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PHARMACEUTICAL RECALLS: STRATEGIES FOR MINIMIZING THE DAMAGE

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With the increasing complexities of the design and manufacturing processes, more stringent inspection procedures, and the product liability and regulatory burdens under which manufacturers operate, the odds are that a pharmaceutical firm will undergo a recall of one of its products.

The ability of a firm to execute an effective recall strategy is crucial in the litigation arena. As a firm enacts a recall plan, its efficiency and effectiveness, its relationship with Food and Drug Administration officials, and the overall perception of the firm's attempt to remove its "harmful" product from public exposure, can have a very powerful positive value in product liability litigation. If done wrong, a recall can impact a company in product liability exposure, sales, manufacturing costs, and public perception.

This article will explore various recall strategies and propose steps by which a firm can minimize its damage. An overview of the involvement of the Food and Drug Administration (FDA) is provided, and appropriate recall strategies are presented.

Key Words: Recall; Pharmaceutical; Food and Drug Administration; Product liability

INTRODUCTION

ON OCTOBER 4, 1982, Johnson and Johnson announced a nationwide withdrawal of 31 million bottles of Tylenol after seven people died from taking cyanide-laced Extra-Strength Tylenol capsules. Johnson and Johnson's swift action enabled it to avoid an FDA-requested recall and minimized the possibility of severe financial losses and significant litigation (1,2).

This article will review the extent of the FDA's power to issue recalls of pharmaceutical products and the internal procedures by which the FDA effectuates recalls. Also, the effect that recalls have on product liability exposure is discussed. Finally, recommendations for conducting voluntary recalls are offered that will help minimize the potentially devastating effect recalls can have on product liability litigation pertaining to the recalled product. An attempt has been made to present information relevant to both regulatory affairs professionals and lawyers.

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AUTHORITY TO ENFORCE THE FOOD, DRUG AND COSMETIC ACT AND CONDUCT RECALLS

Brief Overview of the Food, Drug and Cosmetic Act

The FDA began actively regulating the manufacturing and marketing of numerous prod-

ucts in 1938 with the enactment of the Food, Drug and Cosmetic Act (FDCA) (3). This act is authorized by the constitutional power of Congress to regulate interstate commerce, and strives to keep interstate channels free of deleterious, adulterated, and misbranded articles of specified types for the protection of the public health and safety. In furtherance of this goal, § 331 of the FDCA prohibits certain acts that involve the adulteration and misbranding of any food, drug, device, or cosmetic in interstate commerce. (Section 331 provides, *inter alia*, that the following acts are prohibited: 1. the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, 2. the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce, 3. the receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and 4. the delivery or proffered delivery thereof for pay or otherwise.) In conjunction with those prohibited acts, the FDCA provides various enforcement mechanisms for the FDA to halt FDCA violations, the majority of which are found at §§ 333 to 335.

Congress steadily has increased the FDA's control over the food, drug, device, and cosmetic industry by enacting a succession of comprehensive amendments to the FDCA. (These amendments include, most notably for this paper: the Drug Amendments of 1962, Pub. L. No. 87–781, § 1, amending 21 U.S.C. §§ 321, 331–32, 348, 351–53, 355, 357, 372, 374, 376 381; the Prescription Drug Marketing Act of 1987, Pub. L. No. 100–293, § 1(a), amending 21 U.S.C. §§ 331, 333, 353, 381, 42 U.S.C. § 3512, 15 U.S.C. § 55; the Prescription Drug Amendments of 1992, Pub. L. No. 102–353, § 1(a), amending 21 U.S.C. §§ 333, 353, 381; and the FDA Modernization Act of 1997, Pub. L. No. 105–115.) Currently, the FDCA, along with the accompanying regulations, governs the process by which such products are introduced into and continue in the public domain. Specifically with regard to drugs, manufacturers are required to follow certain procedures to prevent the adulteration and misbranding of their drugs, including investigating and reporting to the FDA adverse incidents (4,5) involving their products, and providing safety analyses or reviews that include thorough and current information regarding the safety and effectiveness of their products (6). (Under the Adverse Action Reports regulations, drug manufacturers must report any adverse event associated with the use of their drugs in humans, even when the event is not deemed drug-related or serious and the event is expected.)

FDA Regulation of Prescriptive Drugs

Sections 351 through 360ee of the FDCA, along with their accompanying regulations, specifically explain how drugs are regulated, including provisions for adulteration, misbranding, sale and distribution, advertising, obtaining approval to sell and distribute, manufacturing, and monitoring a drug's performance. The FDCA also includes various provisions that enable the FDA to penalize pharmaceutical firms that are not in compliance with the regulations.

Contrary to the popular perception that the FDA has broad recall power over all products within its jurisdiction, its mandatory recall power is limited to cases involving infant formulas, biological products, and devices that present a serious hazard to the public's health. With regard to pharmaceutical recalls, the FDA can only *request* a pharmaceutical firm to conduct a recall. The effectiveness of the FDA in having its recall requests implemented by manufacturers is due to the realization that resisting the FDA's request for a recall invites the FDA to pursue its full panoply of administrative, civil, and criminal remedies.

The enforcement tools available to the agency include seizure, injunctions, criminal prosecutions, and recalls. For reasons described below, recalls generally are the preferred remedy of the FDA.

Seizure. "Seizures are an expeditious means of removing violative products from the mar-

ketplace" (7). Section 304 of the FDCA gives the FDA authority to conduct a seizure. Generally, a district will recommend a seizure action to the appropriate center in FDA headquarters after considering issues such as prior warning, significance of the violation, current status of the firm, pending and adjudicated seizure actions, the public health risk, and the amount of product to be seized. A seizure will be considered when there is a likelihood that a significant amount of the product will be moved before seizure is effected or the FDA has reason to believe the devices are adulterated or misbranded (8). Because seizures are less resource-intensive for the FDA than other enforcement actions, a mass seizure can be a very effective tool relative to the resources expended and compliance achieved.

Injunction. An injunction is a court order either requiring an affirmative act or prohibiting specified conduct. Injunctions are sought by the FDA to stop conduct that the FDA concludes violates the FDCA. An advantage of an injunction is that, upon satisfactory proof of irreparable injury, virtually immediate judicial relief can be obtained. Attempts by the FDA to obtain temporary restraining orders, however, are relatively rare (8). Injunctions are sought by the FDA when:

1. There is a current and definitive health hazard or a gross consumer deception that requires immediate action to halt the violative practice and prevent it from reoccurring in the future,
2. Corrective efforts, with notice, have failed and there are significant amounts of violative products owned by the same person in many locations, and multiple seizures are impractical or uneconomical, or
3. There are chronic violative practices that do not amount to a health hazard or gross consumer fraud, but have not been corrected through voluntary or other regulatory approaches (8).

Civil Penalties and Prosecution. The FDCA imposes civil penalties for prescription drug marketing violations (9). Violations of the law pertaining to drug sale, purchase, or trade provisions can result in a civil penalty of not more than $50,000 for up to two violations within a given 10-year period, and not more than $1 million for each violation thereafter during a 10-year period.

If violations are not corrected, or are flagrant, fraudulent, or life-threatening, the federal government may criminally prosecute. Once a prosecution begins, the Department of Justice is charged with conducting the litigation on behalf of the FDA. Any person who commits a "prohibited act," a term broadly defined in § 331 of the FDCA, can be imprisoned for not more than one year or fined up to $1,000 or both. If an intent to defraud or mislead is proven, a defendant can be imprisoned for up to three years or fined a maximum of $10,000 or both.

Recalls

Authority. The FDCA provides the FDA with limited recall authority that reaches only certain products. The regulations for recall of pharmaceuticals are found in the Code of Federal Regulations (CFR), under Title 21, Chapter 7. (The recall regulations apply to all recalls regardless of whether the recall is ordered or requested by the FDA. Because recalls may be ordered or requested, pharmaceutical firms should be aware that the regulations are not mandatory for drug recalls, but it is highly recommended that they be followed.) A recall is defined as "a firm's removal or correction of a marketed product that the [FDA] considers to be in violation of the laws it administers and against that which the agency would initiate legal action. . . . " (10,11). ("Correction" is defined as a "repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.") The scope of these regulations covers all "article[s] subject to the jurisdiction of the [FDA], including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item

subject to a quarantine regulation. . . . " Therefore, despite the fact that the FDCA does not expressly authorize the FDA to order a pharmaceutical recall, the regulations give the FDA the authority to request a firm to conduct a voluntary recall.

Although similarities exist between recalls, market withdrawals, and stock recoveries, there are significantly different consequences that flow from each that must carefully be considered before decisions are made as to how to deal with an alleged violative drug.

Distinction Between Market Withdrawal and Stock Recovery. The regulations governing recalls specifically exclude market withdrawal and stock recovery. Because they are free of a number of the constraints the FDA imposes on recalls, and generally cause less problems in subsequent product liability litigation, manufacturers generally prefer to have a product action designated as a withdrawal or recovery rather than a recall.

Market withdrawal is the: "removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the [FDA] or which involves no violation. . . . " (13). What is meant by a "minor violation" is not clear as the term is not defined in the regulation. Consequently, a firm that discovers what it believes is a "minor violation" has no assurance, in advance of discussions with the FDA, that its assessment will be shared by the FDA. Because the FDA typically is reluctant to characterize violations as minor, it often is difficult to obtain FDA agreement to characterize a product action as a market withdrawal. Nonetheless, a firm would be at a significant advantage to seek in its negotiations with the FDA, to classify the action as a market withdrawal.

A stock recovery is a firm's: "removal or correction of a product that has not been marketed or that has not left the direct control of the firm. . . . " (14). What constitutes "direct control" is open to debate. Thus, the severity of the violation will differentiate a recall from a market withdrawal while the location of the violative product in the distribution chain differentiates a recall from a stock recovery.

As mentioned earlier, one significant benefit in having a product action designated by the FDA as a market withdrawal or stock recovery is that the firm will not be subject to the recall regulations. Consequently, a market withdrawal or stock recovery can be conducted relatively free of FDA oversight and intrusion, although a firm is required to notify the FDA if it conducts a market withdrawal.

A nonrecall product action also provides advantages when the potential for public disclosure is considered. A firm can avoid public disclosure of the product action by conducting a withdrawal or stock recovery. Such actions are not included in the weekly *FDA Enforcement Report*. Pursuant to the recall regulations, the FDA must place in its weekly *FDA Enforcement Report* a description of every recall that it requests or that is initiated by a firm, including its classification and the action taken by the recalling firm. Therefore, if a firm learns that a drug is misbranded or adulterated, efforts should be made quickly to retrieve the drug before it is distributed so that the action can qualify as a stock recovery.

Benefits of Recall. Recall of a product is an anathema to a company committed to quality control and quality assurance. When market withdrawals and stock recoveries are not available, however, an effective voluntary recall in advance of an FDA-requested recall can produce tangible benefits in terms of improved relationships with the FDA and an enhanced image before a jury in a product liability lawsuit (as discussed more fully below).

FDA ORGANIZATION PERTAINING TO RECALLS

The FDA is comprised of five offices: the commissioner, operations, policy, external affairs, and management and systems (Figure 1). Each office is managed by a deputy com-

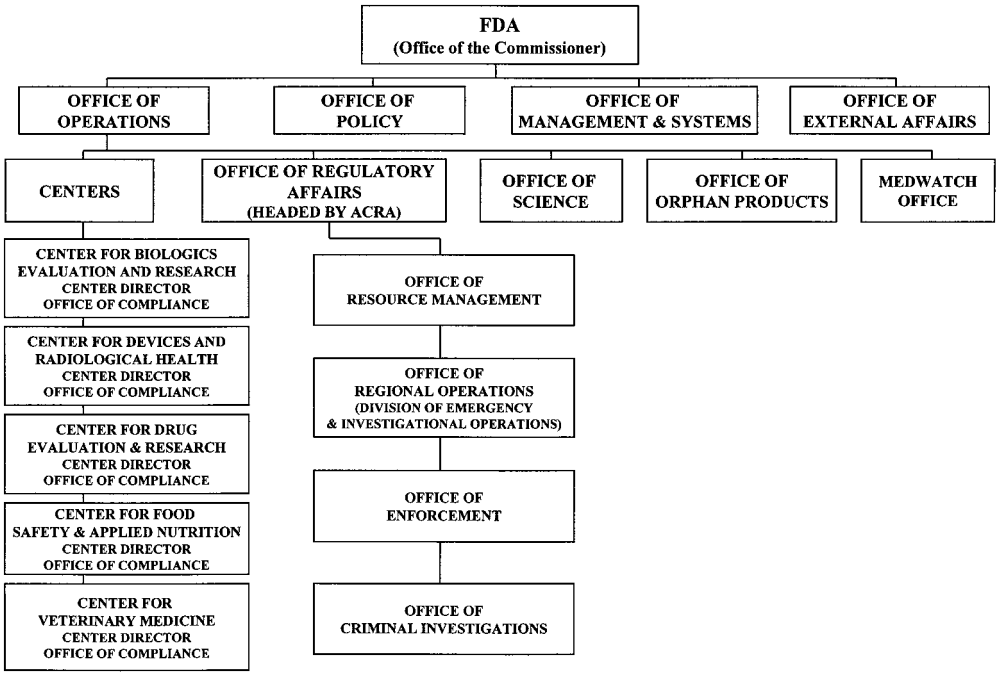

FIGURE 1. Food and Drug Administration Organizational Chart Pertaining to Recalls.

missioner, with the exception of the Office of the Commissioner which is headed by the FDA Commissioner.

Office of Operations

The Office of Operations (operations) is the most important office for the purposes of recalls and the largest organizational unit within the FDA. It includes over 80% of the personnel and resources of the agency, and is responsible for all agency field operations, including initiating and auditing recalls. Operations also provides oversight and coordination for the product review processes. Operations consists of five centers (Biologics Evaluation and Research, Devices and Radiological Health, Drug Evaluation and Research, Food Safety and Applied Nutrition, and Veterinary Medicine), three offices (Office of Regulatory Affairs, Office of Science, and Office of Orphan Products and Development), and the MedWatch Office. The individual centers, along with the Office of Regulatory Affairs (ORA), are primarily involved in recalls.

Office of Regulatory Affairs. The ORA is run by the associate commissioner of regulatory affairs. Generally the ORA is responsible for the activities and operations of the field headquarters staff and the field staff of the FDA. The ORA consists of four individual offices that, while operating independently of each other, do have some related functions. The offices include: Office of Resource Management, Office of Regional Operations, Office of Enforcement, and Office of Criminal Investigations.

With centers responsibile for evaluating recalls and the ORA responsibile for providing the personnel to obtain data needed to evaluate recalls, coordination is essential. The responsibility for coordinating the FDA's resources for a recall lies with the Office of Regional Operations, Division of Emergency and Investigational Operations (DEIO). The Office of Regional Operations (ORO):

1. Coordinates and manages all agency field operations on behalf of the associate commissioner of regulatory affairs,
2. Develops, issues, approves, or clears pro-

posals and instructions affecting field activities, and,
3. Serves as the central point within the agency through which headquarters obtain field support services.

The DEIO provides direction, assistance, and management for the field's domestic and foreign investigative activities, and serves as the agency's focal point for headquarters/field relationships on investigational and inspection problems.

To provide necessary coordination among operations' centers and the ORA, the DEIO collects recall information from the centers and districts. Additional responsibilities of the DEIO include:

1. Evaluating the adequacy of a firm's performance in implementing a recall,
2. Recommending regulatory action if the recall is not progressing satisfactorily,
3. Taking appropriate follow-up action upon receipt of all pertinent recall documents, and
4. Providing review and recommendation to the acting director of regulatory affairs whether to approve an FDA-requested recall and recommendations on all firm-initiated Class I recalls and recalls requiring level A or B audit checks. The DEIO review of the action memorandum is to be performed within one day of its receipt (15,16).

Finally, the DEIO is responsible for notifying the international affairs staff of all Class I and II recalls involving distribution into foreign countries.

Centers. The five centers within operations are responsible for managing programs for products within their respective areas of responsibility. Each center maintains an Office of the Center Director and an Office of Compliance. While each center director has duties specific to the center's overall area of responsibility (17), with regard to recalls, each center director establishes (For example, the CDER center director is responsible for: 1. developing FDA policy on the safety, effectiveness, and labeling of all drug products for human use, 2. reviewing and evaluating new drug applications, 3. developing and implementing standards for the safety and effectiveness of over-the-counter drugs, 4. developing and promulgating guidelines on Current Good Manufacturing Practices, 5. conducting research and developing scientific standards on the composition, quality, safety, and effectiveness of human drugs, 6. collecting and evaluating information on the effects and use trends of marketed drug advertising and promotional labeling, and, 7. analyzing data on accidental poisonings and disseminating toxicity and treatment information on household products and medicines.) and oversees the center's recall activities. Each center's Office of Compliance, along with the ORA, are charged with enforcing FDA policy. Overall enforcement is established by the ORA's Office of Enforcement, and each center's Office of Compliance seeks to ensure conformity with the center's program. The Office of Compliance within each center has significant responsibility for evaluating the effectiveness of recalls or products within its programs. The center and Office of Compliance most relevant for pharmaceutical firms is the Center for Drug Evaluation and Research.

Despite the fact that the centers have responsibility for ensuring that recalls are performed effectively, they do not have direct control or line authority over district field personnel—investigators and inspectors—who perform the recall audits and the Good Manufacturing Practice (GMP) inspections. Field personnel are assigned to districts whose directors report to the associate commissioner of regulatory affairs.

THE RECALL PROCESS

The recall responsibilities of the ORA and centers vary depending upon the recall classification and whether the recall was requested by the FDA or was firm-initiated. A recall may be classified as either I, II, or III. A Class I recall is one in which the FDA con-

cludes there is a strong likelihood that use or exposure to a violative product will cause: "serious, adverse health consequences or death" (18). Class II recalls involve a use or exposure to a product that is in violation of the FDA act which may cause: "temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death is remote" (18). Finally, when exposure to a product is not likely to cause adverse health consequences, it is designated as a Class III recall (18).

FDA-Requested Recalls

The FDA will request that a firm initiate a recall when it believes that a drug violates the FDCA. Specifically, a recall will be requested when the FDA concludes that:

1. A drug that has been distributed presents a risk of illness or injury or gross consumer deception,
2. The manufacturer or distributor has not recalled the drug, and
3. FDA action is necessary to protect the public health (19).

Typically, a request by the FDA that a firm recall a drug is directed to the firm with primary responsibility for the manufacture and marketing of the drug to be recalled.

The two most likely sources within operations for suggesting a pharmaceutical recall are the CDER and the FDA district offices. The CDER, as well as the other four centers, possesses the technical knowledge for particular products and is uniquely situated within the FDA to detect problems. District field personnel are responsible for conducting GMP inspections that may yield evidence suggesting the need for a recall.

Regardless of who suggests a recall within the FDA, certain procedures must be followed before the recall suggestion becomes an agency decision. If the district believes a recall is necessary, it will prepare a recall recommendation (RR) for review by the appropriate center. The RR should include the facts supporting the recall and a recommended recall strategy. A recall strategy should take into account a number of factors including the following:

1. The ease in identifying the product,
2. The degree to which the product's deficiency is obvious to the consumer or user,
3. The degree to which the product remains unused in the marketplace, and
4. The continued availability of essential products (20). (A recall strategy normally should include a health risk evaluation as well. This component, however, usually is incorporated into the recall strategy by the center after its review of the district's RR.)

The recall strategy should include recommendations for the depth of the recall. The recall depth refers to the degree to which the recall will extend through the distribution chain. A recall may extend to any one of three levels:

1. Consumer or user,
2. Retail, and
3. Wholesale (21).

A recommendation as to whether a public warning will be necessary also should be addressed in the recall strategy. Pursuant to FDA regulations, a public warning is: "reserved for urgent situations where other means for preventing use of the recall product appear inadequate" (22).

Finally, the district's RR should include recommendations regarding the "effectiveness checks." "Effectiveness checks" are the degree to which the FDA and the recalling firm will attempt to verify that all consignees at the specified recall depth have received recall notifications and are taking appropriate action (23). Consignees may be contacted by either personal visits, telephone, or correspondence. Generally, the responsibility for conducting effectiveness checks lies with the recalling firm. The FDA will communicate with consignees, however, in order to audit the recall effectiveness.

There are five levels of effectiveness checks:

1. Level A: 100% of the consignees are to be contacted,
2. Level B: more than 10% of the consignees are to be contacted but less than 100%, the exact percentage to be determined by the FDA when the recall is initiated,
3. Level C: 10% of the total consignees to be contacted,
4. Level D: 2% of the consignees to be contacted, or
5. Level E: no effort to contact any consignees (23).

Upon receipt of the district's RR, the CDER refers the RR to its Health Hazard Evaluation Committee (HHEC). The HHEC is comprised of FDA scientists chosen for their expertise and is responsible for analyzing whether a health hazard exists and, if so, the severity of the health hazard. FDA regulations require that a health risk assessment consider a number of factors including the following:

1. Whether disease or injuries have resulted from using the product,
2. Whether existing conditions could contribute to a clinical situation that could expose users to a health hazard,
3. Which segments of the population are exposed to the risks that have the greatest risk exposure,
4. The seriousness of the health hazard,
5. The likelihood of the risk occurring, and
6. The consequences if the danger should be realized (24).

Based upon the district's RR and the Health Hazard Evaluation Committee's analysis, the center will classify the recall and specify the recall depth and effectiveness check level. This information is included in an "action memorandum" and presented to the center director for approval. For all FDA-requested recalls, the action memorandum must be sent to the associate commissioner for regulatory affairs for final approval.

As soon as the action memorandum is approved by the associate commissioner for regulatory affairs, pertinent information regarding the recall is sent to the district in which the recalling firm is located (ie, monitoring district). Upon receipt of this information, the monitoring district's recall coordinator will prepare a recall notification (RN). A number of governmental agencies receive the RN, including each district field installation, appropriate centers, and the DEIO. The RN is to be prepared within two days of the monitoring district receiving the recall number, strategy, and classification from the center.

After the associate commissioner of regulatory affairs has approved the action memorandum, the firm is notified of the requested recall by letter or telegram. Written communication, however, may be preceded by a telephonic communication or a visit by a district investigator. The notification to the firm must detail the specific violation prompting the recall, the recall classification, and the recall strategy (25).

Within 24 hours of the firm being notified of the recall, district investigators are to conduct an establishment inspection to obtain the following:

1. Identity of the recall product,
2. Reason for the recall or correction and the date and circumstances under which the deficiency in the product was discovered,
3. The health risk evaluation by the recalling firm,
4. The number of the products produced within the appropriate time period affected by the recall,
5. An estimate of the total number of products in the distribution chain,
6. Distribution information including the identity of direct accounts,
7. Copies of the recalling firm's proposed recall communication,
8. The firm's recall strategy, and
9. The identity of the employee who will be responsible for conducting the recall (26).

Firm-Initiated Recalls

A firm can recall a drug at any time to remove or correct a distributed product. A firm usually is under no legal obligation to notify the FDA that it is recalling a defective product, but if the firm believes the product is violative, it is requested to notify the FDA immediately (1). Within 24 hours of an FDA district office learning that a firm has initiated a recall or is planning to initiate a recall, it must send out a "24 Hour Alert to Recall Situation" notifying the CDER and the DEIO (1,27). Within five working days, the district must submit its RR to the center which must include an assessment of the firm's ability to conduct an effective recall.

A firm that voluntarily decides to issue a recall will be asked to provide the FDA with certain information, including:

1. Identity of the product involved,
2. Reason for the removal or correction and the date the necessity of such action was discovered,
3. An evaluation of the risk associated with the deficiency,
4. The total amount of such products produced,
5. The total amount of such products estimated to be in production,
6. Distribution information,
7. A copy of the firm's recall communication, or proposed communication,
8. A proposed strategy for conducting the recall, and
9. The name and telephone number of the firm official who should be contacted concerning the recall (28).

Also, the firm is asked to prepare a recall strategy that addresses the factors discussed in the FDA-initiated recall strategy. The firm's recall strategy will be evaluated by the district, HHEC, center director, and DEIO and modified if necessary. The firm eventually will be advised that its recall will be placed in the weekly *FDA Enforcement Report.*

The center performs the same functions in a firm-initiated recall as it does for an FDA-requested recall except that it is not required to prepare an action memorandum for approval by the associate commissioner of regulatory affairs. Nonetheless, a firm need not wait for the recall classification from the center before implementing its recall. There are risks, however, in proceeding with the recall before it is classified by the center. For example, recall communications prepared by the firm may have to be redrafted depending upon the FDA's classification of the recall.

Auditing the Recall

In both FDA-requested and firm-initiated recalls, the district has the overall responsibility to audit the recall. This includes reviewing the firm's periodic recall status reports, conducting audit checks at the recall depth for Class I and II recalls, and monitoring or verifying product disposition.

In Class I and II recalls, within 10 days of receiving the firm's recall communication, the monitoring district will issue and convey audit check assignments to investigating districts. Investigating districts are to provide the monitoring district with audit check reports on a weekly basis for Class I recalls.

Periodic recall status reports also must be submitted by the firm to the monitoring district. The recall status reports assist the FDA, together with the districts' recall audits, in assessing the effectiveness of the recall. Unless otherwise agreed, firm recall status reports should detail:

1. The number of consignees notified of the recall and the method of notification,
2. The number of consignees responding to the recall and the number of products each consignee had upon receipt of the recall communication,
3. The number of consignees not responding to the recall notification,
4. The number of products returned in the recall,

5. The number and results of effectiveness checks conducted by the recalling firm, and
6. Estimated completion date for the recall (29).

If the monitoring district concludes from its audit inspections and the recall status reports that the recall has been ineffective, the monitoring district will provide recommendations for action to be taken to improve the effectiveness of the recall. If the monitoring district concludes that the recalling firm has not been cooperative, recommendations for administrative or judicial action will be made by the district recall coordinator.

The monitoring district also is responsible for providing recommendations to the center for terminating a recall. In Class I and II recalls, as soon as the monitoring district concludes that the recall has been effective, a recall termination notice is prepared and submitted to the center director for review and approval. No more than three months should elapse from the time the monitoring district believes that the recall has been completed to the issuance of a recall termination. A recall termination will not be issued until the recalled product is either put into compliance or destroyed.

EFFECT OF RECALLS ON PRODUCT LIABILITY LAWSUITS

Recalls, whether voluntary or requested, can affect a manufacturer's product liability exposure in several ways. For ease of analysis, the following discussion looks at this issue from two broad themes. The first point is the impact a recall has on generating product liability exposure; second, the evidentiary effect of a recall in a product liability trial is discussed.

Effects of Recall on Generating Product Liability Exposure

For reasons that previously have been discussed, whenever permissible to do so, manufacturers should characterize their product action as a market withdrawal or stock recovery as these actions can be conducted largely outside of the scrutiny of the FDA. Consequently, the probability is reduced that the product action will attract the attention of plaintiffs' lawyers eager to find the next company to sue. When circumstances make a market withdrawal or stock recovery unavailable, the mere fact that a recall has been conducted will generate interest among plaintiffs' lawyers.

How the recall is conducted is one factor that affects the recalling firm's product liability exposure. For example, recalls that are initiated by firms and pursued aggressively send a powerful message to plaintiffs' counsel that the firm is responsible and concerned with the safety of its products. Although it is naive to believe that a well-performed recall will cause all plaintiffs' counsel to lose interest in pursuing the product, it nevertheless is reasonable to conclude that a well-conducted recall will generate less product liability exposure than what otherwise would be the case.

If a recall is not handled effectively, the probability increases that an injury or death may occur from using the drug during the period the recall is being conducted, or worse, after it has been terminated. In such a case, the ineffectiveness of the recall may support a claim for punitive damages on behalf of people injured after the recall began. At a minimum, an ineffective recall will last longer and produce more adverse publicity.

Recalls that are performed ineffectively usually generate correspondence between the recalling firm and the FDA, which often casts the company in a very poor light. Conversely, recalls that are performed quickly and efficiently will generate FDA correspondence that a recalling firm may want to introduce into evidence to show its concern for safety and the reasonableness of its conduct.

Firms should not be too conservative in determining what level recall is appropriate and to what degree consignees should be notified. A firm that errs on the side of expanding a recall will have the increased recall costs offset by the reduced value the case

might otherwise have for plaintiffs' attorneys. Consequently, when considering the extent of a voluntary recall, a firm must consider the consequences on its product liability exposure if the recall does not go far enough.

Finally, the steps as the recall winds down are significant. A firm that is thorough and cautious in the final phases of a recall will impress a jury, whereas one that eases its intensity and tries to cut corners to shut the recall down may be proven negligent if it allows any consumers to slip through the cracks and become injured by the presumably recalled product.

Admissibility of Recall Evidence

Not surprisingly, plaintiffs suing a recalling firm for injuries allegedly resulting from a defect in a drug that precipitated the recall will attempt to introduce into evidence the fact that the drug was recalled. This always should be anticipated by defense counsel when a product has been recalled or is otherwise subject to a product action; subsequent steps should be taken to have pretrial rulings by the court prevent plaintiffs' counsel from introducing evidence of the recall.

The primary argument for excluding evidence of a recall is that it is not relevant to the plaintiff's burden to prove that the product caused the alleged injuries. Other arguments are embodied in the public policy determination that firms should not be discouraged from performing remedial measures out of a concern that their actions will be held against them as evidence of negligence. These arguments are embodied in several state and federal evidentiary rules.

Although an FDA-requested recall is conducted only when there is a reasonable belief that there is a problem either with the warning, manufacture, or design of the drug, the fact that a recall was performed is not probative on whether the drug, in an individual case, was defective and/or had any causal role in causing the plaintiff's alleged injuries. To the extent the evidence has marginal relevance on liability or damages, it is outweighed by the potential for severe prejudice. A jury will equate the fact of a recall with an admission that all of the products recalled were defective (30,31,32).

In cases where the drug is recalled because of a perceived inadequacy in the warning (ie, the inadvertent exclusion of a reported complication), arguably all of the products that are recalled share the same alleged inadequacy in their warning. In this instance, the primary argument to exclude evidence of the recall is the public policy against penalizing a company for taking remedial measures. This public policy is embodied in Rule 407 of the Federal Rules of Evidence. As recently amended, the rule now is clear that evidence of subsequent remedial measures is not admissible to prove allegations of negligence or strict liability (33).

Although arguments of relevance and subsequent remedial measures often will lead to rulings excluding evidence of a recall, an important argument that cannot be overlooked, when applicable, is that the action undertaken by the firm was not a recall but rather a market withdrawal or stock recovery. Because these actions do not carry the regulatory connotations of public health risks associated with class I, II, or III recalls, the probative value of the product action easily is outweighed by its prejudicial effect.

Notwithstanding the above arguments, courts may admit evidence of a recall for a variety of purposes including the fact that the recall may be evidence of malicious conduct by the recalling firm if the recall was done ineffectively. The corrective action taken by the recalling firm may be admissible if the recalling firm challenges the feasibility of correcting the alleged defect. Finally, recalls that are not done effectively, either because the company resisted the FDA's request and/or simply performed the recall poorly, almost invariably generate internal documents by employees critical of the recall. Such documents often are the best evidence the plaintiffs have to support a claim for punitive damages.

Finally, even if the court rules that the fact of the recall is admissible, that does not necessarily mean that all documents that

were created by the recalling firm pertaining to the recall are admissible. Counsel must review carefully the recall documents to determine if individual documents can be excluded on grounds of attorney-client privilege and/or the privilege of self-critical analysis. The work-product rule rarely will be applicable in this situation; however, it should not be overlooked in the evidentiary analysis.

Restatement Third Issues

The "Restatement of the Law Third, Torts: Products Liability" is an aggregation of law as it exists in the 50 states, attempting to distinguish what the majority and minority of states hold with regard to specific issues involving product liability. As the "third edition" was published in late Spring of 1998, it is appropriate to consider briefly how the reporters address the duty to recall. Similarly, though not strictly related to recalls, it is appropriate to point out the reporters' revisions with regard to the liability of prescription drug manufacturers under a defective design cause of action.

Liability for Harm Caused by Postsale Failure to Recall. Although it is beyond the scope of this paper to offer a legal analysis on the body of law pertaining to a postsale duty to warn, suffice it to say that this area is unsettled in the law. Although some states do not recognize a duty of the manufacturer to warn users of its product after its product is sold, other courts have begun recognizing a postsale duty to warn. A close question also exists as to whether there is a duty to recall a product and whether a failure to promptly recall a product can be a separate basis for liability. Both of these questions are addressed by the Restatement Third.

Section eleven of the Restatement Third provides that one engaged in the business of selling or distributing products is subject to liability for harm caused by the seller's failure to recall a product after the time of sale or distribution if:

1. A statute or other governmental regulation specifically requires the seller or distributor to recall the product, or
2. The seller or distributor, in the absence of a recall requirement, undertakes to recall the product and fails to act as a reasonable person in recalling the product (34).

It is important to note that this section imposes liability even when the seller attempts to eliminate the defect through postsale recall. The fact that one who owns or possesses a product that was defective at the time of sale does not respond to a recall notice does not necessarily eliminate the causal connection between the original defect and the plaintiff's harm. In appropriate cases a plaintiff may seek recovery on both a claim of original defect and a claim of postsale failure to recall.

Liability for Defective Prescription Drugs. Section six of the Restatement discusses liability of sellers or other distributors for harm caused by defective prescription drugs and medical devices. The traditional rule is that physicians are learned intermediaries and that drug manufacturers are liable only when their products contain manufacturing defects or are sold without adequate instructions and warnings to them. Section six, while recognizing the general rule, provides an exception to this rule when a manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the warnings or instructions. In such instances, the patient must be warned of the risks directly by the manufacturer.

Under the rule in most states, prescription drug manufacturers cannot be held liable under theories of design defects. This is in large part due to a recognition of the hurdles and restrictions that a prescription drug manufacturer faces with the FDA in getting approval of a drug. Section six of the Restatement Third, however, recognizes an exception and allows liability to be imposed on a prescriptive drug manufacturer when a drug's risks of harm so far outweighs its therapeutic benefits

that reasonable, properly informed health care providers would not prescribe it. (It should be noted that in the Restatement (Third) of Torts, Product Liability retains the learned intermediary rule.)

RECOMMENDATIONS FOR CONDUCTING EFFECTIVE RECALLS

Introduction

For the reasons discussed in this paper, performing an effective recall is critically important in order to maintain a positive relationship with the FDA and to minimize product liability consequences. Maintaining a good relationship with FDA district investigators is important because they have significant input in evaluating the effectiveness of a recall. An adversarial relationship with district investigators will almost guarantee a longer, more costly recall with greater publicity. Moreover, after the recall is terminated, the investigators involved in the recall audits may be responsible for conducting GMP inspections. GMP inspections conducted by investigators who have had bad experiences auditing a firm's recall probably will not proceed as smoothly as one conducted by an investigator who trusts and respects a firm's employees.

Conducting an ineffective recall also may make it more difficult for a firm to obtain FDA approval of other products. A poorly performed recall, particularly if the ineffectiveness was due to incompetence or poor data, may leave lingering doubts within the FDA about the integrity of the data supporting already approved products and future products. A prolonged recall also may impair the ability of the firm to receive government contracts.

Maintaining a good relationship with FDA field personnel has become increasingly more difficult due to a loss of trust following publicized hearings of the FDA's handling of certain devices and the generic drug investigations. These experiences have led FDA investigators to become increasingly distrustful of firms.

Whether a recall was effective is determined by analyzing steps taken by a firm before, during, and after a recall. At each stage there are steps that a firm can take to improve its effectiveness in performing a recall.

Steps to Take Before a Recall

In order for upper management to decide intelligently whether to recall a product, it must have accurate and complete data. In general, if a pharmaceutical firm has complied with the current good manufacturing practices specified in 21 CFR § 211.1 *et seq*, it will have the data and reports needed to make intelligent decisions regarding a recall. It is unlikely, however, that upper management in most firms will have the technical background to analyze such data. Consequently, one goal of a recall plan is to create a team that will be comprised of representatives of each discipline within the firm responsible for the design, production, quality control, and marketing of the product. This team should be given the responsibility of assessing the data, preparing a risk assessment, and submitting recommendations to upper management.

Generally, lead responsibility for the recall team is given to a manager in the quality assurance or regulatory affairs department. The lines of authority and responsibility for decision making must be established clearly so that the effectiveness of the team and the subsequent product action (ie, market withdrawal, stock recovery, or recall) is not undermined by indecision among team members. The plan also should require that if a recall is initiated by the firm, the team should continue to keep its CEO fully informed of all aspects of the recall. This will ensure that corporate decisions or statements that could affect the firm's relationship with the FDA are not made on the basis of incomplete or inaccurate data.

In addition to completing a risk assessment for upper management, the team also should develop a comprehensive recall strategy. A good risk assessment and recall strat-

egy should provide the basic data needed by upper management to enable it to make decisions as to whether to initiate a product action.

As stated earlier, compliance with GMPs will ensure that a firm has in place traceability records that will enable it to quickly and accurately obtain a violative product's manufacturing lot history including catalog numbers, serial numbers, and quantities produced. The ability to readily identify the manufacturing lot history of a violative product may help narrow the scope of a recall. Records required by GMPs also should enable a firm to quickly produce for the FDA the type of information discussed under "FDA Requested Recall" that will be requested immediately after the recall is announced.

In addition to maintaining traceability records, a recall plan must select a method of conducting effectiveness checks. In general, effectiveness checks can be conducted through mail/telex (postal or electronic), telephone, or personal visits. Regardless of the method used, in order to perform an effectiveness check, a firm must have a consignee list, a unique identifying number for each consignee, a questionnaire, and procedures for recording responses from consignees.

The recall plan also should incorporate the FDA's recommendation that when consignees are contacted, certain questions be asked in order to determine whether the notification was received and, if so, whether the product was retrieved and returned to the firm in accordance with the recall notification. It is important to ascertain whether the consignee may have distributed the product after the recall was announced but before the recall notification was received by the consignee and, if so, what, if any, additional efforts were made by the consignee to retrieve the product from the subaccounts. All questionnaires that are returned must be logged in and cross-referenced to the consignee's identification number. If telephones or personal visits are used for effectiveness checks, records must be kept of all efforts expended to reach consignees and of the consignees' responses. Personnel making the telephone calls or visits should be given a standard script to follow to minimize the chance of conflicting advice given to consignees.

The recall plan also should include a diary system for the recall coordinator. The purpose of this system is to remind the recall coordinator to send follow-up notifications to consignees who have not responded previously and identify those to whom the notice should be sent.

Finally, once a recall plan has been created, it should be tested with mock recalls. Mock recalls enable a firm to assess the effectiveness of its recall plan and to make appropriate modifications. Performing mock recalls also can be an important evidentiary fact if the firm must later defend itself from accusations that it acted unreasonably in performing the recall.

Steps to Take During the Recall to Improve its Effectiveness

When a problem has been identified with a product, there are steps that a firm can take to improve the effectiveness of a recall. The first step is to ensure that its risk assessment is completed quickly and is based upon credible data. In a Class I or II recall, the FDA cannot afford to prolong its discussion with a firm regarding the recall classification, depth of the recall, effectiveness check level, and whether public warnings will be necessary. A firm waiting for the FDA to approach it invites disaster, because by then the FDA already will have had its risk assessment performed by the center's HHEC. At that point, it is unlikely that the FDA will be amenable to recommendations by a firm that has not developed a recall strategy nor a risk assessment based upon credible scientific data.

As soon as a problem is ascertained and a risk assessment is performed, the firm should move quickly to meet with the FDA. An early meeting with the FDA puts the firm in a better position to reach an agreeable recall strategy with the FDA. In preparing a recall

strategy, a firm must be sensitive to the fact that a recall strategy limited to advancing the firm's interests will not be successful. A successful recall strategy will incorporate the FDA's perspective. A firm's recall strategy must enable the FDA to defend effectively the recall strategy to public interest groups, the press, and Congress.

A central component of the recall strategy is the content of the recall communication. The FDA's regulations require that a recall communication "should be commensurate with the hazard of the product being recalled" (35). To be acceptable to the FDA, the recall notice must provide a clear message to the recipient that:

1. The product is subject to recall,
2. Further distribution or use must cease immediately,
3. Consignees receiving the product from the recalling firm must notify their subaccounts regarding the recall, and
4. The company must provide specific instructions on what the consignee is to do with the product.

The recall communication should not be promotional. If actual damage has resulted from use of the product, the recall notice clearly should identify the risk rather than include vague references as to what might occur if the product is used.

The regulations also require that a recall notice be brief and that it provide the means by which the recipient of the notice can communicate with the firm regarding the product (ie, self-addressed postcard or collect telephone calls).

A firm should consider ways to motivate recipients of the recall communication. Incentives are used regularly to sell a product; similar incentives can be offered to consignees to encourage them to return recalled products. Providing recall incentives will help refute an argument that a firm was more concerned with its profits than retrieving defective products from its distribution chain.

An effective recall also requires that a firm create a strict quarantine of the recalled product and procedures designed for prompt correction or destruction of the recalled products. The longer recalled products remain in the quarantine area, the greater the probability that some of the products inadvertently will be redistributed.

Steps to Take After Recall Termination

Performing an effective recall also includes the responsibility to take appropriate steps to prevent similar problems from occurring with the product and other products subject to the same defective design or manufacturing process in the future. Implementing such steps not only serves to improve the firm's relationship with the FDA by demonstrating its responsibility, but it also will bolster the firm's ability to defend successfully product liability claims predicated upon ineffective recalls.

If a firm develops a coherent recall policy that is implemented by dedicated, competent personnel, the objective of removing a high percentage of violative products from the distribution chain will be met. As the effectiveness of a recall increases its duration, adverse publicity and product liability consequences will decrease.

MISCELLANEOUS ISSUES

Insurance

Because pharmaceutical companies have a significant investment in the integrity of their products and their customers' faith in their products, an event that jeopardizes the quality of these products directly impacts the firm's bottom line. Consequently, insurance products are available to help mitigate the financial impact of a recall that is triggered by a malicious product tampering or accidental contamination.

Unlike product liability insurance that covers third-party claims, Malicious Product Tampering and Accidental Contamination policies cover a firm's own losses. These policies generally provide coverage for:

1. Costs incurred to recall, inspect, destroy, and replace the product,
2. Lost net profit suffered as a result of lost sales of the contaminated product,
3. Expenses incurred to rehabilitate the product and return sales to the preincident level, and
4. Fees and expenses of independent crisis management consultants.

Purchasing these policies also provides a firm with access to crisis management consultants both for preincident and on-site services in the wake of an incident.

CONCLUSION

Recall is the antithesis of what a quality conscious manufacturer seeks to achieve. When something occurs with a product that requires correction, however, a prudent manufacturer is well advised to proceed aggressively to correct and minimize the damage with the FDA and the public.

A consequence of recalls is product liability exposure. A recall, however, need not be damaging to a manufacturer's product liability defense. A firm that voluntarily performs an effective recall may present very well to a jury, demonstrating its concern for its customers. A company that resists an FDA-requested recall, however, risks not only creating a poor relationship with the FDA, but enhanced consequential, and possibly, punitive damages. Thus, a firm is wise to conduct a recall when appropriate, and do so in a manner that placates the FDA by keeping the public's health at the forefront of the firm's concerns.

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