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Budget Proposals on Biosimilars, 'Pay for Delay' Spark Controversy

Less than a year after the Obama administration finalized two agreements with the brand-name pharmaceutical industry that ended the possibility of its seeking to derail the health reform law, the administration proposed fiscal 2012 budget provisions that would, in effect, undo those agreements. One proposal presented Feb. 14 would cut the number of years from 12 to seven that brand-name biologics would have marketing exclusivity before "biosimilars" are allowed. And the other would empower the Federal Trade Commission to block so-called "pay-for-delay" agreements, under which brand producers pay generic drug makers to settle their patent challenges in a way that delays the arrival of generic competition.

Neither of the budget proposals has very good chances of being adopted, suggests Eric Hargan, a partner in the health and FDA business practice of law firm Greenberg Traurig. In the case of shortening exclusivity on biosimilars, he tells *HRW*, "it is pretty quick for a change of mind" from last year's agreement, as well as not certain to produce the level of savings the administration expects. He adds that the proposed pay-for-delay ban runs into problems because "it's very hard to define what you're trying to shut down." What happens, he asks, for example, when an "innovator" pharmaceutical company makes its own generics as sometimes occurs?

But the potential level of savings in both proposals seems sufficient for the administration to pursue at a time when, as Hargan notes, "they're scrambling to find any way possible to pay for the budget." Specifically, the budget projects that abolishing pay-for-delay arrangements would save $540 million in fiscal 2012 and almost $8.8 billion in the 10-year period ending in 2021. The administration forecasts that shortening biosimilars exclusivity to seven years would save $80 million in 2015 and a total of $2.3 billion through 2021.

PhRMA, BIO Condemn Proposal

The proposals drew perhaps-expected responses from industry groups. Both the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization (BIO) condemned the biosimilars proposal, with PhRMA President and CEO John Castellani's statement calling the 12-year current exclusivity period "the law's only bipartisan provision." BIO President and CEO Jim Greenwood warned against changing this "bipartisan, strongly supported provision…in the name of questionable short-term budget savings that will come at the price of long-term costs to our health care system and our economy."

On the other hand, generic drug makers, which had pushed for no exclusivity period or a shorter one, praised the proposal. And the Pharmaceutical Care Management Association, which represents PBMs, says the budget provision "would save billions for consumers and taxpayers while making life-saving medications more affordable for everyone."

Changing the exclusivity period from 12 to the seven years that generic makers had sought last year "will be a tough sell," Hargan observes, giving it "less than a 50-50 chance." It is possible, he concedes, that there may be a compromise change to a number of years between seven and 12, but this would require changing the reform law.

Moreover, the savings from such a change would not be "enormous," according to Hargan. He contends that, given the very high underlying costs of producing biologics, there might be fewer manufacturers if there were only seven years of exclusivity, so counting on big savings might be "folly."

Abolishing pay-for-delay agreements, he adds, runs into other kinds of problems, especially the freedom of businesses to enter into contracts. And definitions of the forbidden agreements would be difficult since, like what judges have said about pornography, it's more a matter of "knowing it when you see it," Hargan maintains. Getting the change through Congress given such issues would require there to be parties "fully behind" such a move, he says, and it's not apparent that anybody is.

Overall, he continues, "some" in the pharmaceutical industry may see the new budget proposals as a "betrayal" of deals made at the time the reform bills were pending, but it's unlikely that this will translate into opposing the entire law and attacking health reform as a

whole. Such restraint, Hargan says, is "probably wise," especially given the current climate in which "Washington is hungry for money."

One of the biggest issues surrounding the budget proposals — especially the biosimilars one — is that they introduce "new uncertainty" into the industry's future investment climate, says Genia Long, managing principal in Analysis Group, a large privately held economic consulting firm that works on biosimilar issues.

The provisions surrounding biosimilar data exclusivity in the reform law, she tells *HRW*, are more important for future innovation in this product arena than they are for saving short-term money. Long notes that the Congressional Budget Office previously had estimated that biosimilars would bring $7 billion in long-term savings, but that the savings are mainly "backloaded" into the later years.

The issue of assigning savings to biosimilars based on a set of assumptions regarding exclusivity periods, she says, is "tricky." There is a need to look at the situation on a case-by-case basis to factor in supply-and-demand factors, contends Long. She cites as an example intellectual-property disputes that could affect the number of entrants on a biosimilar. On the demand side, Long adds, there are clinical questions about "therapeutic indications" that will help determine how readily physicians and patients accept a biosimilar as a substitute for a brand product.

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