Are Food and Drug Lawyers `Real´ Lawyers?

by John R. Fleder

A recent California case raised this question within the context of the attorney-client privilege: is regulatory advice provided by food and drug lawyers business or legal advice? The distinction is crucial because, under federal law, communications involving "legal" advice are generally protected from disclosure under the attorney-client privilege.[1] In contrast, "business" advice is generally not considered to be privileged, and is usually subject to discovery in litigation (assuming it is relevant to the case).[2]

This California court ruling demonstrates that regulatory advice that food and drug lawyers provide to clients can qualify as "legal" advice. There are, however, several crucial lessons to be learned from this case. First, it is not unprecedented for adverse parties in litigation to argue that food and drug lawyers do not provide legal advice to their clients. Second, unless certain steps are implemented to demonstrate to a court that advice sought and rendered is covered by the attorney-client privilege, communications between food and drug lawyers and their clients may be deemed "business" advice that will not be protected from disclosure.

Food and drug lawyers daily advise their clients regarding the meaning of applicable food and drug statutes and regulations and how they may affect or relate to the clients' business. Food and drug lawyers are also frequently asked to opine with regard to the Food and Drug Administration (FDA) policies, practices, and customs. Put another way, clients routinely ask their counsel to advise regarding what FDA would likely do if a client undertakes a particular business action. Clients ask their counsel to explain the "regulatory risks" of a certain action, and to quantify the likelihood that FDA will object or take some type of regulatory or enforcement action if the client undertakes a particular practice. It could be argued that this type of "regulatory advice" should be deemed "business" advice because the practice of food and drug lawyers is very closely intertwined with clients' business matters, such as product development and marketing issues.

Recent Court Ruling

In *re CV Therapeutics, Inc. Securities Litigation*,[3] a discovery dispute in a securities case led to judicial review of whether certain documents were protected from discovery. Defendants alleged that communications regarding the FDA drug approval process were protected by the attorney-client privilege because they constituted "legal" advice. Plaintiffs claimed that attorney-client communications concerning FDA administrative, regulatory, and legal requirements constituted business communications because they were tied to defendants' business, which is to develop and market drugs. According to plaintiffs, if communications were created to satisfy FDA regulatory requirements, such as submissions to the agency and reviews of applications regarding the drug approval process, then the communications were for defendants' ordinary *business* operations.

The Magistrate Judge's decision was a fundamental ruling on whether food and drug lawyers provided legal advice. Magistrate Judge Chen concluded that "[d]ocuments created in the context of seeking FDA approval, an inherently legal process, present 'a circumstance virtually necessitating legal representation,' as the FDA approval process requires close supervision by legal counsel."[4] The court further found that "[t]he legal nature of the FDA context and the need for review and

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guidance of counsel permeates"[5] the documents at issue.

The communications related to defendants' drug product labeling, draft manuscripts of drug studies, and the submission to FDA of drug applications. The first category of communications consisted of documents that defendants shared with both legal counsel and the company's business personnel. The second category of communications consisted of documents shared with experts that defendants retained as consultants.

The court referred to the first category of documents as "dual purpose" documents.[6] They were distributed widely to both business personnel and legal counsel for their review and comment.[7] Plaintiffs alleged that the privilege did not apply because the main purpose of these documents was to obtain comments equally from legal and business personnel and not for the specific purpose of obtaining legal advice.[8] Defendants argued, on the other hand, that the documents were shared with counsel for the purpose of obtaining legal advice, and that sharing the documents with business personnel did not lessen the legal purpose of the communications.[9]

The court found that a communication is not privileged just because it is sent to an attorney.[10] Thus, the court was obligated to determine on a document by document basis whether each document was covered by the attorney-client privilege. Magistrate Judge Chen appeared to struggle with the applicability of the attorney-client privilege to the "dual purpose" documents for several reasons. First, he found that none of the documents were "expressly directed at legal counsel in order to secure legal advice."[11] Defendants alleged that it was their general practice to send documents to legal personnel for their review and comment and, therefore, the communications did not need to evidence an explicit request for the attorney's advice.[12] Second, legal counsel was only one of a large number of recipients of the documents.[13]

Regarding the second category of documents, the court noted that attorney-client communications disclosed to third parties can lose their privilege if the third-party consultant is hired for non-legal purposes.[14] In this case, consultants were hired to, among other things, assist defendants with the progression of a drug application through the FDA review and approval process, and to serve as advisors on clinical matters.[15] Defendants sought to demonstrate that the communications between the attorney and the consultants were incident to the defendants' obtaining legal (rather than business) advice from counsel.[16]

Considering the totality of the circumstances, the court took into account a number of factors to determine "the extent to which the communication[s] solicit[ed] or provide[d] legal advice or function[ed] to facilitate the solicitation or provision of legal advice"[17]:

- The defendants' normal practice when soliciting legal advice.
- The content and context of the documents/ communications.
- Whether the legal purpose of the document so permeated any non-legal purpose that the two purposes could not be discretely separated from the factual nexus as a whole.
- The breadth of the recipient list.
- Whether a communication explicitly sought advice and comment.

Applying these criteria to the "dual purpose" documents, the court found that some documents were not protected by the attorney-client privilege. One example consisted of emails circulating draft abstracts and manuscripts of drug studies for review. The court ruled that defendants failed to show that the specific purpose of the documents, which had also been sent to non-legal personnel for their review and comment, was to obtain advice of counsel.[18] Defendants failed to demonstrate "that a request for legal advice was central to the communication[s]" and that "the business or technical purpose of the communications were so permeated by the need for legal advice that the documents were created" for the purpose of obtaining legal advice.[19]

Regarding the documents shared with third-party consultants, some were not given protection under the privilege. One example was a draft document containing clinical information that was shared by defendants with several company directors and other third parties. The court ruled that the document was not privileged because defendants did not identify who the third parties were or explain their role in facilitating or obtaining legal advice.[20]

Lessons To Be Learned

The communications at issue in this case are frequently encountered in the practice of food and drug law. Food and drug lawyers routinely review and comment on company-generated documents that relate to FDA regulatory issues that may affect a company's business. Moreover, it is not uncommon for outside and in-house lawyers to work and communicate with the company's non-legal personnel and consultants, such as scientists, clinical investigators, and other health professionals. Non-legal personnel and consultants often will be asked to draft, review, and comment on documents that are involved in legal counsel's work for the company.

To maximize the protection of confidentiality, it is important that companies and/or their outside counsel timely document that counsel *are* rendering *legal* advice to the client when the purpose of the advice sought is, as it normally should be, legal advice. Although such memorialization may well occur when counsel is initially retained, it is a wise precaution that for each matter handled by counsel it is documented in writing that the lawyer is rendering legal advice. This written record should be created when the client sends in a request for comments on a particular document. This also applies to communications that could serve a "dual purpose," for which a written record should be generated showing (where applicable) that the main purpose of the communications is to seek legal advice.

When the company or its counsel is using an outside consultant, it is essential that a written record is generated regarding the consultant's role. Where applicable, the record should note that the consultant was retained to assist legal counsel in rendering legal advice to the company. Furthermore, the ability to assert attorney-client privilege is maximized when outside counsel, rather than the client, retains the consultant for the explicit purpose of assisting that counsel in rendering legal advice. Where possible, the consultant's oral and/or written report should go directly to counsel, who can forward that report to the necessary group of company employees to provide comments to legal counsel.

Finally, to maximize the protection of the attorney-client privilege, persons generating documents should give very careful consideration to the audience that will receive the communication. The wider the dissemination of a communication, whether inside or outside the company, the greater the likelihood that a court will rule that the communication is not privileged.

Conclusion

In summary, a company must have the ability to have a free flow of information that furthers its ability to meet all applicable legal requirements in conducting its business affairs. When documented properly, the company should be able to have candid discussions with legal counsel without unduly fearing that a court will order the company to disclose the communications to adverse parties (the government or private parties) in litigation.

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[1] In re CV Therapeutics, Inc. Securities Litigation, No. C-03-3709, 2006 WL 1699536, at *1 (N.D. Cal. (June 16, 2006)) (citing *In re Grand Jury Investigation*, 974 F.2d 1068, 1070 (9th Cir. 1992)).

[2] *In re* CV Therapeutics, Inc. Securities Litigation, 2006 WL 1699536, at *5.

[3] *Id.* at *1.

[4] *Id.* at *5 (citation omitted).

[5] *Id.*

[6] *Id.* at *4.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.* Nevertheless, the court later concluded that the legal nature of the FDA process established that inclusion of counsel on the recipient list "fairly implied a request for legal advice." *In re* CV Therapeutics, Inc. Securities Litigation, No. C-033709, 2006 WL 2585038, at *2 (N.D. Cal. (Aug. 30, 2006)).

[11] *In re* CV Therapeutics, Inc. Securities Litigation, 2006 WL 1699536, at *4.

[12] *Id.*

[13] *Id.* at *3-4.

[14] *Id.* at *6-7.

[15] *Id.* at *7.

[16] *Id.* at *6.

[17] *Id.* at *4.

[18] *Id.* at *9.

[19] *Id.* at *8, *9.

[20] *Id.* at *9.