UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

ENTERED
SEP 27 2001
SAMUEL L. KAY, CLERK
U. S. District & Bankruptcy Courts
Southern District of West Virginia

MICHAEL McCALLISTER and
WILLIAM DUFFIELD, on behalf
of themselves and all
others similarly situated,

Plaintiffs,

v. CIVIL ACTION NO. 2:01-0543

PURDUE PHARMA L.P., *et al.*,

Defendants.

MEMORANDUM OPINION AND REMAND ORDER

Pending is Plaintiffs' motion to remand this action. For reasons discussed below, the motion is **GRANTED.**

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs filed a class action complaint on May 18, 2001 in the Circuit Court of Putnam County, West Virginia, on behalf of persons who have obtained and ingested OxyContin ("the drug") from a prescription written in West Virginia or from pharmacies or physicians in the state.[1] Defendants are Purdue Pharma, The Purdue Frederick Company, Purdue Pharmaceuticals, the P.F. Laboratories,

[1]Excluded from the class are (a) those prescribed the drug while hospital inpatients, or (b) after being diagnosed with a terminal illness, or (c) those not addicted, who have no belief they are addicted, or have no need for medical assistance in ceasing use of the drug. (Compl. ¶ 3.)

Inc., and PRA Holdings, Inc. (collectively "Purdue"); Abbott Laboratories and Abbott Laboratories, Inc. (collectively "Abbott");[2] Jimmy Adams, D.O.; and Donald L. Hoffman, M.D. Purdue and Abbott manufacture and sell OxyContin. Drs. Adams and Hoffman allegedly prescribed the drug to the named class representatives.

The Complaint alleges OxyContin is an addictive and unreasonably dangerous drug. While making generic allegations standard to strict and negligent liability claims,[3] Plaintiffs further allege Purdue and Abbott encouraged widespread use of OxyContin for off-label uses and doses, while misleading Plaintiffs, both by misrepresentation and omission, about the safety and effectiveness of the drug. Further, Plaintiffs allege Purdue and Abbott encouraged and enlisted physicians and others to mislead Plaintiffs to purchase and take the drug while withholding information about its dangers, particularly its addictiveness. According to the Complaint, the drug's addictive potential necessitates periodic diagnostic medical examinations of patients

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[2]Abbott and Purdue Defendants collectively are referred to as "the drug company Defendants" or "the drug companies."

[3]E.g., "The Purdue [and Abbott] Defendants negligently, carelessly, knowingly, recklessly, wrongfully and intentionally labeled, distributed, advertised, promoted, marketed, prescribed and placed the drug in the stream of commerce for sale in the United States, including the State of West Virginia, and sold the drug to West Virginia residents including your plaintiffs and the class that they seek to represent." (Compl. ¶¶ 19, 20.)

for whom it is prescribed.

Plaintiffs seek relief under the West Virginia Medical Professional Liability Act, W. Va. Code §§ 55B-7-1, *et seq.*, and the state Unfair Trade Practices Act, W. Va. Code §§ 46A-6-101, *et seq.* Plaintiffs also sue under theories of outrage, product liability (including theories of negligence, strict liability and breach of express and implied warranties), misrepresentation, negligence, fraud and medical monitoring.

Defendants[4] timely noticed removal to this Court based on federal question jurisdiction, pursuant to 28 U.S.C. § 1331.[5] The drug companies argue OxyContin's main ingredient, oxycodone, is a highly regulated Schedule II narcotic, the manufacture, promotion and distribution of which is subject to comprehensive federal regulation under both the Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.*, and the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321, *et seq.* They urge that Plaintiffs' claims challenge and seek to override this federal regulatory scheme. In particular, according to the drug companies, Plaintiffs would second-guess the

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[4]Defendants Purdue and Abbott removed with formal consent by Adams. (Notice of Removal ¶ 3.) They note Hoffman has not been served, but once served, aver he will consent formally to removal. (Id.)

[5]Plaintiffs, Defendants Adams and Hoffman are all West Virginia residents. No party argues diversity jurisdiction is satisfied. See 28 U.S.C. § 1332.

federally-mandated content of warning labels and regulators' determinations of the appropriate uses for OxyContin. Defendants also propose Plaintiffs seek an injunction to modify the labeling for the drug, a claim they characterize as completely preempted by federal law. Finally, Defendants assert a need for federal jurisdiction to avoid contradictory pronouncements from state and federal courts.

II. DISCUSSION

A. Standard of Review

Because federal courts are courts of limited jurisdiction, removal statutes must be construed strictly against removal. Mulcahey v. Columbia Organic Chem. Co., Inc., 29 F.3d 148, 151 (4th Cir. 1994). The party seeking to remove a case to federal court has the burden of establishing federal jurisdiction. Id. If federal jurisdiction is doubtful, a remand is necessary. Id.

B. Removal Jurisdiction

A defendant may remove any civil action, brought in a state court, "of which the district courts of the United States have original jurisdiction." 28 U.S.C. § 1441(a). Federal courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. The most familiar explanation of "arising under," although

one not dispositive of all questions and cases, is that of Justice Holmes: "A suit arises under the law that creates the cause of action." Franchise Tax Bd. of the State of Cal. v. Constr. Laborers Vacation Trust for S. Cal., 463 U.S. 1, 8-9 (1983)(quoting American Well Works Co. v. Layne & Bowler Co., 241 U.S. 257, 260 (1916)).

Whether a particular civil action arises under the laws of the United States generally depends on application of the well-pleaded complaint rule. Under that test, "a cause of action arises under federal law only when the plaintiff's well-pleaded complaint raises issues of federal law."[6] Metropolitan Life Ins. Co. v. Taylor, 481

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[6]Plaintiffs' Complaint begins with a disclaimer that would have the effect of automatically purging its face of any federal claims:

> This [state circuit] Court has subject matter jurisdiction over the claims set forth in this Complaint as the claims do not arise out of federal law. The plaintiffs and the class they seek to represent . . . seek no relief under any federal laws or regulations, assert no federal claims, and withdraw any asserted state claim that is preempted by federal law.

(Compl. ¶ 2.) Because the Court finds the Complaint satisfies the well-pleaded complaint rule and, on its face as pled, raises no issues of federal law, it does not consider the reach or effect of such a disclaimer, either on a plaintiff's potential claims or on federal jurisdiction. The Court does note, however, were Plaintiffs to disavow federal claims, successfully attain remand, and then reassert the discarded claims, 28 U.S.C. § 1446(b) would permit Defendants a second, and valid, removal.

U.S. 58, 63 (1987) (citations omitted); see also Franchise Tax Bd., 463 U.S. at 10-11. Federal courts enjoy removal jurisdiction only where "a right or immunity created by the Constitution or laws of the United States [is] an element, and an essential one, of the plaintiff's cause of action." Gully v. First Nat'l Bank, 299 U.S. 109, 112 (1936).

The artful pleading doctrine is a corollary to the well-pleaded complaint rule. Under the doctrine, a plaintiff cannot frustrate a defendant's right of removal by carefully pleading the case without reference to any federal law. 14B Charles A. Wright *et al.*, Federal Practice and Procedure § 3722 (3d ed. 1999). If a court concludes a plaintiff has "artfully pled" claims, it may uphold removal although no federal claim appears on the complaint's face. The two significant types of artful pleading involve state claims that are completely preempted or that necessarily involve a substantial question of federal law.[7] Id. According to

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[7]Purdue cites a third potential category of artfully pled, but essentially federal claims: a state cause of action that is substantially similar to a previously dismissed federal claim brought by the plaintiff. (Purdue Defs.' Mem. Of Law in Opp'n to Pls.' Mot. to Remand at 4.) In 1998, however, the Supreme Court explicitly rejected federal claim preclusion as a basis for removal jurisdiction. "Moitie did not create a preclusion exception to the rule fundamental under currently governing legislation that a defendant cannot remove on the basis of a federal defense." Rivet v. Regions Bank of La., 522 U.S. 470, 478 (1998)(citing Federal

(continued...)

Defendants, Plaintiffs' claims fall under one or both categories of artful pleading. The Court examines each in turn.

1. Preemption: Field, Conflict and Complete

The Supremacy Clause of the United States Constitution, art. VI, cl. 2, supports federal preemption of state law. Congress may impliedly preempt state law by occupying an entire field of regulation (field preemption). Or federal law may preempt state law to the extent it actually conflicts with federal law so that either compliance with both is impossible or state law stands as an impediment to a federal purpose (conflict preemption). See Abbot v. American Cyanamid Co., 844 F.2d 1108, 1111 (4th Cir. 1988). Field and conflict preemption are interposed as defenses to state claims (i.e., federal law made me do it or allows me to do it). As defenses, they do not appear on the face of a well-pleaded complaint, and, thus, do not authorize removal to federal court.[8] Id.

In contrast, complete claim preemption provides removal

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[7](...continued)
Dept. Stores, Inc. v. Moitie, 452 U.S. 394, 398 n.2 (1981)(Footnote two of Moitie had created the initial confusion.).

[8]It is well-settled law that a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case. Franchise Tax Bd., 463 U.S. at 14.

jurisdiction. Where Congress so completely preempts a particular area by express design, any civil complaint raising this select group of claims is necessarily federal in character. Metropolitan, 481 U.S. at 63-64. If "a federal cause of action completely preempts a state cause of action any complaint that comes within the scope of the federal cause of action necessarily 'arises under' federal law." Franchise Tax Bd., 463 U.S. at 24. While such complete preemption[9] is rare, the Supreme Court has held claims under Section 301 of the Labor Management Relations Act and Section 502(a) of the Employee Retirement Income Security Act completely preempt state law claims. The Supreme Court has not stated a test for complete preemption. Our Court of Appeals has focused upon the intent of Congress: "In deciding whether the preemptive force of [an] Act is so extraordinary that a state-law claim . . . becomes federal in nature, the focus of our inquiry must be

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[9]As the Tenth Circuit has explained, "complete" preemption does not refer to the expansiveness of the doctrine:

> We read the term [complete preemption] not as a crude measure of the breadth of the preemption (in the ordinary sense) of a state law by a federal law, but rather as a description of the specific situation in which a federal law not only preempts a state law to some degree but also substitutes a federal cause of action for the state cause of action, thereby manifesting Congress's intent to permit removal.

Schmeling v. NORDAM, 97 F.3d 1336, 1342 (10th Cir. 1996).

congressional intent." Rosciszewski v. Arete Assocs., Inc., 1 F.3d 225, 231 (4th Cir. 1993). Other circuits have drawn from Franchise Tax Board and Metropolitan more precise lessons. Under the Third Circuit test, for example, complete preemption exists only if: (1) "the statute relied upon by the defendant contains civil enforcement provisions within the scope of which the plaintiff's state claim falls" and (2) there is "a clear indication of a Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law."[10] Railway Labor Executives Ass'n v. Pittsburgh & Lake Erie R.R. Co., 858 F.2d 936, 942 (3d Cir. 1988). Considering these standards, the Court examines Purdue and Abbott's arguments Plaintiffs' claims are completely preempted.

a. Plaintiffs Seek No Accurate Labeling Injunction

The drug companies first seek removal because Plaintiffs request an injunction requiring proper and accurate labeling of OxyContin, an area totally governed by federal law. Plaintiffs correctly respond they seek no such injunction. The only explicit

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[10]Under the similar Fifth Circuit test complete preemption exists where (1) the statute must contain a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law, (2) there must be a specific jurisdictional grant to the federal courts for enforcement of the right, and (3) there must be clear congressional intent that claims brought under the federal law be removable. Aaron v. Nat'l Union Fire Ins. Co., 876 F.2d 1157 (5th Cir. 1989).

injunctive relief sought in the Complaint asks "Equitable, injunctive and/or declaratory relief for providing notice and medical monitoring relief to plaintiffs and the class[.]" (Compl. Prayer for relief ¶ 6.) The potential class's "need of accurate information concerning the health effects of the drug," (Compl. ¶ 93) occurs in the series of allegations supporting class certification, and refers to Plaintiffs' allegations that inaccurate and misleading information was supplied, although not through labeling or mis-labeling.

The gravamen of this Complaint is not that OxyContin is incorrectly or inadequately labeled.[11] Rather, Plaintiffs complain that, aside and apart from whatever labeling the federal agencies require, the drug companies have encouraged the use of OxyContin, as the Complaint states, for "off label uses and doses which defendants knew or should have known would reasonably harm plaintiffs and other similarly situated." (Id. ¶ 29) (emphasis added). Their complaint, whether correct or not, is that despite the presumptively accurate labeling, the drug company Defendants

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[11]Defendants observe that "label" and "labeling" are technical terms defined by under 21 U.S.C. § 321, a "label" being a display upon "the immediate container" while "labeling" includes "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(k), (m). This is a distinction without a difference in the context of Plaintiffs' Complaint.

"encouraged and enlisted the physicians and others to prescribe and sell the drug to plaintiffs and the class to purchase and ingest the drug." (Id. ¶ 25.) As Plaintiffs' reply elaborates,

> Plaintiffs' case centers around allegations that defendants took a product that had some proper and approved uses and (despite what the labels say or do not say) took to over-promoting it by marketing and selling it for treatment of garden variety injuries while at the same time de-emphasizing and contradicting the statements contained in the approved labeling. Consist[ent] with this approach, the complaint excludes claims made by persons terminally ill or who received the drugs while hospitalized.

(Pls.' Reply in Supp. of Mot. to Remand at 3-4.) The injunction sought is for medical monitoring notice. Because Plaintiffs do not seek improved warning labels or labeling for the drug, nor an injunction to force it, Defendants' extensive preemption arguments on this ground are not relevant and do not support removal.

b. Federal Requirements May Provide a Preemption Defense

The drug companies point to Plaintiffs' claim,

> The Purdue and Abbott Defendants knew or should have known of the dangers of the drug and owed a duty to provide information to the public, physicians, clinics, pharmacies and others of the dangers of the product and the proper and appropriate warnings which would clearly advise physicians, clinics and the public of the dangers of the use of said drug.

(Compl. ¶ 23.) The Complaint further elaborates the Purdue and Abbott Defendants, "failed and refused to advise" of OxyContin's dangers (¶ 24), "failed . . . to . . . instruct and inform by

warnings. . . and publication of the dangers" of the drug (¶ 27), and withheld information (¶¶ 30, 32, 33).

Defendants protest that all information provided to doctors and the public was approved, regulated, and even mandated by the federal government.[12] Further, the drug companies claim any assertion that class members need "accurate information concerning the health effects of the drug" necessarily calls into question federal regulatory decision-making about the accuracy of information now required to be provided.

Again, however, Defendants misconstrue Plaintiffs' allegations. Plaintiffs' claims are all consistent with allegations the drug companies provided inaccurate information that was itself inconsistent with required labels. Defendants' contentions that 1) all information provided was federally required, 2) the accuracy of the information was determined by federal regulators, and 3) Defendants acted wholly in accord with duties imposed by federal law are potential defenses to Plaintiffs' claims. "As a defense, [however,] it does not appear on the face of a well-pleaded complaint and, therefore, does not authorize

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[12]Defendants' response presumes only federally-approved information was provided. This is, of course, a question of fact, which raises the same issue as Plaintiffs' allegation the drug companies provided misinformation, despite or in addition to, the federally-required information.

removal to federal court." Metropolitan, 481 U.S. at 63 (citing Gully, 299 U.S. at 122).

Beyond the specific allegations of the Complaint, Defendants make a broader argument that all aspects of OxyContin manufacture and distribution are federally controlled because it is a Schedule II drug with "a high potential for abuse," which "may lead to severe psychological or physical dependence." (Abbott Defs.' Mem. of Law in Opp'n at 10) (citing 21 U.S.C. § 812(b)(2)). Even the amount that may be produced is controlled by the government. (Id. (citing 21 U.S.C. §§ 826(a),(c)). While Defendants do not characterize the type of removal preemption claimed,[13] apparently they allude to field preemption. That is, the federal government has so entirely occupied the field of OxyContin regulation that any claim concerning that regulation is necessarily federal. Again, however, the broad argument, even if correct,[14] demonstrates only defensive preemption, not complete preemption necessary for removal jurisdiction.

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[13]Because of the generalized and non-specific nature of Defendants' arguments, the Court also considers, *infra*, Defendants' claim of over-arching federal regulation as potentially raising substantial questions of federal law.

[14]Because the Court determines it lacks subject matter jurisdiction over this action, it would be inappropriate for the Court to determine categorically whether Defendants' proposed defenses in fact involve federal preemption.

c. Complete Preemption under the FDCA or Controlled Substances Act

Defendants' central argument for removal is that either the FDCA or Controlled Substance Act governed every action they took of which Plaintiffs complain. The drug companies do not undertake the necessary analysis, but the FDCA or the Controlled Substances Act completely preempts Plaintiffs' state claims only if it provides a private cause of action, which Congress intended to vindicate the same interest Plaintiffs seek to vindicate in their state action.[15]

The FDCA contains no private civil enforcement provisions which would encompass Plaintiffs' claims. See Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 814 (1986); In re Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled . . . that the FDCA creates no private right of action."); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) ("[Plaintiff], in short, is not empowered to enforce independently the FDCA."); Dawson v. Ciba-Geigy Corp, 145 F. Supp.2d 565, 571 (D.N.J. 2001) (Considering similar claims about Ritalin and concluding, "It is thus without doubt that there is no civil remedy available to Plaintiffs under the FDCA.").

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[15] See discussion *supra* at II.B.1.

Concerning the Controlled Substances Act, neither party has pointed the Court to any case where a defendant has alleged that plaintiff's state law causes of action are completely preempted (or raise a substantial question of federal law) under this Act. The Court agrees with Plaintiffs' representation that a careful review of the Act, 21 U.S.C. §§ 801-971, establishes no Congressional intent to create a private, civil right of action nor to permit removal.[16]

For all these reasons, the Court **FINDS** and **CONCLUDES** none of Plaintiffs' state law claims are completely preempted by federal law so as to create federal jurisdiction and permit removal.

2. Substantial Question of Federal Law Requiring Uniform Interpretation

Alternatively, Defendants propose Plaintiffs' claims require resolution of substantial questions of federal law, including proper interpretation of both the FDCA and Controlled Substances

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[16]Factors relevant in determining whether a private remedy is implicit in a statute not expressly providing one are: (1) is plaintiff one of the class for whose especial benefit the statute was enacted? (2) is there any indication of legislative intent, explicit or implicit, either to create such a remedy or deny one? (3) is it consistent with the underlying purposes of the legislative scheme to imply such a remedy for plaintiff? and (4) is the cause of action one traditionally relegated to state law so that it would be inappropriate to infer a cause of action based solely on federal law? See Cort v. Ash, 422 U.S. 66, 78 (1975). The Controlled Substances Act fails the second condition.

Act. The important need for uniform interpretation of these federal statutes is another area of substantial federal interest.

In Franchise Tax Board the Supreme Court stated that federal question jurisdiction may be appropriate when "it appears that some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims." Franchise Tax Bd., 463 U.S. at 13. The "actual holding in Franchise Tax Board demonstrates that this statement must be read with caution[,]" the Court noted in Merrell: "the central issue presented in [Franchise] turned on the meaning of [ERISA], but we nevertheless concluded that federal jurisdiction was lacking." Merrell, 478 U.S. at 809.

The Merrell court further explained:

> Given the significance of the assumed congressional determination to preclude federal private remedies, the presence of the federal issue as an element of the state tort is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system. . . . We simply conclude that the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently "substantial" to confer federal-question jurisdiction.[17]

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[17]While some courts and commentators suggest this analysis conflates complete preemption and substantial federal question jurisdiction, a lengthy, albeit somewhat enigmatic footnote immediately following the Court's discussion distinguishes "important" federal questions, e.g. the constitutionality of an (continued...)

Merrell, 478 U.S. at 814. Accordingly, interpretive issues under the FDCA and the Controlled Substances Act are insufficient to provide removal jurisdiction, in the absence of a congressionally-mandated private cause of action.

Finally, Defendants propose the need for uniform interpretation of the far-reaching federal scheme for regulation of drug manufacture, labeling, and distribution is a substantial federal interest providing jurisdiction. In Merrell, the Court summarily disposed of the identical argument:

> In addition to the significance of the congressional decision to preclude a federal remedy, we do not agree with petitioner's characterization of the federal interest and its implications for federal-question jurisdiction. To the extent that petitioner is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, petitioner should be arguing, not that federal courts should be able to review and enforce state FDCA-based causes of action as an aspect of federal-question jurisdiction, but that the FDCA pre-empts state court jurisdiction over the issue in dispute. Petitioner's concern about the uniformity of interpretation, moreover, is considerably mitigated by the fact that, even if there is not original district court jurisdiction for these

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[17](...continued)
important federal statute, from less important, e.g. the violation of a federal standard as an element of state tort recovery, which did not fundamentally change the state tort nature of the action. See Merrell, 478 U.S. at 814, n.12.

In the instant action, Plaintiffs may prove their state claims without any allegation or any proof Defendants violated the federal statute. Again, actions comporting with the federal law provide only a potential defense.

> kinds of action, this Court retains power to review the decision of a federal issue in a state cause of action.

Merrell, 478 U.S. at 815.

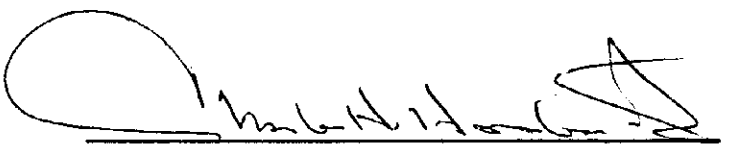
The Court is sympathetic to Defendants' desire for uniform and consistent interpretations of the federal statutes and extensive federal regulatory scheme under which they operate and by which they are guided. Nevertheless, the Supreme Court has rejected defensive preemption as a basis for federal removal jurisdiction, and this Court must observe the jurisdictional boundaries as they, currently, are clearly drawn.

Accordingly, the Court **FINDS** and **CONCLUDES** Defendants have not identified a substantial federal question supporting federal jurisdiction which would allow removal to this Court. Having also considered Defendants' further arguments and finding them without merit, remand is necessary.

III. CONCLUSION

Plaintiffs' motion for remand is **GRANTED.** This action is **REMANDED** to the Circuit Court of Putnam County, West Virginia for all further proceedings. The Clerk is directed to publish this Memorandum Opinion and Order on the Court's website at http://www.wvsd.uscourts.gov, to send a copy to counsel of record, and to send a certified copy to the Clerk of Court for the Circuit Court of Putnam County.

ENTER: September 27, 2001



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