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Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 93N–0334]

Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its public information regulations to help ensure that the identities of those who report adverse events associated with human drugs, biologics, and medical devices, and the identities of patients are held in confidence and not disclosed by FDA or by manufacturers that possess these reports. This final rule preempts the establishment or continuation in effect of any State or local law, rule, regulation, or other requirement that requires or permits disclosure of such identities. This action is being taken to maintain the agency's ability to collect information about safety risks of FDA-regulated products and is vital to the protection of the public health.

DATES: This final rule will become effective on July 3, 1995.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2831.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 3, 1993 (58 FR 31596), FDA announced the availability of a new form for reporting adverse events and product problems associated with human drug products, biological products, medical devices, and other FDA-regulated products. The new form was part of MedWatch, FDA's new Medical Products Reporting Program, which is intended to facilitate the reporting of adverse events and product problems for all FDA-regulated products by the entire health care community (manufacturers, distributors, user facilities, and health care professionals).

The MedWatch program features two versions of the form for reporting adverse events and product problems. One version, FDA Form 3500A, is used by manufacturers, distributors, and user facilities to report adverse events as required under Federal statutes or FDA regulations. The other version, FDA Form 3500, is available for use by health professionals, such as physicians, physician assistants, pharmacists, and nurses, for voluntary reporting.

FDA uses adverse event reports from health professionals and industry to identify possible problems in marketed products. Based on the reports, the agency evaluates the seriousness of the health hazard, takes corrective action if necessary, and communicates that action to the health professional community. Corrective action can be in the form of labeling changes, such as the addition of new precautions, boxed warnings for serious hazards, and product recalls or withdrawals. FDA may also elect to notify health professionals, industry, and others of important information through Medical Alerts, Safety Alerts (for medical devices), the FDA Medical Bulletin, and ''Dear Doctor'' or ''Dear Health Professional'' letters.

The success of the MedWatch program depends in large part on voluntary reporting of adverse events from health professionals, either directly to the agency or to other entities who report to the agency. As stated in the preamble to the proposed rule of January 27, 1994 (59 FR 3944) (the January 1994 proposal), voluntary reporting has revealed significant adverse events and drug interactions associated with products that could not be identified during preapproval testing. For example, voluntary reporting contributed to the removal of the antibiotic temafloxacin (Omniflox) from the market and to the development of warning labeling for latex products. Voluntary reporting also led to research concerning the danger of concurrent use of the antihistamine terfenadine (Seldane) when taken with either the antifungal ketoconazole or the antibiotic erythromycin.

To ensure meaningful reporting under the MedWatch program, the agency proposed to enhance safeguards for protecting the identities of persons who voluntarily submit adverse event reports, as well as the identities of the patients experiencing those adverse events, to FDA and to manufacturers (59 FR 3944 at 3946 to 3947). The January 1994 proposal would also protect the voluntary reporting system through a regulation that preempts the establishment or continuation in effect of any State or local law, rule, regulation, or other requirement that requires or permits disclosure of such identities.

This document makes final the requirements published in the January 1994 proposal.

II. Comments on the Proposed Rule

FDA received 31 comments on the January 1994 proposal. In general, the comments supported the proposed rule, although some comments suggested expanding the rule to include mandatory adverse event reports, and other comments sought additional protection from disclosure.

A. General Comments

1. Three comments suggested that FDA revise the rule to prevent persons who receive adverse event reports from disclosing those reports to other parties. The comments noted that the proposed rule was silent on such disclosures.

FDA declines to accept the comments' suggestion. The agency notes that, under the rule, persons receiving adverse event reports would be those who have obtained consent to disclosure under § 20.63(f)(1)(i) (21 CFR 20.63(f)(1)(i)), are engaged in medical malpractice litigation involving the voluntary reporter (§ 20.63(f)(1)(ii)), or have requested disclosure under § 20.63(f)(1)(iii). Consequently, a person receiving the adverse event report under this rule would either have obtained consent for the disclosure from both the voluntary reporter and subject, or, in the case of medical malpractice litigation, already would have disclosed, through court documents, information surrounding the adverse event.

FDA has amended the rule, however, to state that voluntary reports that are made available to the subject of an adverse event under § 20.63(f)(1)(iii) will not include the names of any other individuals, including that of the voluntary reporter. This change provides further protection against disclosure in the small number of circumstances where the voluntary reporter is not a physician or health care professional known to the patient. FDA believes this clarification will encourage adverse event reporting and does not deny critical information to the subject of the report because the subject will ordinarily know the name of the physician who has performed the procedure or prescribed medication.

2. One comment would revise the rule by adding a new paragraph to declare that the production of adverse event reports containing identifying information, during the discovery phase in litigation, does not constitute ''disclosure'' under the rule if all parties to the litigation agree that the party receiving the adverse event report will not record the identifying information, will not attempt to contact the persons identified in the report, and will remove identifying information from any

adverse event report that the party copies.

FDA declines to amend the rule as suggested by the comment. The mechanism described by the comment would be inappropriate due to wide variations among state court procedures, and the resulting inconsistencies in applying such a mechanism would discourage, rather than encourage, health care professionals from reporting adverse events. The intent of the rule is to ensure that individuals who are not the reporters or other persons identified in the reports do not have access in any way to the identifying information, except in specifically described circumstances. Allowing such individuals to view the identifying information in the context of discovery would not achieve this purpose and would discourage voluntary reporting.

3. One comment said FDA should seek statutory changes to prevent the release of information in addition to issuing a rule.

The agency disagrees that statutory changes are necessary. As stated in the preamble to the January 1994 proposal and elsewhere in this document, FDA believes it has sufficient legal authority to preempt State and local laws, rules, regulations, and other requirements that would permit or require the disclosure of the identities of health care professionals who voluntarily report adverse events and the patients or other individuals named in those reports. Although Congress did not expressly preempt State law in this area, the agency finds Federal preemption to be appropriate because such State or local laws, rules, regulations, or other requirements would impede FDA's ability to monitor product safety after approval to ensure that human drug products, biologics, and medical devices are safe and effective for their intended uses. (See 59 FR 3944 at 3948 to 3949). Thus, under principles of preemption law, congressional intent to preempt State law can be inferred.

4. One comment focused on nuclear medicine and said that FDA should not disclose adverse event reports to the Nuclear Regulatory Commission (NRC) because NRC publishes reports of ''misadventure,'' and such reports often include the physician's and patient's names. The comment said that FDA should assume sole jurisdiction over nuclear medicine.

FDA declines to accept the comment. The agency notes that current regulations (21 CFR 20.85) already establish conditions on disclosures to other Federal government departments and agencies and that ''[a]ny disclosure * * * shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.'' As for assuming sole jurisdiction over nuclear medicine, the issue of NRC and FDA jurisdiction goes beyond the scope of this rulemaking.

5. One comment asserted that the rule would actually make more information available to the public because it would make an entire adverse event report available. The comment claimed that such disclosure would be contrary to the goal of protecting confidentiality and recommended that FDA instead expand § 20.111 (21 CFR 20.111), pertaining to data and information submitted voluntarily to FDA, to protect adverse event reports held by manufacturers from disclosure and to preempt State and local laws and regulations.

FDA believes the comment misinterprets the rule. Section 20.111 describes the types of data and information submitted voluntarily to FDA that are available for public disclosure. In general, under § 20.111(c)(3), adverse reaction reports, product experience reports, consumer complaints, and ''other similar data and information'' shall be disclosed except for certain identifying information. The identifying information that is deleted from the record varies, depending on whether the information was submitted by a consumer, the product's manufacturer, or a third party. For example, if a consumer submitted the record, the agency would not disclose the identity of the consumer. If a manufacturer submitted the record, the agency would not disclose the identity of the person using the product or any third party involved in the report or the manufacturer's identity. (See § 20.111(c)(3)(i) through (c)(3)(iii)).

In contrast, § 20.63 establishes exemptions from disclosure requirements. These exemptions are to be read in conjunction with any conditions imposed under § 20.111. Specifically, § 20.63(f) would authorize the agency and manufacturers possessing adverse event reports to withhold the names of voluntary reporters and other persons identified in such reports, regardless of whether a consumer, manufacturer, or other party submitted a voluntary report.

Furthermore, § 20.63(f) permits identities to be disclosed under three limited exceptions: (1) The voluntary reporter and the person identified in the report (or the person's legal representative) consent, in writing, to disclosure; (2) a court orders disclosure during medical malpractice litigation involving the voluntary reporter and the person experiencing the adverse event; and (3) the individual who is the subject of the report requests the report. These exceptions are reasonable and practical because it would make little sense to withhold the identities of the parties named in an adverse event report if those same parties consent to disclosure or are engaged in litigation or, in cases where the party requesting the report was the subject of the report, must already be aware that he or she is identified in a report.

Thus, while the final rule arguably discloses more information (in the form of identifying information) than § 20.111, that additional information is disclosed to persons who either submitted the voluntary report, have consented to disclosure, or know that a report pertaining to their own adverse experience exists. Furthermore, while § 20.111 describes data and information that are available for disclosure, § 20.63(f) establishes exemptions to disclosure. A preemption provision, which essentially establishes another exception to disclosure, would be more appropriate in § 20.63.

6. The January 1994 proposal referred to voluntary reporters submitting adverse event reports. Proposed § 20.63(f) also stated that it did not affect disclosure of the identities of reporters required by statute or regulation to make adverse event reports and that disclosure of identities of such reporters would be ''governed by the applicable statutes and regulations.'' Seven comments asked FDA to expand the rule to include mandatory adverse event reports required by the Safe Medical Devices Act or other statutes. The comments said that persons who are required to submit adverse event reports should enjoy the same protection offered by the rule to those who voluntarily submit reports. One comment even claimed that, under the rule, voluntary reports enjoyed greater protection than mandatory reports, and this difference could deter compliance with mandatory adverse event reporting requirements.

The agency does not believe it can or should expand the rule as requested by these comments. The policy and final rule are intended to protect voluntary reporting. FDA assumes that those subject to mandatory reporting requirements established by Congress or by Federal regulation comply with those requirements and will continue to do so. The agency also notes that different standards for treatment of disclosure of required and voluntary information is an established part of disclosure law.

(See *Critical Mass Energy Project* v. *NRC*, 644 F.Supp. 344 (D.D.C. 1986), vacated and remanded, 830 F.2d 278 (D.C. Cir. 1987), summary judgment granted, 731 F.Supp. 554 (D.D.C. 1990), rev'd & remanded, 931 F.2d 939 (D.C. Cir. 1991), vacated & reh'g en banc granted, 942 F.2d 799 (D.C. Cir. 1991), vacated, 975 F.2d 871 (D.C. Cir. 1992) (en banc), cert. denied, 113 S.Ct. 1579 (1993).)

B. Comments on Specific Provisions in the Proposal

7. Proposed § 20.63(f) would prohibit disclosure of the names and any identifying information, including the reporter's address or the name or address of the reporter's institution, that would lead to the identification of the reporter or the persons named in a voluntary adverse event report, by FDA or by a manufacturer possessing such reports in response to any request.

Four comments would amend § 20.63(f) to prohibit adverse event reports from being admissible into evidence unless the facility, individual, or physician who made the report knew that the report contained false information. The comments said such a prohibition would be consistent with section 519(b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(b)(3)) regarding mandatory reports from device user facilities.

The agency declines to accept the comments' suggestion. In general, § 20.63(f) is intended to protect against the disclosure of information that would identify a voluntary reporter or a person who may have experienced an adverse event. This policy is designed to encourage voluntary adverse event reporting by health care professionals and others. The agency's policy regarding disclosure of voluntarily submitted adverse event reports has been, and continues to be, that such reports are publicly available after deletion of identifying information. (See § 20.111(c); see also 39 FR 44602 at 44628 to 44629, December 24, 1974 (rejecting comments seeking to limit dissemination of adverse reaction reports and consumer complaints).) This is consistent with the agency's obligations under the Freedom of Information Act, and the agency, therefore, declines to revise the rule to limit disclosure of adverse event reports.

8. Two comments would expand § 20.63(f) to include demands and orders to disclose adverse event reports. The comments explained that a person seeking an adverse event report could do so by request to the agency or manufacturer or, in other contexts, demand or seek a judicial order requiring the agency or manufacturer to provide the reports.

FDA agrees and has modified the rule accordingly.

9. As noted earlier, proposed § 20.63(f) would not affect disclosure of the identities of reporters required by statute or regulation to make adverse event reports and expressly stated that disclosure of the identities of such reporters ''is governed by the applicable statutes and regulations.'' Three comments suggested that FDA modify § 20.63(f) to refer to ''federal statutes and regulations'' because, as written, the rule could arguably be interpreted as being inapplicable to disclosures required by State law or regulation.

FDA agrees and has modified the rule accordingly.

10. One comment asked FDA to clarify the rule's relationship to existing FDA regulations governing information exchanges between the agency and manufacturers.

The rule does not affect information exchanges between FDA and manufacturers. Nor does the rule alter or diminish any regulatory requirements for manufacturers regarding submission of adverse event reports. The rule is directed to requests by third parties for adverse event reports.

11. The proposed rule created three exceptions to the policy against disclosing the identities of the voluntary reporter and the person who experienced the adverse event. Proposed § 20.63(f)(1)(i) contained the first exception and would allow the identities to be disclosed if both the voluntary reporter and the person identified in the report (or that person's legal representative) consented, in writing, to disclosure.

Two comments requested that FDA modify or delete the provision. The comments asserted that the provision could prompt third parties to request or demand that FDA or a manufacturer seek consent from the voluntary reporter or the person identified in the report because the agency and the manufacturer would know their identities. The comments would either delete the provision or modify the rule to contain a specific prohibition against courts and State agencies seeking to have FDA or manufacturers obtain consent from the voluntary reporter or patient.

In response to these comments, FDA has amended § 20.63(f)(1)(i) to state that the agency and manufacturers shall not be required to seek consent on behalf of requesters. As stated in § 20.63(f) and also in § 20.111, the identities of the voluntary reporter and any other person named in an adverse event report shall not be disclosed by FDA or by manufacturers except in limited situations. If third parties could request or demand that FDA or manufacturers seek consent from the voluntary reporter and/or person named in the report, the practical effect would be to eliminate the protection given by FDA's regulations. In addition, the administrative burden of such procedures, in response to third party requests, would detract from agency resources devoted to investigation and assessment of adverse event reports. Consequently, FDA has not in the past and will not entertain such requests, and the burden of seeking consent from the voluntary reporter and the person identified in the adverse event report will continue to rest on the party requesting the adverse event report and identifying information.

12. Proposed § 20.63(f)(1)(ii) would permit disclosure of the identities of the voluntary reporter and a person named in an adverse event report ''pursuant to a court order in the course of medical malpractice litigation involving both the person who experienced the reported adverse event and the voluntary reporter.''

Three comments would delete § 20.63(f)(1)(ii). According to the comments, the provision would encourage plaintiffs to name multiple defendants in medical malpractice cases in order to obtain the identities of persons in an adverse event report.

FDA declines to delete the provision as requested. The agency does not share the comments' underlying assumption that the possible existence of a voluntary adverse event report will prompt plaintiffs to bring a malpractice suit against every person who might have submitted a voluntary adverse event report, especially when the only information that the plaintiff would gain, under § 20.63(f)(1)(ii), would be his or her own name and the name of the voluntary reporter. If a plaintiff did engage in such tactics, some jurisdictions might consider it to constitute an abuse of process and impose sanctions against the plaintiff or the plaintiff's attorneys.

FDA also notes that if a plaintiff knew that a report specific to his or her adverse event existed, the plaintiff would obtain more substantive information regarding the adverse event under § 20.63(f)(1)(iii).

13. One comment would delete § 20.63(f)(1)(ii). The comment stated that § 20.63(f)(1)(ii) was unnecessary because a person who experienced an adverse event could obtain a copy of the

adverse event report under § 20.63(f)(1)(iii).

The agency disagrees with the comment. The two provisions serve different purposes. Many adverse event reports contain little or no identifying information about the person who experienced the reported adverse event, and the person who experienced the adverse event may be unaware that he or she had been the subject of an adverse event report. Thus, under § 20.63(f)(1)(ii), if a person who experienced an adverse event were engaged in medical malpractice litigation, he or she could seek a court order to obtain identifying information, and thus determine whether he or she had been the subject of an adverse event report. In contrast, § 20.63(f)(1)(iii) presumes that the individual requesting a report already knows that a report exists and that the individual is ''the subject of the report.''

14. Two comments sought clarification of § 20.63(f)(1)(ii), particularly the ''identities'' that would be disclosed. The comments indicated that § 20.63(f)(1)(ii) could be interpreted as permitting disclosure of the identities of all persons experiencing an adverse event who were named in a report by the voluntary reporter. The comments suggested revising the provision to limit disclosure to the identities of the voluntary reporter and the person experiencing the adverse report provided that both were parties in the malpractice litigation.

FDA agrees that the identities of persons who experienced an adverse event but are not parties to the medical malpractice litigation should not be disclosed and has revised the rule accordingly.

15. Proposed § 20.63(f)(1)(iii) would permit disclosure of a voluntarily-submitted adverse event report to an individual who is the subject of the report.

One comment would modify the provision to require notice to the voluntary reporter.

FDA believes that an individual who is the subject of an adverse event report should be entitled to the report without prior notice to the voluntary reporter. Additionally, providing notice to the voluntary reporter would confer little benefit because there is no mechanism to allow the voluntary reporter to withdraw or amend a voluntarily submitted adverse event report once it has been submitted. Furthermore, as stated above, the suggested change is unnecessary in light of the agency's revision to the rule, which clarifies that the report will be disclosed to the subject of the report without inclusion of any other names, including that of the voluntary reporter.

16. One comment would make reports inadmissible as evidence unless the facility or reporter knew that the information contained in the report was false. Another comment would revise § 20.63(f)(1)(iii) to state that, ''The report shall be disclosed to the individual who is the subject of the report upon request in any litigation regarding the adverse event referred to in the report and in which the individual is a party.'' The comment asserted that manufacturers should not have to assume the burden of responding to a potentially large number of requests from patients for adverse event reports.

FDA disagrees with the comments. As stated above, the agency believes that an individual who is the subject of an adverse event report should be entitled to the report itself. Such access to the report should not be conditioned on the existence of false information in the report or on litigation.

17. One comment would revise § 20.63(f)(1)(iii) to state that, ''The report, but not the identity of the voluntary reporter or of any other person named in the report, shall be disclosed to the individual who is the subject of the report upon request.'' The comment claimed that this change would be consistent with the protection of identities under § 20.63(f)(1)(i) and (f)(1)(ii).

The agency agrees with the comment and has amended the rule to state that the report will exclude the identities of other persons. As mentioned earlier, this additional protection for the voluntary reporter is unlikely to limit the information available to most subjects of adverse event reports because they are likely to know already the identity of the voluntary reporter. FDA agrees that the identities of any other persons named in the report should also be protected in order to maintain their privacy or preserve the confidentiality of any relationships between the voluntary reporter and other persons. Therefore, the agency has revised § 20.63(f)(1)(iii) to exclude the identities of any other person, aside from the person requesting the report, named in an adverse event report.

III. Descriptiom of the Final Rule

The final rule creates a new § 20.63(f) to prevent FDA and manufacturers of human drug products, biologics, or medical devices from disclosing the names and any information that would identify the voluntary reporter or any other person named in a voluntarily-submitted adverse event report. The rule interprets ''information'' as including ''the name, address, institution, or any other information that would lead to the identities of the reporter or person identified in the report.'' The rule does not apply to the identities of reporters required by statutes (such as the Safe Medical Devices Act or the National Childhood Vaccine Injury Act) to submit reports to FDA and does not alter any disclosure requirements under those statutes.

The final rule also creates three exceptions to the prohibition against disclosure. Under § 20.63(f)(1)(i), the identities may be disclosed to a third party if both the voluntary reporter and the person who is identified in the report consent, in writing, to disclosure. As stated above, persons who seek disclosure of such identities have the burden of obtaining consent; the agency will not seek such consent itself. Under § 20.63(f)(1)(ii), identities may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both the person who experienced the adverse event and the voluntary reporter. Section 20.63(f)(1)(iii) would make the report, except for the identities of any other persons identified in the report, available to the individual who is the subject of the report, upon request.

Section 20.63(f)(2) preempts the establishment or continuation in effect of any State or local law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report, except as otherwise provided by § 20.63(f)(1).

IV. Legal Authority

A. Principles of Preemption Law

Under the Supremacy Clause of the Constitution (U.S. Constitution, Art. VI, clause 2), State laws that interfere with or are contrary to Federal law are invalid. (See *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824).) Federal preemption can be express (stated by Congress in the statute) or implied.

Implied preemption can occur in several ways. Preemption may be found ''where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation'' (*Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985), quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), or where ''the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject'' (*Rice* v. *Santa Fe Elevator*

Corp., 331 U.S. 218, 230 (1947); see *Hines* v. *Davidowitz*, 312 U.S. 52 (1941)).

Federal preemption may also be found where Federal law conflicts with State law. Such conflict may be demonstrated either when ''compliance with both federal and state [law] is a physical impossibility'' (*Florida Lime and Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142–143 (1963)), or when State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'' (*Hines* v. *Davidowitz*, 312 U.S. at 67). State law is also preempted if it interferes with the methods by which a Federal law is designed to reach its goals. (See *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987); *Michigan Canners & Freezers Ass'n* v. *Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 477–478 (1984).)

Additionally, '''a federal agency acting within the scope of its congressionally delegated authority may preempt state regulation' and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law'' (*City of New York* v. *FCC*, 486 U.S. 57, 63–64 (1988) (quoting *Louisiana Public Service Comm'n* v. *FCC*, 476 U.S. 355, 368 (1986)). ''Federal regulations have no less preemptive effect than federal statutes'' (*Fidelity Federal Savings and Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982)).

When an agency's intent to preempt is clearly and unambiguously stated, a court's inquiry will be whether the preemptive action is within the scope of that agency's delegated authority (*Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691, 700 (1984); Fidelity Federal Savings, 458 U.S. at 154). If the agency's choice to preempt ''represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute [the regulation will stand] unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned (''*United States* v. *Shimer*, 367 U.S. 374, 383 (1961)). In *Hillsborough County*, the Supreme Court stated that FDA possessed the authority to promulgate regulations preempting local laws that compromise the supply of plasma and could do so (*Hillsborough County*, 471 U.S. at 721). FDA believes it has similar authority to preempt State and local laws, rules, regulations, and other requirements that compromise the adverse reporting systems that are essential to postmarketing surveillance and protection of the public health.

B. Conflicts Between State Disclosure Laws and Federal Law

Conflicts between State and local disclosure laws and Federal laws and regulations on adverse event reporting justify FDA's preemption of State and local law. Although Congress did not expressly preempt State law in this area, FDA finds preemption is appropriate because such State and local laws significantly interfere with the methods by which the Federal laws and regulations achieve their goals.

FDA is the Federal agency charged with protecting citizens by helping ensure that human drug products, biologics, and medical devices are safe and effective for their intended uses. To further this purpose, Congress established elaborate mechanisms for the Federal government to permit the marketing of new drugs, biologics, and medical devices and to monitor the safety of these products after their approval. (See 21 U.S.C. 355 and 360; 42 U.S.C. 262.) Pursuant to these statutory provisions, FDA has established an extensive regulatory scheme to monitor the safety and effectiveness of human drug products, biologics, and medical devices. (See 21 CFR 310.305, 314.80, 600.80, and 803.1 through 803.36.)

State and local rules of civil procedure, rules of evidence, and other laws and regulations that permit discovery or require disclosure of a voluntary reporter's or patient's identity hinder FDA's monitoring scheme. While other FDA regulations may preserve the confidentiality of some voluntary reporters and the patients identified in an adverse event report, the same report, when in a manufacturer's possession, may be subject to State and local disclosure laws. Such possible disclosure will deter voluntary reporting by health professionals directly to manufacturers. In addition, the threat of disclosure may chill the willingness of reporters to provide information to FDA because the agency may share details about a report with a manufacturer in order to investigate the report further. Thus, this final rule preempts State and local disclosure laws, rules, regulations, and other requirements in order to eliminate obstacles to increased and enhanced voluntary adverse event reporting by health professionals. FDA has determined that the public health value of such reporting outweighs the individual needs of plaintiffs to discover the identities of a voluntary reporter or a patient, other than the plaintiff, who is the subject of the report.

The final rule focuses solely on protecting the identities of the voluntary reporter, the patient, and any other person identified in the report. The final rule does not preempt State or local laws that require disclosure of the substance of adverse event reports. FDA does not believe that disclosure of the substance of adverse event reports will impede its ability to collect such information. Indeed, FDA routinely releases the full substance of all voluntary adverse event reports upon request after deleting identifying information. (See § 20.111(c)(3)(iii).) The final rule also does not affect an individual's ability to obtain specific information about reports concerning his or her own reaction to a product, particularly when the individual is a plaintiff in a medical malpractice lawsuit and a court grants discovery of the plaintiff's records.

C. Legal Authority for the Final Rule

As discussed in the preamble to the proposed rule, there are various statutory provisions that authorize FDA to collect information about regulated products after the products are being legally marketed. These statutory authorities establish FDA's mandate to obtain information about the safety and effectiveness of drugs, devices, and biological products in order to determine whether continued use of these products presents an unreasonable risk to consumers. Through preemption of conflicting State and local rules that permit or require disclosure of voluntary reporter and patient identities, this rule removes an obstacle to full and accurate reporting of adverse events, and enhances the agency's ability to implement the surveillance authorities assigned to FDA.

Under section 505(k) of the act (21 U.S.C. 355(k)), an applicant who has an approved new drug application (NDA) or abbreviated new drug application (ANDA) ''shall establish and maintain such records, and make such reports * * * of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug'' as required by regulations or order. Under section 505(e) of the act, failure to establish a system for adverse event reports or to make reports required by regulation or order constitutes grounds for withdrawing approval of the NDA or ANDA. Under these provisions of the act as well as others, such as the misbranding and adulteration provisions, FDA promulgated regulations requiring specified drug adverse event reporting (21 CFR 314.80, 310.305). (See 50 FR 11478, March 21, 1985). As stated in the proposed rule, the voluntary system of

adverse event reporting that generates and supplements these required submissions is critical to the agency's post-market monitoring capabilities.

For medical devices, section 519 of the act requires manufacturers, distributors, and device user facilities to submit certain adverse event reports to FDA and authorizes the agency to require, by regulation, reports to assure that a medical device is not adulterated or misbranded and ''to otherwise assure its safety and effectiveness.'' As stated in the preamble to the proposed rule, in addition to reports required by the Safe Medical Devices Act, FDA maintains a voluntary device problem reporting program. (See 59 FR 3944 at 3945.) Voluntary medical device reports have been an important part of FDA's postmarketing surveillance system for medical devices and have prompted the agency to take action on several occasions. For example, in 1991, voluntary reports to FDA resulted in an alert to health professionals to potentially fatal hypersensitivity to latex products. A voluntary report from a physician about two patients who experienced blindness after the use of an ophthalmic device during eye surgery resulted in an FDA investigation and the recall and removal of the device from the market. This final rule is intended to ensure that such voluntary medical device reporting continues.

Furthermore, sections 505(k) and 519 of the act provide that regulations and orders issued with respect to postmarketing reporting requirements for drugs and devices ''shall have due regard for the professional ethics of the medical profession and the interests of patients * * * '' (21 U.S.C. 355(k) and 360i). The confidentiality of the physician-patient relationship is a basic tenet of medical ethics. The final rule, which protects both patient and reporter identities, is in furtherance of and consistent with these requirements of the act.

Additional authority to regulate adverse event reporting for biologics can be found in section 351 of the Public Health Service Act (the PHS act). Section 351 of the PHS act provides regulatory authority over biologics, and, pursuant to this section and other statutory authorities, the agency promulgated general adverse experience reporting requirements for licensed biological products, as well as requirements for manufacturers or collection facilities to report deaths related to complications in blood collection or transfusion. (See §§ 600.80 and 606.170(b) (21 CFR 600.80 and 606.170(b)); 59 FR 54034, October 27, 1994).)

The number and the quality of required reports that FDA receives from manufacturers and distributors ultimately depend upon voluntary reporting by health professionals. As FDA explained in the proposed rule, manufacturers and distributors cannot report adverse events if they do not find out about them from the health professionals who observed or were advised of the events. Disclosure of patient or reporter identities serves as a significant disincentive for voluntary reporting by health professionals; preemption of State and local disclosure rules that permit or require such disclosure eliminates an impediment to agency oversight of the postmarketing safety of products under its jurisdiction. The final rule, therefore, which is necessary to implement postmarketing surveillance statutory authorities, is also authorized under the general rulemaking authority set forth in section 701(a) of the act (21 U.S.C. 371(a)).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Executive Order 12612: Federalism

FDA has examined the effects of this final rule on the relationship between the Federal government and the States, as required by Executive Order 12612 on ''Federalism.'' The agency concludes that preemption of State or local rules that permit disclosure of the identities of the voluntary reporter or persons identified in an adverse event report for human drug products, biologics, and medical devices is consistent with this Executive Order.

Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate ''where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope'' (section 3(b)). The constitutional basis for FDA's authority to regulate the safety and efficacy of human drug products, biologics, and medical devices is the statutes created by Congress to regulate products affecting the public health. Congress's decision to vest FDA with the authority to establish a regulatory scheme to monitor the safety of these products demonstrates Congress' view that the safety of human drug products, biologics, and medical devices is a problem of national scope (21 U.S.C. 355(k) and 42 U.S.C. 262)).

Executive Order 12612 expressly contemplates preemption where there is a conflict of State and Federal authority under a Federal statute. (See section 4(a).) State and local rules of civil procedure, rules of evidence, and other rules and regulations that permit or require disclosure of the identities of those who report adverse events associated with human drug products, biologics, and medical devices impede FDA's ability to monitor the safety and efficacy of these products. The guarantee of confidentiality of the reporters' and patients' names is necessary to assure meaningful reporting of adverse events. Additionally, Congress specified that Federal regulations issued to monitor the safety of drug products ''shall have due regard for the professional ethics of the medical profession and the interests of patients.'' (See 21 U.S.C. 355(k) and 360i.) State and local rules and regulations that permit or require disclosure of the identities conflict with this requirement by jeopardizing confidentiality and the physician-patient relationship.

Executive Order 12612 also requires that any Federal preemption be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated (section 4(c)). The final rule is narrowly drawn and focuses solely on protecting the identities of the reporter and patient and other individuals named in the report. The final rule does not preempt State and local laws that require disclosure of the substance of the adverse event reports.

As required by sections 3(a) and 4(e) of Executive Order 12612, FDA consulted the appropriate State officials and organizations and gave States an opportunity to participate in the proceedings to preempt State and local laws. This opportunity came through publication of the January 1994 proposal and through notice sent to each State's Attorney General. The agency received no comments from any State regarding the contents or the concepts expressed in the January 1994 proposal.

Thus, FDA concludes that the policy expressed in this final rule has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; that this policy is not inconsistent with that Order; that this policy will not impose additional costs or burdens on the States; and that this policy will not affect the States' ability

to discharge traditional State governmental functions.

VII. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule would preempt the establishment or continuation in effect of any State or local law, rule, regulation, or other requirement requiring or permitting disclosure of the identities of persons reporting adverse events associated with the use of human drugs, biological drug products, and medical devices and patients' identities. Thus, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

2. Section 20.63 is amended by adding new paragraph (f) to read as follows:

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

* * * * *

(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions*. (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

(2) *Preemption*. No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.

Dated: March 24, 1995

William B. Schultz,

Deputy Commissioner for Policy.

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