What You Say May Be Used Against You

by John R. Fleder and David B. Clissold

The Food and Drug Administration (FDA) has a long history of attempting to bring the American National Red Cross (ARC) into compliance with applicable legal requirements concerning blood products, particularly those related to current good manufacturing practices (CGMPs). Many inspections of regional and national facilities, numerous letters between the parties, a voluntary compliance agreement, a consent decree,[1] court-ordered mediation, and telephone calls and meetings between FDA and ARC representatives apparently have been unsuccessful in convincing FDA that the ARC is in compliance with federal requirements. Now, FDA has asked a judge to hold the ARC in contempt of court for failing to meet the conditions of the 1993 consent decree, and has asked the court to impose a fine of up to $10,000 per day on the ARC.[2]

Challenging an icon of U.S. culture is remarkable. What seems to have escaped public notoriety, however, is that FDA and the Justice Department are basing their case, in part, on conversations between senior ARC officials and high-level FDA employees. Certainly, when the ARC officials made the comments attributed to them they had no reason to expect that the government would quote the conversations in a court pleading or would otherwise use the informal comments as evidence of guilt.

The government's use of these conversations starkly illustrates the risks involved when company officials make even informal observations during meetings and phone calls with FDA personnel. It is apparent that FDA will use a company's acknowledgement that it violated the law as an "admission" by the company. Conversely, FDA will interpret a company's refusal to acknowledge something as unwarranted stubbornness that merits severe sanctions. There may be a solution that will alleviate this "catch-22."

The ARC Statements

In the case against ARC, the government submitted Declarations of senior FDA officials in support of its motion to hold ARC in contempt. Included with the Declarations were: 1) the FDA Commissioner's notes of a telephone call on November 16, 2000, with the President of ARC,[3] and 2) FDA's notes of a meeting held on August 14, 2000, between senior FDA and ARC officials. These two documents are featured prominently in the government's memorandum filed in support of the contempt motion.

The FDA Commissioner's notes of the telephone call, for example, reflect that the President of ARC said that "fines should not be imposed [on ARC] because no one has been harmed, although there have been 'chilling near misses.'" In the government's memorandum, ARC President Healy's statement (as it was memorialized by the FDA Commissioner) was used to show that she "*admitted* that ARC has had some 'chilling near misses.'"[4] To highlight the significance of this statement, ARC's "admission" is followed immediately by the

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statement of FDA's Director of the Office of Blood Research and Review that the observed violations create an "imminent and serious potential for harm to blood donors and recipients."[5]

Likewise, FDA's notes of the meeting with senior ARC officials reflect that "Dr. Healy began [the meeting] by stating that the most recent headquarters inspection was alarming, but that it was a service to the organization and ARC had no disagreements with the FDA-483 [inspection findings form] findings." This sentence is paraphrased in the government's memorandum and placed at the opening of an entire section entitled "ARC *Admits* That It Is Not Complying With CGMP."[6]

Qualified Statements

The use of these documents should serve as a reminder to companies to be extremely careful when making *any* statements to FDA, particularly (but not only) if they are made during the course of an inspection or in response to inspectional findings. FDA will use statements made by company officials in meetings and telephone conversations against the company, regardless of whether the statements were made orally or in writing.

Companies (and individuals) should be mindful that in their rush to implement corrective actions in response to an FDA-483 form or a warning letter (or to convince an FDA investigator of a point during an inspection), broad unqualified statements of agreement may be used later as an "admission" that can and will be used against them in judicial or administrative proceedings. Companies (and individuals) sometimes express broad agreement with FDA inspectional findings in an effort to appease the agency. Qualifying phrases such as "as best we can tell" or "based on what we now know" may help prevent such statements from being used by FDA as company admissions of wrongdoing.

Settlement Statements

There is a judicially accepted means to avoid having one's statements show up in court. Statements made to a government official during settlement negotiations are not admissible in court.[7] Try to get the FDA official to agree, therefore, that the comment is being made in the context of settlement negotiations before actually uttering such a comment. In addition, it is possible to get FDA to agree that any statements made in a meeting or telephone conversation will not appear later in court-filed papers.

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Company officials should think carefully before agreeing (or openly disagreeing) with any FDA statement, particularly with regard to inspectional findings. Broad, unqualified statements of agreement made in an effort to please FDA may result in unpleasant legal consequences for the company and its employees. ⚠

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[1] United States v. Am. Nat'l Red Cross, No. 93-0949 (D.D.C. Consent Decree, May 12, 1993).

[2] United States v. Am. Nat'l Red Cross, No. 93-0949 (D.D.C. filed Dec. 13, 2001).

[3] At the time, Jane E. Henney, M.D., was the Commissioner of Food and Drugs, and Bernadine Healy, M.D., was President of the ARC.

[4] United States v. Am. Nat'l Red Cross, U.S. Memorandum at 3 (emphasis added).

[5] *Id.*

[6] *Id.* at 11 (emphasis added).

[7] FED. R. CRIM. P. 11(e)(6)(D); FED. R. EVID. 410.