

# A Necessary Balancing Act: Accessibility, Cost, and Need for New and Better Cures

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**F**or patients with chronic diseases and disabilities, bringing much-needed new treatments to market gives hope for a better life. Biologic medicines, products derived from living cells and tissues, offer great promise in treating, managing, and even curing many chronic diseases.

These innovative medicines, unlike traditional chemical drugs, are very complex and costly to produce and often very expensive to buy. Congress is considering legislation that would create a regulatory pathway for biosimilars, which are similar but not identical to the original biologic. Like generic medications, biosimilars are expected to be cheaper to produce.

Sadly, too much of the public discussion has focused on when biosimilars may enter the market and what impact they will have on industry, rather than on the end user of the products—the patient.

We need to strike the right balance between access to affordable biologics and, equally important, appropriate incentives that encourage research and development of new treatments. Some expensive biologics currently on the market are used as a predominant method of treatment for specific conditions (eg, multiple sclerosis, rheumatoid arthritis, psoriasis). Other chronic conditions currently have no treatment, and biologic drugs are thought to be the best hope for a treatment or cure (eg, Sjögren's syndrome, amyotrophic lateral sclerosis, Crohn's disease).

Nationwide focus groups of people with chronic diseases and their family caregivers have clearly articulated their support for government-initiated incentives. The participants view incentives as a necessary means of getting something they very much want: better treatments—and, ideally, cures.

In my view, the “right” period of exclusivity has yet to be determined. Congressional committees have approved bills that grant a flat 12-year exclusivity period. The Obama administration supports a 7-year period. The National Health Council has called for 10 years of data exclusivity, which is similar to other international standards.

We understand that pharmaceutical companies need a predictable period of exclusivity as an incentive to encourage the development of new products. But let's fine-tune this incentive to create rewards that will increase the likelihood of research and development in some of the most difficult areas of research (eg, Alzheimer's disease) and in disease categories where the patient populations are too small to produce a sufficient return to cover the cost of research (eg, lupus), or in rare disorders where the patient populations are even smaller.

We have the opportunity to create a regulatory approval process for biosimilars that creates better value for patients.

To that end, the National Health Council has proposed adding an extra year to a base exclusivity period *if* the biologic treatment offers significant clinical benefit, as determined by the US Food and Drug Administration. We also recommend adding additional time specifically for the development of biologics for autoimmune or neurologic disorders that have limited or nonexistent treatments, or biologics for rare disorders or pediatric disorders. And we support extending the exclusivity period for developing new methods of administering biologics, which are now primarily delivered by hospital and clinic staff.

There are many issues to consider in the regulation of biosimilars. A meaningful and effective solution can be found only if we focus first on the needs of patients.

We need to remain attentive to improving access to existing drug therapies, and concerned about the unintended consequences of legislation that could delay the advancement of new treatments. We need to use data exclusivity in targeted ways to foster research and development that lead to breakthrough treatments and cures so desperately needed by patients.

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