National Alliance for Breastfeeding Advocacy
NABA
Policy • Promotion • Education

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Re: Comments on Docket No. 03N-0016

The collection of information regarding any harmful effects of products regulated by the FDA is of extreme importance. The public looks to the FDA to help protect its health through assurances that health products on the market are safe, effective, and will not cause harm. The public also depends on the FDA to provide recourse if a product does not perform properly or is injurious to health. As a registered nurse in the maternal child health field, I wish to speak on the necessity for the continued and more stringent collection of information in this call for comments.

1. Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility: The continued collection of information from the Medical Products Reporting Forms is vital to the protection of consumer health. For example:
    - mothers can be and are injured from breast pumps that generate vacuum in excess of 240mm Hg, that fail to efficiently collect milk even though they are labeled as capable of doing so, and that are shared, re-sold, or not disinfected properly when manufactured as a single-user device.
    - Infant formula allowed on to the market with ingredients new to the human food chain based on the manufacturer's assurances of GRAS. The GRAS assurances for the DHA/ARA supplements currently added to some infant formulas were tested on an insufficient number of infants to reveal the side effects and harmful outcomes currently being reported in some infants. A reporting mechanism is vital to reveal these problems, since the FDA cannot prohibit such products from entering the market and must prove that such additives have unhealthy side effects

2. Ways to enhance the quality, utility and clarity of the information to be collected: The reporting of adverse effects from breast pumps and infant formula is voluntary. Many health care professionals are unaware of the MedWatch program or that they are responsible for reporting adverse effects. Some do not know what an adverse event is regarding a breast pump or new formula. Some are concerned regarding confidentiality when using their name or the name of the patient. Consumers have no idea where to find recourse if they use a pump that fails to perform as expected or find their infant hospitalized from the use of an infant formula. Most consumers are

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unaware of what an adverse event is. Consumers can no longer distinguish the difference between infant formula and human milk because the labels on infant formula cans declare that the ingredients are close to or equivalent to human milk. The microalgae and soil fungus used as sources for the new DHA/ARA additives to infant formula bear no resemblance to the human versions. Parents are not advised on the labels that their infants could experience side effects from these new additives such as vomiting and explosive diarrhea. They are only provided a telephone number of the manufacturer if they have "comments or questions." An infant reacted so severely to one of the new formulas that he had to be admitted into a neonatal intensive care unit for profound dehydration experienced from the unremitting explosive diarrhea.

It would be more helpful if reporting forms/reporting information were included with all breast pumps sold or rented. Infant formula can labels should have a listing of adverse effects, and where and how these can be reported. Many bedside physicians and nurses in hospitals are unaware of safety alerts, recalls, and other avenues that the FDA uses to inform providers of these issues. Market withdrawal of products rarely makes the news. Breast pumps and infant formula used in hospitals should ship with reporting forms. The forms should be easily accessible in hospital maternal and child units. All health care providers and consumers using and/or purchasing the new infant formulas with added DHA/ARA should be informed that these products are under post market surveillance. This should be defined, with parents giving their permission for their infants to be fed these formulas in the hospital.

Because the FDA shoulders the burden of proof to show that a breast pump or infant formula is unsafe, reporting of problems easily and effectively to the FDA is of great importance to the health of the consumers using these products. The current form of reporting is almost unknown to many health professionals and consumers, thus the limited reports on the problems with these products. Labels that promise smarter babies and end in hospitalization are highly misleading. While the Internet is a fast and inexpensive means for education and reporting, some consumers lack access to computers, health providers fear lack of privacy, and the reporting is not happening with the current system. Perhaps all hospitals, pediatric practices, etc should be educated on the need for reporting, what should be reported, and how to report through numerous channels.

Thank you for your attention.

Sincerely,

Marsha Walker

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