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IN PRACTICE

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# Pharmaceutical Compliance Audit Granted Protection

## Application of the self-critical analysis privilege to compliance reports

An internal audit conducted for the purpose of ensuring compliance with federal law and regulations can be protected by the "self-evaluative" or "self-critical analysis" privilege, even if the audit was prompted by a competitor's complaints. That is the holding of a recent decision that offers the potential for enhanced protection of materials generated in the course of compliance activities. In *Bracco Diagnostics, Inc. v. Amersham Health Inc.*, 2006 WL 2946469, 71 Fed. R. Evid. 588 (D.N.J. October 13, 2006), Magistrate Judge Tonianne J. Bongiovanni held that the self-critical privilege protected a report prepared by PricewaterhouseCoopers (PWC) to assist defendant Amersham in complying with government regulatory requirements regarding the sales and marketing of prescription pharmaceuticals.

The self-critical analysis privilege has its origins in *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970), *aff'd*, 479 F.2d 920 (D.C. Cir. 1973), which applied a qualified privilege to minutes and reports of medical staff meetings where doctors had critically analyzed a hospital's medical care. In recent years, many lower courts have implicitly treated the Supreme Court's decision in *University of Pennsylvania v. EEOC*, 493 U.S. 182 (1990), as discouraging application of the self-critical privilege in other areas, and the Third Circuit has not addressed the existence of such a privilege. The *Bracco* decision shows that the self-critical analysis privilege still has life beyond the context of medical care and can be used in the pharmaceutical industry and other highly regulated fields to protect materials created for the purpose of ensuring a company's compliance with federal law.

The *Bracco* case involved allegations of false and misleading advertising and promotion of Amersham's X-ray contrast agent, which directly competed with plaintiff's product. Bracco complained about statements Amersham had made regarding the comparative safety of the competing products. Amersham responded to Bracco's complaints by retaining PWC to conduct an independent review of the Amersham compliance program. Amersham described its purpose as seeking "to best comply with the many laws and regulations that concern the sales of prescription pharmaceuticals," and Bracco acknowledged that Amersham's purpose was "to meet government regulatory requirements." The stage was thus set for the court to determine whether a compliance review, triggered by outside complaints, can be protected by the self-critical analysis privilege.

Citing other federal decisions in New Jersey, Magistrate Judge Bongiovanni identified six factors that have to be balanced to determine whether the self-critical analysis privilege applies in a particular case: (1) whether the information is the result of a self-critical analysis undertaken by the party seeking protection; (2) the extent to which the information is available from other sources; (3) the degree of harm the litigant will suffer from the information's unavailability; (4) the possible prejudice to the party asserting the privilege; (5) the public interest in preserving the free flow of the type of information sought; and (6) whether the information is of the type whose flow would be curtailed if discovery were allowed.

Under the first factor, Bracco argued that the self-critical analysis privilege has generally been limited to hospital committee reports and equal opportunity forms submitted to the government. The court rejected this argument, citing various cases where the privilege has been applied outside these areas. The court then noted that materials protected by the self-critical analysis privilege have generally been those prepared for mandatory government reports. Magistrate Judge Bongiovanni concluded that Amersham's purpose to comply with government regulations regarding its sales and marketing practices satisfied the first factor, i.e., that the report in fact resulted from a self-critical analysis.

After finding that Bracco did not

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have an alternate source for the analysis contained in the PWC report and that this factor favored production, the court considered the third and fourth factors, which require a balancing of the relative prejudice to the parties. Amersham argued that it would likely be dissuaded from repeating such an audit if the results could later be turned against it in litigation. Bracco countered that no such protection is needed because pharmaceutical companies must "self analyze" as a matter of course to comply with regulations, maintain their reputation, ensure patient safety and remain in business. The court determined that Amersham would be prejudiced to a greater degree by disclosure than Bracco would be by nondisclosure, and that Bracco's prejudice would be mitigated in part by the availability of the factual information underlying the PWC report.

The court's analysis of the fifth and sixth factors — the public interest in, and the risk of curtailing the free flow of information of the kind sought — further demonstrated the court's concern with avoiding a chilling effect on compliance efforts, at least in a highly regulated area like prescription pharmaceuticals. The court characterized the PWC report as the result of an internal check, prompted by outside complaints, to ensure Amersham's compliance with all requisite laws and regulations. Amersham claimed that the public interest supports encouraging companies to undertake efforts of this type. Bracco responded that there is a stronger public interest in not allowing a pharmaceutical company to hide the results of an investigation showing that the company made false and misleading statements regarding the safety of its products.

To resolve the clash of these interests, Magistrate Judge Bongiovanni analogized to Federal Rule of Evidence 407, which provides that when measures are taken after an event that would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence. The court concluded that it is in the public interest for organizations, when faced with a possible violation of law or government regulation intended to protect the public, to attempt to expeditiously determine the causes and results, and then to correct them accordingly.

Magistrate Judge Bongiovanni then found that permitting discovery of the PWC report would be likely to curtail the kind of remedial action undertaken by Amersham. "Allowing discovery would perpetuate a chilling effect" by exposing an organization to civil liability if it chooses to conduct a review and correct violations after complaints are lodged. With the fifth and sixth factors favoring Amersham, the court denied Bracco's motion to compel production and held that the PWC report was protected by the self-critical analysis privilege.

Given the lack of a definitive ruling by the Third Circuit Court of Appeals, the *Bracco* decision shows that the governing test for the self-critical analysis privilege in this district can be used to protect compliance reports, even when the internal review was triggered by a competitor's complaints that a company violated government regulations. Many compliance reports are generated in the regular course of business and without involvement by outside counsel. *Bracco* provides a basis for seeking and obtaining broad protection of such reports without having to satisfy the requirements of the attorney-client privilege or work product doctrine. ■