UNFORTUNATELY, many health profes-
sors do not think to report adverse
events that might be associated
with medications or devices to the
Food and Drug Administration (FDA)
or to the manufacturer. That needs to
change, and the FDA is taking steps to encourage
that to happen.

Reports from health professionals of
adverse events or product quality prob-
lems are essential to ensure the safety
of drugs, biologicals, medical devices,
and other products regulated by the
FDA once they are introduced into the
US market.

The large, well-designed clinical
trials that are conducted to gain pre-
market approval cannot uncover every
problem that can come to light once a
product is widely used. A new drug ap-
lication, for example, typically includes
safety data on several hundred to sev-
eral thousand patients. If an adverse
event occurs in perhaps one in 5000 or
even one in 10,000 users, it could be missed
in clinical trials but pose a serious safety
problem when released to the market.

Moreover, patients taking marketed
drugs in conjunction with other drugs
may experience interactions not re-
vealed during the premarketing phase.1

In response to voluntary reports from
physicians to the FDA or the manufac-
turer, the FDA has issued warnings,
required labeling changes, required manu-
facturers to conduct postmarketing
studies, and ordered product withdraw-
als that have ultimately prevented pa-
atient deaths and suffering.

Adverse drug reports from physicians,
for example, prompted the FDA to de-
terminate that torsades-de-pointes ven-
tricular arrhythmias could occur when
terfenadine (Seldane) was taken in com-
ination with the anti-
fungal medicine ketoconazole or the
antibiotic erythromycin.2 This episode
also increased recognition that individ-
ual variability in drug metabolism can
account for significant differences in pa-
tient response3 and underscored the im-
portance of postmarketing studies and
physician observations and reports.

Other examples of FDA actions
prompted by reports of adverse events
include the 1986 recall of suprofen,4 the
1991 alert to health professionals on po-
tentially fatal latex hypersensitivity,5 the
1992 boxed warning and alert to physi-
cians regarding use of angiotensin-con-
verting enzyme inhibitors during the sec-
ond and third trimesters of pregnancy,6
and, most recently, the recall of temo-
foxacin.7

Just as reports enable us to respond
to serious adverse events, lack of re-
porting can delay problem detection. Sil-
lcone breast implants are one example.

Although these devices have been in use
for some 30 years, only re-
cently has evidence accumulated about
a possible association with autoimmune-
like disorders.8 If reports from physi-
cians who diagnosed autoimmune-like
in patients with breast im-
plants had been received years ago, the
possible connection might have been
identified much earlier.

Aside from adverse events associated
with specified vaccines (listed in the Na-
tional Childhood Vaccine Injury Act9),
most reporting by health providers is
voluntary. Manufacturers of drugs and
devices and device distributors are re-
quired to report adverse events,10,11 and
soon manufacturers of biologicals will
face similar requirements. Device manu-
facturers and distributors are also re-
quired to report to the FDA product
problems that may cause death or se-
rious injury if the malfunction were to}
recur.12 Health care facilities are re-
quired to report certain adverse events
associated with devices.13 However,
these groups, like the FDA, depend on
health care professionals' surveillance
and voluntary reporting.

Although the FDA receives many ad-
verse event reports, these probably rep-
resent only a fraction of the serious ad-
verse events encountered by providers.

A recent review article14 found that be-
 tween 3% and 11% of hospital admis-
sions could be attributed to adverse drug
reactions. Only about 1% of serious events
are reported to the FDA, ac-

There are probably several reasons
why some serious events are not re-
ported to either the FDA or the manu-

One factor inhibiting physician re-
porting is that it is not an ingrained
practice—it is not in the culture of US
medicine to notify the FDA about ad-
verse events or product problems. In
other countries such as the United King-

dom, adverse drug reporting is more
frequent.15 A patchwork of reporting
forms and systems may make it difficult
to file reports in the United States and
may discourage even the most conscien-
tious professionals.
A. Patient information

1. Patient identifier:
   - Name:
   - Social Security number:

2. Age or time of event (if known):
   - Date of birth:

3. Sex:
   - Male
   - Female

4. Weight:
   - lbs

B. Adverse event or product problem

1. Adverse event:
   - Date of event:

2. Product problem (e.g., selection/ malfunction):
   - Date of entry:

3. Outcomes attributed to adverse event (check all that apply):
   - Deat:
   - Inguinal hernia
   - Intestinal obstruction
   - Permanent impairment/disability
   - Hospitalization – initial or prolonged

4. Diagnosis for use (indication):

5. Event stated to cause use stopped or dose reduced:
   - Yes
   - No

6. Let # (if known):
   - Exp. date (if known):

7. Event reported after reintroduction:
   - Yes
   - No

C. Suspect medication(s)

1. Name (give label name & strength, if known):

2. Dose, frequency & route used:
   - Dose:

3. Therapy dates (duration):
   - Start:
   - End:

4. Diagnosis for use (indication):

5. Event stated to cause use stopped or dose reduced:
   - Yes
   - No

D. Suspect medical device

1. Brand name:

2. Type of device:

3. Manufacturer name & address:

4. Device available for evaluation:
   - Yes
   - No

5. Operator of device:
   - Health professional
   - Lay user/patient
   - Other

6. Date of manufacture:

7. If implanted, give date:

8. If repaired, give date:

9. Device available for evaluation:
   - Yes
   - No

10. Concomitant medical problems and therapy items (include treatment of event):

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:

2. Health professional:
   - Yes
   - No

3. Occupation:

4. Also reported to:
   - Manufacturer
   - User facility
   - Other

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in box:

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FAX to: 1-800-FDA-0787
ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:
• medications (drugs or biologics)
• medical devices (including in-vitro diagnostics)
• special nutritional products (dietary supplements, medical foods, infant formulas)
• other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:
• death
• life-threatening (real risk of dying)
• hospitalization (initial or prolonged)
• disability (significant, persistent or permanent)
• congenital anomaly
• permanent impairment or damage

Report even if:
• you're not certain the product caused the event
• you don't have all the details

Report product problems — quality, performance or safety concerns such as:
• suspected contamination
• questionable stability
• defective components
• poor packaging or labeling

How to report:
• just fill in the sections that apply to your report
• use section C for all products except medical devices
• attach additional blank pages if needed
• use a separate form for each patient report related to FDA or the manufacturer (or both)

Important numbers:
• 1-800-FDA-0178 to FAX report
• 1-800-FDA-7737 to report by modem
• 1-800-FDA-1086 for more information or to report quality problems
• 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a hospital, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the legal extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The FDA recognizes that the confidentiality of this information.

Our goal in introducing MEDWatch is to underscore the responsibility of providers to identify and report adverse events that may be related to FDA-regulated products. To that end, we want to (1) make it easier for providers to report serious events, (2) make it clear to physicians and others what types of reports the FDA wants to receive, (3) make it easier for providers to report to the FDA, and (4) increase physician understanding and awareness of drug- and device-induced disease.

HOW TO REPORT

Under the MEDWatch program, the separate forms previously used to report adverse drug reactions, drug quality product problems, device quality product problems, and adverse reactions to medical devices have been consolidated into a single, one-page reporting form for health professionals. This form can also be used to report problems with other FDA-regulated products, such as dietary supplements, cosmetics, medical foods, and medical devices.

In addition to making reporting easier for providers, using one form for both device and drug problems should also help the health care community to detect, and the FDA to investigate, adverse events.

One example of how this form might facilitate investigation is the latex-cuffed barium enema tip used to perform many barium enemas. Reports of life-threatening allergic responses in some patients. When the problem was first recognized, practitioners typically believed that patients were reacting to the latex-cuffed barium sulfate or to other medications used in the procedure, and therefore adverse incidents were initially reported as barium sulfate reactions or other allergy problems for Drugs. The new one-page form asks reporters to identify concomitant devices as well as the suspect drug and other drugs used in the procedure. Using the new form might have decreased the follow-up time required by FDA officials, the time needed to identify latex as the problem, and the time until the medical community was alerted.

The unified reporting form (Figures) will be available as a 24-hour-a-day, 7-day-a-week self-mailer included in the Physicians' Desk Reference, the FDA Medical Bulletin, and AMA Drug Evaluations. A 24-hour-a-day, 7-day-a-week toll-free number, (800) FDA-1086, is also now available for providers who want to request forms or obtain the FDA Desk Guide to Adverse Event and Product Problem Reporting.

Providers will no longer be expected to send different reports for devices and medications or different addresses at the FDA; there will now be a single mailing address for these reports. In addition, health professionals will be able to report electronically by computer by calling (800) FDA-7737 and responding to the questions that appear on the screen. Reports can be also sent to the FDA by fax (880) FDA-9310 or by regular mail using the self-mailed included in the form.

In addition to reporting adverse events to the FDA, reports can also be sent to manufacturers, which are required by law to forward reports to the FDA. If the event has occurred in a health care facility, reports of problems with medical devices should also be filed with that facility, which legally must

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Especially important to report are adverse effects from medications or devices that have been on the market for a relatively short time—about 3 years or less—because that is when the most critical problems are discovered. Since most serious adverse events are observed in the hospital setting, practitioners should be especially diligent about reporting these events.

The valid should also be informed promptly of product quality problems such as defective devices, inaccurate or unreadable product labeling, packaging or component mix-up, contamination or stability problems, and particular matter in injectable products. In 1990, a total of 86 drug recalls resulted from reporting of such problems. While pharmacists or risk managers are often the ones in a position to observe these problems, physicians who become aware of such problems should bring them to the FDA's attention by calling (800) FDA-1088 and submitting a report.

One recent example of the importance of this type of report is the possible link reported between hyperkalemia observed in two patients in a medical center intensive care unit and two enteral feeding products. The university's laboratory analysis demonstrated that the products had a potassium content about twice that specified on the label. The FDA follow-up of this report revealed that all product lines of the manufacturer contained potassium 150% to 250% of the declared amount. Because these products are frequently used as a sole source of nutrition, and sometimes in patients with compromised renal function, the FDA initiated a recall of the product.

PROVIDE PHYSICIAN INFORMATION

MEDWatch is aimed at facilitating reporting by providers, but we also want to better inform providers about regulatory actions taken by the FDA in response to reports. We believe this information will not only be useful to physicians and others, but that it will also encourage public and patient reliance on the growing body of data by demonstrating the value of the information. The FDA will therefore take a more aggressive stance in reporting back to providers.

ENHANCE PHYSICIAN UNDERSTANDING

As part of MEDWatch, the FDA hopes to heighten physician awareness of drug- and device-induced disease. Our educational efforts will include a focus on issues such as the importance of the problem, mechanisms of adverse drug and device reactions, and how to evaluate possible adverse events. As part of that effort we plan to hold a conference for health care professionals and FDA officials to help physicians and others to recognize drug- and device-induced problems when they occur, and thereby increase participation in the MEDWatch program.

MEDWatch is an important program that we hope will significantly improve our ability to monitor the safety of products we regulate and to take necessary actions swiftly and effectively. Perhaps most important, we hope MEDWatch will encourage an increased sense of responsibility among physicians and other health care providers about reporting adverse events and product problems. We are eager to work closely with the medical community to ensure the program's success.

Leaders of the Working Group include the following: Sharon Nathans, MPA; Elaine Kennedy, MPH, RPh; Eliot Lazar, MD; Peter Rhodeston, MD, JD, MDs. Members of the Working Group include Chuck Arlee, MD; Dave Barish, RPh; Nina Bernstein, PharmD; Ross Bolger, RPh; Key Cook, JD; Mary Pat Conig, RN, MPH; Jerry Devlin, MD, JD; Phyllis Johnson, DO, MA; Catherine Loomis, MD; Tom McGinnis, PhD; John Nathan, RPh; Stuart Nightingale, MD; Carl Pock, MD; Mary Pendergrass, JD; Sarah Rastogi, PhD; Scott Reynolds, MHA; R. Brent Schaefer, MPH; Linda Tolleson, DVM, Ann Wonn, JD.

References

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