Co-packing Compliance Conundrum

by Stephen Barlas

Medication compliance is a hot topic these days, both in Washington and beyond the Beltway. For example, one of the concerns PBMs have had about a medical data privacy law is that they might not be able to get the kind of patient information they need—from pharmacies or physicians—to run the kind of compliance programs they think are necessary.

Washington will have an impact on compliance in another realm, too. The Food and Drug Administration (FDA) will soon make a decision on whether to approve a Bristol-Myers Squibb (BMS) application to “co-package” two drugs to improve compliance for patients at risk for secondary coronary heart disease. BMS wants to co-package Pravachol, a statin, with aspirin. This follows from the American Heart Association’s clinical guidelines.

Over 12 million Americans are at risk for coronary heart disease (CHD). And many of them, when told by their physician to take aspirin, trot down to their local drugstores and buy aspirin substitutes like Tylenol, which doesn’t work as a CHD prophylactic.

The FDA has already approved the co-packaging of items such as birth control and iron pills and anti-fungal and anti-itch creams. But those applications weren’t very controversial.

Not so the BMS application. On January 18, the FDA’s Cardiovascular and Renal Drugs Advisory Committee voted against it. That doesn’t guarantee that the FDA will veto the Pravachol/aspirin application, but it’s a 99% certainty. The advisory committee had a number of concerns. First, according to one FDA official, the committee had no problem with the concept of physicians recommending Pravachol and aspirin. But this official says that if the FDA approved the BMS application, it would be as if the FDA were endorsing the notion that Pravachol and aspirin should go together: it would be seen as a “global” recommendation.

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The FDA advisory committee was also wary because the agency does not have a policy on the co-packaging of pharmaceuticals, but it is not because of a lack of trying on the part of some people at the agency. The FDA has what is called the Medical Policy Coordinating Committee (MPCC), which has a co-packaging subcommittee. The subcommittee was created two years ago because higher-ups at the agency knew that future co-packaging applications were coming, and they were concerned that the agency was unprepared for them. In 2001, the MPCC sent a draft policy statement to the FDA’s regulatory policy office that must approve it before it can appear in the Federal Register, which would be the first step in establishing a formal policy. In the ensuing year, the regulatory people have taken no action; the draft co-packaging policy is gathering dust.

Clinical guidelines for diabetes and hypertension, to name just two diseases, also call for multiple medications. Co-packaging of drugs for those conditions is also looming in the distance. Some might argue that the FDA’s foot-dragging on a co-packaging policy is understandable, given the absence of an FDA commissioner 16 months into President Bush’s term. But there is no reason why the FDA can’t publish a proposal, ask for comments, and thoroughly consider alternatives in the meantime.

Stephen Barlas is a freelance writer based in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to: rxwashington@qhc.com.