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Affordable Biologics for All

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To paraphrase something that Mark Twain is alleged to have said, "Everybody talks about drug prices, but nobody does anything about them." The last part of the paraphrase is not quite accurate, but to date, none of the major federal proposals to lower drug prices have been enacted, and state legislation, such as the California Preserving Access to Affordable Drugs Act, is under legal challenge from the pharmaceutical industry. Especially hard hit by high prices are uninsured patients who pay the list price. Cost-related treatment nonadherence in low-income US patients was almost 25% according to the results of the Commonwealth Fund 2014 International Health Policy Survey of Older Adults.[1]

However, even patients covered through Medicare Part D are susceptible to high prices, as shown by Erath and Dusetzina[2] in this issue. The authors examined out-of-pocket spending on biologic medicines for patients with rheumatoid arthritis from 2010 through 2019. For the 6 of 17 products available over the entire period, implementation of the Patient Protection and Affordable Care Act was associated with mean annual out-of-pocket spending decreases from $6108 in 2010 to $4801 in 2019. However, most of the savings were associated with the mandatory manufacturer 50% rebate for drugs between 2010 and 2011 while patients were in the coverage gap. Putting aside that initial decrease, the mean out-of-pocket cost increased from $4026 in 2011 to $4801 in 2019, driven by price increases such as a median increase of 160% for the original 6 marketed drugs. Over the coming years, further price increases may continue to erode the initial savings for these patients.

Price increases for biologics do not only affect patients with rheumatologic conditions. First-generation disease-modifying therapies for multiple sclerosis that entered the market in the early to mid 1990s at annual costs of $8000 to $11 000 by 2013 were priced at $60 000 per year; newer agents were introduced at prices 25% to 60% more than existing products.

Although biologics only account for 2% of all prescriptions written in the US, they are responsible for $120 billion or 37% of net drug spending and, since 2014, for 93% of the overall growth in total spending.[3] None of the usual explanations for the price of biologics stand up to scrutiny. Research and development costs for biologics are higher than those for small molecule drugs ($391 million vs $309 million) but not enough to account for their prices. Furthermore, there is no difference in the median premarket development time between biologics and small molecule drugs that would justify the 12 years of data exclusivity that the former group received in 2010. Interviews with 4 leaders in biologics development revealed that, contrary to frequent claims, development costs were not the reason for the prices of the multiple sclerosis drugs. Instead, initial price decisions were based on the price of existing competitors and revenue maximization and corporate growth were the reasons for price escalations.[4]

Use of biosimilars, which have a similar role for biologics as generics do for small molecule drugs, could be associated with lower spending, but by the end of 2019, only 11 of the 26 biosimilars that were approved by the US Food and Drug Administration were actually marketed, and even when biosimilars are available, market penetration is often very poor. This situation is in contrast to the one in Europe, where by May 2018, 39 biosimilars had been launched; in some countries, biosimilars have completely captured a particular market.

One reason why biosimilars have not been successful in the US even after they have been marketed has been the message from drug companies, medical societies, and patient groups—with the latter 2 often having connections to companies—that it is potentially dangerous to switch patients from a reference biologic to a biosimilar. This message continues to have resonance despite

a systematic review[5] concluding that that this type of switching is not associated with increased risk of immunogenicity-related safety concerns or with diminished efficacy. A second reason for the low uptake may be the increasing trend for companies marketing reference biologics to employ nurse educators or ambassadors to assist patients in using complicated medications and helping them to resolve drug-related problems and with insurance paperwork. If physicians were to switch their patients to a biosimilar, that assistance would not be available.

Calls for lower prices for biologics (and other drugs) are typically met with the concern that innovation will suffer. However, only a small minority of new biologics represent significant therapeutic advances over existing products.[6] Moreover, for over a decade, drug companies listed on the S&P 500 Index collectively have spent more of their revenue on dividends and share buybacks than they have on research and development.[7] In 2015, of the top 100 pharmaceutical companies by sales, 64 spent twice as much on marketing and sales than on research and development, 58 spent 3 times as much, 43 spent 5 times as much, and 27 spent 10 times as much.

What can be done to remedy this situation? There are a few proposals that need to be considered. First, Medicare should stop relying on market forces to reduce prices and emulate what other countries do and negotiate directly with drug companies to obtain prices equivalent to those already available to the Department of Veterans Affairs. At those prices, Medicare Part D would have saved 44% of its outlay or $14.4 billion in 2015.[8] Second, substitutions with biosimilars should be made mandatory as the Canadian provinces of Alberta and British Columbia have done, unless there is a medical contraindication to doing so. Third, pharmaceutical companies should publicly justify their claimed research and development expenses, rather than relying on self-reported amounts from a select group of companies that are analyzed by researchers at Tufts University, where the amounts are treated as confidential and therefore unverifiable.

Biologics can be transformational treatments but only if they are affordable at both the individual and societal levels. It is the job of physicians to advocate for prices that make biologics accessible for everyone who would benefit from them.

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