Can Generics Help Heal Our Ailing Healthcare System?

Dalia Buffery, MA, ABD

With cost becoming a major obstacle in any potential healthcare reform, the role of generic drugs is gaining even greater popularity than before among policymakers as a cost-saving feature in the attempt to overhaul our healthcare system. The tension between the makers of generic drugs and brand-name manufacturers notwithstanding, there is a general agreement in government that increased use of generics can substantially reduce overall healthcare costs, especially during the current economic environment.

According to the Generic Pharmaceutical Association (GPhA), the rise in the use of generic medicines in past decades has saved the healthcare system “more than $734 billion in the last decade alone.” Because more generics are being approved by the FDA each month, the potential for even greater future savings is real.

In early July 2009, as part of the House of Agriculture Appropriation bill, the House approved an increase in the funding for the US Food and Drug Administration (FDA)’s Office of Generic Drugs.

But by mid-July, the Senate Committee on Health, Education, Labor, and Pensions (HELP) defeated Rep Henry Waxman’s proposal of a 5-year exclusivity period for a new biosimilars (generic version of biologics) pathway in favor of a 12-year exclusivity period proposed by Rep Anna Eshoo. The 47 to 11 vote in favor of the longer period signals strong support for the biotechnology industry and a delay in the potential financial benefits to consumers and to the healthcare system as a whole. President Obama and the AARP are among those who are favoring a shorter period, with the President supporting a 7-year exclusivity period.

The fight, however, is not over.

In mid-September, Sen Orrin G. Hatch and Rep Waxman—the “fathers” of the Hatch-Waxman Act that led to the current generics pathway (and the creation of the generic industry)—addressed the GPhA’s Annual Policy Conference, advocating for generics and biosimilars as a cost-saving mechanism that can improve our ailing healthcare system, noting that generics have saved the US healthcare system much more money than was initially anticipated.

Sen Hatch reiterated that generics reduce consumer costs, hence the goal is to provide incentives to get high-quality generics to market early, “especially as we consider healthcare reform legislation.” But it was Sen Hatch who introduced the 12-year biosimilar exclusivity period amendment at the HELP Committee markup of its healthcare reform bill.

In contrast, Rep Waxman was focused the ongoing fight for biosimilar legislation. When it comes to the future of biosimilars pathway, he emphasized, the “war is not over,” adding that if the 12-year exclusivity amendment becomes law, it would “impose almost insurmountable barriers to real competition in the biopharmaceutical marketplace….The Eshoo amendment is everything a monopolist could hope for.”

Health and Human Services Secretary Kathleen Sebelius also attended the GPhA conference. She stressed that President Obama is committed to the 7-year biosimilar exclusivity period as part of a general healthcare reform, while also cognizant of the need to promote and encourage innovation.

So in the struggle to introduce a biosimilar pathway, just as is the case with the “wars” on healthcare reform, everyone agrees on the need to enhance cost-saving mechanisms, while also acknowledging that unlike some areas in which innovation is a goal unto itself (eg, education, science), innovation in healthcare requires incentives beyond the reward of improving health. It was not always like that in medicine.

References