



BY JIM DAVIDSON

New Rules for OTC Marketing?

With the new leadership in Washington, there could be a renewed effort to enact legislation that would require ads for OTC products to undergo the same scrutiny as advertising for Rx drugs.

» Two changes – one in the leadership in Congress and one at FDA – could provide momentum to proposals that would overhaul the way over-the-counter drugs are approved by the Food and Drug Administration and advertised under the oversight of the Federal Trade Commission.

In the 110th Congress (we are now in the 111th), Rep. Henry A. Waxman (D-Calif.) and Sen. Edward M. Kennedy (D-Mass.) introduced identical bills in the House (H.R. 4083) and Senate (S. 2311) that would have required a significant number of over-the-counter drugs or categories of these drugs to go through a review and approval process again at FDA to see if they should remain on the market.

Moreover, even though the FTC since 1972 has had the power to determine whether advertising for an OTC drug is truthful and not misleading, the legislation would transfer oversight of all OTC advertising to the FDA and subject it to the same labeling and disclosure rules as those applied to drugs available only with a doctor's prescription.

"The Non-Prescription Drug Modernization Act of 2007" produced bad vibrations among manufacturers and marketers of OTC drugs when it was introduced 20 months ago. However, months have passed and the 110th Congress came to a close without any action by Congress on the bills.

Now important personnel changes may rejuvenate this propos-

al. In the House, Rep. Waxman is the new chairman of the Committee on Energy and Commerce, with jurisdiction over the FDA and the FTC. And at FDA, Dr. Joshua Sharfstein has been installed as the deputy commissioner and presently is the acting commissioner of FDA. Dr. Sharfstein served from 2001 to 2005 on the staff of the House's Committee on Oversight and Government Reform chaired by Waxman.

Dr. Sharfstein subsequently has served as commissioner of public health for the City of Baltimore. He is a pediatrician and in 2007 before joining the agency he helped spark an FDA investigation into the safety and effectiveness of cough and cold medicines for young children.

In a promising signal that they are engaged in self-regulation, the pharmaceutical industry has removed many medicines from the market even while FDA has begun looking into new rules to apply to their approval and marketing. Self-regulation efforts need to be continued and strengthened, because the alternative would be very disruptive to the companies that manufacture these products. Adoption of the legislation would be an unfortunate outcome.

The bills introduced by Kennedy and Waxman in the last Congress would have given FDA extraordinary authority to amend monographs for OTC drugs. For example, if FDA proposes to repeal or amend a monograph, it does not have to give the

public advance notice or the opportunity to comment on the proposal the agency may accelerate the removal or amendment process if it finds the product is associated with a significant risk or is lacking in effectiveness.

In addition, the legislation would have required that all advertising for OTC products undergo the same scrutiny as advertising for prescription drugs. This would include prior submission of advertising content for FDA review, inclusion of either the lengthy "brief summary" in print advertising or the "major statement" of risks in broadcast advertising, and presentation of risks and benefits in some form of "fair balance."

This is an extraordinary set of remedial proposals that seem to far exceed the questions that have been raised by a small category of OTC medicines.

The Obama administration promised change in the ways things have been done, and in this area of FDA jurisdiction the change could be far more than anticipated. «

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