IN THE COURT OF COMMON PLEAS OF PHILADELPHIA

FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

CIVIL TRIAL DIVISION

JERRY E. LEWIS, et al.	:	August 2001
	:	No. 2353
v.	:	
	:	Control # 30453
BAYER A.G., BAYER CORP. et al.	:	Commerce Program
	:	

FINDINGS OF FACT, DISCUSSION, AND CONCLUSIONS OF LAW IN SUPPORT OF ORDER DENYING PRELIMINARY INJUNCTION SOUGHT BY PLAINTIFFS.

Presently before this court is the Motion for a Temporary Restraining Order and for a Preliminary Injunction filed by class action plaintiffs Jerry E. Lewis, et al. Plaintiffs seek to enjoin defendants Bayer AG, and Bayer Corporation ("Defendants") from directly contacting any individual residing in the United States who has ingested the drug Baycol during the course of his or her life.[1] Plaintiffs essentially argue that the Defendants have violated Rule 4.2 of the Pennsylvania Rules of Professional Conduct by communicating directly with represented parties. In addition, plaintiffs request relief under Pa.R.C.P. 1713(a)(2).

After considering the briefs, documents, and arguments presented, plaintiffs' motion is denied. In addition, this court will follow the relevant provisions of the order issued by the Honorable Michael

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[1] During oral argument, plaintiffs withdrew their request for relief directed towards defendants GlaxoSmithKline and GlaxoSmithKline PLC. Transcript of 3/7/2002 Hearing ("N.T.") at 22-24.

J. Davis on March 25, 2002 in In re: BAYCOL PRODUCTS LITIGATION, MDL No. 1431 (MJD), Pretrial Order No. 11. That order reflects the requisite careful weighing of potential abuses with the rights of the parties as set forth in greater detail below.[2]

FINDINGS OF FACT

The Parties

1. Plaintiffs are putative members of a class purporting to represent all persons in the Commonwealth of Pennsylvania and/or the United States who have ingested Baycol, also known as cerivastatin ("Baycol"). Second and Third Substituted Consolidated Amended Class Action Complaints (hereinafter "Complaint"), ¶¶ 1, 53. Plaintiffs propose four classes defined, inter alia, by geographic scope (i.e. state or national) and by whether or not particular plaintiffs have suffered physical injury as a result of taking Baycol. Complaint, ¶ 53.

2. Plaintiffs allege that defendant Bayer AG is a foreign corporation with its principal place of business in Pennsylvania. They also allege that defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Plaintiffs assert that at all relevant times,

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[2] It is, of course, well established that federal precedent is not binding on this court, although it is persuasive. Com. v. Ragan, 560 Pa. 106, 118, 743 A.2d 390, 396 (2000)("this Court is not bound by decisions of federal courts inferior to the United States Supreme Court even though we may look to them for guidance"). It seems prudent to adhere to the relevant guidelines in the order by Judge Davis for several reasons. First, there is a dearth of controlling Pennsylvania precedent on the issues raised by plaintiffs' motion. Second, the order issued by the MDL is narrowly drawn with a careful weighing of the conflicting interests and potential for abuse. Finally, there has been a proliferation of Baycol-related lawsuits not only in the federal courts, but also in the various state courts. In a report dated February 19, 2002, defense counsel estimated that there were approximately 297 Baycol-related lawsuits pending in 23 states with Pennsylvania having the largest concentration of cases. Plaintiffs' 3/27/2002 Memorandum, Ex. C at 4. Charting a unifed course with other courts when appropriate is in the best interests of all parties.

Defendants were engaged in the business of manufacturing and marketing the drug Baycol. Complaint, ¶¶ 4-5.

The Marketing and Withdrawal of Baycol

3. Plaintiffs allege that defendant Bayer submitted an application to submit a New Drug for Human Use ("NDA") for cerivastatin to the United States Food and Drug Administration ("FDA") on June 26, 1996 and that the FDA approved cerivastatin for oral administration to treat hypercholesterolemia and mixed dyslipidemia. Complaint, ¶¶ 14-15; Defendants' 3/13/2002 Memorandum at 1-2.

4. Baycol was withdrawn from the market by Bayer in August 2001. Complaint,¶ ¶ 30, 49: Defendants' 3/13/2002 Memorandum at 2.

5. Plaintiffs allege that Baycol caused a significantly higher percentage of patients to experience such side effects as muscle weakness and rhabdomyolysis, a potentially life-threatening condition. Complaint, ¶¶ 29, 31; Defendants' 3/13/2002 Memorandum at 2.

The Status of the Class

6. There are preliminary objections pending as to the Third Substituted Consolidated Amended Complaint.

7. Plaintiffs' motion for class certification must be filed within thirty days after the close of pleadings. Pa. R.C.P. 1707.

8. Thus, the class has not been certified yet.

9. The named plaintiffs in the Complaint are represented by various counsel. See Findings of Fact 14 infra; Uncontested Facts, ¶ 2.

The Communication at Issue

10. Plaintiffs, on behalf of themselves and all persons in the United States who used Baycol, filed a motion with this court for a temporary restraining order and a preliminary injunction to enjoin the defendants from "directly contacting any individual residing in the United States who has ingested Baycol (cerivastatin) during the course of his/her life." Plaintiffs' 3/6/2002 Motion.

11 More specifically, plaintiffs sought this injunction because Bayer was sending blank medical authorizations to "putative class members for the purpose of obtaining adverse event reports." Plaintiffs' 3/6/2002 Memorandum at 2. Plaintiffs objected to this communication and sought relief initially on two grounds:

(a) They allege that this communication violates Rule 4.2 of the Pennsylvania Rules of Professional Conduct ("Rule 4.02"). Id. at 2.

(b) They assert that under Pa.R.C.P. 1713(a)(2) this court has the authority to issue orders to protect the interests of the class. Id.. at 3.

12. In response to the request for a temporary restraining order, a hearing was held during which plaintiffs' counsel acknowledged that this issue had been raised before the MDL at a monthly status conference; counsel for the defendant noted that the MDL case was pending before Judge Davis in the District of Minnesota. 3/7/2002 N.T. at 7 & 14. Although plaintiffs' attorney believed that an injunction was not being sought in that MDL action, defense counsel suggested that the MDL lawyers were seeking relief under Federal Rule 23 authorizing the court to exercise control over communications to putative class members. She concluded that "functionally, it's exactly the same motion. They are asking for an injunction preventing this conduct by Bayer." 3/7/2002 N.T. at 17-18.

13. Defendants argued at the March 7, 2002 hearing before this court that the authorizations at issue had been sent out by the drug safety personnel at Bayer and not by counsel. Moreover, defendants asserted that these authorizations were mandated by FDA regulations whenever an individual consumer sent an adverse drug event report to Bayer. 3/7/2002 N.T. at 11-12.

14. A hearing on plaintiffs' request for a preliminary injunction was held on March 13, 2002, during which defendants stipulated to facts presented by plaintiffs in the Declaration of Arnold Levin in Support of Statement of Uncontested Facts in Connection with Plaintiffs' Motion for a Preliminary Injunction Relating to Defendant's Communications with Putative Class Members."("Uncontested Facts"). 3/13/2002 N.T. at 14.

15. The parties stipulated that "Bayer Corporation represents that in response to adverse drug experiences reported by consumers, the Bayer Drug Safety Assurance department transmits a blank authorization to the complainant. Uncontested Facts, ¶ 8. That authorization form requests the name, address and telephone number of the prescribing physician and then provides:

> I, the undersigned, do hereby give permission for Bayer Corporation to contact my physician to collect further information about the adverse events I experienced during the use of Baycol. I also grant permission for the physician named above to release medical information to Bayer Corporation regarding the adverse events. Uncontested Facts, Ex. A

16 The authorization form is accompanied by a transmittal letter with the letterhead of "Bayer, Pharmaceutical Division." That letter addressed the individual consumer as follows:

> Thank you for notifying us about the adverse events "rhabdomyolysis," "leg pain," "weakness," "dark urine" and "liver [illegible] unusual" which occurred during treatment with Baycol.

> To obtain more information concerning the adverse events, Bayer would like to contact your prescribing physician. Please complete the enclosed consent form. This will authorize Bayer to contact the prescribing physician to request medical information about the adverse events. Return the completed form in the enclosed prepaid envelope. Any information you can provide will assist us in monitoring the safety of our drugs in the general population. Uncontested Facts, Ex. B.

17. All adverse event reports are stamped by Defendant to reflect the location of arrival. Uncontested Facts, ¶ 10.

18. All adverse events are entered into a database "Clintrace," from which Defendant generates "medwatch" reports. Uncontested Facts, ¶¶ 12-13.

19. The "medwatch" forms "are then submitted to the FDA for the purposes of reporting adverse events in accordance with Defendant's obligations under federal law." Uncontested Facts, ¶ 14 (emphasis added).

20. Although plaintiff stipulated that Bayer was required under federal law to report adverse events, [3] during the March 13th hearing plaintiffs' counsel argued that the timing of the report was determined by the severity of the adverse event and whether the label warned about it. He asserted therefore that only serious, non-labeled events had to be reported to the FDA within 15 days while for people reporting serious "muscle pain and aches" that are already warned about in the label "there's no requirement to get this information to the FDA in 15 days. It's either done quarterly" or annually. 3/13/2002 N.T. at 19. See also Defendants' 3/13/2002 Memorandum, Ex. 1 Arvin Shroff Affidavit, ¶ 4 & Ex. 2 Michael Oliver Affidavit, ¶ 6.

21. Plaintiffs' counsel further argued that in the absence of a class action, there is no

[3] Uncontested Facts, ¶ 14 & 3/13/2002 N.T. at 14.

prohibition with sending out the authorization form. If, however, Bayer is aware of a class action lawsuit, "the letter should be sent to the consumer's attorney for follow up so that the lawyer can protect the rights of the individual." 3/13/2002 N.T. at 23.

22. Defense counsel responded that Rule 4.2 of Professional Conduct was inapplicable for 2 reasons: (1) there was no evidence that the authorizations had been sent by counsel and (2) the rule allows this type of communication because it was "authorized by law." 3/13/2002 N.T. at 40. He further argued that disclosure to counsel would violate the confidentiality prohibitions in the FDA regulatory scheme against revealing the names of the consumers who contacted Bayer with an adverse event report. Id. at 42.

23. There is no evidence in the record to indicate that any communication is occurring between Defendant's class action counsel and the putative class members.

24. There is no evidence in the record to indicate that Defendant is consulting with counsel regarding its communication with the putative class member, although Plaintiffs argue that "it is properly presumed that they are being issued with the approval of Bayer's in-house and/or outside regulatory attorneys. Plaintiffs' 3/27/2002 Memorandum at 2.

25. There is no evidence in the record to indicate that Defendant in its communication with the putative class members is misleading, coercing, or encouraging putative class members to forego any of their rights or claims in any lawsuit.

26. On March 25, 2002, Judge Michael Davis issued his ruling on plaintiffs' motion for a protective order pursuant to Federal Rule 23(d)(2) concerning Bayer's communication to the putative class about adverse drug experiences which, in relevant part, provided:

(a) The Drug Safety Department of Bayer will modify the forms of letter and release used to collect adverse drug experience data "to reflect more clearly that the information sought is only that pertinent to the adverse drug experience reported by the consumer;"

(b) Counsel for Bayer will not have access to patient medical records collected by Bayer's Drug Safety Department unless those records are put in issue by plaintiffs, at which point Bayer may seek access to those records. In re Baycol Products Litigation, MDL No. 1431, Pretrial Order No. 11 (3/25/2002, Davis, J.)(emphasis added).

27. The plaintiffs subsequently asserted that this order by Judge Davis does not address the following concerns that are still before this court:

(a) The order does not require Bayer to advise individuals of their right to counsel, and:
(b) The order does not tell individuals to "turn this correspondence over to their attorneys if they are represented."Plaintiffs' 3/27/2002 Memorandum at 2.

DISCUSSION

Standards for a Preliminary Injunction

The standards for a preliminary injunction are well established. To obtain a preliminary injunction, the moving party has the burden of showing:

(1) that relief is necessary to prevent immediate and irreparable harm which cannot be compensated by damages;
(2) that greater injury will occur from refusing the injunction than from granting it;
(3) that the injunction will restore the parties to the status quo as it existed immediately before the alleged wrongful conduct;
(4) that the alleged wrong is manifest, and the injunction is reasonably suited to abate it; and
(5) that the plaintiff's right to relief is clear.

Santoro v. Morse, 781 A.2d 1220, 1229 (Pa. Super. 2001)(citations omitted).

Pennsylvania courts have emphasized that because preliminary injunctions are extraordinary,

interim measures, they should be granted if the plaintiff demonstrates a clear right to relief to preserve the status quo pending a determination of the issues on the merits. Cappiello v. Duca, 449 Pa. Super. 100, 672 A.2d 1373, 1376 (1996). These requirements "are cumulative, and if one element is lacking, relief may not be granted." Norristown Mun. Waste Auth. v. West Norriton Twp. Auth., 705 A.2d 509, 512 (Pa. Cmwlth.), app. denied, 555 Pa. 723, 724 A.2d 937 (1998).

Plaintiffs seek a preliminary injunction against defendants' communication with the putative class members who have ingested Baycol during the course of his or her life. In their proposed order for a temporary restraining order, they sought the following relief:

a. Defendants shall immediately refrain from transmitting medical authorizations to any individual in the United States who has ingested Baycol;
b. Defendants shall maintain a file containing all original signed medical authorizations that it has received as of this date from individuals in the United States who have ingested Baycol, and provide said file directly to its counsel who shall return the original authorizations to liaison counsel in this litigation;
c. Defendants shall destroy any copies of said medical authorizations and provide the Court with an Affidavit that all copies of all authorizations have been destroyed and have not been disseminated to any individuals other than its counsel... .

Plaintiffs' Proposed Order for Temporary Restraining Order

The main focus of plaintiffs' initial arguments, however, is to obtain an injunction against defendants to enjoin them from contacting putative class members by transmitting blank medical authorizations. To support this request, plaintiffs invoke Rule 4.2 of the Pennsylvania Rules of Professional Conduct and Pennsylvania Rule of Civil Procedure 1713(a)(2). Plaintiffs' 3/6/2002 Memorandum at 2, 5-7. After Judge Davis of the MDL issued his order, plaintiffs argued more specifically that his order did not address their request that Bayer should (1) advise individuals of their right to counsel and (2) tell individuals to turn this correspondence over to their attorneys if they are

represented. Plaintiffs' 3/27/2002 Memorandum at 2. Plaintiffs do not, however, propose any different grounds for this relief.

To determine, therefore, whether plaintiffs have met the criteria for an injunction, it is necessary to analyze their claims under both Rule 4.2 of the Pennsylvania Rules of Professional Conduct ("Rule 4.2") and Pennsylvania Rule of Civil Procedure 1713(a)(2). For clarity, these two grounds for injunctive relief will be analyzed separately.

Plaintiffs' Claim for Injunctive Rule Under Rule 4.2 of the Pennsylvania Rules of Professional Conduct

Plaintiffs argue initially that defendants' communication with the putative class members by sending them the blank medical authorization form violates Rule 4.2 of the Pennsylvania Rules of Professional Conduct. Plaintiffs assert that all members of the putative class are parties to the action whose "interests are represented by class counsel" and it is thus "improper for the defendants to have direct contact with them." Plaintiffs' 3/6/2002 Memorandum at 2.

Plaintiffs thus raise the difficult threshold issue of the representation of putative class members prior to certification.[4] The case plaintiffs invoke to support their claim of class representation, Bell v. Beneficial Consumer Discount Co., 465 Pa. 225, 348 A.2d 734, 738 (1975), is not, however, directly on point. In Bell, the Pennsylvania Supreme Court addressed the issue of whether a pre-trial order dismissing the class aspects of a suit was an appealable order. Bell, 465 Pa. at 226, 348 A.2d at

[4] For general background on this issue, see Johnson, "The Ethics of Communicating with Putative Class Members," 17 Rev. of Litig. 497 (Summer 1998)(noting that the issue of representation of class members prior to certification is unsettled); Steiner & Opsahl, "Attorney Communications in Class Action Litigation," 115 Banking Law J. 430 (May 1998).

734.While in reaching its conclusion that this was an appealable order the Bell court observed that "the class is in the action until properly excluded," it did not address the issue of representation. Id., 465 Pa. at 229, 348 A.2d at 736.

Pennsylvania courts have yet to address the issue of representation of a class action prior to certification. In the absence of controlling Pennsylvania precedent, it is useful to consider nonbinding but persuasive precedent by federal courts and courts from other states. See generally United Artists' Theater Circuit, Inc. v. City of Philadelphia, 535 Pa. 370, 635 A.2d 612, 617, 619 (1993)(analyzing precedent from federal courts and courts of other states for nonbinding guidance and following it where appropriate). Federal courts and courts from other jurisdictions that have addressed this issue of representation have taken conflicting views on this threshold issue. While some courts conclude that prior to class certification putative class members should be given the protections afforded by ethical rules prohibiting communications by an attorney with a represented party,[5] other courts reject the view that the professional rules of conduct can be invoked on behalf of putative class members.[6]

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[5] See, e.g., *Pennsylvania Rules:* Dondore v. NGK Metals, 152 F. Supp.2d 662, 666 (E.D.Pa. 2001)(the "truly representative' nature of a class action suit affords its putative members certain rights and protections, including, we believe, the protections contained in Rule 4.2 of the rules of Professional Conduct"); Haffer v. Temple Univ., 115 F.R.D. 506, 510 (E.D.Pa. 1987)(Defense attorney's phone calls and memorandum to class members violated Disciplinary Rule 7-104(A) of the Code of Professional Responsibility). See also *ABA Code :* Impervious Paint Indus., Inc. v. Ashland Oil, 508 F. Supp. 720, 723 (W.D. Kentucky 1981) ("Reading DR7-104 as a whole, we believe the implication is unavoidable that defendants' counsel must treat plaintiff class members as represented by counsel and must conduct themselves in accordance with both sections of DR7-104")

[6] Atari v. Superior Court, 166 Cal. App.3d 867, 212 Cal.Rptr. 773 (1985). The Atari court was skeptical of arguments that putative class members should be deemed represented by class counsel:

> Respondent Court's reference to rule 7-103 California Rules of Professional Conduct is inapposite. The rule provides that "[a] member of the State Bar shall not communicate directly

It is, however, unnecessary to resolve this issue because of the record presented in this case and the text of Rule 4.2. Rule 4.2 of the Pennsylvania Rules of Professional Conduct provides:

> In representing a client, a lawyer shall not communicate about the subject of the representation with a party the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized by law to do so. Pa. Rule of Prof. Conduct 4.2 (emphasis added).

Defendants argue that this rule does not apply to preclude them from transmitting the medical authorization forms to putative class members for two reasons. First, the forms are sent not by defense counsel but by Bayer Corporation's Drug Safety Assurance Investigators who are responding to an "adverse drug experience" reported by a consumer. Secondly, this communication is required by federal law since the FDA requires pharmaceutical companies to investigate "adverse drug experiences."[7] To support their claim that these communications are authorized by law, defendants invoke 21 CFR 314.80(c)(1)(ii) which provides:

> (c) Reporting requirements. The applicant shall report to FDA adverse drug experience information, as described in this section. The applicant shall submit two copies of each report described in this section to the Central Document Room, 12229 Wilkins Ave., Rockville MD 20852. FDA may waive the requirement for the second copy in appropriate instances.
>
> (1)(i) Postmarketing 15-day "Alert reports." The applicant shall report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the applicant.

> or indirectly with a party whom he knows to be represented by counsel upon a subject of controversy, without the express consent of such counsel. This rule shall not apply to communications with a public officer, board, committee or body." We cannot accept the suggestion that a potential (but as yet unapproached) class member should be deemed 'a party. . .represented by counsel' even before the class is certified; we respectfully disagree to this extent with the federal courts which apparently would accept it.

Id., 166 Cal. App.3d at 873, 212 Cal.Rptr. at 776.

[7] Defendants' 3/8/2002 Memorandum at 2-3.

> (ii) Postmarketing 15 day "Alert reports" - followup. The applicant shall promptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover. 21 CFR § 314.80(c)(1)(i) & (ii).

Defendants suggest that these requirements in the CFR are supplemented by a document entitled "Guidance for Industry" published by the United States Department of Health and Human Services, FDA to provide a "Guideline for Postmarketing of Adverse Drug Experience." See Defendants' 3/8/2002 Memorandum at 3, Ex. B. These guidelines provide that when an adverse drug event report is received from a consumer (including an attorney), "[a] determined effort should be made to obtain additional detailed information from health professionals for all serious reactions initially reported by consumers." Defendants, 3/8/2002 Memorandum, Ex. B at 23.

Although plaintiffs argue that the defendants' communication with putative class members violates Rule 4.2, they do not contest that the medical authorization forms that defendant Bayer sent to putative class members were authorized by the FDA. In fact, they stipulated to the following:

> 8. Bayer Corporation represents that in response to adverse drug experiences reported by consumers, the Bayer Drug Safety Assurance department transmits a blank authorization to the complainant. A sample authorization is attached as Exhibit "A."
>
> 9. This authorization "authorizes Bayer to contact the prescribing physician to request medical information about the adverse events." *See* Letter of Bayer Corporation attached as Exhibit "B."
>
> 10. All adverse event reports are stamped at the time of arrival. Deposition of Vincent Badalamenti, Steiner v. Bayer Corporation et al., Civil Action No. 01-3172, Circuit Court of Montgomery County, Alabama (Jan.10,2002), 30:1-10, attached as Ex. "C." All adverse event reports are assigned a control number, which begins with the year, followed by a 1, and then a sequential number ending in three letters that signify the location in which the report was

received. Id. At 32-33. . . .

12. All adverse reports are entered in "Clintrace."

13. From the Clintrace database, Bayer generates medwatch reports, as well as CIOMS reports ("foreign country medwatch equivalents").

14. The medwatch forms are then submitted to the FDA for the purposes of reporting adverse events in accordance with their obligations under federal law.

Declaration of Arnold Levin in Support of Statement of Uncontested Facts in Connection with Plaintiffs' Motion for A Preliminary Injunction Relating to Defendants' Communications with Putatitve Class Members (emphasis added). See also 3/13/2002 N.T. at 14 (defendants stipulate that the facts in the Levin Declaration are "correct").

With this stipulation, therefore, the plaintiffs concede that defendants are obligated under federal law to report adverse drug events. The logical conclusion from this concession that the defendants were legally authorized to followup on any adverse drug reaction reported to them is that the exception in Rule 4.2 to the prohibition against attorney contact with a represented party "when authorized by law to do so" would thereby be triggered. Plaintiffs, however, attempted at the hearing to avoid this conclusion by making a strained argument premised on the required "timing" of this report and whether or not the label warned of a potential adverse reaction. Thus, plaintiffs' counsel argued:

> You have to look at the label, because the Baycol label advises the treating physician and the consumer of certain known side effects that can be encountered if you take the product. And under the FDA regulations, and its (sic) consistent with the affidavit submitted by the defendant in this case, only serious, non-labeled events have to be promptly reported to the FDA in 15 days.
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> Well, if you look at the label, and I have a copy for the Court, and if you go to page 5 of the label, you see a section of warnings after contraindictions, and it talks about skeletal muscle damage; it talks about acute renal failure, liver problems; and then if you go further in precautions, it lists which drugs are contraindicated to be taken when you take Baycol.
>
> Our position would be, your Honor, that for people who are reporting muscle pains and aches, assuming it's a serious injury, which is the only way they would have to report that to the FDA in a 15-day period, it's already labeled and warned upon in the label, and therefore,

there's no requirment to get this information to the FDA in 15 days.

It's either done quarterly, annually in a periodic report for the first year a drug is approved, or thereafter it's an annual basis.

So the urgency with which to collect this information depends upon the nature of the complaint that's being given to the drug company when either the doctor or patient calls up and says, hey, I took your drug and I got X. 3/13/2002 N.T. at 18-19 (emphasis added).

Plaintiffs' proposal is anomalous on various scores. Plaintiffs appear to be taking the position that the drug company need not be over eager in reporting adverse drug reactions. They seem to argue that the drug company should exercise more discretion in making reports, and especially in the timing of these reports. Thus, rather than urge the filing of expeditious reports with the FDA, the plaintiffs suggest that their class counsel should be interjected into the reporting process:

> I think you have to step back a second, your Honor, and the first time of the event that's important is until there's a filing of a class action lawsuit, then there's no prohibition on a drug company from sending this letter out, except to the extent that it sends out a letter to someone who has filed an individual lawsuit; and in that instance it would be our position that once the company knows there's a lawsuit, the letter should be sent to the consumer's attorney for followup so that the lawyer can protect the rights of the individual, just like the regulatory people are trying to protect the rights of the drug manufacturer. 3/13/2002 N.T. at 23 (emphasis added).

This suggested modification of the FDA reporting procedures to encompass the attorney of an uncertified class action is untenable for various reasons. First, plaintiffs cite no authority for interjecting an attorney into the FDA reporting procedures. From a practical standpoint, such an intrusion could lead to serious delays in the reporting process for adverse drug reactions, thereby endangering the well being not only of the individual consumer but of consumers generally who depend upon an accurate, expeditious reporting procedure. It should also be noted that the Pennsylvania Rules of Civil Procedure require, as part of the process for certifying a class action, that a court determine that "the attorney for

the representative parties will adequately represent the interests of the class." Pa.R.C.P. 1709(1). Plaintiffs, however, suggest that once a class action has been filed, the drug company should send the followup letter to the attorney regardless of whether the certification process has been completed and the adequacy of the representation has been evaluated. Finally, and most importantly, as defendants emphasize the regulatory scheme imposes confidentiality requirements that are potentially incompatible with plaintiffs' suggestion. For instance, 21 CFR § 314.80(h) provides as follows for "patient privacy:"

> Patient privacy. An applicant should not include in reports under this seciton the names and addresses of individual patients; instead the applicant should assign a unique code number to each report, preferably not more than eight characters in length. The applicatnt should include the name of the reporter from whom the information was received. Names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug experience reports are not releasable to the public under FDA's public information regulations in Part. 20. 21 CFR § 314.80 (h).

Indeed, plaintiffs' counsel concedes that confidentiality issues impose serious impediments to general discovery in this area:

> The Court: Well, have there ever been any-- has there ever been any test of the FDA regulatory scheme in this area [i.e. confidentiality of reports] where the question has been raised? Certainly it must have.
>
> Counsel for Plaintiffs: Well, the converse has occurred; and the converse is, in discovery of adverse drug event databases we're not allowed to know the names of reporting physicians or the names of individuals who may have made the complaints to the drug company. They are excised out to protect those rights, those people, and that's by Federal statute. 3/13/2002 N.T. at 30-31.

For all of these reasons, plaintiffs have failed to establish either that defendants violated Rule 4.2 of the Pennsylvania Professional Code of Ethics with their followup procedures for making a legally authorized report of an adverse drug event to the FDA or that this procedure was in any way abusive

to the interests of the putative class action plaintiffs. Hence, plaintiffs have failed to establish the requisite clear right to relief on the basis of Rule 4.2 for a preliminary injunction.

Plaintiffs' Request for Relief Under Pa.R.C.P. 1713 (a)(2)

As an alternative ground, plaintiffs also request relief under Pa.R.C.P. 1713 (a)(2). This rule provides:

> (a) In the conduct of actions to which this rule applies, the court may make appropriate orders
> (2) requiring, for the protection of the members of the class or otherwise for the fair conduct of the action, that notice, other than notice under Rule 1712, be given in such manner as the court may direct to some or all of the members of any step in the action, or of the proposed extent of the judgment, or of the opportunity of members to signify whether they consider the representation fair and adequate;
> Pa.R.C.P. 1713(a)(2).

The explanatory note to this rule notes that Pa.R.C.P. 1713 "copies Federal Rule 23(d)" except that it "omits the Federal provision for an order amending the pleadings." Pa.R.C.P. 1712, Explanatory Note - 1977.

In the absence of controlling Pennsylvania precedent, a critical starting point for analysis of orders to limit communications between parties and potential class members is therefore Gulf Oil Company v. Bernard, 452 U.S. 89 (1981).[8] In Gulf Oil, the United States Supreme Court observed

[8] Gulf Oil focused on a class action involving allegations of racial discrimination in employment by the defendant Gulf Oil Company and one of the unions at its Port Arthur, Texas refinery. After a class action was filed against Gulf on behalf of all black present and former employees, Gulf filed a motion to limit communications between plaintiffs' counsel and the putative class, which the district court granted in the form of a temporary restraining order. In so doing, the court made no findings of fact. The plaintiffs appealed these limitations on their communications, arguing that they exceeded the court's power under Federal Rule 23(d) and they violated the First Amendment. Gulf Oil, 452 U.S. at 89-100.

The Supreme Court reversed. It noted that the court's order was highly injurious to the class action and that the district court failed to engage in the careful weighing of competing interests. Id., 452

that Federal Rule 23 provides courts with a mechanism for protecting against the potential for abuse inherent in class actions: "(b)ecause of the potential for abuse, a district court has both the duty and the broad authority to exercise control over a class action and to enter appropriate orders governing the conduct of counsel and parties."Id. 452 U.S. at 100. In exercising this authority, the Gulf Oil court set forth the following guidelines:

> Because of these potential problems, an order limiting communications between parties and potential class members should be based on a clear record and specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties. Only such a determination can ensure that the court is furthering, rather than hindering, the policies embodied in the Federal Rules of Civil Procedure, especially Rule 23. In addition, such a weighing--identifying the potential abuses being addressed--should result in a carefully drawn order that limits speech as little as possible, consistent with the rights of the parties under the circumstances. Id. at 101-102.

In arguing that this court should invoke Pa.R.C.P. 1713(a)(2) to enjoin defendants from contacting the putative class action plaintiffs with the medical authorization forms, plaintiffs do not cite to Pennsylvania precedent due to the dearth of relevant case law. They rely instead on cases from other jurisdictions that apply Federal Rule 23. See, e.g. Plaintiffs' 3/6/2002 Memorandum of law at 6 (citing Barahona-Gomez v. Reno, 167 F.3d 1228, 1236 (9th Cir. 1999) and Kleiner v. First National Bank, 751 F.2d 1193, 1201 (11th Cir. 1985). Plaintiffs thus argue that a Rule 1713 (a)(2) order can be issued as a notice and does not require the full evidentiary hearing of an injunction hearing. This, however, oversimplifies the issue where, as in this case, a request is made to limit a party's communication to a putative class where that communication is required by law. The Kleiner case cited

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U.S. at 100, 102.

by plaintiffs, for instance, grappled with the inherent tensions in a class action as well as the Supreme Court's Gulf Oil analysis. The facts of that case, with its clear record of abuse consisting of a strategy of stealth communications by the defendant bank, is distinguishable from the present case focusing on communications required by the FDA.

In Kleiner, the Eleventh Circuit concluded that restrictions could be imposed on a defendant Bank's communications with a putative class action consisting of bank customers after the bank engaged in a stealth telephone campaign to persuade class members to opt out of the class. The court observed:

> The bank's subterfuge and subversion constituted an intolerable affront to the authority of the district court to police class member contacts. [9] Accordingly, we hold that the trial court had ample discretion under Rules 23(b)(3) and 23(d) to prohibit the Bank's overtures. Kleiner v. First National Bank, 751 F.2d at 1203.

In concluding that the "Bank's solicitation canvass is a classic example of a major potential abuse which necessitates restraint," the Kleiner court emphasized that in responding to this abuse the district court properly issued a narrowly drawn order "to avoid suppressing utterances worthy of first amendment protection" so that "the ambit of the order was restricted to communications regarding the litigation."Id., 751 F.2d at 1206.

Similarly, in Hampton Hardware, Inc. v. Cotter & Co., 156 FRD 630 (N.D. Texas 1994), a Texas court concluded that restrictions should be imposed on communications by a defendant hardware wholesaler after it sent letters to putative class members to discourage them from joining in

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[9] The trial court in Kleiner had issued a protective order limiting the bank's discovery to depositions of five class members after two years of discovery and certification of certain contract claims for class action treatment. Kleiner, 751 F.2d at 1196-97.

the class action. These letters, the court concluded, sent the clear message to plaintiffs that they would "pay" if they joined in the class action and thus constituted "the type of misleading communications justifying court intervention." Id., 156 FRD at 632-33. Despite this finding of abuse, the court refused to allow plaintiffs to send a corrective letter prior to certification. Once the class was certified, the court reasoned, they could then present the objective information required under Rule 23(c).

Other courts have likewise limited communications to class members after a finding of abuse. In Haffer v. Temple University, 115 FRD 506, 512 (E.D.Pa. 1987), for instance, the district court exercised its authority under Federal Rule 23(d)(2) both to limit a defendant's improper communication with class action members and to order that a corrective notice be sent to members of a putative class after finding that representatives of the defendant university made false and misleading statements about the class action and attempted to discourage them from participating in it.

Alternatively, where there is no finding of potential abuse, courts have refused to impose restrictions on communications to putative class members. In Gates v. Cook, 234 F.3d 221 (5th Cir. 2000), for instance, the Fifth Circuit applied the Gulf Oil analysis to conclude that a no-contact order should not be imposed to preclude ACLU National Prison Project plaintiffs' attorneys from contacting members of a class action of HIV-positive prisoners represented by other counsel. In reversing the lower court that had imposed a restriction on communications, the Fifth Circuit explained:

> The no-contact order in issue here contradicts the principles enunciated in Gulf Oil v. Bernard, 452 U.S. 89 (1981). In overturning a no-contact order issued in a class action, the Supreme Court noted that such orders must be based on a clear record and 'specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties.' Id. at 102. The order resulting from such a process should be carefully drawn in order to limit speech as little as possible. The order in this case bars all contact between NPP attorneys and class members regarding the subject matter of the litigation, i.e. prison conditions,

treatment and healthcare. The order is not narrowly drawn nor is it justified by any factual findings. Gates, 234 F.3d at 227.

In a case involving a letter by a defendant speech language entity to its students who had brought a class action against it, the court in Rankin v. Bd. of Education, 174 FRD 695 (D. Kansas) 1997) applied the Gulf Oil analysis to conclude that this communication should not be restricted. The letter apologized for services that had not been provided and offered to make up for the missed services. This letter, the Rankin court concluded, was not "an abusive practice that requires protection from the court." It made "no reference to the litigation and does not even attempt to seek to discourage or prevent the recipients of the letter from participating in the lawsuit." Id. At 697. Other courts have also refused to prohibit communications aimed at settling class actions prior to certification. Jenifer v. Delaware Solid Waste Authority, 1999 WL 117762 (D.Delaware 1999)(in the absence of a record of abuse, court denied plaintiff's request to enjoin defendant waste disposal facility from communications about a financial deal to decrease plaintiff waste haulers' expenses in exchange for a release); Jankousky v. Jewel Companies, 182 Ill App.3d 763, 538 N.E.2d 689, 131 Ill. Dec. 314 (Ill.App. 1989)(concluding that there is no prohibition against negotiating a settlement of a class action prior to certification and that defendants need not inform putative plaintiffs of the existence of the class action); In re Winchell's Donut Houses LP Securities Litigation, 1988 WL 135503, at *1 (Del. Ch. 1988)("it seems well settled that before a class action is certified, it will ordinarily not be deemed to be inappropriate for a defendant to seek to settle individual claims even though a class claim has been asserted").

In the present action, plaintiffs have failed to make any showing of the potential abuse of

defendants' communication of a medical authorization form sent to putative class action members as part of an effort to satisfy FDA reporting requirements for adverse drug events. In comparison to those cases where the courts found abusive conduct, the communications in this case were in response to a requirement by the FDA. The communications did not seek in any way to deter participation in the class action litigation; in fact, they make no mention of it.

Likewise, plaintiffs failed to present a record that would justify either their requested notice from Bayer of plaintiffs' right to counsel or their request to turn correspondence over to plaintiffs' counsel. See Great Rivers Cooperative of Southeastern Iowa v. Farmland Indus. Inc., 59 F.3d 764, 766 (8th Cir. 1995)(noting that 'if the court finds that defendants have improperly communicated with plaintiffs, the court may order a curative notice' but refusing to order such a notice where there was no record of misrepresentation or the 'likelihood of serious abuses'); Hampton Hardware v. Cotter & Co., 156 FRD 630 (N.D. Texas 1994)(where there was a record of potential abuse but not of actual harm and the class was not yet certified, sending a corrective notice at this point "would be premature and potentially confusing").

There is, of course, a basis for plaintiffs' concern about defendants' communication related to reported adverse drug events and its potential for abuse.. Plaintiffs are undoubtedly troubled by the potential access of defense counsel to the information garnered through this communication. Moreover, if not carefully limited, such a communication could be tantamount to a discovery fishing expedition.

For all of these reasons, this court will follow the well reasoned guidelines set forth by the order issued by Judge Davis in the MDL litigation ("MDL Baycol Order"). That order is narrowly drawn to protect both defendants' reporting requirements to the FDA and plaintiffs' justifiable concern about the

possible misuse of the information garnered with the medical authorization forms. Consequently, as ordered by Judge Davis, the Drug Safety Department of Bayer Corporation will modify its letter and release sent to consumers to indicate more clearly that the information is sought only as it relates to the adverse drug experience reported by the consumer. This will narrowly define the scope of the response. In addition, counsel for Bayer Corporation shall not have access to the medical records collected in this process. If, however, the plaintiffs in litigation related to Baycol obtain through court-supervised discovery and put at issue the contents of these medical records, then defense counsel may seek access to those records. Any disputes may then be moderated through traditional discovery procedures. That portion of the order by Judge Davis relating to the appointment of a Special Master is inapplicable to the present action.

CONCLUSIONS OF LAW

1. To obtain a preliminary injunction, the moving party has the burden of showing "(1) that the relief is necessary to prevent immediate and irreparable harm which cannot be compensated by damages,(2) that greater injury will occur from refusing the injunction than from granting it; (3) that the injunction will restore the parties to the status quo as it existed immediately before the alleged wrongful conduct, (4) that the alleged wrong is manifest, and the injunction is reasonably suited to abate it; and (5) that the plaintiff's right to relief is clear." Santoro v. Morse, 781 A.2d 1220, 1229 (Pa. Super. 2001).

2. These requirements for a preliminary injunction are cumulative and "if one element is lacking, relief may not be granted." Norristown Mun. Waste Auth. v. West Norriton Twp. Auth., 705 A.2d

509, 512 (Pa. Cmwlth. 1998), app. denied, 555 Pa. 724, 724 A.2d 937 (1998)..

3. Rule 4.2 of the Pennsylvania Rules of Civil Conduct provides that in "representing a client, a lawyer shall not communicate about the subject of the representation with a party the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized by law to do so"(emphasis added).

4. Based on the record presented, defendants are not in violation of Rule 4.2 because they are authorized by law to contact consumers when they receive an adverse drug report from a consumer. 21 CFR 314.80(c)(1)(ii). Consequently, plaintiffs fail to establish such prerequisites for a preliminary injunction as a clear right to relief or that the alleged wrong is manifest.

5. Under Pa. R.C.P. 1713(a)(2), a court may make appropriate orders for the protection of the members of the class.

6. In the dearth of relevant Pennsylvania precedent, this court will consider persuasive precedent from other jurisdictions and especially from federal courts interpreting Federal Rule 23 since Pa.R.C.P. 1713 "copies" the federal rule. Pa.R.C.P. 1713, Explanatory Note - 1977.

7. Under Gulf Oil Company v. Bernard, 452 U.S. 89 (1981), an order limiting communications between parties and potential class members "should be based on a clear record and specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties." Id., 452 U.S. at 101-02.

8. In the present action, plaintiffs have failed to make any showing of the potential abuse of defendants' communication of a medical authorization form sent to putative class action plaintiffs as part of an effort to satisfy FDA reporting requirements for adverse drug events.

9. This court adheres to the relevant provisions of the order by the Honorable Michael Davis issued on March 25, 2002 in In re: BAYCOL PRODUCTS LITIGATION, MDL No. 1431 (MJD) Pretrial Order No. 11.

BY THE COURT:

DATE: June 12, 2002

JOHN W. HERRON, J.