UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GRAND JURY SUBPOENA	)	M.B.D. NO. 04-10040-WGY

MEMORANDUM

YOUNG, C.J. March 16, 2004

I. INTRODUCTION

By Order dated February 25, 2004 [Doc. No. 10, M.B.D. No. 04-10040-WGY], this Court DENIED two Motions for a Protective Order [Doc. Nos. 3 and 5, M.B.D. No. 04-10040-WGY]. This Memorandum sets forth the analysis that led to the Court's order.

II. BACKGROUND

This case involves a federal grand jury investigation of a corporation's distribution in interstate commerce of an allegedly adulterated and misbranded device, in violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-97. The grand jury issued an investigatory subpoena duces tecum, seeking testimony from the corporation's attorney, and notes he took during various conference calls involving executives of the corporation and officials from the Food and Drug Administration ("FDA"). The corporation, its attorney, and his law firm moved

for a protective order, barring the grand jury from compelling production of the notes, on the ground that the notes are entitled to protection from disclosure as attorney work product. See XYZ's Motion for a Protective Order [Doc. No. 3, M.B.D. No. 04-10040-WGY]; Attorney's and Firm's Motion for a Protective Order [Doc. No. 5, M.B.D. No. 04-10040-WGY]. The government argued that the work product doctrine does not apply, that any work product "privilege" has been waived, that the crime-fraud exception to the work product doctrine eliminates any entitlement to protection, and that the government has made a sufficient showing of need to justify overcoming any work product immunity. For the reasons stated below, the Court denied the motions for a protective order.

As is typical with cases involving grand jury matters, the papers in this case have been filed under seal, and the Court has taken appropriate steps to preserve the required level of confidentiality. In keeping with the need for secrecy in grand jury cases, see, e.g., Fed. R. Crim. P. 6(e), the Court shall use fictitious names for the parties, and shall strike a careful balance between providing sufficient factual background to explain this decision and related ones that will follow and limiting factual discussion to preserve secrecy. The Court by and large uses the same fictitious names that the First Circuit used in its recent decision in In re Keeper of the Records, 348 F.3d 16 (1st Cir. 2003), which involved an appeal of this Court's

ruling on subpoenas that the grand jury had issued on previous occasions. Just as the Court does not refer to individuals by name, so it does not necessarily refer to them by their actual gender. References to court documents, unless otherwise noted, refer to documents filed in a related case, In re Grand Jury Subpoena, M.B.D. No. 02-10318-WGY.

The following facts are largely undisputed. The Court notes the source of factual averments, and clarifies which facts the parties dispute. Where appropriate, the Court draws reasonable inferences from undisputed facts.

A. The Widget

In 1998, XYZ Corporation ("XYZ")[1] sought to market a newly developed device (the "widget"), which qualified as a Class III device under the FDCA. See Decl. of Assistant U.S. Att'y Pierce Prosecutor ("Prosecutor Decl.") [Doc. Nos. 48-50] ¶ 1(c). XYZ expected sales of the widget to increase gross revenues by a substantial amount. Id. ¶ 1(d).

Like all Class III devices, the widget was sold with an accompanying label, which provided directions for use, warnings, and specifications for how well the device was expected to perform under certain stresses. Id. ¶ 1(c). The widget had especially good specifications for a particular quality, which

[1] To better ensure that readers of this opinion cannot determine the identity of the parties involved, the Court uses "XYZ" to refer to subsidiaries of XYZ Corporation as well.

the Court will refer to as "hardiness." Id. Should a device fail to meet its hardiness specifications, it may cause harm to a patient, possibly even death, although in many cases a failure has no impact. See id.

The widget received FDA approval in the fall of 1998, and commercial shipments began immediately. Id. XYZ and its co-venturer, Smallco, had already built and stockpiled a substantial number of widgets before approval. Id. ¶ 1(f). Such pre-approval activity is common, and the FDA apparently has no objection to it.

Once produced, items were held in finished goods inventory until shipped to customers. Id. ¶ 1(d). After manufacture and prior to shipping, some products were subjected to "final functional testing" ("FFT") -- internal testing of the finished product to ensure that the products produced were continuing to meet specifications. Id. FFT was used to comply with the FDA's Quality System Regulations, under which XYZ had to validate processes that cannot be fully verified by inspection and test. Id. ¶ 1(e)-(f); see 21 C.F.R. § 820.75. Thus, XYZ had to demonstrate through internal testing, using a well-defined testing methodology, that its manufacturing process was consistently producing devices that met specifications. Id. ¶ 1(e).

XYZ's Premarket Approval Application ("PMA") represented that its FFT methodology required demonstration, with 95%

confidence, that 99.9% of the widgets would meet certain standards of hardiness under certain conditions. Id. Thus, if one out of 80 widgets tested failed, the confidence requirement could not be met. Id.

B. Problems in the Widget's Manufacturing Process

During the spring of 1998, XYZ validated the manufacturing processes for widgets for all specifications, in virtually all sizes. Id. Later, but before FDA approval, a widget failed FFT for failing to meet hardiness requirements. Id. ¶ 1(f). The device was examined, although the cause of failure was not determined, and no further steps were taken to discover or correct the cause of the failure. Id.

Shortly after shipping to customers began, two more widgets failed on hardiness grounds during FFT. Id. That day, another widget failed during testing of widgets from the batches that produced the first two faulty widgets. Id.

Within the first two weeks of sales, XYZ started to receive reports from doctors and hospitals of hardiness-related failures, seventeen of them in the first week. Id.; id., Ex. 3, at 80-81 (transcript of grand jury testimony by a quality engineer for XYZ). XYZ characterizes the complaints in the first two weeks as "a handful . . . among the thousands of [widgets] in use." Decl. of XYZ Defense Att'y Allan Advocate ("Advocate Decl.") [Doc. No. 65] ¶ 10.

Shortly thereafter, a fifth widget failed FFT on hardiness grounds. Prosecutor Decl. ¶ 1(f). XYZ engineers pulled 200 widgets for testing, produced just before and just after the date of this device's manufacture. Id. Upon testing, 10% of the devices suffered hardiness-related failures. Id. Among tested devices in the most popular size, the failure rate was 12%. Id.

XYZ also monitored field complaints and Medical Device Reports ("MDRs")[2] in conjunction with its engineering investigation, and conducted health risk assessments for the widget. Advocate Decl. ¶ 11. Field complaints revealed a failure rate of roughly 0.4%-0.6%, and among those failures, very few prevented or interfered with the device's accomplishment of the purpose for which it was designed, and very few caused injury to a patient. Id. The complaint file records were provided to the FDA during an inspection. Id.

XYZ urges that there seemed to be little reason to remove the widget from the market. The company conducted a survey of physicians who reported hardiness failures, and discovered that the majority of them continued to support the product and considered the problems minor, infrequent, and manageable. Id. ¶

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[2] The FDA requires that an MDR be filed when it appears that a device has malfunctioned in such a way that it "may have caused or contributed to a death or serious injury, or . . . has malfunctioned and that such device . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 U.S.C. § 360i(a)(1); see generally 21 C.F.R. Part 803.

12. A contemporaneous search of the FDA's MDR database for information regarding the principal competing products revealed that widgets experienced a lower failure rate than most of those products, and that for all of those products, when they did fail, they did so in a way more likely to cause harm than the widgets' hardiness failures. See id. ¶ 13. As XYZ describes the situation, "[t]he favorable results from the field contrasted with internal 'bench-test' results of certain samples of units -- using a procedure that differed substantially from the conditions of field use -- that showed high [hardiness failure] rates." Id. ¶ 14.

XYZ stopped manufacturing widgets in the fall of 1998, so it could determine what the problem was. Prosecutor Decl. ¶ 1(f). It continued shipping the devices it had already made, however, and during the next month, sent out an average of roughly $1,500,000 worth of widgets each day. Id. ¶ 1(g). The decision to keep shipping was made by XYZ's top management, including XYZ's CEO. Id.

When XYZ's Division President testified before the grand jury, he admitted that XYZ was taking a gamble that the problem would turn out to be one that did not affect the product such as to require a recall and that no one told XYZ's customers about that gamble. Id., Ex. 2, at 96 (transcript of grand jury testimony by XYZ's Division President). XYZ's Division President

also admitted that XYZ had no idea how much of the inventory was affected by the problem. Id. at 98.

XYZ's Division President went on to say that within the two weeks after XYZ stopped manufacturing new widgets, it had enough data to conclude that the problem applied to the entire widget product line. Id. at 115-16. Moreover, XYZ had neither identified the problem nor developed a means of screening out all device failures, and internal tests of hundreds of other devices continued to corroborate the initial test failures, demonstrating how widespread the hardiness problem was. Id. ¶ 1(g).

The government maintains that at this point, XYZ's top management knew, with the concurrence of outside counsel, that it was shipping adulterated and misbranded widgets, in violation of the FDCA. Id. ¶ 1(h). There is support for this contention. XYZ's Division Vice President of Regulatory Affairs ("XYZ's Division Regulatory VP"), who reported to XYZ's Division President, testified that roughly two weeks after manufacturing stopped, she thought the widget was adulterated, because the product label specification for hardiness was no longer true. See id., Ex. 4, at 50-51 (transcript of grand jury testimony of XYZ's Division Regulatory VP). She conveyed this to XYZ's Division President, who was in constant discussions with XYZ's CEO at the time about whether the widget should be recalled. See id., Ex. 2, at 131-33. At the time, XYZ's Division President felt they were moving toward recall because the widget was not

performing at the level the label indicated for an important performance characteristic. Id. at 132-33.

C. The Dear Doctor Letter

Shortly after manufacturing of the widget ceased, and around the time that XYZ first retained Arthur Attorney ("Attorney") and his law firm ("Firm") to seek his advice about the widget problem, Investco, an investment firm, learned about doctor reports of widget hardiness failures and contacted XYZ to find out whether a recall was likely. Id., Ex. 16 (copy of an Investco investment research report). Although Investco accepted XYZ's assurances that a recall was unlikely to occur, and the investment firm did not change its sales estimates for widgets, the government urges that the field failures and recall rumors prompted XYZ to send out a draft letter to physicians (the "Dear Doctor Letter"). Id.; id. ¶ 1(h). The Dear Doctor Letter circulated amongst XYZ employees and counsel for several days. Id. ¶ 1(h).

The Dear Doctor Letter urged physicians to follow label instructions, and implied that reports of failures were attributable to physicians' failure to do so. See id., Ex. 17 (copy of the Dear Doctor Letter). The government emphasizes XYZ's failure to disclose that internal tests revealed failures even when widgets were used as instructed, that the data no longer supported the hardiness claim on the label, that these

facts had led XYZ to cease manufacturing the widget, and that widget failures could be expected even under conditions of proper use. Id. ¶ 1(h). To the extent that the XYZ principals knew they were shipping adulterated or misbranded products in violation of the FDCA (if in fact they were), they obviously did not convey that either. See id., Ex. 17.

D. XYZ's Initial Decision to Withdraw or Recall the Widget, and the "Date A Call"

A few weeks after shipping stopped, XYZ's top management, with concurrence of in-house counsel, decided that withdrawing the widget from the market would be the best course of action. See id. ¶ 1(i). XYZ was no closer to identifying the cause of the failures, see id., Ex. 2, at 133, 142, and had been unable to develop a quality control test that could screen out all potential widget failures, see id., Ex. 2, at 143. Continuing corroboration of the initial FFT results was also a factor. See id., Ex. 4, at 50. Moreover, there were continuing reports from physicians of field failures, although on a much more limited scale than the internal test results might have suggested would occur. Id. ¶ 1(i). Although the government does not mention it, there is also evidence that doctors wanted XYZ to keep the product on the market. See id., Ex. 2, at 131. XYZ describes its decision as a "conservative course of conduct." Advocate Decl. ¶ 14.

The next morning, XYZ's CEO informed XYZ's Division President and another high-ranking executive that he had decided to recall the widget. See Prosecutor Decl., Ex. 2, at 130-31. That afternoon, XYZ convened a "Field Action Committee" -- a committee of top-level XYZ employees -- to determine whether the product should be recalled or withdrawn. Id. ¶ 1(i). A withdrawal would merely mean ceasing further sale and shipping of the product, whereas a recall would, in addition, take back all devices already sold and provide refunds. The Committee rubber-stamped XYZ's CEO's decision to recall. See id., Ex. 2, at 131-32. XYZ employees were thereafter instructed to begin preparing recall packets for the widget. See id. at 131. Later that day, XYZ shipped over $2,000,000 worth of widgets. Id. ¶ 1(i).

XYZ's supply agreement with Smallco, its supplier and co-venturer, required it to consult with Smallco before taking a field action such as a withdrawal or recall, although the ultimate decision whether to take such an action remained within XYZ's sole discretion. See Advocate Decl. ¶ 14; id., Ex. 9 (copy of the agreement). Smallco's CEO and Smallco's Chief Technical Officer ("CTO") objected strongly to withdrawal or recall. Id. ¶ 15. They firmly maintained that federal law did not require a recall, arguing that the widget was not malfunctioning in any material way. Id. ¶¶ 15, 18.

Thus, on the next day, "Date A," a conference telephone call (the "Date A Call") took place involving:

(1) XYZ's CEO;

(2) XYZ's Vice President for Regulatory Affairs ("XYZ's Regulatory VP");

(3) XYZ's Chief Development Officer ("CDO");

(4) XYZ's Division Regulatory VP;

(5) Attorney;

(6) Smallco's CEO;

(7) Smallco's CTO;

(8)) Harold Hippocrates ("Hippocrates"), Smallco's medical advisor, a former investigator for XYZ on various clinical trials, a renowned physician, and since the fall of 1998, a consultant for XYZ on the widget hardiness problem.

Id. ¶ 1(j). The XYZ executives were in XYZ's CEO's office. Each of the other participants was in a separate place. Id. Unbeknownst to all except Smallco's CEO, a Smallco employee tape recorded substantial portions of the conversation, at her behest. Id. Each side in this case has provided a transcript of the call. Id., Ex. 18; Advocate Decl., Ex. 13.

Attorney and the XYZ executives, who took the position that the product should be withdrawn or recalled, were in a fairly defensive posture, because of the Smallco executives' forceful opposition to either course. See generally Advocate Decl., Ex. 13. XYZ's CEO's position was as follows: He believed that a recall or a withdrawal was necessary, because "we are shipping product . . . that does not meet spec." Id. at 7. Further, "it is not arguable that if it doesn't meet the spec that we have to

have some reason to continue shipping it that right now I don't understand or know about." Id. Still, "the issue is not one of safety," but rather "is an internal issue of our manufacturing process failing to produce a product that meets specs." Id. Perhaps most problematic for XYZ, he said "we still find ourselves in a situation where we're in violation of the code and we're in fact shipping adulterated product and we cannot do that." Id. at 7. Smallco's CTO responded, "We're not." Id.

Attorney took the same line as XYZ's CEO. See id. at 1-3, 7-8, 18-20, 24-26. There are multiple interpretations of Attorney's statements, because there were times when he was talking about what the FDA's legal position would be, although he was also arguing that the FDA would win. Moreover, in context, he was trying to win the Smallco executives over to his client's (XYZ's) position, so his statements may not be a reliable indication of his opinions. Nonetheless, the Court finds[3] that the best understanding of his position is that he thought XYZ was

[3] It is appropriate to speak of "findings" here. The two primary questions in this case are whether Attorney's notes fall under the work product doctrine and whether the crime-fraud exception applies. XYZ, Attorney, and Firm have the burden to establish that the doctrine applies, so the Court must interpret the facts that they have submitted to determine the matter, giving due consideration to information that the government submits. On the other hand, the government could meet its burden to show that the crime-fraud exception applies by establishing that a reasonable person could accept the government's argument based on the facts the government presents (unless facts presented by the parties resisting disclosure make such an argument untenable). The Court does not ultimately reach the crime-fraud issue here, however.

shipping adulterated product, regardless of whether there were increased clinical events in the field. See id. at 7-9 ("It's our knowledge of the known and avoidable defect in the product for which that segment that is in existence as [XYZ's CEO] said represents adulteration is how it would be characterized by the [FDA], but clearly a feature to the product that is contrary to the representations that we have made to the FDA in our pre-market approval application."); id. at 18 ("[W]hat you have here is a situation where your device is adulterated by virtue of your manufacture of a defective device for which approximately 10% of that production is known to be defective . . . . I'm making the case for FDA. That is a fact and if I have to litigate that on behalf of the Food and Drug Administration, my client, you're not going to be prevailing on this. And the health issue is a separate issue. I'm just talking about the adulteration side of this."); id. at 19 (responding to Smallco's CTO's argument that adulteration only applies "in case it is important enough in elevating the probability of a serious adverse event," stating: "No. It has nothing to do with serious.").

Thus, in Attorney's view, the best course was to approach the FDA, engage in a conversation about fixing the manufacturing problem, and, without admitting to any violation of the law, voluntarily withdraw the widget from the market. Id. at 2. If XYZ were to continue shipping, without reaching out to the FDA, eventually enough MDRs (one might be enough if it involved a

death) would reach the FDA that it would investigate, and would be "likely to take on a spin that is negative to the company and negative to the product." See id. at 2-3. Moreover, unlike in Attorney's proposed course of action, an FDA investigation would not permit XYZ to control publicity. Id. at 3. Lastly, Attorney noted that, given what XYZ now knew about its manufacturing process, its exposure in the event of a products liability action was substantially increased. Id. at 26. The agreed-upon strategy, by contrast, would "satisfy our regulatory interest as well as the potential products liability, not to mention the exposure of users here, the malpractice, that possibility." Id. at 29.

Attorney made another significant contribution to the conversation: "but I do know that the [FDA] often will remind the manufacturer that what you get reported to you is only a fraction of what's going on in the marketplace, and that you maybe only have 80 events but there could be as many as 800 events." Id. at 20-21. This statement, certainly true as a general matter, suggests that the clinical consequences of shipping adulterated product were potentially more serious than appeared from the MDRs, and that everyone on the call recognized this potential.

The last important viewpoint was Hippocrates's. Hippocrates was basically against the recall, arguing that the FDA was primarily concerned with clinical events, not with technical compliance with Good Manufacturing Practices ("GMP"). See id. at

16. He later testified before the grand jury that he did not know about the internal test results, and that had he known that they showed 10% failure, he would have stopped using the device. See Prosecutor Decl. ¶ 16(m). The credibility of this testimony is undermined by the fact that the 10% figure was mentioned during the phone conversation, but this neither elicited any response from Hippocrates nor caused him to change his mind. In any case, he was "a little bit shocked" at the proposed withdrawal, given his recent discussions with XYZ's Division President and Division Regulatory VP about all the clinical events. He believed that "we fall within the range of appropriate behavior in allowing the device to continue to be used," given what happened to other companies when they initially launched. Advocate Decl., Ex. 13, at 5. Hippocrates was in favor of going straight to the FDA, however. Id. at 13.

XYZ argues that Attorney and XYZ's CEO did not mean what they said about the product being adulterated, but rather that they were taking a strong position in order to persuade the Smallco executives. See Advocate Decl. ¶ 23. XYZ also emphasizes that it planned to contact the FDA as soon as possible, refusing to allow the Smallco executives' personal schedules to delay such contact. Id.

The government notes that later that day, after the conference call, XYZ shipped over $1,500,000 worth of widgets. Prosecutor Decl. ¶ 1(j).

E. Discussions with the FDA, and Attorney's Script

The next day, "Date B," Attorney made a call (the "Date B Call") to Regina Regulator ("Regulator"), a high official in the FDA, to schedule a later call for a more in-depth discussion. Id. ¶ 1(k). Regulator has been interviewed and does not remember significant details from the conversation. Id. The government points out that after that call, XYZ shipped over $2,656,590 worth of widgets. Id.

Before the Date B Call, a script was prepared for Attorney to use, which XYZ has disclosed to the government (*i.e.*, it did not assert work product protection of the script). Id.; id., Ex. 19 (copy of the script). The government argues that the script omitted important information in XYZ's possession. Id. It points in particular to relevant testimony by XYZ's Division President.

XYZ's Division President stated that over the weekend between the two calls to the FDA, he and XYZ's Division Regulatory VP prepared a script -- different from the one Attorney used -- and that he [XYZ's Division President] had never seen the latter script until the grand jury investigation. Id., Ex. 2, at 148-50.

XYZ's Division President objected to three statements in Attorney's script. First, he was not sure what was meant by the point "We have identified a manufacturing process resulting in

the appearance of [hardiness problems] which have been detected using a very sensitive screening method, not part of the routine quality inspection procedures for product release." Id. at 150. XYZ's Division President's testimony suggests that the script was disingenuously implying that the registration of product failures was largely the result of using an overly stringent test, rather than of problems with the produced devices themselves. See id. at 150-51. Moreover, XYZ's Division President said that the type of testing done was the same from the beginning: FFT. See id. at 151. Further, the script's statement "We have identified a manufacturing process resulting in the appearance of [hardiness problems]" implied that XYZ had discovered what was causing the problem, but in fact it had done no such thing. See id.

Second, XYZ's Division President felt that there was only weak support for the theory that certain steps by physicians would reduce adverse clinical events, yet the script said "Company has undertaken a letter to user [the Dear Doctor Letter] which it believes will reduce adverse clinical events." Id. at 152. Third, he found the point "Contemplate making a manufacturing process change to restore performance feature" disingenuous. See id. at 153.

The government points out that the script did not mention the actual internal testing results, XYZ's conclusion that the product had a defect that would cause failures even under proper usage conditions, or the fact that XYZ considered the widget

misbranded and adulterated (XYZ maintains that it did not so believe). Id. ¶ 1(l); see id., Ex. 19. There is no evidence that XYZ told the FDA any of these things. Id. ¶ 1(l).

The second, more in-depth call (the "Date C FDA Call") took place three days later on "Date C," the next business day, between Regulator's staff and Attorney, XYZ's Regulatory VP, XYZ's Division Regulatory VP, and Hippocrates. Id. ¶¶ 1(k)-(l). The XYZ representatives agreed to contact the FDA again in two weeks, and to provide FDA with a health hazard assessment in the interim. Id. ¶ 1(l).

The government is investigating whether during conversations with the FDA, XYZ employees and Attorney withheld material facts from the FDA, made untrue statements, or made statements that were at best exaggerations. Id. Both XYZ's Division President and XYZ's Division Regulatory VP felt that the FDA received a "slanted" presentation that only constituted "part of the picture." Id. XYZ told the FDA that it was still shipping the widgets, but there is no evidence (apart from available inferences) that XYZ sought permission from the FDA to keep shipping or that the FDA gave it. Id. One FDA official testified that while the FDA lacked sufficient information to stop XYZ from shipping, he had questioned XYZ personnel, during the Date C FDA Call and afterwards, as to why they were still shipping widgets. Id.; see also id., Ex. 43, at 20-22, 30-31 (grand jury testimony of the FDA official). XYZ maintains that

there was full disclosure of all material facts on the Date C FDA Call. Advocate Decl. ¶¶ 26, 68-84.

Ten days later, XYZ's CDO sent a letter to an FDA official, summarizing the Date C FDA Call. Id. ¶ 24. The letter stated (XYZ says "reiterated") that "sampling from finished goods inventory showed [hardiness] failures . . . , indicating to us that our manufacturing process was not performing to its validated output," but never mentioned the actual test results. Id.; id., Ex. 17. Around that time, XYZ produced a health hazard analysis for FDA, which emphasized that the product's complaints and injury reports compared favorably with competitive products, suggesting no unreasonable risk to patient health. Id. ¶ 29.

After the Date C FDA Call, XYZ's CEO, Attorney, and other XYZ personnel participated in a second conference call (the "Date C XYZ Call"), in which they determined to keep shipping the widget. Prosecutor Decl. ¶ 1(m). XYZ has asserted attorney-client privilege with respect to the Date C XYZ Call. Id.

Over the next ten days or so, XYZ shipped roughly $15,000,000 worth of widgets. Id. ¶ 1(m).

F. The Withdrawal of the Widget, and Its Aftermath

Roughly two weeks after the Date C calls, on "Date D," the FDA met with XYZ to discuss XYZ's ultimate decision to withdraw the widget (the "Date D Meeting"). Id. ¶ 32. In XYZ's Division President's characterization, XYZ's CEO decided to recall the

product, but went to the FDA in hopes they would tell him that would not be necessary. Prosecutor Decl. ¶ 1(o); id., Ex. 2, at 169. The withdrawal decision, says XYZ, was prompted in part by the "change of heart" experienced by Hippocrates and other physicians whom XYZ contacted during the week leading up to Date D. Id. ¶ 31. The government gives more specifics on these "changes of heart," but also notes that the FDA asked for specific data on how widespread XYZ estimated the problem to be in finished goods inventory, and suggests that this was a motivating factor in the withdrawal decision. Prosecutor Decl. ¶ 1(n).

XYZ asked the FDA whether they could allow physicians who already had widgets to use them if they saw fit; the FDA was apparently open to the idea. See Advocate Decl. ¶ 32. The FDA also approved the press release that XYZ sent out announcing that they would cease shipping widgets. Id. ¶ 33.

After telling the FDA it would cease shipping, later that same day XYZ shipped more than $2,000,000 worth of widgets. Prosecutor Decl. ¶ 1(o). According to an FDA official, in response to a direct question from the FDA, XYZ indicated that shipping was discontinued as of the Date D Meeting. Id.; see id., Ex. 43, at 36. XYZ's Division Regulatory VP corroborates this. See id. ¶ 1(o); id., Ex. 4, at 28-29. She also felt the Date D Meeting did not go well, and was embarrassed to be before the FDA with XYZ's CEO and CDO. See id., Ex. 4, at 27-28. She

told XYZ's CDO that they should have recalled the widget two weeks earlier, and XYZ's CDO replied that they had gotten two more weeks of sales. Id. XYZ states that if such a statement was ever made, it "obviously would have been gallows humor," and points out that XYZ's CDO originally supported recall during the Date A Call. Advocate Decl. ¶ 87.

The general background facts regarding the government's subsequent investigation of XYZ are described in In re Keeper of the Records, 348 F.3d at 19-21.

III. DISCUSSION

A. Standard of Review

As a general matter, the party asserting an applicable privilege has the burden of establishing that it applies. FDIC v. Ogden Corp., 202 F.3d 454, 460 (1st Cir. 2000). The privilege's applicability must be demonstrated by a fair preponderance of the evidence. E.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 190 F.R.D. 287, 289 (D. Mass. 2000). The burden of establishing that an exception to the applicable privilege applies rests with the party seeking discovery of the allegedly privileged materials or information. Ogden, 202 F.3d at 460.

This general framework applies to the work product doctrine as well. The party seeking work product protection has the burden of establishing its applicability. See, e.g., In re Grand

Jury Proceedings, 156 F.3d 1038, 1042 (10th Cir. 1998); In re Grand Jury Subpoena Duces Tecum, 112 F.3d 910, 925 (8th Cir. 1997); Binks Mfg. Co. v. Nat'l Presto Indus., Inc., 709 F.2d 1109, 1119 (7th Cir. 1983); Coastal States Gas Corp. v. Department of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980); Amica Mut. Ins. Co. v. W.C. Bradley Co., 217 F.R.D. 79, 82 (D. Mass. 2003) (Dein, M.J.); City of Springfield v. Rexnord Corp., 196 F.R.D. 7, 10 (D. Mass. 2000) (Neiman, M.J.); Amgen, 190 F.R.D. at 289; City of Worcester v. HCA Mgmt. Co., 839 F. Supp. 86, 88 (D. Mass. 1993) (Gorton, J.); Colonial Gas Co. v. Aetna Cas. & Sur. Co., 144 F.R.D. 600, 605 (D. Mass. 1992) (Bowler, M.J.); Flag Fables, Inc. v. Jean Ann's Country Flags & Crafts, Inc., 730 F. Supp. 1165, 1186 (D. Mass. 1989) (Freedman, C.J.); Sham v. Hyannis Heritage House Hotel, Inc., 118 F.R.D. 24, 25 (D. Mass. 1987) (Alexander, M.J.); Kleinerman v. United States Postal Serv., 100 F.R.D. 66, 70 (D. Mass. 1983) (Freedman, J.); Kozlowski v. Sears, Roebuck & Co., 73 F.R.D. 73, 76 (D. Mass. 1976) (Julian, J.); Restatement (Third) of Law Governing Lawyers [hereinafter "Restatement"] § 90, at 659 (1998). A party invoking the crime-fraud exception to the work product doctrine has the burden of making a prima facie showing that the exception applies. See United States v. Reeder, 170 F.3d 93, 106 (1st Cir. 1999) (describing the showing that a party invoking the crime-fraud exception to the attorney-client privilege must make).

Thus, in evaluating a claim that the work product doctrine applies, courts will weigh all the evidence submitted, without systematically drawing inferences in favor of either party. In determining whether the crime-fraud exception applies, courts will look primarily at the evidence the party invoking the exception has submitted, to determine whether the required prima facie showing has been made.

B. The Work Product Doctrine, and Its Application to Grand Jury Subpoenas

The work product doctrine[4] protects against disclosure of materials that a party, her attorney, or her representative prepares in anticipation of litigation, see Maine v. United States Dep't of Interior, 298 F.3d 60, 66 (1st Cir. 2002), although it does not typically extend to the underlying facts contained within those materials, see, e.g., Resolution Trust Corp. v. Dabney, 73 F.3d 262, 266 (10th Cir. 1995); Fleet Nat'l Bank v. Tonneson & Co., 150 F.R.D. 10, 15 n.6 (D. Mass. 1993)

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[4] Following the usual practice of the Supreme Court and most other courts, this Court will use the term "work product doctrine" rather than "work product privilege." The Court agrees with Professors Wright, Miller, and Marcus that the question whether to characterize work product protection as a "privilege," as a "qualified privilege," or as an "immunity" is a comparatively unimportant semantic matter, so long as courts are clear on the actual substance of the doctrine. See 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, Federal Practice & Procedure § 2023, at 335 & nn.29-30 (2d ed. 1994).

(Karol, M.J.); Restatement, supra, § 87 cmt. g, at 641 (1998); 8 Wright, Miller & Marcus § 2023, at 331 & n.20 (collecting cases); cf. Upjohn Co. v. United States, 449 U.S. 383, 395-96 (1981) (noting the similar limitation on the attorney-client privilege). The work product doctrine preserves a "zone of privacy" in which a party, his attorney, and in many cases his non-attorney "representative" can prepare for litigation, "free from unnecessary intrusion by his adversaries." United States v. Adlman, 134 F.3d 1194, 1196 (2d Cir. 1998) (citing Fed. R. Civ. P. 26(b)(3) and Hickman v. Taylor, 329 U.S. 495, 510-11 (1947)).

The Supreme Court first articulated the work product doctrine in Hickman v. Taylor, although it had existed in state common law and in English law for some time before Hickman was decided, and Hickman itself was a culmination of the lower federal courts' efforts to balance the need of parties and their attorneys to keep their preparations for litigation private with the dramatic expansion in the role of discovery in federal civil litigation. See Special Project, The Work Product Doctrine, 68 Cornell L. Rev. 760, 766-73 (1983) [hereinafter The Work Product Doctrine]. Later, the work product doctrine was partially codified in Federal Rule of Civil Procedure 26(b), as part of the 1970 Amendments to the Federal Rules. Id. at 783.[5] There are

[5] To the extent that Rule 26(b) is instructive, it is only Rule 26(b)(3) that is relevant, so the Court need not discuss Rule 26(b)(4), which deals with the special case of experts.

important differences between the doctrine articulated in Hickman and the text of Rule 26(b)(3), which have given rise to considerable disagreements in the courts. See id. at 783-84. For example, unlike Hickman, Rule 26(b)(3) does not reach "intangible" work product, but Rule 26(b)(3) more clearly protects non-attorney work product than Hickman does. See id.

"The work product doctrine . . . reflects the strong public policy underlying the orderly prosecution and defense of legal claims." United States v. Nobles, 422 U.S. 225, 236-37 (1975) (quoting Hickman, 329 U.S. at 510 (citation and internal quotation marks omitted)). Hickman gives reasons for the doctrine in relation to the work of attorneys, as it was an attorney's work product that was at issue in that case, but the applicability of Hickman's rationales to non-attorneys makes it understandable that Rule 26(b)(3) extended protection to a party's non-attorney "representatives" as well.[6]

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[6] Many courts have held that the work product doctrine applies to litigation-related "documents and other tangible things" produced by non-attorneys, and that appears to be the best reading of Rule 26(b)(3)'s text, which speaks of materials "prepared in anticipation of litigation or for trial by or for another party or by or for that other party's representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent)." See, e.g., In re Ford Motor Co., 110 F.3d 954, 967 (3d Cir. 1997); In re Int'l Sys. & Controls Corp. Sec. Litig., 693 F.2d 1235, 1237-38, 1243 (5th Cir. 1982). Among these courts, however, a number have suggested or insisted that the non-attorney must be working at the behest of an attorney (or presumably of a party, if the party is pro se). See, e.g., Martin v. Bally's Park Place Hotel & Casino, 983 F.2d 1252, 1261 (3d Cir. 1993); Barfoot v. Boeing Co., 184 F.R.D. 642, 645 (N.D. Ala. 1997). The Supreme Court has suggested that

First, the "zone of privacy" that the doctrine creates is necessary to permit an attorney to pursue his responsibilities in "work[ing] for the advancement of justice while faithfully protecting the rightful interests of his clients." Hickman, 329 U.S. at 510; The Work Product Doctrine, supra, at 784-87. Although non-attorneys are not officers of the court, and thus do not have the same public responsibilities as attorneys, there can be little doubt that their role in assembling an effective case for a party is often at least as important as an attorney's. In turn, the careful assembly, sifting, and organization of facts and ideas is a necessary part of making our adversary system of justice work.

Second, and partially independent of the client's and the legal system's interests, there is a need to protect the privacy of the attorney's mental processes. See Hickman, 329 U.S. at 511; Note, Developments in the Law -- Discovery, 74 Harv. L. Rev. 940, 1027-28 (1961). If the Supreme Court believed that failure

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protection extends to attorneys and to non-attorneys acting on their behalf, but perhaps no further. See Nobles 422 U.S. at 238-39 & n.13 (1975). The First Circuit appears to take a broader view of Rule 26(b)(3) in this regard, however. See Sprague v. Director, Office of Workers' Comp. Programs, 688 F.2d 862, 870 (1st Cir. 1982) ("Furthermore, the fact that a doctor and not an attorney prepared this letter is irrelevant for purposes of Rule 26(b)(3) work product protection. Rule 26(b)(3) applies to materials prepared for a party's representative, such as an attorney." (emphasis added)); see also Massachusetts Eye & Ear Infirmary v. QLT Phototherapeutics, Inc., No. 00-0738, 2001 WL 1180694, at *1 (D. Mass. Sept. 25, 2001) (Tauro, J., accepting and adopting report of Bromberg, M.J.).

to protect attorney work product from discovery would result in "[i]nefficiency, unfairness, and sharp practices" in the giving of legal advice and in the preparation for trial, Hickman, 329 U.S. at 511, it is understandable that the Federal Rules would seek to prevent those things among accountants and other representatives who participate in trial preparation.

The doctrine applies in criminal contexts as well as civil. See 18 U.S.C. § 3500; Fed. R. Crim. P. 16(b)(2); Nobles 422 U.S. at 236. It has also been held to apply to IRS summonses, Upjohn, 449 U.S. at 397-402; administrative proceedings, see Sprague, 688 F.2d at 869-70 & n.16; and grand jury proceedings, see, e.g., Donaldson v. United States, 400 U.S. 517, 530 (1971); In re Special Sept. 1978 Grand Jury (II), 640 F.2d 49, 61 (7th Cir. 1980); In re Grand Jury Proceedings (FMC Corp.), 604 F.2d 798, 801 (3d Cir. 1979); In re Grand Jury Proceedings (Duffy), 473 F.2d 840, 842 (8th Cir. 1973); Sherman L. Cohn, The Work Product Doctrine: Protection, Not Privilege, 71 Geo. L.J. 917, 921 (1983).

The work product doctrine's "scope and effect outside the civil discovery context is largely undefined," however, In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d 1007, 1013 (1st Cir. 1988) (citing Nobles, 422 U.S. at 238), and its application in cases involving grand jury subpoenas is particularly unsettled. This is partly because of the unique significance of

the grand jury in our system of government: "Nowhere is the public's claim to each person's evidence stronger than in the context of a valid grand jury subpoena." In re Sealed Case, 676 F.2d 793, 806 (D.C. Cir. 1982) (citing Branzburg v. Hayes, 408 U.S. 665, 688 & n.26 (1972) (citing 4 The Works of Jeremy Bentham 320-21 (J. Bowring ed. 1843))). Moreover, it is not entirely clear whether actions to enforce or quash a grand jury subpoena should be treated like discovery disputes, either civil, governed by Federal Rule of Civil Procedure 26(b)(3), or criminal, governed by Federal Rule of Criminal Procedure 16(b)(2), or in some other manner. Id. at 808 n.49; see In re Special Sept. 1978 Grand Jury (II), 640 F.2d at 61 n.17 ("Neither Rule 26 of the Federal Rules of Civil Procedure nor Rule 16 of the Federal Rules of Criminal Procedure applies to grand jury proceedings"); In re Grand Jury Subpoena, 599 F.2d 504, 509 (2d Cir. 1979) (similar).

Under Federal Rule of Civil Procedure 81(a)(3), the Federal Rules apply to "proceedings to compel the giving of testimony or production of documents in accordance with a subpoena issued by an officer or agency of the United States." Rule 81 thus applies to grand jury subpoenas. See In re Sealed Case, 676 F.2d at 808 n.49; cf. Upjohn, 449 U.S. at 398-99 (holding that Rule 81 applies to internal revenue summons-enforcement proceedings). Moreover, there are important similarities between grand jury subpoenas and pretrial discovery; both involve a broad scope of inquiry and "can be used as a way of preparing for the later . .

. trial." Nobles, 422 U.S. at 247 n.6 (White, J., concurring). Still, that does not resolve the question whether Rule 26(b)(3), which by its terms governs discovery, should define the scope of the work product doctrine in this context. In re Sealed Case, 676 F.2d at 808 n.49; cf. Nobles, 422 U.S. at 242-43 (White, J., concurring) ("I do not believe that the work-product doctrine of Hickman v. Taylor . . . can be extended wholesale from its historic role as a limitation on the nonevidentiary material which may be the subject of pretrial discovery to an unprecedented role as a limitation on the trial judge's power to compel production of evidentiary matter . . . ." (citation omitted)); id. at 244-49 (grounding the concurring Justices' belief in Hickman, the widely shared view of commentators, and various policy arguments); In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1013-15 (holding that the work product doctrine places fewer constraints on judicial case management orders than Rule 26(b)(3) places on discovery orders); Sprague, 688 F.2d at 869 n.16 (applying Rule 26(b)(3) to administrative proceedings under the Longshoremen's and Harbor Workers' Compensation Act because the parties had treated Rule 26(b)(3) as governing, but noting that the Federal Rules likely did not apply independently).

Although the Supreme Court has not firmly resolved this question, it has strongly suggested that Rule 26(b)(3) provides the substantive standard for application of the work product

doctrine in internal revenue summons-enforcement proceedings. See Upjohn, 449 U.S. at 398-99. Grand jury proceedings are similar to such proceedings in many ways. Given that the matter remains open, however, and that the First Circuit has demonstrated a tendency to confine Rule 26(b)(3)'s application to the discovery context, cf. In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1013-15; Sprague, 688 F.2d at 869 n.16, the best answer is that the Federal Rules of Civil Procedure govern the procedures to be used in enforcing grand jury subpoenas, but that the content of the work product doctrine that applies in these proceedings is governed by federal common law, as expressed in decisions like Hickman. See In re Sealed Case, 676 F.2d at 808 n.49.

In determining what scope to give the work product doctrine, whether in the civil discovery context or elsewhere, courts must be careful to give no more protection than is necessary to preserve the values articulated in Hickman. Cf. Herbert v. Lando, 441 U.S. 153, 175 (1979) ("Evidentiary privileges in litigation are not favored.").

1. What Materials Potentially Qualify as Work Product

The range of materials potentially eligible for work product protection is quite broad. Hickman states that a lawyer's "work is reflected, of course, in interviews, statements, memoranda, correspondence, briefs, mental impressions, personal beliefs, and

countless other tangible and intangible ways," and that such "work product," when prepared "with an eye toward litigation," should not be available to opposing counsel "on mere demand." 329 U.S. at 511. Rule 26(b)(3), although it does not govern here, is also instructive. See Sprague, 688 F.2d at 869 n.16 (noting that an administrative agency's application of Rule 26(b)(3) in proceedings where it did not in fact govern was an appropriate means of preserving the values articulated in Hickman). It applies work product protection to any "documents and tangible things otherwise discoverable," so long as they are "prepared in anticipation of litigation or for trial." Id.; see also Restatement, supra, § 87 cmt. d, at 640.[7]

As the Court has already mentioned, work product protection potentially extends to any such material prepared by an attorney, a party, or certain of the party's non-attorney representatives, although the Court has no occasion to pass on whether such a representative must be acting as an agent for the attorney or for

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[7] The Restatement defines work product as follows:

> Work product includes tangible materials and intangible equivalents prepared, collected, or assembled by a lawyer. Tangible materials include documents, photographs, diagrams, sketches, questionnaires and surveys, financial and economic analyses, hand written notes, and material in electronic and other technologically advanced forms, such as stenographic, mechanical, or electronic recordings or transmissions, computer data bases, tapes, and printouts.

Restatement, supra, § 87 cmt. d, at 640.

a pro se litigant. The Court also need not resolve whether common law work product doctrine, which governs here, extends to as broad a range of individuals as Rule 26(b)(3). The Court notes, however, that courts typically do not extend protection to documents prepared by non-parties or their agents. See, e.g., FTC v. Grolier Inc., 462 U.S. 19, 25 (1983) (dictum); In re Grand Jury Subpoena Duces Tecum, 112 F.3d at 924; In re California Pub. Util. Comm'n, 892 F.2d 778, 780-81 (9th Cir. 1989); In re Polypropylene Carpet Antitrust Litig., 181 F.R.D. 680, 691 (N.D. Ga. 1998) (holding that "[d]ocuments prepared by one who is not a party to the present suit are wholly unprotected by Rule 26(b)(3) even though the person may be a party to a closely related lawsuit in which he will be disadvantaged if he must disclose in the present suit" (alteration in original) (quoting 8 Wright, Miller & Marcus, supra, § 2024, at 354-56) (internal quotation marks omitted)). But see National Union Fire Ins. Co. v. Murray Sheet Metal Co., Inc., 967 F.2d 980, 985 (4th Cir. 1992) (holding the contrary sub silentio); In re Sealed Case, 856 F.2d 268, 273 (D.C. Cir. 1988).

2. Opinion Work Product and Ordinary Work Product

Most courts distinguish between "opinion" work product, which includes "materials that contain the mental impressions, conclusions, opinions, or legal theories of an attorney," and "ordinary" work product, which includes everything else that is

eligible for protection as work product, and accord greater protection to the former. In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1014-15 (collecting cases); see Upjohn, 449 U.S. at 399-400 (recognizing the distinction without using the terminology); Hickman, 329 U.S. at 512-13 (suggesting that certain kinds of work product were eligible for more protection than others). This bifurcation also appears in Rule 26(b)(3), which, again, is instructive in this context:

> In ordering discovery of [work product] materials when the required showing has been made, the court shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning litigation.

Id. The bifurcation makes sense, because more than with ordinary work product, "[t]he substantive content of . . . so-called opinion work product is almost certainly of no legitimate use to an opponent." Fleet Nat'l Bank, 150 F.R.D. at 14-15 (citation omitted).

Rule 26(b)(3) permits discovery of ordinary work product "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." Id. Rule 26(b)(3) contains the appropriate standard for common law work product doctrine cases as well, because it essentially codifies Hickman's suggestion that what courts now call ordinary

work product might be discoverable where production "is essential to the preparation of one's case," or where the relevant information would be difficult or impossible to obtain. See Hickman, 329 U.S. at 511.

Opinion work product, on the other hand, qualifies for greater protection, although neither the Supreme Court nor the First Circuit has taken a position in the debate regarding the extent of such protection. See Upjohn, 449 U.S. at 401; In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1015. Beyond the variety of standards, an additional source of confusion is that not all the cases are answering the same question when they describe the level of protection that opinion work product enjoys. The proper question in this context is what showing of need the party seeking discovery must make to overcome the work product immunity, or in proper instances, what public need is sufficient to override the policies protecting opinion work product. The questions of application of exceptions (for example, the crime-fraud exception) and waiver are separate ones. Some courts criticize the cases that give opinion work product "absolute protection" for not taking account of exception and waiver, but the "absolute protection" cases need not be interpreted as making that error.

The Fourth Circuit and the Eighth Circuit are among the courts that have held that protection for opinion work product is absolute. See, e.g., Duplan Corp. v. Moulinage et Retorderie de

Chavanoz, 509 F.2d 730, 734 (4th Cir. 1974); In re Grand Jury Proceedings (Duffy), 473 F.2d at 848 (8th Cir.). But see In re Murphy, 560 F.2d 326, 336 (8th Cir. 1977) ("In our view, opinion work product enjoys a nearly absolute immunity and can be discovered only in very rare and extraordinary circumstances." (emphasis added)). Most courts have accorded it lesser, though still heightened, protection. See, e.g., Adlman, 134 F.3d at 1204 (holding that "at a minimum, . . . a highly persuasive showing" is needed to overcome protection for opinion work product); Director, Office of Thrift Supervision v. Vinson & Elkins, LLP, 124 F.3d 1304, 1307 (D.C. Cir. 1997) ("Opinion work product . . . is virtually undiscoverable."); Holmgren v. State Farm Mut. Auto Ins. Co., 976 F.2d 573, 577 (9th Cir. 1992) (holding that opinion work product "may be discovered and admitted when mental impressions are at issue in a case and the need for the material is compelling"); In re Grand Jury Investigation, 599 F.2d 1224, 1231 (3d Cir. 1979) (holding that interview memoranda "will be discoverable only in a 'rare situation'"); Harper & Row Publishers, Inc. v. Deckler, 423 F.2d 487, 492 (7th Cir. 1970), aff'd by an equally divided Supreme Court, 400 U.S. 348 (1971) ("Of course, the less the lawyer's 'mental processes' are involved, the less will be the burden to show good cause."); Ferrarra & DiMercurio, Inc. v. St. Paul Mercury Ins. Co., 173 F.R.D. 7, 13 & n.8 (D. Mass. 1997) (Bowler, M.J.) (citing Micron Separations, Inc. v. Pall Corp., 159 F.R.D.

361, 364 (D. Mass. 1995) (Collings, M.J.)) (holding that opinion work product "is not absolutely immune from discovery"); Colonial Gas Co., 144 F.R.D. at 605 (noting opinion work product's "heightened protection").

Regardless of what the proper rule may be in the civil discovery context, the appropriate standard in grand jury proceedings is that opinion work product protection can only be overridden in "rare circumstances," upon "a highly persuasive showing." In other words, protection for opinion work product should be "nearly absolute." Affording absolute protection would improperly limit courts' power to supervise the truth-seeking process in cases that involve both the compelling public interest in the prosecution of criminals and a criminal suspect's fundamental right to due process.

3. Who May Invoke the Work Product Doctrine

Obviously, a client may invoke the work product doctrine, if it applies, but given that it seeks in part to protect attorneys' interest in their own intellectual product, many courts have held that an attorney can invoke the doctrine, at least when her interests are not adverse to her client's. See, e.g., In re Grand Jury Proceedings, 43 F.3d 966, 972 (5th Cir. 1994); In re Grand Jury Proceedings, Thurs. Special Grand Jury, Sept. Term, 33 F.3d 342, 348 (4th Cir. 1994); In re Sealed Case, 676 F.2d at 809 n.56; In re Special Sept. 1978 Grand Jury (II), 640 F.2d at 63;

In re Grand Jury Proceedings (FMC Corp.), 604 F.2d at 801 & n.4; In re Grand Jury Subpoena (Zerendow), 925 F. Supp. 849, 853 (D. Mass. 1995) (Saris, J.); Catino v. Travelers Ins. Co., Inc., 136 F.R.D. 534, 539 (D. Mass. 1991) (Collings, M.J.) (holding that when the client waives work product immunity, the attorney can only seek protection of opinion work product, not ordinary work product). Here, XYZ, Attorney, and Firm are all seeking work product protection, so the Court merely notes that, at least in the case of opinion work product, it agrees with the Courts that permit an attorney or other representative to invoke the work product doctrine in most circumstances.

4. Anticipation of Litigation

In order for a document to be eligible for protection as work product, the claimant need not establish that the document was prepared "primarily or exclusively to assist in litigation"; rather, he need only show that "in light of the nature of the document and the factual situation in the particular case, the document can be fairly said to have been prepared or obtained because of the prospect of litigation." Maine v. United States Dep't of Interior, 298 F.3d at 68 (quoting 8 Wright, Miller & Marcus, supra, § 2024, at 343) (internal quotation marks omitted); see also id. at 67 & n.8 (collecting cases). In other words, "the 'because of' standard does not protect from disclosure documents that are prepared in the ordinary course of

business or that would have been created in essentially similar form irrespective of the litigation." Id. at 70 (quoting Adlman, 134 F.3d at 1202 (citing Fed. R. Civ. P. 26(b)(3), Adv. Comm. Note, and National Union Fire Ins. Co., 967 F.2d at 984)).

Speaking in the context of the Freedom of Information Act ("FOIA"), under the exemption thereto for "privileged" materials, see 5 U.S.C. § 552(b)(5), the First Circuit has stated that "at a minimum, an agency seeking to withhold a document in its entirety [by invoking the work product doctrine under 5 U.S.C. § 552(b)(5)] must identify the litigation for which the document was created (either by name or through factual description) and explain why the work-product privilege applies to all portions of the document." Church of Scientology Int'l v. United States Dep't of Justice, 30 F.3d 224, 237 (1st Cir. 1994). While courts should exercise caution in applying FOIA precedents to work product cases outside that context, Church of Scientology makes clear that a party seeking to assert that materials were prepared in "anticipation of litigation" must state with some specificity which litigation was anticipated, and what nexus exists between the anticipated litigation and the contents of the materials in question or the motivation for their creation.

In general, and as will become clear from the discussion below, the "anticipation of litigation" question contains three important concepts: "litigation," "anticipation," and "causation." Among the many courts that, like the First Circuit,

have adopted the test advocated by Professors Wright, Miller, and Marcus, some use it to resolve both the "anticipation" and "causation" questions, whereas others use it primarily for the latter, and articulate a separate standard for the "anticipation" question. Because it is unclear in which manner the First Circuit uses the "because of" test, the Court will discuss other courts' treatment of the "anticipation" question.

a. Litigation

The Restatement takes a broad view of what constitutes "litigation":

> "Litigation" includes civil and criminal trial proceedings, as well as adversarial proceedings before an administrative agency, an arbitration panel or a claims commission, and alternative-dispute-resolution proceedings such as mediation or mini-trial. It also includes a proceeding such as a grand jury or a coroner's inquiry or an investigative legislative hearing. In general, a proceeding is adversarial when evidence or legal argument is presented by parties contending against each other with respect to legally significant factual issues. Thus, an adversarial rulemaking is litigation for purposes of the immunity.

Restatement, supra, § 87 cmt. h, at 641.[8] "Adversarialness" is the touchstone of this approach to the "litigation" question, and a number of courts seem to have followed it to a large degree. For example, numerous courts have held that patent-interference proceedings are enough like "litigation" to trigger the work

[8] The Eighth Circuit has rejected the Restatement's contention that congressional hearings would constitute "litigation." See In re Grand Jury Subpoena Duces Tecum, 112 F.3d at 924.

product doctrine. See Natta v. Zletz, 418 F.2d 633, 637-38 (7th Cir. 1969); Natta v. Hogan, 392 F.2d 686, 693 (10th Cir. 1968); Sperry Rand Corp. v. International Bus. Mach. Corp., 45 F.R.D. 287, 291 (D. Del. 1968); Applied Telematics, Inc. v. Sprint Communications Co., No. Civ. A. 94-4603, 1996 WL 539595, at *5 (E.D. Pa. Sept. 18, 1996). Courts have also held that arbitration counts as "litigation." See, e.g., Caringal v. Karteria Shipping, Ltd., No. Civ. A. 99-3159, 2001 WL 874705, at *2 (E.D. La. Jan. 24, 2001); Walsh v. Seaboard Sur. Co., 184 F.R.D. 494, 497 (D. Conn. 1999); Bertolotti v. Teamsters Local 814 Pension Fund, No. 95-CV-5261, 1998 WL 12169, at *2 (E.D.N.Y. Jan. 8, 1998) (noting this finding of the magistrate judge); Jumper v. Yellow Corp., 176 F.R.D. 282, 286 (N.D. Ill. 1997); Samuels v. Mitchell, 155 F.R.D. 195, 200 (N.D. Cal. 1994).

The Court has found no authority suggesting that a government investigation itself constitutes litigation. Accord Guzzino v. Felterman, 174 F.R.D. 59, 63 (W.D. La. 1997) ("[C]ounsel have not cited, and this Court's research has not revealed any, cases which hold that documents prepared in anticipation of a federal agency's investigation are protected by the work product doctrine."). Many courts have held, however, and this Court agrees, that once a governmental investigation has begun, litigation is sufficiently likely to satisfy the "anticipation" requirement. See Martin v. Bally's Park Place Hotel & Casino, 983 F.2d 1252, 1261 (3d Cir. 1993) (holding that

materials prepared after an OSHA investigation had commenced were in anticipation of litigation); Briggs & Stratton Corp. v. Concrete Sales & Servs., 174 F.R.D. 506, 509 (M.D. Ga. 1997) (holding as much for materials prepared after the EPA had identified potentially responsible parties in an environmental cleanup); Guzzino, 174 F.R.D. at 63 ("Federal courts have concluded that once an investigation by a federal agency has commenced, that a corporation may reasonably be said to anticipate litigation."); Garrett v. Metropolitan Life Ins. Co., No. 95 Civ. 2406, 1996 WL 325725, at *3 (S.D.N.Y. June 12, 1996); Pacamor Bearings, Inc. v. Minebea Co., Ltd., 918 F. Supp. 491, 513 (D.N.H. 1996) (citing Martin v. Montfort, Inc., 150 F.R.D. 172, 173 (D. Colo. 1993)); Bituminous Cas. Corp. v. Tonka Corp., 140 F.R.D. 381, 390 (D. Minn. 1992) (holding that materials prepared after a state pollution control agency began investigating a company were in anticipation of litigation); In re LTV Sec. Litig., 89 F.R.D. 595, 612 (N.D. Tex. 1981) (holding that documents generated during the pendency of an SEC investigation were generated in anticipation of litigation).

b. Anticipation

As the cases finding anticipation of litigation once a federal agency has begun an investigation suggest, "anticipation" requires something more than a mere remote possibility of litigation. Typically, the tests courts use include both

subjective and objective components. This Court adopts the D.C. Circuit's standard: "the lawyer must at least have had a subjective belief that litigation was a real possibility, and that belief must have been objectively reasonable." In re Sealed Case, 146 F.3d 881, 884 (D.C. Cir. 1998); accord, e.g., Martin, 983 F.2d at 1260 (similar); Restatement, supra, § 87 cmt. i, at 642 ("[T]he immunity covers only material produced when apprehension of litigation was reasonable in the circumstances. The reasonableness of anticipation is determined objectively by considering the factual context in which the materials are prepared, the nature of the materials, and the expected role of the lawyer in ensuing litigation."). It does not matter whether the anticipated litigation ever occurs. See, e.g., In re Sealed Case, 146 F.3d at 888; Restatement, supra, § 87 cmt. i, at 642. The fact that litigation ultimately occurred is also not dispositive on the question whether, ex ante, a party reasonably anticipated that litigation would occur. See, e.g., Binks Manufacturing, 709 F.2d at 1118.

Although there is a consensus that some heightened and objective anticipation of litigation, beyond a "remote prospect of future litigation" is necessary, Diversified Indus., Inc. v. Meredith, 572 F.2d 596, 604 (8th Cir. 1977), courts have differed widely in their articulations of the required showing. E.g., Harper v. Auto-Owners Ins. Co. 138 F.R.D. 655, 659-60 (S.D. Ind. 1991); Colorado ex rel. Woodard v. Schmidt-Tiago Constr. Co., 108

F.R.D. 731, 734 (D. Colo. 1985). Some courts hold that the work product doctrine only applies if at the time that the materials are prepared, "the probability of litigating the claim is substantial and imminent." Carver v. Allstate Ins. Co., 94 F.R.D. 131, 135 (D. Ga. 1982) (holding as much in the insurance claims investigation context); accord, e.g., McCoo v. Denny's Inc., 192 F.R.D. 675, 683 (D. Kan. 2000) (requiring that the threat of litigation be "real and imminent," and holding that "even the likely chance of litigation" would not be enough); Collins v. Mullins, 170 F.R.D. 132, 134 (W.D. Pa. 1996) (similar); Snyder v. Winter, 159 F.R.D. 14, 15 (W.D.N.Y. 1994) (similar); APL Corp. v. Aetna Cas. & Sur. Co., 91 F.R.D. 10, 21 (D. Md. 1980) (similar); In re Grand Jury Investigation (Sturgis), 412 F. Supp. 943, 948 (E.D. Pa. 1976) (holding that "[t]he threat of litigation must be more real and imminent" than pertains when "[a]dvising a client about matters which may or even likely will come of litigation"); Burlington Indus. v. Exxon Corp., 65 F.R.D. 26, 43 (D. Md. 1974) (similar); Stix Prods., Inc. v. United Merchants & Mfrs., Inc., 47 F.R.D. 334, 337 (S.D.N.Y. 1969) (suggesting that the work product doctrine is potentially applicable "[i]f the prospect of litigation is identifiable because of specific claims that have already arisen");[9] see also Binks Manufacturing, 709 F.2d at 1119

[9] At least two judges in this District have cited the Stix standard with approval. See In re First Commodity Corp. of

(requiring that "at the very least some articulable claim, likely to lead to litigation, [has] arisen" (alteration in original) (quoting Coastal States Gas Corp., 617 F.2d at 865) (internal quotation marks omitted)).

Other courts, however, adopt tests that sound somewhat less demanding. This group includes the courts that use the "because of" test for both "anticipation" and "causation." See, e.g., Senate of Puerto Rico v. United States Dep't of Justice, 823 F.2d 574, 587 n.42 (D.C. Cir. 1987); Simon v. G.D. Searle & Co., 816 F.2d 397, 401 (8th Cir. 1987). Similarly, at least one judge in this District has held that litigation need not be imminent for the work product doctrine to apply. Massachusetts v. First Nat'l Supermarkets, Inc., 112 F.R.D. 149, 151 (D. Mass. 1986) (Collings, M.J.).

The Third and Fifth Circuits appear to use sliding scales for the "anticipation" and "causation" requirements, allowing a stronger showing on one to compensate for a weaker showing on the other. See United States v. Rockwell Int'l, 897 F.2d 1255, 1266 (3d Cir. 1990) ("[L]itigation need not be imminent . . . as long as the primary motivating purpose behind the creation of the document was to aid in possible future litigation." (alteration in original) (quoting United States v. El Paso Co., 682 F.2d 530,

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Boston Customer Accounts Litig., No. 713, 1987 WL 11621, at *1 (D. Mass. May 15, 1987) (Wolf, J.); American Optical Corp. v. Medtronic, Inc., 56 F.R.D. 426, 431 (D. Mass. 1972) (Campbell, J.).

542 (5th Cir. 1982) (citation and internal quotation marks omitted)).

The Court hereby adopts the approach of the Third and Fifth Circuits. It is consistent with the First Circuit's fact-bound approach, regardless of whether the First Circuit means to use the "because of" test for "causation" only or for both "causation" and "anticipation."

Having determined which test applies to "anticipation," the Court must also answer the somewhat open question whether and to what extent the work product doctrine applies in litigation other than the litigation that was actually anticipated. This question usually arises in situations where the litigation for which materials were prepared has concluded, and the party who prepared them seeks to prevent discovery of them in subsequent litigation.

Some courts have gone as far as to say that the doctrine only applies to the litigation for which the materials were actually prepared. See United States v. International Bus. Mach. Corp., 66 F.R.D. 154, 178 (S.D.N.Y. 1974) [hereinafter IBM]; Honeywell, Inc. v. Piper Aircraft Corp., 50 F.R.D. 117, 119 (M.D. Pa. 1970). The weight of authority requires application of the doctrine in litigation other than the litigation originally anticipated, however. Indeed, in FTC v. Grolier, Inc., the Supreme Court arguably went to the opposite extreme from IBM and Honeywell, and although the Court's holding is subject to

multiple interpretations, under none of them would IBM and Honeywell remain good law.

In Grolier, the Court afforded work product protection to materials that the FTC had prepared for unrelated litigation that had already concluded. See 462 U.S. at 26. Rule 26(b)(3) did not provide the governing standard in Grolier, however. See id. at 25-26; see also id. at 28, 30-31 (Brennan, J., concurring) (noting that the majority had not rested its holding firmly on an interpretation of Rule 26(b)(3), and arguing that it should have). Rather, the question was whether the "privilege" exemption under the Freedom of Information Act, 5 U.S.C. § 552(b)(5), permitted the FTC to refuse disclosure of the materials. Grolier, 462 U.S. at 25-26. The Court's statement that "the literal language of [Rule 26(b)(3)] protects materials prepared for any litigation or trial as long as they were prepared by or for a party to the subsequent litigation" is thus merely dictum. Id. at 25.

Although Supreme Court dicta often provide important guidance, the Supreme Court's statement here provides little predictive value. After describing Rule 26(b)(3)'s "literal" meaning, the Grolier Court also acknowledged that this reading might "engender [problems] in the civil discovery area." Id. at 25. Were the Supreme Court to address this issue squarely, therefore, it might well rely on purposive interpretation, and perhaps even the absurdity canon, to give the Rule a less

expansive meaning than a "literal" reading might permit. Indeed, the Grolier majority included Justices who were willing to interpret statutes in light of their purpose and of the social history surrounding their passage into law, and there are apparently six such Justices on the Court at present. See, e.g., General Dynamics Land Sys., Inc. v. Cline, 124 S.Ct. 1236 (2004) (holding, 6-3, that in light of the purposes of the Age Discrimination in Employment Act and the social and legislative history surrounding its passage, the Act did not prevent an employer from favoring older employees over younger ones, even if the younger employees were over 40, and thus eligible for protection under the dissenters' "plain meaning" interpretation of the Act). Thus the lower courts, while disagreeing with IBM and Honeywell, have taken differing approaches to the application of the work product doctrine beyond the litigation for which materials were prepared.

The Fourth and Eighth Circuits have taken Grolier's approach in work product cases outside the FOIA context. See In re Murphy, 560 F.2d at 335 (8th Cir.) ("The unrelatedness of the subsequent litigation provides an insufficient basis for disregarding the [work product] privilege . . . ."); id. at 334 n.14 (noting the similarity between the work product doctrine and the English concept of professional privilege, which Hickman mentioned, and noting that English courts have adopted the general rule of "once privileged, always privileged" for the

professional privilege doctrine); Duplan, 487 F.2d at 484 & n.15 (rejecting any requirement that the litigation be "closely related" to the litigation actually anticipated); accord Slack v. FTC, 1980 WL 1984, at *3 (D. Mass. Nov. 18, 1980) (Skinner, J.).

The Third Circuit has suggested, without so holding, that the work product doctrine only applies in litigation that is "related" or "closely related" to the litigation anticipated, and various district courts have expressly taken this approach. See In re Grand Jury Proceedings (FMC Corp.), 604 F.2d at 803-04 (3d Cir.); Leonen v. Johns-Manville, 135 F.R.D. 94, 97 (D.N.J. 1990); FDIC v. Cherry, Bekaert & Holland, 131 F.R.D. 596, 605 (M.D. Fla. 1990); Niagara Mohawk Power Corp. v. Stone & Webster Eng. Corp., 125 F.R.D. 578, 586 (N.D.N.Y. 1989); Hercules Inc. v. Exxon Corp., 434 F. Supp. 136, 153 (D. Del. 1977); Midland Inv. Co. v. Van Alstyne, Noel & Co., 59 F.R.D. 134, 138 (S.D.N.Y. 1973); Insurance Co. of N. Am. v. Union Carbide Corp., 35 F.R.D. 520, 522-23 (D. Colo. 1964).

The Second, Fifth, Sixth, and Tenth Circuits have all held that the work product doctrine extends to litigation other than that anticipated, but have not passed on the question whether the litigation must be "closely related" to the litigation anticipated. See Frontier Refining, Inc. v. Gorman-Rupp Co., Inc., 136 F.3d 695, 703 (10th Cir. 1998); In re Grand Jury Proceedings, 43 F.3d at 971 (5th Cir.); Republic Gear Co. v. Borg-Warner Corp., 381 F.2d 551, 557 (2d Cir. 1967) (holding that

the work product doctrine applied to closely related litigation without considering whether it would apply to unrelated litigation); United States v. Leggett & Platt, Inc., 542 F.2d 655, 660 (6th Cir. 1976).

As a general matter, the Court finds the most practical solution to be the one proposed by Professors Wright, Miller, and Marcus. They suggest that work product protection be extended in subsequent litigation, even if it is "unrelated," but that "[t]o the extent that the rule seems to give undue protection to material prepared for some other suit the court can . . . view tolerantly the showing necessary to overcome the work product immunity." 8 Wright, Miller & Marcus, supra, § 2024, at 351-54.[10]

The inquiry does not necessarily end there, however. The Seventh Circuit has stated that the cases requiring protection of

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[10] This approach is consistent with the idea that the central inquiry in work product cases is what actions are required to preserve the policies articulated in Hickman. As another example, in instances where a party in litigation seeks discovery of work product prepared by representatives of a non-party to the litigation, although Rule 26(b)(3) only prevents discovery of materials prepared by or for a party or his representative, courts can nevertheless issue protective orders under Rule 26(c) to prevent discovery, or to prohibit the party seeking discovery from disclosing the discovered information to any non-participant in the litigation. See In re California Pub. Util. Comm'n, 892 F.2d 778, 781 n.2 (9th Cir. 1989); 8 Wright, Miller & Marcus, supra, § 2024, at 354-56. For an argument that such materials could simply be protected under Hickman, even though Rule 26(b)(3) does not apply to them, see Special Project, The Work Product Doctrine, supra, at 862-64 (citing United States v. AT & T, 642 F.2d 1285, 1291 (D.C. Cir. 1980), and Republic Gear, 381 F.2d at 557).

work product in litigation subsequent to that for which they were prepared do not necessarily apply when a criminal grand jury investigation is involved:

> We are dealing here, however, with a criminal grand jury investigation into documents prepared in earlier administrative proceedings. The documents prepared by the Sellers firm were not prepared in anticipation of a potential criminal litigation. Moreover, the focus of inquiry is to determine if their preparation was attended by misconduct. Under these circumstances, we believe that the Government has shown adequate grounds to acquire the documents. The criminal dimension of the instant suit makes it clear to us that the policy considerations in the Duplan Corp. case cannot be analogized to cover this situation.

Velsicol Chem. Corp. v. Parsons, 561 F.2d 671, 676 (7th Cir. 1977). The Seventh Circuit noted that Rule 26(b)(3) itself shows that "[t]he [work product] doctrine is not an absolute one and must be weighed against the exigencies of the situation." Id. at 676 n.3. The court also held that Rule 16(b)(2) did not bar discovery of the documents in question. Id. at 676.

The conflict between Professors Wright, Miller, and Marcus's approach and the one taken in Velsicol is more apparent than real, particularly in light of what the Court has already said about the common-law approach that courts should take to work product questions in cases involving grand jury subpoenas. Work product protection should be potentially available in circumstances like those in Velsicol, but courts should have some freedom to make practical judgments about the showing the government must make to overcome the work product immunity. Cf.

In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1013-15.

Facts considered relevant to and sometimes dispositive of the "anticipation" inquiry include: a party's consultation with a lawyer, see, e.g., Woodard, 108 F.R.D. at 734; a party's retention of a lawyer, see, e.g., EEOC v. Lutheran Soc. Servs., 186 F.3d 959, 968 (D.C. Cir. 1999); a party's receipt of correspondence from the other party's lawyer, see, e.g., McNulty v. Bally's Park Place, Inc., 120 F.R.D. 27, 29 (E.D. Pa. 1988); notice from the government that it believes a party is not in compliance with legal obligation, see, e.g., Bernardo v. Commissioner, 104 T.C. 677, 688 (1995); press articles, see, e.g., Wsol v. Fiduciary Mgmt. Assocs., Inc., No. 99 C 1719, 1999 WL 1129100, at *2 (N.D. Ill. Dec. 7, 1999); issuance of a federal grand jury subpoena, see, e.g., id.; and litigation in foreign countries, see, e.g., Smithkline Beecham Corp. v. Apotex Corp., No. 98 C. 3952, 2000 U.S. Dist. LEXIS 13606, at *12 (N.D. Ill. Sept. 12, 2000).

c. Causation

Although it is unclear, it seems the First Circuit had "causation" primarily in mind when it adopted the "because of" test. See Maine v. United States Dep't of Interior, 298 F.3d at 66-67 (distinguishing this test from the district court's insistence that "the prospect of litigation serve[] as the

primary motivating factor for the preparation of the documents" (quoting the district court's opinion) (internal quotation marks omitted)). Thus, the First Circuit's emphasis on the distinction between its "because of" standard and the "primary purpose" standard is of greatest importance when a strong showing has been made that litigation is "anticipated." As the likelihood of litigation becomes more remote, a stronger "causation" showing may become necessary.

C. The Crime-Fraud Exception

Although the Court does not rest its holding on the crime-fraud exception, the doctrine forms an important part of this analysis, so a discussion of the relevant legal standards is appropriate.

The crime-fraud exception to the attorney-client privilege applies in essentially the same form to the work product doctrine, particularly in the grand jury context. See, e.g., In re Grand Jury Subpoenas, 144 F.3d 653, 660 (10th Cir. 1998); In re Sealed Case, 107 F.3d 46, 51 (D.C. Cir. 1997); Cox v. Administrator, United States Steel & Carnegie, 17 F.3d 1386, 1422 (11th Cir. 1994); In re Antitrust Grand Jury, 805 F.2d 155, 164 (6th Cir. 1986); In re International Sys. & Controls Corp., 693 F.2d 1235, 1242 (5th Cir. 1982); In re John Doe Corp., 675 F.2d 482, 492 (2d Cir. 1982); In re Grand Jury Proceedings, 604 F.2d at 802-03; In re Doe, 662 F.2d 1073, 1079 (4th Cir. 1981);

Ferrara & DiMercurio, 173 F.R.D. at 13 & n.8; In re Grand Jury Subpoena (Legal Servs. Ctr.), 615 F. Supp. 958, 965 (D. Mass. 1985) (Freedman, J.); Restatement, supra, § 93, at 672. As the above-cited cases make clear, permitting an individual to use a lawyer's services to perpetrate a future crime or fraud is as inconsistent with the policies behind the work product doctrine as it is with the policies behind the attorney-client privilege.

In this Circuit:

> To bring the crime-fraud exception to bear [in the attorney-client privilege context], the party invoking it must make a prima facie showing: (1) that the client was engaged in (or was planning) criminal or fraudulent activity when the attorney-client communications took place; and (2) that the communications were intended by the client to facilitate or conceal the criminal or fraudulent activity."

In re Grand Jury Proceedings (Gregory P. Violette), 183 F.3d 71, 75 (1st Cir. 1999). Obviously, the exception does not apply to communications and materials related to past wrongdoing; it only applies when future wrongdoing (which may include efforts to cover up or perpetuate past wrongdoing) is contemplated. See United States v. Zolin, 491 U.S. 554, 562-63 (1989). It is the client's state of mind that controls; the exception applies even if the attorney was entirely innocent. Id. at 79. The client must have actual or constructive intent to engage in wrongful activity: "Thus, the attorney-client privilege is forfeited inter alia where the client sought the services of the lawyer to enable or aid the client to commit what the client knew or reasonably

should have known to be a crime or a fraud." United States v. Rakes, 136 F.3d 1, 4 (1st Cir. 1998); see also Ferrara & DiMercurio, 173 F.R.D. at 13 & n.8 (holding that the crime-fraud exception to the work product doctrine only applies to crime and fraud, not to unfair and deceptive trade practice claims).

Because the First Circuit requires at least constructive intent before the crime-fraud exception applies, the crime-fraud exception does not apply in quite the same way to the work product doctrine that it does to the attorney-client privilege. In the latter context, the attorney's intent does not matter, because the privilege belongs to the client alone. In the former context, however, the attorney or representative who prepared or commissioned the materials in question can seek work product immunity, at least if her interests are not adverse to the client's, so her state of mind may in fact matter. Thus, it appears to be the opinion of every circuit that has addressed the issue that however guilty the client may have been, an innocent attorney can still invoke the work product doctrine. See In re Grand Jury Subpoena, 220 F.3d 406, 408 (5th Cir. 2000); In re Grand Jury Proceedings, Thurs. Special Grand Jury, Sept. Term, 33 F.3d at 349 (4th Cir.); In re Sealed Case, 676 F.2d at 812 (D.C. Cir.); In re Special Sept. 1978 Grand Jury, 640 F.2d at 63 (7th Cir.); In re Grand Jury Proceedings, 604 F.2d at 802 n.5 (3d Cir.). The Court agrees that this is the better view, subject to the caveat that in cases involving federal grand jury subpoenas,

as in the case management context, courts have greater leeway to overcome the work product immunity than they would when presiding over an ordinary civil discovery dispute governed by Rule 26(b)(3).

Should a party seek to invoke the crime-fraud exception, she must provide "something to give color to the charge; there must be prima facie evidence that it has some foundation in fact." Clark v. United States, 289 U.S. 1, 15 (1933) (citations and internal quotation marks omitted). The First Circuit has expressly declined to adopt any of the more particularized formulations of this standard that the other circuits have developed. Violette, 183 F.3d at 78 (collecting cases);[11] see In re Grand Jury Proceedings, 87 F.3d 377, 381 (9th Cir. 1996) ("reasonable cause");[12] In re Antitrust Grand Jury, 805 F.2d at 165-66 (6th Cir.) ("probable cause");[13] In the Matter of Feldberg, 862 F.2d 622, 625-26 (7th Cir. 1988) (evidence that, though less than a preponderance of the evidence, is sufficient to require an explanation by the party asserting work product protection); Haines v. Liggett Group, Inc., 975 F.2d 81, 95-96

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[11] The Tenth Circuit has also expressly refused to settle on a standard. See In re Grand Jury Subpoenas, 144 F.3d 653, 660 (10th Cir. 1998).

[12] See also Restatement, supra, § 82 cmt. f (1992) (articulating a "reasonable basis" test).

[13] The Second Circuit has also adopted this standard. See In re Richard Roe, Inc., 68 F.3d 38, 40 (2d Cir. 1995).

(3d Cir. 1992) (evidence which, if believed, would be sufficient to support a finding that the elements of the crime-fraud exception were satisfied);[14] In re Grand Jury Proceedings, 641 F.2d 199, 203 (5th Cir. 1981) (similar, but evidence to the contrary must be disregarded).

Although it is important to impose sufficient proof requirements on the party invoking the exception to ensure that the work product doctrine's policies are not undermined, it is also important that the Court prevent subpoena disputes from turning into mini-trials on the ultimate question of criminal liability in the crimes the grand jury is investigating. See, e.g., In re Grand Jury Subpoenas, Intervenor v. United States, 144 F.3d 653, 661 (10th Cir. 1998). To the extent the standards for the required showing differ in any meaningful way,[15] therefore, the Court holds that the "probable cause" standard used by the Second and Sixth Circuits best reflect this practical compromise. As the Second Circuit said in a case involving both

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[14] The Eleventh and District of Columbia Circuits have standards similar to the Third Circuit's. See In re Grand Jury Investigation, 842 F.2d 1223, 1226 (11th Cir. 1987); In re Sealed Case, 754 F.2d 395, 399 (D.C. Cir. 1985); accord In re Grand Jury Subpoena (Legal Servs. Ctr.), 615 F. Supp. at 965-66.

[15] See Haines v. Liggett Group, Inc., 140 F.R.D. 681, 692 (D.N.J. 1992) (examining the standards in various circuits and stating that they all "amount to the same basic proposition -- has the party seeking discovery presented evidence which, if believed by the fact-finder, supports the plaintiff's theory of fraud?"); Haines, 975 F.2d at 95-96 (citing this portion of the district court's analysis with approval).

the attorney-client privilege and the work product doctrine, all that is required for the crime-fraud exception to apply is "that a prudent person have a reasonable basis to suspect the perpetration of a crime or fraud, and that the communications were in furtherance thereof." In re Grand Jury Subpoena Dated Sept. 15, 1983, 731 F.2d 1032, 1039 (2d Cir. 1984).

To the extent the Fifth Circuit holds that courts should not consider evidence contrary to that presented by the party invoking the exception, the Court disagrees. Although courts determining whether the exception applies should not really be weighing the evidence on both sides, one can imagine circumstances where the party seeking discovery presents evidence which, standing alone, permits a reasonable inference of crime or fraud, but where the party invoking work product immunity then presents incontrovertible evidence that eliminates any possibility of crime or fraud. Courts encounter an infinite variety of factual scenarios in grand jury cases, and they must have some flexibility to ensure that any enforcement or quashing of subpoenas is consistent with the judiciary's public responsibilities.

Because these determinations are difficult, and because so much turns on them, courts frequently engage in in camera review in grand jury subpoena cases where the crime-fraud exception is raised. "The government may obtain in camera review of the information alleged to be privileged, at the discretion of the

court, upon a showing of a factual basis adequate to support a good faith belief by a reasonable person . . . that in camera review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies." United States v. Edgar, 82 F.3d 499, 509 (1st Cir. 1996) (quoting Zolin, 491 U.S. at 572) (internal quotation marks omitted); see Restatement, supra, § 86 cmt. f, at 634. The First Circuit apparently agrees with other courts that have held that the party invoking the crime-fraud exception need not make as strong a showing to obtain in camera review as he would to establish that the exception in fact applies. See, e.g., In re General Motors Corp., 153 F.3d 715, 716 (8th Cir. 1998); United States v. Chen, 99 F.3d 1495, 1503 (9th Cir. 1996).

The government has argued that the exception applies here, alleging that XYZ continued shipping adulterated and misbranded widgets, even after Attorney advised them to cease shipping, and used Attorney's services both to facilitate the continued illegal shipping and to conceal the illegal conduct from physicians and from the FDA. Gov't's Mem. [Doc. No. 47] at 6-10. The Court need not address this contention, although it sets the parameters within which XYZ, Attorney, and Firm can argue for work product protection.

D. The Regulations and Policies Applicable to XYZ's Conduct

1. The FDCA's Requirements

The widget was a Class III device under the FDCA. As such, it was subject to strict regulatory requirements. 21 U.S.C. § 360c; see United States v. Prigmore, 243 F.3d 1, 4 (1st Cir. 2001). Before such a device can be marketed, the manufacturer must submit a PMA to the FDA and obtain approval. 21 U.S.C. § 360e(a). The FDA will not approve a PMA without "reasonable assurance" that the device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." Id. § 360e(d)(2)(A)-(B). Approval will also be denied if "the proposed labeling is false or misleading in any particular," or if "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform with" GMP under 21 U.S.C. § 360j(f). Id. § 360e(d)(2)(C)-(D).

GMP requirements are now codified under Quality System Regulations, 21 C.F.R. Part 820, which were promulgated pursuant to 21 U.S.C. §360j(f)(1). These regulations require device manufacturers to establish and maintain procedures to ensure that each batch of devices meets acceptance criteria, 21 C.F.R. § 820.80(d), to control products that do not conform to specified requirements, 21 C.F.R. § 820.100, to identify and investigate

the cause of any failure to conform to requirements, id., and to implement corrective actions, id. As one court has put it:

> The GMP provisions of the statute for devices and human drugs and their implementing regulations are prophylactic measures designed to prevent the distribution of poorly manufactured drugs and devices by giving the Food and Drug Administration . . . additional authority to require that sound methods, facilities, and controls be used in all phases of drug [and device] manufacturing and distribution.

United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, 799 F. Supp. 1275, 1285 (D.P.R. 1992) (first alteration in original) (quoting United States v. Bel-Mar Labs., Inc., 284 F. Supp. 875, 881 (E.D.N.Y. 1968)) (internal quotation marks omitted); cf. United States v. An Article of Drug, 484 F.2d 748, 751 (7th Cir. 1973) (upholding condemnation as adulterated of drugs manufactured in violation of GMP regulations). The Court has not found any cases that support XYZ's contention that GMP violations are merely "technical," and the cases cited above obviously take a contrary position, but the Court need not explore this issue, for reasons discussed below.

The FDCA prohibits interstate shipment of "adulterated" or "misbranded" devices. 21 U.S.C. § 331(a). There are many ways a device can qualify as "adulterated." A device is adulterated if it is not manufactured in conformity with the FDA's GMP regulations, see 21 U.S.C. § 351(h), regardless of how well it performs. United States v. Two Units, More or Less, of an Article and Device, 49 F.3d 479, 481 (9th Cir. 1995); 789 Cases,

More or Less, of Latex Surgeons' Gloves, 799 F. Supp. at 1285-86. It is also adulterated if its quality is below that which it purports or is represented to possess. See 21 U.S.C. § 351(c); Dean Rubber Mfg. Co. v. United States, 356 F.2d 161, 163-64 (8th Cir. 1966) (holding that section 351(c) applies to devices as well as drugs);[16] United States v. Torigian Labs., Inc., 577 F. Supp. 1514, 1524-26 (E.D.N.Y. 1984), aff'd without opinion, 751 F.2d 373 (2d Cir. 1984) (adopting magistrate judge's recommendation and opinion).[17] Further, a device is adulterated if it has been modified, without FDA approval, in a way that affects the device's safety or effectiveness. 21 U.S.C. § 351(f)(1)(B); 21 C.F.R. § 814.39. Similarly, a device may become

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[16] Interpretation of 21 U.S.C. § 351(c) is somewhat problematic, but the Seventh Circuit's argument is persuasive. The problem is as follows: Section 351 begins with the text "A drug or device shall be deemed to be adulterated," and is followed by subsections. Id. Subsection (b) defines adulteration for a drug that "purports to be or is represented as a drug the name of which is recognized in an official compendium." Id. Subsection (c) defines adulteration for "Misrepresentation of strength, etc., where drug is unrecognized in compendium." Id.

At the time relevant to the Dean Rubber Manufacturing decision, an interpretation of Section 351 that applied Subsection (c) only to drugs would have meant that the only devices that would be adulterated under Congress's scheme would be those that were also misbranded. Dean Rubber Manufacturing, 356 F.2d at 163. Thus Congress would have passed an adulteration statute that had no independent meaning. Id.

[17] The Court can safely presume that the Second Circuit would not have affirmed a criminal conviction for shipping an adulterated device, based in part on Section 351(c), if the court did not agree that this criminal statutory provision applied to such devices.

misbranded, inter alia, "[i]f its labeling is false or misleading in any particular," as it would be if it falsely represented that it would meet certain performance specifications. 21 U.S.C. § 352(a).[18]

As criminal penalties for interstate shipment of adulterated of misbranded devices, the FDCA imposes strict liability misdemeanor punishment for conduct committed without mens rea, 21 U.S.C. § 333(a)(1); United States v. Park, 421 U.S. 658, 668-69 (1975), and felony punishment for conduct committed with an "intent to defraud or mislead" either consumers or government regulators, 21 U.S.C. § 333(a)(2); United States v. Bradshaw, 840 F.2d 871, 874 (11th Cir. 1988). Imprisonment is an available punishment under both Section 333(a)(1) and Section 333(a)(2).

2. The FDA's Policies

XYZ provides an extensive discussion of FDA policy, with no answer from the government. Although XYZ maintains that its

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[18] The government argues that a device is also misbranded if its labeling lacks "adequate directions for use," id. § 352(f)(1). Prescription devices like the widget are typically exempt from the "adequate directions for use" requirement, so long as the device satisfies regulatory conditions, such as the requirement that the device's labeling bear sufficient information so that licensed physicians can use the device safely. 21 C.F.R. § 801.109(c). The government argues that if a device malfunctions when used pursuant to the manufacturer's instructions, as the government contends that the widget did, it does not qualify for this exemption and is misbranded pursuant to 21 U.S.C. § 352(f)(1). The Court need not evaluate this argument, because, at least in this case, if the widget were misbranded under this theory it would also be misbranded under 21 U.S.C. § 352(a).

product was never misbranded or adulterated, it also argues that "as a matter of law and fairness," the government cannot now seek to punish conduct that was consistent with FDA's regulatory practice. According to XYZ, FDA's policy is (and was in 1998) to issue warning letters to manufacturers of devices experiencing problems, rather than to require product recalls, even if the FDA considers the product to be misbranded or adulterated, so long as the product does not present an unreasonable risk to patient safety. Advocate Decl. ¶ 35.

According to pages copied from FDA Compliance Program 7382.845, see id., Ex. 24, entitled "Inspection of Medical Device Manufacturers," the standard warning letter identifies the product deficiencies, often resulting in FDA inspections of the manufacturer's facilities. Id. ¶ 36. The FDA often characterizes the product as "adulterated" or "misbranded," but rather than instructing the manufacturer to stop shipping, requires it to notify FDA within fifteen working days of steps taken or plans made to correct the noted violations. Id.

Attorney's Firm examined what it believes were all the warning letters issued between January 1, 1997 and December 31, 2002. Id. ¶ 37. In each, the product was identified as "misbranded" or "adulterated." Id. In roughly 150, actual field failure was indicated. Id. In all but four of these roughly 150 cases, the FDA gave the manufacturer at least fifteen business days to return to the agency with a corrective action plan. Id.

XYZ deposed a former FDA official, now a private attorney. Id. ¶ 38. The former official confirmed that this was FDA's policy, that the fact that a product was "technically adulterated" did not "constitute enough for the FDA to take it off the market," and that he did not advise clients with "technically adulterated" products to take them off the market. Id.; id., Ex. 25. He advises clients to remedy any violation as quickly as possible, and communicate with the FDA. Id. He suggests that technically, "probably 90 some percent of the . . . devices on the market today are adulterated." Id.

XYZ points out that a competitive product actually received a warning letter, where the device was called "adulterated," but the FDA merely sought feedback from the manufacturer within "15 working days." Id. ¶ 41; id., Ex. 26. The FDA worked with the relevant parties for over one year to address the product's problems. Id. XYZ was aware of this history when it made its decisions in the fall of 1998. Id.[19]

The Court need not determine whether XYZ's description of FDA regulatory practice is accurate. For purposes of analysis, however, the Court will by and large assume, arguendo, that it is.

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[19] XYZ tries to advance its cause further by looking at the text of regulations regarding voluntary recalls and MDRs, but these arguments are unpersuasive. See id. ¶¶ 39-40.

E. Attorney's Notes Are Not Work Product

1. The Notes Are the Sort of Material that Qualifies

There can be little doubt that if prepared in anticipation of litigation, an attorney's notes of conference calls between a client and a regulatory agency are the sort of materials that the work product doctrine protects. Indeed, they typically qualify as opinion work product, because "when taking notes, an attorney often focuses on those facts that she deems legally significant." Baker v. Gen. Motor Corp., 209 F.3d 1051, 1054 (8th Cir. 2000); cf. Upjohn, 449 U.S. at 399-400 ("Forcing an attorney to disclose notes and memoranda of witnesses' oral statements is particularly disfavored because it tends to reveal the attorney's mental processes."); United States v. Paxson, 861 F.2d 730, 735 (D.C. Cir. 1988) (applying the same principle). Although most of the cases that XYZ, Attorney, and Firm cite deal with investigatory contexts like witness interviews, the Court can see no reason to treat this case differently. After reviewing Attorney's notes in camera, the Court has found that he was "sift[ing] what he considers the relevant from the irrelevant," Hickman, 329 U.S. at 511, just as the attorney in Hickman was doing in taking notes on witness interviews.

At least one judge in this District has treated attorney notes of an interview between a client and government agents as opinion work product entitled to nearly absolute protection. In

re Grand Jury Subpoena (Zerendow), 925 F. Supp. at 854. As Judge Saris noted, the argument for protection as opinion work product is stronger for notes on such interviews than for notes on an interview with a non-party witness; "[i]f it were otherwise, a defense attorney who sought to protect his client's rights by being present at an interview between his client and government agents would risk being required to expose his thought process to opposing counsel, and even worse, risk becoming a witness against his client." Id. The conference call with the FDA obviously falls somewhere between the witness interview context and the criminal investigation context, but that simply means that Attorney's notes should receive at least as much solicitude as would notes from a non-party witness interview. Thus, if Attorney's notes were prepared in anticipation of litigation, opinion work product protection is appropriate, because "disclosure creates a real, nonspeculative danger of revealing the lawyer's thoughts." In re San Juan Dupont Plaza Hotel Fire Litig., 859 F.2d at 1015.

As a general matter, "factual material contained within a document subject to the work product privilege often will be embraced within the privilege, and thus be exempt from disclosure." Church of Scientology, 30 F.3d at 237 n.20; see Crooker v. Tax Div. of United States Dep't of Justice, No. 94-30129, 1995 WL 783236, at *15 (D. Mass. Nov. 17, 1995) (Ponsor, J.). The Court need not address, however, the questions

surrounding the division of documents into opinion and ordinary work product, and whether and to what extent there should be partial disclosure of the portions that fall into the latter category, because the Court holds that Attorney's notes were not prepared in anticipation of litigation.

2. The Notes Were Not Prepared In Anticipation of Litigation

The first question in deciding whether Attorney's notes were prepared in anticipation of litigation is to determine what litigation XYZ and Attorney might have anticipated.[20] XYZ has stated that "[i]t is true, of course, that neither [XYZ] nor [Attorney] anticipated or even imagined that their efforts to seek guidance from the FDA would be the subject of a criminal investigation." XYZ's Mem. [Doc. No. 4, M.B.D. No. 04-10040-WGY] at 7. Even assuming that this is not a binding admission, cf. Fed. R. Civ. P. 56(c); United States v. Dooley, 424 F.2d 1067,

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[20] In their briefs, XYZ and Attorney have anticipated an argument that the government apparently made to them in meetings, although the government did not raise it at oral argument. See, e.g., Attorney's & Firm's Mem. [Doc. No. 6, M.B.D. No. 04-10040-WGY] at 7. The argument is that the First Circuit's statement that "it would be fanciful to suggest that the disclosures [in the Date A Call] were made in anticipation of litigation," In re Keeper of the Records, 348 F.3d at 25, means that materials prepared around that time do not qualify for work product protection. The government has waived that argument with respect to Attorney's notes, see United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990), but the Court notes that the argument would be specious in any event. The First Circuit was talking about subject matter waiver of the attorney-client privilege, and was making the point that XYZ's and Attorney's disclosures during the call were not made to secure litigation advantage. See id.

1067-68 (5th Cir. 1970) (construing counsel's statement at oral argument to concede that facts were not in dispute so that the district court could properly consider entry of summary judgment), it is entirely consistent with the facts that XYZ and Attorney have submitted to the Court in seeking to establish that the work product doctrine applies.

The next possibility is litigation with the FDA. This Court has already established that government investigations do not themselves constitute litigation, so an anticipated FDA investigation would not count. A second possibility would be an FDA enforcement action. There is evidence that Attorney subjectively believed such an investigation might occur. See Advocate Decl., Ex. 13, at 2-3. Given that he stated as much during the Date A Call, id., while presenting a united front with XYZ's principals and after presumably having conferred with them about what points they would make, there is also evidence that XYZ had this subjective belief.

One possibility that the parties do not discuss is that the discussions with the FDA, to the extent they resembled a negotiation, constituted litigation. This argument has some appeal. Although there was little on the surface of these discussions that would suggest that the "negotiations" were adversarial, one could argue that discussions with the government about what conduct constitutes compliance with criminal statutes are always adversarial, insofar as one party to the discussion

has the power to prosecute the other criminally. The Court rejects this argument, however. It would afford work product protection to far too much ordinary compliance work. Regulated industries are in frequent contact with regulators, and a great deal of the work that regulatory attorneys do is in anticipation of such discussions, perhaps even for the "primary purpose" of preparing for such discussions. It is clear from the cases that refuse to extend work product protection to documents prepared in the ordinary course of business that compliance work falls within this latter category. Moreover, if an FDA investigation, which would presumably include discussions with Attorney and XYZ, does not constitute litigation, it is difficult to see how more voluntary contacts, initiated by XYZ and Attorney, could qualify.

The last remaining possibility would be a products liability action. Again, there is evidence in the record that Attorney and XYZ subjectively believed that such an action might occur. See Advocate Decl., Ex. 13, at 26.

The next question is to what extent XYZ and Attorney could reasonably have anticipated litigation. XYZ's retention of Attorney is probative of subjective belief that litigation was likely, but is by no means dispositive, and in this particular case it has little bearing on the objective prong of the "anticipation" inquiry. Retention of outside expert counsel for regulatory advice is by no means uncommon, even when no litigation is subjectively anticipated.

The case law suggests that the "anticipation" requirement is not met when a corporation anticipates that a governmental investigation might begin some time in the future, and that the investigation might in turn lead to litigation. Although commencement of a governmental investigation is typically a sufficient condition to satisfy the "anticipation" requirement, courts seem to treat it like something close to a necessary one as well; *i.e.*, if the government is not currently investigating a party, the party cannot reasonably anticipate litigation. The better view, however, is that in some cases, the likelihood of an enforcement action or litigation may be so great that materials prepared before an investigation begin to qualify for work product protection.

Thus, to satisfy the "anticipation" requirement, XYZ, Attorney, and Firm must establish that XYZ reasonably believed that either an FDA enforcement action or a products liability suit was likely. To the extent that they base their argument on incidents "in the field," however, they encounter a Catch-22 in arguing for either avenue to "anticipation of litigation."

XYZ and Attorney have decent arguments that the crime-fraud exception does not apply in this case, but those are difficult to maintain while simultaneously invoking the work product doctrine. XYZ's position is that, although it recognized it was not in compliance with FDA regulations, this was only true in a

"technical" sense, because there was no reason to believe that elevated failure rates in what XYZ characterizes as the unnecessarily stringent FFT process were translating into any increased risk for patients "in the field." XYZ also seems to go further, arguing that it was not even in "technical" violation. XYZ argues that given the FDA's regulatory practices, continued shipping under conditions of "technical" violation was not criminal, because the FDA would only demand that the company investigate the manufacturing problem and promptly provide the FDA with a plan for fixing it, all of which XYZ intended to do.

It is obvious why XYZ and Attorney would argue that they did not believe or have reason to believe that failures in the field were occurring with any more frequency than the widget's label would suggest. Although it may be that even "technical" violations of the FDCA are sufficient to make the crime-fraud exception applicable, particularly when such "technical" violations are intentional, it also may be that some higher level of criminality is required, in terms of harm caused, intent, or fraudulent actions taken with regard to customers or the FDA. Whatever the standard of culpability necessary to trigger the crime-fraud exception, and whatever this Court may ultimately have to say on which sorts of actions are sufficiently criminal or fraudulent under the FDCA and other relevant law to make the exception applicable, it is clear that the more XYZ and Attorney knew or had reason to know that widgets were failing and causing

injury at elevated rates (if in fact they were), the more likely it is that the crime-fraud exception would apply.

Thus, XYZ's argument that it anticipated litigation is not based on an increased rate of field incidents, or on a belief that an increase was occurring, but rather on the possibility that a patient or the FDA might unfairly come after XYZ. The company basically argues that it anticipated that an injured patient might file a lawsuit, just as such a patient would be likely to do had there been a device failure but no technical violation in the manufacturing process. XYZ can and arguably does make a similar contention with regard to an FDA investigation and enforcement action. Such an action might come regardless of the lawfulness of XYZ's actions.

The test for "anticipation" has both a subjective and an objective component, and the possibility of litigation must be more than inchoate. If, as XYZ maintains, its technical violations were not leading to increased failures in the field, there was no reason to believe that a products liability action was any more likely than it would have been before the technical violation occurred. In other words, the likelihood was no higher than it was when the possibility of litigation was merely inchoate. Admittedly, XYZ's exposure in the event of a products liability suit was now higher, given what it knew about the technical violations, but this is not a BPL-type inquiry. See United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir.

1947) (defining an alleged tortfeaser's duty in negligence cases as taking such adequate precautions ("B") as would be less costly than the product of the gravity of the injury that would occur absent such precautions ("L") and the probability that injury would occur ("P") -- *i.e.*, B < PL). The magnitude of potential harm to XYZ from litigation is irrelevant -- only the likelihood of litigation matters. Particularly in light of the fact that the work product doctrine often applies to opinions and fact-gathering done by non-attorneys, XYZ's argument would afford work product protection to an extraordinary amount of routine quality control testing, risk assessment, and other common business activities. XYZ cannot have it both ways. Either products liability litigation was likely because its violation was more than "technical," or it cannot claim the work product privilege based on anticipation of such litigation.

A similar problem applies to the potential FDA actions. XYZ cannot, under this first theory, argue that any increased likelihood of FDA action existed, beyond the inchoate possibility that always exists, if the incidence of failures in the field remained as low as it would have to be for continued shipment of the widget to remain lawful. Indeed, that inchoate possibility was even less for the widget than would ordinarily be the case, given that when functioning according to specifications, the widget had less incidence of failure in the field than most or

all of its competitors. XYZ's position would have to be that the work product privilege extends to ordinary efforts to remain in compliance with regulations, and that simply is not the law.

XYZ, Attorney, and Firm appear to have only two possible avenues of navigating the strait between Scylla and Charybdis. The first is to argue that continued shipping in spite of a higher incidence of failure in the field than the label specifications indicate would still not be unlawful, so long as XYZ was working to fix the problem and promptly went to the FDA to work out how to return to compliance. If this were true, than XYZ could admit that it believed field failures were rising, and could make a stronger argument that it reasonably anticipated litigation. XYZ has in fact made a strong showing that FDA normally addresses the problem of Class III devices failing to perform to specifications by sending warning letters, which permit continued shipping but require prompt design and implementation of a plan to correct the violation.

The Court holds, however, that to the extent that XYZ, Attorney, and Firm argue that they were shipping a product that was failing at a rate higher than label specifications suggest, and that they knew field failures were likely to occur at such a rate, the crime-fraud exception makes any claim to work product immunity invalid. 21 U.S.C. § 331, which applies to the widget, prohibits shipment in interstate commerce of misbranded or adulterated devices, and subjects those who violate this

prohibition to criminal penalties. E.g., Penobscot Poultry Co. v. United States, 244 F.2d 94, 97 (1st Cir. 1957). One who argues that violation of a criminal statute is not a crime has a very long row to hoe. Arguing that intentional violation of a criminal statute is not a crime is even more difficult. It is well-nigh impossible to argue against the criminality of intentional shipping of a product that is more dangerous to health than its label suggests, in violation of a criminal statute which, though it reaches "technical" violations, is primarily concerned with whether the product is in reality more dangerous than it represented.

The argument from FDA's regulatory practice, though attractive on some level, is not ultimately persuasive. The FDA must ensure the safety of all food, drugs, cosmetics, and medical devices in interstate commerce, all on a remarkably small budget. It is unsurprising that it can only make limited use of command-and-control, criminal prosecution-type enforcement methods. It must also refer any prosecutions to the Department of Justice ("Justice"). Absent some showing that Justice is in some way bound to take its cue from FDA practice, such practice cannot erase the criminality of intentional, serious violations of the FDCA. See United States v. Morgan, 222 U.S. 274, 281 (1911) ("If, for any reason, the executive department failed to report violations of [the Pure Food and Drug Act, the precursor to the FDCA], its neglect would leave untouched the duty of the district

attorney to prosecute 'all delinquents for crimes and offenses cognizable under the authority of the United States.'" (quoting Rev. Stat. § 771)).

Admittedly, laws can perhaps become unenforceable by long disuse, cf. Nashville, Chattanooga & St. Ry. v. Browning, 310 U.S. 362, 369 (1940) ("Deeply embedded traditional ways of carrying out state policy . . . are often tougher and truer law than the dead words of the written text."), but the relevant provisions of the FDCA do not fall under that category. The treatment of non-complying manufacturers would have to be virtually uniform for this Court even to consider accepting Attorney's and XYZ's argument, yet the parties have provided no information as to whether other companies in situations like XYZ's have ever been subjected to a criminal prosecution. According to one commentator, "[d]evice adulteration has been a relatively rare subject of prosecutions, except for the prophylactic holes cases." 1 James T. O'Reilly, Food and Drug Administration § 18:11 n.427 (citing Dean Rubber, 356 F.2d 161, as an example). After a cursory search, the Court has found cases where a manufacturer was prosecuted for shipping an adulterated device, including one of the "prophylactic holes cases." See Dean Rubber, 356 F.2d at 163-64; Torigian Labs., 577 F. Supp. at 1524-26 (involving intraocular lenses). The Court has also found cases involving prosecution for misbranding. See

United States v. Shabbir, 64 F. Supp. 2d 479, 483 (D. Md. 1999); Torigian Labs., 577 F. Supp. at 1524-26.

Without some stronger showing that the history of non-prosecution under the FDCA made XYZ's conduct lawful, any admission by XYZ that it deliberately shipped widgets that failed at a higher rate than label specifications suggested would be sufficient for the government to meet its "probable cause" burden for the crime-fraud exception. XYZ and Attorney must, therefore, come forward with such information to avoid application of the crime-fraud exception, or else abandon this line of argument.

This analysis, of course only speaks to the applicability of the work product doctrine, not to the liability to which XYZ would be exposed, were it found guilty of deliberately shipping widgets that it knew were less safe than the label suggested. It may be that a judge can or must impose a minimum penalty, given the expectations that the government has created over the years with regard to conduct in this arena. The nature of penalty or remedy does not, however, change the fact of criminality.

The Court also notes that even if continued shipping in spite of a higher incidence of failure in the field than the label specifications indicate did not bring the crime-fraud exception into play, XYZ, Attorney, and Firm would encounter another Catch-22. Their argument in this regard relies on an assertion that the government virtually never does more than send a warning letter to manufacturers of adulterated or misbranded

products, and on an assertion that "probably 90 some percent of the . . . devices on the market today are adulterated." Advocate Decl., Ex. 25. If adulteration and misbranding are so common, and prosecution so rare, XYZ, Attorney, and Firm cannot easily argue that they reasonably anticipated an FDA enforcement action. Similarly, if adulterated and misbranded devices are the norm, such that virtually all device manufacturers are shipping misbranded and adulterated devices, then XYZ was exposed to nothing more than the inchoate background likelihood of products liability litigation. This is insufficient to satisfy the "anticipation" requirement's objective prong. If the Court were to hold otherwise, it would necessarily extend work product protection to most ordinary compliance activities by most device manufacturers, and such a result plainly would be at odds with existing law.

XYZ, Attorney, and Firm may yet have a second possible avenue of escape. When Attorney submitted his notes for in camera review, he also submitted a declaration, the last paragraph of which states: "It is my understanding that plaintiff-side product liability lawyers began to publicize the [widget] recall after it was announced . . . ." Attorney Decl. ¶ 10 [Doc. No. 100]. This statement, in context, may be meant to suggest that at the time of the Date A Call, the participants in that call were concerned that litigation would arise out of the withdrawal or recall itself. If so, this is the first time in

the roughly sixteen months that the parties have been before the Court on these matters that such a suggestion has been made. Neither XYZ, Attorney, nor Firm has pointed the Court to any mention of increased exposure from the recall anywhere in the record. The transcript of the Date A Call reveals that the parties were concerned about litigation that might occur if XYZ did not recall the product.

Indeed, neither XYZ, Attorney, nor Firm has made this argument anywhere in their recent briefs. Rather, to show that XYZ and Attorney "expressly contemplated the possibility that problems with the [widget] might trigger products liability litigation as well as an investigation by the FDA that also could easily culminate in litigation," XYZ points to Attorney's statements during the Date A Call about the likelihood that events in the field would trigger litigation. See XYZ's Mem. at 8. XYZ describes the decision to approach the FDA as "a critical part of the Company's strategy to avoid litigation with the agency or with private parties," and the approach to the FDA contemplated that recall or withdrawal was likely. Id.; see also Advocate Decl., Ex. 13, at 29 (transcript of the Date A Call) ("[T]his approach is one that I believe will satisfy our regulatory interest as well as the potential products liability, not to mention the exposure of the users here, the malpractice, that possibility.").

XYZ and Attorney might argue that they did not mention recall concerns during the Date A Call because they were trying to convince Smallco's executives to go along. This argument has some force, but XYZ, Attorney, and Firm must still point to something else in the record suggesting concern that the recall would lead to litigation, and they have yet to do so.

Even if the Court were to assume that XYZ and Attorney were subjectively anticipating products liability litigation from any recall, there was not then a sufficient objective basis for anticipation of litigation. XYZ's health hazard assessment, performed shortly before the recall, claimed negligible field complaint and field injury rates. Advocate Decl. ¶¶ 29, 87-88; id., Ex. 16, at 3. The difference between the rate at which potential legal claims, frivolous or otherwise, were arising then, and the rate before any "technical" violation was discovered, cannot meaningfully be different. XYZ and Attorney thus maintain that there were few potential claims out there. Next, it was by no means certain that a recall would even occur. The government has provided evidence that, up to the last day, XYZ was hoping that a recall would not be necessary, Prosecutor Decl. ¶ 1(o); id., Ex. 2, at 169, and neither XYZ, Attorney, nor Firm has proffered any evidence to the contrary. The fairest reading of the evidence that XYZ has submitted, particularly when considered in light of what the government has revealed to the Court about XYZ's profits from continued sale of widgets, is that

XYZ was at least hoping that a recall would not be necessary at all.

If XYZ had intended that a withdrawal or recall occur, no matter what, then it is somewhat difficult to understand why the company continued shipping widgets. If the product were only withdrawn, the users most likely to return the devices would be the ones who purchased during the widget's last weeks on the market. They would have the least experience with the devices they had purchased, and would thus have both the least reason for confidence in their new devices, and the most malpractice liability exposure, if they continued using a device without some history of positive past performance. Thus, the more certain the recall was, the more speculative any profits were, and the less credible XYZ's and Attorney's argument becomes. Moreover, every new device shipped would increase XYZ's exposure to the litigation that, under this theory of "anticipation," it considered "likely." The Court does not have nearly enough information to determine what course of action a "reasonable bean count" would have suggested, but at the least there are some difficult questions that XYZ and Attorney, the parties with the burden of establishing the work product doctrine's applicability, have not answered.

Thus, XYZ and Attorney can at best argue that there was a small number of conceivable claims, and a likelihood (but by no means a certainty) of a recall. They can argue that this

possible recall would likely lead enterprising plaintiffs' lawyers to look into the possibility of bringing a lawsuit. Those lawyers might, if they were lucky, find a sufficient number of potential claimants, and convince them all to litigate. The lawyers would then have to determine that this small number of claims, virtually all frivolous and for minor injuries, according to XYZ and Attorney, would be worth litigating. To the extent the lawyers could only connect with some small portion of the small number of claimants, that would probably make litigation even less likely. This piling of possibilities upon possibilities does not add up to objective anticipation.

Obviously, as remote as the possibility of products liability litigation was under this theory, the possibility of an FDA enforcement action was even more so. The FDA would not have brought an enforcement action until after an investigation, during which it would have had a reasonable opportunity to discover that XYZ was correct in asserting an absence of unlawful conduct. The FDA could make a mistake, of course, but so could the plaintiffs' lawyers. Products liability litigation could also arise if the plaintiffs' lawyers acted in bad faith, and although the Court can divine from Attorney's declaration that he would not put such conduct past this segment of the bar, Attorney does not suggest that the FDA would act in bad faith.

3. The Notes Were Not Prepared Because of Litigation

As already noted, as the "anticipation" showing grows weaker, the "causation" showing may well have to grow stronger. If XYZ, Attorney, and Firm could overcome the "anticipation" prong, however, they would still falter on the "causation" prong. Even under the First Circuit's "because of" standard, there is here no sufficient nexus between Attorney's note-taking and the possibility of litigation.

The only litigation that could conceivably satisfy the "anticipation" prong is a potential products liability action. Thus the only question is whether, "in light of the nature of [Attorney's notes] and the factual situation in the particular case, the [notes] can be fairly said to have been prepared or obtained because of the prospect of [products liability] litigation." Maine v. United States Dep't of Interior, 298 F.3d at 68.

Had there been no prospect of products liability litigation, what would XYZ and Attorney have done? The evidence demonstrates that XYZ and Attorney would have contacted the FDA in any event. XYZ describes its decision as a "conservative course of conduct." Advocate Decl. ¶ 14. In the Date A Call, Attorney gave less attention to the products liability issue than to the possibility that if the FDA investigated XYZ, rather than XYZ voluntarily approaching the FDA, widgets would be recalled rather than withdrawn, it would take longer for the product to get back on the market, and XYZ might suffer harmful, possibly fatal

publicity. The decision to approach the FDA was thus much more like a routine interaction between regulated entity and regulator, to ensure compliance and a good public image, than like an initial maneuver in preparing for a products liability suit. The work product doctrine simply does not extend to such "ordinary course of business" transactions.

During routine compliance discussions, it also goes without saying that any attorney participating would take notes. There does not appear to be anything in Attorney's notes to indicate that products liability exposure was on his mind as he was writing them. Although the "because of" standard extends work product protection to materials the preparation of which was not "primarily" motivated by the possibility of litigation, there is nothing to suggest that potential products liability litigation was even an important motivating factor in Attorney's decision to take notes.

Thus, the work product doctrine does not apply to Attorney's notes. Under these circumstance, the Court need not reach the government's crime-fraud exception and waiver arguments.

IV. CONCLUSION

For the above reasons, the Motions for a Protective Order [Doc. Nos. 3 and 5, M.B.D. No. 04-10040] were DENIED.

/s/ William G. Young

WILLIAM G. YOUNG
CHIEF JUDGE

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