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AdvaMed
Advanced Medical Technology Association

December 16, 2011

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

Re: Docket No. FDA-2011-N-0766: Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of 'Health Care Providers' Responses to Medical Device Labeling

Dear Sir/Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to provide these comments in response to the comment request regarding FDA's proposed collection of information on a survey of health care providers regarding medical device labeling.

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. These members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than $30 million in sales annually.

AdvaMed has a number of concerns with the proposed collection of information. We respond to the questions and issues posed in the Federal Register notice below.

1. **Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.**

The survey will have limited utility because of the narrow scope of the fictitious labeling and fictitious device – a single channel large volume infusion pump and a quick reference guide. The survey asks participants to evaluate what seems to be a quick reference guide ("abbreviated document"; "quick reference") or short version of instructions for use for the

fictitious "Tohamadi Large Volume Infusion Pump." The quick reference is a subset of the types of instructions provided by device manufacturers. The format and level of information provided by manufacturers in device labeling is directly related to the audience and the device for which the instructions are written. Surveying a group of potential users on the value of a very specific device (a single channel large volume infusion pump) and a very specific type of instructions (the quick reference) appears to lack value if it is to be extrapolated to *all* types of device instructions for *all* types of devices. In short, it is difficult to understand how the results of the proposed survey can be extrapolated to the broad range of device types and diverse users of medical devices.

The survey questions also appear to focus on information provided in the fictitious device labeling as well as the labeling format. It is inappropriate and of little utility for the survey to ask about the information (e.g., questions 27, 28) for a fictitious device. The survey questions should be limited to the format of the labeling.

In addition, the FR notice states that the survey will build "upon the research methodology and success of the approach FDA used to evaluate drug labeling...". It is important to understand that devices are not drugs. Drug instructions are typically written for two audiences: the physician and the user. In contrast, devices are a widely diverse group of products – from the very simple to the very complex. Depending on the device type, instructions for their safe use can be very short or must be very complex, detailed and technical. Device instructions must also frequently be written for a diverse audience with a wide range of education and experience, e.g., physicians, nurses, technicians, biomedical engineers, and patients. It seems unlikely that the drug experience would be helpful in assessing medical device labeling.

We support FDA's mission to ensure safe and effective devices are released to the market and it is appropriate for FDA to ensure adequate information is provided to users. It may be helpful to industry to have recommended formats and contents of labeling but these must be carefully chosen to ensure they are applicable to all devices and users. It is not certain that the information gathering focused on a single channel large volume infusion pump will provide the necessary information.

2. The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

We question the underlying premise of the collection of information and its associated methodology and assumptions. The Federal Register notice indicates that the survey of health care providers will help FDA "to evaluate the quality of labeling (e.g., instructions for use, directions) for a medical device and to report the degree to which they could follow those instructions, how useful the information is, and how well organized the information is." It is not clear how a survey on one specific device type – single channel large volume infusion pumps, as proposed in the actual survey – can inform FDA's regulatory approach on standardized device labeling for all medical devices. A survey focused on a labeling for a

fictitious infusion pump will only inform as to the labeling for that product and perhaps other devices with the same intended use, user base, etc. Extrapolation of the survey data to other device types (e.g, surgical, implantable, patient-used) is not addressed. It is unclear how the survey will have the practical utility the agency has described given the diversity of all medical device types and given the diversity found within infusion pump device types.

Additionally, it can be anticipated that different health care practitioners or technicians will provide different answers based on their individual professional needs. For example, medical doctors (with the exception of anesthesiologists) rarely interact with infusion pumps. However, nurses and biomedical engineers will frequently interact with infusion pumps. If this is the case, what will FDA do with conflicting information from different professionals? Will one professional group's responses be accorded greater status? Will safeguards be established to ensure that comments are only accepted based on experience with the device in question?

Finally, if the focus of the survey is generic device labeling as suggested by the Federal Register notice, the single-minded focus on infusion pump labeling in the survey is misleading and confusing. Rather, it appears the objective of the survey is to improve labeling for a particular device type – single channel large volume infusion pumps. If so, the Federal Register notice should be reissued to better align the purpose of the collection of information with the actual survey. Alternatively, if the objective of the survey is to improve generic device labeling, the survey should be altered to create a fictitious device with no known intended use to accord with that objective.

3. **Ways to enhance the quality, utility, and clarity of the information to be collected.**

To improve the quality and utility of the survey instrument, FDA should add a baseline question to the survey regarding whether the health care professional ever uses or reads device labeling in their day-to-day professional life. If not, why not? It may be useful to understand how to improve *access to current* device labeling in addition to improving future device labeling. FDA has also neglected a key device user group – biomedical engineers. Biomedical engineers should be survey targets and should be added to the list of occupations in survey Question 3.

FDA should also carefully review the survey instrument and consider modifying it to improve the utility and value of the survey. For example, rather than asking whether a table of contents should always, never or sometimes be included in device labeling, FDA should ask "have you ever used a table of contents to find information" or "how useful do you find a table of contents"? It has been reported to us by manufacturers that in observational studies used to validate device labeling, users searched for the information but never looked at the Table of Contents or the index. When asked, the participants said it never occurred to them to look in the Table of Contents or the index for the topic – they simply hunt until they find things. Responses to questions like this may also vary by professional group.

Although a subjective opinion survey on what to include and how to organize labeling for medical devices will yield some valuable information, FDA should also employ human factor approaches to the study. It is typical to pilot surveys first with a small group to uncover unintended biases in the survey design. For example, an objective, task-based usability study including navigating the labeling for a fictitious device with no intended use and answering questions after finding targeted information from the labeling would provide objective evidence that the survey format is appropriate. In short, a formative evaluation of the survey itself could yield higher quality results in the end.

If FDA proceeds with a survey of the fictitious "Tohamadi Large Volume Infusion Pump," it should be aware that the format of the fictitious labeling will likely not be appropriate for all devices. Indeed, it would be misleading to design all medical device instructions based on a study limited to just one device type. It would be better to conduct objective usability tests with a range of medical device types including simple mechanical devices, simple electrical devices, complex software-based devices, patient-use devices, physician-use devices, nurse-use devices and caregiver-use devices to name a few.

In conclusion, thank you for the opportunity to provide input on the collection of information. Please do not hesitate to contact me if you have any questions.

Sincerely,

Tara Federici

Tara Federici
Vice President
Technology and Regulatory Affairs