SPECIALTY PHARMACY NEWS

President Reignites Biologics Exclusivity Battle With Proposal for Seven Years

President Obama's proposed HHS budget for fiscal year 2012 included a provision on an issue that pharmaceutical industry stakeholders thought had been settled through the health reform law. That law provides innovator biologics companies with 12 years of exclusivity — but the proposed budget suggests shortening that to seven years. While many industry experts agree that the provision probably will not supplant the one in the reform law, there are multiple takeaways from the entire situation.

At stake is the amount of time before follow-on biologics could come onto the U.S. marketplace and compete with innovator biologics. However, similar to the health reform law, the budget refers to simply "exclusivity" and does not indicate whether this is data exclusivity — in which follow-on manufacturers will not have access to the innovator's data that is needed for the FDA application — or marketing exclusivity — which would mean the FDA could consider applications during those 12 years but not actually approve them until after the period has expired (see box, p. 11).

Citing a June 2009 Federal Trade Commission report as support, the proposal contends that "12-year exclusivity is unnecessary to promote innovation by brand biologic drug manufacturers and can potentially harm consumers by directing scarce research and development funding toward developing low-risk clinical data for drug products with proven mechanisms of action rather than toward new products to address unmet medical needs." Seven years of exclusivity, however, "strikes a balance between promoting affordable access to medication while at the same time encouraging innovation to develop needed therapies."

The exclusivity issue "was discussed in great detail by the Congress in leading up to the ACA [i.e., the Patient Protection and Affordable Care Act]," points out Dan Mendelson, CEO of Avalere Health, LLC. "At the time, it represented broad consensus as to what" seemed like a reasonable amount of exclusivity for innovator products. Congressional members "debated the issue extensively" and felt, he says, that they "were done with the issue."

However, "the fact that something is put in legislation does not exempt it from further discussion," Mendelson tells *SPN*. He terms the provision's inclusion in the budget a "big deal. The fact that this was proposed means the issue is reopened."

He also notes that there were "a number of liberal Democratic members that wanted seven years.…[Reps. Henry] Waxman, [Pete] Stark and the like were principal advocates for a smaller number" of years. However, following last year's congressional elections, many of the people who favored seven years "have less power than they did before."

"The proposal is a little bit of a repeat of an earlier administration position on the issue," says Genia Long, managing principal of Analysis Group, an economic consulting firm *(SPN 7/09, p. 4)*. For that reason, the proposed budget provision is "perhaps not entirely surprising."

However, attorney Eric Hargan points out that the administration worked closely with the pharmaceutical industry on the reform law. "I'm certain there are a lot of angry people in the industry," he says. "Innovators would have to feel there was a bait and switch done on them in the last year. The White House just came to an understanding with them."

Hargan, a former deputy secretary and regulatory policy officer with HHS, terms the subsequent inclusion of the provision in the budget "highly uncommon." He contends that "you'd have to be a true psychic or an absurdly cynical pessimist to think the deal [struck for the health reform law] would go away within a year — but such is the stress seen on the monetary side with the federal government.…I've seen a lot of programs that stand to be cut on both sides, but this stands out."

Administration Is Looking for Offsets

Ultimately, though, Mendelson says he believes the proposal will "not be taken seriously by the members" of Congress. *So why include the provision within the proposed budget?* Mendelson, who was associate director for health at the Office of Management and Budget during the Clinton administration, explains that the budget is a balancing act, with proposals for both spending and reducing costs. With the $60 billion increase in spending for physicians, the administration "needed offsets."

"My perception," says Mendelson, is that the provision's inclusion was motivated by "the necessity of coming up with something that was a cost saver, not a deep abiding viewpoint."

"The context of looking really hard for savings is the context in which this [proposal] should be evaluated," agrees Long. "These are times when the administration is looking under every rock for offsets."

If the exclusivity period were changed from 12 years to seven, says Mark Armstrong, a member of the Health Care and Life Sciences practice of Epstein Becker Green Wickliff & Hall in the firm's Houston office, it "would mean significant savings to both Medicare and Medicaid funds.…We're facing significant shortfalls, and this is an opportunity to diminish the shortfalls by allowing less expensive generic biologics onto the market. If biosimilars are approved earlier, they could reduce costs to patients and payers."

"I think there is going to be pressure to get this done because of the savings," Armstrong tells *SPN*. "However, there will be difficulties in getting this done. Most manufacturers believed they had accepted a 12-year exclusivity period, and the rules of the game seem to have been changed a little."

Still, he says, "it's rational to think that if the administration believes they could save the Medicare Trust Fund the type of money they're saying in the budget,…then I could see this getting passed."

Provision Is Not 'Huge Saver'

Hargan, though, maintains that the $2.3 billion in estimated savings between 2012 and 2021 with biosimilars that the administration includes in the budget "is not a huge saver" overall, relatively speaking. "When you're scurrying around for $60 billion to $100 billion in cuts, $2.3 billion is not a lot."

For the pharma industry, "one thing that they probably need to figure out is who else was being listened to during the budget creation process," says Hargan. "Where did this come from?…Was this always on the table? Who were the counterparties in the last discussion? Are they still there?…Was the agreement they came to never going to happen?"

According to Hargan, "at some point, people lose credibility if they can't be trusted. Many calculations went into" the reform law provision. "Someone has shed some of their credibility as a negotiator."

According to Long, "the exclusivity period is fundamentally important to the economics of the industry. It will have an immediate effect on products that are on the market now." In addition, she says, "the larger effects of the exclusivity period are in the signals it gives to investments in the industry." Down the road, the pharma pipeline could suffer if investors are skittish about their prospects for recouping their research and development costs. "The larger impact is really not on products on the market today but on incentives," she contends.

She tells *SPN* that she recently worked with Duke University's Henry Grabowski to update research on the different exclusivity periods *(SPN 2/09, p. 5).* That study, which was also co-authored by Richard Mortimer of Analysis Group and appeared in the January issue of *Nature Reviews Drug Discovery,* found that innovators "will fail to break even under both seven- and 10-year market exclusivity periods" — but will break even under 12- and 14-year market exclusivity periods. "So a change from 12 years to seven years would represent a significant change," she explains.

Data exclusivity, Long says, can offer innovators "additional protection to the degree patents do not." Data exclusivity, she says, is "a little bit of a belt and suspenders kind of approach," where the belt is patents and suspenders are data-exclusivity protection. She maintains that it will be interesting to see how data exclusivity and patents interact within the biologics space, including "what percentage of the time is data exclusivity really needed to provide adequate incentives? The million-dollar question is what patent litigation will look like in this area. How will it fill in any gaps? No one knows the answer."

What Is Impact on FDA?

So will the budget proposal throw a wrench into the FDA's plans for hammering out the details of the biosimilars provision within the health reform law?

"It's business as usual at the FDA," asserts Hargan. If the length of exclusivity changes, "this is important, but it doesn't require the FDA to hash out an issue where there is a gray area. It is a problem, but a problem that is more binary" in that the agency is not being asked "to go into an area where the borders are ill-defined or there is conflict."

The FDA, says Mendelson, "is going to implement whatever Congress tells them to do." Issuing guidance, he says, "is going to take some time."

The biosimilars issue "is complicated," Mendelson maintains. The FDA "must make sure they're assuring safety because biologics are not easy to produce. If they screw up, they can kill people, plus kill any consumer surplus" that could result from biosimilar cost efficiencies. In addition, the agency is faced with other "pressing" issues, including negotiations on the Prescription Drug User Fee Act (PDUFA) reauthorization and user fees for generic drug makers.

For these reasons, the FDA "will not rush this; they'll take their time," he contends.

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