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Massachusetts U.S. Senate Candidate -Questionnaire

Government leaders in the United States have long had 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 that face policy makers 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.

All our issues are related to innovation and progress. They all ultimately affect patients and their families, 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.

With this questionnaire, we aim to capture the issues with an impact on this industry that is vital to Massachusetts, the United States, and the world.

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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.

Do you agree that to be successful, we must have a reformed system that embraces and makes accessible innovative medical technologies, incorporates best practices such as chronic disease management, and overhauls outdated payment methods?

Yes, and funds were made available, for example, for medical IT in the American Recovery and Reinvestment Act. At that time I wrote to David Blumenthal, National Coordinator for Health Information Technology at HHS, expressing my concern that medical IT systems be made interoperable, as I understand they are not now, even within I-95.

One cannot be opposed to “best practices” but I would note, in connection with some well-publicized examples, success may be attributable to demography of patient population. Only about 5 % of Mayo Clinic patients are Medicaid eligible, and, last month, the Clinic further restricted Medicare and Medicaid patients.

Do you agree that biotechnology products add great value to health care in cost-effective ways and that the impact of reform measures on the biotechnology industry must be considered in designing a reformed federal system? Further, do you believe that a reformed federal system should build upon models, which may include the Massachusetts Health Care Reform Act as well as SCHIP and Medicaid expansion that are not financed through biopharmaceutical price controls or mandated discounting?

Yes, I believe prices should be negotiated, not mandated.

BIOSIMILARS

MassBio supports the establishment of an abbreviated regulatory pathway for approval of biosimilars (also referred to as follow-on biologics), as 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 their data. These fundamental principles have been upheld and articulated in legislation reported by Senator Kennedy’s Health, Education, Labor and Pensions (HELP) Committee and the House of Representatives Committee on Energy and Commerce- - both include a 12 year data exclusivity period for innovator products. A carefully crafted pathway to biosimilars is crucial to protecting innovation that drives the biotechnology industry. Do you support this period of data exclusivity for innovator products?

Yes, I am privileged now to represent great universities, research institutes, and teaching hospital. My district thrives on intellectual capital, and its discoveries offer hope to the world. I support the 12 year period of protection.

Another important aspect of the pathway to biosimilars is safety. Clinical studies in patients with the disease being treated are essential to detect risks that cannot be detected through chemical and physical assays, animal studies, and limited studies in healthy subjects, and to ensure effectiveness. Clinical studies are the only way to understand whether small differences in products (and there will be differences because biosimilars are not identical with the products they copy) or in their

manufacture will be clinically meaningful for, and not harmful to, patients. Do you support requiring clinical testing for these complex, large molecule biologics that will ensure that patients will be treated with a safe and effective product?

Yes, I support clinical testing for any product that will be used for medical purposes. It is essential also to staff and fund the FDA so that its scientists will be able adequately to assess cutting-edge research. I am aware of weakness within the FDA and also within the PTO. The federal government must be able to attract and retain a higher level of scientific talent.

SMALL BUSINESS INCENTIVES

Senator Kerry has cosponsored a Therapeutic Discovery Project Tax Credit amendment, included in the Senate Finance Committee's package on health care reform. This credit will enable small biotech companies, the majority of our members, to continue to conduct research and add jobs that will provide the cures for tomorrow. Do you support these kinds of incentives that will position Massachusetts to continue as the leader in life saving innovation?

Yes

Small Business Innovation Research (SBIR) grants provide critical seed money to new business innovators, including biotechnology companies. In 2003, the Small Business Administration (SBA) ruled that companies whose ownership consists of multiple venture capital firms exceeding 51% are not eligible for SBIR funding. Do you support overturning the SBA's ruling in order to allow to allow majority venture-funded companies to apply for a portion of SBIR grants?

Yes, given the nature of biotech -- the entrepreneur may be a brilliant post-doc or junior faculty member with huge student loans to repay --- venture capital is essential to this industry.

STEM CELL RESEARCH

We have long been an advocate for embryonic stem cell (ESC) research and have led successful efforts to pass pro-stem-cell legislation in the Commonwealth of Massachusetts, as stem cell research is one of the strengths of the Massachusetts biotechnology super-cluster and embryonic stem cells have the greatest potential for treating a wide variety of diseases and conditions. Do you support embryonic stem cell research and without restrictions on federal funding for such research?

I have supported embryonic stem cell research since it first became controversial in the summer of 2001. I met then with Eric Lander, George Daley, and others at the Whitehead Institute to better understand ESC. I wanted to be able to explain the method and the great promise it holds to my colleagues in the House. I urged the scientists to find an expression for replace “therapeutic cloning” which gave rise to serious misunderstandings. George Daley proposed “cell therapy” and I regret it has not caught on. I will continue to fight for federal funding without restriction, save that of requiring the informed consent of the donor.

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. Do you agree, and do you believe that because of the inability to regulate scrupulously products imported from many foreign sources, we must refrain from allowing these potentially unsafe or counterfeit medications into our domestic drug system? Importation proposals have also been rendered irrelevant by dramatically increased access afforded by Medicare Part D and patient assistance programs. Do you oppose the importation of pharmaceuticals from foreign countries?

I have always maintained that drug importation was not a good solution for US consumers. There are safety issues: advanced industrial countries permitted the use of thalidomide. Moreover, this is a very short-term fix: countries that subsidize pharmaceuticals for their own citizens will surely be unwilling to provide them indefinitely to Americans. I support reforms which would empower the federal government to negotiate drug prices for public programs, Medicare, Medicaid, and, if progress continues on health reform, the new public option.

PATENT REFORM

For some time, Congress has attempted to reform the current patent system. Senator Kennedy was instrumental in leading efforts for a compromise between the many industries a patent overhaul would affect due to differing business models. Do you support patent reform that would reinforce strong patent protections and discourage patent infringement ensuring a balanced and fair outcome?

I support patent reform, and a strong global defense of intellectual property rights.

I voted against Permanent Normal Trade Relations with China on these grounds, and also because the treaty did not protect fundamental human rights, including the right to organize free trade unions, or impose minimal environmental regulations.

INCREASED FUNDING

The National Institutes of Health (NIH) plays an important role in funding the great ideas of our academic institutions and teaching hospitals in Massachusetts. It is important to continue and increase this funding, which results in more jobs and local economic growth, as well as therapies that improve the lives of patients around the world. Do you support increased funding for the NIH?

I have consistently supported increased funding for both the NIH and the NSF. We need basic research in life sciences, but also in mathematics and physics. Without these, we would not have CAT scans, MRI's, or the advanced computers on which biomedical research crucially relies.

While it is unusual for an industry to request more funding for the entity by which it is regulated, we believe it is imperative that we improve the average of 10 years and \$1billion that it takes for a new therapy to be developed and submitted for approval – and the majority of projects fail. Expediting early drug development and reducing the number of failures requires efforts by both companies and the FDA, which currently does not have the resources for this essential task. Do you support increased funding for the Food & Drug Administration?

Absolutely. See above p. 3.

OTHERS

Do you support government price controls on pharmaceuticals procured through the Medicare Part D drug benefit?

No, I support negotiations on prices.

Do you support making the federal Research & Development tax credit permanent?

I would support multi-year provision of R&D tax credits, so that businesses may plan with stable expectations. I would prefer that Congress review the credits from time to time. There may be sound reasons to increase them, and I am averse to removing any program from Congressional scrutiny.

Do you support making the federal Research & Development tax credit refundable?

No.

Please return to MassBio by Friday, November 13th.

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