Docket#03N-0168

AARP

Testimony by
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at

the FDA Public Hearing
on

The Current Status of Useful Written Prescription Drug Information for Consumers

July 31, 2003

03N-0168 TS 2

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Good Morning. My name is John Rother, and I am the Director of Policy and Strategy for AARP.

It should come as no surprise that the availability of high-quality written information about prescription medicines is important to AARP members, since so many members use these medicines -- often multiple prescriptions -- every day. "High-quality" relates both to the content and the format of this information. As we all know, vision diminishes with age, and for this reason, written materials must be properly designed to ensure that older consumers can read them.

There is a general consensus that high quality, written information about prescription drugs, geared to consumers, can have a beneficial impact on public health. This information can reduce preventable, medication-related problems by clearly highlighting potential risks and possible side effects. With so many people still failing to take their medications as directed, this information can also help improve compliance.

There is continuing disagreement, however, about how best to provide this written prescription drug information: should it be mandated by a government regulation or can it be successfully implemented through a voluntary program?

AARP has consistently supported a mandatory approach to the provision of written information because we believe that this is the best way to ensure that useful information reaches the greatest number of consumers. Today, we once again urge FDA to reconsider a mandatory approach to providing written prescription drug information, and we suggest some options for the agency to consider. At the same time, we recognize that FDA may choose to give the voluntary program more time and, for this reason, we

also offer some suggestions on what both the private sector and the agency must do to make the voluntary program more effective.

Why do we believe that it is time to reconsider a mandatory approach? Dr. Svarstad's research provides the answer: despite the widespread distribution of written information about prescription drugs, the quality of this information is seriously lacking. The expert panelists who participated in Dr. Svarstad's research found that the leaflets with written prescription information that are currently being distributed are deficient in many areas, especially relating to risk information. In addition, the consumer participants were particularly critical of the print size, print quality, and overall ease of reading.

The fact that we are already six years into the voluntary program, and there are still such significant problems with the quality of the written leaflets that are being distributed, is why we fear that the voluntary program will not ultimately succeed.

Even though AARP supported a mandatory regulation in this area, we did participate in the development of the Action Plan that is the "blueprint" for the voluntary program. We were instrumental in drafting the format guidelines for written information and the sample information leaflets that were included in the plan.

Here is a sample pamphlet. I would like to know why there aren't more prescription drug leaflets available today that look like this one? It's printed in a readable type size and style, it uses headings in the form of questions, and arranges information using bullets. The result is a leaflet that is easy to read.

I'm concerned that one of the reasons why we haven't seen more pamphlets like this one is because the Action Plan has not been widely distributed. This may be due to

the fact that the law that established the voluntary program failed to establish any procedure for its implementation.

The sample leaflet I just held up looks alot like the food label and the new "Drug Facts" label that is now required for all over-the-counter drugs. That's because all three were designed by the same advertising firm.

The experience with the food label is instructive here: after years of a voluntary program for providing nutrition information on food labels, it took a mandatory regulation to finally ensure that consumers received consistent, easy-to-read information about the foods they eat, information that helps them make more healthful food choices. AARP believes that, when it comes to prescription drugs – which can have an even greater impact on health -- consumers deserve even better information.

Some have expressed concern that a mandatory regulation might be too resource-intensive for an already overburdened agency. We believe that this concern is overstated because FDA need not reinvent the wheel here. There is an existing regulation governing the mandatory distribution of "medication guides" for drugs that present "serious and significant public health concerns." This regulation can be a starting point for the agency, which can then consider appropriate revisions, in light of the Action Plan.

Further, the FDA could consider alternate approaches to enforcement that would minimize any undue burden. Currently, FDA preapproves the mandatory medication guides for all "serious and significant" drugs. For other drugs, however, the agency may not need to pre-approve every written information leaflet. As is the case with the nutrition label, the regulation could set out all of the requirements, including specific format guidelines and samples, and FDA could then rely on post-market surveillance of

information leaflets to ensure compliance. This approach would require additional resources, but these would not be as significant as those required with a preapproval system.

In addition, FDA could take other actions short of issuing a mandatory regulation. For example, the agency could issue a policy statement or guidance document governing written information leaflets. Although not enforceable like a regulation, such a statement or document developed by the regulatory agency often has more weight than one that is developed outside of the agency.

If FDA determines that the voluntary approach deserves more time, then the private sector must make a serious commitment to making it succeed. This requires a commitment to spend the money and time necessary to disseminate the Action Plan and assist in its implementation. The private sector must move quickly to ensure that the voluntary program meets the year 2006 goals established by law. It must establish and meet specific timetables and targets; without these, this program has little hope of success.

FDA still has a central role to play here. First, it could do more to assist in the dissemination of the Action Plan. For example, a simple step would be to provide a link to the Action Plan on the FDA website. This is particularly important since the website for the Keystone Center, which wrote the Action Plan, is no longer in operation.

Most important is FDA's responsibility to assess the voluntary program. Rather than waiting until the end of 2006 to determine whether the voluntary program has met its goal, FDA should engage in an on-going review of the written prescription

information leaflets that are being distributed. Such an on-going review would allow for mid-course corrections, thereby better ensuring the success of the program.