

July 21, 2004

Food and Drug Administration
Docket No. 2003N-0342
RIN 0910-AC35
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products

To Whom It May Concern:

The National Council on Patient Information and Education (NCPIE), a non-profit coalition dedicated to improving patient safety through enhanced communication about medicines, is pleased to submit comments on the proposed rule (April 22, 2004), "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products."

Our comments do not necessarily reflect the opinion of each of the 115 organizations that comprise the NCPIE coalition, some of whom have submitted their own comments for the Docket.

Since our founding in 1982, NCPIE (www.talkaboutrx.org) has always endorsed the concept that more communication is better when it comes to safe, appropriate use of medicines. For example, themes for our "Talk About Prescriptions" Month – a national health observance held each October since 1986 – have included, "Communicate Before You Medicate," and "Educate Before You Medicate." This proposed rule could promote valuable communication between a patient/caregiver and his/her healthcare professional.

Further, timely communication about side effects and/or adverse events could promote adherence with therapy, and/or timely substitution of an alternate therapy.

Also, although voluntary reporting systems historically lead to under-reporting of adverse events, urging consumers to self-report will boost the total 'numerator' of MedWatch reports. This anticipated increase could provide additional valuable post-marketing safety information that could, in turn, strengthen the evidence to update a product's PI and/or issue public warnings.

Below, please find our comments on specific issues raised by the proposed rule:

1. Use of the term "side effects": We agree that, for consumers, this term is more easily understood than "adverse events." NCPIE recently published a brochure, "Get the Most from Your Medicines: Managing Side Effects," written by Dorothy Smith, Pharm.D., President of the Consumer Health Information Corporation. The brochure is available from NCPIE (see web URL above).

2. Use of qualifier to help avoid unintended consequences: We suggest that the word “serious” be added to precede the term “side effects” in the proposed statement, “Call your doctor for medical advice about serious side effects. You may report side effects to FDA at 1-800-FDA-1088.” The proposed rule was published to comply with the Better Pharmaceuticals for Children Act (BCPA). Unfortunately, the BCPA was not written with sufficient clarity in regard to the mandating disclosure of the FDA toll-free number for reporting side effects. The BCPA does not categorize the types of side effects that should be reported. Rather the required language suggests that all side effects should be reported. This may lead to large numbers of unnecessary reports to FDA for side effects that are not serious and are well known and expected. The unintended consequence of the requirement may be that the FDA may have less time to devote to monitoring more serious or unexpected side effects that have a potential for significant morbidity or mortality. It is imperative that this rule not overwhelm the FDA’s ability to safeguard the public health at the expense of managing a large volume of reports of complaints that are well established and do not represent a serious public health threat.
3. Distributing the side effects statement: From our perspective, placing the statement within the “Side Effects” section of the existing consumer medicine information (CMI) leaflet is the most logical place for the statement to be conveyed. Further, by incorporating the statement and 1-800 number into the CMI, educational outreach to consumers about the side effects statement could be built into public awareness for the CMI Initiative (coordinated by the National Council on Patient Information and Education, per FDA’s request) whereby the private sector is working to meet targets by 2006 for “useful” CMI per Public Law 104-180. Inclusion of the statement and 1-800 number on FDA-approved Medication Guides and on Patient Package Inserts (PPIs) are also viable options.
4. Consumer Outreach and Education: In conjunction with finalization of this rule, we recommend that FDA support the development of a comprehensive, collaborative, consumer outreach and education program about MedWatch and its goals. NCPPIE would be pleased to participate in the formulation and implementation of such an important program.
5. Tracking awareness and use: FDA is encouraged to add specific questions to its ongoing National Surveys of Prescription Medicine Information Received by Consumers (at the physician’s office and pharmacy) to track awareness of the statement and 1-800 number, and to what extent consumers report contacting the agency to report a side effect.

Please do not hesitate to call me at (301) 656-8565 or at bullman@ncpie.info if you have any questions about the above comments. We appreciate your consideration.

Sincerely,

Wm. Ray Bullman
NCPPIE Executive Vice President