

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

Annie TUMMINO, *et al.*,

Plaintiffs,

v.

Dr. Margaret A. HAMBURG, in her official
capacity as Commissioner of Food & Drugs,

Defendant,

and

CONCERNED WOMEN FOR AMERICA,
CHRISTIAN PHARMACISTS
FELLOWSHIP INTERNATIONAL, and
CHRISTIAN MEDICAL & DENTAL
ASSOCIATIONS,

Movants for Intervention.

)
) **MEMORANDUM OF LAW IN**
) **SUPPORT OF MOTION TO**
) **INTERVENE**

) No. 05-CV-366 (ERK/VVP)

) (Korman, J.)

) (Pohorelsky, M.J.)

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MEMORANDUM OF LAW IN SUPPORT OF MOTION TO INTERVENE

Pursuant to Local Rule 6.1, movants Concerned Women for America (“CWA”), Christian Medical & Dental Associations (“CMDA”), and Christian Pharmacists Fellowship International (“CPFI” and, collectively, “Movants”) file this memorandum of law in support of their motion to intervene as of right and permissively pursuant to FED. R. CIV. P. 24(a) and (b). Movants seek to intervene for the limited purpose of challenging the Court’s subject-matter jurisdiction, particularly with respect to the plaintiffs’ lack of standing and the lack of a waiver of sovereign immunity for review of the supplemental new drug application (“SNDA”) that the Food & Drug Administration (“FDA”) approved for the “Plan B” as an “emergency contraceptive.”

First, Movants contend that, as an emergency contraceptive, the initial injury from a future emergency is too remote to constitute the imminent injury required for standing. The case cited by the Court for relying on the present injury from “fear or anxiety of future harm” as providing standing, *Ross v. Bank of Am., N.A. (U.S.A.)*, 524 F.3d 217, 222 (2d Cir. 2008) (quoting *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006)), is inapposite. *Ross* and *Denney* involved finding future injury that sprung from a past concrete injury caused by the defendant’s past injury to the plaintiff.¹ Here, FDA is not responsible for the future emergency

¹ See *Denney*, 443 F.3d at 264-65 (“[f]or example, exposure to toxic or harmful substances has been held sufficient to satisfy the Article III injury-in-fact requirement even without physical symptoms of injury caused by the exposure”); 7AA CHARLES ALAN WRIGHT, ARTHUR R. MILLER, MARY KAY KANE, FED. PRAC. & PROC. Civ.3d § 1785.1 (2005) (requiring a “direct injury” such as exposure before relying on that injuries’ “future effect” for standing); *Denney*, 443 F.3d at 264 (future risk of negative implications from faulty tax advice already received); *Ross*, 524 F.3d at 220-21 (antitrust violations from banks that conspired to coerce plaintiffs to agree to unlawful arbitration agreements or denied them credit cards if they refused the arbitration agreements).

that allegedly will require access to an emergency contraceptive. Perhaps worse, these cases are pleadings-based cases, not a judgment on the merits. As the Supreme Court held on March 9, 2009, mere pleadings cannot provide the standing (on which plaintiffs bear the burden of proof) to support a judgment on the merits:

The dissent proposes a hitherto unheard-of test for organizational standing: whether, accepting the organization's self-description of the activities of its members, there is a statistical probability that some of those members are threatened with concrete injury. Since, for example, the Sierra Club asserts in its pleadings that it has more than “ ‘700,000 members nationwide, including thousands of members in California’ ” who “ ‘use and enjoy the Sequoia National Forest,’ ” post, at 1154 (opinion of BREYER, J.), it is probable (according to the dissent) that some (unidentified) members have planned to visit some (unidentified) small parcels affected by the Forest Service's procedures and will suffer (unidentified) concrete harm as a result. This novel approach to the law of organizational standing would make a mockery of our prior cases, which have required plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm.

Summers v. Earth Island Institute, 129 S.Ct. 1142, 1151 (2009). By contrast, without distinguishing *Summers*, on March 23, 2009, this Court held that “plaintiffs are responding to a motion to dismiss, so their allegations in the complaint must be accepted as true for purposes of standing.” Slip Op. at 32. In light of *Summers*, that holding is untenable and cannot support a merits judgment.

It is equally clear that the federal sovereign has not waived its immunity from suit for equitable or declaratory relief, except through the Administrative Procedure Act's waiver of sovereign immunity. 5 U.S.C. §702. But in pertinent part, 5 U.S.C. §704 limits that waiver to “final agency action.” According to plaintiffs, FDA allegedly unlawfully withheld approval of Plan B for minors until the drug's sponsor capitulated to an offer to approve Plan B for adults only (*i.e.*, those eighteen and older). Assuming *arguendo* that the FDA pressure was unlawful

while it lasted, the drug sponsor could at any time have forced the issue by having FDA deny the SNDA, but that “agency action” would not have been final because the drug sponsor would have had intra-FDA appeals. 5 U.S.C. §704. Instead, once the sponsor capitulated by amending its SNDA to request approval for adults, the plaintiffs lost any ability to challenge the former conduct. Here, FDA’s final agency action approved *what the sponsor requested*. The prior pressure (like the denial of approval for seventeen-year-olds) is simply not reviewable because Congress has not waived sovereign immunity to challenge non-final action.²

I. INTRODUCTION

CWA is the nation’s largest public-policy women’s organization and, since 1979, has worked for “the protection of all innocent human life from conception until natural death.” Decl. of Wendy Wright, ¶ 4. CWA has been a leading advocate against over-the-counter access to Plan B, both before FDA and its advisory panels, as well as in public. *Id.* ¶¶ 5-6. CMDA is a nonprofit national organization of Christian physicians and allied healthcare professionals with over 10,000 members nationwide, Decl. of Eugene Rudd, ¶ 2. In addition to its interests in its members as healthcare professionals and their interests in their patients’ health, CMDA opposes the practice of abortion as contrary to Scripture, a respect for the sanctity of human life, and traditional, historical and Judeo-Christian medical ethics. *Id.* at ¶ 3. CPFI is a non-profit organization of Christian pharmacists with more than 1,000 nationwide. Eckel Decl. ¶ 7. CPFI opposes abortion for religious, moral, and ethical reasons, and are committed to the sanctity of human life. *Id.* ¶ 8.

² The *Ex parte Young* doctrine of suing an officer, like the defendant, is inapposite if the violation is not ongoing. *Green v. Mansour*, 474 U.S. 64, 68 (1985) (entirely past violations of federal law cannot support prospective relief under *Ex parte Young*).

In addition to their concerns about Plan B from a religious and ethical perspective, Movants and their members each desire access to safety data on Plan B for girls generally and seventeen-year-old girls specifically to assess the safety of Plan B for their patients (CMDA) and customers (CPFI) and to use in their advocacy against Plan B, particularly for minors (CWA). Rudd Decl. ¶ 4; Eckel Decl. ¶ 9; Wright Decl. ¶ 7. In addition, each Movant would welcome the opportunity to participate in a rulemaking to oppose the removal of Plan B from the prescription requirements of the Food, Drug & Cosmetic Act. Rudd Decl. ¶ 5; Eckel Decl. ¶ 10; Wright Decl. ¶ 8.

II. JURISDICTION AND VENUE

As explained in the following two sections, this Court has jurisdiction over Movants' proposed intervention, and venue in this Court appears proper. Although not required at this stage, Movants' discussion of jurisdiction also establishes their standing.

A. Jurisdiction

Although Movants will argue that this Court lacks jurisdiction over the plaintiffs' claims, this Court nonetheless has jurisdiction to determine its jurisdiction. *Estate of Pew v. Cardarelli*, 527 F.3d 25, 28 (2d Cir. 2008) ("we have jurisdiction to determine our jurisdiction"). Whatever jurisdictional defects the plaintiffs face, the federal defendants obviously have standing to defend FDA's actions. Because the Second Circuit does not require an intervener to establish its standing independent from the party with which the intervener will align itself, *U.S. Postal Serv. v. Brennan*, 579 F.2d 188, 190 (2d Cir. 1978), that is all the standing that the Movants need in this Court. Because FDA has determined not to appeal this Court's finding of jurisdiction, however, Movants will need standing to appeal independently of the federal defendants. *See*,

e.g., *Bender v. Williamsport Area School Dist.*, 475 U.S. 534, 543 (1986). For that reason, Movants establish their independent standing here.

A membership organization has standing to sue if its members have standing to sue on their own behalf, the interest that the suit seeks to protect are germane to the organization's purpose, and neither the asserted claims nor the requested relief require the members' individual participation. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977). *First*, as explained in the following subsections on Movants' specific theories of standing, Movants and their members have cognizable rights under the underlying statutes. *See, e.g.*, *Warth v. Seldin*, 422 U.S. 490, 514 (1975) ("Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of statute"). *Second*, protecting those rights is germane to Movants' purposes. *See* Rudd Decl. ¶ 6; Eckel Decl. ¶ 11; Wright Decl. ¶ 9. *Third and finally*, nothing requires individual members' participation because, as *defendants*, Movants do not assert individualized claims and seeks only dismissal of the plaintiffs' claims on jurisdictional grounds. FED. R. CIV. P. 12(b)(1), (c), (h)(3); *Int'l Union v. Brock*, 477 U.S. 274, 287-88 (1986) (individual participation not required to litigate a "pure question of law: whether the Secretary properly interpreted the [statutes'] provisions"). Under the *Hunt* test, Movants have standing to defend the FDA actions challenged here.

1. Informational Standing under PREA

The 2007 amendments to the Pediatric Research Equity Act ("PREA") provide the public (and thus Movants and their members) a right to safety information on drugs approved by FDA. 21 USC §355c(g)(2), (h)(1)-(2). As indicated above, such statutorily rights can form the basis for standing, where here takes the form of access to information. *See FEC v. Akins*, 524 U.S. 11, 25

(1998). By short-circuiting the SNDA that Plan B’s sponsor otherwise would have had to seek to obtain approval to distribute Plan B without prescription to seventeen-year-olds, this Court’s judgment denied Movants access to the otherwise-required information. As *Akins* recognizes, *vacatur* would restore the parties to their proper positions, where they should have been all along, which provides enough redress even if FDA *potentially could* take action on remand that would leave plaintiffs no better off.³ Remand redresses injury “even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason.” *Id.* Significantly, the PREA-required information would be useful not only in CWA’s advocacy but also in the professions of CMDA’s and CPFI’s members. As such, this Court’s judgment denies Movants access to information to which Congress entitled them by statute.

2. Procedural Standing under FDCA §503(b)(3)

Under FDCA §503(b)(3), FDA can remove a drug from the FDCA’s prescription requirements only by rulemaking. 21 U.S.C. §353(b)(3). If (and only if) Movants have substantive standing, they also have procedural standing for injuries such as the denial of the rulemaking mandated by §503(b)(3) and 21 C.F.R. §310.200(b). *See Summers v. Earth Island*

³ Because redressability is a forward-looking analysis of likely redress, PREA 2007 does not impermissibly “attach[] new legal consequences to events completed before its enactment.” *Landgraf v. USI Film Prod.*, 511 U.S. 244, 269-70 (1994), primarily because “[w]hen the intervening statute authorizes or affects the propriety of *prospective relief*, application of the new provision is not retroactive.” *Id.* at 273 (emphasis added). Even if it were retroactive, Congress expressly intended the new, information-granting PREA provisions to apply to such situations. Pub. L. No. 110-85, §402(b)(2), 121 Stat. 866, 875 (Sept. 27, 2007) (“An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under [21 USCA §355c], as in effect on or after such date of enactment”).

Institute, 129 S.Ct. 1142, 1151 (2009). Because Congress recognized that the prescription/non-prescription (“Rx-OTC”) distinction affects consumers, pharmacists, physicians, and drug manufacturers,⁴ the rulemaking that Congress mandated is “designed to protect [the] threatened concrete interest of his that is the basis of [such plaintiffs’] standing.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n.8 (1992). As with informational standing, Movants need not show that holding the required procedures will redress their substantive injuries. *Summers*, 129 S.Ct. at 1151; *Akins*, 524 U.S. at 25. To the contrary, procedural standing *relaxes* the standing inquiry’s redressability and immediacy requirements. *Defenders of Wildlife*, 504 U.S. at 572 n.7 (procedural-rights plaintiffs “can assert that right without meeting all the normal standards for redressability and immediacy”). By short-circuiting the rulemaking required to remove Plan B’s prescription requirements for seventeen-year-olds, this Court’s judgment inflicts procedural injury on Movants, which therefore relaxes the immediacy and redressability requirements, thereby making it *easier* to prove Movants’ substantive injuries.

3. Pharmacists’ Standing to Avoid Holding Misbranded Drug for Sale

A drug that is not properly removed from the FDCA’s prescription-requirements or that lacks PREA-required data can be misbranded. 21 U.S.C. §§353(b)(1), 355c(d)(1). For regulated professionals like pharmacists, the standing doctrine does not require violating the profession’s ethical requirements or violating the law by dispensing or holding for sale a misbranded drug. *See NRDC v. SEC*, 606 F.2d 1031, 1042 (D.C. Cir. 1979) (investors who wish to behave in

⁴ *See* S. REP. NO. 82-946, at 2 (“the bill... will benefit drug manufacturers, retail druggists, medical practitioners, and the public”); 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”).

“ethically sound manner” have standing to redress “arguabl[e] impair[ment]” from “lack of [allegedly required] information”). Moreover, because several states *require* pharmacists to sell Plan B, the decision to hold dual Rx-OTC Plan B for sale is no self-inflicted injury. *Nat’l Parks Conserv. Ass’n v. Manson*, 414 F.3d 1, 6 (D.C. Cir. 2005) (where state and federal regimes are “intertwined,” “the challenged federal action alters the [state] legal regime,” completing an otherwise-indirect causal chain) (alteration in original). Under the circumstances, the Court’s judgment imposes this special variant of informational injury on pharmacists.

4. Physicians’ Third-Party Standing on Behalf of Patients

Physicians have third-party standing to assert patients’ rights if the physicians have suffered a constitutional injury in fact, have a close relationship with patients, and some hindrance prevents the third party’s asserting its own rights. *Powers v. Ohio*, 499 U.S. 400, 415 (1991). “Unawareness of the injury” qualifies as a sufficient hindrance, *Am. Immigration Lawyers Ass’n v. Reno*, 199 F.3d 1352, 1363 (D.C. 2000) (“*AILA*”), which applies here because patients trust in the safety inherent in government approval generally and FDA approval specifically. Similarly, courts find third-party standing where the rights holder has “little incentive” to bring suit because “of the small financial stake involved and the economic burdens of litigation.” *Powers*, 499 U.S. at 415. If patients learn about Plan B’s unproven safety for repeat use and for young women, they simply will avoid it. As in *Powers*, they have little incentive to sue, leaving physicians “by default [as] the right’s best available proponent.” *AILA*, 199 F.3d at 1362. Accordingly, physicians have third-party standing to assert the interests of seventeen-year-olds injured by exposure to Plan B without the data that PREA would require, in the absence of this Court’s judgment.

5. Authorization of Illegal Conduct

Even if Plan B were not misbranded when held for over-the-counter sale to seventeen-year-olds, this Court's judgment authorizes distribution of Plan B to seventeen-year-olds without a prescription, which previously was illegal. That change in status removes causal and redressability issues that otherwise might make it more difficult for a party to challenge this Court's judgment. *Simon v. E.K.W.R.O.*, 426 U.S. 26, 45 n.25 (1976) (injury traceable to government action if injurious conduct "would have been illegal without that action"); *see, e.g.*, M.C.L.A. §§333.16215, 333.17708(2)-(3), 333.17745(12) (limiting the dispensing of prescription drugs in Michigan to various types of physicians and dentists and to staff under their supervision). Injury is "fairly traceable to the [government] action contested... if that action *authorized* the conduct or established its legality." *Tel. & Data Sys., Inc. v. FCC*, 19 F.3d 42, 47 (D.C. Cir. 1994) (emphasis added); *Los Angeles v. Lyons*, 461 U.S. 95, 105-06 (1983). As such, Movants have standing to challenge this Court's judgment.

6. Movants' Interests Are Within Relevant Zones of Interest

Standing's "zone of interest" test is a prudential doctrine that asks "whether the interest sought to be protected by the complainant is *arguably* within the zone of interests to be protected... by the statute." *N.C.U.A. v. First Nat'l Bank & Trust, Co.*, 522 U.S. 479, 492 (1998) (emphasis and alteration in original). Appellants are within the zone of interests, which is inapposite to *ultra vires* actions, and are "suitable challengers" even if outside the zone.

At the outset, therefore, Movants readily fall within the zone of interests, which has "struck the balance in a manner favoring review, but excluding those would-be plaintiffs not even arguably within the zone of interests to be protected or regulated by the statute." *Clarke v. Securities Industry Ass'n*, 479 U.S. 388, 396-397 (1987). "[N]ot meant to be especially

demanding,” “it suffic[es] to establish reviewability” under the test if “the general policy implicit in the [relevant statutes] was ‘apparent’ and that ‘those whose interests are directly affected by a broad or narrow interpretation of the Acts are easily identifiable.’” *Clarke*, 479 U.S. at 399-400 & n.14. Physicians’ and pharmacists’ interest in PREA-required data is obvious.

More significantly, this Court’s judgment denies pharmacists their statutory right to labeling that clearly indicates “which drugs may be sold on prescription and which drugs may be sold freely over the counter,” which the House floor manager considered the first question behind the Durham-Humphrey Amendments. 97 Cong. Rec. at 9321 (Rep. Wolverton).⁵ That right is the dead center of the Durham-Humphrey Amendments’ zone of interests.

“For a court to pronounce upon [the merits] when it has no jurisdiction to do so, is ... for a court to *act ultra vires*.” *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 583 (1999) (citations omitted). Because the standing inquiry assumes the relevant party’s merits views (here, that the Court lacks jurisdiction for plaintiffs’ claims), the zone-of-interest test either does not apply or implicates zone of interests of the overriding constitutional issues such as Article III’s limitations and separation of powers. *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 812 (D.C. Cir. 1987); *Metro. Washington Airports Auth. v. Citizens for the Abatement of Aircraft Noise*, 501 U.S. 252,

⁵ See *id.* at 9328 (“druggists throughout this country have figuratively been swinging on the jailhouse door, because... the druggist oftentimes is unable to know whether he is violating the law by selling a drug... without a prescription”) (Rep. Carlyle); *id.* at 9330 (“druggists of this country want this thing nailed down so that they will not be slammed in jail” and calling clear Rx vs. OTC labeling “belling the cat”) (Rep. Roberts); *id.* at 9336 (report lists over 100 druggists “convicted for over-the-counter sales of drugs, many... selling them innocently”) (Rep. Beckworth); *id.* at 9343 (same); *id.* (“Under the present law he does not know whether the drugs he sells over the counter are in violation of the law”) (Rep. Thornberry); *id.* at 9344-45 (“he does not know whether he is violating the law if he sells the drug over the counter... What the druggist is seeking is certainty”) (Rep. Williams).

271 (1991) (“the separation-of-powers principle, the aim of which is to protect... the whole people from improvident laws”); *Ass’n of Data Processing Serv. Org’ns v. Camp*, 397 U.S. 150, 153 (1970) (test asks whether plaintiff is “arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question”). Because Movants allege that this Court has acted without jurisdiction, prudential doctrines such as the zone of interests do not apply to evaluating Movants’ standing.

In any event, even if the zone of interest applies and Movants are not the intended beneficiaries of the relevant statute or constitutional provision, Movants nonetheless can satisfy the zone of interests as “suitable challengers” if their “interests... [are] 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. N.C.U.A.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993). Concerns about the zone of interests are “inapposite when a [party] sues to enforce a *statutory demarcation*, such as an *entry restriction*, because the potentially limitless incentives of [adverse parties are] channeled by the terms of the statute into suits of a limited nature brought to enforce the statutory demarcation.” *Honeywell Int’l, Inc. v. EPA*, 374 F.3d 1363, 1370 (D.C. Cir. 2004) (citing cases) (emphasis added, alteration in original), *withdrawn on part on other grounds*, 393 F.3d 1315 (D.C. Cir. 2005); *Scheduled Airlines Traffic Offices, Inc. v. D.O.D.*, 87 F.3d 1356, 1360-61 (D.C. Cir. 1996). If they have constitutional standing, Movants have prudential standing to enforce Article III’s subject-matter jurisdiction restrictions as “entry-like restrictions” that are not subject to manipulation.

B. Venue

For suits against federal defendants, 28 U.S.C. §1391(e)(3) makes venue proper *inter alia* in any judicial district where a plaintiff resides, provided that “no real property is involved in the action.” Because this action involves no real property, venue appears proper in this Court.

III. INTERVENTION AS OF RIGHT

To intervene as of right, Rule 24(a)(2) and this Circuit require that a party meet four criteria:

Upon [1] timely application anyone shall be permitted to intervene in an action ... when the applicant claims [2] an interest relating to the property or transaction which is the subject of the action and [3] the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, [4] unless the applicant's interest is adequately represented by existing parties.

Washington Elec. Co-op., Inc. v. Massachusetts Mun. Wholesale Elec., 922 F.2d 92, 96 (2d Cir. 1990) (quoting FED. R. CIV. P. 24(a), alterations in original); *American Lung Ass’n v. Reilly*, 962 F.2d 258, 261 (2d Cir. 1992). The following four sections establish Movants’ right to intervene under each of these four tests.

A. Motion is Timely

To determine whether an intervention motion is timely, this Circuit considers four factors: “(1) how long the applicant had notice of the interest before it made the motion to intervene; (2) prejudice to existing parties resulting from any delay; (3) prejudice to the applicant if the motion is denied; and (4) any unusual circumstances militating for or against a finding of timeliness.” *U.S. v. Pitney Bowes, Inc.*, 25 F.3d 66, 70 (2d Cir.1994); *In re Bank of New York Derivative Litigation*, 320 F.3d 291, 300 (2d Cir. 2003). Because of the potential for delay and prejudice to existing parties, “post-judgment intervention ... is *generally* disfavored.” *United*

States v. Yonkers Bd. of Educ., 801 F.2d at 596 (collecting authorities, emphasis added). While “generally disfavored,” however, post-judgment intervention is *not necessarily* untimely. Instead, courts consider all the circumstances to determine whether the movant acted promptly after entry of judgment:

The critical inquiry in every such case is whether in view of all the circumstances the intervenor acted promptly after the entry of final judgment. Here, the respondent filed her motion within the time period in which the named plaintiffs could have taken an appeal. We therefore conclude that the Court of Appeals was correct in ruling that the respondent's motion to intervene was timely filed and should have been granted.

United Airlines, Inc. v. McDonald, 432 U.S. 385, 395-96 (1977); cf. *Spirit v. Teachers' Insurance & Annuity Association*, 93 F.R.D. 627, 637 (S.D.N.Y.) (denying intervention request filed “approximately two years after a final judgment was entered in the *Spirit* action”), *aff'd in part and rev'd in part on other grounds*, 691 F.2d 1054 (2d Cir. 1982), *vacated on other grounds*, 463 U.S. 1223 (1983).⁶

1. **Movants Acted Expeditiously**

As set forth in their accompanying letter motion for FED. R. APP. P. 4(a)(5)'s extension of time within which timely to file a notice of appeal, Movants have acted timely under *McDonald*. Alternatively, Movants seek leave to file a motion for reconsideration with this Court under FED. R. CIV. P. 60(b)(4), which also is timely. Significantly, the need for Movants to intervene at all was occasioned by the new administration's decision to allow a somewhat-unprecedented judgment, without jurisdiction and in violation of PREA, to stand without appeal. Movants have

⁶ The *Spirit* case is one of the cases collected by *Yonkers Board of Education*, 801 F.2d at 596).

acted within 30 days of FDA's failing to appeal by the deadline (May 26, 2009) provided by FED. R. APP. P. 4(a)(i)(B).

2. Existing Parties Will Not Suffer Prejudice

The federal defendant will suffer no prejudice, as FDA is subject to litigation in the D.C. Circuit on the very same approval, which will address the very same issue of this Court's jurisdiction. Moreover, if FDA were to approve Plan B for distribution to seventeen-year-olds, as this Court has ordered, FDA will face new litigation that challenges that approval for following an order by a court without jurisdiction.

Because the court lacks jurisdiction to hear their claims and to order their requested relief, the plaintiffs suffer no cognizable injury. *See* Section III.A.4, *infra* (collecting cases on lack of prejudice to plaintiffs whose claims lack jurisdiction).

3. Denial Will Prejudice Movants

In addition to denying Movants access to the safety information and participation in the rulemaking that FDA otherwise would require to effect what the Court summarily ordered, this Court's order faces the legitimate prospect of a multiplicity of suits over the same issue. *See, e.g.*, 11A WRIGHT AND MILLER, FED. PRAC. & PROC. Civ.2d §2944 (1995 & Supp. 2005) ("legal remedy may be deemed inadequate if [*inter alia*] effective legal relief can be secured only by a multiplicity of actions"); *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 273-74 (1997) ("federal court's equitable jurisdiction [can be] necessary to avoid ... [the] possibility of [a] multiplicity of suits causing irreparable damage") (interior quotations omitted, textual alterations in original, ellipsis added, citing Charles Warren, *Federal and State Court Interference*, 43 HARV. L. REV. 345, 377-78 (1930)); *Reed Enterprises v. Corcoran*, 354 F.2d 519, 523 (D.C. Cir. 1965) (finding multiplicity of legal proceedings to constitute irreparable harm).

4. Unusual Circumstances Warrant Intervention

The plaintiffs' lack of standing provides three unusual factual circumstances that warrant intervention. First, lacking standing, the plaintiffs do not face any injury from whatever delay intervention would occasion. In essence, however, this is a variant of the second prong of the four-part test for timeliness.

Second, because of the importance of Article III's limitations to the proper functioning of the federal courts, "the existence of a substantial question about the district court's jurisdiction ... is a special factor that supports finding timeliness." *Ceres Gulf v. Cooper*, 957 F.2d 1199, 1203 (5th Cir. 1992); *see also Elliott Industries Ltd. Partnership v. BP America Production Co.*, 407 F.3d 1091, 1103-04 (10th Cir. 2005) ("any prejudice to either party resulting from Dichter's intervention on appeal is minimal compared with the importance of addressing the question of subject matter jurisdiction").

This is not a case in which the United States was simply seeking to weigh in on the merits. Rather, the Government's sole purpose in intervening was to raise a highly tenable challenge to the District Court's subject matter jurisdiction ...[¶] In the face of these weighty interests, appellees assert no prejudice arising from the United States' intervention. Nor could they, given the District Court's independent obligation to assure itself of its own jurisdiction.

Acree v. Republic of Iraq, 370 F.3d 41, 50-51 (D.C. Cir. 2004), *abrogated on other grounds, Republic of Iraq v. Beatty*, ___ S.Ct. ___, 2009 WL 1576569.

Third, the federal defendants failed to point this Court to *Summers* not only once it came out (*i.e.*, before this Court's decision) but also after this Court based a merits decision on the plaintiffs' allegations of standing. Under the circumstances, that suggests a lack of adverseness that constitutes a special circumstance that warrants intervention. *Cf. Butler, Fitzgerald & Potter v. Sequa Corp.*, 250 F.3d 171, 180 (2d Cir. 2001) (including "evidence of collusion" within a

non-exhaustive list of factors that would justify intervention). As the Supreme Court put it today, in the context of an un-appealed judgment and a Rule 60(b)(5) motion, the un-appealed judgment appears to reflect a lack of “true challenge.” *Horne v. Flores*, ___ S.Ct. ___, 2009 WL 1789470.

B. Movants Have a Sufficient Interest

To meet the second criterion for intervention as of right, Movants must “have an interest in the proceeding” that is “direct, substantial, and legally protectable.” *Washington Elec.*, 922 F.2d at 96-97 (citing cases). Interests “remote from the subject matter of the proceeding” or “contingent upon the occurrence of a sequence of events” do not satisfy this criterion. *Id.* Here, on behalf of themselves, their members, and their physician and pharmacist members’ patients and customers, Movants seek to enforce the statutory rights to drug-safety information and administrative process. *See* Section II.A, *supra*. These statutory protections and entitlements create legally protectable interests. *See, e.g., Warth v. Seldin*, 422 U.S. 490, 514 (1975) (quoted *supra*). Far from “remote,” Movants’ interests are thus identical with the “subject matter of the proceeding.” As explained further in the next section, moreover, the impairment of the interests of Movants and their members will flow directly from the action in which Movants seek to intervene, not from a remote contingent sequence of events.

C. This Action May Impair Interests of Movants and their Members

To meet the third criterion for intervention as of right, Movants must establish that “proceeding without the involvement of [Movants] would impair [Movants’] ability to protect [their] interest.” *Washington Elec.*, 922 F.2d at 98. Here, the issue does not merely involve the precedential effect of the ultimate resolution of this litigation under *stare decisis*, which itself suffices to meet the third criterion for cases of first impression. *Id.* Instead, this litigation purports to compel the federal sovereign under issue preclusion and *res judicata*, which

potentially could bind the rights of Movants and their members. *See City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 340-41 (1958) (judgment against a government can bind its citizens). Under the circumstances, concerns about *stare decisis*, issue preclusion, and *res judicata* all suffice to meet the third criterion.

Moreover, the litigation seeks *vacatur* or modification of agency actions that, in part, protected the interests of Movants and their members, which necessarily would impair the interests of Movants and their members. *NYPIRG v. Regents of University of State of N.Y.*, 516 F.2d 350, 352 (2d Cir. 1975) (“Pharmacists also have an interest in the action as professionals since any lifting of the prohibition against advertising prescription drug prices might well lead to significant changes in the profession and in the way pharmacists conduct their businesses”) (*per curiam*); *cf. Sierra Club v. EPA*, 129 F.3d 137, 139 (D.C. Cir. 1997) (“no doubt” that affected public has standing to challenge removal of regulation that requires consideration of the public’s exposure to statutory harm). Even in the absence of *stare decisis*, issue preclusion, or *res judicata* (which all exist sufficiently to meet the third criterion), therefore, allowing this Court’s March 24, 2009 judgment to stand unchallenged would itself meet the third criterion by impairing the interests of Movants and their members in the agency actions that the Court modified or vacated.

D. No Party Adequately Represents Movants’ Interests

To meet the fourth criterion for intervention as of right, Movants must establish that the existing parties *may* inadequately represent the interests of Movants or their members, a showing that courts should treat as minimal. *Trbovich v. United Mine Workers of America*, 404 U.S. 528, 538, n.10 (1972). Of course, “[i]f the interest of the absentee is not represented at all, or if all existing parties are adverse to him, then he is not adequately represented.” *Mountain Top*

Condominium Assoc. v. Dave Stabbert Master Builder, Inc., 72 F.3d 361, 368 (3d Cir. 1995) (quoting 7C WRIGHT, MILLER & KANE, FEDERAL PRACTICE & PROCEDURE §1909). Because the plaintiffs plainly are adverse, the only question is whether FDA adequately represents Movants.

Until FDA declined to appeal this Court's jurisdictional findings, FDA had adequately represented Movants' interests in challenging this Court's jurisdiction. By failing to file a notice of appeal against a judgment that this Court lacked jurisdiction to enter, the FDA ceased to represent Movants adequately.

The Second Circuit has adopted a "presumption of adequate representation that arises when [a putative intervener] has the same ultimate objective as a party to the existing suit." *Brennan*, 579 F.2d at 191. Under Second Circuit precedent, given an "identity of interest between a putative intervenor and a party, adequate representation is assured." *Washington Elec.*, 922 F.2d at 98; *Butler, Fitzgerald & Potter v. Sequa Corp.*, 250 F.3d 171, 179 (2d Cir. 2001) ("we have demanded a more rigorous showing of inadequacy in cases where the putative intervenor and a named party have the same ultimate objective"). Here, until FDA declined to appeal, FDA and Movants shared the same ultimate objective: dismissal of plaintiffs' suit. For FDA to claim adequate representation, FDA would need to commit to "litigate vigorously and to present all colorable contentions." *NRDC v. N.Y. State Dept. of Env't'l Conservation*, 834 F.2d 60, 61-62 (2d Cir. 1987). While FDA could claim that before it declined to appeal, it no longer can claim it. Indeed, failure to appeal is an appropriate basis for revisiting the issue of intervention. *U.S. v. Hooker Chemicals & Plastics Corp.*, 749 F.2d 968, 993 (2d Cir. 1984).

For purposes of the adequacy of the federal defendants' representation, it is significant that the "interest asserted" and the "contentions sought to be put forth" overlap completely. *Cf. N.Y. State Dept. of Env't'l Conservation*, 834 F.2d at 61-62 (representation remains adequate if

interest asserted has no nexus with contentions to be put forward). Indeed, Movants seek intervention for the limited purpose of establishing the lack of jurisdiction, and it is entirely appropriate for a court to grant intervention for limited purposes. *See, e.g., Stringfellow v. Concerned Neighbors in Action*, 480 U.S. 370, 378 (1987) (approving limited intervention). While FDA has chosen not to join Movants' defense, FDA can no longer stand in the way.

IV. PERMISSIVE INTERVENTION

To intervene permissively pursuant to FED. R. CIV. P. 24(b), a movant must (1) timely file for intervention, without unduly delaying the adjudication of the original parties' rights; and (2) have a claim or defense that has "question[s] of law or fact in common" with the main action. *AT & T Corp. v. Sprint Corp.*, 407 F.3d 560, 561-62 (2d Cir. 2005). Even if the Movants do not meet the test for intervention as of right, they plainly meet the test for permissive intervention. *See, e.g., Ionian Shipping Co. v. British Law Ins. Co.*, 426 F.2d 186, 191-92 (2d Cir. 1970) (denial of intervention as of right does not pre-ordain denial of permissive intervention). Moreover, Rule 24 is part of the Federal Rules' "pragmatic" attempt to "minimize[e] meddling in private lawsuits" while avoiding a multiplicity of lawsuits. *Id.* Given the complete overlap of issues and Movants' ability to file their own litigation to enjoin or vacate FDA's actions to comply with this Court's orders, pragmatism calls for intervention to resolve this issue here.

Specifically, Movants can file their own lawsuit, even in this Court, to seek declaratory relief that the Court lacked jurisdiction to enter injunctive relief against FDA. *Luckenbach S. S. Co. v. U.S.*, 312 F.2d 545, 551-52 (2d Cir. 1963) ("the action for a so called negative declaration is simply a broadening of the equitable action for the removal of a cloud from title to cover the removal of clouds from legal relations generally") (*quoting* EDWIN BORCHARD, DECLARATORY JUDGMENTS, 21 (2nd ed. 1941)); *see also* 28 U.S.C. §§1331, 2201. This Circuit has recognized

such independent rights to sue as justifying intervention. *See Hooker Chemicals*, 749 F.2d at 985 (recognizing that intervention depends in part on whether movant has an “independent right to sue”) (citing Note, *Intervention in Government Actions*, 89 HARV. L. REV. 1174, 1178-98 (1976)). Where parties like Movants have their own litigable interests, the argument for excluding that party carries little weight:

[T]he argument that Congress intended that the government enjoy sole discretion in determining enforcement policy *carried little weight in [connection with] litigable interests*. When the private interest is nonlitigable, however, this argument becomes far more persuasive.

Intervention in Government Actions, 89 HARV. L. REV. at 1189-90 (footnote omitted, emphasis added). Again, pragmatism counsels for intervention.

For the reasons already set forth above, the motion to intervene is timely. *See, e.g., Catanzano by Catanzano v. Wing*, 103 F.3d 223, 234 (2d Cir.1996). Under Rule 24(b), therefore, the only question that remains is whether Movants’ intervention and the actions already before this Court have sufficiently common questions of law or fact. Insofar as Movants seek to intervene *as a defendant* solely to challenge jurisdiction, Movants respectfully submit that Rule 24(b)’s second criterion is automatically met: Movants seek to intervene on precisely the questions of law and fact necessary for this Court to entertain this litigation in the first place, as well as to enter and enforce its judgment. Accordingly, even in the absence of intervention as of right, Movants respectfully submit that this Court should allow permissive intervention.

V. CONCLUSION

For the foregoing reasons, Movants respectfully requests that this Court grant the motion to intervene in this action to appeal the jurisdictional aspects of this case and, in the alternative,

to file a motion for reconsideration under FED. R. CIV. P. 60(b)(4) to void the judgment as lacking jurisdiction.

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Respectfully submitted,

/s/ {SIGNED ELECTRONICALLY}

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