

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

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February 6, 2004

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

Re: Docket No. 2003N-0529, Amending the MedWatch Forms to Collect Postmarketing Adverse Event Data Relating to Race and Ethnicity

Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, I am pleased to submit comments on whether FDA's MedWatch forms (Forms 3500 and 3500A) should be amended to collect race and ethnicity data.

AdvaMed represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$71 billion in health care technology products consumed annually in the United States, and nearly 50 percent of the \$169 billion purchased around the world annually.

AdvaMed opposes the proposed collection of racial and ethnic data on MedWatch Forms 3500 and 3500A. We have provided both general and specific comments below in response to FDA's request for comments.

General Comments

It is clear from the content and focus of the December 8 *Federal Register* Notice and Request for Comment that the proposal to modify the MedWatch forms to include race and ethnicity data is based on drug requirements. The notice explicitly states that "drug regulations require sponsors to present an analysis for data according to demographic subgroups (age, gender, race) as well as an analysis of modifications of dose or dosage intervals for specific subgroups. . . ." and cites 21 CFR 314.50(d)(5)(vi)(a). As you may know, the collection of racial and ethnic data is not currently required by either the

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medical device reporting (MDR) regulation or the medical device tracking regulation. Nevertheless, a modification of Form 3500 and 3500A would have a significant and costly impact on the device industry because the proposed changes affect the section of the Form 3500/3500A that is also used by the medical device industry.

The potential racial and ethnic variations in the metabolism of drugs may make the collection of such data relevant for drugs, although a recent note in *Science* by Suzanne Haga and Craig Venter pointed out that “Several studies have confirmed that greater genetic variation exists within groups than among them. Geographical origin (ancestry) seems to be more relevant than a person’s self identified race.”¹ Self identification of race and ethnicity frequently represents social rather than scientific information. Thus, it is not clear that the collection of such data makes sense even in the case of drugs – arguably the area where it makes the most sense – not to mention combination products where the arguments tend to fall apart or devices where the arguments make no sense at all. For the vast majority of devices, race and ethnicity have no bearing on device function. Instead, the dominant and relevant factors for devices, such as patient size, weight and anatomy, transcend race and ethnicity.

In addition, we believe that the medical device industry would be prohibited by the Health Insurance Portability and Accountability Act (HIPAA) from collecting such information. HIPAA provides an exemption for the collection of protected health information when federal regulations require the collection of such data. However, there are no federal regulations that require the collection of such data for devices. As noted above, the medical device reporting and medical device tracking regulations do not require the collection of racial or ethnic data. We believe these regulations would have to be amended in order to allow the collection of such data under HIPAA. We also believe it is unlikely that hospitals will voluntarily provide the device industry with racial and ethnic data. We have heard from some companies that, with the implementation of HIPAA, some hospitals are reluctant to provide the information that is necessary for device companies to complete adverse event investigations. For this reason, AdvaMed discussed with FDA the possibility of FDA’s developing guidance to educate user facilities about the relationship between HIPAA and federal requirements, and hospital responsibilities under the MDR and medical device tracking regulations. In sum, we believe it is unlikely that hospitals will voluntarily provide medical device manufacturers with racial and ethnic data.

Finally, we would like to highlight that from a medical device perspective, the proposal to collect racial and ethnic data on the MedWatch forms moves away from rather than toward harmonized adverse event reporting that is being implemented by the Global Harmonization Task Force (GHTF), of which FDA is a founding member. The GHTF document entitled “Medical Device Postmarket Vigilance and Surveillance Universal Data Set for Manufacturer Adverse Event Reports” prepared by Study Group 2 and

¹ Haga, S.B. and J.C. Venter, “FDA Races in Wrong Direction,” *Science*, Vol. 301, p. 466 (25 July 2003)

finalized in February 2003 does not list racial or ethnic data among the required data set elements. Instead, it requires factors such as age, gender and weight, among others.

Specific Comments

In response to the specific questions listed in the *Federal Register*, AdvaMed provides the following responses.

1. Should the MedWatch forms (Forms FDA 3500A and 3500) be amended with a special field or fields to capture adverse event data on race and ethnicity?

For the reasons listed in our general comments, AdvaMed opposes the addition of a special field or fields to capture adverse event data on race and ethnicity unless it is made clear in the amended field(s) that the requirement for racial and ethnic data applies only to drug adverse events and does not apply to device adverse event reporting. FDA should also grant an automatic exemption to allow medical device firms to continue to use the current form. Device manufacturers already find it difficult to obtain basic required information from hospitals about adverse events related to devices such as age, sex, and weight. The addition of racial and ethnic data would make it even more challenging and difficult for device manufacturers to complete adverse event investigations in a timely manner.

In addition, for firms relying on computer-generated forms, software modifications and validations will be necessary to accommodate any modification of the 3500 or 3500A forms. Further, validating changes is timely and costly and companies need to be able to budget and plan for both. The medical device industry is already undergoing an unplanned and unscheduled modification of the MedWatch forms to accommodate the provisions of Sec. 303 of the Medical Device User Fee and Modernization Act (MDUFMA) related to reprocessed single use devices. Multiple form modifications will be costly, time-consuming and overly burdensome to the medical device industry.

2. What is the financial impact associated with adding a special field or fields to the MedWatch forms to collect data on race and ethnicity?

At least one medical device company has estimated that the costs associated with making additional changes to the MedWatch forms will be \$10,000 per system. Such costs are related only to the modification and validation of computer software and do not include costs to modify personnel training, telephone scripts and the costs associated with the additional effort that will be needed to obtain race and ethnicity data. Many medical device companies have multiple systems, each supporting different medical device product lines.

In conclusion, AdvaMed opposes the proposed collection of racial and ethnic data on MedWatch Forms 3500 and 3500A. If FDA proceeds with the proposed modifications, FDA should make clear that the proposed modifications apply only to drug adverse events and FDA should grant an automatic exemption to allow medical device firms to

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continue to use the current form as recently modified by Sec. 303 of MDUFMA. If you have questions, feel free to contact me at 202/434-7208 or tfederici@advamed.org.

Sincerely,

A handwritten signature in cursive script that reads "Tara Federici".

Tara Federici
Associate Vice President
Technology and Regulatory Affairs