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Clearing the Way for Low-Cost Biogenics

Now that the United States is in to China, we need to save money. One answer is cutting healthcare costs, with the lowest hanging fruit being *biologics*. Biologics are protein-based, rather than chemical-based, medicines. They are wonder drugs, treating cancer, diabetes, Crohn's, arthritis, and a range of other heartbreaking diseases. But their prices are out of sight, averaging 22 times the price of chemical medicines and running as high as \$100,000 per year.

These costs are beyond the reach of the 47 million uninsured Americans. And those with drug coverage, including Medicare participants, are starting to be charged extremely high co-pays for these vital medicines.

The prices of biologics won't fall and access to biologics won't rise without competition from generics. So Congress needs to do for biologics what it did in 1984 for chemical medicines via the Hatch-Waxman Act. This act authorized the Food and Drug Administration to approve generic alternatives to chemical-based drugs. Thanks to this act, the public saves \$12 billion annually.

The same amount or more could be saved if Congress would let the FDA approve biogenics – something it's close to doing. But if it's not careful, Congress will deliver biogenics stillborn. Why? Because generics can't compete with brand drugs as long as they are under patent or protected by special patent restoration and exclusivity provisions. And three leading biogenics Congressional bills that authorize biogenics include exceptionally long exclusivity periods of 12 to 14 years.

Patents provide inventors 20 years of monopoly protection. However, drug companies receive additional protection to restore time spent clinically testing a product and obtaining FDA approval. You're also granted exclusivity, but it lasts only five years.

The typical new brand biologic drug would receive 30 years of monopoly protection – 50 percent longer protection than that afforded non-medicinal inventions and 30 percent longer protection than that afforded new chemical medicines. But that's not all. Thirty years gives brand biologic companies lots of time to *evergreen* their drugs -- to make minor modifications to their products, obtain FDA approval of these changes, and then garner another 12 to 14 years of exclusivity.

Over-protecting brand biologics could, thus, indefinitely keep low-cost biogenics from reaching the market. Worse, it would keep other innovators from building, in a timely manner,

on the stock of knowledge embedded in existing biologics, much of which was accumulated at public expense.

Biologics are incredible gifts to mankind, making us naturally reluctant to do anything that impairs their inventors' prospects. But today's inventors are generally not tomorrow's. The reason is clear: Today's inventors have strong incentives to milk their discoveries, not make new ones whose arrival would undermine existing profits.

Economic study after economic study shows that competition, not protection, is the true source of innovation and that over-extending protection can be counterproductive. It may do little or nothing to incentivize discovery. Thus, charters of government monopoly can lead to *less*, not more, innovation over time.

Proponents of extensive exclusivity argue that biologics require more time and money to develop and are riskier to produce. In fact, average development time for new biologics is only seven months longer than that for new chemical drugs. This is surely no justification for providing brand biologics seven to nine more years of exclusivity than are provided brand chemicals.

And when it comes to innovation incentives, it is the expected profits from pursuing a possible invention, not the cost per se, which matters. Expected profits are higher in biologics than in chemical medicines, which is why biologics represent a rising share of new medicines.

As for risk, the probability of any particular biologic drug succeeding is low. But brand companies, like book publishers, develop many products and make profit on average. The real risk is how the industry moves with the market. Here, modern finance speaks clearly. The biologic industry is much less risky than its chemical cousin.

The Hatch-Waxman Act has proved remarkably successful in balancing the interests of brand companies and the public, and in stimulating discovery of new chemical medicines. Given this success and the absence of any compelling differences between biologics and chemicals indicative of longer monopoly protection, Congress should limit biologics exclusivity to at most the five years in Hatch-Waxman.

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