Inapplicability of the Self-Critical Analysis Privilege to the Drug and Medical Device Industry

PATRICIA L. ANDEL

I. INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (FDCA) requires drug and medical device manufacturers to investigate and report to the United States Food and Drug Administration (FDA) incidents involving their products, even though personal injuries may not have resulted. After the necessary reports are filed, third parties may seek discovery of the reports under the Freedom of Information Act (FOIA) or directly from the manufacturer if litigation ensues. Thus, the compliance efforts of a drug or medical device manufacturer may be used against it by a litigant in a products liability action. Despite substantial civil and criminal penalties that may be imposed on drug and medical device manufacturers failing to report product complaints, malfunctions, or defects, wide-
spread underreporting exists in this area, primarily due to the specter of products liability exposure.

Because the attorney-client privilege and the work-product doctrine are inadequate to protect the FDA-required internal product-safety analyses performed by drug and medical device manufacturers, commentators have suggested that the emerging common-law privilege of self-critical analysis is another possible alternative to preserve the confidentiality recall, or imprisonment. See, e.g., 21 U.S.C. §§ 331-335c, 355(e), 360e(e), 360f, 360h(e); 21 C.F.R. pt. 7 & §§ 314.80(c), 314.81(d), 814.45, 814.46 (1996).


7. See infra notes 24-52 and accompanying text.

of these self-analytical reports. Authors of myriad cases and commentaries over the past twenty-five years have debated the viability of this evolving, nascent privilege. Originating in a medical peer review context, the privilege modernly has been applied to corporate self-critical studies in a variety of different settings.

If applied, the self-critical analysis privilege prevents disclosure of self-evaluative material when the public interest in maintaining confidentiality outweighs the public's need for full discovery. Ideally, assertion of the privilege would protect a corporation's internal investigations and resulting self-analytical reports from discovery, even though such documents admittedly may be highly relevant to a lawsuit. Commentators argue that without the privilege, which "is intended to promote the societal goal of encouraging candid appraisal of problems as an aid to implementing beneficial change," a "chilling effect" on such self-analyses would result.

Despite the privilege's origins over twenty-five years ago and resultant widespread application in the 1970s and 1980s, its evolution has been impeded by two competing societal interests: a general policy

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10. See infra notes 62-71 and accompanying text.


13. Commentators have referred to a "dual chilling effect." First, corporations faced with potential litigation and possible punitive damages exposure are less likely to compile potentially damaging "paper trails" or "road maps" for plaintiff's lawyers. Second, aware that damaging information could lead to reprisals should liability result, individuals within the corporation will be reluctant to be candid without an assurance of confidentiality. See Harvard Note, supra note 9 at 1091-93; Beck, supra note 12, at 358; see also Bush, supra note 8 at 634-35, 637; Conway, supra note 8, at 635-37, 657-59; Paul B. Taylor, Note, Encouraging Product Safety Testing by Applying the Privilege of Self-Critical Analysis When Punitive Damages are Sought, 16 HARV. J.L. & PUB. POL'Y 769, 796-97 (1993); James T. O'Reilly, Environmental Audit Privileges: The Need for Legislative Recognition, 19 SETON HALL LEGIS. J. 119, 124, 126, 133 (1994); David P. Leonard, Codifying a Privilege for Self-Critical Analysis, 25 HARV. J. ON LEGIS. 113, 117 (1988) [hereinafter Leonard, Codifying a Privilege]; Peter A. Gish, The Self-Critical Analysis Privilege and Environmental Audit Reports, 25 ENVTL. L. 73, 80 & n.38 (1995).

14. See infra notes 62-71 and accompanying text.
favoring the free flow of information and the litigant's right to liberal
discovery.\textsuperscript{15} These opposing interests have led to inconsistent applications
of the privilege by the courts, which must balance the equities in
each particular case before applying the privilege.\textsuperscript{16} The growing trend
by the courts is to construe the self-critical analysis privilege narrowly
either by severely limiting its application or by questioning its existence
and refusing to apply the privilege at all.\textsuperscript{17} Such judicial disfavor has
resulted in an inconsistent case-by-case approach, leading to unpredict-
able outcomes for corporations relying on the privilege to maintain the
confidentiality of their self-analytical documents.

Because of the unsettled nature of this emerging privilege, businesses
and commentators recently have clamored for legislation creating a
qualified statutory privilege for internal self-analyses.\textsuperscript{18} While several
model statutes have been proposed, only one state has enacted legislation
that encourages self-critical analysis by product manufacturers, with the
underlying goal of encouraging product-safety innovation for consumers'
benefit and protection.\textsuperscript{19}

Although the self-critical analysis privilege seems especially important
in the drug and medical device industry where product performance is
continually monitored by critical self-evaluation and is crucial to the

\begin{itemize}
\item \textsuperscript{15} See, e.g., Harvard Note, supra note 9, at 1084; Bush, supra note 8, at 603;
Gish, supra note 13, at 77, 80, 75 n.8 ("The competing policy considerations of a
plaintiff’s interest in full and complete discovery and a defendant’s interest in privacy
and confidentiality have long been a source of debate in the law of privileges."); Beck,
supra note 12, at 358-60; David P. Leonard, \textit{An Emerging Privilege for Self-Critical}
Analysis, \textit{14 Litigation} 1, 3 (Spring 1988) [hereinafter Leonard, \textit{An Emerging}
Privilege].

\item \textsuperscript{16} See, e.g., Harvard Note, supra note 9, at 1087, 1091; Bush, supra note 8, at
607-08; Gish, supra note 13, at 77; Leonard, \textit{An Emerging Privilege}, supra note 15, at
3.

\item \textsuperscript{17} See \textit{infra} notes 101-17 and accompanying text.

\item \textsuperscript{18} See, e.g., Harvard Note, supra note 9, at 1085 n.11; Bush, supra note 8, at
641-45; Murphy, supra note 8, at 499-502; Murphy & Oyer, supra note 8, at 15;
Crisman & Mathews, supra note 8, at 172-74; Leonard, \textit{An Emerging Privilege}, supra
note 15, at 58-59; Leonard, \textit{Codifying a Privilege}, supra note 15, at 123-25; O’Reilly,
supra note 13, at 141-46 (creating qualified privilege for environmental audits).

\item \textsuperscript{19} In perhaps the most aggressive move toward codifying this common-law
privilege, Arizona recently enacted legislation that encourages self-critical analysis for
products manufacturers and forges the path of the privilege away from a discovery
prohibition and toward an evidentiary restriction. Under the Arizona legislation, a
qualified evidentiary privilege prohibits the ultimate admissibility—not the
discoverability—of self-analytical product-safety reviews. \textit{See ARIZ. REV. STAT. § 12-
681 (West 1992); id. § 12-687 (West Supp. 1996); see also John Kaites, \textit{Encouraging}
Safety Innovation Through Self-Critical Analysis, LEADER’S PRODUCT LIABILITY LAW
AND STRATEGY} 3 (July 1995).
\end{itemize}
preservation of human life,\textsuperscript{20} that industry is subject to the liberal public disclosure requirements of the FOIA. Because neither Congress nor the FDA has exempted product-safety analyses from public disclosure, it is unlikely that the courts or state legislatures will extend the privilege to protect such information from discovery by a litigant. Consequently, drug and medical device manufacturers will not be released from their current Hobson’s choice: comply with the stringent FDA reporting requirements, or fail to do so in an effort to curtail the products liability and punitive damages exposure\textsuperscript{21} resulting from public disclosure of their product-related safety reports.

This Article analyzes the inapplicability of the self-critical analysis privilege to the drug and medical device industry. Part II traces the historical development of the privilege and the increasing judicial reluctance to expand the privilege beyond the medical peer review context. Part III outlines the drug and medical device reporting requirements under the FDCA. Part IV provides an overview of both the public disclosure requirements under the FOIA and its counterpart requirements under the FDCA and argues that application of the privilege to the drug and medical device industry is federally preempted. Finally, in Part V, the Article concludes that the strong public interests of liberal discovery and the right to access government records do not justify expansion of the self-critical analysis privilege to product-safety analyses submitted to the FDA by the drug and medical device industry.

\section*{II. HISTORICAL DEVELOPMENT OF THE SELF-CRITICAL ANALYSIS PRIVILEGE}

Unlike the well-established and widely recognized attorney-client privilege and work-product doctrine, the self-critical analysis privilege is of relatively recent common-law origin. Although strong precedent exists for applying this nascent privilege to reviews generated by medical peer reviews, many courts are hesitant to extend the privilege to other types of internal self-critical reviews due to the long-standing judicial


reluctance to recognize any new privilege absent a statute. This reluctance has resulted in inconsistent, ad hoc applications of the privilege.

A. Genealogy of the Self-Critical Analysis Privilege: The Attorney-Based Protections

The traditional attorney-based protections—the attorney-client privilege and the work-product doctrine—represent the earliest genealogy of the self-critical analysis privilege. Although certain types of self-analytical materials may be safeguarded by the attorney-client privilege or the work-product doctrine, neither offers adequate security because, in most cases, the information sought does not meet the requirements of either type of protection.

1. The Attorney-Client Privilege

Under the well-established attorney-client privilege, confidential attorney-client communications are absolutely privileged from disclosure. Absent this inveterate privilege, full and frank disclosures of all


23. See Murphy & Oyer, supra note 8, at 13 (“The work-product concept of protecting another party’s review and analysis, and the attorney-client privilege policy of encouraging compliance with law, are all roots of this privilege.”)


25. The attorney-client privilege is the oldest privilege for confidential communications. See 8 JOHN H. WIGMORE, WIGMORE ON EVIDENCE, § 2290, at 547 (McNaughton ed., 3d ed. 1940).

26. See 8 WIGMORE, supra note 25, § 2292, at 558; Diversified Indus., Inc. v. Meredith, 572 F.2d 596, 601 (8th Cir. 1977) (en banc) (acknowledging the “long-established rule that confidential communications between an attorney and his client are absolutely privileged from disclosure against the will of the client”). The attorney-client privilege remains a common-law privilege in the federal system. Congress rejected proposed Rules 502-513 of the Federal Rules of Evidence, which contained a specific provision recognizing the attorney-client privilege. See 10 JAMES W. MOORE, MOORE'S FEDERAL PRACTICE § 500.03, at V-4 to V-5 (2d ed. 1996); 8 CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 2020, at 312-13 (2d ed. 1994). Communications between attorney and client are not privileged, however, where the advice is sought in furtherance of a crime or fraud. See 4 MOORE, supra, § 26.11[2], at 26-188 to 26-190 (2d ed. 1996); WRIGHT ET AL., supra, § 2017, at 257.
relevant information between attorney and client would be curtailed. This rationale is similar to that underlying the self-critical analysis privilege.

The Supreme Court’s opinion in *Upjohn Co. v. United States* is touted as the “seminal articulation” of the corporate attorney-client privilege. In *Upjohn*, the Court unanimously rejected a restrictive interpretation of the attorney-client privilege because such a narrow reading threatened “to limit the valuable efforts of corporate counsel to ensure their client’s compliance with the law.” The Court affirmed the strong public policy underlying the protection of internal corporate compliance efforts when it acknowledged that corporate clients need to consult lawyers because of the “vast and complicated array of regulatory legislation confronting the modern corporation.” Similarly, the fundamental goal underlying the self-critical analysis privilege is to encourage corporate self-evaluation and self-correction by assuring the confidentiality of such actions.

The attorney-client privilege, however, protects only the confidential communication itself. Neither the underlying information nor the self-

27. *See* Moore, *supra* note 26, ¶ 26.11[2], at 26-174. The policy underlying the attorney-client privilege is to encourage a client to be forthright with his or her attorney without apprehension of compelled disclosure by the attorney. *See* Upjohn Co. v. United States, 449 U.S. 383, 389 (1981) (noting that the purpose of the attorney-client privilege is to promote “full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice”); *see also* Wigmore, *supra* note 25, § 2291, at 550.


30. 449 U.S. at 392. In *Upjohn*, the IRS had attempted to obtain a company-wide internal review directed by Upjohn’s general counsel to investigate whether the company was involved in making improper payments to foreign government officials.

31. *See* Murphy & Oyer, *supra* note 8, at 13. As one commentator noted, the *Upjohn* decision “very easily could have become the cornerstone of the critical self-examination privilege.” *See* Rickerson, *supra* note 8, at 507.

32. 449 U.S. at 392 (noting that compliance with such legislation “is hardly an instinctive matter”).

33. *See* Murphy, *supra* note 8, at 496. The *Upjohn* Court, however, did not resolve the dilemma underlying the self-critical analysis privilege: the corporation’s desire to maintain the confidentiality of self-evaluative activities while attempting to comply with its regulatory agency’s need to access such information. *See* Crisman & Mathews, *supra* note 8, at 126. In such cases, the legislature and courts should not “tinker” with the traditional attorney-based privileges. “Rather, Congress should focus directly on whether it should grant corporations a carefully tailored self-evaluative privilege designed to promote maximum law compliance at minimum cost . . . .” *Id.* at 127.
critical evaluations of a client are protected. Additionally, the privilege does not attach to information obtained by an attorney from public documents or from third parties. Another drawback of the attorney-client privilege in the context of internal corporate evaluations is that the privilege can be waived easily. Even limited disclosure of otherwise privileged information to government agencies may be deemed a waiver. Moreover, the "veil of secrecy" imposed by the attorney-client privilege is not practical with such compliance efforts, which are primarily educational and motivational. Yet another limitation of the

34. See EDWARD W. CLEARY ET AL., MCCORMICK ON EVIDENCE § 89, at 213-14 (3d ed. 1984) [hereinafter MCCORMICK ON EVIDENCE]; 8 WIGMORE, supra note 25, § 2306, at 589-90; 4 MOORE, supra note 26, ¶ 26.11[2], at 26-178 to 26-179. See also Leonard, Codifying a Privilege, supra note 13, at 121; Conway, supra note 8, at 632.

35. See WRIGHT ET AL., supra note 26, ¶ 2017, at 266-67. See, e.g., American Cyanamid Co. v. Hercules Powder Co., 211 F. Supp. 85, 89-90 (D. Del. 1962) (refusing to extend attorney-client privilege to documents consisting of analyses of patents, claims, and products manufactured under patents where such information was on file in the patent office and thus public).


37. See 8 WIGMORE, supra note 25, § 2311, at 600, § 2327, at 630; 4 MOORE, supra note 26, ¶ 26.11[2], at 26-185 to 26-187. A party must zealously protect the confidentiality of communications with counsel to prevent waiver of the privilege. Even inadvertent disclosure can result in waiver. See, e.g., In re Sealed Case, 877 F.2d 976, 980 (D.C. Cir. 1989) (indicating that a party must "treat the confidentiality of attorney-client communications like jewels—if not crown jewels").


39. See Murphy & Oyer, supra note 8, at 13. See, e.g., FTC v. TRW, Inc., 479 F. Supp. 160, 163 (D.D.C. 1979) (rejecting application of attorney-client privilege for an internal compliance review because the findings of the review "were sufficiently circulated within TRW as to negate the intention of confidentiality").
attorney-client privilege is that it does not apply when the in-house attorney, who regularly wears several hats, is performing work that requires management expertise rather than work that requires legal acumen. Nor is it practical or cost-effective to utilize attorneys for routine compliance efforts. And even if an attorney is included in such efforts, there is no guarantee that the privilege will protect the evaluative reports from disclosure. Consequently, the attorney-client privilege does not provide reliable protection for most self-analytical documents.

2. The Work-Product Doctrine

Like the attorney-client privilege, the work-product doctrine has an extensive history, tracing its origins to the 1947 Supreme Court decision in Hickman v. Taylor. The doctrine subsequently was codified in Rule 26(b)(3) of the Federal Rules of Civil Procedure, and the majority of states have adopted identical or substantially similar work-product statutes. The work-product doctrine is not technically a privilege. Rather, the doctrine offers qualified protection to an attorney's work product prepared for trial or "in anticipation of litigation." Such protection, however, is not absolute: it may yield where a party seeking disclosure shows "substantial need" for the information and shows
inability to obtain the information elsewhere without suffering "undue hardship." 47 Furthermore, the requirement that the information be compiled "in anticipation of litigation" has been interpreted narrowly. 48 Reports made in the regular course of business fall outside of the work-product protection. 49

Similar to the attorney-client privilege, the work-product doctrine has its shortfalls when applied to self-analytical reports. One of the primary purposes underlying corporate compliance efforts is to prevent litiga-

47. An attorney's work product may be discovered "upon a showing that the party seeking discovery has substantial need of the materials in the preparation of the party's case and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means." FED. R. CIV. P. 26(b)(3); see also Hicman, 329 U.S. at 511-12. As with the attorney-client privilege, a crime-fraud exception applies to the work-product doctrine. See 4 MOORE, supra note 26, ¶ 26.15[4], at 26-324 to 26-326.

48. See WRIGHT ET AL., supra note 26, § 2024, at 338-43 nn.7-10; 4 MOORE, supra note 26, ¶ 26.15[2], at 26-296. See, e.g., Martin v. Bally's Park Place Hotel & Casino, 983 F.2d 1252, 1250 (3d Cir. 1993) (holding that "anticipation of litigation" test looks to whether party claiming work-product protection has reasonable unilateral belief that litigation will ensue); National Union Fire Ins. Co. v. Murray Sheet Metal Co., 967 F.2d 980, 984 (4th Cir. 1992) ("'[T]he mere fact that litigation does eventually ensue does not, by itself, cloak materials' with work product immunity. ... The document must be prepared because of the prospect of litigation when the preparer faces an actual or a potential claim following an actual event or series of events that reasonably could result in litigation."") (emphasis omitted) (quoting Binks Mfg. Co. v. National Presto Indus., Inc. 709 F.2d 1109, 118 (7th Cir. 1983)); Garfinkle v. Arcata Nat'l Corp., 64 F.R.D. 688, 690 (S.D.N.Y. 1974) (holding remote possibility of litigation is insufficient); Flores v. Fourth Court of Appeals, 777 S.W.2d 38, 41 (Tex. 1989) (holding investigations are not made in anticipation of litigation unless litigation is "imminent"); National Tank Co. v. Brotherton, 851 S.W.2d 193, 204 (Tex. 1993) (holding anticipation of litigation test met where reasonable person believes there is a substantial chance of litigation").

49. See FED. R. CIV. P. 26(b)(3) advisory committee's note (1970 amendment) ("Materials assembled in the ordinary course of business, or pursuant to public requirements unrelated to litigation, or for other nonlitigation purposes are not under the qualified immunity provided by this subdivision."). See, e.g., Sanders v. Alabama State Bar, 161 F.R.D. 470, 473 (D. Ala. 1995) (holding that even where litigation is already a prospect, documents prepared in regular course of business, rather than for purpose of litigation, are not privileged under work-product doctrine); Simon v. G.D. Searle & Co., 816 F.2d 397, 403 (8th Cir. 1987), cert. denied, 484 U.S. 917 (1987) (holding risk-management documents prepared to keep track of and anticipate costs of products liability litigation not protected work product); Smith v. Conway Org., Inc., 154 F.R.D. 73, 78 (S.D.N.Y. 1994) (holding that where a party or its attorney prepares a document in the ordinary course of business, it will not be protected work product, even if party believes that document may be useful in the event litigation ensues); Harper v. Auto-Owners Ins. Co., 138 F.R.D. 655, 682-63 (D. Ind. 1991) (holding a document prepared by an insurer to evaluate an insured's claim in the ordinary course of business was not protected work product even if prepared after litigation was reasonably anticipated because "it is the very nature of an insurer's business to investigate and evaluate the merits of claims").
tion. Thus, while self-critical studies performed at the request of an attorney for purposes of trial preparation might be protected from discovery, many routine compliance efforts do not possess the requisite tie to litigation to invoke work-product protection. Additionally, like the attorney-client privilege, protection under the work-product doctrine does not extend to facts that can be gleaned from protected documents, and the protection may be waived.

B. Common-Law Origins of the Self-Critical Analysis Privilege

Although the self-critical analysis privilege can trace its roots to the attorney-based protections, courts and scholars have attributed the common-law origins of the self-critical analysis privilege to a 1970 federal district court opinion. In Bredice v. Doctors Hospital, Inc.,

50. See Murphy & Oyer, supra note 8, at 14; see also O’Reilly, supra note 13, at 138-39.
51. See Hickman, 329 U.S. at 511 (1947); see also Wright et al., supra note 26, § 2023, at 330-33, § 2024, at 337.
52. See supra note 38 and accompanying text. See, e.g., In re Leslie Fay Cos. Sec. Litig., 152 F.R.D. 42, 45 (S.D.N.Y. 1993) (refusing to extend work-product immunity where corporation’s audit committee voluntarily disclosed report to SEC); In re Worlds of Wonder Sec. Litig., 147 F.R.D. 208, 212 (N.D. Cal. 1992) (holding work-product immunity waived by voluntarily producing documents to SEC, even where corporation expressly reserved all of its rights and submitted the information confidentially). But because the primary goal of the work-product doctrine is to protect the adversary process, as opposed to protecting a client’s confidences, disclosure of work product to a third party does not necessarily waive work-product protection. See 4 Moore, supra note 26, ¶ 26.15[4], at 26-322 to 26-324; Wright et al., supra note 26, § 2024, at 367-69.
53. See, e.g., Taylor, supra note 13, at 799; Bush, supra note 8, at 603; Crisman & Mathews, supra note 8, at 171-72; Beck, supra note 12, at 358; Harvard Note, supra note 9, at 1087; Murphy, supra note 8, at 490; Murphy & Oyer, supra note 8, at 11; Jean D. Reed, Comment, Corporate Self-Investigations Under the Foreign Corrupt Practices Act, 47 U. Chi. L. Rev. 803, 820-21 (1980); Comment, Civil Procedure: Self-Evaluative Reports—A Qualified Privilege in Discovery?, 57 Minn. L. Rev. 807, 814 (1973); O’Reilly, supra note 13, at 148; Zick, supra note 6, at 401; Flanagan, supra note 20, at 552 n.8; Gish, supra note 13, at 78; Leonard, Codifying a Privilege, supra note 13, at 117; Rickerson, supra note 8, at 505; Dowling v. American Hawaii Cruises, Inc., 971 F.2d 423, 426 n.1 (9th Cir. 1992); Shipes v. Bic Corp., 154 F.R.D. 301, 306 n.4 (M.D. Ga. 1994); In re Grand Jury Proceedings, 861 F. Supp. 386, 387 (D. Md. 1994); FTC v. TRW, Inc., 628 F.2d 207, 210 (D.C. Cir. 1980); Combined Communications Corp. v. Public Serv. Co., 865 F.2d 893, 898 (Colo. Ct. App. 1993); Konrad v. Oesterling, 149 F.R.D. 592, 595 (D. Minn. 1993). But see Leonard, Codifying a Privilege, supra note 13, at 118 n.15 (noting that others have suggested that the privilege possibly was first recognized in Richards v. Maine Central Railroad, 21 F.R.D. 593, 594
the court rejected a medical malpractice plaintiff's request for production of minutes and reports generated by the defendant hospital's staff committee meetings. The court noted that the sole objective of those self-analytical meetings, which were conducted with the expectation of confidentiality, was the "improvement in care and treatment of hospital patients." The intent of maintaining confidentiality in the medical peer review context is to encourage physicians to candidly criticize and review one another in an atmosphere that is closed to civil litigants pursuing malpractice claims against a physician. The court emphasized that confidentiality is crucial to ensure the unimpeded flow of this type of information, thus protecting society's interest in improved health care and treatment. Acknowledging that exposure of these confidential and sensitive deliberations to discovery absent "a showing of exceptional necessity, would result in terminating such deliberations," the Bredice court held that medical peer review meetings are entitled to a qualified self-critical analysis privilege "on the basis of the overwhelming public interest" in improving prospective medical care.

(D. Me. 1957), which protected from discovery in a wrongful death action defendant railroad's investigatory documents that were required by statute to be filed with the state's Public Utilities Commission because "to require the production of such reports would clearly violate the public policy evidenced by the statute (mandating those reports)").

55. Id. at 250 (quoting Standards of Hospital Accreditation, ch. II, pt. C, § 4 (Jan. 1964)).
56. See Konrady, 149 F.R.D. at 598 (D. Minn. 1993). The Bredice court wisely noted: "Candid and conscientious evaluation of clinical practices is a sine qua non of adequate hospital care. . . . Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit." 50 F.R.D. at 250.
57. Bredice, 50 F.R.D. at 250.
58. Id.
Subsequently, many courts have applied, and most states have

codified, the common-law privilege enunciated in *Bredice* to protect medical peer review documentation. Moreover, in an effort to extend the privilege beyond the medical peer review setting, litigants have asserted it in a variety of different contexts. For example, the privilege has been asserted successfully in employment discrimination and wrongful discharge cases in an attempt to shield self-evaluative affirmative action plans and equal employment opportunity policies.


\(^{63}\) See Kott v. Petini, 283 F. Supp. 1, 2 (N.D. Ohio 1968) (holding records of police department privileged and not subject to subpoena in petition for writ of habeas corpus); Brown v. Thompson, 430 F.2d 1214, 1215 (5th Cir. 1970) (holding government documents privileged and not subject to disclosure); Frankenhauser v. Rizzo, 59 F.R.D. 339, 342 (E.D. Pa. 1973) (discussing "chilling effect" on police investigations and calling the privilege an "executive privilege": "[T]he government's privilege to prevent disclosure of certain information whose disclosure would be contrary to the public interest"); Ostoin v. Waterford Township Police Dep't, 471 N.W.2d 666, 668-69 (Mich. App. 1991) (upholding qualified privilege to internal documents reflecting governmental agency's "evaluative" or "deliberative processes"); Santos v. O'Neill, 80 F.R.D. 448, 449-51 (E.D. Pa. 1974) (acknowledging qualified "executive" privilege, but not applicable to facts); Alemann v. Bonnstetter, No. 89 C 2480, 1991 WL 32757, at *7-8 (N.D. Ill. March 6, 1991) (applying qualified privilege because plaintiff showed no
ic peer reviews,\textsuperscript{65} accident investigations,\textsuperscript{66} and environmental au-

\textit{exceptional circumstances). But see} Wood v. Breier, 54 F.R.D. 7, 10-13 (E.D. Wis. 1972) (holding police chief not entitled to protective order preventing discovery of investigation of alleged assault by policemen); Denver Police\- man's Protective Ass'n v. Lichtenstein, 660 F.2d 432, 435-36 (10th Cir. 1981) (ordering disclosure of police investiga-


\textit{See, e.g.,} Keyes v. Lenoir Rhyne College, 532 F.2d 579, 581 (4th Cir. 1977), \textit{cert. denied}, 434 U.S. 904 (1977) (upholding trial court's refusal to require production of confidential faculty member evaluations in Title VII suit, but without specifically mentioning privilege); Gray v. Board of Higher Educ., 692 F.2d 901, 907-09 (2d Cir. 1982) (acknowledging privilege, but holding it outweighed by constitutional concerns); EEOC v. University of Notre Dame, 715 F.2d 331, 340 (7th Cir. 1983) (applying privilege to peer review materials in racial discrimination claim by professor), \textit{overruled by} University of Pa. v. EEOC, 493 U.S. 182 (1990); Zaustinsky v. University of Cal., 96 F.R.D. 622, 624 (N.D. Cal. 1983), \textit{aff'd}, 782 F.2d 1055 (9th Cir. 1983) (acknowledging confidentiality of materials in peer evaluation files in tenured faculty member's Title VII action based on gender discrimination); McKillop v. Regents of Univ. of Cal., 386 F. Supp. 1270, 1275 (N.D. Cal. 1975) (applying privilege to tenure files). \textit{But see} University of Pa. v. EEOC, 493 U.S. 182 (1990) (refusing to recognize privilege in Title VII case to protect tenure peer review materials from disclosure where such materials were relevant to charges of racial or sexual discrimination); In re Dinnan, 611 F.2d 426, 427 (5th Cir. 1977), \textit{cert. denied sub nom.} Dinnan v. Blaubers, 457 U.S. 1106 (1982) (holding vote in tenure review not protected by privilege).

dits. Furthermore, the privilege has been raised to shield investigative reports from discovery in securities, products liability, antitrust, 


66. See Diversified Indus., Inc. v. Meredith, 572 F.2d 596, 611 (8th Cir. 1977) (en banc) (holding that disclosure of information to the SEC did not constitute waiver of privilege: "To hold otherwise may have the effect of thwarting the developing procedure of corporations to employ independent outside counsel to investigate and advise them in order to protect stockholders, potential stockholders and customers."); In re Grand Jury Subpoena dated July 13, 1979, 478 F. Supp. 368, 374-75 (E.D. Wis. 1979) (applying privilege to internal analyses written by attorney); In re Crazy Eddie Sec. Litig., 792 F. Supp. 197, 205-06 (E.D.N.Y. 1992) (prohibiting discovery of internal review of conduct, audit and letter commenting on internal quality controls); In re LTV Sec. Litig., 56 F.R.D. 355, 361 (N.D. Tex. 1973) (holding that materials generated by special officer retained to implement SEC consent decree were privileged); Byrne v. IDS Realty Trust, 85 F.R.D. 679, 686-89 (S.D.N.Y. 1980) (applying privilege to documents in possession of securities lawyer who had counseled defendants, even though the information had been previously disclosed to the SEC); In re Deyco Derivative Sec. Litig., 99 F.R.D. 616, 619-21 (S.D. Ohio 1983) (holding special committee report prepared by outside counsel privileged). Diversified and In re Grand Jury Subpoena actually were decided under the attorney-client privilege, but the rationale employed supports the self-critical analysis privilege. See also New York Stock Exch. v. Sloan, 22 Fed. R. Serv. 2d (Callaghan) 500, 505 (S.D.N.Y. 1976) (applying privilege in private action under Securities Exchange Act to employee evaluations prepared by corporate auditor).

and libel actions.\footnote{71} In addition, commentators have advocated extend-
ing the privilege to other types of corporate self-evaluations.\textsuperscript{72}

The rationale for protecting self-analytical materials from disclosure is the same in all these cases: the public’s interest in encouraging candid institutional self-analysis outweighs the public’s concern of ensuring complete disclosure of all relevant information to a litigant.\textsuperscript{73} As poignantly summarized by one court, “[t]he common theme linking all these cases is that, in each, the policies in favor of confidentiality—protecting individuals’ expectations of privacy and/or promoting free communication of candid evaluations and criticisms within an organization—have been deemed strong enough to justify restrictions on liberal pretrial discovery.”\textsuperscript{74} Supporters of the privilege suggest that to allow disclosure of self-evaluative materials would have a “chilling effect” on candid and thorough self-appraisals.\textsuperscript{75} As several courts have recognized, “[c]onfidentiality and candor are complimentary to one another. Destroy one and the other vanishes.”\textsuperscript{76}

In order to balance the competing policy interests between liberal discovery and the need for candid self-critical analysis, courts acknowledging the privilege generally require four criteria before applying it. The first three criteria were enunciated by the \textit{Bredice} court: first, the information sought to be protected must result from a self-critical analysis performed by the party claiming the privilege; second, the free flow of this type of information must advance a strong public interest; and third, the information sought must result from the type of analysis that would be curtailed if discovery were allowed.\textsuperscript{77} The fourth

\textsuperscript{72} See, e.g., Bush, \textit{supra} note 8, at 614-15; Leonard, \textit{Codifying a Privilege}, \textit{supra} note 13, at 116-19; Crisman & Mathews, \textit{supra} note 8, at 175-76; Murphy, \textit{supra} note 8, at 499. \textit{But see} Flanagan, \textit{supra} note 20, at 582.

\textsuperscript{73} See \textit{Gish}, \textit{supra} note 13, at 79-80.

\textsuperscript{74} New York Stock Exch. v. Sloan, 22 Fed. R. Serv. 2d (Callaghan) 500, 504 (S.D.N.Y. 1976).

\textsuperscript{75} \textit{But see} \textit{Flanagan}, \textit{supra} note 20, at 582; \textit{Harvard Note}, \textit{supra} note 9, at 1091-93; \textit{Beck}, \textit{supra} note 12, at 358; \textit{see also} \textit{Hardy v. New York News, Inc.}, 114 F.R.D. 633, 640 (S.D.N.Y. 1987) (noting the privilege “is based upon the concern that disclosure of documents reflecting candid self-examination will deter or suppress socially useful investigations and evaluations or compliance with the law or professional standards”).


criterion is the general proviso underlying the law of privileges—the
document sought to be protected was prepared with the expectation that
it would be kept confidential and in fact has remained so. Unfortunately, this balancing test as applied by the trial courts has resulted in widely conflicting decisions and inconsistent applications of the privilege.

C. Judicial Impediments to Development of the Self-Critical Analysis Privilege

Even where the basic Bredice criteria for the self-critical analysis privilege are satisfied, however, the existence of the privilege remains uncertain, and self-analytical evaluations may be deemed discoverable. The judiciary has been increasingly reluctant to apply the self-critical analysis privilege in cases beyond the medical peer review context. In fact, neither the United States Supreme Court nor the circuit courts have definitively denied the existence of the privilege or accepted the privilege and defined its scope. Those courts that have acknowledged the privilege are in conflict regarding its application. The privilege “at the most remains largely undefined and has not generally been recognized.”

1. General Judicial Reluctance to Expand Privileges

The traditional concept of privileges is enunciated in the Federal Rules of Civil Procedure and the Federal Rules of Evidence, which have been

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78. See 8 WIGMORE, supra note 25, § 2285, at 527; see also SHIPES, 154 F.R.D. at 307; In re Grand Jury Proceedings, 861 F. Supp. at 388; Dowling, 971 F.2d at 426; Combined Communications Corp., 865 F.2d at 898; Peterson, 112 F.R.D. at 363; Westmoreland v. CBS, Inc., 97 F.R.D. 703, 706 (S.D.N.Y. 1982); Flanagan, supra note 20, at 554-76; Gish, supra note 13, at 81.

79. See Gish, supra note 13, at 82.

80. See Dowling, 971 F.2d at 426 n.1; In re Grand Jury Proceedings, 861 F. Supp. at 387.

adopted by most states. Under the Federal Rules of Civil Procedure, discovery is liberally allowed for "any matter, not privileged, which is relevant to the subject matter involved in the pending action." "Relevance" is construed liberally. Even information potentially inadmissible at trial is discoverable, absent a privilege, if such information could lead to the discovery of admissible evidence. Thus, the scope of relevance in discovery is broader than the standard of ultimate admissibility at trial.

In contrast to the concept of relevance, it is well-settled that the term "privileged" as used in the Federal Rules of Civil Procedure corresponds with the concept of "privilege" as developed by the Federal Rules of Evidence. Thus, in discovery, the concept of privilege "is neither

82. States have enacted substantially similar liberal discovery rules. E.g., CAL. CIV. PROC. CODE § 2017 (West 1983 & Supp. 1997).

83. "The purpose of discovery is to allow a broad search for facts, the names of witnesses, or any other matters which may aid a party in the preparation or presentation of his case." FED. R. CIV. P. 26(b) advisory committee's note (1946 amendment) (citations omitted); see Gish, supra note 13, at 76 n.13.

84. FED. R. CIV. P. 26(b)(1). These liberal discovery provisions reflect the primary goal of the Federal Rules of Civil Procedure: "to secure the just, speedy, and inexpensive determination of every action." FED. R. CIV. P. 1.

85. See, e.g., Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978) ("[Relevance] has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case."); Coughlin v. Lee, 946 F.2d 1152, 1159 (5th Cir. 1991) (noting that "relevance" traditionally has been interpreted very broadly and declining to uphold a discovery ruling that failed to adhere to the "liberal spirit" of the discovery rules); Miller v. Pancucci, 141 F.R.D. 292, 296 (C.D. Cal. 1992) ("The requirement of relevancy should be construed liberally and with common sense, rather than in terms of narrow legalisms.")

86. "The information sought need not be admissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(b)(1).

87. See 4 MOORE, supra note 26, ¶ 26.07[1], at 26-120 through 26-121; WRIGHT ET AL., supra note 26, § 2008, at 99-100. For the purpose of admissibility at trial, evidence is "relevant" if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED. R. EVID. 401.

88. Rule 1101(c) of the Federal Rules of Evidence provides that "[t]he rule with respect to privileges applies at all stages of all actions, cases, and proceedings." FED. R. EVID. 1101(c); see also United States v. Reynolds, 345 U.S. 1, 6-7 (1953) ("We think it should be clear that the term 'not privileged' . . . refers to 'privileges' as that term is understood in the law of evidence."); Memorial Hosp. v. Shadur, 694 F.2d 1058, 1061 (7th Cir. 1981) ("Rule 501 of the Federal Rules of Evidence provides the framework for determining whether material sought in discovery is privileged."); Roberts v. Carrier Corp., 107 F.R.D. 678, 685 (N.D. Ind. 1985); Peterson v. Chesapeake & Ohio Ry. Co., 112 F.R.D. 360, 363 (W.D. Mich. 1986) (holding evaluation and recommendation portions of derailment report unprivileged); infra note 90 and accompanying text.
broader nor narrower than that which would be applied at trial. 89

Under Rule 501 of the Federal Rules of Evidence, privileges are governed by common-law principles as interpreted by the federal courts, but where state-law claims or defenses are involved, privileges are determined by state law. 90 Unlike relevance, privileges are construed narrowly. 91 Although the spirit behind Rule 501 92 encourages courts

89. 4 MOORE, supra note 26, ¶ 26.11[1], at 26-172. See, e.g., Peterson, 112 F.R.D. at 362; Diversified Indus., Inc. v. Meredith, 572 F.2d 596, 596 (8th Cir. 1977); In re Grand Jury Investigation, 575 F. Supp. 777, 777 (N.D. Ga. 1983); In re LTV Sec. Litig., 89 F.R.D. 595, 600-06 (N.D. Tex. 1981) (allowing corporation to assert attorney-client privilege and work-product doctrine to preclude discovery of attorney-generated materials for the SEC).

90. [T]he privilege of a witness [or] person . . . shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege . . . shall be determined in accordance with State law.

FED. R. EVID. 501. Typically, only federal privileges law will apply to a federal claim. But in diversity actions where state law civil claims or defenses are involved, the state law of privileges will apply. Id.; see, e.g., Samuelson v. Susen, 576 F.2d 546, 549 (3d Cir. 1978) (“Rule 501 requires a district court exercising diversity jurisdiction to apply the law of privilege which would be applied by the courts of the state in which it sits.”); see also WRIGHT ET AL., supra note 26, § 2016, at 223-24. See generally Martin I. Kaminsky, State Evidentiary Privileges in Federal Litigation, 43 FORDHAM L. REV. 923 (1975); Olin Guy Wellborn III, The Federal Rules of Evidence and the Application of State Law in Federal Courts, 55 TEX. L. REV. 371 (1977).

When both state and federal claims are present in one case and a privilege exists only under one set of laws, the privilege will be unavailable. See, e.g., Perrignon v. Bergen Brunswig Corp., 77 F.R.D. 455, 458 (N.D. Cal. 1978) (“If a communication were privileged under state law but not under federal law [or vice versa], it would be meaningless to hold the communication privileged for one set of claims but not for the other. Once confidentiality is broken, the basic purpose of the privilege is defeated.”)

91. 4 MOORE, supra note 26, ¶ 26.11[1], at 26-173.

92. See S. Rep. No. 93-1277, 93d Cong., 2d Sess. 11 (1974), reprinted in 1974 U.S.C.C.A.N. 7051, 7059, which indicates that Congress opted for the common-law approach in enacting Rule 501: “It should be clearly understood that, in approving this general rule as to privileges . . . our action should be understood as reflecting the view that the recognition of a privilege . . . should be determined on a case-by-case basis.” See also Upjohn Co. v. United States, 449 U.S. 383, 396 (1981) (referring to “the spirit of Federal Rule of Evidence 501” and rejecting a request to develop standard in determining whether a privilege exists); University of Pa. v. EEOC, 493 U.S. 182, 189 (1990) (acknowledging that Rule 501 reflects Congress’s intent to grant courts “flexibility to develop rules of privilege on a case-by-case basis”). In fact, Congress rejected proposed Rules 502-513 of the Federal Rules of Evidence, which specifically enumerated thirteen privileges, including a privilege for reports required by governmental entities. See FED. R. EVID. 501 advisory committee’s note regarding H.R. 93-650; see
to remain flexible in developing the law of privileges on a case-by-case basis, privileges are generally disfavored and extended cautiously because they frustrate the truth-finding process by impeding the discovery of relevant information.

While neither the Federal Rules of Civil Procedure nor the Federal Rules of Evidence define "privilege," Professor Wigmore espouses four requirements before courts can recognize a privilege: first, the communications must have occurred with the expectation of confidentiality; second, confidentiality of such communications must be necessary for the full maintenance of the relationship between the parties; third, the relationship must be one that public policy encourages; and fourth, the injury that the relationship would suffer by disclosure must outweigh the benefit of disclosure. Thus, Wigmore’s approach attempts to balance the societal interests in confidentiality against the societal costs. Wigmore’s approach has been widely accepted by the courts, which generally recognize the existence of a privilege only when the public’s need for confidentiality outweighs the public policy favoring full disclosure of all relevant information.
2. Judicial Limitations to the Self-Critical Analysis Privilege

Assertions of privilege typically originate during the discovery stage of a dispute; consequently, the law of privileges has been uniquely molded by the trial courts.100 But because the self-critical analysis privilege is still in the early stages of development, it has not been accorded the wide judicial acceptance given to the more traditional privileges.101 Expressing skepticism of this common-law privilege, courts have modified the original four-part test espoused in Bredice and its progeny by enumerating additional criteria that must be met before they will apply the self-critical analysis privilege, thus narrowing its application.

Typically, modern courts concede the possible existence of the privilege under limited circumstances, but they ultimately hold that the documents at issue do not fall within the scope of the privilege.102 For example, numerous courts have required that the materials sought to be protected must have been prepared for mandatory government reports.103 Information voluntarily disclosed does not fall within the

100. See Taylor, supra note 13, at 796; Flanagan, supra note 20, at 573; Leonard, Codifying a Privilege, supra note 13, at 149; Leonard, An Emerging Privilege, supra note 15, at 3; Harvard Note, supra note 9, at 1085 n.12. A trial court’s rejection of the privilege during discovery will not determine the ultimate admissibility of that information during trial. In contrast to the liberal discovery standards, the standards for admissibility are more stringent. See Leonard, Codifying a Privilege, supra note 13, at 149. Even if discovery of self-analytical documents is allowed, various rules of evidence may prevent the admission of such information at trial. See, e.g., Fed. R. Evid. 407 (precluding evidence of subsequent remedial measures to prove negligence or other culpable conduct); see infra note 267 and accompanying text. But see Flanagan, supra note 20, at 558 (noting that such information could be admissible as an admission against interest or as a report of regularly conducted business activity). See generally Leonard, Codifying a Privilege, supra note 13, at 149-51. But an evidentiary privilege that prevents the admission of certain information at trial also applies to prevent discovery of that information. See Fed. R. Evid. 1101(c),(d); Flanagan, supra note 20, at 553 n.12.

101. See Flanagan, supra note 20, at 573.

102. See, e.g., In re Burlington N., Inc., 679 F.2d 762, 765 n.4 (8th Cir. 1982).

privilege. Moreover, most courts have agreed that the privilege extends only to subjective or evaluative materials; factual or objective data contained in the same reports are not privileged.

Courts also uniformly have held the privilege inapplicable where the documents at issue are sought by a governmental agency or pursuant to a grand jury subpoena. The courts’ refusal to apply the privilege against the government is logical in that the strong public interest in “having administrative investigations proceed expeditiously and without impediment” outweighs the public’s need for confidentiality of internal documents.

Further, the courts have imposed some of the limitations of the attorney-based protections on the self-critical analysis privilege, as well. As applied by the courts, the self-critical analysis privilege resembles the work-product doctrine more than the attorney-client

Conway, supra note 8, at 637-38.


106. See, e.g., FTC v. TRW, Inc., 628 F.2d 207, 210-11 (D.C. Cir. 1980) (refusing to apply privilege to reports compiled by credit reporting agency in course of National Consumer Relations Audit); United States v. Dexter Corp., 132 F.R.D. 8, 9 (D. Conn. 1990) (refusing to apply qualified privilege to corporate defendant’s self-evaluative documents); Emerson Elec. Co. v. Rumsfeld, 609 F.2d 898, 907 (8th Cir. 1979); United States v. Noall, 587 F.2d 123, 125-26 (2d Cir. 1978) (holding privilege inapplicable in proceeding to enforce an IRS production order where Congress has established a policy requiring disclosure); Reynolds Metal Co. v. Rumsfeld, 564 F.2d 663, 667 (4th Cir. 1976) (holding affirmative action reports unprivileged where defendant was aware that information would be used for administration of Civil Rights Act); see also Bush, supra note 8, at 609-10; Conway, supra note 8, at 652-54; Gish, supra note 13, at 84-85.

107. See, e.g., in re Grand Jury Proceedings, 861 F. Supp. 386, 391 (D. Md. 1994) (refusing to apply privilege to internal audits by company subject to jurisdiction of FDA and being investigated by grand jury for possible violations of FDCA).

108. Id. at 388; FTC v. TRW, Inc., 628 F.2d at 210; see also FMC v. Port of Seattle, 521 F.2d 431, 433 (9th Cir. 1975) (“[t]he very backbone of an administrative agency’s effectiveness in carrying out the congressionally mandated duties of industry regulation is [its] exercise of the power to investigate . . . .”).

109. Commentators have suggested that when possible, given the uncertainty of the nascent self-critical analysis privilege, corporations should structure compliance efforts so they qualify under one of the traditional attorney-based protections. See Murphy & Oyer, supra note 8, at 12. See generally Nancy C. Cody, The Attorney-Client Privilege and the Work Product Immunity Doctrine for the Corporate Client, 15 U. BALT. L. REV. 251 (1986).
privilege. Similar to the work-product doctrine, the application of the self-critical analysis privilege is qualified and may be overcome where the party seeking disclosure can demonstrate a compelling need for the information. Also analogous to the work-product doctrine, courts have applied the self-critical analysis privilege only in the discovery context. Moreover, like the attorney-based protections, to the extent a privilege for self-critical analysis exists, it can be waived easily.

Over the past few years, the evolution of the self-critical analysis privilege has been retarded even more by the 1990 Supreme Court decision in University of Pennsylvania v. EEOC. In a unanimous opinion, the Court admonished that before it would recognize a privilege, the privilege must promote "sufficiently important interests to outweigh the need for probative evidence." Acknowledging the spirit of Rule 501 of the Federal Rules of Evidence, the Court cautioned against exercising such authority "expansively," stating, "[w]e are especially reluctant to recognize a privilege in an area where it appears that Congress has considered the relevant competing concerns but has not provided the privilege itself." The Court, reiterating the

110. See Leonard, An Emerging Privilege, supra note 15, at 3; see also supra notes 43-52 and accompanying text.


112. See Leonard, An Emerging Privilege, supra note 15, at 3; see also supra notes 60, 62-71, 100 and accompanying text.

113. The traditional view is that any disclosure results in waiver. See WRIGHT ET AL., supra note 26, § 2016.2, at 241. Because the existence of a privilege typically depends on confidentiality, "broaching this confidentiality as to one person destroys it as to the world... unless the disclosure was itself privileged." Id. § 2016.2, at 248-49; see also Leonard, Codifying a Privilege, supra note 13, at 141-47; Leonard, An Emerging Privilege, supra note 15, at 4; Conway, supra note 8, at 656-57; supra notes 37, 52 and accompanying text.


115. Id. at 189.

116. Id.
judiciary's traditional view that the policy favoring open discovery requires privileges to be "strictly construed," thus refused to extend the self-critical analysis privilege to faculty comments or decisions made during a faculty peer review procedure.

The courts' inconsistent applications of the self-critical analysis privilege and the Supreme Court's failure to recognize the privilege have caused its validity to be questioned. As acknowledged by the Supreme Court, "[a]n uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all." Proponents of the self-critical analysis privilege suggest that its questionable applicability has led corporations to fear that their self-analytical reviews will be used against them in future litigation, thus thwarting or "chilling" the candor with which such evaluations are performed. The wide-spread judicial reluctance to extend the self-critical analysis privilege and the resultant unpredictability of the privilege's application to internal analytical reviews have prompted commentators and various committees of the American Bar Association to advance several proposals for codifying a broad self-critical analysis privilege beyond the medical peer review context.

But as discussed below, such statutes, which attempt to prevent discovery of self-analytical reports, cannot be applied to product-safety analyses performed by drug and medical device manufacturers because the statutes fly in the face of the FOIA and FDCA public disclosure requirements.

III. OVERVIEW OF DRUG AND MEDICAL DEVICE REPORTING REQUIREMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The FDA, whose primary objective is protecting the public's health, began actively regulating the manufacturing and marketing of drugs and medical devices in 1938 with the enactment of the FDCA. In response to the public's health and safety concerns

117. Id.
119. Leonard, Codifying a Privilege, supra note 13, at 119-20, 123-48; Murphy, supra note 8, at 497-502.
121. Prior to enactment of the FDCA, Congress's first attempt to regulate the drug industry occurred in 1906 when it enacted the Federal Pure Food and Drugs Act of 1906,
caused by expanded modern medical technology, Congress steadily has increased the FDA's control over the drug and medical device industry by enacting a series of comprehensive amendments to the FDCA.122

Under the extensive regulatory scheme set forth in the FDCA and its accompanying regulations, drug and medical device manufacturers have a continuing obligation to provide the FDA with numerous product-safety analyses or reviews123 that include thorough and current information regarding the safety and effectiveness of their products.

For example, manufacturers must include complete product safety and effectiveness data in all applications for investigational devices124 and

which banned adulterated and misbranded drugs from interstate commerce. Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 (1906). In 1938, the FDCA added the requirement that drug manufacturers demonstrate a drug's safety prior to marketing. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-95 (1994)).


123. "Product safety analysis or review" is perhaps best defined as "any investigation, inquiry, review, evaluation or other means by which a person or entity seeks to determine, calculate, predict, estimate, evaluate or report the safety or health effects of the use of any of its products, systems, services or processes." ARIZ. REV. STAT. § 12-681 (1996).

124. A device manufacturer that sponsors a clinical investigation of one of its medical devices must comply with the Investigational Device Exemption (IDE) regulations. See 21 C.F.R. §§ 812.1-812.150 (1996); see also 21 C.F.R. pt. 813 (1996). The sponsoring manufacturer must submit a report of all "unanticipated adverse device effects" to the FDA within ten working days after receiving notice of those effects. 21 C.F.R. 812.150(b). An "[u]nanticipated adverse device effect" is defined as "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified
in the underlying premarket submissions for each medical device. Additionally, the FDA requires medical device manufacturers to submit various reports for each marketed device. Medical Device Reports (MDRs) constitute the majority of these postmarketing reports. Under the MDR regulations, device manufacturers must inform the FDA of all deaths or serious injuries potentially related to a medical device and of those device malfunctions when serious injury or death could result if the malfunction were to recur. Moreover, under the FDA’s Good Manufacturing Practice regulations (GMPs), device manufacturers must maintain accurate manufacturing, packaging,

... in the investigational plan ..., or any other unanticipated serious problem associated with a device ....” 21 C.F.R. § 812.3(s).


126. In addition to the MDRs that a device manufacturer must file, the FDA regulations require the manufacturer to file, for each newly marketed device, annual baseline reports, see 21 C.F.R. § 803.55 (1996), and an annual certification that it has filed all necessary MDRs during the previous year, see 21 C.F.R. § 803.57 (1996).

127. A “serious injury” is defined in 21 C.F.R. § 803.3(aa)(1) as “an injury or illness that:

(i) Is life threatening;

(ii) Results in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.


128. A “malfunction” is defined as “the failure of a device to meet any of its performance specifications or otherwise perform as intended.” 21 C.F.R. § 803.3(m).

129. Under the MDR regulations, a medical device manufacturer must submit an MDR to the FDA within thirty days after the manufacturer receives or otherwise becomes aware of information (e.g., in medical or scientific literature) that reasonably suggests that one of its marketed devices: “(1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and ... would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.” 21 C.F.R. § 803.50(a) (1996); see also 21 C.F.R. §§ 803.20(b)(3)(i)-(ii) (1996). Device malfunction MDRs must be filed even when no injuries have resulted. See 21 C.F.R. § 803.3(q)(2)(ii). But when the manufacturer becomes aware that a reportable event requires remedial measures “to prevent an unreasonable risk of substantial harm to the public health,” 21 C.F.R. § 803.53 (1996), it must submit a five-day report to the FDA instead of the typical thirty-day report, 21 C.F.R. §§ 803.20(b)(3)(iii) (1996). Device manufacturers also have the obligation to supplement any MDRs with additional information they may receive regarding a reportable event. See 21 C.F.R. § 803.56 (1996). See generally 21 U.S.C. § 360i (1996).
quality assurance, and distribution records\textsuperscript{130} to assure the FDA that all devices are safe and effective.\textsuperscript{131}

Similarly, drug manufacturers are required to file numerous reports regarding the safety and effectiveness of their investigational\textsuperscript{132} and marketed drug products. As with devices, companies must include complete product safety and effectiveness information in all underlying drug submissions.\textsuperscript{133} Adverse Reaction Reports (ARRs)\textsuperscript{134} are the most common postmarketing reports\textsuperscript{135} that drug manufacturers


\textsuperscript{131} See \texttt{21} C.F.R. § 820.1.

\textsuperscript{132} Under the regulations governing investigational new drug applications (INDs), a drug manufacturer that sponsors a clinical investigation for a drug must submit an IND Safety Report within ten working days after the initial receipt of information of any adverse experience associated with the use of an IND drug that is both "serious" and "unexpected." \texttt{21} C.F.R. § 312.32(c)(1) (1996). A "serious" adverse experience is defined as "any experience that suggests a significant hazard, contraindication, side effect, or precaution... [This] includes any experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose." \texttt{21} C.F.R. § 312.32(a). An "unexpected" adverse experience is defined as one "that is not identified in nature, severity, or frequency in the current investigator brochure; or... in the risk information described in the general investigational plan or elsewhere in the current application." \texttt{Id.} If the experience was fatal or life-threatening, however, the manufacturer must make a telephone report to the FDA within three working days. \texttt{See} \texttt{21} C.F.R. § 312.32(c)(2). Drug manufacturers also must submit annual reports for each IND containing a brief report of the progress of the investigation, including a summary of all IND Safety Reports submitted during the prior year. \texttt{See} \texttt{21} C.F.R. § 312.33 (1996).

\textsuperscript{133} Drug manufacturers must submit either a New Drug Application (NDA) and or an Abbreviated New Drug Application (ANDA) containing complete safety and effectiveness data for each drug. \texttt{See} \texttt{21} C.F.R. §§ 314.50, 314.94 (1996); \texttt{21} U.S.C. § 355 (1996).

\textsuperscript{134} Previously, these reports were known as Adverse Drug Reports (ADR\textsuperscript{s}) and currently may be called Adverse Experience Reports (AE\textsuperscript{s}) under the FDA's proposed rule. \texttt{See} \texttt{59} Fed. Reg. 54,046 (1994).

\textsuperscript{135} The FDA requires drug manufacturers to submit other postmarketing reports, including an "NDA-Field Alert Report," which must be submitted within three working days of a manufacturer's receipt of information concerning any incident that causes the drug or its labeling to be mistaken for or applied to another product or information concerning a drug's contamination, alteration, deterioration, or failure to meet specifications. \texttt{See} \texttt{21} C.F.R. § 314.81(b)(1) (1996). Drug manufacturers also must submit annual reports for each approved drug application. Among other voluminous information, the annual report for each drug must include a summary of significant new information that could affect the safety, effectiveness, or labeling of the drug, and summaries of clinical data on safety and effectiveness. \texttt{See} \texttt{21} C.F.R. § 314.81(b)(2).
file.136 Under the ARR reporting regulations,137 drug manufacturers must report “any adverse event associated with the use of” their drugs in humans, even when the event is not deemed “drug-related” or “serious”138 and the event is “expected.”139 Additionally, like device manufacturers, drug manufacturers must comply with the FDA’s drug GMPs to assure the FDA that all drugs are safe and effective.140

These myriad reports enable the FDA to better protect the public health and safety by ensuring that drugs and medical devices are not “adulterated”141 or “misbranded”142 and are “safe and effective for their intended use.”143 To assist the FDA in its protective function, the

136. Drug manufacturers are required to submit ARRs under the NDA and ANDA regulations. See 21 C.F.R. §§ 314.80, 314.98 (1996).

137. ARRs consist of several types. The “Fifteen-Day ‘Alert Report,’” must be submitted by a drug manufacturer in four instances. First, such a report must be filed within fifteen working days of the manufacturer’s initial receipt of information for an adverse drug experience that is both “serious” and “unexpected.” 21 C.F.R. § 314.80(c)(1)(i). Additionally, a Fifteen-Day Alert Report Followup must be submitted within fifteen working days of receipt of any additional information. Id. Second, a manufacturer also must file a Fifteen-Day Alert Report if it discovers during a periodic review that the frequency of serious, expected adverse drug experience reports or of therapeutic failures has significantly increased. 21 C.F.R. § 314.80(c)(1)(ii). Drug packers and distributors have identical mandatory reporting requirements in these first two scenarios. 21 C.F.R. § 314.80(c)(1)(iii). Third, a Fifteen-Day Alert Report is required if a drug manufacturer discovers in the scientific and medical literature reports of serious, unexpected adverse drug experiences or reports of a significant increase in the frequency of serious, expected adverse drug experiences or of therapeutic failures. 21 C.F.R. § 314.80(d). Fourth, a Fifteen-Day Alert Report is required during postmarketing studies if a serious, unexpected adverse drug experience occurs and a reasonable possibility exists that the drug caused the experience. 21 C.F.R. § 314.80(e). Drug manufacturers also must file “Periodic Adverse Drug Experience Reports” quarterly for three years from the date of each drug application approval, and annually thereafter for all adverse drug experiences that are not both serious and unexpected. 21 C.F.R. § 314.80(c)(2). See generally 21 U.S.C. § 355(k).

138. Similar to the definition of “serious” for an IND Safety Report, “serious” for the purposes of an adverse reaction report under an NDA or ANDA is defined as “an adverse drug experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose.” 21 C.F.R. § 314.80(a).

139. For purposes of an ARR, “unexpected” is defined as “an adverse drug experience that is not listed in the current labeling for the drug and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity.” Id.


141. A drug or device is “adulterated” when it fails to comply with the FDA’s standards for current good manufacturing practices. See 21 U.S.C. § 351.

142. A drug or device is “misbranded” when its labeling fails to comply with the FDA’s labeling requirements. See 21 U.S.C. § 352.

reporting requirements require drug and medical device manufacturers to include highly sensitive and self-evaluative information in their product-related reports.

For example, the regulations governing investigational devices require a manufacturer sponsoring a clinical study on a device to submit an investigational plan to the FDA, including a “risk analysis” for the investigational device,\(^4\) and to submit evaluations of any unanticipated adverse effects that result from use of the device.\(^5\) Similarly, the MDR reporting statute requires the device manufacturer to include not only factual information in its reports,\(^6\) but also self-analytical information, such as a summary of how the device was involved in the event, any environmental conditions that may have influenced the event, relevant laboratory data, and a summary of the event evaluation performed by the manufacturer.\(^7\) If the FDA determines that additional information is necessary to protect the public health and safety, it may require the manufacturer to submit additional self-evaluations of the device’s risk of death or serious injury,\(^8\) including failure analyses and any laboratory testing or other analyses used by the manufacturer,\(^9\) any evaluation of whether the reported incident is attributable to

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144. See 21 C.F.R. § 812.25(c) (1996).

145. See 21 C.F.R. § 812.150(b)(1) (1996); discussion supra note 132.

146. Such required factual information includes the name of the device, its model and serial numbers, the name, address, and telephone number of the manufacturer, the name and address of the individual providing the information to the manufacturer, and a factual narrative of the event giving rise to the report. See 21 C.F.R. § 803.52 (1996).

147. See id. Under the 1995 regulations, the manufacturer also was required to assess whether the event “has occurred or [was] occurring more frequently or with greater severity” than was stated in the device’s labeling or than was usual for the device. See 21 C.F.R. § 803.24(e)(7) (1995), repealed effective 1996 by 60 Fed. Reg. 63,590 cmt.41 (1995). The manufacturer also must assign an “evaluation code” from the FDA Coding Manual to the event. See 21 C.F.R. § 803.52(f)(6).


the device and the basis for that determination, \textsuperscript{150} the basis for determining whether remedial action is necessary, accompanied by an outline of a remedial action plan, \textsuperscript{151} and any evaluations or analyses used by the manufacturer to determine whether the event "has occurred or is occurring more frequently or with greater severity" than is expected. \textsuperscript{152}

Analogous to their device counterparts, the various drug reporting regulations require a drug manufacturer not only to include in its various mandatory reports factual information, such as the name of the drug and the time period during which the increased frequency arose, but also to include critical self-evaluative information. For example, a drug manufacturer sponsoring a clinical study of an investigational new drug must analyze the significance of any adverse drug experience. \textsuperscript{153}

Further, the regulations for marketed drugs require a drug manufacturer to alert the FDA of a significant increase in the frequency of adverse drug experience reports and to supply the manufacturer's method of analysis and its interpretation of the results. \textsuperscript{154}

Another prime example of when the FDA requires self-analytical information from drug and medical device manufacturers is when a drug or device is recalled. While most recalls are voluntary actions undertaken by drug and medical device manufacturers in “carry[ing] out their responsibility to protect the public health and well-being from products that present a risk of injury or . . . are otherwise defective,” \textsuperscript{155} various factual and analytical data relating to the recall must be submitted to the FDA. Initially, the manufacturer will be asked to provide the FDA with its evaluation of any risks associated with the product being recalled. \textsuperscript{156} Additionally, under the FDA recall policy, the manufacturer must prepare a "Health Hazard Evaluation," which includes an evaluation of the health hazard posed by the product being recalled and assessments of the degree of seriousness, the likelihood of occurrence, and the consequences of the hazard. \textsuperscript{157}

\textsuperscript{150} Id. § 803.24(e)(6).
\textsuperscript{151} Id. § 803.24(e)(8).
\textsuperscript{152} Id. § 803.24(e)(7).
\textsuperscript{154} 21 C.F.R. § 314.80(c)(1)(ii) (1996). Further, each Periodic Adverse Drug Experience Report submitted to the FDA must contain an analytical summary of the information contained in the report, an analysis of each Fifteen-Day Alert Report submitted during the interval covered by the Periodic Report, and a history of actions taken since the prior Periodic Report due to adverse drug experiences. 21 C.F.R. § 314.80(c)(2)(ii); see discussion supra note 137.
\textsuperscript{155} 21 C.F.R. § 7.40(a) (1996).
While these numerous FDA-required reports do not necessarily constitute an admission by the manufacturer that the device malfunctioned or caused or contributed to a death or serious injury, or that a drug caused or contributed to an adverse experience, once the reports are submitted, the desired confidentiality of any self-analytical efforts is jeopardized. Under the liberal FOIA disclosure provisions and FDA regulations governing access to FDA records, the public has an immediate right to access the nonexempt portions of such reports.

IV. PUBLIC DISCLOSURE REQUIREMENTS UNDER THE FREEDOM OF INFORMATION ACT

The FOIA, enacted in 1966, established for the first time an effective public statutory right to access all federal agency records, unless such records are protected from disclosure by one of nine specific

159. See 21 C.F.R. §§ 312.32(e), 314.80(f) (1996). Indeed, prudent manufacturers routinely deny such an admission by including appropriate exculpatory language in the reports they submit to the FDA.
160. See infra notes 161-77, 191-206 and accompanying text.
163. State agencies are not subject to the FOIA, but most have enacted state counterparts. Twenty-nine states have state freedom of information laws modeled after the federal FOIA, while the other twenty-one states have somewhat different state open records statutes. See 15 Federal Procedure § 38:24, at 48-49 (Lawyers ed. 1990); 2 Franklin & Bouchard, supra note 162, state statutes app. See generally 2 O'Reilly supra note 162, §§ 27.01-.05, at 27-1 to -25.
exemptions. "Agency records" consist of records that are created or obtained by a federal agency and under agency control at the time of the disclosure request. An FOIA request can be made by "any person," including an attorney acting on behalf of a client. Moreover, FOIA requests need not be explained or justified; rather, such requests can be made for any purpose, and no showing of relevancy is required.

The fundamental principle underlying the FOIA is that "an informed citizenry is essential to the democratic process." Congress realized,

164. The exemptions are enumerated in 5 U.S.C. § 552(b)(1)-(9) (1994); see infra note 171. See also BRIDGES & VILLAGER, supra note 162, at 3; 1 FRANKLIN & BOUCHARD, supra note 162, § 1.02, at 1-12. Agency records also can be protected from disclosure by one of three exclusions relating to law enforcement records, 5 U.S.C. § 552(c)(1). Even if the requested information falls within one of the enumerated exemptions, however, the exemptions generally are deemed discretionary in nature and not mandatory. See, e.g., Chrysler Corp. v. Brown, 441 U.S. 281, 293 (1979) ("Congress did not design the FOIA exemptions to be mandatory bars to disclosure."); see also OIP Guidance: Discretionary Disclosure and Exemption 4, FOIA UPDATE (Office of Information & Privacy, U.S. Dep't of Justice), Summer 1985, at 3; Memorandum from Att'y Gen. Reno to Heads of Departments and Agencies (Oct. 4, 1993), in FOIA UPDATE (Office of Information & Privacy, U.S. Dep't of Justice), Summer/Fall 1993, at 4-5 [hereinafter Reno's FOIA Memorandum] (encouraging discretionary disclosures of otherwise exempt information whenever possible). See generally 1 FRANKLIN & BOUCHARD, supra note 162, § 1.14[1], at 1-383 to -392; 1 O'REILLY supra note 162, § 9.05, at 9-15 to -18.


166. "Person" is defined broadly to include individuals, partnerships, corporations, associations, and public or private organizations. See 5 U.S.C. § 551(2) (1994).


168. See Toran, supra note 162, at 844. See, e.g., United States Dep't of Justice v. Reporters Comm. for Freedom of the Press, 489 U.S. 749, 771 (1989) (noting that the purpose for which records are sought under the FOIA has no bearing upon the merits of the request); North v. Walsh, 881 F.2d 1088, 1096 (D.C. Cir. 1989) (holding requester's identity and intended use of information not proper factors in determining rights to access information under FOIA). The FOIA enumerates only two prerequisites for FOIA requests: First, the request must "reasonably describe" the information sought, and second, the request must be made in compliance with the particular agency's published procedural regulations. See 5 U.S.C. § 552(a)(3)(A)-(B) (1994).

169. Memorandum from President Clinton to Heads of Departments and Agencies (Oct. 4, 1993), in FOIA UPDATE (Office of Information & Privacy, U.S. Dep't of Justice), Summer/Fall 1993, at 3 [hereinafter Clinton's FOIA Memorandum]; see also NLRB v. Robbins Tire & Rubber Co., 427 U.S. 214, 242 (1976) ("The basic purpose of [the] FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed."). During the debate of the FOIA in the House of Representatives, Rep. Rumsfeld quoted one of the Founding Fathers in supporting the FOIA: "Knowledge will forever govern ignorance. And a people who mean to be their own governors, must arm themselves with the power knowledge gives. A popular government without popular
however, that achieving an “informed citizenry” is a societal goal that can conflict with other societal interests, such as preserving the confidentiality of sensitive information. Congress reconciled these countervailing concerns by enacting nine specific exemptions from disclosure under the FOIA. Because of the emphasis on the “fullest
possible disclosure," courts have applied a balancing test that "weighs the magnitude of the privacy invasion against the public interest to be served by disclosure" in determining whether information can be withheld under one of the circumscribed FOIA exemptions. Although courts consider numerous factors in applying this balancing test, the primary factor is whether disclosing the information sought will increase the public's ability to monitor governmental action. Because the FOIA mandates courts "to tilt the balance in favor of disclosure," it is unlikely that courts will deny public access to government records, absent exceptional circumstances.

Moreover, the Department of Justice has undertaken a recent "openness-in-government" campaign under the directives of President Clinton and Attorney General Janet Reno, who both issued new FOIA policy statements in October 1993. Calling upon governmental agencies to follow the "spirit" as well as the letter of the FOIA, President Clinton

(7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.


172. 1965 Senate Report, supra note 162, at 3, 38.
173. Lorman et al., supra note 162, at 28; see, e.g., Ripskis v. Department of Hous. & Urban Dev., 746 F.2d 1, 2-3 (D.C. Cir. 1984); Sullivan, Inc. v. Veterans Admin., 617 F. Supp. 258, 260 (D.D.C. 1985); see also Lorman et al., supra note 162, at 22-30.
174. See, e.g., Marzen v. Department of Health & Human Serv., 825 F.2d 1148, 1152 (7th Cir. 1987); Washington Post Co. v. Department of Health & Human Serv., 690 F. 2d 252, 264 (D.C. Cir. 1982); see also Lorman et al., supra note 162, at 29-30.
175. Getman v. NLRB, 450 F.2d 670, 674 (D.C. Cir. 1971).
declared that "[o]penness in government is essential to accountability and the [FOIA] has become an integral part of that process."

This pronouncement of a "sunshine government" was bolstered by Attorney General Reno's articulation of Congress's primary objective in enacting the FOIA: achieving "maximum responsible disclosure of government information."177

A. The Interface Between the FOIA and the Discovery Rules

Similar to the disclosure provisions of the FOIA, which reflect a congressional policy favoring open disclosure of federal records to the general public, the discovery provisions of the Federal Rules of Civil Procedure have an underlying goal of promoting the liberal disclosure of relevant information to civil litigants.178 Also, as with the FOIA disclosure provisions, courts and commentators have interpreted the discovery rules as favoring broad pretrial disclosure of information.179

The FOIA was "fundamentally designed to inform the public about agency action and not to benefit private litigants."180 Despite the Supreme Court's admonition that the FOIA was "not intended to function as a private discovery tool,"181 neither the FOIA nor the discovery rules prohibit the concurrent use of both systems.182 Addi-
tionally, Congress considered—and specifically rejected—a 1981 proposal by the Reagan Administration to absolutely bar private litigants from utilizing the FOIA as a supplement to discovery.183 Thus, civil litigants successfully have supplemented their discovery by FOIA requests,184 even though the FOIA was not enacted to aid them.185

If the information sought is, by statute, public information, it does not follow that a party can make a successful claim of privilege under the discovery rules.186 Indeed, federal courts have held that the government cannot raise a privilege defense in response to a discovery request if the FOIA required it to release the information to the public.

For example, the Fourth Circuit, in holding that a government agency could not raise a privilege claim for a document that is already in the public domain by virtue of the FOIA, stated that “Rule 26(b) does not authorize an agency to withhold any records which the [FOIA] commands it to disclose.”187 Further, a district court, in ruling on the government’s privilege claims in an antitrust suit, determined that “[i]nformation obtainable by a member of the public under the [FOIA] is not privileged.”188

Thus, the general approach in the federal courts is that information available under the FOIA is not privileged and therefore discoverable if relevant. It would be incongruous to apply different standards to the discovery provisions of the FOIA and to claims of privilege under the discovery rules. As one commentator noted, “[b]ecause both systems are

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183. The proposal, introduced as S. 1751, 97th Cong. (1981), provided: “A requester shall not make or maintain a request under this paragraph for records relating to the subject matter of any ongoing judicial or adjudicatory administrative proceeding . . . to which the requester, or any person upon whose behalf the requester acts in making the request, is a party.” See also Tomlinson, supra note 167, at 192 & n.353.


185. But see Renegotiation Bd. v. Bannercraft Clothing Co., 415 U.S. at 30 (Douglas, J., dissenting) (arguing that one of the purposes of the FOIA was “discovery for litigation purposes”).

186. See 4 MOORE, supra note 26, ¶ 26.12[3], at 26-224; Toran, supra note 162, at 849.

187. Moore-McCormack Lines, Inc. v. I.T.O. Corp. of Baltimore, 508 F.2d 945, 950 (4th Cir. 1974); see also Firestone Tire & Rubber Co. v. Coleman, 432 F. Supp. 1359, 1371 n.23 (N.D. Ohio 1976) (“Information which the government must disclose to the public generally may not be withheld from a member of the public who engages the government in litigation.”)

188. United States v. AT&T, 86 F.R.D. 603, 635 (D.D.C. 1979); see also Jupiter Painting Contract Co. v. United States, 87 F.R.D. 593, 597 (E.D. Pa. 1980) (noting that “FOIA availability should . . . defeat a claim of privilege under Rule 26(b)(3) where a litigant has demonstrated the relevance of the information sought”).
explicitly intended to increase the flow of information, the use of both systems together should facilitate . . . access to information."¹⁸⁹

B. Public Disclosure Regulations Under the FDCA

The FOIA requires each federal agency to publish its own procedural regulations governing access to its records.¹⁹³ The FDA, under its public disclosure regulations,¹⁹¹ endorses the FOIA policy of full public disclosure of nonexempt agency records, regardless of whether a requester has demonstrated any justification or need for such records.¹⁹² The FDA regulations mirror the FOIA and include specific exemptions for trade secrets and confidential commercial or financial information,¹⁹³ for inter-agency or intra-agency communications,¹⁹⁴ for materials that would constitute an invasion of personal privacy,¹⁹⁵

¹⁸⁹. Toran, supra note 162, at 871.
¹⁹⁰. 5 U.S.C. § 552(a)(1), (a)(4)(A) (1994). These regulations must inform the public of where and how to address requests for agency records, of the types of records maintained by that agency, of the applicable fees, and of procedures to be followed in appealing a refusal to disclose requested information. Id.
¹⁹². See 21 C.F.R. § 20.20.
¹⁹⁴. See 21 C.F.R. § 20.62; see also Exemption 5 of the FOIA, 5 U.S.C. § 552(b)(5). See generally 1 FRANKLIN & BOUCHARD, supra note 162, § 1.08, at 1-183 to 1-227; 2 O’REILLY, supra note 162, §§ 15.01-15.19, at 15-2 to 15-91; BRIDGES & VILLAGER, supra note 162, at 67-90. This exemption is also known as the “deliberative process privilege,” id. at 71-79, the purpose of which is to “prevent injury to the quality of agency decisions,” NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975). Similar to the policy underlying the self-critical analysis privilege, one key policy underlying the deliberative process privilege is to encourage free and frank discussions on matters of policy within the agency without being questioned by the public. 1 FRANKLIN & BOUCHARD, supra note 162, § 1.08[2], at 1-190 & n.41; 2 O’REILLY, supra note 162, § 15.02, at 15-3 to 15-5; BRIDGES & VILLAGER, supra note 162, at 71. Even the deliberative process privilege, however, is narrowly construed and is inapplicable to factual portions of otherwise deliberative documents. See, e.g., Coastal States Gas Corp. v. Department of Energy, 617 F.2d 854, 867 (D.C. Cir. 1980); see also 1 FRANKLIN & BOUCHARD, supra note 162, § 1.08[2], at 1-190 to -195; 2 O’REILLY, supra note 162, § 15.05, at 15-20 to 15-27; BRIDGES & VILLAGER, supra note 162, at 77-78.
¹⁹⁵. See 21 C.F.R. § 20.63; see also Exemption 6 of the FOIA, 5 U.S.C. § 552(b)(6). See generally Lawton et al., supra note 162; 1 FRANKLIN & BOUCHARD, supra note 162, § 1.09, at 1-227 to 1-268; 2 O’REILLY, supra note 162, §§ 16.01-16.14.
and for information compiled for law enforcement purposes. These exemptions, however, may be waived once a record is disclosed to any member of the public.

Although drug and medical device manufacturers routinely stamp submitted reports as "confidential," this will not suffice to protect the reports from public disclosure. But when the confidentiality of requested information is uncertain, the FDA will consult with the manufacturer who has submitted the information before determining whether to disclose it. If the FDA rejects a manufacturer's request of confidentiality, the manufacturer can institute a "reverse FOIA suit" to prevent disclosure. In its FOIA regulations, the FDA specifically has announced the public availability of data regarding the safety and effectiveness of investigational and marketed drugs and devices, and of all product-related reports, subject to the removal of exempt information. The public disclosure provisions relate not only to a

at 16-1 to 16-38; BRIDGES & VILLAGER, supra note 162, at 90-107. Such information includes information that would identify patients, research subjects, or voluntary reporters or other persons associated with any adverse event involving a human drug or device. 21 C.F.R. § 20.63.

196. See 21 C.F.R. § 20.64; see also Exemption 7 of the FOIA, 5 U.S.C. § 552(b)(7). See generally 1 FRANKLIN & BOUCHARD, supra note 162, at 1-268 to 1-364; 2 O'REILLY, supra note 162, §§ 17.01-17.18, at 17-2 to 17-4; BRIDGES & VILLAGER, supra note 162, 107-45.


198. See generally 1 FRANKLIN & BOUCHARD, supra note 162, at 1-268 to 1-364; 2 O'REILLY, supra note 162, §§ 17.01-17.18, at 17-2 to 17-4; BRIDGES & VILLAGER, supra note 162, 107-45.


201. See 21 U.S.C. §§ 355(f), 368(h) (1994); 21 C.F.R. §§ 211.180-211.198 (drug GMPs), 312.130 (IND), 314.430(e)(2) & (f) (NDA & ANDA), 807.93 (510(k)), 812.38 (IDE), 814.9 (PMA), 820.180 (device GMPs) (1996).

202. These include IDE reports, see 21 C.F.R. §§ 812.38, 814.9(f)(3) (1996), MDRs, see 21 C.F.R. §§ 20.100(c)(36), 803.9, IND Safety Reports, see 21 C.F.R. §§ 312.130, 314.430(e)(4) (1996), and ARRs, see 21 C.F.R. §§ 20.100(e)(17), 314.430(e)(4) (1996).

203. If a requested record contains both exempt and nonexempt information, the exempt portions must be redacted prior to disclosure. See 21 C.F.R. §§ 20.22, 20.60(b) (1996); see also 5 U.S.C. § 552(b) (1994). But the entire record can be withheld if the two types of information are "so inextricably intertwined that it is not feasible to separate them." 21 C.F.R. § 20.22; see also 5 U.S.C. § 552(b). Information such as names of patients, health care providers, and user facilities are not releasable to the public under the FDA's public disclosure regulations. See 21 C.F.R. §§ 314.80(h), 314.430(e)(2)(i)(a), 314.430(e)(4)(i), 803.9(b) (1996); see also 21 C.F.R. pt. 20 (1996).
manufacturer's mandatory FDA submissions, but also to voluntary reports. Furthermore, all correspondence and all written summaries of oral discussions between a drug or device manufacturer and the FDA are available for public disclosure.

C. Possible Preemption of the Self-Critical Analysis Privilege Under the FOIA

State statutes and cases applying the self-critical analysis privilege to maintain the confidentiality of information submitted to federal agencies, such as the FDA, prohibit disclosure of the precise type of information Congress sought to make public under the FOIA. Consequently, such state laws may be invalid under the Supremacy Clause, which mandates that the federal constitution and all federal laws "made in pursuance thereof . . . shall be the supreme Law of the Land." Federal law is broadly defined to include not only the federal constitution and federal statutes, but also federal regulations promulgated by federal administrative agencies acting within the scope of their congressionally delegated authority. Federal law not only preempts conflicting state statutes.

Additionally, trade secret and confidential commercial or financial information is not available for public disclosure. See 21 C.F.R. §§ 314.430(g), 803.9(b).

207. Article VI, Clause 2 of the Constitution states: This Constitution, and the Laws of the United States which shall be made in pursuance thereof, and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art VI, cl. 2.
and regulations, but also preempts conflicting judicial decisions.209

The purpose underlying the Supremacy Clause is "to avoid the introduction of disparities, confusions and conflicts which would follow if the Government's general authority were subject to local controls."210 Although the federal government has limited powers with respect to the states,211 states cannot exercise inconsistent powers in those areas in which the federal constitution grants the federal government the power to act.212 Accordingly, state courts and legislatures have the obligation to guard and enforce every right guaranteed by the federal constitution.213 Neither state common law nor state legislative action can supersede a conflicting federal law; rather, state laws that conflict with federal laws are subordinate and necessarily must yield under the Supremacy Clause.214 Absent Congress's express preemptive intent,215 its intent to supersede state law in a specific area may be implicit.216 Congress's intent to preempt state law in a given area may be implied in several ways.217 First, such intent can be implied from

211. See, e.g., Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (“Consideration of [preemption] ‘starts with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress.’”) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); Maryland v. Louisiana, 451 U.S. 725, 746 (1981) (holding that it initially must be presumed that “Congress did not intend to displace state law”).
214. See, e.g., Maryland v. Louisiana, 451 U.S. at 751 (holding that state tax law inconsistent with federal scheme was preempted).
216. See Savage v. Jones, 225 U.S. 501, 533 (1912) (“[W]hen the question is whether a Federal act overrides a state law ... that which needs must be implied is of no less force than that which is expressed.”)
217. See Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991) (holding Congress's intent to preempt state law may be implicit where (1) the federal regulatory scheme is pervasive, (2) the federal interest in the subject matter is dominant, and (3) the goals sought to be obtained reveal a purpose to preclude state control); Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 369 (1986) (holding Congress's intent to preempt state law may be implicit where (1) there is an actual conflict between federal and state laws, (2) compliance with both federal and state laws is impossible, (3) Congress has legislated comprehensively, or (4) the state laws serve as an obstacle to the accomplishment of Congress's objectives); see also Maryland v. Louisiana, 451 U.S. at 751; Landen, supra note 208, at 89-94.
the legislative history underlying a federal statute or regulation.\textsuperscript{218} Second, preemptive intent can be implied when the federal regulatory scheme is so pervasive that it leaves no room for supplemental state regulation.\textsuperscript{219} Third, when Congress has a dominant federal interest in a particular subject matter,\textsuperscript{220} or when national uniformity is desired in a particular area,\textsuperscript{221} congressional intent to preclude state authority may be inferred. Finally, state law is preempted to the extent it directly conflicts with federal law.\textsuperscript{222} Thus, in determining whether a state law conflicts with a federal law, a court can ask whether it is impossible to comply with both the federal and state laws, or whether the state law interferes with or frustrates congressional intent.\textsuperscript{223}

\textsuperscript{218} See, e.g., Campbell v. Hussey, 368 U.S. 297, 301-02 (1961) (holding that "sweeping effect" of Federal Tobacco Inspection Act and its stated goal of providing national "uniform standards" for classification and inspection of tobacco preempted state attempt to classify tobacco).


\textsuperscript{220} Howard, 719 F.2d at 1560 (holding plaintiff's state law cause of action against a federal contractor for discrimination preempted under the Federal Rehabilitation Act due in part to the federal government's dominant interest "in determining with whom and on what conditions it will contract").

\textsuperscript{221} While legislative history may express the desire for national uniformity, see supra note 215 and accompanying text, courts may infer preemptive intent absent such an expressed desire. See, e.g., Transcontinental Gas Pipe Line Corp. v. State Oil & Gas Bd., 474 U.S. 409, 423 (1986) (holding that state regulation of interstate gas pipelines "disturbs the uniformity of the federal scheme"); Allis-Chalmers Corp. v. Lueck, 471 U.S. 202, 211 (1985) (holding that uniformity and predictability are desirable in labor contract disputes and thus preempting plaintiff's state cause of action for bad faith under Federal Labor Management Relations Act of 1947).


Although Congress has vested the FDA with jurisdiction over the regulation of drugs and medical devices, that jurisdiction is not exclusive. The FDCA expressly provides that its provisions do not preempt state law unless there is a direct conflict between the two. With the enactment of the Medical Device Amendments of 1976, however, Congress expressly preempted states from enacting laws that are “different from, or in addition to,” federal requirements applicable to medical devices. Thus, while the federal government and the states, absent a direct conflict, may have concurrent jurisdiction in drug regulation, state requirements applicable to medical devices are expressly preempted absent an exemption.

While the FOIA and the FDCA and its corresponding regulations do not expressly preempt state discovery laws, to the extent that state courts or legislatures act in a manner inconsistent with the public interest

224. 21 U.S.C. § 903 provides:
No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

225. See supra note 122.

226. 21 U.S.C. § 360k provides:
(a) General rule. Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

227. 21 U.S.C. § 360k provides:
(b) Exempt requirements.
Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
(2) the requirement—
(A) is required by compelling local conditions, and
(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(a) (1994); see also Stewart v. International Playtex, Inc., 672 F. Supp. 907, 909-10 (D.S.C. 1987) (holding that state’s common law, to extent it attempts to regulate matters already addressed by FDA, constitutes a “requirement” within the meaning of section 360k of the FDCA, and is thus preempted).

21 U.S.C. § 360k(b).
concerns manifested by those federal laws, they appear to violate congressional intent. A state law prohibiting disclosure of information that federal statutes and regulations make generally available to the public stands as an obstacle to the efficient operation of the FOIA and FDCA reporting scheme. Moreover, in enacting the comprehensive scheme guaranteeing public disclosure of federal agency records under the FOIA and the FDCA, Congress arguably has “occupied the field” regarding the disclosure of such information.

The FDA’s increasingly comprehensive regulation of the drug and medical device industry and the “spirit of open government” promoted by Congress in enacting the FOIA lead to the conclusion that, to the extent state statutory or common laws prohibit the discovery of self-critical documents prepared by drug and medical device manufacturers under the FDCA, such state laws are repugnant to the federal constitution and thus federally preempted.

V. INAPPLICABILITY OF THE SELF-CRITICAL ANALYSIS PRIVILEGE TO DRUG AND MEDICAL DEVICE MANUFACTURERS

Even if the FOIA public disclosure requirements do not impliedly preempt application of the self-critical analysis privilege to drug and medical device product-safety analyses, any attempt to accord that industry’s use of the privilege either with the federal disclosure requirements or with Wigmore’s privileges analysis poses philosophical dilemmas. Moreover, even without the privilege, the drug and medical device industry has other strong incentives to conduct candid and thorough product-safety reviews.

A. Inapplicability Under the FOIA

Under the FOIA, the drug and medical device industry’s desire to maintain the confidentiality of its product-safety analyses does not comport with the public’s right to access government records. Indeed, to allow product-safety reviews to remain confidential would undermine the purpose of the FOIA and the current spirit of open government.

Moreover, the sine qua non of the self-critical analysis privilege is the need to maintain confidentiality of self-evaluative documents so that fear

of disclosure will not discourage open and frank internal criticism. The
policy underlying this privilege is not satisfied in the drug and medical
device industry when the FDA regulations themselves permit disclosure
under the FOIA mandate.

Furthermore, Congress, in enacting the FOIA exemptions, already
exercised its judgment regarding which categories of information it
believes are entitled to protection. Under Exemption 3 of the FOIA,
which incorporates disclosure prohibitions contained in other federal
statutes, Congress has prohibited, on several occasions, the disclosure of
agency documents that were submitted because required by a govern­
mental agency. For example, in 1972, Congress enacted the Consumer Product
Safety Act (CPSA), which empowered the Consumer Product Safety
Commission (CPSC) to regulate the safety of consumer products. Like the FDA, one of the CPSC’s primary functions is to protect the
public’s safety. Under section 15(b) of the CPSA, a product
manufacturer must report any products that fail to comply with the
consumer product-safety rules and any product defects that could create
a “substantial product hazard.” At the request of product manufac­
turers that feared these reports could be divulged to product liability

229. See generally 1 FRANKLIN & BOUCHARD, supra note 162, § 1.06, at 1-97 to
1-118; 1 O’REILLY, supra note 162, §§ 13.01-13.09, at 13-1 to -25; BRIDGES &
VILLAGER, supra note 162, at 44-52.

confidentiality of documents submitted to the Antitrust Division in response to a civil
investigative demand by specifically exempting such documents from disclosure under
both the FOIA and the Federal Rules of Civil Procedure); H.R. Rep. No. 94-1343, at 15
(1976), reprinted in 1976 U.S.C.C.A.N. 2572, 2609-10. A submitter of such documents,
however, could obtain such documents if it subsequently became a defendant in an
antitrust action brought by the government. Id. Similarly, in the Federal Trade
of documents submitted in response to a civil investigative demand. Other than to
Congress or to federal or state officials, the FTC can only disclose such documents in
adjudicatory proceedings by the FTC or in judicial proceedings to which the FTC is a
2(d)(1)(c)). See also BRIDGES & VILLAGER, supra note 162, at 47-48 for more examples
of federal statutory exemptions under Exemption 3 of the FOIA.


232. See 15 U.S.C. § 2053; see also Frances E. Zollers, The Implementation of
the Consumer Product Safety Act Section 6(b) and the Conflict with Freedom of Information

233. See 15 U.S.C. § 2051(b)(1); see also Zollers, supra note 232, at 64.

litigants through FOIA requests, Congress enacted section 6(b) with the 1981 amendments to the CPSA.

The purpose of section 6(b) is to safeguard product manufacturers' reputations from unfair public disclosures by the CPSC of inaccurate or incomplete information regarding a product. Specifically, section 6(b)(5) prohibits the CPSC from releasing any information about a product from which the public readily could identify a manufacturer or private labeler unless the CPSC has taken reasonable steps to assure the accuracy and the fairness of the disclosure under the circumstances and has given the manufacturer the opportunity to review and respond to the information.

Nevertheless, Congress has not created a discovery exemption in either the FOIA or the FDCA, although it has demonstrated that it knows how. If drug and medical device manufacturers have a true need for confidentiality of drug and medical device safety analyses, it seems logical that either Congress or the FDA would address that need. It is unlikely that Congress will amend the FOIA to protect such information; rather, Congress has increasingly broadened the disclosure requirements under the FOIA, while narrowing the exemptions. Because disclosure is

238. See generally Zollers, supra note 232. But section 6(b)'s prohibition against disclosure does not apply where there is an adjudicative or judicial proceeding concerning the product, nor does it apply where the CPSC has filed an action against the product to have it declared an "imminently hazardous product." See 15 U.S.C. § 2055(b)(4)(A)-(B); see also GTE Sylvania, Inc., 447 U.S. at 122 (holding that section 6(b) sets forth sufficiently definite mandatory conditions precedent to disclosure under Exemption 3); Lamitie v. Emerson Elec. Co., 535 N.Y.S.2d 650, 652 (N.Y. App. Div. 1988) (holding that the nondisclosure requirement of section 6(b) (5) of CPSA is inapplicable to disclosure "in the course of or concerning a judicial proceeding"); Roberts v. Carrier Corp., 107 F.R.D. 678, 682-83 (N.D. Ind. 1985) (holding that section 6(b) nondisclosure requirement does not apply to civil discovery requests and refusing to apply self-critical analysis privilege to communications between manufacturer and Consumer Product Safety Commission).
239. The 1974 FOIA amendments, in the wake of the Watergate scandal, considerably narrowed the scope of the law enforcement and national security exemptions. Again, in 1976, Congress narrowed the FOIA's incorporation of disclosure prohibitions of other statutes. But in 1986, Congress broadened the exemption for law enforcement information. See BRIDGES & VILLAGE, supra note 162, at 5-6; FRANKLIN & BOUCHARD, supra note 162, § 1.02, at 1-18 to 1-20; see also Zollers, supra
the predominant objective underlying the FOIA,240 it does not follow that the public legitimately can be denied access to product-safety reviews and other self-analytical information submitted to the FDA by drug and medical device manufacturers.

B. Inapplicability Under Wigmore's Privileges Analysis

Moreover, when Wigmore's classical privileges approach241 is applied to the self-critical analysis privilege in the context of the drug and medical device industry,242 at least three elements of the test fail. First, a privilege would not exist with respect to FDA-mandated drug and medical device product-safety analyses because, unlike the medical peer review setting, manufacturers do not have an expectation of confidentiality for such reports; rather, the product-safety analyses are part of the FDA's public files under the FOIA.243 And the FDA is empowered to make public disclosures of such information upon request. As one court acknowledged, "[i]t would make little sense to allow material to be protected from discovery that was not intended to be protected by those originating it."244 Because the public's interest in preserving the free flow of self-evaluative information undergirds the self-critical analysis privilege, there is no foundation for applying the privilege to materials already in the public domain.

Second, confidentiality of product-safety analyses is not necessary to maintain the relationship between drug and medical device manufacturers and the FDA, nor would the ongoing relationship suffer by requiring continued disclosure of product-safety analyses. Drug and medical device manufacturers would have difficulty proving that confidentiality is essential to the full maintenance of their relationship with the FDA, or that their candor with the FDA, mandated in any event by the FDCA, would be sufficiently enhanced by making their communications with

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240. See 1 FRANKLIN & BOUCHARD, supra note 162, § 1.02, at 1-13.
241. See supra notes 97-98 and accompanying text; see also McNab, supra note 8, at 683-84; Flanagan, supra note 20, at 574-75; Bush, supra note 8, at 639-41.
242. See Flanagan, supra note 20, at 574-76; McNab, supra note 8, at 683 (arguing that Wigmore's analysis of privileges does not support recognition of the self-critical analysis privilege). But see Bush, supra note 8, at 639-41 & nn. 281-83 (rebuking those arguments).
243. See, e.g., Peterson v. Chesapeake & Ohio Ry., 112 F.R.D. 360, 363 (W.D. Mich. 1986) (refusing to apply self-critical analysis privilege to investigative analysis because it was not "performed with the expectation that the analysis [would] remain confidential" and had not been kept confidential); Westmoreland v. CBS, Inc., 97 F.R.D. 703, 706 (S.D.N.Y. 1983) (holding privilege waived by failing to treat self-evaluative report as confidential).
244. Peterson, 112 F.R.D. at 363.
that agency—communications that traditionally have been subject to broad public disclosure requirements—now privileged. 245

By virtue of being an FDA-regulated industry, drug and medical device manufacturers must provide complete and accurate disclosures regarding the safety and effectiveness of their products or face serious civil or criminal penalties for noncompliance. 246 It is only by agreeing to comply with such disclosure requirements that these manufacturers have the right to market their products at all. Indeed, if confidentiality were crucial to the maintenance of the drug and medical device industry's relationship with its regulatory agency, either Congress would have provided for appropriate confidentiality provisions in the FOIA, or the FDA would have implemented appropriate exemptions in its own regulations.

While there are no reported FDA cases dealing with the necessity of confidentiality of product-safety analyses to maintain a reporting relationship with the FDA, several cases under the analogous CPSA are instructive on this point. Although product manufacturers subject to regulation by the CPSC have claimed that their mandatory self-critical product analyses must be protected to encourage full and frank communications with the CPSC, 247 courts have rejected that premise as "a bald assumption," noting that "this recital is never explained nor demonstrated." 248 Similar to drug and medical device manufacturers under the FDCA reporting requirements, product manufacturers subject to the police powers of the CPSC do not have discretion to report safety-

245. See Lamitie v. Emerson Elec. Co., 535 N.Y.S.2d 650, 653-54 (N.Y. App. Div. 1988) (refusing to protect from discovery manufacturer's communications with Consumer Product Safety Commission in part because manufacturer did not show that confidentiality was "essential to the full maintenance of the relationship between it and the CPSC or that [its] full candor with the CPSC ... would be sufficiently enhanced by making its communications with [the CPSC] privileged to outweigh the benefits of the truth seeking process from disclosure").

246. See supra note 4.

247. See, e.g., Scroggins v. Uniden Corp. of Am., 506 N.E.2d 83, 84 (Ind. Ct. App. 1987) ("The need to encourage full and frank disclosure of information to the government regarding defective products is of crucial importance to the consuming public. The success of the reporting scheme would be severely undercut if manufacturers feared that their frank disclosures might be used against them in lawsuits.") (quoting Ashley v. Uniden Corp. of Am., Civil No. SA-84-CA-2383 (W.D. Tex. July 23, 1986)).

248. Scroggins, 506 N.E.2d at 86; see also Roberts v. Carrier Corp., 107 F.R.D. 678, 683 (N.D. Ind. 1985) ("The court is simply not persuaded by [these] policy arguments under the terms of the [CPSA].").
related information concerning their products. Rather, product manufacturers are required to report such information immediately. Accordingly, "the incentive (not to violate the law) is the same whether the information is discoverable or not."

Finally, the fourth prong of Wigmore's test—the purported injury that the relationship would suffer by disclosure must outweigh the benefit of disclosure—also fails when attempting to apply the privilege to the drug and medical device industry. Because the FDA plays an increasingly aggressive role in regulating drugs and devices that affect the health and safety of the public, the public's interest in the disclosure of submissions made by drug and medical device manufacturers is undeniably strong. The FDA's action or inaction in response to submissions involving the safety and effectiveness of drugs and devices can have immediate and far-reaching ramifications on the health and safety of the entire nation. As one district court noted, the strong public interest in safe and efficacious health-care products is best "fostered under the watchful eye of public scrutiny—scrutiny effectuated through FDA . . . policies of reporting, inspection, review, and disclosure."

Application of the self-critical analysis privilege not only defeats the strong public policy favoring liberal discovery, but also provides subterfuge for drug and medical device manufacturers by potentially allowing them to conceal crucial and material evidence regarding their knowledge of product defects. As emphasized by the Ninth Circuit in Dowling v. American Hawaii Cruises, Inc., information regarding a manufacturer's safety procedures and its response to a particular safety risk is invaluable to a litigant trying to prove that injuries were caused by the manufacturer's negligence. Applying a discovery privilege to such product-safety reviews would serve as "a nearly insurmountable barrier" for a products liability plaintiff who must prove malice to recover punitive damages. Crucial information a manufacturer's product-safety reviews will reveal includes whether the manufacturer knew of the safety hazard, whether it regarded the safety risk as serious or dangerous, whether it attempted to remedy the problem swiftly and effectively, and whether it maliciously or fraudulently concealed its knowledge of the safety hazards of its products.

251. 971 F.2d 423 (9th Cir. 1992).
252. Id. at 427.
253. Id.
254. Id.
Applying the self-critical analysis privilege to product-safety analyses could "threaten[] the public health and safety by posing formidable obstacles to the search for truth" in drug and medical device litigation.\footnote{255} The privilege not only defeats the strong public policy favoring liberal discovery, but it also provides possible subterfuge for drug and medical device manufacturers wishing to conceal crucial and material evidence regarding their knowledge of product-safety concerns. As Justice Brandeis once poignantly observed, "[s]unlight is . . . the best disinfectant."\footnote{256}

Thus, tested by the foregoing analysis, application of the self-critical analysis privilege to bar discovery of communications between the FDA and drug and medical device manufacturers related to the safety of their products does not appear justified.

C. Other Incentives for Candid and Thorough Product-Safety Analyses by Drug and Medical Device Manufacturers

The suggested policy consideration underlying the self-critical analysis privilege—that the production of self-analytical studies and reports would hamper honest, candid self-evaluative efforts geared toward the improvement of product safety and the prevention of future product defects—is unpersuasive when applied to the drug and medical device industry. It is unlikely that, absent the privilege, drug and medical device manufacturers, charged with the safety and well-being of their consumers, would hesitate to evaluate the safety of their products with candor and thoroughness. Rather, the industry has other strong incentives to investigate thoroughly and continually the safety and effectiveness of its products, the most important of which is the desire to avoid products liability exposure with its concomitant threat of substantial punitive damages awards in today's highly litigious society.\footnote{257}

\footnote{255. Eli Lilly & Co. v. Marshall, 850 S.W.2d 155, 161 (Tex. 1993) (Doggett, J., dissenting).}
\footnote{257. See generally Taylor, supra note 13, at 775-78 & nn.25-35 (1993) (discussing reality of large punitive damages awards, often many times the size of compensatory damages awards, due to information gathered during product-safety reviews); Owen, supra note 21.}
As the Ninth Circuit in *Dowling* wisely noted, simply because safety reviews may be discoverable does not mean that such reviews will be curtailed.\textsuperscript{258} Manufacturers have many incentives to conduct product-safety reviews, and "[t]he most prominent of these is surely the desire to avoid law suits [sic] arising from unsafe conditions."\textsuperscript{259} A related incentive for conducting ongoing product-safety reviews is to maintain one’s reputation in the marketplace.\textsuperscript{260}

The *Dowling* court heeded the Supreme Court’s warning that privileges should be "strictly construed"\textsuperscript{261} and refused to extend the self-critical analysis privilege to a corporation’s routine internal pre-accident safety reviews, noting those reviews "are designed to preempt litigation."\textsuperscript{262} The court declared that it would be "perverse to assume that the candid assessments necessary to prevent accidents will be inhibited by the fear that they could later be used as a weapon in hypothetical litigation they are supposed to prevent."\textsuperscript{263}

Moreover, even in the absence of confidentiality assurances, it is unlikely that safety analyses and investigations will be stifled in an industry traditionally regulated by a federal agency that is committed to policing the health and safety of the public. It is unreasonable to assume that a drug or medical device manufacturer, aware that its product poses a health or safety risk, would misrepresent the hazard to the FDA and knowingly continue to market the drug or device\textsuperscript{264} while facing civil and criminal penalties, including substantial fines, product seizure, withdrawal of marketing approval, product recall, or imprisonment.\textsuperscript{265} These incentives alone outweigh any harm that could result from disclosure.

Additionally, protective orders limiting discovery to litigation purposes will reduce the “chilling effect” of disclosing sensitive business information.\textsuperscript{266} And the evidentiary prohibition against admitting

\begin{footnotesize}
\textsuperscript{258} 971 F.2d at 426.
\textsuperscript{259} Id.
\textsuperscript{260} Id.
\textsuperscript{262} See also Combined Communications Corp. v. Public Serv. Co., 865 P.2d 893, 898 (Colo. Ct. App. 1993) (refusing to apply privilege to pre-accident safety review in wrongful death action).
\textsuperscript{263} *Dowling*, 971 F.2d at 427.
\textsuperscript{264} See, e.g., Scroggins v. Uniden Corp., 506 N.E.2d 83, 86 (Ind. Ct. App. 1987) ("We believe that a responsible manufacturer who discovered a dangerous article and filed a self-critical analysis reflecting the danger, would cease distribution of it... ").
\textsuperscript{265} See discussion supra note 4.
\textsuperscript{266} Federal Rule of Civil Procedure 26(c) gives the courts broad discretion for "good cause shown" to impose protective orders "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense," including an order.
\end{footnotesize}
subsequent remedial measures to prove negligence or other culpable conduct\textsuperscript{267} will provide drug and medical device manufacturers with protection for post-accident investigations at trial.

VI. CONCLUSION

While there is merit underlying the public policy arguments in favor of a self-critical analysis privilege to protect companies required by law to engage in self-evaluation, this discovery privilege should not be available to protect product-safety analyses submitted to the FDA by drug and medical device manufacturers.

Under the FOIA, with a few enumerated exceptions, the public is provided a broad statutory right of access to governmental agency files. Thirty years after its enactment, the FOIA remains a viable and valuable means of public access to governmental information. In light of the pro-disclosure atmosphere of modern government and in view of the Supreme Court’s warning that courts should not exercise their privilege-making authority “expansively,”\textsuperscript{268} courts should not apply the self-critical analysis privilege as a bar to discovering information submitted to the FDA by the drug and medical device industry, absent further direction from Congress. Although it may be somewhat unfair to require that drug and medical device manufacturers produce to a litigant “self-
damning" documents that the FDA has required them to prepare.\(^{269}\) Congress itself has decided that policy issue, and it is not for the courts or state legislatures to second-guess that determination.

Moreover, even without the confidentiality afforded by the self-critical analysis privilege, drug and medical device manufacturers have strong incentives to perform their FDA-mandated product-safety analyses in a candid and thorough manner. Accordingly, the strong public policy of promoting public health and safety will not be thwarted if the privilege is inapplicable to protect these product-safety analyses.