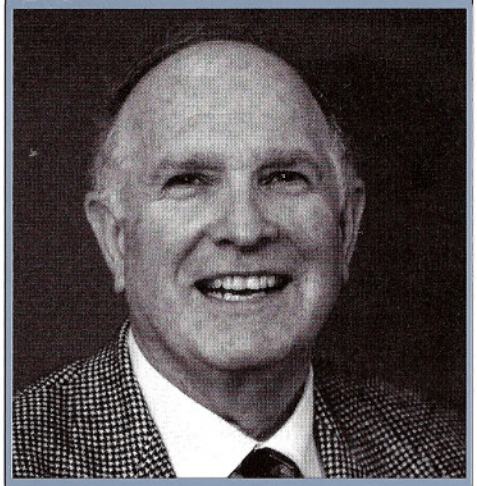
POINTED VIEW

# A Word to the Wise as Managed Care Enters Rx Communications

*Health plans have big ideas for pushing therapeutic substitution under Medicare. But when payors alert consumers to cheaper alternatives, they need to operate under the well-established rules governing drug promotion.*



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With the recent expiration of **Merck & Co. Inc.**'s patent covering *Zocor* (simvastatin), I thought it timely to expand on the comments I shared with the staff of *The RPM Report* earlier this year warning that health plan communications do not have a free pass from government restrictions against false and misleading promotions. The subject came to mind as I read an article on the implementation of Medicare Part D and a "sidebar" entitled "Humana's 'Rifle Shot' At Expensive Brands." *(See The RPM Report, February 2006.)*

According to the article, it is **Humana Inc.** President Michael McCallister's goal to use the company's monthly statements to Medicare beneficiaries to encourage "switches to cheaper medicines." One of the requirements of Medicare Part D is that health plans provide enrollees a monthly statement concerning their benefits.

Now, one might ask, what is wrong with communicating ways for patients to save money? The answer is nothing—so long as the communication is truthful, and not false and misleading.

## Are Health Plans Subject to FDA Oversight?

As Humana and other health plans move forward with their patient communication plans, they need to be cognizant of the various regulatory requirements that the pharmaceutical industry has faced over the years in communicating about its products.

First and foremost are the FDA requirements concerning prescription drug promotion. The issue of FDA jurisdiction is somewhat intriguing: should Humana's messages support a particular drug product, one might consider that they were acting "on behalf" of the pharmaceutical manufacturer. That, in turn, could result in FDA regulatory action against the product, manufacturer and possibly the health plan if the communications were false and misleading.

Issues can arise if unsubstantiated product comparisons or claims are made. Take the statin class as an example. The breadth of claims varies from statin to statin and claims for a product can only be made by the manufacturer if it is approved in the specific product labeling. It would be false

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and misleading, therefore, to state that information in *Lipitor* labeling is applicable to generic simvastatin if it does not appear in simvastatin's labeling.

Similarly, claims relating to comparative safety or effectiveness would need to be supported by "substantial evidence" under FDA regulations. "Substantial evidence" is defined in FDA regulations as consisting of adequate and well-controlled studies. Similar substantiation requirements could apply even if it is determined that health plans are not subject to FDA jurisdiction. Federal Trade Commission jurisdiction could be applicable and similar issues could be raised under the Federal Trade Commission Act prohibiting unfair methods of competition and/or unfair or deceptive acts or practices.

**"Health plan communications under MMA need to meet the established standards of 'truthfulness'."**

Any false or disparaging claims about a product could also be subject to action under the federal Lanham Act. Pharmaceutical companies have previously resorted to Lanham Act, Section 43 litigation against competitor's claims and representations. In at least one instance, similar issues were pursued by the government under fraud and abuse laws years after a successful Lanham Act action.

## A Plethora of Fraud and Abuse Laws

Potential applicability of the False Claims Act and Anti-Kickback Statute to health plan communications provides additional reasons to ensure the accuracy and truthfulness of these communications. Both the Department of Justice and the Department of Health & Human Services' Office of the Inspector General have publicly expressed concern that actions motivated as a result of practices prohibited by the anti-kickback or false claims laws can result in patient harm.

Should patient safety be affected by false and misleading health plan communications, one would expect the government to focus on this as a priority area, assuming other elements of anti-kickback or false claims actions are present.

The area of off-label claims has been a particular focus of fraud and abuse investigations by the government. Coupling this with the government's announced expectations that the Medicare Part D drug benefit will provide a fertile area for fraud and abuse prosecutions, one can expect that inappropriate health plan actions and communications could easily fall within the extremely broad reach of the government.

Might health plans also be subject to product liability claims if harm occurs as a result of a patient switching to another medication as a result of a communication by a health plan? It's an interesting possibility, particularly when one considers that the direct communication to the patient by the health plan may also undermine any "learned intermediary" defense that might otherwise be applicable.

Finally, there is the plethora of state consumer protection and fraud and abuse acts that could come into play, depending on the truthfulness of the content of health plan communications. Usually reserved for actions against manufacturers, it might not take much to encourage an increasingly hungry trial bar to look here as well. And, of course, hovering overhead will always be the potential of class action lawsuits.

Health plan communications under the Medicare Modernization Act can serve several useful purposes, and it's not my intent to discourage appropriate interactions with patients. But such communications do need to meet the established standards of truthfulness.

Lest we believe this is only an academic exercise, a reason for such a concern is to ensure that communications do not result in harm to the patient. It's particularly pertinent in cases in which health plans will benefit (as may their patients) if they move their enrollees to cheaper pharmaceuticals. But cheaper may not always be better—or even the same. RPM