FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER Facility Reporting

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Confidentiality of User Facility Reports Is Governed by Freedom of Information Act & Section 519 of FD&C Act

By Joseph M. Sheehan, JD

The public availability of information contained in a user facility report is governed by law, specifically, the Freedom of Information Act (FOIA) and section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Under FOIA, the Food and Drug Administration (FDA) is required to provide to the public, upon request, reports received under the user facility reporting requirements. However, before a report is made available, FDA must delete any information:

- that would constitute an invasion of personal privacy if disclosed, or
- that constitutes trade secret or confidential commercial information.

The personal privacy exemption applies to the patient or subject of the test; **it does not apply** to the health professional who makes the report.

Section 519(b)(2) of the FD&C Act provides that FDA may not disclose the identity of a device user facility except in:

- an action to enforce the user facility reporting requirements;
- a communication with the manufacturer of the device that is the subject of the report;
- a disclosure relating to a report that must be made by a manufacturer or distributor under section 519(a); or
- a communication with an employee of the Department of Health and Human Services, the Department of Justice, or duly authorized Congressional committees and subcommittees. (continued on page 2)

SOME ANTIMICROBIAL SUSCEPTIBILITY TESTS FAIL TO DETECT RESISTANCE

By Roxanne G. Shively, MT, SM (ASCP), MS

The Food and Drug Administration (FDA) is concerned about the ability of commercial susceptibility tests to accurately detect the resistance of pneumococci to penicillin (and possibly other drugs) and the resistance of enterococci to multiple drugs, particularly vancomycin and ampicillin.

These concerns about commercial susceptibility tests have been documented in surveys by the College of American Pathologists and independent studies (published and unpublished) conducted by the Centers for Disease Prevention and Control (CDC) and others. (continued on page 3)

In This Issue:

DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service • Food and Drug Administration
Center for Devices and Radiological Health

Confidentiality of User Facility Reports ... (from page 1)

If a user facility report is forwarded to FDA by a manufacturer or distributor as part of its report, the identity of the user facility and the individual in the facility who submitted the report would be disclosable because the report is governed by section 519(a). Manufacturers and distributors routinely include user facility reports in their reports, thus the identities of the the user facility and the reporting individual are usually available.

Nonetheless, the law does protect user facilities and affiliated individuals who submit reports. A report required under user facility reporting may not be used in a civil action by private parties against:

- the device user facility,
- an individual who is employed by or otherwise formally affiliated with such facility, or
- a physician who is not required to make the report — unless the facility, individual, or physician who made the report knew the report contained false information.

These disclosure rules are mandated by statute. However, FDA may provide additional protection to individuals who **voluntarily** submit reports not required by law. In June 1993, FDA initiated its MedWatch program to facilitate the reporting of adverse events and product problems for all FDA-regulated products. On January 27, 1994, FDA proposed a rule to protect the identity of persons who voluntarily submit adverse event reports not required by law, as well as the identities of patients who experience those adverse events. The proposed rule would also preempt (thus prohibiting states from enforcing) any state or local law, regulation, or requirement that would require or permit disclosure of the identities of reporters or patients. FDA expects to finalize this rule shortly.❖

Joseph M. Sheehan is Chief of the Regulations Staff in the Office of Standards and Regulations.

CONFERENCE HELD ON UNPROTECTED CABLES & ELECTRODE LEAD WIRES

By Sheila Murdock, PhD

On July 15, about 200 persons attended a one-day conference in Washington, D.C., on unprotected patient cables and electrode lead wires. The conference was sponsored by the Food and Drug Administration, the American Hospital Association, and the Health Industry Manufacturers Association.

The conference was part of an agency effort to develop an effective solution to safety problems in the use of cables and electrode lead wires that are often used with medical monitoring devices. It provided a rare opportunity for mutual interaction among the healthcare community. Medical device users, user facilities, manufacturers, other health professionals, and FDA heard informed and comprehensive discussions of the problem.

Five small group sessions were held to focus on the questions published in the May 19, 1994, *Federal Register* notice concerning unprotected patient cables and leads. The ensuing discussions, along with any written comments received by FDA, will be considered during the rulemaking process. The purpose of such rulemaking is to prevent the potential hazards presented by the use of unprotected patient cables and electrode lead wires with medical devices.

To date, FDA has received information about five fatalities of infants or children that resulted from this device problem. Serious injuries were also reported.

Please remember your reporting responsibilities under the Safe Medical Devices Act. Keep in mind that you are required to make timely reports of problems with medical devices. For specifics about user facility reporting, see the questions and answers on pages 4 and 5.❖

Sheila Murdock is a Public Health Analyst in the Office of Surveillance and Biometrics.

Antimicrobial Susceptibility Tests ... (from page 1)

An important factor in the management of emerging resistance in bacterial pathogens is the ability to accurately detect such resistance, not only for therapeutic management of patients but also for surveillance and for development of prevention strategies. Since many of the currently available commercial tests were introduced prior to the emergence of resistance in these and other pathogens, their ability to detect resistance may be unknown or variable. In addition, most commercial tests are designed for testing rapidly growing bacterial pathogens, while pneumococci and enterococci tend to be fastidious and slow-growing.

The failure to detect the emergence of resistant pathogens raises significant public health concerns. Accurate detection of this resistance is critical for determining therapeutic options and for appropriate control of nosocomial infections. Due to these concerns, FDA is asking manufacturers of commercial antimicrobial susceptibility tests (antimicrobial disks and microbroth dilution panels) to take action to minimize the risk of inaccurate susceptibility categorization of pneumococci and enterococci.

By October 14, 1994, manufacturers will be notifying clinical laboratories and physicians about any diagnostic limitations of their products. On May 31, 1994, Baxter Diagnostics, Inc. (MicroScan Division) advised its customers to discontinue reporting penicillin susceptibility results for pneumococci tested with MicroScan™ Pos Combo Type 6, Pos MIC Types 6 and 8, and Pos Breakpoint Combo Type 6 panels. Also, a warning statement is being added to the Limitation Section of future product inserts.

Laboratories and clinicians in facilities where microscan systems are used must understand these limitations to avoid failing to detect penicillin resistance in pneumococci.

A cooperative effort by FDA, CDC, and device manufacturers is underway to assure that effective devices for detecting pneumococcal and enterococcal resistance will be available to users. Until the ability of commercial systems to detect resistance has been validated, testing laboratories should use only methods recommended by the National Committee for Clinical Laboratory Standards (NCCLS).

Please remember your reporting obligations under the Safe Medical Devices Act. Patient deaths, serious injuries, and serious illnesses must be reported to the manufacturer and/or to FDA. It is important for us to learn about failures of commercial susceptibility tests. Even if you determine that a failure does not result in a death, serious injury, or serious illness, please consider reporting it voluntarily through our MedWatch program by calling 1-800-FDA-1088 or filing FDA MedWatch Form 3500.❖

Roxanne G. Shively is a scientific reviewer in the Division of Clinical Laboratory Devices, Office of Device Evaluation.

Back Issues Available

Back issues of this Bulletin are available. If your collection is incomplete, just let us know which issues you need. Our mailing address is on the last page.

QUESTIONS & ANSWERS

by Susan E. Bounds

Q Where should I report adverse incidents, and to whose attention?

A The address is:

Food and Drug Administration
Center for Devices and
Radiological Health
FDA MDR User Facility
Reporting
P.O. Box 3002
Rockville, MD 20847-3002

All reports that user facilities are required to file with FDA (reports of death and semi-annual reports) are to be sent to the above address. The reports will be delivered to the staff that processes them. There is no need to name a specific individual on the staff, but remember to write on the outside mailing envelope:

MDR User Facility Report
or
Semi-Annual Report

Q What information must be reported?

A Frankly, the answer person is disappointed that after three years of mailing educational materials to medical device user facilities, many facilities still do not have reporting procedures in place.

FDA provided guidance on medical device reporting in the *Federal Register* of November 26, 1991. This guidance is also included in a December 1991 publication that was mailed to all medical device user facilities; to date over 150,000 copies of *Medical Device Reporting for User Facilities: Questions and Answers Based on the Tentative Final Rule* have been distributed.

The medical device reporting requirements became effective for user facilities on November 28, 1991. Since then, FDA has developed a new reporting form, FDA MedWatch Form 3500A. Until a final implementing regulation becomes effective, you may use either FDA MedWatch Form 3500A or FDA Test Form 3375 (found in the above question-and-answer booklet). All applicable sections of the forms should be completed.

For free copies of the question-and-answer booklet, write to:

Editor, User Facility Reporting
Bulletin
Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-230)
5600 Fishers Lane
Rockville, MD 20857

To obtain up to 10 copies of the mandatory reporting version of the MedWatch form (FDA MedWatch Form 3500A), instructions for completing the form, and the medical device coding manual, call 1-800-638-2041 or write to:

Food and Drug Administration
Center for Devices and
Radiological Health
DSMA (HFZ-220)
5600 Fishers Lane
Rockville, MD 20857

Q Must a facility submit a written report within 10 days of notification of an incident? Is there a phone number or FAX number for more timely reporting?

A All 10-day reports must be submitted in writing. If there is an emergency involving a device and FDA should know about it, we encourage you to call the MedWatch reporting number to report it: 1-800-FDA-1088. You may also notify your local FDA field office. A telephone report, however, does not satisfy the reporting requirements.

Q What is the penalty for not reporting within 10 days?

A The civil penalty can be up to $15,000 per violation, not to exceed $1,000,000 for all violations adjudicated in one proceeding for significant or knowing departures from the reporting requirements. (continued on page 5)

Questions & Answers (from page 4)

You may also refer to the enforcement section of the November 26, 1991, *Federal Register* (page 60029) referenced above. It explains the various possible penalties for violations. For example, there are penalties for refusal to permit authorized FDA personnel to inspect records, failure to establish or maintain records, and failure to make reports as required by the Safe Medical Devices Act.

Q Is there a local contact person or organization?

A From your question, I assume that you are referring to an FDA contact in your geographical area whom you can call for information about the reporting requirements. You may contact your local FDA field office if you have questions about reporting. It is also likely that any inspection to verify your compliance with SMDA reporting requirements would be done by that office.

Q Should incidents be reported when patient outcome is not yet known or there is a potential for delayed illness, serious illness, or death? For example, what if a ventilator supplies excessive oxygen, raising the possibility that an infant's eyes may have been damaged?

A It is important to notify FDA if you believe a medical device problem has occurred that may later have serious health consequences, such as in the example. This will enable FDA to take appropriate action promptly, even if the outcome is not immediately apparent. You can make a voluntary report through MedWatch by filing FDA MedWatch Form 3500 or calling 1-800-FDA-1088.

Q The newsletter says to report to FDA or the manufacturer. I thought we had to contact both. Please clarify.

A The information in the *User Facility Reporting Bulletin* is correct. To reiterate:

- The Safe Medical Devices Act specifically requires a user facility to report to the manufacturer any serious injury or serious illness associated with use of a medical device.
- A report must be sent to both the device manufacturer and FDA when a device causes or contributes to a patient's **death**.
- If a device adverse event occurs and the manufacturer is not known, the facility must report the event to FDA. (We're not certain how we'll identify the manufacturer, either.)❖

Susan E. Bounds, a Consumer Safety Officer in the Office of Surveillance and Biometrics, is a specialist in user facility reporting.

PRELIMINARY RESULTS OF THE READER SURVEY

Over 4500 readers returned their completed surveys and approximately 95 percent reported that the *User Facility Reporting Bulletin* should continue to be printed and mailed to the facilities. We will provide a detailed analysis of the returns in a later issue of the *Bulletin*.

We are also planning to make the *Bulletin* available through the Food and Drug Administration's electronic docket. We will provide you with instructions for accessing it as soon as we have the back issues on line. Later, we plan to have all issues available through FAX. More details will follow.

Thank you for taking the time to answer our questions. As a result of your answers, we hope to provide better information on topics of particular concern to your facility. We also hope to better target the personnel who should receive the *Bulletin*.