, Congress also agrees. Congress has begun to provide the FDA with some of the resources it urgently needs, adding \$145 million into the agency's base in FY 2008 and another \$150 million in FY 2009. In addition, FDA received \$150 million in the FY 2008 supplemental appropriations. Any one of these amounts represents more growth than FDA received in the 5 previous fiscal years combined.

The MBC supports the Alliance for a Stronger FDA's call that FDA's appropriated budget for FY 2010 be \$2.25 billion, which will provide resources for it to start to rebuild its infrastructure and to fund its programs to assure the safety of foods and cosmetics and the safety and efficacy of drugs and medical devices.

Congress and FDA must continue the trend toward increased and adequate funding, in order to meet the 21st century challenges referred to by Dr. Woodcock.



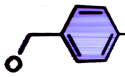
MEDICARE AND NON-INTERFERENCE

The Medicare Part D drug benefit's strong success has been driven by competition, and the MBC supports the continued "non-interference" policy toward government oversight of Part D pricing. Marketplace competition under Part D has produced significant savings for beneficiaries and taxpayers.

A survey commissioned by the Biotechnology Industry Organization (BIO) found that private sector negotiations provide both savings and choice, making government interference and price controls unnecessary and undesirable.

Through Part D, over 39 million Medicare beneficiaries now have comprehensive prescription drug coverage. Part D enrollees are saving an average of \$1,200 per year on the cost of their medications, and over 80% are satisfied with their plan. Marketplace competition under Part D has produced significant savings for beneficiaries and taxpayers, as well as expanded choices for patients and their doctors. Overall, Part D savings have been much larger than anticipated. Average beneficiary premiums dropped to \$22 per month in 2007, which is 42% below original estimates. In addition, the CMS actuary projected \$113 billion in Part D savings over the next 10 years, with \$96 billion directly attributable to competition leading to lower-than-expected plan bids.

Lower Part D bids have largely been driven by plans' ability to secure substantial volume price discounts and rebates on drugs furnished to Medicare beneficiaries. This is the case for medicines that treat the most common conditions afflicting the elderly population, as well as for innovative, breakthrough therapies that target cancer and other less common and devastating diseases. Significant discounts and beneficiary savings on innovative "single source" Part D medicines were found in the retail price survey conducted by BIO using publicly available information. These savings demonstrate that mandatory government negotiation or price reductions for such therapies is unnecessary, and would likely lead to unintended outcomes such as an increase in drug pricing, decreased investment in drug and biologics research and development, and reduced beneficiary access without providing significant savings.



PATENT REFORM

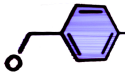
S. 1145, a major patent reform vehicle in 2008, contained numerous provisions that would have weakened patent rights, reduced incentives for innovation, created business and investment uncertainty, and negatively impacted Massachusetts' growing technological leadership in a competitive national and global economy. In particular, the bill put at risk the increasing economic development that has been spurred by technology transfer of university-based patents to start-up companies across the spectrum of technological innovation, funded by venture capital and other public and private sources. The bill's policy implications related to apportionment of damages, inequitable conduct provisions, an indefinite post-grant opposition system, and excessive venue restrictions, would have significantly and irreparably undermined innovation and new technology development.

We support efforts to develop a more consensus-oriented patent reform bill that could be considered by the 111th Congress. We applaud such efforts, and urge Congress and the Massachusetts delegation to work actively and aggressively to ensure that any patent reform legislation meet the following criteria before being brought up for consideration:

- Any statutory language on the calculation of reasonable royalty damages should --
 - Preserve the discretion of courts and juries to apply any and all applicable factors and methodologies under current law;
 - Not direct courts or juries to engage in "prior art subtraction" or otherwise seek to separate out certain elements of a patent claim;
 - 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.
- 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.
- 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.
- 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.
- Any bill must contain major reforms of the current "inequitable conduct" doctrine, as recommended by the National Academies of Science and the PTO, under which the draconian "unenforceability" penalty would be reserved for patent applicants who deceive the PTO into allowing an invalid patent claim and where such deception was the cause for the claim's issuance.
- 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.

We believe failure to address these core principles appropriately will stifle innovation, harm the Massachusetts and national economies, and drive high paying jobs overseas.

We remain committed to strengthening the U.S. patent system in ways that will preserve and promote innovation across the broad spectrum of the Massachusetts and U.S. economies.



TAX CODE: MAKING R&D CREDITS PERMANENT, REFUNDABLE

MBC supports making the R&D credit permanent in the interests of good tax policy and business planning, and refundable, so that companies amassing credits through significant investment but lacking tax liability against which to apply credits can still gain benefit from positive economic behavior.

Tax policy can be a form of capital formation for cash strapped biotechnology companies, especially in times of tight credit, as Congress acknowledged in the recent housing stimulus bill to allow companies not taking the depreciation allowance to monetize R&D credits. It has been a goal of the biotechnology industry for many years to let our “pre-profitable” companies turn earned but unusable tax credits into capital for reinvestment.

Life sciences companies labor under a unique business plan that results in most losing money for years due to the long and difficult biotech product development cycle. Yet these companies accrue significant tax benefits – mostly due to significant and continuing investment in research, development, new plant and equipment.

Tax benefits are designed as incentives and as rewards for positive economic behavior. High tech and life sciences companies have made significant investments in the Massachusetts and national economies, for which they have rightly earned tax credits and other tax benefits. But most of these benefits and credits expire long before the companies have taxable income. Making credits refundable provide deserving emerging companies with cash *today* to create jobs and promote growth *today*. This fundamental fact was clearly recognized by the Governor and General Court of Massachusetts, which in passing their landmark \$1 billion Life Sciences Initiative in 2008 included nine specific tax benefits/incentives to spur growth in the life sciences, three of which are refundable in cash for qualifying companies with no outstanding tax liability.

Congress recently took a step toward ensuring the federal government will continue to support technological innovations as we move through the 21st century. Despite allowing the R&D credit to expire at the end of the 2007, and holding several previously unsuccessful votes to revive the credit earlier this year, Congress recently delivered a two-year, seamless extension of the credit, essentially paving the way for critical breakthroughs in research and development to continue.

Massachusetts Life Science Industry Fact Sheet

- There are over 450 biotechnology companies located in MA
 - 277 companies are researching and developing new therapeutic drugs
- For every biopharmaceutical manufacturing job created, 5 additional supporting jobs are created in other industries
- There are 43,981 biotechnology employees in Massachusetts, who are responsible for over \$5 billion of in-state payroll
- 2,156 drugs are being developed in Massachusetts, representing almost 7% of the global drug pipeline
- 25% of venture capital invested in Massachusetts is in the biotechnology industry
- 17% of US biotechnology venture capital was invested in Massachusetts companies in 2007
- Massachusetts is home to the top 5 NIH funded hospitals
 - (1) Mass General Hospital
 - (2) Brigham and Women's Hospital
 - (3) Dana-Farber Cancer Institute
 - (4) Beth Israel Deaconess Medical Center
 - (5) Children's Hospital Boston
- Massachusetts has received 10% or more of annual NIH funds since 2005 and consistently ranks #1 in NIH funding per capita (National Institutes of Health, 2007)
- Massachusetts has received over 13% of national SBIR funding since 2003, and ranked #1 in SBIR funding per worker in 2006 (National Institutes of Health, 2007)
- 67 colleges & universities in Massachusetts award life science degrees or certificates

National Biotechnology Industry Fact Sheet

- Biotechnology has created more than 200 new therapies and vaccines, including products to treat cancer, diabetes, HIV/ AIDS and autoimmune disorders.
- There are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.
- Biotechnology is responsible for hundreds of medical diagnostic tests that keep the blood supply safe from HIV and detect other conditions early enough to be successfully treated.
- Agricultural biotechnology benefits farmers, consumers and the environment by increasing yields and farm income, decreasing pesticide applications and improving soil and water quality, and providing healthful foods for consumers.
- Environmental biotech products make it possible to clean up hazardous waste more efficiently by harnessing pollution eating microbes.
- Industrial biotech applications have led to cleaner processes that produce less waste and use less energy and water in such industrial sectors as chemicals, pulp and paper, textiles, food, energy, and metals and minerals. For example, most laundry detergents produced in the United States contain biotechnology-based enzymes.
- As of Dec. 31, 2006, there were 1,452 biotechnology companies in the United States, of which 336 were publicly held.
- Market capitalization, the total value of publicly traded biotech companies (U.S.) at market prices, was \$360 billion as of late April 2008 (based on stocks tracked by BioWorld).
- The biotechnology industry has mushroomed since 1992, with U.S. health care biotech revenues from publicly traded companies rising from \$8 billion in 1992 to \$58.8 billion in 2006.
- Biotechnology is one of the most research-intensive industries in the world. U.S. publicly traded biotech companies spent \$27.1 billion on research and development in 2006.
- There were 180,000 employed in U.S. biotech companies in 2006.
- The top five biotech companies invested an average of \$170,000 per employee in R&D in 2007.
- Most biotechnology companies are young companies developing their first products and depend on investor capital for survival. According to BioWorld, biotechnology attracted more than \$24.8 billion in financing in 2007 and raised more than \$100 billion in the five-year span of 2003-2007.
- The biosciences - including all life-sciences activities - employed 1.3 million people in the United States in 2006 and generated an additional 7.5 million related jobs.
- The average annual wage of U.S. bioscience workers was \$71,000 in 2006, more than \$29,000 greater than the average private-sector annual wage.