In re Phenylpropanolamine

Decided Nov 12, 2003

MDL NO. 1407

November 12, 2003

ORDER GRANTING WYETH'S MOTION TO COMPEL PRODUCTION OF DOCUMENTS FROM THE FOOD AND DRUG ADMINISTRATION AND DENYING THE GOVERNMENT'S MOTION TO QUASH

BARBARA ROTHSTEIN, District Judge

THIS MATTER comes before the Court on Wyeth's (formerly known as American Home Products Corporation) Motion to Compel Production of Documents from the Food and Drug Administration ("FDA") and the Government's Motion to Quash.[1] Having heard the arguments of counsel and having reviewed the briefs and letter briefs submitted by the parties,[2] the Court rules as follows: *2

[1] This matter was transferred to this Court by order of a magistrate judge from the United States District Court for the District of Columbia pursuant to In re Subpoenas Served on Wilmer, Cutler Pickering and Goodwin Proctor LLP, 255 F. Supp.2d 1 (D.D.C. 2003) (holding that where the underlying litigation is subject to a consolidated proceeding, non-party discovery disputes should be decided by the MDL judge).

[2] Letter briefs in support of Wyeth's motion were filed by some of the manufacturing defendants in MDL 1407, including Novartis Consumer Health, Inc. ("Novartis"), GlaxoSmithKline ("GSK") and Bayer Corporation ("Bayer").

I. INTRODUCTION

This case involves a third-party subpoena served on the PDA by Wyeth concerning documents relating to the PDA's regulation of Phenylpropanolamine ("PPA"). The subpoena seeks production of certain documents withheld by the PDA when it responded to a subpoena issued in a case now pending in MDL 1407, Kerrigan v. Whitehall Robins (the "Kerrigan subpoena"). In response to the Kerrigan subpoena, the PDA asserted the deliberative process privilege, and produced a log showing that some documents had been withheld, redacted, or released only in part. Wyeth's subpoena seeks all documents and information withheld from the PDA's production in response to the Kerrigan subpoena for which the PDA specifically asserted the deliberative process privilege.

The Government asserts that the deliberative process privilege protects the documents from disclosure, contending that the documents withheld reflect the agency's internal decision-making process, disclosure of which would chill future agency dialogue.

The parties were unable to resolve this dispute, and Wyeth moved to compel production of these documents. The PDA in turn moved to quash Wyeth's subpoena. The Court has reviewed the

withheld documents in camera to determine whether the deliberative process privilege protects
3 the documents at issue. *3

II. DISCUSSION

A. Background

In the early seventies, the PDA began reviewing and publishing reports regarding the safety of PPA-containing products. In the seventies, eighties and early nineties, the PDA held public meetings, and sought comment regarding the safety and effectiveness of PPA-containing over-the-counter products. Despite some evidence suggesting that PPA might pose a health risk to consumers, the PDA never classified PPA as unsafe or required the withdrawal of PPA-containing products from the market. In late 2000, however, after evaluating data from the Yale Hemorrhagic Stroke Project, the PDA asked the manufacturers of PPA to voluntarily discontinue marketing PPA-containing products. The manufacturers acceded to this request.

B. The Deliberative Process Privilege

The deliberative process privilege is a qualified privilege allowing government agencies to withhold those documents that would reveal opinions, deliberations or recommendations constituting the process by which government policies are formulated. In re Sealed Case, 121 P.3d 729, 737 (D.D.C. 1997). The primary policy behind the privilege is to encourage candid debate among governmental decision-makers.Id.

The party claiming the privilege has the burden of proving its applicability. Cobell v. Norton, 213 F.R.D. 1, 4 (D.D.C. 2003). To properly assert the deliberative process privilege, the government
4 must establish that the information is both *4 predecisional and deliberative. In re Sealed Case, 121 F.3d at 737. A formal invocation requires a claim by the head of the department having control over the requested information,[3] an assertion of the privilege based on actual personal consideration by that official, and a detailed specification of the information for which the privilege is claimed, explaining why it falls within the scope of the privilege. Cobell, 213 F.R.D. at 5.

[3] In this case, given the time pressure created by the state court trial, the Court ordered the FDA to designate an appropriate individual within the agency able to perform the necessary review and assertion in a timely manner.

Since the deliberative process privilege is a qualified privilege, even if it applies, it may be overcome by a sufficient showing of need.In re Sealed Case, 121 F.3d at 737. Once the elements of the privilege are met, the burden shifts to the party seeking disclosure to show that its need for the information outweighs the government's interest in confidentiality. Cobell, 213 F.R.D. at 5. "This need determination is to be made flexibly on a case-by-case, ad hoc basis." In re Sealed Case, 121 F.3d at 737.

C. Applicability of the privilege

After reviewing the documents in camera, the Court finds that the documents are within the class of documents that the deliberative process privilege is designed to protect. These documents are both predecisional and deliberative. In re Sealed Case, 121 F.3d at 737. Many reflect the personal opinions of a particular employee, rather
5 than a position adopted by the FDA *5 itself. Cobell, 213 F.R.D. at 6. There are also a number of drafts of the same documents, and such drafts are typically protected by the privilege. Id. The Court's inquiry, however, does not end with this conclusion.

D. Balancing the interests

The government having established that the documents fall within the ambit of the privilege, the burden shifts to Wyeth to establish that its need for the information outweighs the government's interest in confidentiality. In re Sealed Case, 121 F.3d at 737-38. Wyeth and the other manufacturing defendants proffered several

reasons for needing the documents. The most compelling of these is the position taken by the plaintiffs in coordinated proceedings in Lutz v. Bayer, and O'Neill v. Novartis AG, currently in trial in California state court. The presiding judge in that consolidated case has allowed the plaintiffs to argue to the jury[4] that in the yearsprior to 2000, the PDA concluded that PPA was unsafe, and informally advised the manufacturing defendants of its position. Plaintiffs also have been permitted to argue that the PDA's reason for not issuing a finding that PPA was unsafe was political pressure. Wyeth and the other manufacturing defendants in MDL 1407 contend that the PDA's decisions were based solely on an analysis of scientific data, and that prior to 2000, they were never informed by the PDA that the agency considered PPA to be unsafe. Defendants claim
6 that *6 without the complete set of FDA documents, they are unable to dispute plaintiffs' allegations.

[4] Defendants have read to the Court portions of plaintiffs' opening statements.

In balancing the interests of parties, this Court considered the following factors: (1) the interest of the private litigant; (2) the relevance of the evidence sought; (2) the availability of other evidence; (3) the role of the government in the litigation; (4) the impact of disclosure upon the effectiveness of government employees; (6) the seriousness of the litigation; and (7) the public's interest in knowing how effectively government is operating. In re Sealed Case, 121 F.3d at 737-38; Cobell, 213 F.R.D. at 3.

1. *Interest of the private litigant*

Wyeth has demonstrated a compelling need for the documents on behalf of the manufacturing defendants in the California case. Without the documents, defendants have no way of disputing plaintiffs' claims that the PDA had reached a conclusion early on as to PPA being unsafe, and had informed the manufacturers of this conclusion.

2. *Relevance of the evidence/Availability of other evidence*

There are no alternative forms of evidence that would be as useful as internal FDA documents outlining the agency's thought processes over the years in formulating its decisions concerning PPA.

3. *Role of the FDA in the litigation/Impact of disclosure upon the effectiveness of government employees*

The Court is of the opinion that because the
7 regulation of *7 PPA by the FDA is not ongoing, the agency's interest in confidentiality is somewhat lessened. Further, although the FDA is not party to lawsuits alleging injuries stemming from the ingestion of PPA-containing products, its role as regulator of the drug for over 20 years is not insignificant.

4. *The seriousness of the litigation*

There can be no doubt as to the seriousness of the litigation, given the number of cases pending in MDL 1407, and the gravity of the injuries claimed.

5. *The public's interest in knowing how effectively government is operating*

Finally, the public has a strong interest in knowing whether government agencies are performing their regulatory duties properly. "[W]here there is reason to believe the documents sought may shed light on [an allegation of] government misconduct, the [deliberative process privilege] is routinely denied, on the grounds that shielding internal government deliberations in this context does not serve the public's interest in honest, effective government." In re Sealed Case, 121 F.3d at 738 (citations and quotation marks omitted).

After considering these factors, this Court concludes that Wyeth's need overcomes the government's privilege claim, and that Wyeth's motion to compel disclosure of the documents
8 withheld by the FDA should be granted.[5] *8

5 Certain documents provided to the Court for in camera review contain no information that could be of any use to defendant. For example, there are several documents that consist solely of handwritten notes of unknown origin. These basically useless documents (see p. 9, lines 8-9) need not be produced.

The Court remains acutely aware, while performing the balancing test, of the importance of protecting candid discussions of agency employees and officials and protecting the integrity of agency decisions.Cobell, 213 F.R.D. at 4. The Court is also cognizant of the potential threat to FDA resources if in every case involving litigation over the safety of a drug, the FDA was forced to search its documents in order to assert the deliberative process privilege or produce all documents regardless of the privilege. The critical work of the FDA would be seriously undermined by such a burden.

This dispute involves two unique circumstances that merit further discussion. First and foremost, is the ruling referenced above by a California state court judge which has allowed the plaintiffs in those consolidated cases to present evidence that the FDA bowed to political pressure urging it not to classify PPA as unsafe, while at the same time informing defendants that the drug was unsafe.

Second, there is the 20 year history of the FDA's involvement with the regulation of PPA, which has been long and extremely complex.See Background section, p. 3.

The Court emphasizes that this ruling is strictly limited to the facts of this case. The instant matter presented a specific set of circumstances, which, taken together, have led the Court to conclude that the documents, though part of the deliberative 9 *9 process, should be produced.

III. CONCLUSION

For the foregoing reasons, the Court GRANTS Wyeth's Motion to Compel. The PDA's Motion to Quash is DENIED. The Court ORDERS the PDA to produce all information and documents that were provided to the Court for in camera review and for which the PDA claims the deliberative process privilege, except documents bearing the following bates numbers: PHE 0138, PHE 0139, PHE 01795, PHE 01864, PHE 01865, PHE 01866, PHE 03552. The PDA should produce these documents to Wyeth immediately.

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