



The “Advice of Counsel Defense” and Waiver in Pharma, Biotech, and Device Investigations

Brien T. O’Connor

Monday, June 7, 2004

Pharma, Biotech, and Device Colloquium

Boston
New York
San Francisco
Washington, DC

The Key Privileges

- Attorney-Client Communications
 - Legal/regulatory advice related to conduct under review
 - Communications with employees after company knows of potential issue
 - Counsel's advice to business leaders during internal review and government investigation
- Attorney Work Product
 - Employee Interviews
 - Internal Investigation Reports
 - Privileged Consultant Audits/Reports

Why do these issues so often arise in health care investigations?

- Complex regulatory environment
- Core business practices and corporate programs investigated
- Offenses and civil causes of action require proof of wrongful intent/scienter
 - Conspiracy Statute (18 U.S.C. § 371)
 - Anti-Kickback Act (42 U.S.C. § 1320a-7b)
 - Obstruction Statutes, (e.g. 18 U.S.C. § 1518)
 - Civil False Claims Act (31 U.S.C. § 3729a)

Is the “Defense” a “Silver Bullet”?

- “Round 2 for Quattrone, in Post-Tyco World” *The Wall Street Journal*, April 8, 2004

“Many executives accused of improper accounting argue that they had no criminal intent by insisting that they relied on advice or approval from lawyers, boards of directors or auditors. ‘In dealing with arcane areas,’ an advice-of-counsel defense can be ‘a silver bullet,’ says George Canellos, a former federal prosecutor. Prosecutors often counter that the defendant didn’t give the lawyer complete information.”

What are the elements of “the defense”?

1. The defendant must in good faith seek the advice of an attorney whom it considers competent . . .
2. for the purpose of securing advice on the lawfulness of future conduct.
3. The defendant must have made a full and accurate disclosure of all relevant facts to the attorney,
4. the defendant has to reasonably rely on its attorney’s advice, and
5. act in strict accordance with it.

When do companies consider waiving the privilege?

- Early in an investigation, to stop the government from investigating further and thereby causing collateral damage to the company
- During an investigation, when the government requests a waiver
- Late in an investigation, after the government has made a preliminary determination of criminal or civil wrongdoing
- During settlement negotiations

Under what circumstances will the government request a waiver?

- Thompson Memorandum
 - “Contemporaneous advice” and “factual internal investigation” only
 - Obviates need to immunize
- Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines
 - Seeking evidence against individuals (EDNC)
 - Seeking evidence against *corporate entities* as well as individuals (SDNY and NDMS)
 - To counter advice of counsel defense by individuals (DMASS)
- June 4, 2004 WSJ article re: KPMG

Factors Relevant to Waiver Decision

- How strong is the government's case? What other "defenses" are available?
 - Doctrine of respondeat superior
 - Collective knowledge doctrine
 - Thompson Memorandum (waiver an important element of cooperation)
 - Ashcroft Memorandum ("pursue the most serious, readily provable offense")
 - *Do you really have a choice?*

Factors Relevant to Waiver Decision

- Was counsel competent and reasonably independent?
- Were all relevant facts provided to counsel?
- How unqualified was the advice?
- Does the advice reflect a legitimate and diligent effort to understand the law?

Factors Relevant to Waiver Decision

- Will third parties seek the waiver materials?
 - Selective Waiver Doctrine
 - Need to limit scope
- Do you know your prosecutor?
 - Track record?
 - Will you receive credit?
 - Whose discretion will be exercised?
 - Arthur Andersen