



Better Safe than Sorry

By Mariann E. Butch
and Eric L. Zalud

Keeping safety committee minutes safe and proprietary product evaluations out of the courtroom.

Maximizing Protection of Internal Documents

Product manufacturers and their counsel face a vexing and paradoxical “Hobson’s Choice” as they strive to improve both the quality and the safety of their products. This constant quest for product improvement

results in internal meetings, task forces, quality control teams and the commensurate testing, quality control and product safety documents that emanate from them. The documents created during these processes fulfill their internal purpose of facilitating the process of product improvement, both in terms of quality and safety. However, often they become landmines during subsequent product liability litigation relating to the product.

The confounding and inversely logical nature of this dichotomy is magnified for manufacturers with formal product safety committees. Arguably, these manufacturers are some of the most “safety conscious” in the industry. Their product safety committees meet regularly to review new products and their safety characteristics, review and improve warnings and cautionary statements, analyze and prevent potential claims and conduct other work that will improve product safety and commensurately reduce future claims. Iron-

ically though (and unfortunately), these safety conscious manufacturers, by the very nature of their enhanced safety processes, procedures and self-evaluations, may be creating and generating information and documents that may be used against them for products already out in the marketplace.

Courts, policymakers and various legislatures have struggled with this frustrating double-edged sword, to create doctrines that will facilitate the constant improvement of product quality and safety, while not simultaneously suffocating the free flow of reasonable discovery. These efforts have resulted in a patchwork quilt of doctrines and partial uses of extant privileges that attempt to facilitate those oftentimes conflicting goals. These judicial doctrines and devices range from the oft mentioned, but rarely enforced, privilege of self-critical analysis, to variants on the work product doctrine and attorney-client privilege doctrine.



■ Mariann E. Butch is a partner with the Trial Practice Group of Benesch, Friedlander, Coplan & Aronoff LLP, where her practice is concentrated on issues commonly faced by manufacturers and distributors, including product safety, product liability, distribution issues, contract issues and franchise disputes. Eric L. Zalud is a partner and chair of the Trial Practice Group of Benesch, Friedlander, Coplan & Aronoff LLP in Cleveland, where he focuses his practice primarily upon product liability prevention and litigation.

This article will summarize the state of the law relating to those doctrines, as applied to internal investigations. This article will also point out certain methodologies to protect internal investigations from unnecessary discovery and lessen inhibitions on the internal actions taken to monitor product safety. Finally, the article will provide a summary of helpful points for the practitioner with regard to these issues.

The Current Discovery Climate: Open Season, With a Grudge

The Federal Rules of Civil Procedure provide for the discoverability of information: “regarding any matter, not privileged, which is relevant to the claim or defense.” Fed. R. Evid. 26(b). To resolve disputes over attempts to limit this broad discovery, courts repeatedly rely upon the Supreme Court’s proclamation that: “testimonial exclusionary rules and privileges contravene the fundamental principle that the public... has a right to every man’s evidence.” *Trammel v. United States*, 445 U.S. 40, 50 (1980).

Similarly, while states have shown a willingness to temper the right to broad discovery by enacting statutes creating a privilege pertaining to internal investigations that are conducted in the medical field, no such trend has taken hold in the area of product liability. Despite substantial tort reform efforts throughout the country specifically related to product liability claims, no effort has been made to offer manufacturers similar protection for the investigations undertaken to evaluate information concerning potential safety problems with their products.

The overwhelming bias toward discoverability as it relates to product safety investigations may largely be due to the current public perception of the ethics of the business community, and more specifically, to the (mis)perceived willingness of product manufacturers to obfuscate regarding evidence related to product safety. As one court observed: “society has no interest in fostering deceptive trade practices of the concealment of hazards in the use of products. No doubt the tobacco companies will be held up as the paradigm of the type of corporate marketing misbehavior and research manipulation that should entail liability.” *Hunt v. Air Products & Chemicals*, 2006 WL 1229082 (Mo. Cir. April 20, 2006).

This underlying sentiment can be seen in the court decisions during the past two years related to internal investigations by corporations. Specifically, the burden that must be met before information compiled and discussed regarding product safety, will be protected from discovery by assertion of potentially applicable privileges, has apparently risen significantly in the past two years. Indeed, in certain instances, the burden may have become insurmountable. As a result, to protect the unwarranted disclosure of internal safety investigations or quality control procedures, defense counsel must be aware of the issues involved before taking a position or placing a “discovery label” upon the information being sought. In addition, companies, their in-house counsel and outside lawyers must plan more effectively in advance of such requests, to maximize the possibilities for protecting such information from unnecessary public disclosure.

Katie Bar the Door! Asserting Privilege to Bar the Production of Information

Privileges “are not lightly created nor expansively construed, for they are in derogation of the search for truth.” *United States v. Bryan*, 339 U.S. 323, 321 (1950).

A Threshold Issue: Determining What Privilege Law Applies

Because information that is deemed privileged falls outside the scope of discovery, ensuring that internal product evaluations and safety investigations are protected from discovery is the first line of defense to minimizing unnecessary liability exposure, while simultaneously enhancing product safety. The first challenge in determining whether a privilege exists is determining the substantive privilege law that will apply. Federal Courts look to Rule 501 of the Federal Rules of Evidence for guidance in determining the application of discovery privileges. However, the process is by no means a simple one.

Rule 501 provides that for federal claims, federal statutory and common law will apply. However, the analysis to determine the applicable state law in non-federal cases can be a complex one, as illustrated in *Bondi v. Grant Thornton International*, 2006 WL 1817313 (S.D.N.Y. 2006). The plaintiff in

Bondi asserted claims alleging professional malpractice, fraud, negligent misrepresentation, theft and diversion of corporate assets. The plaintiff sought to compel the production of internal “practice reviews.” Deloitte Touche Tohmatsu had withheld the internal review documents, claiming that they were protected by the “self-evaluative” privilege. The court first observed that Rule 501 of the Federal Rules of Evidence provides that state law applies in diversity cases, and proceeded to apply the appropriate state law concerning privilege. The case was pending in New York, but had been transferred from Illinois. Thus, the court was required to apply the substantive law of Illinois as the transferring forum. Illinois followed the Restatement (Second) of Conflict of Laws which provides that: “[e]vidence that is privileged under the local law of the state which has the most significant relationship to the communication but which is not privileged under the local law of the forum will be admitted unless there is some special reason why the forum policy favoring admission should not be given effect.”

The application of the Restatement by *Bondi* illustrates that it is extremely difficult to prognosticate whether or not a company’s internal investigations will be afforded protection from discovery. *Bondi* found that: “even if the material at issue here is protected by the law of another jurisdiction having a more significant relationship with the relevant communications,” *the information was discoverable under Illinois law* unless Illinois barred discovery of the information or a special reason existed to ignore the law of Illinois as the forum. Illinois had a statutory self-evaluative privilege applicable to accountants. The natural assumption then would be that the information would be protected from discovery. However, while applying Illinois privilege law, *Bondi* found that the Illinois statute providing the privilege did not apply to: “accounting firms that are not registered in Illinois and not providing services to an Illinois client.”

Based upon the difficulty of predicting the substantive law that will determine if a privilege exists and how the chosen law will be applied by the courts, defense counsel must formulate a strategy before conducting investigations that pertain to the safety of a particular product, and must take steps

to preserve the privileges that might be deemed applicable.

Self-Critical Analysis Privilege— The “So-Called” Privilege

It would seem that situations of product safety analysis and quality control review would be ripe for the assertion of the privilege of self-critical analysis. Indeed, these situations seem to fit squarely into the definition of that privilege, the applicability of which was recently cogently summarized in *Wimer v. Sealand Serv., Inc.*, 1997 WL 375661 (S.D.N.Y. July 3, 1997):

[I]f a party has conducted a confidential analysis of its own performance in a matter implicating a substantial public interest, with a view towards correction of errors, the disclosure of that analysis in the context of litigation may deter the party from conducting such a candid review in the future.

Id. at *1, citing *Chemical Bank v. Affiliated FM Ins. Co.*, 1994 WL 89292, at *1 (S.D.N.Y. Mar. 16, 1994); accord, *Trezza v. Hartford, Inc.*, 1999 WL 511673 at *1 (S.D.N.Y. July 20, 1999). Typically, a product safety committee will evaluate complaints with regard to the safety aspects of a product out in the marketplace (or to be marketed), and work toward improving that product's quality and, most importantly, that product's safety. This is conduct that arguably should be encouraged from a societal and policy standpoint. However, the very same court that explained this privilege also noted that the privilege had led a “checked existence in the federal courts.”

As noted, the birth of the self-critical analysis privilege was predicated upon the tenet that the public has an overwhelming interest in allowing a free internal flow of ideas, unimpeded by the threat of the very existence of such an internal analysis. Thus, in *Bredice v. Doctors Hospital, Inc.*, 150 F.R.D. 249 (D.D.C. 1970), the court created a self-critical analysis privilege to encourage internal evaluations that would lead to greater public safety. While the privilege gained some acceptance, a vast majority of the recent cases discussing the self-critical analysis, the self-evaluative analysis and the self-examination privilege refuse to recognize these privileges. This phenomenon is especially true in product liability and safety cases. The cases refusing the privilege do

so by undercutting the very grounds upon which the privilege was founded. Those courts reason that a failure to evaluate product safety would subject the manufacturer to increased liability. Thus, the courts conclude that businesses have a strong financial incentive to conduct such investigations in any event. Consequently, they reason, failing to recognize the privilege will *not* chill the type of internal investigations into product safety that are at issue.

Many courts in various circuits have expressly stated that the self-critical analysis is *not* a viable privilege under federal common law. See, e.g., *Adduntan v. Hospital Authority of Clarke County*, 2005 WL 2074248 (M.D. Ga. 2005) (stating that: “as a matter of federal common law, the self-critical analysis privilege does not exist”). One Ninth Circuit case actually referred to the self-critical analysis privilege as the “so called” privilege, as if to suggest that the privilege has *never* been viable. *Adams v. Teck Cominco Alaska, Inc.*, 232 F.R.D. 341 (D. Alaska 2005). Also, recently, *Granberry v. Jet Blue Airways*, 228 F.R.D. 647, 60 (N.D. Ca. 2005), observed that neither the Supreme Court nor any circuit court had expressly accepted the privilege or defined its scope, but “when confronted with a claim of privilege” the courts instead refused to apply it to the facts before them.

All is not lost though. Some courts *do* recognize the privilege, although often with proscriptions. Generally, courts recognizing the self-critical analysis apply a four part test: 1) the information must result from self-critical analysis undertaken by the party seeking protection; 2) the public must have a strong interest in preserving the free flow of the type of information sought; 3) the information must be of the type whose flow would be curtailed if discovery were allowed; and 4) no document should be accorded the privilege unless it was prepared with the expectation that it would be kept confidential. See *Hickman v. Whirlpool Corp.*, 186 F.R.D. 362, 363 (N.D. Ohio 1999), see also, *In re Fed'n Internationale de Basketball*, 117 F. Supp. 2d 403, 407 (S.D.N.Y. 2000); *Flynn v. Goldman, Sachs & Co.*, 1993 WL 362380 at *1 (S.D.N.Y. 1993); *Cobb v. Rockefeller University*, 1991 WL 222125 at *1 (S.D.N.Y. 1991); *Reilly v. Metro-North Commuter R.R. Co.*, 1995 WL 105286 at *1 (S.D.N.Y. Mar. 13, 1995); *Hardy v. N.Y. News, Inc.*, 114 F.R.D. 633, 640 (S.D.N.Y. 1987).

Courts' strict application of these requirements is exemplified by the courts' refusal to find the existence of a self-critical analysis privilege in *In re Guidant Defibrillators Products Liability Litigation*, 2006 WL 692292 (D. Minn.). In that case, Guidant had established an independent panel of experts to review issues related to a cardiac device. At the time they established the panel, Guidant issued a press release stating that the goal of the panel was to “assess the surveillance of device problems and patient/physician education, with the goal of establishing industry wide guidelines and processes for patient notification systems.” During litigation concerning the device, plaintiff sought: “[a]ny and all documents and communications that refer, relate or pertain to the Independent Panel that was convened to consider information related to the Devices including but not limited to all documents provided to the Independent Panel and any minutes of the Independent Panel.” *Id.* Guidant objected to the request, claiming that: a) the documents and communications of the panel were privileged based upon the self-critical analysis privilege; b) the request was overbroad and unduly burdensome; and c) the request was not calculated to lead to the discovery of admissible evidence, because it was not limited to the recall of failed mechanisms and relevant devices at issue in the litigation. The *Guidant* court denied the existence of a the privilege under the circumstances, stating that “[a]ny fair scrutiny of the press release by the Defendants in this case and the asserted purpose of the Independent Panel establishes that the purpose of the Panel was not evaluative for the Defendants.” *Id.*

In these cases then, courts apply self-critical analysis parameters narrowly—if at all. Nonetheless, it is important to continue to raise the privilege, because the policy arguments behind it remain vital and strong. Finally, even if a party *can* prevail on protecting certain aspects of an internal investigation using the self-critical analysis privilege, a court will most certainly limit the protection to subjective or evaluative content, and not the facts analyzed.

Attorney-Client Privilege: Presence in the Room Does Not Equal Protection

Often, there is essentially a knee-jerk response among clients, and counsel, to

the mere presence of an attorney, equating to, essentially a privilege panacea. To wit, clients and counsel often believe that merely *having an attorney present* at an internal meeting, a product safety meeting, an inspection, or an interview, renders that entire process, and all documents generated from it, completely undiscoverable, via the ironclad strictures of the attorney-

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The existence of a confidentiality agreement may not be sufficient to preserve a privilege.

client privilege. Similarly, in-house counsel often assume that actions taken at their request are protected by privilege. Clients and their counsel, however, are often surprised to learn that courts *do not* apply the privilege in such a blanket fashion in situations involving internal manufacturing processes, inspections and investigations.

The challenges of using in-house counsel to shield information using the attorney-client privilege are highlighted in *Adams v. Teck Cominco Alaska, Inc.*, 232 F.R.D. 341 (D. Alaska 2005). In that case, internal reports prepared by a mining company were forwarded to its parent company to be compiled into a single report. The final report was then given to the general counsel for the parent company, so that the in-house counsel could provide legal advice to the parent company, on all aspects of risk management. Keeping in mind that the burden of establishing a privilege falls upon the proponent of the privilege, the court in *Adams* found that the mining company had *not* met its burden. First, the court reasoned, the mining company had not established an attorney-client relationship with the general counsel of its parent. Secondly, the court determined that the communications were not for the purpose of obtaining counsel, but were routine reports compiled for some modicum of circulation, rather than disclosures made in confidence. Moreover, the reports were not held in confidence, since they were publicly

available throughout the company on the computer network. In short, *Adams* concluded that the mere fact that the information was eventually forwarded to an attorney *did not* cause it to transform into a confidential communication worthy of protection. *Id.* at 345. The privilege then does not automatically apply in all situations in which an attorney is present. Certain factual matters raised during discussions with an attorney may be discoverable in and of themselves, if they are clearly delineated from attorney-client consult. Further, the dissemination of the reports is a factor that will weigh heavily when determining privilege

Work Product Privilege: Pinpointing the Scent of Litigation

Another putative weapon in the arsenal of non-disclosure in these cases is the work product doctrine. The critical linchpin points of any analysis of materials that may be protected by the work product doctrine primarily involve two facets. Most importantly, courts make determinations as to when there was an “anticipation of litigation.” Courts also analyze issues as to extension of the scope of this privilege to documents generated by persons other than attorneys. In these cases, if the work is done at the behest of counsel, there is generally a strong argument that materials prepared by paralegals, consultants and other non-lawyers in the pre-litigation process, can be protected by this privilege. As one district court recently summarized: “The protective ambit of the work product doctrine extends to materials prepared by an attorney’s consultant.” *Drayton v. Pilgrim’s Pride Corp.*, 2005 WL 2094903 (E.D. Pa. 2005).

Whether an investigative report or analysis will be protected is determined in large part by the communications concerning the commissioning of the investigation, and the contents of the report itself. To determine whether the work product privilege applies, courts will begin by focusing upon the purpose of the investigation being conducted. Courts then proceed to conduct a balancing test based upon public policy considerations and the needs of the litigant. This process and its pitfalls are exemplified in *Wells Dairy, Inc. v. American Industrial Refrigeration*, 690 N.W.2d 38 (Iowa 2004). In that case an explosion at an ice cream

plant caused the dairy to hire a consultant to evaluate the dairy’s refrigeration system. The dairy presumed that the report prepared by the consultant would be confidential. During discovery the dairy was served with a motion for “any and all reports prepared as a result of any investigation relating to the facts of the lawsuit.” The plaintiff learned of the existence of the report during a deposition and sought to compel its production. The dairy objected, arguing that the document was protected by both the work-product and self-critical analysis privileges. The trial court compelled the production of the document, finding that it was prepared for business purposes and not in “anticipation of litigation.” In doing so *Wells* applied the standard used by the Eighth Circuit in *Simon v. G.D. Searle & Co.*, 816 F.2d 397, 401 (8th Cir. 1987), which had been excerpted directly from Wright and Miller, *Federal Practice and Procedure* §204:

[T]he test should be whether, in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation. But the converse of this is that *even though litigation is already in prospect, there is no work product immunity for documents prepared in the regular course of business rather than for purposes of litigation.*

Id. (emphasis added).

Plaintiff’s counsel challenged the use of this standard under Iowa privilege law, which mirrors and is predicated upon the federal rules. As a result, the appellate court in *Wells* conducted an in depth analysis, which illustrates the various tests applied by the courts throughout the country to determine when a document will be deemed “prepared in anticipation of litigation.” Numerous courts apply a test that requires a finding as to the “essential” or “motivating purpose” behind the creation of the document or investigation. *Id.*, at 44–46. These courts have historically found that the protection is afforded only when the primary purpose was to “assist in pending or threatened litigation.” See, e.g., *Aull v. Cavalcade Pension Plan*, 185 F.R.D. 618, 628 (D. Colo. 1998). Under this standard, if the primary motivating purpose behind the creation of the document

is deemed to be a routine business purpose, then the privilege does not attach. The *Wells* court noted that this test is simply too restrictive, and has been rejected by such courts as the Second Circuit, in *United States v. Adlman*, 134 F.3d 1194, 1198 (2d Cir. 1998). Courts such as *Adlman* recognize that managing litigation itself is a business purpose that could ultimately eviscerate the privilege. *Adlman* reasoned that a document should not be denied privileged status merely because it was prepared to assist in a business decision. *Id.* at 1199. The privilege should attach if the document was obtained or prepared “because of the prospect of litigation.” *Id.* at 1202, quoting Wright and Miller (emphasis added). Thus, documents prepared for litigation purposes that resolve or evaluate business operations are not automatically stripped of the privilege. The essential inquiry under the “but for” test becomes, “Would the document have been prepared but for the prospect of litigation?”

The investigative report in the *Wells* case failed both tests because of poor pre-investigation planning and report drafting. The dairy, in commissioning the investigation, stated several goals. However, the expressly stated goals had “nothing to do with the explosion or the manner in which litigation should be addressed.” *Wells* at 48. In fact, the report itself expressly stated that “investigating and evaluating this incident was not directly in the investigator’s scope of work...” *Id.* Based upon the contents of the report itself, it is not surprising that both the trial and the appellate courts found that the investigation had been conducted for business purposes, despite testimony by employees of the dairy detailing the use of the report to respond to litigation claims. *Id.*

Waiver of Privilege: You Don’t Know What You’ve Got ‘til It’s Gone

The decision in *Wells* highlights yet another pervasive problem in successfully asserting privileges—waiver. A fundamental issue in determining whether any type of privilege claim can be made as to an internal testing, quality control, or product safety documents is whether the document itself, or the information contained in the document, was intended by the manufacturer to be kept confidential. Consequently, items

such as investigative reports and testing documents disseminated to third parties without proprietary protection in the normal course of business may lose the privilege that they might otherwise have by the very virtue of the methodology of their dissemination.

It is well established that: “[a]ny voluntary disclosure by the client to a third party [of the document or information protected by attorney client privilege] waives the privilege.” *United States v. Jones*, 696 F.2d 1069 (4th Cir. 1982). “An intent to waive [the attorney-client] privilege is not necessary for such a waiver to occur.” *In re Grand Jury Investigation*, 604 F.2d 672, 675 (D.C. Cir.), cert. denied, 444 U.S. 915 (1979). For example, in the *Wells* matter discussed above, the dairy disclosed the contents of the investigation that it sought to declare privileged during the course of the litigation concerning its production. Accordingly, plaintiffs sought to have the discovery dispute rendered moot, due to waiver principles.

Manufacturers of consumer products are frequently confronted with the same decision. For example, to defend the safety of their products, manufactures both “voluntarily,” or pursuant to regulations, are required to make disclosures to the Consumer Product Safety Commission regarding the safety of their products. Similarly, manufacturers of medical devices may be required to make certain disclosures to the FDA. Both these agencies have mechanisms by which the manufacturer can seek to protect the confidentiality of information produced to the respective governmental agencies. See, e.g., 16 C.F.R. §1115.15 and 1015.18(c) and 5 U.S.C. §§552. However, these mechanisms are limited in scope and do not always preserve any privilege that may have attached to the documents. Similarly, the existence of a confidentiality agreement may not be sufficient to preserve a privilege based upon the confidentiality of the underlying communications. For instance, in *Bowne of New York City, Inc. v. AmBase Corp.*, 150 F.R.D. 465, 480 (S.D.N.Y.1993) the court found that: “even if the disclosing party requires, as a condition of disclosure, that the recipient maintain the materials in confidence, this agreement does not prevent the disclosure from constituting a waiver of the

privilege; it merely obligates the recipient to comply with the terms of any confidentiality agreement.”

The Tenth Circuit opinion in *In Re Qwest Communications International, Inc.*, 450 F.3d 1179 (10th Cir. 2006), provides a multi-jurisdictional review of developing federal case law regarding attempts to apply the concept of a “selective privilege waiver” to privileged communications provided to governmental and regulatory agencies. In that case, Qwest had supplied documents to the SEC and DOJ that were protected by the attorney-client privilege and the work product doctrine. Qwest subsequently urged the court to accept the doctrine of “Selective Waiver.” Noting that a vast majority of jurisdictions have rejected the concept as it applies to the attorney client privilege, the *Qwest* court essentially adopted the rationale used by the D.C. Circuit:

[t]he client cannot be permitted to pick and choose among his opponents, waiving the privilege for some and resurrecting the claim of confidentiality to obstruct others, or to invoke the privilege as to communications whose confidentiality he has already compromised for his own benefit. . . . We believe that the attorney-client privilege should be available only at the traditional price: a litigant who wishes to assert confidentiality must maintain genuine confidentiality.

Permian Corp v. United States, 665 F.2d 1214, 1220–21 (D.C. Cir. 1981). While, as noted in *Qwest*, some courts have applied the concept to the production of “opinion” attorney work product, courts are not so inclined when the work product does not contain attorney opinions. As the Sixth Circuit in *In re Columbia/HC Health-Care Corp. Billing Practices Litigation*, 293 F.3d 289 (6th Cir. 2002) commented: “even more than attorney-client privilege waiver, waiver of the protections afforded by the work product doctrine is a tactical litigation decision.”

What Can Be Done? Practical Lessons to Maximize Protection Preserve Objections Even if They May Turn Out to Be Inapplicable

One message should be loud and clear here: Do not waive any possible privilege or objection. The presumption that a privilege, such as the self-critical analysis priv-

ilege, will not apply because of its limited acceptance can create an almost subliminal decision not to assert the privilege. However, the only thing that can be said with certainty about the self-critical analysis privilege is that, if counsel fails to assert the privilege at the time of the first request, it will not apply and will be lost. Beyond that, defense lawyers need to continue to strive

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diligently to have the privilege accepted in the context of product liability litigation. The grounds for recognizing the privilege are the same as those accepted in the medical community, and when the smoke clears, courts and legislatures may be ready to recognize that penalizing manufacturers for timely investigations and internal analysis *does* chill the process and *does not* promote public welfare. Hopefully, the cases cited in this article will help facilitate that process.

Enter Into Protective Orders Early in the Litigation

Protective orders are an essential containment tool in the event that the production of internal safety evaluations is compelled. It is advisable to enter into a protective order at the onset of litigation, to protect all proprietary and confidential information if possible. The courts, however, and particularly federal courts, have begun to resist blanket confidentiality orders that restrict public access to information. For example, in *Winstanley v. Royal Consumer Information Products*, 2006 WL 2523437 (D. Ariz. 2006), the court ordered Royal to produce documents evidencing communications between Royal and the CPSC. Royal sought a court order limiting the assumption that documents obtained during discovery are presumptively public. The court noted that “the fruits of pre-trial discovery are, in the absence of a court order to the contrary, presumptively public,” and that

for the court to issue such an order, the burden fell upon Royal to show that good cause existed pursuant to Rule 26(c).

Royal argued that in certain jurisdictions the communications would be privileged from production pursuant to the self-critical analysis privilege. Accordingly, Royal argued that its rights would be unfairly prejudiced if a protective order was not issued, because there were courts “where there is either litigation pending or the possibility of litigation” in jurisdictions that might be inclined to grant a privileged status to the documents. The court denied the request, stating that Royal had failed to provide specific instances of litigation in states that recognized the privilege and that the claimed prejudice was “simply too speculative to satisfy the good cause requirement.” *Id.*

Presume That Information Given to Anyone, Is Information That Will Be Available to Everyone

Despite efforts to the contrary, providing internal investigations relating to reports of product complaints to agencies such as the CPSC places the documents in the public domain and outside defense counsel’s control. The pressure to demonstrate to the CPSC that the manufacturer’s products are safe, in order to avoid a costly recall, is great. Unfortunately, the cost of making those same documents available to every plaintiff’s counsel that wants to bring a product liability action against the manufacturer is also great.

The courts place the burden upon the manufacturer to preserve its privileges. It is unequivocally appropriate to take steps to help preserve privileges when determining how to communicate with the CPSC and other governmental agencies. It is a manufacturer’s obligation to maintain awareness that once the document has been produced, it in all likelihood becomes discoverable. Counsel should carefully scrutinize each document to be produced to the agency, with an eye toward a focused response. Unessential documents need not be produced. For example, sometimes the *result* of the investigation, rather than production of the underlying internal report, may suffice. It is also appropriate to deferentially assert the privilege with the agencies if necessary. Alternatively, if for strategic

reasons, counsel and client determine that the document must be produced, counsel should develop a plan to defend the document when it resurfaces during subsequent litigation.

Timing and Relevancy Are Everything—Do Not Assume All Documents Related to the Product Investigation Are Discoverable

The role of the “actors” and the character of the documents they generate may change as litigation approaches. Thus, materials generated by a single person or entity that at one point in the product sequence would be discoverable may, as supplemented after the fact, essentially convert into privileged documents by virtue of the anticipation of litigation ensuing. For example, in *Drayton v. Pilgrim’s Pride Corp.*, 2005 WL 2094903 (E.D. Pa. 2005), Pilgrim’s Pride hired Ernst & Young as a consultant to prepare a food safety review before and after Pilgrim’s Pride was to recall a product suspected to have caused a listeriosis outbreak. On August 23, 2002, Ernst & Young produced a report entitled “Food Safety Review,” which was to include “a risk assessment within the food safety process, identify and evaluate controls over significant risks and to test the controls over the most significant risks.” After the recall began in October 2002, counsel for Pilgrim’s Pride authored an engagement letter requesting Ernst & Young to assist in any litigation involving the recall.

Pilgrim’s Pride did not contend that the report prepared prior to the litigation was prepared in anticipation of litigation, but *did* contend that the documents generated *after* the outbreak *were* covered by the work product doctrine, because “its counsel engaged the consultant to assist him in any litigation arising out of the outbreak.” *Id.* at *1. Plaintiffs argued that the engagement was a “disingenuous preemptive attempt to shield otherwise discoverable material.” *Id.* at *2. The court noted that drawing the line between what would have been a continuing safety review and documents prepared in anticipation of litigation might pose a difficult proposition. The *Drayton* court did not expressly face the proposition, but did not order the production of the documents prepared after the litigation retention. Instead, the court

found that plaintiffs had not shown that they had a “substantial need” for the documents prepared after the outbreak.

Counsel for Pilgrim’s Pride did not fall into the trap of lumping the Ernst & Young engagement into a single pot in evaluating discoverability and privilege. Also, the action taken by Pilgrim’s Pride to clarify and document the changing role of the consultant, further illustrates the need to adhere to the next practice pointer discussed below.

Designate Investigations Related to Litigation as Having Litigation Implications

As noted above, the most common reason that the work-product doctrine does not attach to internal investigations is that the documents comprising the investigation state (implicitly or explicitly) that the purpose for the investigation was a “business purpose.” Obviously, simply intoning that the document was prepared “in anticipation of litigation” does not make it so as a matter of law. Contrarily though, stating in the document that it was generated for business evaluation generally *will* subject it to production. Thus, counsel and clients should make certain that, where applicable, the stated objective of any internal or external investigation clearly supports the assertion that it is being prepared to respond to and address pending, future or nascent litigation. Doing so has several benefits. First, the designation supports the assertion that the investigation was privileged if counsel chooses to make the argument. Secondly, if the production of the document is compelled, counsel can still argue that it cannot be introduced into evidence, because it constitutes evidence of subsequent remedial measures under Rule of Evidence 407 (depending upon the temporal relationship of the product development cycle to the litigation). However, preventing a jury from considering internal investigations based upon federal and state evidentiary

rules is no easy task. Such evidentiary rules commonly bar the use of evidence of subsequent remedial measures to discourage the development of safety features when the claim asserted sounds in negligence. To that effect, in *Hyjek v. Anthony Industries*, 944 P.2d 1036 (Wash. 1997), the court observed that while the doctrine clearly applies when the product liability action is based in negligence, the applicability of the rule “varies from state to state and across the federal circuits” as to actions asserted under a strict liability theory. *Id.* at 1038. *Hyjek* also provided an enumeration of state courts applying Rule 407 to product liability actions and a list of statutory schematics relating to subsequent remedial measures. Importantly, the analysis by the *Hyjek* court concerning the decision to amend the Federal Rules to make Rule 407 applicable to strict liability cases provides a helpful format to argue for similar treatment in state courts. As the court summarized, “regardless of the theory used to require a manufacturer to pay damages, the deterrent to taking the remedial measures is the same, namely the fear that the evidence may ultimately be used against the defendant.” *Id.* at 1040.

Don’t Forget to Turn the Tables

Finally, if all else fails, and the document is admitted into evidence, do not despair. Instead, seek to extract positives for the client by its introduction. Often, these documents can be used to show that the manufacturer takes safety concerns seriously, investigates them thoroughly and responds appropriately. This argument goes a long way with juries and courts that may currently be predisposed to the contrary.

Conclusion: Be Alert, and Assert, Assert, Assert

The lesson for counsel as to maximizing protection of internal investigative documents, product safety committee related

documents and quality control documents in product liability actions is to maintain a heightened awareness of the legal doctrines and factual aspects that exist in these situations. All the privileges and doctrines discussed in this article should be considered in every discovery and pre-litigation situation. Similarly, when dealing with governmental agencies such as the CPSC and FDA, counsel should strive to maximize the statutory and regulatory protections afforded by those agencies to enhance and broaden the protection of confidential information. Simultaneously, while dealing with those governmental agencies, counsel and clients must realize that, if not all, then certainly some, of the documents that are being produced to the governmental agency will be discoverable in subsequent product liability litigation. Consequently, responses to these agencies should be specifically focused upon the exact, specific questions and inquiries made. Counsel and clients should also be cognizant of the applicability—or non applicability—of these doctrines and privileges during attorney’s consult on product liability prevention related matters, product safety committee meetings and internal investigations and witness interviews. As noted, privileges such as the self-critical analysis privilege, although infrequently recognized and often emasculated, should nonetheless be asserted. There is nothing to lose by asserting the privilege. Some courts *have* recognized it, although they are reluctant to apply it. Nonetheless, it has a viable basis and sound policy and societal considerations, which may help aid courts in broadening its applicability. Once the information and/or documents are out, they cannot be brought back in—never. Consequently, a heightened awareness and aggressive, reasoned assertion of these privileges can only help counsel’s manufacturing clients, both in litigation and in furthering the development of better and safer products. 