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COMPLIANCE PERSPECTIVES

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Keeping Legal Advice In-House: Protecting the Attorney-Client Privilege

Given that laboratories operate in a heavily regulated environment, the advice of legal counsel is integral to ensuring compliance with the many laws and regulations that govern the laboratory industry. Luckily the attorney-client privilege[1] protects legal advice from disclosure to regulatory agencies, enforcement authorities, and opposing parties in litigation, including whistleblowers in False Claims Act (FCA) cases. This protection is crucial because it allows laboratories to seek legal guidance on potential compliance issues without fearing that their proactive efforts to comply with the law could later be used against them in a legal proceeding.

The privilege is the bedrock of open and honest communication between attorneys and their clients. It encourages full and frank communication "to protect not only the giving of professional advice to those who can act on it but also the giving of information to the lawyer to enable [them] to give sound and informed advice."[2] The privilege doctrine thus eliminates the possibility that these confidential communications must be disclosed (with some limited exceptions),[3] which means that preservation of the privilege is important when requesting and receiving legal advice.

The practical implications are significant. Legal adversaries might question the application of the privilege if the laboratory seeks to withhold privileged communications from its response to an information request from a regulatory agency, a subpoena from a health care enforcement agency, or a discovery request in litigation. Because the privilege prevents disclosure of otherwise discoverable information, the party invoking the privilege must establish its existence. If the laboratory fails to protect potentially privileged communications at the time they are made, these communications will likely be subject to disclosure.

This article provides an overview of the privilege; examines how the privilege applies (or does not apply) to communications to and from in-house counsel, outside counsel, and compliance professionals; discusses common privilege issues; and offers practical tips for protecting the privilege.

A Primer on the Attorney-Client Privilege

Who Holds the Privilege?

The privilege belongs to the client (or a person or entity seeking to become the attorney's client). When the client is a corporation or other legal entity, such as a laboratory, the entity holds the privilege. Because the client holds the privilege, neither an individual employee (whether current or former) nor an attorney or an attorney's agent may decide to waive the privilege.

1. Though not addressed here in detail, the attorney work product doctrine and the joint or common interest privilege are two other privilege doctrines that may apply to legal advice. The *attorney work product doctrine* protects documents prepared by an attorney, or at the request of an attorney, in anticipation of litigation. The *joint or common interest privilege* prevents a party from waiving privilege when confidential information is shared among joint defendants of a lawsuit.
2. *Upjohn, Co. v. United States*, 449 U.S. 383, 391 (1981).
3. *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No: 6:09-cv-1002, 2012 U.S. Dist. LEXIS 158944 at *6 (M.D. Fla, Nov. 6, 2012).

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The privilege extends to communications between a corporation's attorneys and individual employees where information is needed to supply the basis for legal advice.[4] The information sought must relate to the scope of the employee's duties, and the employee must know that the information is being sought so that the company can obtain legal advice.[5] The privilege also protects communications between employees transmitting legal advice received from an attorney to those who have a need to know about the advice in the scope of their corporate responsibilities.[6]

Is a Communication Privileged?

To assess whether a specific communication is privileged, a laboratory and its attorneys should consider the following factors:

- *Was there a communication?* A communication may be oral or written. Written communications may be in hard copy or electronic form.
- *Was the communication made in confidence?* The party holding the privilege must intend the communication to remain confidential and must reasonably believe that the information will not be shared with a third party.
- *Was the communication made for the purpose of obtaining legal advice?* Only communications made for the purpose of obtaining legal advice are protected. In contrast, communications made for business purposes are not privileged.
- *Was the communication made to or by an attorney or client?* The communication must be made between a client and a duly licensed attorney or an agent of the attorney working under the attorney's supervision and control. Examples of attorney-agents may include assistants and paralegals and, in some cases, experts and consultants.
- *Was the privilege waived?* Clients may inadvertently waive the privilege by, for example, discussing privileged legal advice when a third party is present or by accidentally sending a privileged e-mail to a third party. A client may also make a strategic decision to waive the privilege and defend its position based on the advice of counsel defense.

Although surprising to many, courts treat communications to and from in-house counsel and outside counsel differently when assessing whether the privilege applies.

Common Privilege Considerations

When applying the privilege doctrine in practice, laboratories seeking to protect legal advice from disclosure should be aware of several important privilege-related issues to avoid confusion over whether a communication will be privileged.

Communications With In-House and Outside Counsel Are Treated Differently

Although surprising to many, courts treat communications to and from in-house counsel and outside counsel differently when assessing whether the privilege applies. Some courts have decided that communications between a corporate client and outside counsel (usually a law firm) are presumptively privileged. But communications with in-house counsel are not afforded this same status. Instead, a client must show that the "purpose and intent" of the communication with in-house counsel was to render legal advice because in-house counsel frequently provide nonlegal advice on business, technical, scientific, public relations, and advertising issues. Advice on such matters is not protected by the privilege even if conveyed by attorney to a client because the "purpose and intent is not to communicate legal advice."[7]

4. *Upjohn Co.*, 449 U.S. at 394.
5. *See Id.*
6. *See Halifax,* 2012 U.S. Dist. LEXIS 158944 at *10.
7. *Id.* at *9.

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Compliance Program Documents Are Not Always Privileged

Laboratories often have compliance personnel who are responsible for ensuring compliance with relevant laws and regulations. Internal communications with compliance personnel and documents generated by compliance personnel are not privileged. Where a lawyer serves as in-house counsel and also as a compliance department employee, the lawyer should be clear about the purpose of the communication and his or her role when providing legal advice. That way, if a court later scrutinizes the communication, the privilege will be apparent.

A recent case illustrates the complexities of the privilege as applied to compliance department documents. In *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*, a relator in an FCA case challenged a hospital's assertion of privilege over documents and communications related to audits and reviews performed by the hospital's compliance department. The hospital maintained a log of possible Medicare compliance issues that might require investigation, and it listed each complainant, complaint, and the hospital's corrective action. It also contained an incident sheet for each complaint, addressed to the attention of the general counsel, and all pages were stamped "Confidential Attorney-Client Privileged Information." Among other items, the relator sought disclosure of the compliance logs.

The primary reasons to conduct a privileged internal investigation under an attorney's direction are to preserve the confidentiality of the investigatory record, to allow employees to speak freely, and to enable counsel to provide frank legal advice under the protection of privilege.

The court decided that none of the documents evidenced that the hospital sought or received legal advice concerning the log. In particular, the court explained that no lawyer commented on the compliance log and that employees in the compliance department never indicated that they planned to seek the advice of counsel with respect to the contents of the log. Further, the court characterized some of the information in the log as a recordation of facts, which is not privileged.[8] The bottom line is that merely labeling documents as privileged does not make them so.

Copying Counsel on a Communication Does Not Confer Privilege

Similarly, copying in-house counsel on otherwise nonprivileged communications does not deem those communications privileged. For example, one court recently decided that communications related to a pharmacy's corporate restructuring process, including e-mails copying in-house counsel, were not privileged because they concerned factual matters or business-related considerations rather than requests for legal advice. In that case, the court explained that the company needed to "make a 'clear showing' that the 'speaker' made the communications for the purpose of obtaining or providing legal advice" to protect the communications from disclosure.[9] Because the company could not make the required showing, the court required disclosure of the communications to the opposing party in a lawsuit.

Conducting Privileged Internal Investigations Is Beneficial

Laboratories should carefully consider how best to protect the privilege before undertaking internal investigations of compliance-related issues, such as compliance hotline complaints, potential billing errors, or compliance audit issues. At the outset of the investigation, the laboratory should decide whether to conduct a privileged investigation under the direction of counsel and, if so, whether to work with in-house or outside counsel.

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8. *Id.* at *21.
9. *Craig v. Rite Aid Corp.*, No. 4:08-cv-2317, 2012 U.S. Dist. LEXIS 16418, at *28 (M.D. Pa. Feb. 9, 2012).

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The laboratory's decision whether to use in-house or outside counsel should be driven by a number of factors. First, the laboratory should consider the fact that courts typically presume that communications with outside counsel are privileged. Working with outside counsel is thus more protective. In addition, outside counsel may have more experience conducting internal investigations and offer the added benefit of having independence. By contrast, in-house counsel will generally know the organization and its politics better than outside counsel.

During an internal investigation, the laboratory or its lawyers may need to call upon an outside consultant to work with counsel on technical issues, such as coding or billing matters. The consultant's work is not privileged unless it is necessary, or at least highly useful, for the effective consultation between the client and the lawyer.[10] Courts have held that the privilege is not waived where a client allows disclosure to an agent assisting the attorney in giving legal advice to the client. To maintain the privilege, counsel should retain the consultant, and the consultant should work under the lawyer's direction.

Tips for Preserving the Privilege

Laboratories and their employees, including legal and compliance department personnel, can take several simple steps to preserve the privileged status of their communication:

- Be explicit about seeking or providing legal advice. Even though it may seem formal, consider clearly stating that a communication's purpose is to request or obtain legal advice.
- Separate business and legal discussions whenever possible so that the two types of advice are clearly distinguishable.
- Only include those who need to know on communications with attorneys.
- Instruct all employees (especially the sales force and others who communicate directly with clients) to be cautious when forwarding e-mails. If a company's legal advice is sent to a third party, the privilege is waived.
- An employee who fulfills legal and compliance roles should clearly state when acting as a lawyer or as a compliance professional.
- Work with outside counsel where appropriate, especially when conducting sensitive internal investigations.
- If documents are created by nonlawyers in connection with an internal investigation, they should be created at counsel's direction and should reference that fact.

Conclusion

Protecting the privilege is critical in an environment of growing government health care enforcement and an exploding number of FCA lawsuits filed by relators, who are often former employees who may be privy to—and may attempt to use—confidential and privileged information in the lawsuit. Fortunately, laboratories can take steps to protect the legal advice the must often seek to comply with a highly complex statutory and regulatory regime governing their operations, provision of services, relationships with physicians and referrers, and billing requirements.

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10. *United States v. Kovel*, 296 F.2d 918, 922 (2d Cir. 1961).

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