UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LAWRENCE D. BERNHARDT,	:	
Plaintiff,	:	
v.	:	00 Civ. 4042 (LMM)
Pfizer, Inc.,	:	
Defendant.	:	
ARNOLD LIEBMAN,	:	
Plaintiff	:	
v.	:	00 Civ. 4379 (LMM)
PFIZER, INC.,	:	
Defendant	:	

STATEMENT OF INTEREST OF THE UNITED STATES

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STATEMENT OF INTEREST OF THE UNITED STATES

PRELIMINARY STATEMENT

The United States of America (the "United States") respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517, and pursuant to the Court's request by letter dated September 21, 2000, to express its views with respect to plaintiffs' request that this Court require modifications to the approved Cardura labeling in the form of revised labels and warnings.

Congress has assigned to the Food and Drug Administration (the "FDA" or "Agency") the exclusive responsibility to regulate and enforce the laws with respect to prescription drugs sold in the United States. Because the FDA's mission to protect the public

health rests on its ability to maintain exclusive control over approved prescription drug labeling, the injunctive relief sought by plaintiffs -- both modifications to approved product labeling and the issuance of labeling in the form of warning letters – intrudes upon the FDA's role and is preempted. In other words, to ensure that the public receives uniform, consistent information with respect to prescription drugs, and that this information is based on highly developed expertise, any request to order changes related to the approved drug labeling must be addressed directly and exclusively to the FDA; accordingly, plaintiffs fail to state a claim for injunctive relief with respect to modification to Cardura's labeling and those claims should be dismissed.

Moreover, even if plaintiffs state a claim with respect to injunctive relief, that request should be denied because the FDA has primary jurisdiction. Finally, because plaintiffs' claims for injunctive relief are actually veiled attempts to assert, on behalf of the FDA, that defendant violated the Federal Food Drug and Cosmetic Act, 21 U.S.C. 301 et seq., ("FDCA" or "the Act"), these claims are not permitted because the FDCA does not permit a private right of action; correspondingly, to the extent that plaintiffs are challenging the fact that the FDA has brought no enforcement action, this claim is barred because plaintiffs have not exhausted their administrative remedies.

BACKGROUND

I. This Action

The United States, taking no position on the merits of this action, understands the factual allegations, as set out in plaintiffs' complaints, as follows. Pfizer manufactures and markets the prescription drug doxazosin mesylate under the brand name Cardura. (Bernhardt Complaint at ¶ 13; Liebman Complaint at ¶¶ 6, 7). Cardura, which is prescribed to treat both

benign prostatic hyperplasia and hypertension, has been approved for sale by the FDA. (Bernhardt Complaint at ¶ 18; Liebman Complaint at ¶ 8).

In 1994, the National Heart, Lung and Blood Institute ("NHLBI"), a division of the National Institute of Health ("NIH"), began an eight-year study called the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial ("ALLHAT"). (Bernhardt Complaint at ¶ 23; Liebman Complaint at ¶ 11). On March 8, 2000, the NHLBI announced that it had discontinued the portion of the ALLHAT study that compared Cardura with chlorthalidone, a prescription drug used to treat hypertension. (Bernhardt Complaint at ¶ 24; Liebman Complaint at ¶ 12). The NHLBI announced that it had discontinued the portion of the study comparing Cardura to chlorthalidone because of its finding that Cardura users were twice as likely to be hospitalized for congestive heart failure and had a higher chance of suffering from certain other serious cardiac events than the users of chlorthalidone. (Bernhardt Complaint at ¶¶ 4, 24; Liebman Complaint at ¶ 12).

Plaintiffs, on behalf of themselves and prospective class members, seek equitable, injunctive, declaratory and monetary relief. (Bernhardt Complaint at ¶¶ 72, 74; Liebman Complaint at ¶ 17). Among other injunctive relief, plaintiffs ask this Court to provide "emergency notice and revised drug warnings" to Cardura users (Bernhardt Complaint at ¶ 41; Liebman Complaint at ¶ 50) and to "provid[e] Class members with revised warnings on Cardura labels and packaging." (Bernhardt Complaint, Prayer for Relief at (b)(3); Liebman Complaint, Prayer for Relief at ¶ 2).

Further, plaintiffs have moved by order to show cause to have this Court order defendant to provide the following notices to patients and doctors:

Notice to Patients

Dear (patient name):

You have been prescribed Cardura (doxazosin) for the treatment of hypertension. A recent study by the National Heart, Lung and Blood Institute (the "NHLBI") has demonstrated that Cardura is less effective in preventing heart failure compared to a widely used diuretic drug known as chlorthalidone. As a result, you are requested to consult with your doctor regarding your use of Cardura to treat hypertension and other possible treatment options.

DO NOT STOP TAKING YOUR CARDURA MEDICATION UNTIL YOU CONSULT WITH YOUR DOCTOR, BECAUSE THE MEDICATION MAY HELP TO KEEP YOUR BLOOD PRESSURE CONTROLLED DURING THAT TIME AND THERE MAY BE OTHER REASONS WHY YOUR DOCTOR CHOSE THIS DRUG FOR YOUR TREATMENT. After reviewing your individual circumstances, your doctor may or may not recommend that another treatment will be of more benefit to you.

(Exhibit A to Order to Show Cause dated September 8, 2000).

Notice to Physicians

Dear (physician name):

A recent study by the National Heart, Lung and Blood Institute (the "NHLBI") has demonstrated that Cardura (doxazosin) is less effective in preventing heart failure compared to a widely used diuretic drug chlorthalidone. This information is being provided to you as you may have prescribed Cardura for the treatment of hypertension to your patients.

The results of the study known as the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial ("ALLHAT") have been published in Volume 283, Number 15 of JAMA, on April 19, 2000. You are requested to familiarize yourself and your staff with these results, as Cardura patients are being simultaneously notified of the ALLHAT findings and instructed to contact their physicians regarding the effect of the ALLHAT study on their hypertension treatment options based on their individual circumstances.

(Exhibit B to Order to Show Cause dated September 8, 2000).

Plaintiffs do not claim to have petitioned the FDA to require modifications to Cardura's labeling.

II. Regulatory Background

As set forth in the FDCA, the Federal Government, through the FDA, is responsible for regulating prescription drugs. 21 U.S.C. § 393. The FDCA's scheme of prescription drug regulation is designed to ensure that drugs on the market are safe and effective for conditions of their use. 21 U.S.C. §§ 355, 393(b). Thus, the FDCA prohibits the sale of any new drug unless it has first been approved by the FDA, 21 U.S.C. § 355(a), and attaches criminal sanctions to persons who distribute unapproved drugs. 21 U.S.C. § 331(d). A new drug normally obtains FDA approval by virtue of a "new drug application" ("NDA"), which must demonstrate that the drug is safe and effective for its intended uses. 21 U.S.C. § 355(b). An NDA must include, among other things, samples of the drug and "a specimen of the labeling proposed to be used," as well as extensive studies, including both laboratory and clinical investigations, to show that the drug is safe and effective for its intended uses. Id.; see also 21 C.F.R. § 314.50 (detailing contents of NDA). The approval process of an NDA includes an evaluation of the drug's labeling. 21 U.S.C. § 355(b). Indeed, prescription drug labeling is the labeling authorized in the approved NDA. 21 C.F.R. § 201.100(c)(2).

"Labeling" is defined to include "all labels[1] 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). "Accompanying such article" is interpreted to include materials that explain the uses of a drug, including warnings. Kordel v. United States, 335 U.S. 345, 347-49 (1948) (holding that literature sent by the manufacturer of a drug was "labeling" under the

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[1] The statute defines "label" to "mean [a] a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k).

FDCA when it supplemented or explained materials sent with the drug); Walls v. Armour Pharm. Co., 832 F. Supp. 1467, 1482-83 (M.D. Fla. 1993) ("Dear Doctor" letter a form of labeling), aff'd, 53 F.3d 1184 (11th Cir. 1995).

If a drug manufacturer disseminates labeling that the FDA determines to be "false or misleading in any particular," that drug is deemed "misbranded." 21 U.S.C. § 352(a). The FDCA prohibits the manufacture and distribution of misbranded drugs. 21 U.S.C. § 331(a)-(c), (k). If the FDA determines that a drug's labeling is misbranded, the United States may bring an enforcement action against the drug's manufacturer. 21 U.S.C. §§ 331, 332, & 334.

Notwithstanding the ability of the United States to bring an enforcement action, when the FDA determines that warnings are inadequate or improper, the FDA may request that the drug manufacturer revise its labeling. 21 U.S.C. § 393(b)(4). Further, the FDA has the authority to send "Dear Doctor" letters or otherwise disseminate information regarding a drug that it determines creates an "imminent danger to health or gross deception of the consumer." 21 U.S.C § 375(b).

Finally, the FDA's regulations provide for any person to submit a "citizen petition" requesting that the Agency take a particular action. 21 C.F.R. § 10.30. Review of a final administrative action with respect to a citizen petition may be had pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701- 706. See 21 C.F.R. § 10.45(d).

ARGUMENT

I. Plaintiffs' Claim For Injunctive Relief Is Preempted Because It Would Interfere With The FDA's Ability To Regulate Prescription Drug Labeling Effectively

Plaintiffs' request that this Court both require changes to Cardura's labels and packaging and order Pfizer to send warning letters to doctors and patients advising them of the NHLBI announcement is preempted.

The Supreme Court has decided that

> [u]nder the Supremacy Clause, U.S. Const., Art. VI, cl.2., the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and, finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 698-99 (1984) (internal quotation marks and citations omitted); see also English v. General Electric Co., 496 U.S. 72, 78-79 (1990); Association of Int'l Auto Mfrs., Inc. v. Abrams, 84 F.3d 602, 607 (2d Cir. 1996). Although the portions of the FDCA regulating prescription drugs do not contain an express preemption clause, the Government believes that plaintiffs' claims for injunctive relief seeking labeling changes in the form of warnings are preempted by implication because such relief would frustrate the FDA's ability effectively to regulate prescription drugs by having the Court substitute its judgment for the FDA's scientific expertise See Ass'n of Int'l Auto Mfrs, Inc., 84 F.3d at 607 (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)).

As determined by Congress, the FDA's mission with respect to drugs is to protect the public health by ensuring that "drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). Accordingly, as the Second Circuit has explained, "[t]he entire statutory scheme envisages that the FDA will perform the difficult task of investigation and scientific evaluation usually required to determine whether a drug product is safe and effective." Premo Pharm. Lab., Inc. v. United States, 629 F.2d 795, 803 (1980). Were courts to order injunctive relief that would require changes to approved product labeling or that would modify the terms of that labeling in the form of the warning letters proposed by plaintiffs, such judicial action would interfere with the FDA's role as the governmental body responsible for protecting the public interest with respect to prescription drugs. See American Home Products Corp. v. Johnson & Johnson, 672 F. Supp. 135, 146 (S.D.N.Y. 1987) (noting that the FDA must consider not only possible hazards to public health, but also the interest of the public in freedom from groundless alarm).

Should the FDA determine that new warnings are appropriate with respect to Cardura, there exists the very real possibility that such warnings would differ from those requested by plaintiffs. Competing warnings from the FDA and a federal district court about prescription drugs would create unacceptable confusion among users of the drug and in the medical community as a whole.

Further, to ensure that physicians and patients receive correct, consistent, and clear information with respect to the safety and efficacy of prescription drugs, the regulatory scheme established by Congress contemplates that the complex scientific and public health issues involved in drug labeling will be resolved by the agency created for that purpose. See Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248 , 1255 (10th Cir. 1999) ("claims that require direct

interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA") (quoting Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 26, 1997)); American Home Products Corp. 672 F. Supp. at 145 ("[T]he public interest is presumed to be adequately represented by the FDA, whose control over [] drug labeling is . . . 'pervasive and complete.'"). Rather than rely on the FDA to undertake a review of the research that plaintiffs claim calls into question the safety and efficacy of Cardura, and thus justifies labeling changes in the form of warnings, plaintiffs would have this Court simply order the warnings that they deem appropriate. See Grundberg v. UpJohn Co., 140 F.R.D. 459, 469 (D. Utah 1991) (denying non-parties request for confidential documents produced in context of private lawsuit involving Halcion and noting that "[t]he FDA, and not any proposed intervenor, has the responsibility to put into place regulations and to take action to assure public health and safety" with respect to drugs). Were courts to order prescription drug labeling changes and warning letters such as those at issue here, the public would receive information that lacked the benefit of the FDA's scientific expertise and consideration of the relevant policy issues. See Henley v. Food and Drug Admin., 77 F.3d 616, 621 (2d Cir. 1996) ("The FDA possesses the requisite know-how to conduct [an analysis of conflicting studies] by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug"); Public Citizen Health Research Group v. Commissioner, Food & Drug Admin., 740 F. 3d 21, 29 (D.C. Cir. 1984) (whether a drug "is sufficiently dangerous to require a warning label is a factual question demanding the medical expertise that FDA possesses and [courts] lack"); Premo Pharm. Lab., Inc., 629 F.2d at 803

(whether a drug is safe and effective "is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue"). Further, the information disseminated to the public would not have the benefit of the wide range of opinions – opinions that can be rendered outside the constraints of the adversary process and the Federal Rules of Evidence – that the FDA considers in reaching a conclusion on whether warnings should be issued with respect to a particular drug. See Weinberger v. Bentex Pharm., Inc., 412 U.S. 645, 654 (1973) (noting that agency expertise is superior to courts' by virtue of their "specialization, insight gained through experience, and by more flexible procedures"). Consultation with a full range of experts, as well as cooperation with all those affected, is what the FDA does and is precisely what Congress desired. See 21 U.S.C. § 393(b)(4) (where determined appropriate by the Secretary, the Agency should attempt to carry out its mission in "consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.").[2]

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[2] There is also a concern that when private plaintiffs seek to effect labeling changes without going through the administrative process, the interests of those plaintiffs will not take sufficient account of other drug users who are not similarly situated. To take one example, plaintiffs' claims are based on a recent study that they allege establishes that Cardura is less effective in preventing congestive heart failure than another available anti-hypertensive drug. Assuming arguendo that this is true, the complaint makes no claims with respect to the effectiveness of Cardura with respect to its other approved use, namely, treatment of benign prostatic hyperplasia. It cannot be expected that those individuals suffering from hyperplasia will have their interests fully considered in this litigation; nor can the Court be expected to evaluate the effect of the proposed warnings in terms of its likely effect on all Cardura users. See Premo Pharm. Lab., Inc., 629 F.2d at 803 ("The rule that the FDA rather than the courts must first determine the safety and effectiveness of a drug is but an extension of the general principle that the agency is usually better equipped by reasons of its expertise to make the determination than the court."). In fact, although plaintiffs seek to have their proposed labeling changes sent only to Cardura users taking the drug for hypertension, it is unclear how either party will be able to

Plaintiffs seek to avoid the FDA's exclusive role with respect to prescription drug labeling by drawing the Court's attention to cases permitting plaintiffs to bring state common law damages actions based on allegations of inadequate warnings. Although in certain circumstances a common law tort action may be brought alleging that a drug had insufficient warnings,[3] any request for injunctive relief in the form of changes to approved prescription drug labeling or labeling changes in the form of the warnings requested here is preempted. See National Women's Health Network, Inc. v. A.H. Robins Co., 545 F. Supp. 1177, 1181 (D. Ma. 1982) (FDCA preempted claim for injunctive relief seeking notification and warning campaign regarding the dangers of the intrauterine device known as the Dalkon Shield); see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 491, 501 (1996) (plurality opinion) (observing that were a court hearing a common law cause of action to issue a decree establishing a substantive requirement on manufacturers of medical devices that conflicted with those required by the FDCA, the court-imposed requirement would be subject to conflict pre-emption analysis).

In addition, were the Court to grant plaintiffs' request that changes be made to Cardura's label and packaging, this would create a direct conflict by requiring a labeling change at odds with the specific product labeling that was approved by the FDA, even though changes to labels and packaging must be specifically approved by the FDA. See Guidance for Industry: Changes to an Approved NDA or ANDA at 2-3, 24-5, http://www.fda.gov/cder/guidance/index.html (setting out requirements for changes to product

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identify this sub-class of all Cardura users.

[3] The United States takes no position with respect to plaintiffs' claims seeking monetary relief.

labeling).[4] Thus, plaintiffs' request that the Cardura package be modified is also preempted. See Grocery Mfrs. of Am., Inc. v. Gerace, 755 F. 2d 993 (2d Cir.) (state law labeling requirement for artificial cheese preempted because it conflicted with FDA labeling requirement), aff'd, 478 U.S. 801 (1985).

The FDA's ability to regulate prescription drug labeling effectively is best served by ensuring that decisions with respect to the dissemination of warnings such as those at issue before this Court are made by the agency equipped to evaluate the studies on which such warnings would be based. Accordingly, plaintiffs' claims for injunctive relief ordering a change in Cardura's approved product labeling and seeking the dissemination of warning letters are preempted and should be dismissed.

II. Should The Court Determine That Plaintiffs State A Claim For Injunctive Relief, The Court Should Recognize The FDA's Primary Jurisdiction With Respect To The Labeling Changes Requested In This Action

Were the Court to determine that plaintiffs state a claim with respect to injunctive relief in the form of labeling changes, the Court should nevertheless exercise its discretion and allow the FDA to determine what revised labeling, if any, should be required.

As the Second Circuit has explained,

> [t]he doctrine of primary jurisdiction allows a federal court to 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. Specifically, courts apply primary jurisdiction to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.

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[4] The FDA published the Guidance for Industry after the regulation governing changes to an NDA or ANDA, 21 C.F.R. § 314.70, expired pursuant to the Food and Drug Administration Modernization Act of 1997, codified at 21 U.S.C. § 356a.

National Communications Ass'n., Inc. v. A.T. & T., 46 F.3d 220, 222-23 (2d Cir. 1995) (internal quotation marks and citations omitted); see United States v. Western Pacific R.R. Co., 352 U.S. 59, 63-4 (1956) (holding that primary jurisdiction applies where "enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body"). As discussed above, the decision whether (and in what form) to modify labeling with respect to warnings calls on the precise "technical and intricate questions of fact and policy" for which the FDA was established. See supra at 8-10; Henley, 77 F.3d at 621; Public Citizen Health Research Group, 740 F.2d at 29; Premo Pharm. Lab., Inc., 629 F.2d at 803; Great White Fleet, Ltd. v. Fed. Container Line, Inc., No. 92 Civ. 1255 (LMM), 1992 WL 367110, at *2-3 (S.D.N.Y. Nov. 23, 1992) (granting motion to stay action and referring certain issues to agency because "agencies created by Congress for regulating the subject matter should not be passed over") (quoting Far East Conference v. United States, 342 U.S. 570, 574 (1952)); Heller v. Coca-Cola Co., 230 A.D.2d 768, 770, 646 N.Y.S.2d 524, 526 (2d Dep't 1996) (staying class action that sought, inter alia, to require labeling change to diet soda and referring decision to FDA on the ground that the Agency has primary jurisdiction with respect to issues of labeling).

In "determining whether an agency has primary jurisdiction, four factors . . . have generally been the focus of the analysis":

> (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 at 222-23. In addition to these factors, "[t]he court must also balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings." Id. at 223.

As applied to this case, these factors weigh heavily in support of referring to the FDA the issue of whether or not the labeling changes sought by plaintiffs should be required. First, any decision with respect to plaintiffs' proposed warnings involves complex scientific analysis with respect to the ALLHAT study as well as policy considerations pertaining to whether, to what extent, and in what form, warnings should be issued.[5] Second, the issue of what is acceptable labeling with respect to the safety and efficacy of a drug is not only particularly within the agency's discretion, it is an issue that Congress has vested entirely with the FDA. See supra at 8-10. Third, should the Court grant the relief requested by plaintiffs and the Agency determine that any of the statements were not supported by the evidence, and thus misleading, Cardura would be deemed misbranded. Alternatively, were the FDA to determine that a warning was required, but were to issue such warning in a form different than that requested by plaintiffs, not only would Cardura be misbranded, but the public would be receiving competing warnings

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[5] In arguing that the FDA's expertise is not required in this case, plaintiffs place considerable emphasis on the Seventh Circuit's decision in Ryan v. Chemlawn Corp., 935 F.2d 129 (7th Cir. 1991), in which plaintiff filed a tort action for injuries allegedly caused by exposure to defendant's pesticide product. Id. at 130. In holding that there was no primary jurisdiction with the EPA, the court relied on the following facts: (1) "plaintiff ha[d] dropped her claim for injunctive relief," id. at 131; (2) "no regulation or registration provision of the EPA [was] involved," id. at 132; and (3) "issues raised in the complaint did not implicate any EPA action," id. at 132. In contrast, plaintiffs here seek injunctive relief, regulations of the FDA are involved, and the issues raised in the complaint implicate FDA action with respect to prescription drug labeling. In other words, for each reason that the EPA lacked primary jurisdiction in Ryan, the FDA has primary jurisdiction here.

from different branches of government. The doctrine of resting primary jurisdiction with the governmental agency created to address a specific issue is designed to prevent just this type of problem. See Fulton Cogeneration Assocs. v. Niagara Mohawk Power Corp., 84 F.3d 91, 97 (2d Cir. 1996) ("The aim of the [primary jurisdiction] doctrine . . . is to ensure that courts and agencies with concurrent jurisdiction over a matter do not work at cross-purposes."). Only the fourth factor – whether a prior application has been made – adds nothing to the balance of whether primary jurisdiction should rest with the FDA. However, the fact that no application was filed does not weigh in favor of denying the FDA primary jurisdiction; were it otherwise, it would only encourage bypassing the administrative process established to hear petitions with respect to drug labeling.

The considerations that must be balanced against these four factors – potential costs resulting from complications and delay in the administrative proceedings – do not weigh against referring the issue of labeling to the FDA. Although plaintiffs argue that delay is a "critical concern" because "users of Cardura are being exposed to serious risk of heart disease and stroke as long as they remain uninformed," Plaintiffs Memorandum of Law at 18-9, this allegation only begs the question at the heart of this case, namely, "Does the current scientific evidence warrant labeling changes in the form of warnings with respect to Cardura?" This question is not answered by the rhetoric of the pleadings and briefs; rather it can be decided only with appropriate scientific analysis and consideration of issues of public policy; this is the job of the FDA.[6] Absent careful review of all relevant data, there is considerable risk that statements

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[6] Indeed, all cases involving the safety and efficacy of drugs that are being used by (or withheld from) the public raise serious issues of risk to the health of individuals. The very purpose of the FDA is to assess these risks and act accordingly. See Weinberger v. Hynson,

with respect to the efficacy of any drug will be incorrect and, correspondingly, there exists a risk of groundless alarm. American Home Products Corp., 672 F. Supp. at 146 (noting that FDA must consider not only possible hazards to public health, but also the interest of the public in freedom from groundless alarm). Not only does unwarranted alarm create its own risks in any one case, but it has the potential to undermine the authority of the government with respect to drug warnings. To ensure that warnings are required only when appropriate and that when issued they are in an accurate form, it is imperative that such decisions be made by the governmental body best equipped to decide such issues.

That primary jurisdiction rests with the FDA with respect to whether a drug should be designated safe or effective was made clear by the Supreme Court nearly thirty years ago. See Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973); Weinberger v. Bentex Pharm., Inc., 412 U.S. 645 (1973); and CIBA v. Weinberger, 412 U.S. 640 (1973). In these cases, the Court addressed whether the district court or the FDA was the appropriate body to determine whether a particular drug was properly defined as a "new drug" under 21 U.S.C. § 321(p)(1). Hynson, Westcott & Dunning, Inc., 412 U.S. at 613. Section 321(p)(1) defined a new drug as "a drug not generally recognized among experts as effective as well as safe for its intended use." Id. The Court held that the district court should "stay its hand" with respect to questions "within the peculiar expertise of the [FDA]." Bentex Pharm., Inc., 412 U.S. at 654; see CIBA, 412 U.S. at 644 ("the district court might well stay its hand, awaiting an appropriate administrative determination of the threshold question" with respect to the safety and efficacy of

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Westcott & Dunning, Inc., 412 U.S. 609, 624 (1973) ("FDA is indeed the administrative agency selected by Congress to administer the Act.").

a drug). Such a result was the appropriate course in light of the fact that whether a drug is generally recognized as safe and effective within the meaning of [the FDCA] necessarily implicates complex chemical and pharmacological considerations.[7] Bentex Pharm., Inc, 412 U.S at 654.

In light of the complex task of reviewing studies designed to determine the safety and efficacy of drugs, and of determining whether warnings are appropriate, and, if so, what form those warnings should take, the Government respectfully submits that this Court should recognize the FDA's primary jurisdiction to determine whether the labeling changes sought by plaintiffs should be made and deny plaintiffs' request for injunctive relief. Further, should plaintiffs choose to continue their effort to require labeling changes and warnings with respect to Cardura, they should be required to follow the proper administrative procedures.

III. Plaintiffs May Not Assume For Themselves The FDA's Role With Respect To The Enforcement Of The FDCA

Plaintiffs' efforts to have this Court require modifications to labeling and to order Pfizer to issue warnings is nothing more than an attempt to bring an enforcement action for alleged misbranding. Such an action, were it to exist here, may be maintained only by the FDA; in other words, there is no private right of action to enforce the provisions of the FDCA. See PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997) (rejecting plaintiff's attempt

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[7] Plaintiffs describe these cases as "easily distinguishable as they concerned attempts to challenge the FDA's action in separate court actions." Plaintiff's Memorandum of Law at 19. The Supreme Court, however, did not see this distinction as relevant: "Cases may arise where there has been no formal administrative determination of the 'new drug' issue, it being first tendered to a district court. Even then, however, the district court might well stay its hand, awaiting an appropriate administrative determination of the threshold question." CIBA Corp., 412 U.S. at 644.

to "privately enforce alleged violations of the FDCA" on the ground that the FDCA does not provide a private right of action); Cottrell, Ltd v. Biotrol Int'l, Inc., 191 F.3d at 1255 (holding that claims requiring interpretation and application of FDCA must be addressed to FDA, the agency Congress vested with enforcement power); Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F. 2d 222, 230 (3rd Cir. 1990) (rejecting Lanham Act claim accusing drug manufacturer of misleading drug labeling on ground that such "claim is no more than an allegation of a misbranding violation under the FD&C Act, and that, although [plaintiff's] allegation may create a cause of action for the FDA, [it] does not give rise to a cause of action for a private plaintiff under the Lanham Act"). As Judge Connor explained, "the public interest is presumed to be adequately represented by the FDA, whose control over [] drug labeling is . . . 'pervasive and complete.' If the intercession of a private attorney general is needed to press the FDA to perform that duty with respect to a particular product label, the quickest and most effective relief could be obtained through a direct petition to the agency . . . ." American Home Products Corp. 672 F. Supp. at 145 (citation omitted).

IV. Having Never Petitioned The Agency To Act, Plaintiffs Have Failed To Exhaust Their Administrative Remedies

Because plaintiffs do not have a private right of action that permits them to enforce the FDCA, their claim for injunctive relief is properly understood as an effort to obtain judicial review of the fact that the FDA has taken no enforcement action with respect to the alleged misbranding of Cardura. However, "[g]iven the allocation of responsibility in the statutory scheme, [plaintiffs'] request for initial judicial ruling on the misbranding issue amounts to an attempt to bypass the administrative process." Public Citizen Health Research Group, 740

F.2d at 29.

> The Supreme Court has explained that administrative
>
> > [e]xhaustion is required because it serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency. As to the first of these purposes, the exhaustion doctrine recognizes the notion, grounded in deference to Congress' delegation of authority to coordinate branches of Government, that agencies, not the courts, ought to have primary responsibility for the programs that Congress has charged them to administer. Exhaustion concerns apply with particular force when the action under review involves exercise of the agency's discretionary power or when the agency proceedings in question allow the agency to apply its special expertise.

McCarthy v. Madigan, 503 U.S. 140, 145 (1992)

Plaintiffs attempt to flout the administrative regime established by Congress by bringing to this Court what is properly a citizen petition addressed to the FDA. See 21 C.F.R. § 10.30. The Supreme Court has cautioned that "exhaustion principles apply with special force when 'frequent and deliberate flouting of administrative processes' could weaken an agency's effectiveness by encouraging disregard of its procedures." Id. (citations omitted). Furthermore, it serves Congress's purpose and promotes judicial economy to provide the FDA an opportunity to develop a factual record, apply its expertise, and exercise its discretion. See Public Citizen Health Research Group, 740 F.2d at 29.

Plaintiffs should not be permitted to undermine Congress's goal of placing with the FDA responsibility for regulating drug labeling. Accordingly, plaintiffs' claim for injunctive relief should be dismissed.

CONCLUSION

For the foregoing reasons, the United States respectfully submits that this Court should dismiss plaintiffs' claim to the extent it seeks modifications to the approved Cardura labeling in the form of revised labels and warnings

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