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COMMENT ON

AGENCY INFORMATION COLLECTION ACTIVITIES; PROPOSED COLLECTION
MEDWATCH: THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

BY

NATIONAL CENTER FOR POLICY RESEARCH FOR WOMEN AND FAMILIES
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The MedWatch program is an important part of FDA's mission to ensure that medical products are safe and effective. It is essential that this program be preserved and strengthened.

The MedWatch program logged approximately 85,000 voluntary reports, mostly from health professionals, in the first five years of its current form.(1993-1998). [1] This statistic suggests an underutilized reporting system, given the billions of doses and products used each year, and that concern is supported by recent reports and studies. For example, a recent report from the Office of the Inspector General of the U.S. Department of Health and Human Services concluded that current surveillance systems for identifying adverse reactions from dietary supplements probably detected less than one percent of adverse reactions.[2] A recent article in *The British Journal of Clinical Pharmacology* reported that 515 face-to-face interviews with individuals taking herbal remedies revealed that a substantial proportion of individuals would not consult their general practitioners or pharmacists following serious adverse drug reactions to conventional over-the-counter medicines or herbal remedies.[3]

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[1] MedWatch:FDA's "Heads Up" on Medical Product Safety, available at http://www.fda.gov/fdac/features/1998/698_med.html

[2] Bent, Stephen et al., "The Relative Safety of Ephedra Compared with other Herbal Products", Ann Intern Med 2003, 138 citing U.S. Department of Health and Human Services, Office of Inspector General. Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve, OEI-01—180, Washington, D.C., U.S. Department of HHS, 2001, accessed at http://oiq.hhs.gov/oei/reports/oei-01-00-00180.pdf

[3] Barnes, J et al. "Different Standards for Reporting ADR's to herbal remedies and conventional OTC medicines: face to face interviews with 515 users of herbal remedies", Br. J. Clin Pharmacol 1998 May: 45 (5):496-500

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The MedWatch program is an important part of postmarketing surveillance, which is essential for providing additional safety information "that cannot realistically be collected before approval of a drug."[4] Clinical trials cannot assess the effects of every new drug in combination with every other approved drug. Moreover, clinical trials are conducted on relatively small numbers of patients; adverse reactions are often more obvious when the product is used by thousands or millions of patients.[5]

There are more rigorous models in other countries. For example, the European Network System for reporting adverse events, Eudranet, provides for the regulatory transfer of information between any company and any authority in Europe during the whole life cycle of a medical product.[6]

It is unfortunate that the FDA's MedWatch program discourages the reporting of unusual and unanticipated adverse events unless the adverse event qualifies as "serious". The FDA defines serious adverse event in terms of outcomes such as death, life- threatening event, hospitalization, disability, congenital anomaly or requiring intervention to prevent permanent impairment/damage. Much important information is lost as a result. In contrast, the Canadian Adverse Drug Reaction Monitoring Program Guidelines define an adverse drug reaction as a "noxious and unintended response to a drug which occurs with use or testing for the diagnosis , treatment or prevention of a disease or the modification of an organ function. This includes any undesirable patient effect suspected to be associated with drug use... A temporal or possible association is sufficient for a report to be made...Adverse Drug Reactions that should be reported include all suspected adverse drug reactions which are: unexpected, regardless of their severity, i.e. not consistent with product information or labeling; or serious, whether expected or not; or reactions to recently marketed drugs (on the market for less than five years) regardless of their nature or severity".[7]

A successful surveillance system must accommodate the urgent need for the detection of all unusual and unexpected phenomena resulting from the use of medical products, as well as any adverse reactions that may outweigh the benefits of the product. The FDA should do more to encourage reporting (including simplifying the MedWatch form), educate the public on quality reporting, and communicate suspected risks. Reporting should be taken seriously and the safety concerns of the public weighed favorably against the FDA's time management concerns.

Rather than weaken or dismantling the MedWatch system, the FDA should borrow ideas from more rigorous systems in other countries. The FDA should provide ongoing education and incentives for quality reporting by both health professionals and consumers. Adverse event reporting forms should be easier to obtain, complete, and use. These changes would enable the FDA to better fulfill its mission to protect the public health.

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[4] World Health Organization, Department of Communicable Disease Surveillance and Response OECD/WHO Consultation on Xenotransplantaion Surveillance:Summary, October 26, 2001, available at http://www.who.int/emc-documents/zoonoses/docs/whocdscsreph20011.pdf

[5] Cf. MedWatch:FDA's "Head's Up" on Medical Product Safety

[6] WHO, supra.

[7] Health Canada: Canadian Adverse Drug Reaction Monitoring Program-Report and Reporting Guidelines HC/SC 4016 (04-02)