UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-0668-JDB
FOOD & DRUG ADMINISTRATION, *et al.*,	)	
Defendants,	)	
and	)	
DURAMED PHARMACEUTICALS, INC.,	)	
Defendant-Intervenor	)	

PLAINTIFFS' OPPOSITION TO MOTIONS TO DISMISS

In opposition to the defendants' and defendant-intervenor's motions to dismiss under Rules 12(b)(1) and 12(b)(6) of the FEDERAL RULES OF CIVIL PROCEDURE and their accompanying memoranda of law, plaintiffs in this action hereby file the attached memorandum of law. Plaintiffs respectfully request an opportunity for oral argument.

A proposed order is attached.

Dated: October 17, 2007

Respectfully submitted,

/s/ Lawrence J. Joseph
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Defendant-Intervenor	)	

[Proposed] Order

On considering defendants' and defendant-intervenor's motions to dismiss, the memoranda in support thereof and in opposition thereto, and the absence of a record herein, the Court holds that plaintiffs have alleged cognizable injuries in fact within the Court's jurisdiction and that the Court can grant the requested relief. For the foregoing reasons, it is hereby

ORDERED that defendants' and defendant-intervenor's motions are denied.

Dated: _____, 2007

_____
UNITED STATES DISTRICT JUDGE

Copy to:

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DURAMED PHARMACEUTICALS, INC.,	)	
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MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S OPPOSITION TO MOTIONS TO DISMISS

Lawrence J. Joseph, D.C. Bar No. 464777

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Counsel for Plaintiffs

Dated: October 17, 2007

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PRELIMINARY STATEMENT

In this action, Plaintiffs Association of American Physicians & Surgeons, Inc. ("AAPS"), Concerned Women for America ("CWA"), Family Research Council ("FRC"), and Safe Drugs for Women ("SDW") challenge agency actions and inaction by Defendants U.S. Food & Drug Administration ("FDA") and its Commissioner, Dr. Andrew C. von Eschenbach, in his official capacity and his individual capacity under color of legal authority (collectively, hereinafter "FDA"). Specifically, Plaintiffs challenge the following actions and inaction:

(1) FDA's approval of levonorgestrel tablets, 0.75 mg (hereinafter "Plan B") for age-bifurcated, dual prescription ("Rx") and over-the-counter ("OTC") distribution;

(2) FDA's proceeding without required rulemakings;

(3) FDA regulations, to the extent that they limit Plaintiffs' right to judicial review here; and

(4) FDA's deciding, or appearing to decide, to take items (1) and (2) under improper pressure from two U.S. Senators in the form of a "hold" on Dr. von Eschenbach's confirmation as FDA Commissioner.

The Court granted a motion by Duramed Pharmaceuticals, Inc. ("Duramed") to intervene as of right pursuant to FED. R. CIV. P. 24(a)(2) to defend its interests in Plan B. This memorandum of law sets forth the applicable standards of review for FDA's and Duramed's motions to dismiss, summarizes the applicable legal and factual background, establishes this Court's jurisdiction, and rebuts the merits arguments by FDA and Duramed for dismissal of Counts II, IV, V, and VI. In summary, the First Amended Complaint ("Compl.") and this memorandum establish that Duramed repeatedly refused to provide the pediatric data required to support its product and instead relied on political pressure to short-circuit the required public process and to coerce FDA into approving Plan B via a creative, but patently illegal, regulatory shortcut.

STANDARDS OF REVIEW

By moving to dismiss the entire complaint under Rule 12(b)(1) and four counts under 12(b)(6), FDA and Duramed contend both that this Court lacks jurisdiction to hear any of this challenge and that Plaintiffs cannot prevail as a matter of law on Counts II, IV, V, and VI. This section outlines the standards of review relevant to the FDA and Duramed motions to dismiss.

Rule 12(b)(1). Motions to dismiss under Rule 12(b)(1) allege that the pleadings fail to establish subject-matter jurisdiction. FED. R. CIV. P. 12(b)(1). To assess subject-matter jurisdiction – *i.e.*, "courts' statutory or constitutional *power* to adjudicate the case," *Steel Co. v. Citizens for a Better Envt.*, 523 U.S. 83, 89-90 (1998) (emphasis in original) – courts "must assume the challenging party's view of the merits." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 439 (D.C. Cir. 1986) (ripeness); *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003) (same for standing); *Sierra Club v. Gorsuch*, 715 F.2d 653, 658 (D.C. Cir. 1983) (same for final agency action). In ruling on Rule 12(b)(1) motions, courts take the plaintiff's factual allegations as true and also "presume[] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990); *accord Nat'l Wildlife Fed'n v. Burford*, 835 F.2d 305, 311-12 (D.C. Cir. 1987); *Kean for Congress Committee v. Federal Election Comm'n*, 398 F.Supp.2d 26, 31 (D.D.C. 2005). As FDA notes, courts may explore matters outside the pleadings to determine their jurisdiction. FDA Mot. at 4 n.2 (*citing Land v. Dollar*, 330 U.S. 731, 735 n.4 (1947)); *Herbert v. National Academy of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992). Before going outside the pleadings, however, a court first should provide notice to the parties and an opportunity to submit affidavits and other materials. *Gordon v. Nat'l Youth Work Alliance*, 675 F.2d 356, 360 (D.C. Cir. 1982); *Herbert*, 974 F.2d at 198 ("ruling on a Rule 12(b)(1) motion may be improper before the plaintiff has had a chance to discover the facts

necessary to establish jurisdiction"). Where jurisdiction merges with the merits (*i.e.*, "where the question of jurisdiction is dependent on decision of the merits"), courts may combine the merits and jurisdictional stages. *Land*, 330 U.S. at 735; *Herbert*, 974 F.2d at 198 (if "disputed jurisdictional facts… are inextricably intertwined with the merits of the case [the court] should usually defer its jurisdictional decision until the merits are heard").

Rule 12(b)(6). Motions to dismiss under Rule 12(b)(6) allege that the pleadings fail to state a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6). "FED. R. CIV. P. 8(a)(2) requires only a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the… claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1964 (2007) (citations and interior quotations omitted). "[A] complaint attacked by a Rule 12(b)(6) motion… does not need detailed factual allegations," *id.*, provided that the plaintiff alleges "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." 127 S.Ct. at 1965. "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (citations, interior quotations, and footnote omitted). With "other things… equal," courts "prefer[] adjudication of cases on their merits rather than on the basis of formalities." *Ciralsky v. CIA*, 355 F.3d 661, 674 (D.C. Cir. 2004). Under that judicial preference, such dismissals are appropriate where a "plaintiff has no claim to state," but inappropriate where the "plaintiff has imperfectly stated what *may* be an *arguable* claim." *Alley v. R.T.C.*, 984 F.2d 1202, 1208 (D.C. Cir. 1993) (emphasis added). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 127 S.Ct. at 1969.

Rule 56 Conversion. FDA and Duramed include many exhibits and internet references outside the pleadings, which could convert their Rule 12(b)(6) motions into motions for summary judgment, FED. R. CIV. P. 12(b), and thereby trigger a "reasonable opportunity to present all material made pertinent to such a motion by Rule 56." *Id.*

Judicial Review on Administrative Record. When a district court reviews the actions of an administrative agency, it essentially sits as an appellate court reviewing the administrative record on which the agency acted. *Marshall County Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Significantly, the administrative record "includes all materials compiled by the agency... that were before the agency at the time the decision was made." *James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996) (internal quotation marks and citations omitted).[1] As explained in Section II.B, *infra,* FDA has not yet certified its record.

Where the record in question is judicially noticeable, the "district court can consult the [administrative] record to answer the legal question before the court" without converting a motion to dismiss into a motion for summary judgment. *Id.* & n.6. In the absence of a judicially noticeable or certified record, however, a court has no basis to go beyond the pleadings. FED. R. CIV. P. 44(a)(1); *Langston v. Johnson,* 478 F.2d 915, 918 n.17 (D.C. Cir. 1973) ("well settled that a certified transcript of… administrative proceedings may be considered on a motion for

[1] *See also Camp v. Pitts,* 411 U.S. 138, 142 (1973) ("focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court"); *Burlington Truck Lines v. U.S.,* 371 U.S. 156, 170 (1962) ("an agency's discretionary order [will] be upheld, if at all, on the same basis articulated in the order by the agency itself"); *SEC v Chenery Corp.*, 332 U.S. 194, 196 (1947) ("a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency [, which if] inadequate or improper, the court is powerless to affirm").

summary judgment"). Without a certified or judicially noticeable administrative record, this Court cannot evaluate FDA's extra-pleading assertions about the record. *SEC v Chenery Corp.*, 318 U.S. 80, 94 (1943) ("courts cannot exercise their duty of review unless they are advised of the considerations underlying the action under review"); *accord Ballard v. C.I.R.*, 544 U.S. 40, 62 (2005) ("the reviewing court shall evaluate the 'whole record'") (*quoting* 5 U.S.C. §706).

BACKGROUND

Statutory Background. This action involves four statutes: the Federal Food, Drug, and Cosmetic Act ("FFDCA"), its 1951 Durham-Humphrey Amendments, the Pediatric Research Equity Act of 2003 ("PREA"), and the Administrative Procedure Act ("APA").

Congress enacted FFDCA's predecessor in 1906 to ensure safe and efficacious drugs:

> A century ago many Americans relied on stories to pick their medicines, especially from snake oil salesmen. Thanks to scientific advances and to the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1906, we now rely on rigorous scientific proof to assure the safety and effectiveness of new drugs.

Drug Enforcement Administration, *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10,499, 10,502 (Mar. 26, 1992) (citations omitted). As relevant here, FFDCA prohibits marketing and sale of a "new drug" unless it has been proven safe and effective through approval of a new drug application ("NDA") or supplemental new drug application ("SNDA"), requiring the applicant to submit an extensive battery of analytical tests, animal studies, and human clinical safety and efficacy trials. 21 U.S.C. §355(a)-(b). FDA cannot lawfully approve an NDA or SNDA that is inadequate under even one of seven FFDCA-specified "grounds for denying approval." 21 U.S.C. §§355(c)(1), 355(d)(1)-(d)(7).

Prior to the enactment of the Durham-Humphrey Amendments, *see* Act of Oct. 26, 1951, ch. 578, 65 Stat. 648 (*codified at* 21 U.S.C. §353(b)), FFDCA addressed the distinction between Rx and OTC drugs by regulation. In pertinent part, the Durham-Humphrey Amendments re-

quired that new drugs approved for Rx distribution be dispensed via written, certain oral, or refill prescriptions, 21 U.S.C. §353(b)(1), unless FDA "by regulation remove[d the drug]… from the requirements of [§503(b)(1)] when such requirements are not necessary for the protection of the public health." 21 U.S.C. §353(b)(3); H.R. REP. NO. 82-700, at 16. Under §503(b)(4)(A), a drug "subject to paragraph (1)" (*i.e.*, an Rx drug) is "misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only.'" 21 U.S.C. §353(b)(4)(A). By contrast, §503(b)(4)(B) renders a "drug to which paragraph (1) does not apply… misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A)." 21 U.S.C. §353(b)(4)(B).

For NDAs and SNDAs filed after April 1999, PREA requires data packages to include an assessment and data for each relevant pediatric age group to enable FDA (a) to assess the drug's safety and efficacy for the claimed indications in all relevant pediatric subpopulations, and (b) to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. 21 U.S.C. §355c(a)(2)(A)(i)-(ii). Significantly, PREA limits the first criterion to claimed indications, but not the second criterion. Like FDA's Pediatrics Rule, 63 Fed. Reg. 66,632 (Dec. 2, 1998), on which it is based, PREA does not specify or define rigid age ranges for pediatric subpopulations. 63 Fed. Reg. at 66,650-51 (opposing proposed rule's rigid age ranges, adopting a flexible approach, and considering pediatric populations aged up to 21 years old).

The APA requires executive agencies such as FDA to conduct notice-and-comment rulemaking when promulgating or amending certain rules. 5 U.S.C. §553(b)-(c). Although an initial interpretation of a regulatory or statutory provision often is exempt from the notice-and-comment requirements, 5 U.S.C. §553(b)(A), the APA nonetheless requires agencies to undergo notice-and-comment rulemaking when *amending* certain rules. 5 U.S.C. §551(5) ("'rule making'

means agency process for formulating, amending, or repealing a rule").

Regulatory Background. This action primarily involves two sets of regulations: FDA's regulation to implement the Durham-Humphrey Amendments, 21 U.S.C. §310.200 (hereinafter, "§310.200"), and FDA's rules of administrative practice, 21 C.F.R. pt. 10. Plaintiffs describe those two regulations in detail in Sections II.C.1.b ("§310.200 *Did Not* Switch Regulation for Order") and I.E ("Exhaustion of Administrative Remedies"), *infra*, respectively.

Factual Background. For purposes of a motion to dismiss, the facts are those set forth in the complaint, including any reasonable inferences from those facts. In summary, in 1999, FDA approved an Rx-only NDA for Plan B, subject to a one-time PREA waiver. In 2003, Plan B's sponsor (now Duramed) sought to switch Plan B to OTC distribution, but FDA had safety concerns about young women. In response to FDA not-approvable letters based on safety concerns for younger women, Duramed proposed age bifurcation (*i.e.*, Rx for younger women, OTC for older women). FDA found that approach to present "difficult and novel issues," on which it issued an advance notice of proposed rulemaking ("ANPRM") on which Plaintiffs and their members filed comments. Two Senators publicly announced a hold on Acting Commissioner von Eschenbach's nomination as FDA Commissioner until FDA took final action on Plan B. Because FDA could not approve Plan B for OTC distribution without additional data on younger women, and Duramed had serially declined to submit such data, FDA had only two options: approval or an extended rulemaking (delaying Senate confirmation). On the eve of the confirmation hearing, FDA suddenly and without reasoned explanation resolved the "difficult and novel issues" and approved Plan B for age-bifurcated Rx-OTC distribution. According to Duramed's sworn testimony in conjunction with its motion to intervene, Plan B sales have more than doubled since OTC distribution began, and prescription sales have declined. Niemann Dec. ¶¶46-48.

ARGUMENT

I. THIS COURT HAS SUBJECT-MATTER JURISDICTION

A. Standing. To establish standing, a plaintiff must show that: (1) the challenged action constitutes an "injury in fact," (2) the injury is "arguably within the zone of interests to be protected or regulated" by the relevant statutory or constitutional provision, and (3) nothing otherwise precludes judicial review. *Ass'n of Data Processing Serv. Org., Inc. v. Camp,* 397 U.S. 150, 153 (1970). An "injury in fact" is (1) an actual or imminent invasion of a constitutionally cognizable interest, (2) which is causally connected to the challenged conduct, and (3) which likely will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-62 (1992). Statutes can confer rights, the denial of which constitutes injury redressable by a court. *Warth v. Seldin,* 422 U.S. 490, 514 (1975). For injuries directly caused by agency action, a plaintiff can show an injury in fact with "little question" of causation or redressability, but when an agency causes third parties to inflict injury, the plaintiff must show more to establish causation and redressability. *Id.* Under these standards, Plaintiffs have standing.

1. Injuries in Fact. Injury includes both injury and threatened injury, *Los Angeles v. Lyons,* 461 U.S. 95, 101-02 (1983), which "need not be to economic or… comparably tangible" interests, and an "identifiable trifle" suffices. *Pub. Citizen v. FTC,* 869 F.2d 1541, 1547-48 (D.C. Cir. 1989). Although an abstract or generalized interest (*e.g.*, proper government operation, getting the "bad guys") cannot *establish* standing, the mere fact that many people share an injury cannot *defeat* standing. *FEC v. Akins,* 524 U.S. 11, 23 (1998). Further, a membership organization may establish standing either in its own right or on behalf of its members. *Hunt v. Washington State Apple Adver. Comm'n,* 432 U.S. 333, 343 (1977). An association may sue on behalf of "any one" of its members, notwithstanding that that member's interest conflicts with the interests of other members. *National Lime Ass'n v. E.P.A.*, 233 F.3d 625, 636 (D.C. Cir. 2000). At the

summary disposition phase, the member's affidavit will suffice, *id.*, but at the pleadings phase a mere allegation suffices. *Burford*, 835 F.2d at 312-13.[2] Plaintiffs allege several injuries.

a. Informational Injury. By denying the public (and therefore Plaintiffs) access to FFDCA-required label information, Compl. ¶¶17-18, FDA injured Plaintiffs. *Pub. Citizen v. FTC*, 869 F.2d 1541, 1546-52 (D.C. Cir. 1989) (informational standing for product warning labels); *Pub. Citizen v. DOJ*, 491 U.S. at 449-51; *Akins*, 524 U.S. at 21 ("plaintiff suffers an 'injury in fact' when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute"); *Sargeant v. Dixon*, 130 F.3d 1067, 1070 (D.C. Cir. 1997) ("receipt of information is a tangible benefit the denial of which constitutes an injury").[3] At the purely informational level, a party seeking statutorily required information "need show [no] more than that they sought and were denied specific agency records," *Pub. Citizen v. DOJ*, 491 U.S. at 449; *Am. Friends Serv. Comm. v. Webster*, 720 F.2d 29, 55 (D.C. Cir. 1983) (professional researchers

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[2] *Sierra Club v. Morton*, 405 U.S. 727 (1972), asked whether advocacy for the natural environment qualified a corporation (the Sierra Club) as the natural environment's guardian *ad litem*, without alleging that Club members would suffer injury from a proposed ski resort in the Sierra Mountains. *Morton*, 405 U.S. at 750 n.8 (Douglas, J., dissenting). Although deforestation was a "setback" to the corporate Sierra Club's "abstract social interests," nothing in *Morton* prevented the Sierra Club from establishing its standing by amending its complaint to allege that its members not only intended to visit the forest in question but also "conducted regular camping trips" there. *Morton*, 405 U.S. at 735 n.8. Because Plaintiffs seek to enforce their members concrete rights, *Morton* is inapposite here.

[3] In *Am. Farm Bureau*, this Court held that informational standing did not create a right to the informational product of an agency's FFDCA programmatic activities, which "simply has not yet been generated." *Am. Farm Bureau v. E.P.A.*, 121 F.Supp.2d 84, 98 (D.D.C. 2000) (rejecting informational standing based on any "governmental failure to implement or enforce [a] statutory provision simply because government action creates information"). Although *Am. Farm Bureau* states that "FFDCA is not [an information-rights] statute… [because] Section 408(p) does not require EPA to share the results of the endocrine disruptor screening program with the public," *Am. Farm Bureau*, 121 F.Supp.2d at 99, that statement about FFDCA §408(p) does not (and could not) cover FFDCA §503 drug labeling. *See Pub. Citizen*, 869 F.2d at 1546-52.

and those seeking information for use in possible litigation are within the zone of interests of records-preservation statutes). Label-based informational injuries support Counts I, II, and III.

b. Safe and Efficacious Drugs. Public-safety statutes such as FFDCA (Count I), PREA (Count III), and the Durham-Humphrey Amendments (Counts II, III, and VI) create rights, the denial of which (Compl. ¶¶18, 82-95) establishes standing. *Warth*, 422 U.S. at 514; *Am. Trucking Ass'ns v. Dep't of Transp.*, 166 F.3d 374, 385 (D.C. Cir. 1999) (exposure to unsafe activity is constitutionally and prudentially sufficient for standing to challenge agency action under safety statute). Safety- and efficacy-based injuries support Counts I, II, III, and VI.

c. Competitive Injury. Under the "competitor standing doctrine… when a challenged agency action authorizes allegedly illegal transactions that will almost surely cause [a] petitioner to lose business, there is no need to wait for injury from specific transactions to claim standing." *El Paso Natural Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499 (D.C. Cir. 1996) ("injury claimed here is not lost sales, *per se;*… [r]ather the injury claimed is exposure to competition"); *Liquid Carbonic Indus. Corp. v. FERC*, 29 F.3d 697, 701 (D.C. Cir. 1994) ("Increased competition represents a cognizable Article III injury") (citing cases). As Duramed itself admitted, prescription sales of Plan B are down. Niemann Decl. ¶48; Joseph Decl. ¶3 (Ex. 1); *Diamond v. Charles*, 476 U.S. 54, 66 (1986) (doctors have standing to challenge state actions that financially affect their abortion practices). Here, physicians clearly have competitive standing because FDA's action (and FDA's action alone) enabled the non-physicians to dispense Plan B, and this Court's vacating the Rx-OTC switch would terminate the non-physicians' authority to compete with physicians on this issue. Compl. ¶¶19-20. Although FDA argues that exposure to *legal* competition is not an injury, FDA Mot. at 15, this competition is *illegal*. *See* Compl. ¶¶44, 85-86, 103, 112; *see also* Section

II.C.1, *infra* (Plan B misbranded when held for sale); *Tel. & Data Systems, Inc. v. FCC*, 19 F.3d 42, 47 (D.C. Cir. 1994) ("injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality"). Physicians' competitive injuries support Counts II, III, IV, VI, and VII.

d. Economic Injury and Regulatory Burden. SDW's pharmacist members suffer economic and regulatory injuries: expanded legal liability caused by removing physicians from the Rx process; expense and administrative burden of implementing the CARE program; and compelled speech and other conscience-based objections to Plan B. *See* Compl. ¶¶23-26. Regarding liability, pharmacists often have immunity from malpractice suits when they correctly fill a physician's prescription. *See, e.g., Madison v. Am. Home Products Corp.*, 358 S.C. 449, 451, 595 S.E.2d 493, 494 (S.C. 2004); David J. Marchitelli, *Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R.5th 393 (1996 & Supp. 2007). Taking the physician out of the dispensing chain not only takes away that immunity, but also imposes CARE program's additional burdens of consulting with consumers, with or without compensation. Compl. ¶25. Of course, pharmacists' economic injuries are just as justiciable as physicians' economic injuries. *Diamond*, 476 U.S. at 66.

Similarly, the administrative burdens arbitrarily imposed on them "[c]learly… me[e]t the constitutional requirements, and… [they] therefore ha[ve] standing to assert [their] own rights," the "[f]oremost" of which is the "right to be free of arbitrary or irrational [agency] actions." *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 263 (1977). Finally, many pharmacist members oppose Plan B on religious grounds, *e.g.*, Pontifical Academy for Life, Statement on the So-Called "Morning-After Pill" (Oct. 31, 2000) ("the proven "anti-implantation" action of the morning-after pill is really nothing other than a chemically induced abortion [and]

[a]ll who, whether sharing the intention or not, directly co-operate with this procedure are also morally responsible for it") (Ex. 2), and would prefer not to be involved with Plan B's distribution. These desires – even more than the imposition of additional administrative burden – implicate legally cognizable interests that SDW seeks to protect, *Menges v. Blagojevich*, 451 F.Supp.2d 992, 999-1002 (C.D. Ill. 2006) (pharmacists state a claim against a state contraceptive rule under First Amendment's Free Exercise clause), particularly in states (such as Washington State and Illinois) that compel pharmacists to distribute Plan B. Compl. ¶¶6, 15, 24-26. Pharmacists' economic injuries and regulatory burdens support Counts II, III, IV, VI, and VII.

e. Enforcement and Illegality. Under Plaintiffs' view of the law, Plan B is misbranded when held for sale. Section II.C.1, *infra;* Compl. ¶103. As such, pharmacists face the threat of prosecution for dispensing Plan B. *See, e.g.*, S.D. CODIFIED LAWS §36-11A-46(10); 63 PA. CONS. STAT. §390-5(a)(9)(vii); WASH. REV. CODE §§69.04.040(1), (3), .540; 410 ILL. COMP. STAT. 620/3.1, 3.3, 16. Significantly, many states would exempt Duramed – but not pharmacists – because of FDA's approval. S.D. CODIFIED LAWS §36-11A-46(10). Thus, for example, to halt the unlawful distribution of Plan B, a South Dakota prosecutor would need to prosecute a pharmacist, not Duramed. Pharmacists have standing to seek a declaration of the law, rather than risk committing criminal and professional violations. See *Diamond*, 476 U.S. at 66; *Tele. & Data Systems*, 19 F.3d at 47; *Indep. Bankers Ass'n of Am. v. Heimann*, 613 F.2d 1164, 1167 (D.C. Cir. 1979) (standing to challenge agency action that forces regulated entity to choose between more costly and otherwise illegal sales method versus risking prosecution and unethical conduct); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 62 (1976) ("[person] against whom [the act] directly operate[s]… assert a sufficiently direct threat of personal detriment"). To the extent that Plaintiffs must establish a "credible threat of prosecution" to seek pre-enforcement

review, *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979), Plaintiffs require jurisdictional discovery. Joseph Decl. ¶4. Plaintiffs contend, however, that the threat-of-enforcement restriction does not apply with equal force to threats from administrative action as to those from presumptively valid statutes. *See Chamber of Commerce v. FEC*, 69 F.3d 600, 603-04 (D.C. Cir. 1995) (unlike statutes, administrative action "is typically reviewable without waiting for enforcement, [which makes] this case… *a fortiori* to the statutory cases"); *cf. Mass. v. EPA*, 127 S.Ct. 1438, 1454 (2007) (States' interest in preserving sovereignty alters standing analysis). Pharmacists' enforcement-based injuries support Counts I, II, III, IV, and VI.

f. Procedural Injury. "The history of liberty has largely been the history of observance of procedural safeguards." *Dart v. U.S.*, 848 F.2d 217, 218 (D.C. Cir. 1988) (*quoting McNabb v. U.S.*, 318 U.S. 332, 347 (1943)). Plaintiffs allege FDA's failure to observe several such safeguards, Compl. ¶¶121, 124, 125, for which "those adversely affected… generally have standing to complain." *FEC v. Akins*, 524 U.S. 11, 25 (1998) (citing cases). Rescission and remand may produce the same result, *id.*, but until that happens, the initial injury remains "fairly traceable" to the agency's initial action, and redressable by an order striking the initial agency action, *id.* Although *FEC v. Akins* did not involve a rulemaking violation, this Circuit has extended its causation and redressability rationale to such violations. *ALDF*, 154 F.3d at 444. Plaintiffs need not show that a rulemaking will provide the desired result: "If a party claiming the deprivation of a right to notice-and-comment rulemaking . . . had to show that its comment would have altered the agency's rule, section 553 would be a dead letter." *Sugar Cane Growers Co-op. of Florida v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002).

In addition to the foregoing administrative-law procedural injuries, FDA's regulations purportedly require Plaintiffs to file an administrative petition with FDA before filing this litiga-

tion. FDA Mot. at 32-34; Duramed Mot. at 19-21. Although Plaintiffs dispute it in Section I.E, *infra*, assuming *arguendo* that FDA's regulations indeed require Plaintiffs to file an administrative petition prior to filing this litigation, that regulatory requirement violates Plaintiffs' rights under the First Amendment to petition this Court for relief. *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) ("right of access to the courts is indeed but one aspect of the right of petition"); *Int'l Primate Protection League v. Adm'rs of Tulane Educ. Fund*, 500 U.S. 72, 77 (1991) (losing the opportunity to file in the "forum of… choice" is a cognizable injury in fact); Compl. ¶37. Further, FDA's restricting Plaintiffs' ability to seek preliminary relief would violate separate-of-powers principles. *Metro. Washington Airports Auth. v. Citizens for the Abatement of Aircraft Noise*, 501 U.S. 252, 271 (1991) ("separation-of-powers principle, the aim of which is to protect…. the whole people from improvident laws") (citations and internal quotations omitted). While Plaintiffs do not doubt that *Congress* could place limits on their First Amendment rights in appropriate circumstances, *see, e.g.*, *Int'l Union v. Nat'l Right to Work Legal Def. & Ed. Found., Inc.*, 590 F.2d 1139, 1147 (D.C. Cir. 1978), Congress has neither done so here nor delegated FDA any authority to do so.

Because Plaintiffs also allege several concrete injuries, *see* Sections I.A.1.a-f, *supra*, they have standing to challenge FDA's procedural violations. *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664-65 (D.C. Cir. 1996) ("procedural-rights plaintiff must show not only that the defendant's acts omitted some procedural requirement, but also that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest") (*en banc*); *Defenders of Wildlife*, 504 U.S. at 571-72 & n.7 (only parties with an underlying *concrete* interest – *e.g.*, those living next to a proposed dam – can base standing on *abstract* procedural rights). Given these concrete injuries, redressability and immediacy apply to the *present proce-*

dural violation, which may someday injure the concrete interest, rather than to the concrete (but less certain) future injury. *Nat'l Treasury Employees Union v. U.S.,* 101 F.3d 1423, 1428-29 (D.C. Cir. 1996). In light of the existing concrete injuries on Counts I, II, III, and IV, procedural injuries support Counts V, VI, VII, and VIII.

2. Zone of Interests. The "zone of interest" prong of standing is a prudential doctrine that asks whether the interests to be protected *arguably* fall within those protected by the relevant statute. *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust, Co.,* 522 U.S. 479, 492 (1998). Congress can waive the judiciary's prudential standing doctrines, and here FDA itself has waived it. Compl. ¶31; *cf.* Section I.E (this action complies with FDA's rules of practice). In any event, if it applies, this generous and undemanding test focuses not on Congress' intended beneficiary, but on those who in practice can be expected to police the interests that the statute protects. *Animal Legal Defense Fund v. Glickman,* 154 F.3d 426, 444 (D.C. Cir. 1998) (*en banc*); *Am. Friends Serv. Comm. v. Webster,* 720 F.2d 29, 52 (D.C. Cir. 1983) ("the relatively rigorous requirements for establishing congressional intent to create a private right of action should not be equated with the 'slight' indicia standard under the 'zone' test") (footnote omitted). To show that they are *arguably* "protected" by a statute, plaintiffs may demonstrate that they are either the statute's intended beneficiaries or "suitable challengers" to enforce the statute.

a. Intended Beneficiaries within Zone. For intended beneficiaries, "'slight beneficiary indicia' are sufficient to sustain standing." *Am. Friends Serv. Comm.,* 720 F.2d at 50 & n.37. Pharmacists and consumers unquestionably are at the center of Durham-Humphrey Amendments' zone of interests: "to protect the public from abuses in the sale of potent prescription drugs" and "to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs safe for use without the supervision of a physician." S.

REP. NO. 82-946, at 1; *accord* H.R. REP, NO. 82-700, at 2 (Jul. 16, 1951). Physicians also fall within the zone: "the bill... will benefit drug manufacturers, retail druggists, medical practitioners, and the public." S. REP. NO. 82-946, at 2; *accord* H.R. REP. 700, at 9 (House "committee [was] deeply conscious of the fact that the power to determine which drugs are prescription drugs and which are over-the-counter drugs is one which affects drug manufacturers, drug wholesalers, retail druggists, pharmacists, physicians, and, last but not least, the general public"). In applying the zone of interests test, courts must focus on the specific statutory provision rather than the overarching statute (*e.g.,* §503(b)(3) or PREA, rather than the entire FFDCA) and look to the legislative history to gauge the arguable zone of interests. *Amgen, Inc. v. Smith,* 357 F.3d 103, 108-110 (D.C. Cir. 2004) ("court [incorrectly] focused on the broad purpose of the Medicare Act 'to provide more adequate and feasible health insurance protection for the elderly,' and neglected the more specific interest protected by § (t)(6) itself, namely, preventing 'restricted beneficiary access to drugs, biologicals and new technology'") (internal citations omitted, *citing* H.R. REP. NO. 106-436(I), at 53). Because of physicians' nexus with the dispensing of drugs and with the prescription-OTC dichotomy, their authority over prescription drugs, and their patients' interest in safe and effective drugs, physicians fall within the relevant statutory zones of interest as both first-party and third-party plaintiffs, as Congress recognized by making Rx-removal proceedings an open regulation rather than a closed SNDA proceeding.[4]

[4] The zone of interests can limit procedural standing, *Defenders of Wildlife,* 504 U.S. at 571-72 & n.7 (only a party with an underlying concrete interest can enforce an agency's obligation to create an environmental impact statement); *Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 883 (1990) (court reporter lacks prudential standing to challenge failure to comply with a statutory mandate to conduct hearings on the record), but Plaintiffs fall within the procedural zones for the same reasons that they fall within the concrete zones. In other words, Plaintiffs' members live near this particular dam. *Defenders of Wildlife,* 504 U.S. at 571-72 & n.7.

b. Suitable Challengers within Zone. Even if not intended beneficiaries, plaintiffs satisfy the zone of interests as "suitable challengers" if they have "interests… sufficiently congruent with those of the intended beneficiaries that [they] are not more likely to frustrate than to further the statutory objectives." *First Nat'l Bank & Trust Co. v. Nat'l Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993); *Reytblatt v. Nuclear Regulatory Comm'n*, 105 F.3d 715, 721 (D.C. Cir. 1997) (same); *MD Pharm., Inc. v. D.E.A.*, 133 F.3d 8, 13 (D.C. Cir. 1998) (same). Thus, even if certain statutory provisions are intended to benefit only pharmacists or non-patient consumers, physicians remain a "suitable" first-party and third-party challenger because their interests and their patients' interest in safe, accurately labeled drugs "further[s]," rather than "frustrate[s the]… statutory objectives." Although Plaintiffs and FDA disagree on what the statute requires, Plaintiffs do not seek relief inconsistent with their view of what the statute requires, which this Court assumes to decide standing. *City of Waukesha,* 320 F.3d at 235.

c. Zone Inapposite for *Ultra Vires* Actions. Finally, even if plaintiffs are not intended beneficiaries or suitable challengers, they may challenge *ultra vires* agency action, to which the zone-of-interest test essentially does not apply. *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 811-12 & nn.13-14 (D.C. Cir. 1987).

> It may be that a particular constitutional or statutory provision was intended to protect persons like the litigant by limiting the authority conferred. If so, the litigant's interest may be said to fall within the zone protected by the limitation. Alternatively, it may be that the zone of interests requirement is satisfied because the litigant's challenge is best understood as a claim that *ultra vires* governmental action that injures him violates the due process clause.

Haitian Refugee Ctr., 809 F.2d at 812 n.14; *accord Chiles v. Thornburgh*, 865 F.2d 1197, 1210-11 (11th Cir. 1989). Because FDA acted outside its authority (*i.e., ultra vires*) on all counts except Count I, the zone of interest test does not limit physicians' standing (except for Count I),

even if Plaintiffs fall outside the relevant statutory zones and fail as suitable challengers.

3. Members' Injuries. Three categories of members suffer injury: consumers, physicians, and pharmacists. All three suffer the informational injuries alleged here, consumers for their own use (or their minor children's use) and physicians and pharmacists for professional purposes. The next three sections address the other injuries to each member category.

a. Consumer Injuries. Contrary to Duramed's views on its product, the standing inquiry assumes the *Plaintiffs' view*, *City of Waukesha*, 320 F.3d at 235, under which the Plan B label is highly misleading, Compl. ¶¶67-72 (Plan B label is misleading, as Duramed's own label-comprehension study confirmed[5]). Under *Plaintiffs' view*, women patients are exposed to a drug that Plan B's sponsor falsely and misleadingly advertised, as found by FDA's Division of Drug Marketing, Advertising, and Communications, Compl. ¶71, in violation of statutory rights that FFDCA creates in these patients to non-misleading labeling. *Warth*, 422 U.S. at 514 (statutes can confer rights, the denial of which constitutes injury). Duramed repeatedly avoided preparing the pediatric data that PREA requires, which endangers adolescents – above and below 18 years of age – when they take Plan B in misplaced reliance on FDA and Duramed. Compl. ¶¶21-22. Finally, by illegally removing Plan B from prescription requirements, FDA has exposed not only adults but also minors (for whom even FDA found it unsafe) to Plan B. Compl. ¶¶70, 76, 95.

b. Physician Injuries. AAPS and SDW allege that their physician members face heretofore-unlawful competition from pharmacists because – prior to Plan B's switch from Rx to OTC distribution, only their physician members lawfully could provide access to Plan B, but

[5] Duramed claims that its labeling changed after the label comprehension study, which renders the study inapposite to the current labeling. Duramed Mot. at 12 n.12. Neither Plaintiffs nor the Court can evaluate that claim, much less the extent of changes, without a certified record.

now pharmacists can provide that access without a physician's prescription. Compl. ¶¶19-20; Ritter Decl., ¶¶3-6 (Ex. 3). In addition, the Complaint and Dr. Ritter allege (1) a constitutional injury (namely, the foregoing exposure to otherwise-illegal competition), (2) a close relationship with patients, Compl. ¶¶21-22; Ritter Decl., ¶9, and (3) the hindrance to his patients' asserting their own rights, Compl. ¶21-22; Ritter Decl., ¶9. Based on the foregoing, Dr. Ritter as well as many more similarly situated physician-members assert injuries under the Durham Humphrey Amendments, PREA, and FFDCA.

Following *Powers v. Ohio*, 499 U.S. 400, 411 (1991), this Circuit allows third-party standing *inter alia* where the first-party has suffered a constitutional injury in fact, has a close relationship with the third party, and "some hindrance" prevents the third party's asserting its own rights. *American Immigration Lawyers Ass'n v. Reno*, 199 F.3d 1352, 1361-62 (D.C. 2000). Significantly, "unawareness of the injury" qualifies as a sufficient hindrance, *id.*, at 1363 (*citing Lepelletier v. FDIC*, 164 F.3d 37, 43 (D.C. Cir. 1999)), which applies here. *See* Ritter Decl., ¶9 ("patients tend to trust in the safety inherent in government approval generally and FDA approval specifically, these patients will neither appreciate nor even recognize the risks"). Thus, unlike the aliens in *American Immigration Lawyers Ass'n*, 199 F.3d at 1363, AAPS members' patients generally and Dr. Ritter's specifically will not know of their exposure to the statutory harm. Similarly, in *Powers*, the third party had "little incentive" to bring suit because "of the small financial stake involved and the economic burdens of litigation." 499 U.S. at 415. If patients learn about Plan B (*e.g.*, its overstated efficacy, unproven safety for repeat use, and lack of safety data for young women), they simply will avoid it. As in *Powers*, they will have little

incentive to sue.[6] As such, physicians can "by default [become] the right's best available proponent." *American Immigration Lawyers Ass'n*, 199 F.3d at 1362 (quotations omitted).

c. Pharmacist Injuries. SDW alleges several injuries on behalf of pharmacist members: expanded legal liability caused by removing physicians from the Rx process; expense and administrative burden; and compelled speech and other conscience-based objections. Compl. ¶¶23-26. As with physicians' injuries, these pharmacists' injuries are justiciable and either within the relevant zone of interests or imposed by FDA's *ultra vires* actions, to which no zone of interest applies. Duramed alleges that many of these injuries, if injuries at all, are imposed by third parties. Duramed Mot. at 19 n.16. In *Nat'l Parks Conserv. Ass'n v. Manson*, 414 F.3d 1 (D.C. Cir. 2005) ("*NPCA*"), this Circuit found standing based on federal regulations that legally required third-party state regulators to *consider* (and to *justify* a departure from) a federal adverse-impact determination. *NPCA*, 414 F.3d at 6. Even this low regulatory threshold – requiring only *consideration* and *justification* – nonetheless "alters the legal regime" sufficiently to "undermine[]" the federal government's invocation of third-party standing cases that involve independent actors. *Id.* (*quoting Bennett v. Spear*, 520 U.S. 154, 169 (1997), *distinguishing Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)). Plaintiffs seek to establish that OTC Plan B is misbranded when held for sale, *see* Compl. ¶103; Section II.C.1, *infra*, Plaintiffs' prevailing here would free members from state-law (or employers') compulsion to distribute it,

[6] Duramed argues that consumers would not have standing to sue because their injuries are speculative and not imminent. Duramed Mot. at 6-8 (citing *inter alia Pub. Citizen v. NHTSA*, 489 F.3d 1279, 1296 (D.C. Cir. 2007)). Further, given the prospect of jurisdictional discovery by Duramed, Plaintiffs have had difficulty finding a consumer or consumer parent affiant willing to subject their personal affairs to this litigation. Joseph Decl. ¶5. Both issues further hinder the rights-holder's bringing suit and commend third-party standing for physicians.

U.S. CONST. art. VI, cl. 2, which more than meets the *NPCA* test for establishing that relief here will protect these pharmacists from the injuries that Plan B's OTC dispensing inflicts on them.

4. Other Factors. Aside from the bases for dismissal pressed by the FDA and Duramed motions, no legal or equitable principles preclude this action.

B. Federal-Question Jurisdiction. Notwithstanding that the Complaint alleges various violations of FFDCA, the Durham-Humphrey Amendments, PREA, and APA, FDA cites two strands of inapposite cases to argue this action does not "arise under" federal law for 28 U.S.C. §1331: (1) state-law claims with a federal defense, and (2) an appeal to a federal court of limited jurisdiction (the Federal Circuit). FDA Mot. at 27-28. Here, by contrast, Plaintiffs allege violations of federal law in a federal court of general jurisdiction. *See Herero People's Reparations Corp. v. Deutsche Bank, A.G.*, 370 F.3d 1192, 1195 (D.C. Cir. 2004) (claim arises under federal law when the complaint alleges a violation of federal law). In 1976, Congress expanded §1331's subject-matter jurisdiction to all challenges to federal administrative agencies and officers by removing the then-applicable amount-in-controversy requirement:

> An anomaly in Federal jurisdiction prevents an otherwise competent United States district court from hearing certain cases seeking 'nonstatutory' review of Federal administrative action, absent the jurisdictional amount in controversy required by [§1331], the general 'Federal question' provision. These cases 'arise under' the Federal Constitution or Federal statutes, and the committee believes they are appropriate matters for the exercise of Federal judicial power regardless of the monetary amount involved.

Califano v. Sanders, 430 U.S. 99, 105 (1977) (*quoting* S. REP. NO. 94-996 at 12 (1976)) (Court's emphasis). As the Court noted, "[t]he *obvious* effect of [eliminating §1331's amount-in-controversy requirement against federal agencies and officers], subject only to preclusion-of-review statutes created or retained by Congress, is to confer jurisdiction on federal courts to review agency action, regardless of whether the APA of its own force may serve as a jurisdic-

tional predicate." *Sanders*, 430 U.S. at 107 (emphasis added). Because FDA cannot allege that a statute *precludes* review, its federal-question argument is exceptionally baseless.

C. Judicial Review Generally. FDA implies that, because FFDCA has no relevant *statutory* review (*i.e.*, no FFDCA-specific provisions for judicial review applicable to Plaintiffs), Plaintiffs lack a cause of action. FDA Mot. at 27-32. FDA's argument ignores *nonstatutory* review (*i.e.*, general review from a non-FFDCA source), such as the Administrative Procedure Act ("APA") and non-APA, nonstatutory review (*e.g.*, Declaratory Judgment Act, this Court's equity jurisdiction, officer suits under *Ex parte Young*). The following two sections address APA review (including its waiver of sovereign immunity) and non-APA review, respectively.[7]

1. Administrative Procedure Act. Under the APA, persons aggrieved within the meaning of a relevant statute are entitled to judicial review of *inter alia* final agency action for which the plaintiff lacks an adequate legal remedy. 5 U.S.C. §§702-704. Under the APA, courts "shall… compel agency action unlawfully withheld," "set aside agency action… found to be… arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory… authority," or "without observance of procedure required by law." 5 U.S.C. §706. Absent clear and convincing evidence of legislative intent *to preclude* review, agency action is reviewable. *Block v. Community Nutrition Inst.*, 467 U.S. 340, 345 (1984); *Abbott Labs., Inc., v. Gardner*, 387 U.S. 136, 141 (1967). Significantly, §702 waives sovereign immunity.

a. Final Agency Action. FDA is an APA "agency." 5 U.S.C. §§101, 551(1),

[7] In arguing against Plaintiffs' interest in the challenged agency actions, FDA appears to assume the merits of its position that §503(b)(3) and §310.200(b) allowed FDA to proceed without a *public* rulemaking, in which Plaintiffs and their members *would participate* (and in which they *did participate* with respect to the ANPRM). Compl. ¶27. This Court must conduct its jurisdictional analysis under Plaintiffs' view of the law. *See* Section I, *supra*, at 8.

701(b). Although FDA does not seriously contest it, the challenged actions are "agency action," which the APA defines to include "an agency rule, order,… or the equivalent or denial thereof, or failure to act." 5 U.S.C. §551(13). And "order" means:

> *the whole or a part of a final disposition,* whether affirmative, negative, injunctive, or declaratory in form, *of an agency in a matter other than rule making* but including licensing[.]

Id. §551(6) (emphasis added). In sum, the challenged actions here (*e.g.*, approval of an SNDA, failure to conduct discrete rulemakings) clearly constitute "agency action" under the APA.[8]

Bennett v. Spear, 520 U.S. 154, 177-78 (1997), sets a two-part test to determine whether agency action is *final:* (1) it "must mark the 'consummation' of the agency's decision making process" and not "merely tentative or interlocutory" in nature; and (2) it "must be one by which rights or obligations have been determined, or from which legal consequences will flow." All of the relevant actions and inaction here are final because FDA has concluded its deliberations (*e.g.*, approved the SNDA, without the required rulemakings), with legal consequences (*e.g.*, OTC availability of Plan B without the required public process).

b. Adequate Remedy. Under the APA, "final agency action for which there is no other adequate remedy *in a court* [is] subject to judicial review." 5 U.S.C. §704 (emphasis added). Plaintiffs lack *any* alternate remedy *in court.* Section I.E, *infra,* responds to the argument

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[8] FDA mischaracterizes the limits on APA's reach found in *Norton v. S. Utah Wilderness Alliance,* 542 U.S. 55 (2004) ("*SUWA*"). FDA Mot. at 31. *SUWA* found that APA inaction extends only to inaction on discrete actions that the agency was legally required to take, as distinct from programmatic inaction. *SUWA,* 542 U.S. at 62-63. Where agencies indeed act, the APA allows a programmatic challenge. *Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 890 n.2 (1990) ("If there is in fact some specific order or regulation, applying some particular measure across the board to all individual classification terminations and withdrawal revocations,... it can of course be challenged under the APA... and the entire [regulatory program] insofar as the content of that particular action is concerned, would thereby be affected").

that Plaintiffs failed to exhaust *administrative* remedies.

c. Legally Wronged, Aggrieved, and Adversely Affected. As FDA notes, the APA provides an action when agency action causes legal wrong or aggrieves or adversely affects a person within the meaning of a relevant statute. FDA Mot. at 30 (*citing* 5 U.S.C. §702). Significantly, §702 was the predicate for the Supreme Court's initial invocation of the "zone of interests" test. *Camp*, 397 U.S. at 153-54. Accordingly, FDA's reprise of its zone-of-interests argument in its APA discussion serves no purpose. *See* FDA Mot. at 30-32. If Plaintiffs lack standing, it would not matter whether the APA applies. The opposite also is true: "[w]ant of right and want of remedy are justly said to be reciprocal" so that "[w]here… there has been a violation of a right, the person injured is entitled to an action." *Alabama Power Co. v. Ickes*, 302 U.S. 464, 479 (1938). The Attorney General cited *Ickes* as the leading case on the existing law codified by this section of the APA (now §702). Administrative Procedure Act, Legislative History, 79th Cong., S.Doc. No. 248, 79th Cong., 2d Sess., at 230 (1946) (hereinafter "APA Leg. Hist."). Because Plaintiffs are in the zone of interests, *see* Section I.A.2, *supra*, they also satisfy §702.

d. Committed to Discretion by Law. Under 5 U.S.C. §701(a)(2), courts will find agency actions "committed to agency discretion by law" in "those *rare instances* where statutes are drawn in such broad terms that *in a given case* there is no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (interior citations omitted, emphasis added); *accord Heckler v. Chaney*, 470 U.S. 821, 830 (1985) ("if no judicially manageable standards are available for judging how and when an agency should exercise its discretion," then §701(a)(2) precludes review). Of course, that an agency *has discretion* does not preclude judicial review. *See* 5 U.S.C. §706(2)(A) (judicial review of *abuse of discretion*). Instead, to preclude review, discretion must be "committed to [the] agency… by law." 5 U.S.C. §701(a)(2).

No law irrevocably commits any of the challenged actions to FDA's discretion.

2. Non-APA Nonstatutory Review. As indicated, Plaintiffs assert several non-APA bases for judicial review here. Significantly, the APA does not limit these non-APA actions. *Nat'l Treasury Employees Union v. Campbell,* 589 F.2d 669, 673 n.7 (D.C. Cir. 1978) (Mandamus Act, APA, and other nonstatutory review are distinct, alternate causes of action) ("*NTEU*"); *Chamber of Commerce v. Reich,* 74 F.3d 1322, 1328 (D.C. Cir. 1996) (APA did not alter the pre-APA nonstatutory judicial review doctrines); *Dart v. U.S.,* 848 F.2d 217, 224 (D.C. Cir. 1988) ("[n]othing in the subsequent enactment of the APA altered [or] repeal[ed] the review of *ultra vires* actions recognized long before"). Significantly, "inquiry into whether suit lies under *Ex parte Young* does not include [merits] analysis," *Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.,* 535 U.S. 635, 636-37 (2002), and thus does not allow dismissal without a merits analysis. As FDA notes, however, the Court's finding APA review would obviate the need to resort to these non-APA bases for judicial review.[9] FDA Mot. at 45.

a. This Court's Equity Jurisdiction. This Court long has had equity jurisdiction over federal officers that exceeds that of other district courts. *Kendall v. U.S. ex rel. Stokes,* 37

[9] By contrast, as signaled by the *NTEU, Reich,* and *Dart* decisions cited above, there are numerous (and controlling) instances where a plaintiff who lacked an APA cause of action nonetheless could sue under the alternate, pre-APA modes of judicial review. *See also, e.g., Indep. Broker-Dealers' Trade Ass'n v. SEC,* 442 F.2d 132, 143 & n.18 (D.C. Cir. 1971) ("[if APA] should be given narrow reading, the action is sustainable by reference to the general equity jurisdiction of the District Court"); *Franklin v. Massachusetts,* 505 U.S. 788, 801 (1992) (equitable review of agency action that did not qualify for APA review); *Pickus v. U.S.,* 543 F.2d 240, 243-44 & n.10 (D.C. Cir. 1976) (*citing* cases); *Webster v. Doe,* 486 U.S. 592, 601-03 (1988); *cf. Texas Rural Legal Aid, Inc. v. Legal Serv. Corp.,* 940 F.2d 685, 696-97 (D.C. Cir. 1991) (non-APA agency's decisions remain "subject to the pre-APA requirement that administrative decisions be rationally based – a standard that courts have held is equivalent to the APA's requirement that agency action not be arbitrary or capricious").

U.S. (12 Pet.) 524, 580-81 (1838); *Stark v. Wickard*, 321 U.S. 288, 290 n.1 (1944); *Peoples v. Dep't of Agriculture*, 427 F.2d 561, 564 (D.C. Cir. 1970). Neither the APA nor the Mandamus Act displaced or limited this historic jurisdiction, which derives both from the court's enabling legislation and Maryland's ceding the District's territory to form the District as a federal enclave. *Peoples*, 427 F.2d at 565; *Gamen v. Heckler*, 746 F.2d 844, 851 (D.C. Cir. 1984).[10]

b. *Ultra Vires* Action. Plaintiffs allege that FDA acted (and continues to act) *ultra vires* its authority. Under the "*Larson-Dugan* exception," an equitable action lies against a federal officer's actions beyond the officer's constitutional or statutory authority, on the grounds that "where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions." *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949); *Dugan v. Rank*, 372 U.S. 609, 621-23 (1963); *accord Clark v. Library of Congress*, 750 F.2d 89, 102 (D.C. Cir. 1984) (citing cases). "[Agencies are] creature[s] of statute," that have "no constitutional or common law existence or authority, but only

[10] The current statute confers the same jurisdiction as that on which the *Peoples* court relied. *Compare* D.C. Code §11-501 *with* D.C. Code §11-521 (1967) (Ex. 4). Both versions grant this Court "any other jurisdiction conferred *by law*" in addition to "jurisdiction as a United States district court." The "law" establishing this Court confers it with "general jurisdiction in law and equity." *See* Act of March 3, 1863, 12 Stat. 762; Act of June 25, 1936, 49 Stat. 1921. The District of Columbia Court Reorganization Act of 1970 did not repeal this jurisdiction, but instead retained the jurisdiction granted to this Court "by law," D.C. Code §11-501, which cannot impliedly repeal the prior jurisdiction. *Schlesinger v. Councilman*, 420 U.S. 738, 752 (1975) ("'repeals by implication are disfavored,' and this canon of construction applies with particular force when the asserted repealer would remove a remedy otherwise available"). Indeed, the legislative history of the 1976 statute waiving sovereign immunity for equitable relief notes that, under the then-current law, plaintiffs could escape the then-applicable $10,000 amount-in-controversy requirement by seeking to enjoin federal officers in the District of Columbia. H.R. Rep. No. 94-1656, at 15-16, *reprinted in* 1976 U.S.C.C.A.N. 6121, 6136. In other words, Congress itself recognized in 1976 that its 1970 Reorganization Act had left intact this Court's equitable jurisdiction over federal actors.

those authorities conferred upon it by Congress." *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001). Without statutory authority, the agency has none. *Id; Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) (recognizing that "an agency literally has no power to act… unless and until Congress confers power upon it").

c. Declaratory Judgment Act. The Declaratory Judgment Act, 28 U.S.C. §§2201-2202 ("DJA"), authorizes declaratory relief "whether or not further relief… could be sought." *Id.* §2201(a); *Duke Power Co.*, 438 U.S. at 70-71 n.15 ("While the [DJA] does not expand our jurisdiction, it expands the scope of available remedies" where plaintiffs sought declaratory relief that a statute was invalid, as an alternate remedy to seeking compensation for a taking). Since 1976, §1331 has authorized DJA actions against federal officers, regardless of the amount in controversy. *See* Section I.B, *supra; Sanders*, 430 U.S. at 105 (§1331's 1976 amendment authorizes DJA action against federal officers) (*citing* Pub. L. 94-574, 90 Stat. 2721 (1976)); *see also* H.R. Rep. No. 96-1461, at 3-4, *reprinted in* 1980 U.S.C.C.A.N. 5063, 5065 (§1331's 1980 amendment did not repeal its 1976 amendment); *Hurley v. Reed*, 288 F.2d 844, 848 (D.C. Cir. 1961) ("fact that another remedy would be equally effective affords no ground for declining declaratory relief" against federal officers); *Tierney v. Schweiker*, 718 F.2d 449, 457 (D.C. Cir. 1983) (same); APA Leg. Hist., at 37, 212, 276 (APA no barrier to DJA actions against federal officers). Thus, either in conjunction with, or as an alternative to, relief under other legal theories, this Court may issue the requested declaratory relief. *Nat'l Treasury Employees Union v. Nixon*, 492 F.2d 587, 616 (D.C. Cir. 1974).

D. Judicial Review against Individual-Capacity Officers. FDA asks this Court to dismiss Dr. von Eschenbach in his individual capacity under color of legal authority. FDA does not address – much less credibly dispute – the historical fact that the blackletter, judge-made, offi-

cer-suit exception to the judge-made sovereign-immunity doctrine was a founding principle of this democracy and its judiciary. Compl. ¶35; Section of Administrative Law & Regulatory Practice of the American Bar Association, *"A Blackletter Statement of Federal Administrative Law,"* 54 ADMIN. L. REV. 1, 46 (2002) ("Under the longstanding officer suit fiction recognized in *Ex Parte Young,* 209 U.S. 123 (1908), suits against government officers seeking prospective equitable relief are not barred by the doctrine of sovereign immunity").[11]

Indeed, contrary to FDA's argument, Congress expressly has recognized a distinction between color-of-legal-authority and official-capacity actions for judicial-review against officers in the APA, 5 U.S.C. §702 (listing official-capacity and color-of-legal-authority actions as distinct), as well as judicial review generally. 28 U.S.C. §1391(e) (same); *cf.* 18 U.S.C. §2337(1)-(2) (same); *Stafford v. Briggs,* 444 U.S. 527, 539 (1980) ("By including the officer or employee,

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[11] *See* U.S. CONST. art. III, §2 ("judicial power shall extend to all cases, in law and *equity*") (emphasis added); THE FEDERALIST NO. 78, at 464-66 (Alexander Hamilton) (Clinton Rossiter ed., Signet 2003) (1961) (discussing judicial review); Robert Yates, Brutus Essay XI (1788), *reprinted in* THE ESSENTIAL ANTIFEDERALIST, at 187-90 (W.B. Allen & Gordon Lloyd, ed., 2002) (same); Judiciary Act of 1789, ch. 20, §16, 1 Stat. 72, 82 (establishing equity jurisdiction); *Atlas Roofing Co., Inc. v. Occupational Safety & Health Review Comm'n,* 430 U.S. 442, 459 n.14 (1977) (Judiciary Act's §16 was "declaratory of *existing law*" of equity in 1789) (emphasis added); Louis L. Jaffe, *Suits against Governments and Officers: Sovereign Immunity,* 77 HARV. L. REV. 1, 5-18 (1963) (describing centuries of development of various petitions and writs against the Crown's actions *with its consent* and against the Crown's officers' unlawful actions *without consent*); *Marbury v. Madison,* 5 U.S. (1 Cranch) 137, 165 (1803) ("the law… entertains no respect or delicacy [for the Crown's officers]; but furnishes various methods of detecting the errors and misconduct of those agents, by whom the king has been deceived and induced to do a temporary injustice") (*quoting* 3 WILLIAM BLACKSTONE, COMMENTARIES *255); *Osborn v. Bank of U.S.,* 22 U.S. (9 Wheat.) 738, 843 (1824) ("it would be subversive of the best established principles, to say that the laws could not afford the same remedies against the agent employed in doing the wrong, which they would afford against him, could his principal be joined in the suit"); Louis L. Jaffee, *The Right to Judicial Review I,* 71 HARV. L. REV. 401, 433 (1958) ("that the King's courts… could order his officers to account for their conduct [] was the essence of… "the rule of law." Whatever the logical contradictions between this doctrine and sovereign immunity, [it] had become firmly established [and] as much a part of the law as… sovereign immunity").

both in his official capacity and acting under color of legal authority, the committee intends… to include also those cases where the action is nominally brought against the officer in his individual capacity even though he was acting within the apparent scope of his authority and not as a private citizen. *Such actions are also in essence against the United States but are brought against the officer or employee as an individual only to circumvent what remains of the doctrine of sovereign immunity.*") (*quoting* H.R. Rep. No. 86-1936, at 3-4 (1960)) (Court's emphasis).[12] The foregoing authorities clearly allow naming Dr. von Eschenbach individually, even under the APA, for exceeding his official authority.

E. Exhaustion of Administrative Remedies. When challenging "final agency action," an APA plaintiff has no duty to exhaust optional administrative remedies unless the disputed agency action remains inoperative during that further administrative process:

> A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. *Except as otherwise expressly required by statute,* agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an

[12] *See also Young*, 209 U.S. at 160 (officer acting without valid authority is "stripped of his official or representative capacity and is *subjected in his person* to the consequences of his *individual conduct,*" and suit is "against [him] *personally as a wrongdoer* and not against the State") (emphasis added); *Georgia R.R. & Banking Co. v. Redwine*, 342 U.S. 299, 305 (1952) ("this action against appellee *as an individual* is not barred as an unconsented suit against the State") (emphasis added); *U.S. v. Lee*, 106 U.S. 196, 210 (1882) (Robert E. Lee's family's suit to eject federal officers from Arlington National Cemetery was "against [officers], *as individuals,* to recover possession" notwithstanding that "the officers who are sued assert no personal possession, but are holding as the mere agents of the United States") (emphasis added); *U.S. v. Boutwell*, 84 U.S. (17 Wall.) 604, 607 (1873) ("[i]f he be an officer, and the duty be an official one, still the writ is aimed exclusively against him as a person, and he only can be punished for disobedience…. It is, therefore, in substance, a personal action, and it rests upon the averred and assumed fact that the defendant has neglected or refused to perform a personal duty"); *cf. In re Iraq and Afghanistan Detainees Litigation*, 479 F.Supp.2d 85, 119 (D.D.C. 2007) (declaratory relief unavailable against individual-capacity defendants) (*dicta* because of lack of standing).

> application for a declaratory order, for any form of reconsideration, or, *unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative,* for an appeal to superior agency authority.

5 U.S.C. §704 (emphasis added). Nothing in the FFDCA, Durham-Humphrey Amendments, or PREA renders FDA's actions anything other than final.

As the Supreme Court noted in *Darby v. Cisneros,* "[i]t perhaps is surprising that it has taken over 45 years since the passage of the APA for this Court definitively to address th[e] question" whether §704 "limits the authority of courts to impose additional exhaustion requirements as a prerequisite to judicial review." *Darby v. Cisneros,* 509 U.S. 137, 145 (1993). In that 1993 decision, the Court completely rejected the view put forward here by FDA and Duramed for actions *under the APA:*

> Of course, the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA. But where the APA applies, an appeal to "superior agency authority" is a prerequisite to judicial review *only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review. Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the agency action has already become "final" under [§704].

Darby, 509 U.S. at 153-54 (emphasis in original).

It is perhaps *not* surprising that FDA and Duramed cite only pre-1993 and non-APA cases for their now-discredited proposition optional administrative remedies somehow displace APA review of otherwise final agency action. *See* FDA Mot. at 32-34; Duramed Mot. at 19-21. Directly or indirectly, both FDA and Duramed rely primarily on *McCarthy v. Madigan,* 503 U.S. 140 (1992), which *Darby* expressly distinguishes as a "non-APA case" just before noting that "the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA." *Darby,* 509 U.S. at 153-54; *see also Assoc. of Flight Attendants v. Chao,* 493

F.3d 155 (D.C. Cir. 2007) (non-APA case under Declaratory Judgment Act and mandamus); *Garlic v. FDA*, 783 F. Supp. 4, 4-5 (D.D.C. 1992) (no final action); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 4-6 (D.D.C. 1989) (no final action); *National Gay Rights Advocates v. HHS*, 1988 WL 43833, *1 (D.D.C.) (no final action); *American Disabled for Attendant Programs Today v. H.U.D.*, 170 F.3d 381, 389-90 (3rd Cir. 1999) (no final action and an adequate alternate remedy *in court*).[13] If Plaintiffs had brought this suit only on APA grounds, FDA's and Duramed's exhaustion arguments would be frivolous.

If it finds the APA inapposite, the Court may consider prudential exhaustion. Where it applies, prudential exhaustion serves three functions: allowing agencies the opportunity to correct their errors, affording parties and courts the benefits of the agency's expertise, and compiling an administrative record adequate for judicial review. *Avocados Plus Inc. v. Veneman*, 370 F.3d 1243, 1247 (D.C. Cir. 2004). Plaintiffs respectfully submit that the second and third functions are fully met here. Under the circumstances, moreover, the first is both inapposite and essentially futile: if FDA reverses its action, Duramed will sue; if FDA does not reverse, Plaintiffs will sue. Either way, the same questions would return to court.

In any event, the filing of this litigation is entirely consistent with, and authorized by, FDA's administrative procedures. By its express terms, FDA's exhaustion provision "applies to court review of final administrative action taken by the Commissioner, including action taken under §§10.25 through 10.40." 21 C.F.R. §10.45(a). First, the challenged FDA action and inac-

[13] FDA also cites the jurisdictional dismissal in *Burt Lake Band of Ottawa & Chippewa Indians v. Norton*, 217 F. Supp. 2d 76, 78 (D.D.C. 2002) (Indian tribes must seek tribal recognition from the Bureau of Indian Affairs and cannot seek recognition directly from court), notwithstanding that FDA acknowledges that FDA's exhaustion argument is not jurisdictional. FDA Mot. at 33 & n.23.

tion clearly constitute "administrative action," which "includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner." 21 C.F.R. §10.3(a). Second, the "administrative action" is indisputably final. *See* Section I.C.1.a, *supra.* Third, while §10.45(a) in no way limits itself to "action taken under §§10.25 through 10.40," this litigation concerns two actions under §10.25: (1) Duramed's "petition" to remove Plan B from the prescription drug requirements, *see* 10 C.F.R. §§10.25(a)(1), 310.200(b); and (2) FDA's ANPRM and its final conclusion that it could proceed without rulemaking, 10 C.F.R. §10.25(b). Given FDA's final positions on these "administrative actions," FDA's regulations do not require an "interested person" (*i.e.*, one who petitioned, commented, objected, or otherwise seeks to participate) to petition for reconsideration before seeking judicial review. 21 C.F.R. §§10.3(a), .45(e). Because all of the Plaintiffs qualify as "interested persons," *see* Compl. ¶27, they need not seek reconsideration of the final administrative actions here.[14]

II. DEFENDANTS' DISPOSITIVE MOTIONS LACK MERIT

In addition to challenging this Court's jurisdiction for the entire complaint, FDA and Duramed seek merits dismissal of Counts II, IV, V, and VI for failure to state a claim on which this Court can grant relief. In doing so, FDA and Duramed make arguments under both *Chevron* "Step One" and *Chevron* "Step Two":

> Under *Chevron* Step One, we always first examine the statute *de novo*, employing traditional tools of statutory construction. If the intent of Congress is clear, we accord the agency's interpretation

[14] Because Plaintiffs can rely on any argument made by any commenter, *State of Ohio v. EPA*, 838 F.2d 1325, 1329 (D.C. Cir. 1988), FDA cannot argue that the Court must limit itself to arguments made during the administrative proceedings without first producing the administrative record, even under FDA's view of the law. In any event, having refused to convene a required rulemaking, FDA cannot credibly argue that the public failed to comment.

> no deference, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. But if Congress has [not] directly spoken to the precise question at issue, we proceed to *Chevron* Step Two. Under Step Two, [i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are... manifestly contrary to the statute.

National Ass'n of Clean Air Agencies v. E.P.A., 489 F.3d 1221, 1228 (D.C. Cir. 2007) (citations and interior quotations omitted, alterations in original) ("*NACAA*"). Assuming that this Court has jurisdiction, Plaintiffs agree that the Court can and should reach the legal merits for any counts that the Court can decide under *Chevron* Step One (*i.e.*, where FDA's actions unambiguously comply with or violate the relevant statute). Before rebutting the FDA and Duramed arguments for dismissal of Counts II, IV, V, and VI, however, Plaintiffs first argue that the unquestionable political pressure here (Count VII) and FDA's failure as yet to certify the relevant administrative record(s) preclude dismissal under *Chevron* Step Two.[15]

A. Political Pressure Precludes *Chevron* Step Two. Under *Chevron* "Step Two," a reviewing court defer to an agency's "reasonable interpretation," provided that "its action is not otherwise arbitrary and capricious" and has not "relied on [improper] factors." *NACAA*, 489 F.3d at 1228-29 (interior quotations omitted, alteration in original). Here, the plaintiffs credibly allege that FDA buckled to improper political pressure, with a direct nexus between the pressured defendants and the challenged agency actions and inaction. Compl. ¶¶73-77 (Plan B approval *quid pro quo* to lift hold on Dr. von Eschenbach's Senate confirmation), 127-131 (Count VII).

[15] *See* FDA Mot. at 36-39 (Count II), 39-40 (Count IV), 43(Count VI) (invoking Chevron Step Two); Duramed Mot. at 26-34 (Count II), 45 (Count VI) (same).

Indeed, Dr. von Eschenbach testified that he was "acutely aware of the Agency's need for… permanent leadership with a Commissioner that is not only the choice of the President but also confirmed by the United States Senate." Compl. ¶75. That political pressure not only constitutes an independent count of the complaint that warrants *vacatur* under Count VII, *see, e.g., District of Columbia Fed'n of Civic Ass'ns v. Volpe,* 459 F.2d 1231, 1246 (D.C. Cir.); *Koniag, Inc., Village of Uyak v. Andrus,* 580 F.2d 601, 610 (D.C. Cir. 1978); *Sierra Club v. Costle,* 657 F.2d 298, 408-10 (D.C. Cir. 1981); *ATX, Inc., v. U.S. Dep't of Transp.*, 41 F.3d 1522, 1527 (D.C. Cir. 1994), but also constitutes an "improper factor" under *NACAA* that negates any deference that *Chevron* Step Two otherwise would provide FDA on the other counts.

The political-pressure argument applies with particular force when an agency acts in an adjudicatory fashion, reaching not only improper pressure but the appearance of improper pressure.[16] *ATX, Inc.*, 41 F.3d at 1527. As indicated in Section I.E, *supra,* Plaintiffs are interested parties for the proceedings that FDA commenced. Even if they were not interested parties, however, the underlying fairness of the proceedings requires that "a court must consider whether… the agency's decisionmaking process was irrevocably tainted so as to make the ultimate judgment of the agency unfair, either to an innocent party *or to the public interest that the agency was obliged to protect.*" *Professional Air Traffic Controllers Organization v. F.L.R.A.,* 685 F.2d 547, 564 (D.C. Cir. 1982) (emphasis added) (*ex parte* communications).

Here, the FDA defendants acted suddenly, summarily, and without explanation on what had been "difficult and novel issues." Compl. ¶70. Short-circuiting the agency's review of those

[16] Drug approvals are adjudications. *American Bioscience, Inc. v. Thompson,* 269 F.3d 1077, 1084 (D.C. Cir. 2001); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 625 (1973); FDA Mot. at 41; Duramed Mot. at 26.

"difficult and novel issues" to obtain Senate confirmation is both "arbitrary and capricious" and "reli[ance] on [improper] factors." *NACAA,* 489 F.3d at 1228-29. Before this Court can defer to FDA's actions, FDA must act without a gun to its head.

B. Reviewing Merits without Administrative Record. "The Administrative Procedure Act and the cases require that the complete administrative record be placed before a reviewing court." *NRDC v. Train,* 519 F.2d 287, 291 (D.C. Cir. 1975) (*citing* 5 U.S.C. §706 and *Citizens to Preserve Overton Park, Inc. v. Volpe,* 401 U.S. 402, 419-21 (1971)). Under the Administrative Procedure Act ("APA") and *Overton Park,* judicial review "[is] based on the full administrative record that was before the [agency] at the time [it] made [its] decision." *Overton Park,* 401 U.S. at 419-20*; see also Walter O. Boswell Memorial Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("to review an agency's action fairly, [a court] should have before it neither more nor less information than did the agency when it made its decision"). Without an administrative record, "the district court [will] not have the opportunity to consider the [agency actions'] legality in terms of that record or the APA and the case law under it," *Perot v. FEC,* 97 F.3d 553, 561 (D.C. Cir. 1996), leaving this litigation "simply not in a posture to permit an important question of this sort to be properly adjudicated." *Id.* Significantly, as indicated in Section I.A, *supra,* the question of standing merges with the merits, which makes an administrative record all the more important before the Court reaches anything but the clearest of statutory issues under *Chevron* Step One.

Under the circumstances, this Court cannot rely on FDA's – much less Duramed's – un-supported views of FDA's actions or the basis for (and rationality of) those actions:

> Rather than calling for the administrative record, the district court appears to have relied on the parties' written or oral representations to discern the basis on which the FDA acted. Surely that was not sufficient.

Am. Bioscience, Inc. v. Thompson, 243 F.3d 579, 582 (D.C. Cir. 2001). Significantly, *American*

Bioscience held that the district court "should have required the FDA to file the administrative record" in order to "determine[] the grounds on which the FDA granted [the abbreviated new drug] application" before the Court assessed the plaintiff's probability of success on the merits for a preliminary injunction. *Id. A fortiori*, this Court should require an administrative record before granting a Rule 12(b)(6) motion premised on deference to FDA's reasoned actions.

C. FDA and Duramed Not Entitled to Dismissal. With that background, Plaintiffs now address the arguments of FDA and Duramed against Counts II, IV, V, and VI. Because Counts II and VI are interrelated, Plaintiffs address them together.

1. Counts II and VI: Rx-OTC Dichotomy and Procedure. Count II alleges that Plan B violates the Durham-Humphrey Amendments' Rx-OTC dichotomy by simultaneously bearing Rx and OTC labeling in violation of §503(b)(4)(A)-(B). Assuming *arguendo* that Plan B remains an Rx drug under §503(b)(4)(A) at all times, Count II further argues that Plan B violates the Durham-Humphrey Amendments by failing to have been removed from the Rx requirements of §503(b)(1) "by regulation" under §503(b)(3) for its OTC sales. *See* Compl. ¶¶102-103. Echoing the second charge, Count VI alleges that §503(b)(3) required a rulemaking to remove the prescription requirements for OTC sales and that – to the extent that §310.200(b) purports to allow such removal by merely approving an SNDA – that §310.200(b) is *ultra vires* FDA's authority under §503(b)(3). Compl. ¶¶124-125. FDA and Duramed argue that Plan B is at all times a prescription drug under §503(b)(4)(A), which renders §503(b)(4)(B) inapposite. FDA Mot. at 38 & n.27; Duramed Mot. at 30-31.[17] Further, FDA and Duramed argue that §310.200(b)

[17] FDA and Duramed take the counter-intuitive position that Plan B's OTC version falls always under §503(b)(4)(A), never under §503(b)(4)(B), because FDA approved Plan B for duel Rx-OTC dispensing. Although Plaintiffs dispute that this bridges §503(b)(4)'s Rx-OTC dichot-

(Footnote cont'd on next page)

is a regulation that – consistent with §503(b)(3) – authorizes FDA to remove prescription requirements merely by approving an SNDA. FDA Mot. at 42-43; Duramed Mot. at 44-45.[18]

The following two sections demonstrate that (1) FDA's interpretation of §503(b)(3) and §310.200(b) fails at *Chevron* Step One, and (2) FDA never intended §310.200(b) to eliminate the requirement to proceed by regulation. FDA today simply has no idea what §310.200(b) meant, as promulgated in 1954 through 1976. Thus, Duramed is wrong to suggest that "federal courts do not have [the] extensive experience" needed here. *See* Duramed Mot. at 28. Quite the contrary, this Court is expert at interpreting statutes and tracing regulatory promulgations back to their sources, while agencies under improper political pressure (and powerful private interests) often sidestep required procedures to force through their narrow interests, as quickly as possible.

Before addressing the procedures required by §503(b)(3) and §310.200(b), however, Plaintiffs first address §503(b)(4)'s prohibition against dual Rx-OTC labeling.[19] When enacting the Durham-Humphrey Amendments' statutory OTC-Rx dichotomy, Congress expressly deemed

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(Footnote cont'd from previous page.)

omy, it nonetheless does not save Duramed: the admission that Rx-OTC Plan B falls always under §503(b)(1) renders Plan B "misbranded while held for sale" under §503(b)(1)'s express terms because FDA never promulgated the "regulation" that §503(b)(3) requires to remove Plan B from §503(b)(1)'s prescription requirements.

[18] Duramed claims that Plan B complies with 21 C.F.R. §201.100, Duramed Mot. at 29, but ignores the requirement that drugs "be dispensed in accordance with section 503(b)." 21 C.F.R. §201.100(a)(2). Without an FDA removal *by regulation*, Plan B is misbranded under §503(b)(1).

[19] The various examples in the administrative record of FDA-approved drug products with an Rx and OTC version are inapposite. *See* 70 Fed. Reg. at 52,051. Those examples involve the same active ingredient (*e.g.*, ibuprofen) appearing in different drug products (*e.g.*, 400 mg. as Rx and 200 mg. as OTC). *See* Duramed Mot. at 28 n.20. Plan B involves the same drug product (*i.e.*, the identical pill and box) with simultaneous Rx and OTC distribution, which FDA had never previously approved. Compl. ¶53.

the presence or absence of the Rx legend as mutually exclusive for Rx and OTC products, respectively. The Senate Report expressed this intent:

> Paragraph (4) of the new subsection requires that, in addition to the labeling requirements of prescription drugs specified in paragraph (2) of the subsection, the interstate label on such drugs must bear the statement "Caution: Federal law prohibits dispensing without prescription." On the other hand, *over-the-counter drugs are forbidden to bear a label containing this caution statement.*

S. Rep. No. 82-946, at 10 (1951) (emphasis added). Although this history supports the clear dichotomy that §503(b)(4)(A) and §503(b)(4)(B) create, FDA and Duramed argue around it by claiming that Plan B is not an OTC drug because it is at all times subject to prescription (*i.e.*, subject only to §503(b)(4)(A)) and that Plan B's dual Rx-OTC legend is not false. FDA Mot. at 38; Duramed Mot. at 33-34.[20]

Unfortunately, FDA's contemporaneous and longstanding interpretation of the Durham-Humphrey Amendments does not support their latter-day legerdemain:

> *Prescription legend not allowed on exempted drugs.* The use of the prescription caution statement quoted in section 503(b) (4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

21 C.F.R. §310.200(d) (emphasis in original). Like Plaintiffs' interpretation of 21 C.F.R. §310.200(b), this regulatory interpretation goes back to 1954, 19 Fed. Reg. 7347, 7348 (Nov. 13, 1954), and clearly provides that drugs exempted under "this section" – including §310.200(b) – cannot bear the Rx legend. In other words, notwithstanding their unsupported statements to the

[20] On the other hand, Duramed admits that OTC Plan B is technically a separate new drug from the former Rx-only Plan B. Duramed Mot. at 25 n.19; FDA Mot. at 39-40.

contrary, FDA consistently has interpreted the Durham-Humphrey Amendments to preclude dual Rx-OTC labeling.[21] The question of whether a label statement falsely limits a drug product to prescription use applies only to statements other than the Rx legend. 21 C.F.R. §310.200(d).

a. §310.200 Cannot Switch Regulation for Order. Plaintiffs contend that the Durham-Humphrey Amendments plainly require FDA to act "by regulation" to remove prescription requirements for a new drug. See 21 U.S.C. §353(b)(3). FDA and Duramed claim that §310.200 constitutes a "regulation" that allows FDA to remove prescription requirements by approving an SNDA. FDA Mot. at 42-43; Duramed Mot. at 44-45.

In *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002), this Circuit considered a similar question under a statute that provided that the agency "shall by regulation establish methods and procedures for making tests under this section." EPA had adopted "CAP 2000" to "provide[] criteria for individual automobile manufacturers to develop their own test methods and procedures, which the EPA approves in a process that does not involve rulemaking." Calling CAP 2000 "the only 'regulation' in the picture," the Court noted that it did not fulfill the statutory purpose (*i.e.*, "establish methods and procedures for making tests"). *Id.* For that reason, the D.C. Circuit held that EPA had violated the statutory command to proceed by regulation. *Ethyl Corp.*, 306 F.3d at 1150; *accord MST Express v. Dep't of Transp.*, 108 F.3d 401, 403, 406 (D.C. Cir. 1997). Like FDA and Duramed, EPA argued that "proceeding by regulation would be administratively burdensome," which court rejected because that "[o]bviously… cannot overcome

[21] Although it amended the Rx legend's text in 1997, Congress did not alter the Durham-Humphrey Amendments' Rx-OTC dichotomy. Compl. ¶50; *Fourco Glass Co. v. Transmirra*, 353 U.S. 222, 227 (1957) ("it will not be inferred that Congress, in revising and consolidating the laws, intended to change their effect unless such intention is clearly expressed").

a clear congressional command." *Ethyl Corp.*, 306 F.3d at 1150.[22]

Duramed goes to some length to establish that the Durham-Humphrey Amendments improved the clarity of the Rx-OTC distinction, to the benefit of pharmacists and the public. Duramed Mot. at 31-34. All of that history equally supports Plaintiffs' views, provided that FDA follow the statutorily mandated rulemaking procedure and that the resulting drug product does not violate the statutory Rx-OTC dichotomy. Duramed also argues that Plaintiffs' view would violate §503(b)(1) and (b)(3), which require Rx distribution only when necessary and allow OTC distribution when Rx distribution is unnecessary. Duramed Mot. at 23-24; *see also id.* at 26 (rejecting this purportedly absurd result). Consistent with the statute, however, Plaintiffs merely ask that FDA proceed publicly by regulation, rather than secretly by order, and that the resulting new drug product (if approved) have labeling that complies with the statute (*e.g.*, an Rx box and an OTC box). FDA's own regulations demonstrate that such regulations have occurred often in the past, 21 C.F.R. §310.201, and nothing precludes or allows FDA to proceed differently here.

b. §310.200 Did Not Switch Regulation for Order. Even if FDA could interpret §310.200(b) to allow removing prescription requirements from new drugs, FDA did not interpret §310.200(b) that way when FDA promulgated it in 1954. To the contrary, and contemporaneously with the Durham-Humphrey Amendments' adoption, §310.200(b)'s predecessor required a rulemaking to remove prescription requirements from a new drug. Until FDA amends that origi-

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[22] Duramed makes the hyper-technical argument that §503(b)(3)'s divergent use of singular and plural for rulemaking and drugs somehow precludes Plaintiffs' interpretation. Duramed Mot. at 24. There is nothing inconsistent about a single rulemaking's addressing multiple, similar drugs. In any event, the Dictionary Act precludes Duramed's argument. *See* 1 U.S.C. §1 ("In determining the meaning of any Act of Congress… words importing the singular include and apply to several persons, parties, or things [and] words importing the plural include the singular"). That FDA must proceed *by rulemaking* does not limit FDA to a *single rulemaking.*

nal interpretation, both FDA and Duramed must live with (and within) it.

In 1954, FDA promulgated §310.200(b)'s first predecessor (former 21 C.F.R. §1.108(c)) expressly pursuant to §503(b)(3). 19 Fed. Reg. 7347, 7347-48 (Nov. 13, 1954). In 1963, FDA proposed and finalized §311.200(b)'s direct predecessor (former 21 C.F.R. §130.101(b)) expressly pursuant to §503(b)(1) and §503(b)(3). 28 Fed. Reg. 1449 (Feb. 14, 1963); 28 Fed. Reg. 6377 (June 20, 1963). In pertinent part, and consistent with the plain statutory text (*see* Section II.C.1.a, *supra*), the 1954 and 1963 versions both expressly required a rulemaking to remove a new drug from prescription requirements under §503(b)(1), even if the "petition" that triggered the rulemaking came to FDA via an SNDA or on FDA's own initiative. *See* 19 Fed. Reg. at 7347-48 (promulgated 21 C.F.R. §1.108(c)); 28 Fed. Reg. at 6385 (promulgated 21 C.F.R. §130.101). Specifically, in both 1954 and 1963, the final regulation provided as follows:

> A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b) (1) (C) [now §503(b)(1)(B)] of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, which petition may be in the form of a supplement to an approved new-drug application. Upon receipt of such a petition, or on his own initiative at any time, the Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption[.] Whenever the Commissioner concludes… that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose…. As soon as practicable after the completion of the hearing, the final regulation granting or refusing the exemption shall be issued[.]

21 C.F.R. §130.101(b) (1964) (Ex. 5); *accord* 21 C.F.R. §1.108(c) (1955) (Ex. 6); *accord* 21 C.F.R. §310.200(b) (1976) (Ex. 7). Thus, from 1954 through 1976 at least, FDA's current interpretation of current §310.200(b) would have been untenable.

Before they can hold FDA to its initial regulatory interpretation of §503(b)(1), §503(b)(3), and §310.200(b), Plaintiffs must establish first that former §130.101 is current §310.200 and second that any intervening amendments did not change FDA's initial interpretation. Both tasks are quite easy. First, when it recodified its regulations in 1974, FDA plainly designated "Old section" §130.101 as "New section" §310.200. 39 Fed. Reg. 11,680 (Mar. 29, 1974) (Ex. 8). Second, since then, FDA has adopted only one substantive amendment to §310.200(b), as part of its rulemaking in the mid-1970s to adopt its uniform rules of administrative practice. 40 Fed. Reg. 40,682, 40,769 (Sept. 3, 1975) (proposed amendment to §310.200(b)); 42 Fed. Reg. 4680, 4714 (Jan. 25, 1977) (promulgated amendment to §310.200(b)).[23] As FDA's rulemaking record demonstrates, adopting the uniform rules for administrative practice did not alter the type of administrative action required to remove drugs from the Rx requirements of §503(b)(1). Instead, the notice of proposed rulemaking merely provided that "Section 310.200(b) would be revised to replace the procedure now set out in that provision with a reference to Part 2." 40 Fed. Reg. at 40,716 (Ex. 9). The mere elimination of §310.200(b)'s rulemaking process in deference to the new general-purpose Part 2 process does not suggest a *sub silentio* intent to do away with rulemakings altogether. *U.S. v. Wilson,* 290 F.3d 347, 359-60 (D.C. Cir. 2002) (drafter "unlikely to intend any radical departures from past practice without making a point of saying so"). Henceforth, FDA would simply convene §503(b)(3)'s required rulemakings under the general provisions of Part 2, not the specific provisions of §310.200(b).

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[23] In a 1977 recodification, FDA amended §310.200(b) to change the reference from the original rules of practice (former 21 C.F.R. pt. 2) to the recodified ones (current 21 C.F.R. pt. 10). 42 Fed. Reg. 15,673, 15,674 (Mar. 22, 1977) ("Section 310.200(b) is amended by changing the reference to 'Part 2' to read 'Part 10'"). Technical amendments in 2007 changed citations to §505(b)(1)(C) to the now-current §505(b)(1)(B). 72 Fed. Reg. 15,043 (Mar. 30, 2007).

FDA's rulemaking to add §310.200(e) on OTC-panel procedures confirms that, in 1976, FDA interpreted §310.200(b) consistently with the statute (and opposite its current position):

> [T]he Commissioner described the two procedures by which a prescription drug ingredient may lawfully be marketed for OTC use. Ingredients limited to prescription use under section 503(b)(1)(C) of the [FFDCA] may acquire OTC status by a petition submitted pursuant to the procedures set forth in § 310.200 []; the OTC drug review process provides another procedure.

41 Fed. Reg. 32,580, 32,581 (Aug. 4, 1976) (citations omitted). As indicated, "the procedures set forth in § 310.200" clearly contemplated that FDA would act "by regulation," even if the "petition" came to FDA in the form of an SNDA or if FDA acted on its own initiative. 21 C.F.R. §310.200(b) (1976). To change its interpretation of its regulation (*i.e.*, to switch the required procedures from a regulation to an order), FDA would need to undertake a rulemaking. *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (course change requires reasoned analysis beyond that required to act in the first instance); Duramed Mot. at 42 ("As to a substantive regulation, an agency may change its interpretation only by notice and comment where the change would constitute an amendment of the regulation") (emphasis in original). FDA has not taken any *lawful* final action to amend its procedures.

2. Count IV: Third Category of BTC Drugs. Count IV alleges that Plan B's dual Rx-OTC labeling, the CARE program, and the resulting requirement to maintain Plan B behind the counter ("BTC") creates an unlawful third category of drug that is neither Rx nor OTC. *See* Compl. ¶¶114-119. FDA and Duramed argue that Plan B is at all times a prescription drug under §503(b)(4)(A), FDA Mot. at 38 & n.27; Duramed Mot. at 30-31, and that FDA did not impose this BTC regime on Duramed. FDA Mot. at 40 ("FDA did not mandate specific distribution channels for Plan B… it was *Barr* that developed the CARE proposal") (emphasis in original); Duramed Mot. at 35. Of course, without the administrative record, neither Plaintiffs nor this

Court can determine whether Barr/Duramed or FDA required BTC distribution. "Surely [it is] not sufficient," however, for the Court to "rel[y] on the parties' written or oral representations to discern the basis on which the FDA acted." *Am. Bioscience*, 243 F.3d at 582.[24]

Both FDA and Duramed admit that OTC Plan B technically is a separate product from Rx Plan B. FDA Mot. at 39-40; Duramed Mot. at 25 n.19. They also claim that dual Rx-OTC Plan B is at all times an Rx drug. FDA Mot. at 38 & n.27; Duramed Mot. at 30-31. The record will make clear that one or both parties invented the dual Rx-OTC approach to evade the negative implications of OTC availability (*e.g.*, minors' access to the product). Unfortunately, the FFDCA provides only two options, and if Plan B is not safe for OTC distribution, it is not safe for OTC distribution. FDA cannot invent, or acquiesce in the invention of, a third category.

3. Count V: Rulemaking for Meaningful-Difference Test. Count V alleges that FDA amended its meaningful-difference test to add patient-related parameters, without the APA-required notice-and-comment rulemaking. *See* Compl. ¶¶120-122. FDA and Duramed argue that FDA had not previously adopted a meaningful-difference rule for its Plan B action to amend. FDA Mot. at 41-42; Duramed Mot. at 35-44. Even FDA and Duramed acknowledge, however, that "FDA has interpreted… [§503](b)(1) of the act to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference

[24] Although FDA admits that it did not rely on 21 C.F.R. §314.520(a), it notes that that regulation allows limited distribution in some circumstances. FDA Mot. at 40 n.28. As just indicated, however, neither Plaintiffs nor the Court can know what basis FDA relied on until FDA files its administrative record. *Am. Bioscience,* 243 F.3d at 582; *cf. Burlington Truck Lines v. U.S.*, 371 U.S. 156, 170 (1962) ("an agency's discretionary order [will] be upheld, if at all, on the same basis articulated in the order by the agency itself"). Nor are FDA's examples of *prescription drugs* dispensed under limited distribution relevant to the hybrid Rx-OTC labeling (and product) that FDA approved. FDA Mot. at 40 n.28.

exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner." *See* Duramed Mot. at 35-36 (quoting 70 Fed. Reg. at 52,051); *see also* Compl. ¶53 (meaningful-difference test interpreted both FFDCA *and FDA's regulations*).[25]

Moreover, "Plan B is the first instance of FDA approval of the 'marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation' with no physical difference between the product dispensed Rx and the product dispensed OTC." Duramed Mot. at 36 (quoting 70 Fed. Reg. at 52,051). In a meeting with some of the Plaintiffs, FDA acknowledged that the Plan B approval added age as a new criterion to FDA's meaningful-difference test. Compl. ¶81. Although FDA and Duramed now quibble on whether FDA acted in a sufficiently rule-like final action, an agency can create a rule in almost any way. *See, e.g., CropLife America v. E.P.A.*, 329 F.3d 876, 881 (D.C. Cir. 2003) (statement in press release required notice-and-comment rulemaking). Here again, the administrative record would answer some of the questions that divide the parties. *Am. Bioscience,* 243 F.3d at 582.

CONCLUSION

WHEREFORE, Plaintiffs respectfully ask this Court to deny the motions to dismiss.

[25] That the meaningful-difference test interprets both the FFDCA and *FDA's regulations* renders inapposite the cases cited by Duramed for the proposition that agencies can change *statutory* interpretations without notice-and-comment rulemaking. *See* Duramed Mot. at 41-43. As Plaintiffs demonstrate in Section II.C.1.b, FDA has changed its interpretation of §310.200 on Rx-OTC switches without the required notice-and-comment rulemaking. Plaintiffs readily meet the standard of "stat[ing] adequately" and "support[ing] by showing any set of facts consistent with the allegations in the complaint" that FDA has impermissibly changed its regulatory and statutory interpretations. *Twombly,* 127 S.Ct. at 1969.

Dated: October 17, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of October 2007, I electronically filed the foregoing "Opposition to Motions to Dismiss" with the Clerk of the Court using the CM/ECF system, which I understand to have caused service of Jane M. Lyons of the U.S. Attorney's Office for the District of Columbia, on behalf of the federal defendants, and of Richard M. Cooper, on behalf of defendant-intervenor Duramed Pharmaceuticals, Inc.

/s/ Lawrence J. Joseph
Lawrence J. Joseph