



ENFORCEMENT, LITIGATION,
AND COMPLIANCE CONFERENCE

Privilege Issues in Internal Investigations for FDA-Regulated Companies

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Topics for Discussion

- Basics of Attorney Client Privilege and Work Product Doctrine
- How and Why Privilege and WP Protection Applies to Internal Investigations
- Application: Events Triggering an Internal Review
- Application: Scope and Purpose of the Review, Establishing the Review Team
- Application: Interviews of Current and Former Employees, 3rd Parties
- Application: Collection and Review of Documents
- Application: Internal Reporting of the Review Results
- External Reporting: Auditors, Insurers, Government Agencies
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Basics of Attorney Client Privilege and Work Product Doctrine

- An attorney.
- A client.
- Communication.
- In aid of legal advice.
- Confidentiality.

Overview (cont'd)

- Many aspects of an FDA-regulated company's business is regulated by the federal and/or state government
 - Most judges (and special masters) can recognize traditional attorney-client communications and work product
 - But they often have little to no idea what regulatory lawyers and/or compliance officers actually do
- Pervasive regulation does not make all communications with counsel privileged. Special Master Rice in Vioxx case:
 - “Without question, the pervasive nature of governmental regulation is a factor that must be taken into account when assessing whether the work of in-house attorneys in the drug industry constitutes legal advice” **BUT**
 - “The fact that the industry is so pervasively regulated does not justify dispensing with each company's burden of persuasion on the elements of attorney-client [privilege]”

Report of Special Master Paul Rice,

In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 789, 800-01 (E.D. La. 2007)

Work Product Doctrine

- Related, but not the same as A/C P.
- A discovery rule – not a privilege.
- In anticipation of litigation or for trial.
- Do not over designate.

How and Why Privilege and WP Protection Applies to Internal Investigations

- Privilege can apply to internal investigations where the purpose is to gather facts and perform analysis in order to provide legal advice to a client.
 - Such communications are privileged
 - The underlying facts are not privileged
- Privilege attaches to communications that occur during the internal investigation (e.g., employee interviews) since they are for the purpose of providing legal advice.
- Work product protection can apply to materials prepared during an internal investigation when done in anticipation of litigation.

Application: Events Triggering an Internal Review

- Internal sources
 - Hotline
 - Formal or informal communication to legal or compliance
 - Results from an internal review or audit
- External sources
 - Subpoena, CID or government inquiry
 - Warning or untitled letter
 - Trade complaint
 - Allegations in civil litigation

Application: Scope and Purpose of the Review, Establishing the Review Team

- Important to establish the purpose and scope of the review at the outset (recognizing that both may evolve)
- Purpose:
 - Establish facts to assess whether the incoming allegation or complaint is true
 - Prevent further misconduct and establish accountability
 - Demonstrate responsible corporate response to allegations of misconduct
- Scope
 - Sufficient to get to bottom of allegations
 - Challenges when inquiry identifies potential different issues
 - Assess against law, company policy, or both

Application: Establishing the Review Team

- Privilege is strongest when reviews are performed by outside counsel
- In-house legal departments can perform privileged internal reviews despite their having dual role
 - Certain procedural steps can bolster privilege claims (e.g., memo from GC to lawyers conducting the review about scope, purpose of the review)
 - Observing privilege formalities as to how review is conducted
 - Limiting disclosure of results
- Non-lawyers can perform privileged reviews when done at the direction of counsel (e.g., members of the compliance department, internal audit)
 - Particularly important to observe formalities and establish the role of the non-lawyers at the outset

Application: Review for Compliance with Law, Company Policies, or Both?

- Non-lawyer professional commenting on whether proposal or material complies with Company policy → not privileged
- In-house lawyer commenting on whether proposal or material complies with Company policy:

“Suffice it to say, the advice envisioned by the attorney-client privilege is advice about the laws imposed on us by society, not the rules that we impose on ourselves through guidelines, manuals, or otherwise. The interpretation and application of the latter does not require either a law degree or admission to a bar association. While the principles and policies that prompted the creation of this Medical Legal Reference Manual may have been laws, both statutory and regulatory, their interpretation and application must stand on their own Consequently, we interpreted Merck’s references to its Manual as illustrating regulatory principles to which it believed it was bound, but not as a basis to apply the privilege protection.”

Report of Special Master Paul Rice,
In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 789, 803-04 (E.D. La. 2007)

Application: Interviews of Current and Former Employees, 3rd Parties

- Generally, communications in the course of interviews of current and former employees will be privileged
- Interview memos should be protected to extent they reflect privileged communications; may also be protected under work product if prepared in anticipation of litigation
- Applicability of privilege to communications with third parties (e.g., a speaker bureau vendor; a PR firm helping with crisis communications) is more challenging

Application: Collection and Review of Documents

- Documents reviewed in the course of an internal investigation are not, themselves, privileged
- The process used to collect documents, or the compilation of documents (reflecting attorney strategy and impressions), may be protected as work product
- Materials prepared by others (e.g., forensic consultants, auditors, expert consultants) is privileged if it is prepared at the direction of counsel and is for the purpose of assisting counsel in providing legal advice
 - Materials should be labeled: Privileged and Confidential/Prepared at the Direction of Counsel
 - Materials should be kept in segregated files that are labeled appropriately

Application: Internal Reporting of the Review Results

- Communicating the results of the review requires balancing of interests
- Multiple functions may have legitimate need to be briefed on the results of the review: Board, senior management, investor relations, internal audit, HR, and others
- But disclosing results too broadly can risk waiver of the privilege (by not satisfying the requirement that the communication(s) be kept confidential)
- Here again, observing formalities can be helpful (making clear the reporting may involve privileged communications; limiting what is disclosed; asking anyone taking notes to mark them as privileged)
- Auditors: Experienced auditors understand privilege issues and often will work with companies to avoid waiver
 - When disclosure is necessary, consider disclosing underlying facts or results – but not legal advice
 - In some instances, disclosure to auditors not considered a waiver

External Reporting to Government Agencies

- Voluntary Disclosure: Companies may sometimes want to disclose results of privileged reviews to government regulators or enforcement agencies (e.g., FDA, SEC, OIG, DOJ, State Attorneys General)
- Compelled Disclosure of Related Documents: In other instances, government subpoenas routinely require production of non-privileged audits, investigations and internal reviews (and, often, there will be non-privileged records of such inquiries – e.g., incoming hotline call, non-privileged update to outside auditors)
- Potential ways of handling these situations:
 - Seek agreement that production to relevant agency does not constitute a waiver as to other matters (not uncommon in SEC proceedings)
 - Disclose underlying facts – but not legal advice or work product
 - Provide oral briefings of results

Standard HIPAA Subpoena Provisions for Privilege Log

9. If the Company withholds any document on the ground of any claimed privilege, it shall provide a statement with respect to each document setting forth
 - a. The name and title of the author (and if different, the preparer and signatory);
 - b. The name(s) and title(s) of the individual(s) to whom the document was addressed;
 - c. The name(s) and title(s) of the individuals to whom the document or a copy of the document was sent or to whom the document or a copy, or any part thereof, was shown;
 - d. The date of the document;
 - e. The number of pages;
 - f. A brief description of the subject matter;
 - g. A statement of the specific basis on which privilege is claimed; and
 - h. The paragraph or subparagraph in Section III of this Attachment ("Documents to Be Produced") to which it is responsive.

Final Thoughts: Privilege Decisions as a Risk for Lawyers Themselves

- Privilege claims are not necessarily forever:
 - Companies may waive privilege (particularly as to government) (e.g., privileged communications of a company that the client has acquired; to obtain extraordinary cooperation credit; to assert advice of counsel defense)
 - Government agencies or private counsel may challenge privilege claims (e.g., invalid claims; crime fraud exception)
- Overly broad claims – if successfully challenged – can have very negative consequences when dealing with prosecutors/enforcement agencies and/or judges in private litigation
- In extreme cases, privilege claims made in bad faith can subject lawyers to sanctions or – in at least one case – allegations of liability under the civil FCA for causing false claims to be submitted (case was later dismissed on other grounds)

ABA Model Ethics Rules

- Rule 1.6 – Confidentiality of Information

- (a) A lawyer shall not reveal information protected by the attorney-client privilege under applicable law or other information gained in the professional relationship that the client has requested be held inviolate or the disclosure of which would be embarrassing or would be likely to be detrimental to the client unless the client consents after consultation, except for disclosures that are impliedly authorized in order to carry out the representation, and except as stated in paragraphs (b) and (c).

Ethics Rules

- Commentary [3] to Rule 1.6:
 - “The principle of confidentiality is given effect in two related bodies of law, the attorney-client privilege (which includes the work product doctrine) in the law of evidence and the rule of confidentiality established in professional ethics.”

Ethics Rules: Attorney Disclosure of Privileged Communications

- (b) To the extent a lawyer reasonably believes necessary, the lawyer may reveal:
 - (1) such information to comply with law or a court order;
 - (2) such information to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client;
 - (3) such information which clearly establishes that the client has, in the course of the representation, perpetrated upon a third party a fraud related to the subject matter of the representation;
 - (4) such information reasonably necessary to protect a client's interests in the event of the representing lawyer's death, disability, incapacity or incompetence;
 - (5) such information sufficient to participate in a law office management assistance program approved by the Virginia State Bar or other similar private program;
 - (6) information to an outside agency necessary for statistical, bookkeeping, accounting, data processing, printing, or other similar office management purposes, provided the lawyer exercises due care in the selection of the agency, advises the agency that the information must be kept confidential and reasonably believes that the information will be kept confidential;
 - (7) such information to prevent reasonably certain death or substantial bodily harm.

Ethics Rules

- (c) A lawyer shall promptly reveal:
 - (1) the intention of a client, as stated by the client, to commit a crime reasonably certain to result in death or substantial bodily harm to another or substantial injury to the financial interests or property of another and the information necessary to prevent the crime, but before revealing such information, the attorney shall, where feasible, advise the client of the possible legal consequences of the action, urge the client not to commit the crime, and advise the client that the attorney must reveal the client's criminal intention unless thereupon abandoned. However, if the crime involves perjury by the client, the attorney shall take appropriate remedial measures as required by Rule 3.3; or
 - (2) information concerning the misconduct of another attorney to the appropriate professional authority under Rule 8.3. When the information necessary to report the misconduct is protected under this Rule, the attorney, after consultation, must obtain client consent. Consultation should include full disclosure of all reasonably foreseeable consequences of both disclosure and non-disclosure to the client.
- (d) A lawyer shall make reasonable efforts to prevent the inadvertent or unauthorized disclosure of, or unauthorized access to, information protected under this Rule.

Model Rule Relevant to Employee Interviews

- Section 4.3 of the ABA's Model Rules:

In dealing on behalf of a client with a person who is not represented by counsel, a lawyer shall not state or imply that the lawyer is disinterested. When the lawyer knows or reasonably should know that an unrepresented person misunderstands the lawyer's role in the matter, the lawyer shall make reasonable efforts to correct the misunderstanding. The lawyer shall not give legal advice to an unrepresented person, other than the advice to secure counsel, if the lawyer knows or reasonably should know that the interests of such a person are or have a reasonable possibility of being in conflict with the interests of the client.