

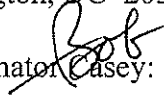
CITY OF PHILADELPHIA

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MICHAEL A. NUTTER
Mayor

June 30, 2009

The Honorable Robert Casey Jr.
United States Senate
383 Russell Senate Office Building
Washington, DC 20510

Dear Senator  Casey:

I am writing to ask you to please consider the importance of the bioscience industry to the economy of the Greater Philadelphia area when the Senate considers the creation of an approval pathway for biosimilars as a part of health care reform this year.

Philadelphia has a long history as a leader in medicine, medical education and research. The region is also home to the nation's finest concentration of leading medical/bioscience institutions, including The University of Pennsylvania (ranked 2nd in the nation for NIH funding), Thomas Jefferson University, The Children's Hospital of Philadelphia, Temple University Hospital, The Wistar Institute, the Fox Chase Cancer Center, Hahnemann Hospital / Drexel University, which collectively received more than \$2.5 billion in NIH research funding in 2005. In all, more than 20 universities and non-profit institutions are engaged in bioscience research.

According to a 2009 Milken Institute, report the Greater Philadelphia region ranks 3rd nationally in biosciences. Eight of the world's largest pharmaceutical companies are within a 50-mile radius of Philadelphia. The study showed that the life sciences sector in Greater Philadelphia employed 94,400 workers in the region, generated \$7.7 billion in earnings and \$17.5 billion in output.

Accounting for ripple effects, broader economic impact of the industry is responsible for 380,800 jobs, \$20.2 billion in earnings and \$39.7 billion in output. In other words, the life sciences directly and indirectly accounts for one out of every six jobs and drives roughly 15% of all economic activity in the region.

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The Commonwealth and City have made substantial commitments to growing this industry through public-private partnerships with BioAdvance, Ben Franklin Technology Partners, Innovation Philadelphia, Select Philadelphia and The University City Science Center.

I ask you to support the creation of a responsible pathway for biosimilars that balances the needs to reduce health care costs and protect patient safety, while promoting the incentives for innovation that are so critical to our economy.

This issue of biologics has a direct impact on our region's economic future; many of these therapies come from risk-taking small- and medium-sized companies. Others come from public and private research investments and technology transfer initiatives at colleges and medical centers in the Greater Philadelphia region. The manufacturing of biologics poses considerable R&D, manufacturing and clinical trial challenges that can drive up their development costs. Bringing a new biologic to market can cost as much as \$800 million and take as long as 15 years. Without adequate protections for these investments, both innovation of new treatments and our economy will suffer.

A reasonable period of data exclusivity is necessary to ensure investors are motivated to continue to invest in new research. While a great deal of discussion has been given to what constitutes a reasonable period of time to provide companies the exclusive use of their data, I am concerned that biosimilar legislation might inadvertently undermine a critical part of our region's economy for meager long-term savings.

Scoring by the Congressional Budget Office estimated that providing innovator companies 12 years of data exclusivity would result in savings of \$9,200 million over 10 years. Similar scoring by the Office of Management and Budget for President Obama estimated that a 5 year period of data exclusivity would yield \$9,240 million in savings over the same period – a difference of only \$40 million over 10 years.

Rising health care costs are certainly an issue at all levels of government; however, I am concerned that we risk being penny-wise and pound-foolish on the issue of biologics.

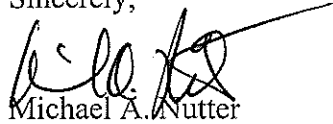
I believe the approach taken in the bi-partisan Kennedy-Hatch legislation, which passed unanimously in the Senate HELP Committee in 2008, achieves the right balance between reducing health care costs, protecting patient safety and promoting incentives for innovation.

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The bill provides innovators with a 12-year period of data exclusivity which will promote continued investment in the innovation of next generation medicines to treat serious illnesses. The legislation also includes necessary provisions for protecting patient safety. It requires clear and sturdy testing requirements for biosimilar products, provides that biosimilars could be deemed interchangeable only through an FDA guidance process, and prevents patient confusion by requiring biosimilars to have a name that is distinct from the original product.

Thank you for your attention to this request and for your continued service to the City of Philadelphia and the Commonwealth of Pennsylvania.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Nutter", with a long horizontal stroke extending to the right.

Michael A. Nutter
Mayor