

July 21, 2004

Department of Health & Human Services
Food & Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852



Docket No.: 2003N-0342 - RIN 0910-AC35

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

To Whom, It May Concern:

For many years the National Consumers League has encouraged the FDA to provide an easy and efficient way for consumers to report adverse drug events directly to the agency. As the oldest consumer advocacy organization in the country, NCL appreciates the opportunity to submit comments on the proposed rule (April 22, 2004), "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products."

Given the complexity of the current health care delivery system, it is especially important that consumers be able to directly report medication mistakes, errors, and adverse drug events. At present, too many incidents of medication errors and serious adverse drug events go unreported. Not only are some health care institutions and professionals neglectful in reporting, but also they may be discouraged or afraid to report because it could impact their exposure to litigation when they admit that an error or mistake has occurred. As such, NCL strongly supports use of the MedWatch system as a vehicle for capturing valuable post-market safety information.

Please find below our comments on the proposed rule for FDA's approach to the Best Pharmaceuticals for Children Act (BPCA):

1. Modification of the Current MedWatch System: By informing consumers about the MedWatch reporting system, FDA hopes to increase its awareness of, and data for, adverse events. These data may result in additional review of the safety and/or effectiveness of certain drug products on the market, and will provide the FDA with the information it needs to take appropriate action. To do this effectively, the FDA will need to modify the existing MedWatch telephone recording, report forms, and web site to 1) better prioritize consumer messages, 2) reflect (as proposed) the broader range of possible reports, and 3) modify the language and instructions to be more user friendly.
2. Use of the term "side effects": NCL agrees that the terminology "adverse drug event" is confusing to consumers, and should be replaced with more intuitively appealing language. However, using the term "side effect" may encourage consumers to report every side effect,

even those that are mild and expected with a medication. FDA might consider the term “serious side effect” or another term that would better convey to the consumer when to call the FDA. We encourage the FDA hold focus groups or conduct other types of research to determine the best and most precise terminology for use in this situation.

In addition, we strongly support the message that a consumer should contact a physician for medical advice. In fact, we urge the FDA to make this the first message conveyed to any consumer calling into the MedWatch system. At that point, it would be important to inform the consumer that - in addition to talking to a doctor and taking care of the event - he or she could then call the FDA to report the incident.

3. Labeling for samples: NCL disagrees that the term “authorized dispensers” not include the distribution of product samples. Often samples are given to consumers without consumer medicine information (CMI), and all dispensed drugs should have the Medwatch number and information. Samples are also dispensed in free clinics and through other means. They should not be exempt from the law.
4. Multiple options for pharmacies to distribute the side effects statement: NCL agrees that FDA should provide pharmacies with multiple options for satisfying the statement requirement. However, NCL is greatly concerned about the potential for consumers to lose or dispose of paper messages (e.g., the consumer medication information option, or the separate sheet of paper option) after initial receipt - meaning that the MedWatch number would NOT be available as needed.

The paper only options are troublesome for two primary reasons:

- Paper is often discarded, so the information likely would not be available when needed (i.e., when a side effect is experienced), and
- Presumably, the side effects message conveyed on the paper (in whatever format) would include other useful information about the product. This is an important vehicle for providing message reinforcement, but NCL is concerned that the side effects message could be lost among the various other messages conveyed.

As such, NCL strongly urges the FDA to require that manufacturers and pharmacists work together to include the message on either the sticker or preprinted vial cap option. Printed materials could be provided as a supplement, but should not substitute for one of the first two options. If the package has no cap, if there is no room on a package for a sticker, or if the product already requires a sticker for a different reason, NCL would suggest that the sticker be included inside the package. That way, consumers could affix it in a place that would be useful to them, such as a medicine chest or pill caddy.

5. Consumer awareness, outreach, and support: After full implementation of the law and all necessary modifications to the MedWatch system, we encourage FDA to conduct extensive consumer outreach, educating the public about their right to report. FDA should work with consumer educators and health professionals to provide clear information and educational materials on how, what, and when to report.

6. Using the data to improve patient safety: Finally, it is important that the FDA do something with the information that they receive from the new MedWatch program. It should be a resource for immediate response when a medication should be withdrawn from the market or labeling changes should occur. This will encourage quality reporting and public confidence that participation in the program is improving the public health for everyone

Thank you for the opportunity to comment on this important new provision. Please do not hesitate to call me at (202) 835-3323 if you have any questions about the above comments. We appreciate your consideration.

Sincerely,



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