Selected Developments in Biotechnology Law and the Biotechnology Industry

By STEVEN J. ZWEIG

U.S. CONGRESS CONSIDERING BILLS PERTAINING TO THE COST OF BIOSIMILARS

Recently, two biosimilar bills were introduced in Congress—both are (as of writing) in congressional committees.

- H.R. 6179, the Increased Access to Biosimilars Act of 2020, would implement a “shared savings model” for biosimilar prescriptions. This would give health care providers (*e.g.*, physicians) a percentage of any net savings from shifting patients to biosimilars, in order to incentivize the use of biosimilars. The idea is that if doctors can make money by helping patients, insurers, and society save money, they will do so. A February 2020 HarrisX poll found 73% of Americans in favor of shared savings.
- S. 3466 is a bill that would waive out-of-pocket expenses (*i.e.*, result in \$0 copays) for biosimilars for seniors who receive their medication under the Medicare Part B program. This would again encourage the use of lower-priced biosimilars over their higher-priced reference drugs.

BIOSIMILARS SLOW TO GAIN TRACTION FOR INFLAMMATORY BOWEL DISEASE IN THE U.S.

A recent study¹ found that U.S. physicians are unwilling to prescribe biosimilars, despite the enormous potential cost savings and evidence that the biosimilars are safe and effective to use for inflammatory bowel disease (IBD).

There does not appear to be any reason for this reluctance: the authors of this study cite other studies showing, for example, that biosimilar infliximab CT-P13 (Inflectra, Remsima) has equivalent safety and efficacy as the originator drug, Remicade, as well as studies showing positive patient outcomes with biosimilars. Despite this, and despite the European Crohn’s Disease and Colitis Organization recommending the use of biosimilars, the American Gastroenterological Association continues to recommend that U.S. physicians avoid switching patients from a reference drug to its biosimilar(s).

The potential cost savings from wider use of biosimilars—and so the cost savings which U.S. doctors are leaving on the table—are significant: in countries as varied as Norway, France, and Japan, IBD biosimilars result in 45% to 67% price reductions compared to the originator drugs. And with IBD increasing in prevalence, as the study’s authors note, the gains to the U.S. from wider use of biosimilars could be enormous.

COVID-19 MAY IMPACT THE AVAILABILITY OF MANY DRUGS

By now, we’re all aware that U.S. President Donald Trump’s pushing of hydroxychloroquine as a remedy for COVID-19 has led to people hoarding the drug, reducing its availability for those who need it for various serious conditions, such as lupus. However, the deleterious impact of the coronavirus pandemic may extend to drugs and pharmaceuticals having nothing whatsoever to do with the virus.

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¹San Hyoung Park, Jae Cheol Park, Milan Lukas, Martin Kolar, and Edward V. Loftus, Jr., *Biosimilars: Concept, Current Status, and Future Perspectives in Inflammatory Bowel Diseases*, 18(1) *INTESTINAL RES.* 34–44 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7000642/>

For example, the U.S. Food and Drug Administration (FDA) temporarily suspended overseas inspections of food, drugs, and medical devices in order to protect its employees from exposure to the coronavirus through travel, as well as in acknowledgment of the impact of various nations' travel restrictions. During the suspension, the FDA relied on border inspections of products as well as review of product data provided by manufacturers. However, that is a less-well-developed way of ensuring drug quality and safety than on-site inspections, and so there is a fear that it will result in delays in the acceptance of drugs.

Or alternately, there may be impairment of drug safety without on-site inspections of Indian pharmaceutical manufacturing plants, which provide a significant fraction of pharmaceuticals consumed in the U.S.: a 2019 report by the FDA's Center for Drug Evaluation and Research found that during a seven-year period, only 83% of Indian manufacturing facilities were nondeficient (compared to 90% of Chinese plants, 93% of U.S. plants, and 98% of European plants), which means that 17% of India's manufacturing facilities were deficient. That highlights the important role that FDA on-site inspection plays in ensuring the safety and quality of Indian pharmaceuticals.

Furthermore, India is the source of 18% of active pharmaceutical ingredients used in the U.S., but is experiencing labor and transportation issues due to COVID-19 and steps taken to stem or reduce its transmission. Also, India itself gets many of its raw pharmaceutical ingredients from China—a large percentage specifically from Hubei province, which was the center of the COVI-19 outbreak—so that supply source has experienced disruptions as well. Those disruptions will then flow through the supply chain.

All of these factors together mean that the COVID-19 pandemic will have an impact on drug availability—including of biologicals and biosimilars—and/or quality or safety extending far beyond drugs or medical devices used to protect against or treat COVID-19 itself.

BIOTECHNOLOGY IN THE FIGHT AGAINST COVID-19

According to the World Health Organization (WHO), 70 potential coronavirus vaccines are in

development and are being fast-tracked. Of those, the three that are furthest along as of this writing, are all biotechnology products:

- Chinese drugmaker CanSino has a recombinant COVID-19 vaccine which is in phase 2 trials.
- U.S.-based Moderna is working on an mRNA-based virus and received approval in March to begin human trials.
- Another American company, Inovio Pharmaceuticals, has a DNA vaccine in human trials which is based on its DNA vaccine for a related coronavirus which causes MERS. According to Dr. J. Joseph Kim, Inovio's President, and CEO, "[u]sing our modern DNA medicines platform, we designed our DNA vaccine INO-4800 in three hours after the publication of the genetic sequence of the novel coronavirus that causes COVID-19." Such rapid adaption of an existing vaccine would not be possible without biotechnology.

Biotechnological approaches offer the chance to cut not merely months but years off the traditional vaccine development timeline. Whereas vaccines have typically taken 10–15 years to bring to market, the hope that a COVID-19 vaccine can be produced in a year, give or take.

NEPEXTO RECEIVES POSITIVE OPINION FROM EUROPEAN MEDICINE AGENCY

Nepexto is an etanercept biosimilar based on the reference product Enbrel. The European Medicines Agency's (EMA's) Committee for Medicinal Products issued a positive opinion, recommending use of the product. The positive opinion extends to the biosimilar's use for all indications of the reference product, such as for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, pediatric plaque psoriasis, and axial spondyloarthritis. The EMA's opinion, which was based on studies finding Nepexto equivalent to Enbrel in terms of its safety, efficacy, and immunogenicity, brings Nepexto a large step closer to being available in the European market.

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