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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Comments of members of the Patient, Consumer, and Public Health Coalition
on Medical Device Patient Labeling
[Docket No. FDA-2000-D-0067]

As members of the Patient, Consumer, and Public Health Coalition, we appreciate the opportunity to comment on Medical Device Patient Labeling. The 2001 FDA Guidance on Medical Device Patient Labeling states that "medical device patient labeling is any information associated with a device targeted to the patient or lay caregiver." Medical device patient labeling can be in numerous formats, including patient brochures, user manuals, informational webpages, and online training videos. Patient labels should provide information such as proper use, risks and benefits, maintenance, and mode of action in language the patient or caregiver can read and

understand. We are commenting on current medical device patient labeling and on advancing development of labels.

Comments on Current Medical Device Patient Labeling

We support the emphasis in the workshop on using human factors engineering to ensure they are understandable to the public. We strongly support FDA's use of objective evidence of usability. This requires labels to be written at an appropriate reading level as measured by a validated testing method and that labels be focus-group tested with a representative sample of potential users with a wide range of reading levels as well as health literacy levels. Although making the information understandable is key, it is equally important to make it as interesting to read and visually appealing as possible. Microscopic fonts and lack of white space has been a problem with labels for years, and that is a major reason why they are not read.

Comments on Advancing Development

At the "Medical Device Patient Labeling" workshop, a couple of points received less attention than they should have. As the 2001 Guidance states, there are two general categories of labels: (1) Risk-benefit information and (2) Instructions for use. While readability and organization of both types of labels are critical to assure safe and effective use, there are some considerations that differ for the two categories. For example, being concise was brought up many times as critical to the effectiveness of instructions for use. While avoiding wordiness and repetition is important and being concise is a desirable goal, **understandable and complete information are much more important for risk-benefit labels**, which are often key sources of information for patients while making healthcare decisions. Complete information does not, however, require the inclusion of information of no interest to patients. Patient booklets that are 20 or 30 pages long are almost never appropriate and putting risk information, contraindications, or warnings on page 8 or later is never appropriate. The most important information – risks and benefits – should be first.

Also, while labels are required to describe the *known* risks and benefits, labels should also clearly include what is *not known*. This is particularly important in the case where no clinical trials were conducted, no comparison samples were included in clinical trials, or surrogate endpoints rather than clinical outcomes were used to clear or approve the device. In these cases, the label should clearly state that the benefits or risks for patients' health are unknown at this time, or the benefits and risks compared to other treatment options are unknown.

In addition, labels should tell patients if the device is proven to be safe and effective for specific demographic subgroups, such as women, men, people of specific racial/ethnic groups, people who are over 65, or people with particular comorbid conditions. For most of the 20th Century, clinical trials were predominantly conducted on white men and the data was simply assumed to apply to all patients. However, increasingly research has shown that not to be true. For that reason, it is important for FDA to provide information about data analyses specific to those demographic subgroups on the device label. If no such subgroup analysis has been done, this should be stated explicitly on the label along with the reason why (for example, that there were not enough patients of that demographic in the clinical trial for an analysis to be performed).

Unfortunately, so little subgroup scientific data are available for most devices that it will be easy to provide this information in a sentence or two.

Conclusions

Members of the Patient, Consumer, and Public Health Coalition strongly support the FDA's use of objective usability evidence and requiring labels to be written at an appropriate reading level that is easy and interesting to read. However, FDA should focus more on key issues around "advancing development" of labels such as noting on the label if risks and benefits were determined with surrogate endpoints, whether clinical trials were conducted, and whether the device was analyzed on subpopulations.

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National Center for Health Research
National Consumers League
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