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**FDA Risk Communication Advisory Committee
Proposes New Standardized Template for FDA
Press Releases Announcing Product Recalls**

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On February 25 and 26, 2010, the Risk Communication Advisory Committee of the U.S. Food & Drug Administration (FDA RCAC) held a public meeting to discuss strategies for improving postmarket safety communications to health care providers, patients, and the general public.¹ The meeting, which was chaired by Nancy M. Ostrove, PhD, FDA Director for Risk Communication, focused broadly on risk communication related to drugs, biologics, medical devices, and veterinary medicines. The meeting examined the clarity and effectiveness of recent FDA postmarket safety communications. For illustrative purposes, the examples included FDA communications relating to external cardiac defibrillators, multi-slice CT scanning systems, several prescription drugs, vaccines, and veterinary pain medication.

One of the most important outcomes of the meeting was the presentation of a proposed standard template for the communication of recall safety information in FDA press releases. This updated template was presented in follow-up of a RCAC meeting held on February 28 - 29, 2008 where FDA's proposed template for press releases announcing product recalls was first presented and discussed.² Although the revised template is intended to be used by the FDA, the agency may later recommend its adoption by manufacturers. There was no announcement at the meeting regarding the timeline for implementation of the template by FDA.

We wish to alert our clients to the proposed format of the press release for FDA announcement of product recalls. The updated draft template and an illustrative example are now available on the FDA website.³

Proposed content and format of the FDA press release. The model FDA press release includes a standard large and bolded headline to inform the general public and the press about the seriousness (*e.g.*, "urgent") and scope (*e.g.*, "nationwide" or "global") of the recall. A subheading is intended to cite the specific product and the scope of patients (*e.g.*, "all" or "certain") who are at risk. The content section includes a boxed listing of "Fast Facts"



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followed by a more detailed discussion in the following highlighted subsections:

- **What is the problem?** The section will include the company name, the specific action (*e.g.*, “recalling, correcting usage and/or patient monitoring instructions”), the scope of affected products (*e.g.*, lots and quantity subject to recall), a description of what is wrong with the product, and how it may adversely affect the public.
- **What are the symptoms of the illness/injury related to exposure to the product?** Information will be provided so that symptoms can be identified by both healthcare professionals and consumers/patients. The RCAC stressed that 1) emphasis should be given to symptoms of most severe injury or risk and 2) information should be provided about injuries or adverse events that have already occurred.
- **Who is at risk (and what is the frequency of defective products)?**
 - Specific information will be provided about groups (*e.g.*, subpopulations) most likely to be affected.
 - In addition, RCAC provides recommendations regarding disclosure of the likely incidence of defective products and a “denominator” of how many products are in use. Specific quantitative statements that are understandable by consumers (*e.g.*, “1 in 100 are failing”) will be provided rather than qualitative statements.
 - The cause of the problem will be explained; if there is uncertainty or no data, an explanation will be provided.
 - Specific circumstances that put the patient at risk will be explained. RCAC explicitly cites the example of “whether an implant is more likely to fail within a specific period of time.”
- **What do patients and healthcare providers (or consumers/product sellers) need to do?** Information will be provided that is as specific as possible on steps to be taken to minimize risk. Additional tools/references will be provided to “enable patients and clinicians to help decide what to do next.” In addition, information is to be provided to “enable patients to ask the right questions of their doctors.”
- **What does the product look like?** In addition to written descriptions, RCAC recommends provision of figures and links to digital photographs, where appropriate.
- **Where is the product distributed?** Specific geographic areas, and where appropriate, links to specific stores where the product is sold, will be provided.
- **What is being done about the problem?** Actions being taken to resolve the problem as well as information about how distributors and customers are being notified will be disclosed.
- **How was the problem detected?** Information will be provided about how the problem was identified.
- **Who will be contacted?** Information will be provided with the contact telephone number at FDA and the contact number for the manufacturer related to the recall. Direct electronic links will be



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provided to the press release and any Dear Doctor/Dear Patient letters on the company's website and not just the company homepage. In addition, where appropriate, information is to be provided on how to report to FDA "any possible problem-related injuries to FDA" and in some instances, instructions for filing MedWatch reports and complaints with consumer complaint coordinators in FDA district offices.

The expectation for communication of the above information by the manufacturer to FDA is underscored by the proposed disclaimer statement that is to be included in each press release:

"The information in this press release reflects FDA's best efforts to communicate what the manufacturer has reported to FDA."

Potential challenges for adoption of this safety communication format by manufacturers

- It is not clear that "one size fits all" for all FDA-regulated products. As an example, precise and detailed description of specific lots and product identifiers is particularly important for medical devices where a safety recall may involve only a subset of devices manufactured and distributed within a narrow time window.
- The discussion of "Who is at risk?" includes an instruction, "Add other useful information which puts risk in context, especially, for example, in the case of ICDs or pacemakers..." RCAC provides the following illustrative statement: "This is a life-saving device. Malfunctions and failures are rare. Even if the device fails to work properly, it will not harm the patient." Whereas FDA and medical professional societies may provide such a subjective judgment of relative risk and benefit without penalty, recent experiences of multiple manufacturers with recalls related to ICDs, pacemakers, and their leads suggest that the provision of such statements by manufacturers, even if correct, would subject the manufacturers to criticism by FDA or the public of "downplaying risk" and/or making medical judgments that will be made in the context of the physician and his/her individual patient.
- Although prior public forums regarding postmarket safety communication have emphasized the importance of the estimation of any future increase in incidence of product failure and/or likelihood of patient injury to guide clinical decision-making about recalled products, the template does not provide clear guidance as to how this modeled estimate of future risk is to be communicated.
- The template does not address the inclusion of independent formal recommendations regarding mitigation of risk and clinical actions to be taken from relevant medical professional societies, if available. Consideration of this element may be particularly important for life-sustaining drugs and implanted devices.

Implications for drug and device manufacturers

The proposed format for FDA press releases that announce product recalls has direct implications for manufacturers as well as physicians and medical societies.



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- Although this press release template is not yet required for manufacturers, there will be an incentive for manufacturers to adopt the content and format of the FDA press release template, where possible, to avoid concern by patients and physicians if information about product safety appears to differ in communications from FDA and the manufacturer.
- Physicians and medical societies will also need to be prepared to respond to the specific content elements to advise individual patients and to deliver broader recommendations regarding risk-benefit of continued use of a drug or implanted device that is not withdrawn from the market.
- In addition, many manufacturers may wish to examine the company's current process for developing an internal health hazard evaluation, including its content elements of risks, severity, and incidence to ensure that appropriate factual content and estimation of safety risk will be provided to FDA for its use in preparing recall-related press releases.

The FDA has not opened a docket for this issue. However, comments regarding the proposed FDA recall-related press release template may be sent directly to Lee L. Zwanziger, Designated Federal Official, 5600 Fishers Lane, Rm 14-90, HFP-1, Rockville, MD 20857 or via e-mail to Ms. Zwanziger at RCAC@fda.hhs.gov.

King & Spalding will continue to monitor FDA documents and practices related to the conduct of recalls related medical products, health hazard evaluations, and the communication of safety information.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

¹ 75 Fed. Reg. 5335 (Feb. 2, 2010).

² 73 Fed. Reg. 7567 (Feb. 8, 2008).

³ The proposed format of a recall-related press release is accessible at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM202278.pdf>. An illustrative example (salmonella contaminated pet food) is accessible at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM202281.pdf>