Pennsylvania
U.S. Senator Bob Casey

WHAT HEALTH CARE REFORM MEANS FOR PENNSYLVANIA BIOTECH FIRMS

The high cost of health insurance is a huge burden on American businesses large and small, stunting their ability to grow, innovate, compete, hire American workers, and ultimately rebuild the American economy. The Patient Protection and Affordable Care Act is good for business, good for jobs, and good for the economy of PA. The legislation lowers health care costs to allow American businesses to focus on what they do best, not on health care costs, and includes other provisions to directly create jobs and get our nation's economy moving again.

Pennsylvania's bioscience industry at a glance (2008)

- 77,413 employees across 1,736 business establishments
- 339,439 total employment impact from ripple jobs (4.38 multiplier)
- $5.9 billion in total wages
- Average employee salary of $76,306, which is nearly twice the average private sector wage ($41,013) for all workers in the state

Health Care Reform includes the Biologics Price Competition & Innovation Act

The Biologics Price Competition and Innovation Act, which is included in the Patient Protection and Affordable Care Act, creates an approval pathway for biosimilar and interchangeable biological products while preserving the incentives that have fueled the development of these medicines.

Approval Process

- Allows the submission of a biological license application for a biosimilar or interchangeable biological.
- Requires a biosimilar applicant to demonstrate that there are no clinically meaningful differences in safety, purity, and potency between a biosimilar product and the brand or product. A demonstration of biosimilarity requires analytical data, animal testing and clinical studies, unless a requirement is determined by the Secretary to be unnecessary.
- Allows approval of a biosimilar product as interchangeable either at the time of initial approval or after a supplemental approval. An interchangeable product is a biosimilar product that can be substituted for the brand product without the intervention of the health care provider who prescribed the product. A demonstration of interchangeability requires evidence that the biosimilar product will produce the same clinical result as the brand product in any given patient and that it presents no additional risk if a patient is switched between products.

Guidance Documents

- Allows the Food and Drug Administration (FDA) to issue guidance documents that will aid in disseminating the standards and criteria that it will use in approving biosimilar and interchangeable biological products.

- Permits the FDA, following a public process, to issue guidance related to the approval of biosimilar and interchangeable biological products. The absence of a guidance document does not prevent the approval of a biosimilar or interchangeable biological product.

Patent Resolution

- Creates a process that accelerates the litigation of patents while preserving the innovators' patent protection.
- Requires the biosimilar applicant to provide information about its manufacturing process to the brand company. A series of informational exchanges then occur in which the biosimilar applicant and the brand company identify patents that each believes to be valid, invalid, infringed or noninfringed.
- At the end of this process a list of patents that are in question is identified. The validity of the claims of infringement can then be adjudicated.

Exclusivity

- Awards brand manufacturers and innovators 12 years of data exclusivity from the approval date of the product. The first biosimilar applicant to demonstrate interchangeability receives a full year of exclusivity. This is a provision that I supported strongly both in the Health, Education, Labor, and Pensions Committee, and on the Senate floor.
- Provides incentives to ensure that the innovation and development of new life-saving medicines by universities and companies continues, as well as incentives to encourage the development of interchangeable biological products.

Pediatrics

- Provides the application of certain provisions of the section 505A of the Food, Drug and Cosmetic Act to biological products.
- Provision provides an additional six months to the period of exclusivity otherwise applicable to the biological product but only if the applicant agrees to and completes pediatric studies of such products as request by the FDA and makes applicable labeling changes.
- Requires sunset of this provision after five years, similar to the existing authority under section 505A of the Food, Drug and Cosmetic Act.

How does health care reform serve all Pennsylvania employers?

- Health care costs for the uninsured will no longer be shifted onto employers and those with insurance coverage, approximating a savings of $1,000 for a family policy.
- Reforms of the health care delivery system improvements will increase the quality of employers' health plans.
- Streamlines health plans to keep premiums lower by instituting a premium rate review process and setting standards for how much insurance companies can spend on administrative costs.
- Expands coverage to 32 million uninsured Americans, which will increase labor supply by reducing disability and absenteeism in the work place.
- Ends coverage limitations based on pre-existing conditions and expands portable coverage options, which will help to reduce "job lock," freeing workers to be more flexible, and increasing the flexibility and productivity of the economy.

Please visit Senator Casey's website for more information on what health care reform means for PA's small businesses. There is detailed information about the small business tax credits, shared responsibility requirements, and new Exchanges that will improve bargaining power for PA's Biotech industries.