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Comment from Celia Besore, National Association of Hispanic Nurses (NAHN)

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General Comment

Comments to Docket: FDA-2014-N-1960
Thank you for the opportunity to review and comment on the FDA MedWatch: The FDA Medical Products Reporting Programâ€"(OMB Control Number 0910-0291)â€"Extension.
The National Association of Hispanic Nurses (NAHN) is a professional association composed of nurses of Latino/Hispanic ethnic background and other healthcare practitioners who serve the Latino community. Part of the NAHN mission is to advocate for improved health outcomes within the Latino community and other underserved populations.
As indicated in the request for comments, the FDA wants to receive comments on whether the FDA Medical Products Reporting Program collects the necessary information for the proper performance of FDA's functions and whether the methodology and assumptions used are valid regarding the FDA's estimate of the burden of the proposed collection of information.
We believe the current system does not adequately fulfill the stated purpose of the FDA Medical Products Reporting Program since the MedWatch forms (and especially those for use of consumers) are only provided in English.
Our comment and recommendation is also related to another of the stated reasons for the comment period -- that of finding ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents.
To ensure the marketing of safe and effective products, postmarketing adverse outcomes and product

problems must be reported for all FDA-regulated human healthcare products and other specified products, and since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, their patients, and consumers via the MedWatch reporting process.
It is very important to ensure that voluntary reporting be facilitated as much as possible to ensure robust participation that is inclusive and reflective of the diverse populations in our country.
To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use since the data will be used to assess and evaluate the risk associated with the product.
While many in the U.S. population do not speak English at a sufficient level, Form FDA 3500B, which is used for voluntary reporting by consumers (i.e., patients and their caregivers) is only available in English.
According to the U. S. Census Bureau, some 60.6 million people, or nearly one-in-five people in the U.S. aged 5 or older, spoke a language other than English at home in 2011, up from 23 million in 1980, or almost one-in-11. Of 291.5 million people aged 5 and over, 60.6 million people spoke a language other than English at home.
Among the non-English speakers, two-thirds speak Spanish, with about 37.6 million in the U.S. speaking Spanish at home in 2011, up from about 11 million in 1980.
Among those who speak another language, 22 percent said they speak English "not well" or "not at all.â€ Spanish speakers were less likely to speak English â€œvery wellâ€ (56 percent) than those who spoke another language (61 percent). The percentage of those who spoke Spanish and spoke English less than â€œvery wellâ€ among the US population was 5.6 percent in 2011.
A large sector of the U.S. residents lack the necessary language skills to report any post-marketing adverse outcomes and product problems. They are excluded from the systems since the only way for those with limited English skills to participate is to have to rely on others.
This situation also goes against President Bill Clintonâ€™s Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency," which requires federal agencies to identify the need for services to those with limited English proficiency (LEP) and to implement a system to provide meaningful access to language-assistance services.
Complicating further the situation among the Latino population is that Latinos have experienced low levels of participation in clinical trials. A recent study describes enrollment of only 2.2% Hispanic patients of 104,337 participants in an array of cancer clinical trials conducted between 2001 and 2010. Other studies have found similar results.
In summary, our findings indicate that the current system does not currently reflect the potential harm or adverse reactions impact that many of the products under the review of the FDA may be experienced by a significant segment of the population.
As the professional society for Hispanic nurses and healthcare practitioners who serve Hispanic patients and caregivers, we strongly urge the inclusion of a Spanish version of FDA Form FDA 3500B.
Respectfully Submitted,
Celia Trigo Besore
Executive Director
On behalf of the National Association of Hispanic Nurses

Attachments

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