

# REDUCING DATA PROTECTION FOR BIOLOGICS WOULD SLOW MEDICAL PROGRESS AND CHILL R&D INVESTMENT IN THE U.S.

Biologic medicines have resulted in and will continue to result in tremendous medical advances against the most challenging and costly diseases affecting American patients. The Biologics Price Competition and Innovation Act, which was broadly supported by both sides of the aisle in both the House and Senate, created an abbreviated approval pathway for biosimilars (biologics that are similar to innovative biologics), as well as provided a 12-year period of data protection for innovator biologics – striking an appropriate balance between making room for additional competition and maintaining incentives for continued innovation. Data protection is critical to ensuring continued medical progress, R&D investment, and economic growth. Reducing data protection for innovator biologics could reduce R&D investment in the U.S. and could shift high-value, high-wage R&D jobs to other countries with more favorable intellectual property policies.

## What is data protection and why is it critical for biologics?

Data protection, sometimes referred to as data exclusivity, prohibits third parties for a set period of time from using or relying upon an innovator's valuable clinical data to obtain FDA approval for their product. Providing innovators with data protection recognizes the time, costs, and uncertainty related to the R&D process for medicines and the substantial investment required to develop the clinical data needed for FDA approval. Data protection allows a biologic to be on the market for a set period before a biosimilar application can be approved based on the innovator's clinical data and protects against the uncertainties caused by patent challenges early in a product's life.

## Why is a 12-year period of data protection required?

To advance the discovery of new biologics, the data protection period must be long enough to allow innovators, who undertake costly and uncertain R&D and the FDA approval process, to earn a positive rate of return. Duke University economist Henry Grabowski has calculated that a representative biologic would not recoup its R&D costs with a data protection period of less than 12 years.<sup>1</sup> Since this analysis was completed, new estimates of the investment and uncertainty associated with developing new medicines have gone up – it now costs an average of \$2.6 billion over the course of 10 to 15 years to develop one new medicine, and only 12% of candidate medicines entering clinical testing ever receive FDA approval.<sup>2</sup> Thus, the 12-year period of data protection is more important than ever to create the environment needed to support large-scale investment in biologic discoveries.

Cutting data protection for biologics could also cost U.S. R&D jobs and reduce U.S. economic growth. The sector directly provides more than 810,000 high-wage jobs, supports a total of 3.4 million jobs across the U.S. economy, and generates a total economic output of nearly \$800 billion. With many countries strengthening their intellectual property rights and other incentives to attract this sector, the U.S. is facing increasing competition for the high-wage jobs and economic contributions this industry offers and reducing data protection for innovative biologics would make the U.S. less competitive with these other countries.

## Why isn't patent protection enough to spur investments in biologic R&D?

Patent protection is often less robust for biologics than for small molecule drugs. Many biologic patents are process patents or relatively narrowly drawn product patents. These may be susceptible to work-arounds, especially under a regulatory regime that permits biosimilars to differ in their structural features from innovator products. Furthermore, if a biologic's development time is extended, there may be a very limited period of patent protection remaining once a product is approved. Given the increased potential for biologics patents to be "worked around" by biosimilar manufacturers making patents less certain, 12 years of data protection for biologics is needed.

## What could happen if the data protection period for biologics is reduced?

A data protection period of less than 12 years would multiply uncertainties about potential returns on investment and increase the risk that biologics could not achieve a positive return, driving R&D investment away from supporting the discovery of new biologics. If the incentives for continued R&D investment are inadequate, companies large and small may choose not to invest in biologics because of concerns that there would be insufficient time to recoup their investment and/or could shift their R&D operations to other countries with a more favorable environment for innovation. This could jeopardize the development of new biologics for our most challenging and costly diseases.

1. Grabowski, H., Long, G., and Mortimer, R. Data exclusivity for biologics. *Nature Reviews Drug Discovery* 2011(10):15.

2. Tufts Center for the Study of Drug Development, Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion (Nov. 18, 2014), [http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study).