Open Public Hearing No. 4
My Fight for Nonprescription Mevacor
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Late last year, I had the opportunity to testify during Open Public Hearing (OPH) No. 4 before the advisory committee of the Food and Drug Administration (FDA). The committee was then considering approving the over-the-counter (OTC) use of a 20-mg dose of lovastatin (Mevacor, Merck). By now, most of our readers know that the OTC status for Mevacor was once again rejected at a joint meeting of the FDA’s Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee.

I’d like to share aspects of my testimony from that fateful, tension-filled day at a nondescript Hilton in suburban Washington, DC.

The regulatory history of the recommendation for an OTC switch for Mevacor is a lengthy one. A Web site sponsored by Thomson Scientific (www.thomsonscientific.com) details the chronology of the switch of statins from a prescription to a nonprescription status and instills a deep appreciation for every question that was posed to the advisory committee. The site also summarizes special trials that Merck undertook in the past two years, including SELECT (Self-Evaluation of Lovastatin to Enhance Cholesterol Treatment) and CUSTOM (Customer Use of OTC Mevacor).

If you’ve never attended an FDA advisory committee hearing, it is an interesting exercise in health policy. Committee members sit behind a roped-off area. Those who are scheduled to testify sit beside them. Invited members of the public, like me, sit in a third area, which is entirely separated from the FDA by security personnel.

A large number of press employees are present, cameras are rolling, and many of our colleagues from Wall Street are in the audience. It is a highly scripted affair, with an overwhelming number of PowerPoint slides and posturing by virtually every speaker.

I am proud to reveal that for the past eight years, I have been involved with a joint venture with Merck and Johnson & Johnson that has brought together famous cardiologists, bench researchers, and policy leaders to debate the merits of an OTC form of Mevacor. During my long association with this group, I’ve learned much from such cardiology giants such as Scott Grundy, MD, PhD; Antonio Gotto, MD; and Bill Roberts, MD.

Because of my past efforts to bring Mevacor to OTC status, I felt obligated to comment during the hearing of the most recent advisory board meeting. During my three-minute presentation, I explained that I supported policies that would improve public health. I told the assembled experts that I felt their efforts were misguided, in that we find ourselves working in a completely failed health care system. As most readers of P&T know, Americans receive the appropriate care they deserve only about 50% of the time, both in doctors’ offices and in hospitals. Heart disease remains our number one killer, and we could certainly do a better job of educating the public about the risk of coronary artery disease (CAD), the long-term morbidity associated with CAD, and its burdensome cost to our society. In a nutshell, I suggested that by making Mevacor available as a nonprescription product, we would be contributing to the health of the general public, despite our failing system.

Next, I stated in simple terms that statins represent a successful primary prevention strategy for CAD. The drugs are safe, especially at a low dose, and the notion of the need for continuous liver enzyme monitoring has been discredited by hundreds of peer-reviewed papers. I admonished the advisory committee that people should be able to play a greater role in improving their own health.

Finally, I mentioned that Towers Perrin had produced three reports over the past seven years, under contract with Merck. These reports consistently showed no future disruption of the payment system under managed care if Mevacor were to become an OTC drug. Managed care executives, medical directors, policymakers, and others repeatedly told Towers Perrin that OTC Mevacor would not jeopardize the health of patients needing higher doses and that there would be no wholesale push to make all patients take Mevacor on an OTC basis; these fears were simply unfounded. I reminded the committee that the United Kingdom’s experience of having simvastatin (Zocor, Merck) “behind the counter” had not had a detrimental public health impact.

I concluded with a tongue-in-cheek comment: I stated that the panel members should not approve Mevacor OTC; instead, they should simply put a low dose of Mevacor in the nation’s water supply! That line got a good laugh; it was apparently picked up by all the wire services and ended up in hundreds of newspapers and other media outlets.

Naturally, I share Merck’s disappointment in failing to bring Mevacor to OTC status. I will continue to promote such an important agenda for the health of consumers. I would certainly be willing to go back again to speak to another FDA advisory board to try to convince our national experts about the value of consumers’ involvement in their own health care.

If you are interested in learning more about the Mevacor OTC switch, I recommend the Thomson Scientific Web site. All FDA proceedings are available to the public at the FDA’s Web site as well (www.fda.gov).

As always, I am interested in your comments. You can reach me at my e-mail address, david.nash@jefferson.edu. I also hope you’ll visit my new blog at http://departmentofhealthpolicy.blogspot.com.

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