Pharmacy Distribution of Consumer Drug Information Emerges as a Problem

FDA to Seek Solutions

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An advisory committee meeting at the FDA, scheduled for late February, is expected to re-ignite a debate over point-of-prescription information that pharmacies provide to consumers. The debate has been going on since the waning days of President Jimmy Carter’s administration, believe it or not, and finally resulted in legislative requirements set up by Congress in 1995. As a result, pharmacies were faced with the task of voluntarily meeting certain yardsticks for distributing consumer medication information (CMI). These targets have clearly not been met, according to an FDA report published in December 2008.

Janet Woodcock, MD, Director of the FDA’s Center for Drug Evaluation and Research, said: “The current voluntary system has failed to provide consumers with the quality information they need in order to use medicines effectively and safely. Because the congressional goals have not been met, the FDA intends to seek public comment on initiatives that can be used to meet the goals.”

A CMI is a computer-generated, one-page sheet that pharmacists can staple to or place inside the bag into which a prescription vial is placed before they hand it to the consumer. A CMI differs from the professional labeling that drug companies produce for each drug. A drug product’s labeling can run for 30 pages or more; it covers uses, contraindications, and warnings, and it is intended for physicians. Pharmaceutical companies also produce consumer medication guides about specific drugs that the FDA has identified as particularly risky in terms of potential adverse effects. Pharmacies distribute the guides, which are required for about 40 drugs.

The pharmacy, not the drug company, is responsible for producing the CMI and for attaching it to the prescription. Private third-party vendors write a meticulously worded CMI for each drug and then update the information. The pharmacy decides which elements of each CMI it will actually print and attach to the prescription for the consumer.

The idea of requiring pharmacies to hand out a brief summary of a drug’s potential adverse effects originated during the Carter administration. A regulation was readied by the FDA, but the incoming Reagan administration put it on the back burner in 1982. It stayed there until President Bill Clinton took office. In 1995, the FDA dusted off the Carter initiative and published a proposed rule that would require 75% of prescriptions filled in the year 2000 to be accompanied by useful CMI—whose format the FDA would dictate—and that percentage would increase to 95% by the year 2006. After pressure from the pharmaceutical industry, Congress stepped in and adopted the FDA’s timetable, but it allowed the pharmacy industry to develop the leaflets on its own.

The study released by the FDA this past December showed that pharmacies are still falling far short of the 95% goal of providing “useful information” that the 1995 legislation endorsed. The 2008 report was based on CMI that shoppers had picked up when two drugs—lisinopril (Zestril, AstraZeneca; Prinivil, Merck) and metformin (Glucophage, Bristol-Myers Squibb)—were purchased at 365 chain and independent pharmacies in 41 states. The report, written by University of Florida Pharmacy School professors, said that although the distribution method via pharmacies appeared effective, the content of the information was problematic. The shortcomings highlighted in the report included a lack of critical information about managing the medications, a significant redundancy of information resulting in excessively long leaflets, poor formatting, and illegibility; they also indicated that the material was written for an inappropriate reading level.

CMIs for the same drug vary widely from pharmacy to pharmacy. The report cites two metformin leaflets, both of which were based on information provided by one of the two major third-party suppliers, First Databank. One pharmacy handed out a metformin CMI with 760 words and 30% adherence to the FDA’s guidance criteria for content; the other CMI contained 2,457 words and met 88% adherence to the criteria.

Ray Bullman, Executive Vice President of the National Council on Patient Information and Education, says that there are several reasons for the shortcomings detailed in the 2008 University of Florida report. The FDA finalized its guidance on CMI only as recently as July 2006, nine years and seven months into a 10-year program.

“That was certainly not helpful or supportive,” he stated.

He added that it has been a challenge getting pharmacies to make what could be major investments in changes to hardware and software systems with the capacity to generate a comprehensive CMI monograph.

Pharmacy groups are certain to testify at the February advisory committee meeting that electronic prescribing and anti-counterfeiting imperatives are already sopping up large amounts of funds for investing in software and hardware and that there isn’t much money left over for CMI development. Moreover, John Rector, Senior Vice President and General Counsel at the National Community Pharmacists Association, argues that the FDA actually has no jurisdiction over pharmacies’ handling of CMI because pharmacy operations are regulated by state boards of pharmacy.

Of course, Congress can hand over that authority to the FDA. As CMI initiatives have picked up steam under past Democratic administrations, the February meeting is also likely to witness rallying cries from groups such as Public Citizen demanding that Congress admit the failure of the 1995 law and urging that it institute mandatory requirements.