



Bristol-Myers Squibb Company

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**Dockets Management Branch
Food and Drug Administration, 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, Reference to 68 Federal Register 68402 (December 8, 2003)

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2002 alone, Bristol-Myers Squibb dedicated \$2.2 billion for pharmaceutical research and development activities. The company has more than 5,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises of approximately 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal to amend the Medwatch Forms to Collect Postmarketing Adverse Event Data relating to race and Ethnicity that was published in the Federal Register on December 8, 2003. We commend the FDA for a well-written and concise proposal. However, we would like to take this opportunity to offer general comments, followed by more specific concerns with the proposal.

General Comments

We commend the FDA for its interest in understanding race and ethnicity patterns in postmarketing adverse events. However, we do not believe amending the Medwatch forms to collect race and ethnicity data will achieve the desired goal. Rather we believe the proposed amendments to the Medwatch forms will create difficulties for the acquisition of valid data with respect to the accurate interpretation of race and ethnicity.

The current Office of Management and Budget (OMB) category definitions of race and ethnicity reflect the unique sociocultural construct of society in the United States. As such, these category definitions are not particularly applicable to other countries where there exist differing interpretations of race and ethnicity characterizations. For example, the term "Latino" can be overly broad and confusing thereby giving rise to the risk of inconsistent responses from Spanish speaking peoples, particularly those outside of the United States. Consequently, race and ethnicity

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data captured in spontaneous reports from other countries will not be consistent with data collected in the United States. Further, we believe any changes to MedWatch forms should bring them closer to ICH standards.

Moreover, there may be significant rates of refusal to report race and ethnicity. Both healthcare professionals and consumers may be resistant to responding to questions about race and ethnicity. In addition, race and ethnicity may be categorized differently by a health care provider and a patient.

Specific Comments

The proposal recommends a two-question format for requesting race and ethnicity, with the ethnicity question preceding the question about race. The minimum choices for ethnicity are designated as Hispanic or Latino versus not Hispanic or Latino. Even within the United States, the meaning of these terms may vary. Hence, one cannot expect US residents originating from geographic areas such as Central or South America, to provide consistent responses to these choices.

In addition, the FDA proposal recommends individuals should be permitted to designate a multiracial identity. If an individual can designate him or herself as belonging to more than one racial category, this will impact the way race will be reported. Instead of reporting race into mutually exclusive categories (White, Black, Asian), reporting will have to be made for each category with its complement (e.g. Black/fractional Black versus non-Black, etc). We would prefer the guideline seek a subject's primary race in order to avoid this increased level of complexity in reporting and analysis.

The FDA is also seeking comments on the implications that collecting such data would have for international reporting of postmarketing adverse events. The meaning of race and ethnicity categories vary from one geographic or political region to another. The terminology chosen in this proposal is generally inappropriate outside of the United States. In particular, the definition of the Hispanic and Latino ethnicity needs to be clarified as to whether a patient of Spanish or Portuguese heritage should be categorized as Hispanic or Latino ethnicity. The collection of race and ethnicity data may also contradict the patient privacy laws of other countries.

Moreover, the proposed racial categories are not exhaustive. Specifically, there are no accurate classifications for indigenous people of non-U.S. countries. The proposal should recommend how to include these significant groups within the proposed categories, or as an added category, such as "other". As an example, the proposal should clarify within which category to classify Australian Aborigines.

The FDA proposal recommends the terms "Native Hawaiian or Other Pacific Islander" and "American Indian or Alaska Native" as choices for race. For international reporting purposes the terminology should not be biased toward a U.S. audience. Accordingly, we suggest these racial choices be designated as "Native Pacific Islander" and "North American Indian or Alaska Native."

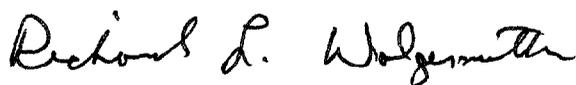
Historically, Bristol-Myers Squibb receives most spontaneous adverse event reports by telephone. Of these, the majority come directly from consumers. Taking this historical reporting structure into consideration, one may expect patients themselves to be resistant to providing reporters with sensitive information about race and ethnicity, especially over the telephone. In addition, health care professionals may be tentative or uncertain about accurately reporting the racial or ethnic background of a patient under their care. Consequently, there may be significant rates of refusal to report race and ethnicity or inaccurate reporting.

Furthermore, healthcare professionals may report race and ethnicity differently than patients due to differing interpretations of category definitions. Therefore reports on race and ethnicity may not be comparable between these two reporting groups. Pharmaceutical companies routinely follow up with a patient's health care professional if the original report was received directly from the patient. If the information is discrepant between the two reporters for race or ethnicity, additional follow up will be necessary. This will be particularly burdensome if race and ethnicity are included in the "Full Data Set", requiring active follow up and tracking, as described in the FDA proposed rule on Safety Reporting Requirements for Human Drug and Biologic Products (Reference to 68 Federal Register 12046, March 14, 2003).

Lastly, the addition of any new items to the MedWatch form will impact the electronic submission of data to the FDA and other regulatory agencies. It is the opinion of BMS that it would be more appropriate to address this issue with the newly formed ICH E2B(M) Expert Working Group. This would ensure the addition of any new fields to the E2B(M) standard would be the product of ICH consensus, and therefore suitable for the collection of worldwide data.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,



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