How Biosimilars Affect Health Care

This issue of *Clinical Advances in Hematology & Oncology* features an interview with Dr Gary H. Lyman about a topic in health care that is increasingly important—the role of biosimilars. In this interview, Dr Lyman describes the differences among biosimilars, biologic agents, simple small molecules, and generics, and the process by which biosimilars obtain FDA approval and gain use in clinical practice. The use of biosimilars affects our health care system in numerous ways, but I would like to focus on two critical areas: cost and innovation. I am not an expert on these topics, but as a practicing oncologist, I am able to provide the "man in the street" perspective that hopefully will resonate with readers.

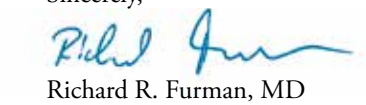
Regarding cost, physicians find themselves on the front lines of this issue when they argue for insurance approval of procedures and therapies they believe are necessary for their patients. It might stand to reason that the cost savings provided by biosimilars would enable greater drug access for patients. But this thinking is flawed for several reasons. There are currently nine biosimilars, based upon three reference biologic agents, that are approved as therapies for oncologic indications by the FDA (see the Table on page 545). Although biosimilars require shorter times to approval and lower costs compared with biologic agents, they still are far more difficult and costlier than generics to produce. Looking at Europe, where biosimilars have gained far more use than in the United States, the market prices of biosimilars are not based upon the costs of development, but rather represent a 20% to 25% reduction from the reference biologic agent. Although this cost is still substantial, it does translate into a large cost savings when factored over the number of uses. But the main rationale for cost savings related to biosimilar use focuses on the ability of competition to bring about lower prices. This competition is usually not between the reference biologic agent and the biosimilar, but among multiple biosimilars. Of the nine approved biosimilars in oncology, two are for bevacizumab, five are for trastuzumab, and two are for rituximab. Given the short intervals between the approvals of these agents, significant competition could be expected. But in our health care system of large health care corporations and negotiated prices, is there room for competition in the traditional market sense?

The other consideration is the optimal period of market exclusivity for biologic agents, which is currently 12 years based on the 2009 Biologics Price Competition and Innovation Act. (This Act created an abbreviated licensure pathway for biologic products that are demonstrated to be biosimilar to, or interchangeable with, FDA-approved biologic products.) Is this the correct amount of time? It certainly is longer than the five years' exclusivity given to standard agents. On the other hand, this is still far less than protections on works of literature and music, which are copyrighted for years beyond the lifetime of the creator. The song "Yesterday" will be copyrighted for 70 years beyond Paul McCartney's death (long may he live). The goal is to find the right balance between lowering health care costs and promoting innovation.

The advances we have seen over the past 30 years have led to such impressive advances in the understanding of human biology on the molecular level that our therapies are now rationally designed. The path for translating basic science findings into novel therapeutics is extremely tortuous and filled with failures, so both human ingenuity and health-care industry dollars are essential. I have seen firsthand enough benefits to patients from biologics (such as rituximab and filgrastim) as well as another class of extremely expensive therapeutics—kinase inhibitors—(which include ibrutinib and venetoclax) to know that the future for many of our patients is brighter than ever could have been realistically imagined decades ago. These advances should continue.

At the same time, I struggle with the fact that so many in the world are unable to access health care. In 2018, the United States spent 18% of its gross domestic product on health care. As more highly expensive therapeutics are developed, and the population lives longer, this number will climb dramatically. How much are we willing to spend on health care? One-fifth of our gross domestic product? One-fourth? One-third? How do we decide what is appropriate, and what is too much? The answer depends on many factors, including whether you are the person receiving the care, the one paying for it, or the one administering it. Determining our priorities as a nation is a debate that will continue for many years.

Sincerely,



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