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The Importance of Consumer Reporting Side-effects with Regulated Products: The New Consumer Friendly FDA 3500B MedWatch Form

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The Food and Drug Administration (FDA) has a new voluntary consumer friendly MedWatch Form 3500B [1]. The new MedWatch form uses lay friendly language with a simplified layout making it easier for consumers to report problems with drugs and other regulated products to the FDA. Consumer reports to the MedWatch system are increasing [2] and have been shown to make a difference in recognizing new and serious drug adverse events. Consumers often have the most details about what they are experiencing, and are in a unique position to identify new safety signals earlier. Every Medwatch report is important; a single report can identify a safety problem and prompt the FDA into action. Recent Consumer reports alerted scientists at the FDA to a critical health issue about the accidental exposure and harm to children from to Testosterone gel used by Men [3]. These early reports prompted the FDA to mandate stronger warning labels that required that the gel be covered after applying to the skin so other people would not be exposed [3].

Using expert input from social scientists and comments from the public, the FDA recognized that FDA MedWatch Form 3500 needed to be rewritten for consumers. The MedWatch Form 3500 used by doctors and pharmacists had language that was too technical and was not easy to use for the general consumers. The new MedWatch Form 3500B is a five page form in ordinary language requesting information about the drug/device, the problem experienced, and information about the patient who experienced the problem. The consumer MedWatch FDA Form 3500B will request the same information included in MedWatch Form FDA 3500. Certain existing fields, not considered essential but present on the HCP version of Form FDA 3500, have been removed. Form 3500B can be submitted by mail or fax, an online submission process is expected in the future and may take up to 25 minutes to complete.

What to Report

MedWatch is for reporting adverse events that occur while using FDA regulated products such as:

- Prescription and over-the-counter medications
- Medical devices from contacts and breast implants to test kits and pacemakers.
- Nutritional products (for example, dietary supplements and herbal remedies)

Report what happened as soon as possible. Give names, addresses and phone numbers of persons affected. Include your name, address and phone number, as well as that of the doctor or hospital if emergency treatment was provided [4].

- State the problem clearly. Provide Product name, dose, and how it was given
- How long the product was used
- Age of the person taking the Product
- Other medications or medical conditions present at the time of event

The FDA launched MedWatch Learn, a new web-based training tool to help consumers understand how to report adverse events. Consumers have the opportunity to practice filling out the Med Watch Form [5]. There are several case studies that give examples of the information the FDA is seeking.

How to Report

- Online-Use the interactive FDA Form 3500 FDA encourages online reporting because it is the quickest and most direct route. The Consumer 3500B form is expected online soon.
- Mail-Download the pre-addressed FDA Form 3500B or call 1-800-FDA-1088 to request the form.
- Fax-Get the form (as above) and fax to 1-800-FDA-0178.
- Phone-Call 1-800-FDA-1088 Mon–Fri between 8:00 a.m. and 4:30 p.m. EST.

What remains to be seen is how the reports will inform the FDA how the FDA will use the consumer reports its investigations concerning the safety of medicine and devices.

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