UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: PROPULSID	:	MDL NO. 1355
PRODUCTS LIABILITY LITIGATION	:	SECTION L
	:	
	:	JUDGE FALLON
THIS DOCUMENT RELATES TO ALL CASES	:	MAG. JUDGE AFRICK

PHILADELPHIA COUNTY MASS TORT PROGRAM PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MOTION FOR INJUNCTION

INTRODUCTION

This Motion for Injunction claims to seek "management or coordination among the 37 states in which these actions are pending." Yet the relief requested -- an order removing all state proceedings to this Court, and an injunction effectively staying all state proceedings -- is extraordinary, and raises powerful Constitutional and federalism issues. Although defendants couch their motion under the need to coordinate pre-trial discovery and class certification, the facts reveal significant coordination and cooperation among MDL and state court based counsel, virtually eliminating duplication, and obviating the need to coordinate proceedings here. Rather, the current discovery methods have assisted plaintiffs in establishing defendants' liability.

The claimed need for discovery and pre-trial coordination fosters defendants' goal of this Court taking complete control over all Propulsid litigation. In so doing, defendants seek to use the All Writs Act to forum shop for a court it perceives, or hopes, is more favorable to it, and delaying or preventing any other court -- regardless of its jurisdiction, policies and concerns -- from certifying any classes, including one solely of citizens from a defendant's home state, and delaying individual state court plaintiffs from obtaining a prompt trial.

This request is inconsistent with long-standing and fundamental law and policy that an injured *plaintiff* has the right to file a lawsuit, and have it heard in the forum of *plaintiff's* choosing. While not absolute, a plaintiff's right to choose the forum is a longstanding tenet of our jurisprudence. To allow the defendants to use procedural devices to forum shop violates centuries old policy allowing a plaintiff to select a forum for litigating civil wrongs.

The sole basis for this unprecedented request is the "in aid of its jurisdiction" authority of the All Writs Act, and the related exception to the Anti-Injunction Statute. These arguments must fail as a matter of law, because: (1) this Court does not have *subject matter jurisdiction* over state law claims between non-diverse parties, whose putatively fair settlement value is less than the jurisdictional threshold for diversity; (2) this Court does not have *personal jurisdiction* over absent class members; and, (3) this Court, therefore, cannot act in furtherance of its jurisdiction.

This Court may not try this case, even if jurisdiction attaches. Moreover, the facts underlying the Motion fail to make a colorable claim under the law, and demonstrate that the defendants have unclean hands, precluding this Court from granting their Motion. For the following reasons, this Court should deny this extraordinary and unprecedented request.

STATEMENT OF FACTS

I. FACTUAL BACKGROUND

Defendants developed Cisapride (commonly known by its brand name, "Propulsid®"), to treat nocturnal heartburn caused by gastroesophogeal reflux disease ("GERD"). GERD is a motility disorder in which inadequate operation of the muscles of the esophagus, stomach, and esophageal sphincter causes hydrochloric acid from the stomach to back up into the esophagus, which in turn causes discomfort and other medical consequences.

Defendants launched Propulsid in October 1993, amid much fanfare, as a new way to treat nocturnal heartburn by increasing lower sphincter tone, improving esophageal peristalsis, and promoting gastric emptying, as opposed to simply reducing stomach acid levels. Although

Propulsid's approved use, treatment of nocturnal heartburn from GERD, is relatively narrow, the defendants actively (and successfully) sought to have physicians prescribe the drug for various unapproved, "off-label" uses that dramatically expanded its market and profitability.

Defendants' studies and consultants agree that Propulsid was only minimally effective, and it caused serious heart ailments. Defendants were aware of these dangerous, sometimes fatal, side effects, yet chose to conceal them and otherwise mislead the public through aggressive marketing and promotions. In July 2000, when the defendants were no longer able to suppress the drug's minimal efficacy -- and the significant risk factors attendant to its use -- did they stop selling the drug. Since August 2000, Propulsid is only available under a limited access protocol.

A. BEFORE PROPULSID'S LAUNCH IN OCTOBER 1993, THERE WAS STRONG EVIDENCE THAT IT CAUSED ADVERSE CARDIAC CONSEQUENCES

Before its 1993 launch, studies and reviews linked Propulsid to adverse cardiac events:

1986: D.N. Bateman presented evidence that Cisapride was cardiotoxic. *See*, D.N. Bateman, "The Action of Cisapride on Gastric Emptying and the Pharmacodynamics and Pharmocokineticcs of Pral Diazepam," *European Journal of Clinical Pharmacology*, 30, 205-208.

May 1987: Defendants discontinued the Compassionate Clearance Program. Among the reasons were adverse experiences, including two participants who died from congestive heart failure and pulmonary edema/cardiac arrest. (J0017449 - 511, Exhibit "1").

1992: An article reported seven cases studies of tachycardia during Cisapride treatment. *See*, Olsson and Edwards, *British Med. Journal*, V. 305, September 26, 1992 (J0280707, Exhibit "2"). In each case, withdrawal of Cisapride resulted in normalization of the heart rate. Symptoms returned in all three patients re-challenged with Cisapride, , demonstrating an unmistakable link between Cisapride use and heart problems.

Clinical Trial Results: In clinical trials, the risk/benefit ratio for Propulsid was muddy at best. The defendants' own documents assess the benefit profile from the original studies as "demonstrat[ing] only a moderate benefit for a narrow non-life threatening indication." (J0990972, Exhibit "3"). Later studies, such as CIS-107, "cloud the efficacy presentation." (J0990972).

Food & Drug Administration Review: The FDA's Gastrointestinal Advisory Committee assessed the drug's risk profile, and discussed two episodes of syncope and 80 deaths during clinical trials. The Committee concluded, based on defendants' evidence about the causes of death, that almost all

deaths were caused by underlying disease, and recommended approval of the drug to treat nocturnal heartburn in adults caused by GERD.

B. TOTAL SALES OF CISAPRIDE EXCEEDED $2,000,000,000

Although frequently criticized by the FDA, the defendants' aggressive marketing campaign for Propulsid was enormously successful, and sales increased dramatically as shown below:

Year	Annual Sales
1994	$170,000,000.00
1995	$330,000,000.00
1996	$416,000,000.00
1999	$958,000,000.00
Cumulative Total Sales (10/1993 to 7/2000)	*More than $2,000,000,000.00*[1]

C. THE DEFENDANTS SHIELDED THE FDA'S SAFETY CONCERNS FROM THE PRESCRIBING MEDICAL COMMUNITY

By November 1997, the FDA had become increasingly concerned about the safety of Propulsid. Following the FDA's denial of an application for a Propulsid *BID* dosing supplement, the defendants had a telephone conversation with Dr. Botstein of the FDA. In that conversation, Dr. Botstein stated that the FDA was very concerned about the safety of Propulsid, and that safety concern was the foundation of their non-approval decision. (J0526004, Exhibit "4").

Worsening adverse events reports, recognized as a small percentage of actual adverse events, validated the FDA's apprehensions. By April 1998, 28 deaths were reported with serious ventricular arrhythmias (J0453176-179, Exhibit "5"). By July 1998, there were 147 reported serious ventricular arrhythmias in the U.S. (J0452877-84; J0452769, Exhibit "6"). By August 1998, defendants' data showed 97 cases of ventricular tachycardia, 15 of supraventricular tachycardia, 46 heart arrest, 66 of syncope, and 93 of *torsades de pointes*. (J0505703, Exhibit "7").

[1] In 1997, Propulsid ranked 63rd in prescriptions filled. *See*, Zoeller, J., "The Top 200 Drugs," *American Druggist*, No. 2, Vol. 216, p. 41 (February 1, 1999, Exhibit "4"). In 1999, global sales exceeded $958,000,000.00 on over 6,000,000 prescriptions. In seven years on the market, Propulsid generated more than $2,000,000,000.00 in total sales. (J0532322 – 34, Exhibit "8").

An October 1998 article also strongly supported the conclusion that accumulation of Cisapride in the blood causes arrhythmia. *See*, Vitola, *et al.*, *Journal of Cardiovascular Electrophysiology*, 1998. Most important, by July 1998, defendants' internal documents (*see Section D(1) below*) show Propulsid caused prolonged QT intervals. (J0455299-301, Exhibit "9")

D. DEFENDANTS' PATTERN OF CONCEALING INFORMATION

1. JUNE 4, 1998 CARDIOVASCULAR CONSULTANTS ADVISORY MEETING

Janssen convened a June 4, 1998 "Propulsid Cardiovascular Consultants Advisory Meeting" to discuss cardiovascular safety issues with six world-class consultants: Jean. Barbey, M.D. (Georgetown Univ. Medical Center), Allan Hordof, M.D. (Babies Hospital of New York), Ralph Lazarre, M.D. (Oklahoma Univ. Health Science Center), Michael Rosen, M.D. (College of Physicians and Surgeons of Columbia Univ.), Raymond Woosley, M.D. (Georgetown Univ. Medical Center), and, Douglas Zipes, M.D. (Krannert Institute of Cardiology). In a July 27, 2998 Memorandum (Exhibit "9"), Dr. Klausner summarizes that the consultants were:

> . . .**not particularly impressed with the efficacy of Propulsid in GERD when considered relative to the potential arrhythmic AEs....The consultants felt it was very clear that Propulsid can prolong the QT interval.**(emphasis supplied)

Dr. Klausner reports some consultants "felt that we should try to identify gender differences in the data, since females have longer QT intervals and may be more susceptible to arrhythmias." He concludes:

> **They felt that the risk/benefit ratio for GERD alone was not optimal . . . They felt that the drug can clearly prolong QT intervals in certain settings and that we should be completely up front about this at an advisory committee.**
> (emphasis supplied)

In their motion, the defendants certify that essentially all domestic documents have been produced. *See, Urquhart Affidavit* ¶ 11(q). Mysteriously, although eight high-level Janssen employees are identified as participants at this meeting, *plaintiffs cannot locate any documents authored by any participants at the meeting and cannot locate any documents discussing the*

opinions held by any expert. Based upon the importance of the meeting, the stature of the experts, and the many Janssen personnel attending, the plaintiffs believe these documents exist and, for some reason, have not been produced. *See*, Affidavit of Daniel J. Siegel, Esquire (Exhibit "10").

The Plaintiffs' belief that these documents exist, or existed, is not mere speculation. It is supported by other documents provided by the defendants on this type of meeting. For example:

2. October 1998 Meeting About Prolonged QT and Pharmacology

In an October 1998 meeting about prolonged QT and pharmacology, which Mark Klausner "covered" for Janssen's Propulsid hierarchy, the minutes reveal, **"Prolonging QTc in therapeutic dose range [ie. at prescribed dosages] is a surrogate for sudden death."** (J0453084, Exhibit "11") (emphasis supplied). Shortly after Dr. Klausner noted this, Janssen convened another meeting of experts to discuss the prolonged QT problem with Propulsid.

3. Janssen Follow-Up Meeting with Consultant Raymond Woosley, M.D.

Among those consulted for this meeting of experts was Raymond Woosley, M.D. of Georgetown University, widely regarded as one of the world's foremost authorities on drug induced prolonged QT. The minutes of this meeting reveal again that the defendants routinely concealed or ignored important data. At this meeting, Dr. Woosley made key points that the defendants simply disregarded (J0452688-J0452689, Exhibit "12 "), including:

1 "[F]emales are more at risk than males, which is due to the involvement of the Ikr channel." The defendants did not contraindicate two-thirds of the market on their label, and never even suggested heightened scrutiny of the cardiac health of females.

2. If a drug induced a mere "5 millisecond increase in Qtc", this was "significant because if it is associated with a potassium depletion, it may be enough to cause T.d. P. [*Torsades de pointe* - a potentially lethal arrhythmia]." A few weeks later, in dealings with the Swiss regulatory agency, the defendants again asserted there must be at least a thirty (30) millisecond increase for it to be significant. (*See Id.*)

3. "Cisapride effect on QTc mirrors terfenadine [the generic name for Seldane] effect." Terfenadine had been removed from the market once its QT prolonging potential was revealed. This portended badly for Hismanal, defendants' version of Seldane, also removed from sale because of the causing possible arrhythmias. (*See Id.*)

4. Dr. Woosley would work with them only "when we [Defendants] develop a protocol regarding cardiovascular safety." This was more than five years after the time that defendants began to market Propulsid in the United States. (*See Id.*)

4. December 1999 London Consultants Meeting

Defendants' pattern of concealment and disinformation is also revealed by Dr. Klausner's statements at a December 1999 London meeting convened by Janssen's Belgium headquarters (J0453413-444, Exhibit "13"), three months before taking it off the market, seven years after it was on the market, and nine years after the NDA. Invited to and present was William Shell, M.D., whom defendants have attempted to impeach in New Jersey litigation, *even though he is not an expert for plaintiffs*. Dr. Shell asked Dr. Klausner a simple, direct question: "Does cisapride alone prolong the QT?" (emphasis in original), and Dr. Klausner replied: **"We do not have good data on this, but there is some evidence."** *Id.* at J0453419. (emphasis supplied)

The late date of this statement is not the only reason it is astonishing. It is crucial to realize that, to the end, defendants claimed they had "good data," had studied this data, the data were submitted to regulators world-wide, and, Propulsid by itself did not prolong QT. The difference between what they said in public and what said to consultants in private is revealing.

5. The Swiss Government's Findings on Propulsid

Propulsid was also under attack or scrutiny by foreign regulators. In December 1998, defendants received a letter from the Intercantonal Drug Control Office (IDCO) in Switzerland, in which this regulatory body observed the "problem of severe arrhythmias did not become obvious until 1996 and related reports have been increasingly frequent since that time." (J0452596-602 Exhibit "14") The letter cites 304 cases of severe ventricular arrhythmias, and reports the data indicate an "effect of Cisapride on the QT interval" (emphasis in original). The letter concludes, "[the data] leads to the assumption that even without detectable risk factors, Cisapride can cause serious and sometimes fatal cardiac arrhythmias in the form of ventricular tachycardia, ventricular

fibrillation, torsades de pointes and QT prolongation." (emphasis supplied), and notes "children constitute a particularly vulnerable group." (J0452596 – 602, Exhibit "14").[2]

In light of extensive information obtained in litigation, it is no surprise that defendants seek to enjoin this litigation, and prevent state court plaintiffs from establishing defendants' liability. Accordingly, plaintiffs offer the following analysis why defendants' Motion should be denied.

LEGAL ARGUMENT

I. PRINCIPLES OF COMITY REQUIRE THAT A FEDERAL COURT MAY NOT ENJOIN PREEXISTING STATE COURT LITIGATION RAISING EXCLUSIVELY STATE LAW CLAIMS OVER WHICH THE DISTRICT COURT HAS NO SUBJECT MATTER JURISDICTION

Federal Courts do not have supervisory powers over state courts, and may not substitute their judgment about the proper outcome of state proceedings, nor exercise their power to obstruct ongoing state proceedings. These basic principles of comity underlie the functioning of our federal system. *See*, Rules of Decision Act, first placed in the Judicial Code by the Judiciary Act of 1789. These principles are made express by the very terms of the Anti-Injunction Act, 28 U.S.C. § 2283:

[2] There is extensive evidence about efforts to foster a large pediatric market, despite FDA refusal to approve this. Although "independent groups" have issued policy/consensus statements about cisapride in pediatric, the conclusions are questioned by independent commentators:

> . . .cisapride was no better than placebo for relief of symptoms in children with uncomplicated GER." . . .we would not recommend it as a stand-alone therapy in children with uncomplicated GER. ***Furthermore, the recommendations of the expert committee from ESPGHAN [authored by a Janssen consultant] were made without a single randomized, controlled trial demonstrating efficacy of cisapride in relief of symptoms and little evidence supporting its use in the treatment of complicated reflux. . . . . Safety profile of cisapride -There are several recent reports recommending cisapride not be given to infants and young children because it may cause cardiac rhythm disturbances. The fact that it is "safer" than other medication used for treatment of GER in children does not make it appropriate to use if it is no more efficacious than placebo.*** *Journal of Pediatrics*, 137:2 at 289 (Aug. 2000) (emphasis supplied)

> A Court of the United States may not grant an injunction to stay proceedings in a State Court, except as expressly authorized by Congress, or, where necessary, in aid of its jurisdiction, or to protect or effectuate its judgments.

The relief sought is not authorized by Congress, nor is there any judgment for this Court to protect or effectuate. Therefore, an injunction lays only in aid of this Court's jurisdiction. Under the facts here, any injunction violates the Anti-Injunction Act. In particular, there are ongoing proceedings in state courts, and there is no basis for this Court to assert jurisdiction over the state court litigants, let alone act in aid of jurisdiction it does not have.

Apart from the Anti-Injunction Act interdiction of enjoining state court proceedings, entrenched principles and provisions of "Our Federalism," *Younger v. Harris,* 401 U.S. 37, 91 S.Ct. 756, 27 L.Ed.2d 669 (U.S., 1971), prohibit federal judicial interference with ongoing state judicial proceedings. *See, Pennzoil Co. v. Texaco, Inc.*, 481 U.S. 1, 107 S.Ct. 1519, 95 L.Ed.2d 1 (U.S.N.Y., 1987) (refusing federal injunction against ongoing state proceedings because "exercise of the federal judicial power would disregard the comity between the States and the National Government."). So strong is the Act's non-interference command that an anti-suit injunction cannot issue even when, unlike here, the federal court, alone, has exclusive jurisdiction. *See, e.g., Atlantic Coast Line R. Co. v. Brotherhood of Locomotive Engineers*, 398 U.S. 281, 90 S.Ct. 1739, 26 L.Ed.2d 234, 74 L.R.R.M. (BNA) 2321, 63 Lab.Cas. P 10,931 (U.S., 1970); *Brown v. Gilmore,* __ S.Ct. __, 2001 WL 1056666 (Sept. 12, 2001) ("injunctive relief under the All Writs Act is to be used 'sparingly and only in the most critical and exigent circumstances.'") (citations omitted)

The defendants' Affidavits provide compelling, uncontradicted facts that destroy any notion that the center of this litigation is the MDL, or that this Court has jurisdiction over state court plaintiffs. Among the facts presented by the defendants:

(1) There are far more pending state court lawsuits than federal court lawsuits. *See,* Urquhart Affidavit ¶¶ 2, 4.

(2) New Jersey and Pennsylvania are situses for 364 and 24 lawsuits, respectively. *See,* Urquhart Affidavit.

(3) State court plaintiffs have already been to verdict. *See,* Urquhart Affidavit, ¶17.

(4) State court attorneys have taken most of the fifteen (15) depositions of past and present company employees referred to by the Urquhart Affidavit.

(5) Pennsylvania plaintiffs have coordinated discovery with the New Jersey Propulsid Plaintiffs' Committee (*See,* Affidavit of Marc Weingarten, Esquire, Exhibit "15").

(5) New Jersey state court plaintiffs have extensively briefed and, on October 24, 2001, argued a Motion for Class Certification seeking, among other things, a proper study to determine long-term risks from Cisapride exposure.

(6) No discovery in the Urquhart Affidavit is overlapping, duplicitous, or vexatious.

(7) State court lawyers are preparing their cases for trial.

Against these facts, defendants claim an injunction enjoining the state courts is necessary and warranted because of the expense and disruption of discovery. That assertion is not a basis for discarding well-established principles of federal/state court comity. As to the expense of the litigation, defendant Johnson and Johnson's gross sales exceed $20,000,000,000.00 annually from 1996 to 1998 (Exhibit "16"). During that time, the company's net earnings, before taxes, exceeded $4,000,000,000.00 each year (Exhibit "20"). Thus, an estimated total expense of $4,200,000.00 (0.105 percent of the defendant's net earnings) for to collect, copy, and electronically image documents domestically and in Belgium is a small expense to a multinational corporation defending over 500 active lawsuits. (*See* Urquhart Affidavit, ¶ 11)[3]

3 In its 2000 Annual Report, Section 18, "Legal Proceedings," Johnson & Johnson reports: "The Company is involved in numerous products liability cases in the United States, many of which concern adverse reactions to drugs and medical devices. . . the Company believes that if any liability results from such cases, it will be substantially covered by reserves established under its

As a very large, international company engaged in mass marketing of drugs, defendants know, as a cost of doing business, they need to defend themselves if a drug is defective or tortioulsy-marketed and, as here, is alleged to have injured thousands. The cost of accumulating documents is a one-time cost, and the cost of responding to other similar discovery requests is essentially the same no matter how many lawsuits are filed. Moreover, state court plaintiffs have cooperated with their MDL brethren, and no discovery set forth in the Urquhart Affidavit is overlapping, duplicitous, or vexatious. (*See* Certification of James J. Pettit, Esquire, Exhibit "18")

Ironically, defendants' conduct during discovery has been less than forthright. As verified by the Affidavits of James Pettit, Esquire and Arnold Levin, Esquire (Exhibit "19"), defendants agreed not to seek or conduct discovery in the MDL about ongoing Propulsid studies. On the other hand, in New Jersey litigation, they have and continue to vigorously seek this discovery, necessitating motion practice. Even more ironic is the fact that the only ongoing study of which the New Jersey plaintiffs are aware is by Dr. Shell, the same Dr. Shell the defendants consulted, and the same Dr. Shell the defendants spend pages attacking in their Answer to the New Jersey Motion for Class Certification. Thus, defendants' conduct during discovery has been vexatious.

These state court case raises no federal claims. New Jersey is the home of Johnson & Johnson, and Janssen's home is Pennsylvania. This means that this Court does not have jurisdiction over these cases or the parties, precluding removal to this or any federal court. Additionally, the Pennsylvania class action involves individual claims under $75,000.00 per class member. It is inconceivable how divesting state courts of the power to hear a state law claim

self-insurance program and by commercially available excess liability insurance." After discussing other litigation, the section concludes: "The Company believes that the above proceedings, except [cases other than the Propulsid litigation], would not have a material adverse effect on its results of operations, cash flows or financial position." (Exhibit "17")

between Pennsylvania residents and a Pennsylvania corporation that could not be filed in or removed to federal court, is consistent with principles of comity and federalism.

II. THE ANTI-INJUNCTION ACT FORECLOSES THE RELIEF SOUGHT

Beyond general principles of comity and federalism, this Court should not invoke the "necessary in aid of its jurisdiction" exception to the Anti-Injunction Act as the basis for assuming jurisdiction. The Supreme Court carefully cautions that a fundamental prerequisite for invocation of this exception is that a state court proceeding must "seriously impair" a federal court's "authority to decide that case." *Atlantic Coast Line R.R. Co., supra,* 398 U.S. at 295.

Because this Court does not have subject matter jurisdiction over the state court cases, it follows ineluctably that this Court is without the requisite "authority to decide that case." Parallel state court actions will neither frustrate nor disrupt the orderly resolution of these proceedings. This Court cannot and should not be the ultimate trier of fact. *See, Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 118 S.Ct. 956, 140 L.Ed.2d 62, 98 Daily Journal D.A.R. 2041, 98 CJ C.A.R. 940, 11 Fla. L. Weekly Fed. S 361 (U.S.Ariz., 1998).

The cases on which defendants rely *do not* provide the claimed power to stop ongoing state court proceedings involving individual state law causes of action. For example, the main authority the defendants cite arose when a separate state court class action was filed in an effort to circumvent a *previously filed* federal class action that was preparing for final settlement approval. *See, e.g., Carlough v. Amchem Products, Inc.*, 10 F.3d 189 (3rd Cir.(Pa.), 1993) (anti-suit injunction proper because the recently filed state court class action would "cause havoc" with the pending federal settlement and was an end run around the settlement).

The New Jersey and Pennsylvania class action predates the MDL class by more than one year, and clearly was not filed to circumvent a proposed federal court settlement or to evade a federal court's jurisdiction. The defendants fail, however, to cite those cases that outline the

circumstances when a federal court properly invokes its jurisdiction to stay a concurrent state proceeding *See, e.g., Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 98 Daily Journal D.A.R. 8001 (9th Cir.(Cal.), 1998), (jurisdiction to issue anti-suit injunction upheld where a state court class action is filed after an approved settlement in federal court in which all previously filed state court class actions had been consolidated); *In re Corrugated Container Antitrust Litigation*, 659 F.2d 1332, 1981-2 Trade Cases P 64,340 (5th Cir.(Tex.), 1981) (injunction against state court class action purporting to cover same parties and same issues as ongoing federal court class action). *Hanlon* and *In re Corrugated Container* show the narrow facts under which an injunction is appropriate.

Most cases that allow a federal court to assume jurisdiction over state court cases address wholly different facts, including a need for the federal court to assume supervisory power over the assets of the defendant. *See, e.g., White v. National Football League*, 41 F.3d 402, 147 L.R.R.M. (BNA) 3075, 1994-2 Trade Cases P 70,811, 31 Fed.R.Serv.3d 293 (8th Cir.(Minn.), 1994) (order in protection of limited fund); *In re Consolidated Welfare Fund ERISA Litigation*, 798 F.Supp. 125, 15 Employee Benefits Cas. 1352 (S.D.N.Y., 1992) (order in preservation of federal court power over dissolution of an ERISA fund). Other cases permit a federal court to issue an Order to prevent parties properly subject to the federal court's jurisdiction from using other litigation to evade the Court's supervisory power over the case. *See, e.g., Winkler v. Eli Lilly & Co.*, 101 F.3d 1196, 65 USLW 2472 (7th Cir.(Ind.), 1996) (injunction to prevent federal court litigants from using state court proceeding as an end-run around a federal court's discovery Orders); *In re Columbia/HCA Healthcare Corp. Billing Practices Litigation,* 93 F. Supp. 2d 876 (M.D. Tenn. 2000) (same); *In re School Asbestos Litigation,* 1991 WL 61156 (E.D. Pa. 1991) (plaintiff who failed to opt out of federal class action enjoined from proceeding in parallel state court action); *In re Baldwin-United Corp. (Single Premium Deferred Annuities Ins. Litigation)*, 770 F.2d 328, 2

Fed.R.Serv.3d 1156 (2nd Cir.(N.Y.), 1985) (Court with jurisdiction over securities class action enjoined states from bringing subsequent cases seeking the same relief for class members).

None of these cases even remotely stands for the proposition that filing a federal court class action automatically vests that court with injunctive powers against pre-existing state law claims. Certainly, these cases do not stand for the proposition that a district court's injunctive powers reach beyond that court's jurisdictional authority. Whatever the ultimate contours of a federal court's injunctive powers in furtherance of its jurisdiction, it cannot reach beyond the confines of its actual jurisdiction. Judge Posner writes, in the context of a Rule 23(f) appeal:

> The fact that an appeal is interlocutory does not excuse the absence of adequate jurisdictional statements, for unless a case is within the jurisdiction of the district court, we cannot decide the merits of an appeal; we can only direct that the suit be dismissed.

Isaacs v. Sprint Corp., ___ F.3d ___, 2001 WL 930177 at *3 (7th Cir. 2001). Nowhere do the defendants even purport to identify the source of this Court's subject matter jurisdiction.

III. THIS COURT MAY NOT ISSUE AN INJUNCTION BECAUSE IT DOES NOT HAVE PERSONAL JURISDICTION OVER THE STATE COURT PLAINTIFFS

The overwhelming majority of the actions to be enjoined by this Court involve state law disputes between individual plaintiffs and the defendants. There are no transactional relations between the overwhelming majority of these state court plaintiffs and the defendants that would vest personal jurisdiction over this controversy in a Louisiana court, state or federal. Simply put, there are no minimum contacts between the state court plaintiffs and Louisiana. Additionally, there is no reasonable argument that these state court plaintiffs have taken any action, or failed to take any action, which could be deemed to vest this District Court with personal jurisdiction.

The Supreme Court makes it clear in *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 105 S.Ct. 2965, 86 L.Ed.2d 628, (U.S.Kan., 1985) that the jurisdictional minimum requirement for assertion of personal jurisdiction over absent class members, who have no minimum contacts with

the forum state, is personal notice and the opportunity to opt out. Although *Shutts* involves a state court proceeding, a federal court has only the personal jurisdiction equivalent to that of the highest court of the state in which it sits. The requirements in *Shutts* for minimum contacts -- personal notice and an opportunity to opt out -- must be met for a federal court to assert jurisdiction over parties who, otherwise, are not under the injunctive power of that court.

Until notice and the opportunity to opt out of the class are in place, and in the absence of minimum contacts, the assertion of personal jurisdiction over state court litigants violates due process. The Third Circuit clearly addresses this issue in *In re Real Estate Title and Settlement Services Antitrust Litigation*, 869 F.2d 760, 57 USLW 2526, 1989-1 Trade Cases P 68,471, 13 Fed.R.Serv.3d 500, 52 Ed. Law Rep. 476 (3rd Cir.(Pa.), Mar 07, 1989) (NO. 87-1815):

> [I]f the member has not been given the opportunity to opt out in a class action involving both important injunctive relief and damage claims, the member must either have minimum contacts with the forum or consent to jurisdiction in order to be enjoined by the district court that entertained the class action. Because neither factor is present, the injunction must be set aside.

869 F.2d at 769 (footnote omitted). Thus, the assertion that this Court may enjoin an ongoing state court proceeding to preserve its jurisdiction is fatally flawed. This Court does not have jurisdiction over absent putative class members from outside Louisiana unless and until those absent class members receive an opportunity to consent, or refuse to consent, to this Court's exercise of jurisdiction over them. *Carlough, supra.* Under no circumstance may a district court enter an injunction in which the opportunity to opt out will not arise for many months to come.[4]

[4] The defendants are silent about what law they will ask this Court to apply; they prefer Louisiana law, not the law of each state in which cases are pending. Yet, they did not make this request in cases that went to trial, including when ten plaintiffs were each awarded $10,000,000.00. It appears that defendants fear state law will not treat them and their conduct kindly; they should not be permitted to transfer the venue on the remaining cases and hope this Court may be more hospitable to them.

On October 29, 2001, the 6th Circuit, in *Drummer v. Sulzer Orthopedics, Inc.*, No. 01-4039 (C.A., 6th Cir.) reversed a district court Order granting an injunction against the initiation or prosecution of claims against defendants. The underlying Order, in conjunction with a proposed nationwide class action, had enjoined all putative class members from exercising their right to opt out of the conditionally certified class until after January 5, 2002. In reversing, the panel states:

> Because the September 17 injunction prevents litigation by putative class members prior to any opportunity to opt out of the Rule 23(b)(3) class., the authority of the district court to issue such broad injunctive relief is questionable [citing *Carlough, supra*] . . . . Limitations on the right to opt out raise the due process concerning address in *Ortiz v. Fiberboard Corp.*, 527 U.S. 815 (1999), and *In re Telectronics Pacing Systems, Inc.*, 221 F.3d 870 (6th Cir. 2000).

Drummer, supra, Slip Op. at 3. (A copy of the Order is attached as Exhibit "20.") The defendants' motion seeks relief similar to the relief the *Drummer* court questions, and stands *Shutts* on its head. The defendants assert that the All Writs Act may be invoked whenever a subset of filed cases is transferred to a federal court lacking personal jurisdiction over absent class members pursuant to 28 U.S.C. § 1407. Thus, rather than having to establish personal jurisdiction as a precondition of issuing orders in preservation of jurisdiction, this Court may, according to the defendants, presume that the filing of a relatively small number of federal claims, irrespective even of first-in-time considerations, and a subsequent transfer Order, is a sufficient basis for the Court to overcome the clear mandate of the Anti-Injunction Act: "A Court of the United States may not grant an injunction to stay proceedings in a State Court . . ."

The Anti-Injunction Act, the All Writs Act, their legislative purposes, and interpretive case law, offer no basis to adopt defendants' expansive view of federal power, in derogation of state

court proceedings. The Court should also recognize plaintiffs' right to select their forum, particularly when plaintiffs are not parties to the MDL nor subject to this Court's jurisdiction.[5]

Simply stated, state court plaintiffs are not parties to this litigation unless and until they are given constitutional notice, and the right to opt out. Without the minimum contacts defined in *International Shoe* and its progeny, this Court cannot assert injunctive jurisdiction over the state court plaintiffs, at least until notice has been served pursuant to *Shutts*. Until it acquires such jurisdiction, this Court may not issue any Order directed to the state court plaintiffs. *See, Hanlon v. Chrysler Corp*., 150 F.3d 10119th Cir.(C.A.Cal., 1998) (noting federal court had jurisdiction by virtue of consolidation in that court of all previously filed state court class actions).[6] Even then, a federal court's jurisdiction over many putative class members will vanish almost immediately after it attaches because large numbers of the state court plaintiffs will surely opt out at their first opportunity. As the Third Circuit clearly states::

[5] Federal jurisprudence affords plaintiffs, if possible, the right to select the forum for their cases. *See, e.g., VanDusen v. Barrack*, 376 U.S. 612, 84 S.Ct. 805, 11 L.Ed.2d 945 (U.S., Mar 30, 1964), (in the context of *forum non-conveniens* under 28 U.S.C. § 1404(a), the Court does not allow the *defendants* to forum shop to change the substantive law of the case). This prevents defendants from defeating the advantages accruing to plaintiffs who choose a forum that, although inconvenient, is a proper venue. The Court reaffirms this in *Ferens v. John Deere Co.*, 494 U.S. 516 at 527-28, 110 S.Ct. 1274, 108 L.Ed.2d 443 (U.S., 1990), even if plaintiff moves for transfer.

A plaintiff's right to select the forum to prosecute his or her case also comes from the Rules of Decision Act, 28 U.S.C. § 1612, first placed in the Judicial Code in 1789, which now states: "The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the Courts of the United States, in cases where they apply." 28 U.S.C. § 1652

In *Erie R. Co. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (U.S., 1938)the Court holds, in diversity cases, the Act requires a federal court to apply, the statutory and common law of the state in which it sits. Similarly, in *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 61 S.Ct. 1020, 85 L.Ed. 1477 (U.S., 1941), the Court holds that, in diversity cases, federal courts must follow conflict of laws rules of states in which they sit. *Erie* and *Klaxon* are undermined by application of the transferee court's choice-of-law principles in a defendant-initiated transfer. *See*, *VanDusen*, 376 U.S. at 637-640.

[6] *Ferens* affirms *Erie* and *Klaxon's* goal of preventing "forum shopping" between state and federal systems. Plaintiff's forum choice must be honored in federal and state court; in the latter, a case cannot be transferred to another state. *Ferens,* 494 U.S. at 534-35.

> Although an inference of consent might have been drawn from silence or inaction after notice and the running of the opt out period, *Shutts*, 472 U.S. at 806-14, we find no precedent for assuming consent prior to notice and the commencement of the opt out period. . . . Thus, with neither minimum contacts, ***and prior to notice and the commencement of the opt out period, the District Court did not have personal jurisdiction over the*** [absent class member] plaintiffs and did not have authority to bind their actions when it issued the injunction.

Carlough, 10 F.3d at 200 (emphasis supplied).

Even preliminary class certification is a constitutionally intolerable burden on the right to opt out. Because an injunction can only be directed to parties, a class member seeking to proceed to trial in another forum would simply opt out and be free of any court restraints. This is why the anti-suit injunction makes sense if a later filed state court class action tries to divest a federal court of power, as in *Hanlon*. If due process requires the ability of individual absent class members to opt out, an injunction that terminates as soon as the right to opt out is invoked serves no purpose.

IV. DEFENDANTS HAVE UNCLEAN HANDS, BARRING THE RELIEF THEY SEEK

The doctrine of "unclean hands" prohibits a party from receiving equitable relief. In *American Sugar Refining Co. v. McFarland*, 229 F. 284 (E.D.La., 1916), this Court holds that "granting of the relief sought cannot be made the means of protecting the [party] from the consequences of any misconduct of which it may have been guilty, or of enabling it in the future to do anything which it has not a right to do." *Id.* at 287-288. In *Bishop v. Bishop*, 257 F.2d 495 (3rd Cir., 1958) (citations omitted), the Court summarizes the law of "clean hands:"

> It is an ancient and established maxim of equity jurisprudence that he who comes into equity must come with clean hands. If a party seeks relief in equity, he must be able to show that on his part there has been honesty and fair dealing. . . . This presupposes a refusal on its part to be 'the abettor of iniquity.' Thus while 'equity does not demand that it suitors shall have led blameless lives,' as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue." (citations omitted)

Where a suit in equity concerns the public interest, and private interests of litigants, the doctrine assumes more significant proportions. If a Court properly uses the maxim to withhold

assistance, it prevents a wrongdoer from enjoying the fruits of its transgression and avoids injury to the public. *See, e.g., Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S. 488, 62 S.Ct. 402, 86 L.Ed. 363 (U.S., 1942), *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.,* 324 U.S. 806, 65 S.Ct. 993, 89 L.Ed. 1381 (U.S., 1945)

The defendants do not enter this Court with clean hands. This Memorandum highlights the lengths they will go to avoid disclosing dangers they reasonably had to know were caused by Propulsid. Faced with this evidence of injuries and death, defendants did not withdraw the drug; instead, they continued to fuel their marketing machine and build sales and profits.

Defendants offer no credible explanation for not acknowledging what the FDA and foreign bodies saw: Propulsid is dangerous, and its risks far outweigh its benefits. Defendants offer no credible explanation for failing to warn women, the consumers with the highest risk and majority of the drug's users (J0454268, Exhibit "21"); they offer no credible explanation for resisting label changes; they offer no credible explanation for marketing off-label uses to children, when data show it ineffective for that use, and the FDA denied such requests; and they offer no credible excuse for using medical literature and seminars to promote off label uses.[7]

Defendants offer no credible explanation for continued sales of Propulsid except one -- *Cumulative Total Sales* (1993 to 2000), Over *$2,000,000,000.00.* This Court need not look further than Johnson & Johnson's credo for measuring clean hands (See Exhibit "22" for the Credo):

> We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services....Research must be carried on, innovative programs developed and mistakes paid for.

Defendant Johnson & Johnson's website explains the history of its corporate credo:

[7] Medical journals refer to this practice as "mak[ing] a mockery of clinical investigation [that] erode[s] the fabric of intellectual inquiry [and] also make[s] medical journals party to potential misrepresentation, since the published manuscript may not reveal the extent . . . the authors were powerless to control the conduct of a study." *See,* Davidoff, *et al.,* "Sponsorship, Authorship, and Accountability," *New Eng. J. of Med.,* 2001, 345:825-827, Sep 13, 2001.

> . . . Johnson saw to it that the Credo was embraced by his company . . .Putting customers first, and stockholders last, was a refreshing approach to the management of a business. [Johnson] believed that by putting the customer first the business would be well served, and it was.

http://www.johnsonandjohnson.com/who_is_jnj/cr_index.html. Can the defendants' actions in developing and marketing Propulsid even remotely be described as putting the customer first?

CONCLUSION

Defendants do not come before this Court with the clean hands needed to receive the extraordinary equitable relief they seek. Their assertions about discovery are disingenuous, and they discount or ignore their acts before and during litigation. Defendants fail to disclose relevant facts, and those they disclose are rose-colored. Documents are missing, despite representations about full production, and discovery violations are by defendants who seek "management or coordination among the 37 states." Management or coordination is not necessary or warranted.

Rather, defendants seek relief while deflecting attention from their own conduct. In addition, they avoid the merits of the case, because to go there would, at best, show the defendants' conduct as grossly negligent in developing and marketing Propulsid, and in the continued marketing of the drug when it became clear that it was causing significant injuries.

This Court should consider the words by which the defendants claim to operate their business in the context of this case. Unless this Court can say that the defendants have acted consistently with this credo, equity requires that the defendants' Motion for Injunction be denied.

Respectfully submitted,

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Dated:_____
ORIGINAL SIGNED DOCUMENT ON FILE WITH THE COURT

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Dated: Nov 1, 2001

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CERTIFICATE OF SERVICE

I hereby certify that, on the date below, a true and correct copy of the Philadelphia County Mass Tort Program's Memorandum In Opposition To Motion For Injunction has been served on Liaison Counsel, James Irwin, at the address below by U. S. Mail and e-mail or by hand delivery and e-mail and upon all parties electronically by Verilaw in accordance with Pre-Trial Order No. 4.

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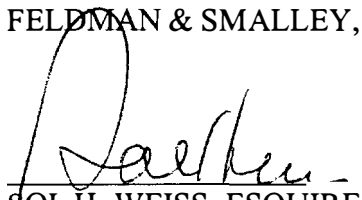

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