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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ALEX CAIN and WILLIAM WATKINS,

Plaintiffs,

01 CV 3441 (SJ)

-against-

MEMORANDUM
AND ORDER

MERCK & CO., INC., PHARMACIA
CORP., PFIZER INC. and G.D. SEARLE
& CO.

Defendants.

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A P P E A R A N C E S:

BOIES, SCHILLER & FLEXNER LLP
570 Lexington Avenue, 16th Floor
New York, New York 10022
By: David A. Barrett
Nicholas A. Gravante, Jr.
Kenneth G. Walsh
George F. Sanderson III
Attorneys for Plaintiff

SIDLEY AUSTIN BROWN & WOOD
875 Third Avenue
New York, New York 10022
By: Steven M. Bierman
James D. Aiden
Attorneys for Defendants Pharmacia Corporation
and G.D. Searle LLC (f/k/a G.D. Searle & Co.)

SIDLEY AUSTIN BROWN & WOOD
Bank One Plaza
Chicago, Illinois 60603
By: Sara J. Gourley
Richard F. O'Malley
Susan A. Webber
Neil H. Wyland
Sherry A. Knutson

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Of Counsel for Defendants Pharmacia Corporation
and G.D. Searle LLC (f/k/a G.D. Searle & Co.)

KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022

By: David Klingsberg
Steven Glickstein
John J.P. Howley
Melissa C. Morrow, *Of Counsel*
Attorneys for Defendant Pfizer Inc.

HUGHES HUBBARD & REED LLP
One Battery Park Plaza
New York, New York 10004

By: Norman C. Kleinberg
Theodore V.H. Mayer
Robb W. Patryk
Attorneys for Defendant Merck & Co., Inc.

JOHNSON, District Judge

Plaintiffs, Alex Cain and William Watkins ("Plaintiffs"), on behalf of themselves and the class of persons who have taken the prescription drugs brand named Vioxx and Celebrex, have brought the instant action based on claims for failure to warn, strict product liability, negligence, and breach of express and implied warranty against Defendants Merck & Co., Inc. ("Merck"), Pharmacia Corporation ("Pharmacia"), Pfizer Inc. ("Pfizer") and G.D. Searle & Co. (Searle) (collectively referred to as "Defendants"). Plaintiffs seek injunctive, equitable, and monetary relief. Presently before this Court is Defendants' motion to dismiss Plaintiffs' claim for mandatory injunctive relief pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. For the reasons stated herein, the

Court finds that the Food and Drug Administration ("FDA") has primary jurisdiction and stays the present motion until the FDA decides Plaintiffs' request for an emergency notice and revised warning labels.

BACKGROUND

Defendant Merck manufactures and markets the prescription drug rofecoxib under the brand name "Vioxx" for the treatment of osteoarthritis. Vioxx was approved by the FDA on May 21, 1999. Defendants Pharmacia, Pfizer, and Searle manufacture and market the prescription drug celecoxib under the brand name "Celebrex" also for the treatment of osteoarthritis. Celebrex was approved by the FDA in early 1999.

Osteoarthritis, which afflicts 21 million Americans, is the most common form of joint disease. Osteoarthritis is a condition that results from normal wear and tear on the joints, such as knees, hips or from an injury. Some of the symptoms related to osteoarthritis include considerable pain, inflammation and loss of movement, as cartilage covering the ends of bones at the joints wears away.

Both Vioxx and Celebrex belong to a class of drugs known as Cox-2 inhibitors. Cox-2 is a natural enzyme found in the human body that contributes to arthritis pain and inflammation. Vioxx and Celebrex help to reduce the pain and inflammation associated with osteoarthritis by selectively targeting and blocking the Cox-2 enzyme.

Plaintiffs assert that new clinical research conducted by Merck, also known as the

Vioxx Gastrointestinal Outcomes Research (“VIGOR”) study,¹ indicates that “patients who take Vioxx suffer heart attacks, strokes and cardiac illness and/or are significantly more likely to suffer heart attacks, strokes and other cardiac illness than patients who take alternative, less expensive medications to treat conditions like osteoarthritis.” (Am. Compl. ¶ 11.) Plaintiffs allege that Celebrex, which is chemically equivalent to Vioxx, has the same harmful effects. Id.

Plaintiffs contend that the current package inserts and labels found on Vioxx and Celebrex do not alert patients to these serious health risks and dangers. Nonetheless, Plaintiffs allege that Defendants continue to market Vioxx and Celebrex as “highly effective” and “safer than alternative pain relievers.” (Am. Compl. ¶¶ 10, 14.) Plaintiffs seek an order requiring Defendants to send a notice to Vioxx and Celebrex users alerting them “of the serious health dangers and risks of these drugs as compared to more traditional pain relief medication used to treat similar conditions.” (Pls.’ Opp’n Mem. at 7.) In addition, Plaintiffs seek an order requiring Defendants to “(1) create a trust fund, at Defendants’ expense, to finance a medical monitoring program to deliver services,

¹ Attached as Exhibit A to the Declaration of George F. Sanderson III submitted in support of Plaintiffs’ Memorandum in Opposition to Defendants’ Motion to Dismiss Claim for Injunctive Relief is a copy of a letter from Thomas Abrams, Director, Division of Drug Marketing, Advertising, and Communications for the FDA, to Raymond V. Gilmartin, President and CEO of Merck & Co., Inc., dated September 17, 2001. The letter addresses the FDA’s concerns with regard to Defendant Merck’s promotional campaign for Vioxx, which the FDA believes “minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx.” The letter advises Defendant Merck to submit an “action plan” that includes a “comprehensive plan to disseminate corrective messages about the issues discussed in [the] letter to the audiences that received these misleading messages.”

such as testing, preventive screening, and surveillance for conditions resulting from, or potentially resulting from, the use of Vioxx and Celebrex; (2) provide class members with revised and updated warnings on drug labels and drug packaging; and (3) include new warnings on [D]efendants' [i]nternet websites and in the Physicians' Desk Reference ("PDR")." Id.

DISCUSSION

Defendants argue that Plaintiffs' request for injunctive relief should be denied because the relief Plaintiffs seek is preempted by the Food, Drug and Cosmetics Act ("FDCA"), and that the FDA has primary jurisdiction to determine whether the findings of the VIGOR study warrant any labeling changes or the issuance of "emergency notices." Because the Court agrees that the FDA has primary jurisdiction, it is unnecessary to address Defendants' other arguments.

The doctrine of primary jurisdiction allows a federal court, in the exercise of its discretion, to stay an action and refer a matter extending beyond the "conventional experiences of judges" or "falling within the realm of administrative discretion" to an administrative agency with more specialized experience, expertise, and insight. Far East Conference v. United States, 342 U.S. 570, 574 (1952). Courts generally apply the doctrine "whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an

administrative body.” United States v. Western Pac. R.R. Co., 352 U.S. 59, 64 (1956); see also Johnson v. Nyack Hosp., 964 F.2d 116, 122-23 (2d Cir. 1992). In deciding whether to apply the primary jurisdiction doctrine, a court should take into account the doctrine’s two primary interests: resolving technical questions of fact through an agency’s specialized expertise prior to judicial consideration of the legal claims; and consistency and uniformity in the regulation of an area which Congress has entrusted to a specific agency. See Golden Hill Paugusset Tribe of Indians v. Weicker, 39 F.3d 51, 59 (2d Cir. 1991). Referral of an issue to an agency on the grounds of primary jurisdiction is inappropriate when the issue in question is a purely legal one, see Board of Educ. v. Harris, 622 F.2d 599, 607 (2d Cir. 1979), or turns on a factual matter requiring no technical or policy expertise. See National Communications Ass’n Inc. v. American Tel. & Tel. Co., 46 F.3d 220, 223 (2nd Cir. 1995).

While no fixed formula governs the application of the doctrine, courts generally consider the following four factors:

- (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise;
- (2) whether the question at issue is particularly within the agency’s discretion;
- (3) whether there exists a substantial danger of inconsistent rulings; and
- (4) whether a prior application to the agency has been made.

National Communications Ass'n, 46 F.3d 220 at 222. In addition, courts should “balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings.” Id. at 223. If a court finds that an administrative agency has primary jurisdiction over a claim, the court stays the matter and directs plaintiff to file a complaint with the agency. See Reiter v. Cooper, 507 U.S. 258, 268-69 (1993).

The above factors favor application of the primary jurisdiction doctrine in the instant case. The relief Plaintiffs seek does not involve resolution of a purely legal question, such as whether the findings of the VIGOR study trigger a statutory or regulatory notification requirement on the part of Defendants, but rather raise factual questions that cannot be decided without specialized knowledge and expertise. Plaintiffs are essentially asking this Court to determine that the findings of the VIGOR study warrant a change in the labeling and package inserts included with Vioxx and Celebrex, as well as emergency notification to all users of Vioxx and Celebrex. The FDA, not this Court, has the relevant expertise to make such a determination. See Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973) (“The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations.”).

Congress has entrusted the FDA with the responsibility to ensure that drugs marketed in the United States are both safe and effective. 21 U.S.C. § 393(b)(1). Prior

to marketing a drug, a pharmaceutical manufacturer must submit a New Drug Application (“NDA”) to the FDA. 21 U.S.C. § 355(b). An NDA, which usually consists of thousands of pages, contains extensive data on the chemical composition of the drug, manufacturing methods, proposed labeling, safety, effectiveness, pharmacology, toxicology, and clinical data. 21 C.F.R. §§ 314.50(d)(2), (3) and (5). If the NDA application is approved, the FDA then begins its drug review. In its review process, the FDA balances the drug’s therapeutic effect against the risk of known and unknown side effects. See Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140 (2000). If the drug’s therapeutic effect outweighs the side effects, the drug is approved for market. Id. Even after a drug is approved for market, it is subject to FDA oversight. Drug manufacturers must report on a continuous basis any unexpected side effects, adverse reaction, or toxicity, “whether or not considered drug related.” 21 C.F.R. § 310.303(a).

In addition to overseeing drug formulation, production, and testing, the FDA is also responsible for the regulation and approval of prescription drug labeling. Labeling includes not only “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article,” 21 U.S.C. § 321(m), but also literature sent separately by the drug manufacturers that supplements or explains the materials accompanying the drug. Bernhardt v. Pfizer, Inc., 2000 WL 1738645, Nos. 00 Civ. 4042 LMM, 00 Civ. 4379 LMM, at * 3 (S.D.N.Y. Nov. 22, 2000)

(citing Kordel v. United States, 335 U.S. 345, 349-50 (1948)). As part of the NDA process, drug manufacturers must provide and the FDA must approve the exact language that will appear on the drug's labeling. 21 U.S.C. § 355(b)(1)(F) (requiring "specimens of the labeling proposed as part of the NDA").

Plaintiffs point out, however, that while certain proposed changes with regard to drug labeling may be made only after FDA approval, other changes may be made prior to FDA approval. (Pls.' Opp'n Mem. at 8.) For example, a drug manufacturer may change a drug's labeling to "add or strengthen a contraindication, warning, precaution, or adverse reaction," without prior FDA approval. 21 C.F.R. § 314.70(c)(2). Plaintiffs argue that the fact that a drug manufacturer may add warnings to a previously approved NDA without prior FDA approval belies the argument that the FDA has primary jurisdiction. (Pls.' Opp'n Mem. at 20.) This Court disagrees. There is a vast difference between a drug manufacturer voluntarily choosing to add a warning to a drug's labeling and this Court directing a drug manufacturer to revise a drug's labeling by providing it with the specific language to include. Any such directive by this Court would set a new standard, above the minimum standards established by the FDA. The FDA, and not this Court, has the technical expertise to make such determinations. See Weinberger v. Hynson, Wescott and Dunning, 412 U.S. 609, 626-27 (1973) (recognizing the FDA's expertise and primary jurisdiction vis-a-vis the courts).

The FDA has the authority to either alert Vioxx and Celebrex users if it

determines that these drugs create "an imminent danger to health or gross deception of the consumer" 21 U.S.C. § 375(b), or to request Defendants to revise the labeling for Vioxx and Celebrex. 21 U.S.C. § 393. As pointed out by Plaintiffs, the FDA is already exercising this authority by demanding that Defendant Merck (1) cease all violative promotional activities, and the dissemination of violative promotional materials for Vioxx; (2) issue a "Dear Healthcare provider" letter to correct false and misleading impressions; and (3) issue a written statement of Merck's intent to comply with items (1) and (2). (Ex. A to Decl. of George F. Sanderson III at 7.) Because the FDA is already aware of the findings of the VIGOR study and taking appropriate action, no substantial delay will result from the application of the primary jurisdiction doctrine in this case. Therefore, it is of no consequence that Plaintiffs have not made a prior application to the FDA for the issuance of revised labeling and notices.

In addition, deferring Plaintiffs' claims for mandatory injunctive relief to the expertise of the FDA will avoid duplicative proceedings and inconsistent directives. The FDA has already asked Defendant Merck to submit a comprehensive action plan in response to its "Warning Letter" issued on September 17, 2001. See Friends of Santa Fe County v. LAC Mineral Inc., 892 F. Supp. 1333, 1349-1350 (D.N.M. 1995) (deferring plaintiff's request for injunctive relief and remediation with respect to a contaminated mine site where the state environmental agency was dealing with the issue and had already issued an order providing appropriate relief). Therefore, if this Court were to

grant the relief requested by Plaintiffs, there is a strong likelihood that Defendants would be subject to inconsistent directives.

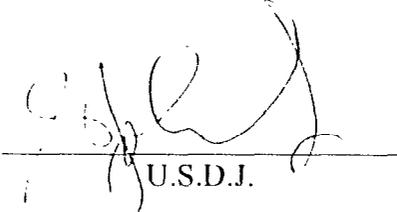
The above review of the relevant regulatory scheme convinces this Court that whether the relief requested by Plaintiffs is warranted is "a decision that has been squarely placed within the FDA's informed expert discretion." Bernhardt, 2000 WL 1738645, at *3 (deferring the question of whether a notice of warning to drug users should be issued to the FDA). Accordingly, this Court defers Plaintiffs' claims for injunctive relief to the FDA.

CONCLUSION

This Court grants Defendants' motion to dismiss as to Plaintiffs' claim for injunctive relief. Plaintiffs are directed to submit their request for injunctive relief to the FDA for review. The Court hereby stays such part of Plaintiffs' case until a determination is reached by the FDA.

SO ORDERED.

Dated: August 14, 2002
Brooklyn, New York



U.S.D.J.