UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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ANNIE TUMMINO et al.,

Plaintiffs,

MEMORANDUM & ORDER

- against -

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

MARGARET HAMBURG,* *in her official capacity as Commissioner of the Food and Drug Administration*,

Defendant,
and

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

Proposed-Intervenors.
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KORMAN, *J.*:

Concerned Women for America ("CWA"), Christian Medical & Dental Associations ("CMDA"), and Christian Pharmacists Fellowship International ("CPFI"), referred to for the sake of convenience as "intervenors," although they are seeking merely to leave to intervene, are three non-profit membership organizations whose members oppose abortion. CWA is "public policy women's organization" that works for "'the protection of all innocent human life from conception until natural death.'" (Intervenors' Mem. at 3.) CMDA is an "organization of Christian physicians and allied healthcare professionals" who "oppose[] 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.*) CPFI is an organization of Christian pharmacists who

* Pursuant to Federal Rule of Civil Procedure 25(d), Commissioner Margaret Hamburg has been substituted for former Acting Commissioner Frank M. Torti as defendant in this case.

"oppose[] abortion for religious, moral and ethical reasons, and are committed to the sanctity of human life." (*Id*.) They seek leave to intervene in order to appeal from the judgment, entered March 24, 2009. *See Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009). They also seek an extension of time to file a notice of appeal.

The present litigation began in January 2005 when plaintiffs – individuals and organizations advocating wider distribution and access to emergency contraceptives, as well as parents and their minor children seeking the same – filed a complaint challenging the Food and Drug Administration's ("FDA") denial of a Citizen Petition, which had requested that the FDA make Plan B, a prescription-only emergency oral contraceptive, available over-the-counter to women of all ages. The underlying facts concerning the FDA's consideration of and final determinations regarding both the Citizen Petition and a number of parallel proposals submitted by the Plan B drug sponsor – referred to as supplemental new drugs applications ("SNDAs") – are exhaustively detailed in *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009). Briefly, after denying the Citizen Petition and rejecting two SNDAs – the first, proposing that Plan B be made available without a prescription to women of all ages and the second, proposing it be made available without a prescription to women 16 and older – the FDA, in August 2006, approved a third SNDA for Plan B, and permitted Plan B's manufacturer to market Plan B to women 18 and older without a prescription. As approved, Plan B's point-of-sale was restricted to pharmacies and certain health clinics.

Plaintiffs in *Tummino* alleged that "the FDA's decisions regarding Plan B – on the Citizen Petition and the SNDAs – were arbitrary and capricious [under the Administrative Procedure Act]" and "made in bad faith because they were improperly influenced by political considerations wholly outside the scope of the FDA's statutory authority." *Id*. at 523, 538. On

March 23, 2009, I vacated the denial of the Citizen Petition, and ordered the FDA to permit Plan B's manufacturer "to make Plan B available to 17 year olds without a prescription, under the same conditions as Plan B is now available to women over the age of 18." *Id.* at 550. I remanded to the FDA the issue of whether Plan B should be made available without a prescription to women younger than 17. *Id*. The judgment was entered on March 24, 2009 and, pursuant to Fed. R. App. P. 4(a)(1)(B), a notice of appeal had to have been filed within 60 days of the entry of judgment. If, as here, the last day of the 60 day period falls on a weekend or "legal holiday," a party seeking to appeal has until the next business day to file. Fed. R. App. P. 26(a)(3). Here, the last day fell on a Saturday, May 23, 2009 and the next Monday, May 25, 2006, was Memorial Day, a "legal holiday" under Fed. R. App. P. 26(a)(4). Thus, intervenors had until Tuesday, May 26, 2009 to file their notice of appeal.

On April 22, 2009, the FDA announced that "[t]he government will not appeal this decision." FDA Statement, Updated FDA Action on Plan B (levonorgestrel) Tablets (Apr. 22, 2009), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149568.htm. On the same day, CWA President, Wendy Wright, who submitted a declaration in support of the instant motion, issued a statement criticizing the decision: "'This decision is driven by politics, not what is good for patients or minors. . . . The FDA should have challenged the decision.'" CWA, *FDA Caves to Pressure, Plans to Endanger 17-Year-Olds*, Christian Newswire, April 22, 2009, 3:33 pm. GMT. The FDA's decision was also widely covered by the national media. *See, e.g.*, Rob Stein, *U.S. Would Allow Sale of `Morning-After' Pill to Minors*, Washington Post, Apr. 22, 2009, *available at* 2009 WLNR 7528441; Noam N. Levey, *FDA Signals Shift in Birth-Control Debate; Morning-After Pill Will Be Sold to 17-Year-Olds Over the Counter*, Los Angeles Times, Apr. 23, 2009, at A1; Gardiner Harris, *Agency Agrees to Ease Access to*

Emergency Contraceptive for 17-Year-Olds, New York Times, Apr. 23, 2009, at A14; Jennifer Corbett Dooren, *FDA Expands Access to Morning-After Pill, Wall Street Journal*, Apr. 23, 2009, at B11. Nevertheless, intervenors, who argue that "the need . . . to intervene at all was occasioned by the new administration's decision to allow" the judgment "to stand without appeal" (Intervenors' Mem. at 13), did not move to intervene and appeal within 60 days of the March 24, 2009 judgment. Instead, they waited until June 25, 2009 to file a motion (1) to intervene, pursuant to Fed. R. Civ. P. 24(a), (b), for the purpose of filing a notice of appeal to challenge plaintiffs' standing and (2) for an extension of time to file that appeal, pursuant to Fed. R. App. P. 4(a)(5).

Discussion

Because intervenors are not parties to the underlying action, "the threshold (and ultimately dispositive) question" is whether they may properly intervene. *Farmland Dairies v. Comm'r of New York State Dep't of Agric and Mkts.*, 847 F.2d 1038, 1043 (2d Cir. 1988). They clearly cannot because they do not have standing to intervene and because the motion to intervene was not timely filed. Their motion for extension of time to file a notice of appeal is also denied for this reason and because they have not made the showing otherwise necessary to obtain such relief.

I. Motion to Intervene

While the Second Circuit does not ordinarily require intervenors to establish their own standing, *U.S. Postal Serv. v. Brennan*, 579 F.2d 188, 190 (2d Cir. 1978), "an intervenor's right to continue a suit *in the absence of the party on whose side intervention was permitted* is contingent upon a showing by the intervenor that he fulfills the requirements of Art. III." *Diamond v. Charles*, 476 U.S. 54, 68 (1986) (emphasis added). Of course in this case,

intervention was never permitted. Nevertheless, because the party on whose side intervention could have been sought during the course of the litigation has decided not to appeal, intervenors must establish that they are sufficiently harmed by the judgment to give them independent standing.

A. Intervenors Lack Standing To Intervene

Intervenors bear the burden of proving each element of standing: (1) that they have "suffered an 'injury in fact' – an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) 'actual or imminent, not "conjectural" or "hypothetical;"'" (2) that there is a "causal connection between the injury and the conduct complained of," and (3) that it is "'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Moreover, intervenors may establish their representational or associational standing if: (1) at least one of its members has standing to sue in his or her own right; (2) the interests the association seeks to protect are germane to its purpose; and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit. *Bldg. & Const. Trades Council of Buffalo, N.Y. and Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 144 (2d Cir. 2006) (quoting *Hunt v. Wash. State Apple Adver. Com'n*, 432 U.S. 333, 343 (1977)).

Intervenors present a number of theories in support of standing. All are without merit.

1. Informational Standing

By way of background, under certain circumstances the Pediatric Research Equity Act ("PREA") requires a person who submits a drug application to the FDA to submit along with that application data "to assess the safety and effectiveness of the drug . . . for the claimed indications in all relevant pediatric subpopulations" and "to support dosing and administration for each

pediatric subpopulation for which the drug . . . is safe and effective." 21 U.S.C. § 355c(2)(A). Unless an assessment has been deferred until after approval, *id*. § 355c(a)(3), waived, *id*. § 355c(a)(4), or has been deemed unnecessary by the FDA, *id*. §§ 355c(a)(2)(B) (FDA may conclude that pediatric effectiveness and safety can be extrapolated from studies in adults), the FDA must review the pediatric safety assessment prior to approval of the drug application. *Id*. § 355c(f). When a pediatric safety assessment is required, the FDA "shall make available to the public . . . the reviews of such pediatric assessments." *Id*. § 355c(h).

Intervenors argue that they have suffered an informational injury because the judgment, which ordered the FDA to permit Plan B to be marketed to 17 year olds without a prescription, deprived them of access to pediatric safety information that the FDA otherwise would have been required to consider and make available to the public before approving such use by 17 year olds. There is little support, however, for the proposition that a plaintiff's (or in this case a proposed-intervenor's) interest in access to information compiled during agency proceedings is, in and of itself, sufficient to confer standing. Indeed, in the *United States v. Richardson*, 418 U.S. 166 (1974), the Supreme Court rejected a similar claim for informational standing on the ground that the effect on the plaintiff there from the lack of information was undifferentiated and common to all members of the public. *Id*. at 176-80.

Moreover, to the extent that the concept of informational standing has received any recognition, it is has been limited to "very specific statutory contexts where a statutory provision has explicitly created a right to information." *See Ass'n of Am. Physicians & Surgeons v. FDA*, 539 F. Supp. 2d 4, 15 (D.D.C. 2008) (internal quotation marks omitted); *Animal Legal Defense Fund, Inc. v. Espy*, 23 F.3d 496, 502 (D.C.Cir. 1994). The 2007 amendments to the PREA upon which intervenors rely, simply require that, if the FDA determines that a pediatric safety

assessment is necessary before approving a drug application – including a switch in a drug's prescription status – it is obligated to require that the drug's label include information about the results of the assessment, 21 U.S.C. §§ 355c(g)(2), and to provide the public with pediatric safety information on that drug, *id*. § 355c(h)(1)(2). Thus, such "[a] study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group." 21 U.S.C. § 355c(a)(2)(B)(ii); *id*. § 355c(a)(2)(B)(i) ("the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies."); *see also Tummino*, 603 F. Supp. 2d at 527 (noting FDA's "'long history of extrapolating findings from clinical trials in older patients to adolescents.'"). Moreover, a pediatric assessment may be waived where the "necessary studies are impossible or highly impracticable." 21 U.S.C. §§ 355c(a)(4)(A)(1), (B)(1).

In this case, the FDA's scientific review staff working within the Center for Drug Evaluation and Research found that a pediatric safety assessment was not necessary. Instead, it concluded that data showing the safe and effective use of Plan B by adults in an over-the-counter setting could be extrapolated to over-the-counter use of Plan B by adolescents, because "the data 'do[es] not suggest that adolescent women are significantly different from older women in their comprehension of the labeling or appropriate use of [Plan B] in the OTC setting'" and there is "no 'compelling scientific reason' to 'distinguish[] the safety and efficacy of Plan B . . . among different ages of women of childbearing potential.'" *Tummino*, 603 F. Supp. 2d at 532. Moreover, the FDA subsequently acknowledged that the sale of Plan to 17 year olds without a prescription was "consistent with the [foregoing] scientific findings made in 2005 by [its] Center for Drug Evaluation and Research." FDA Statement, Updated FDA Action on Plan B

(levonorgestrel) Tablets (Apr. 22, 2009), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149568.htm. Thus, intervenors attenuated argument that, were it not for the judgment, the FDA would have been required to request pediatric safety data on Plan B, much less disseminate that data to the public, fails for this reason alone.

Moreover, the amendments on which intervenors rely apply only to drug applications submitted *after* September 27, 2007. *See* 21 U.S.C. § 355c(a)(1) ("A person that submits, on or after September 27, 2007, a[new drug] application (or supplement to an application) . . . shall submit with the application" a pediatric safety assessment); *see also Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d at 16 n.3. All of the applications concerning the prescription status of Plan B – the Citizen Petition and the three SNDAs – were submitted well *before* 2007.

In sum, under the circumstances here, intervenors alleged "injury"– that they "desire [to] access . . . 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)" (Intervenors' Mem. at 4) – is not sufficient to confer standing. *See Found. on Econ. Trends v. Lying*, 943 F.2d 79, 84-85 (D.C.Cir. 1991) (citing *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)). "[A] mere 'interest in a problem,' no matter how long standing the interest and no matter how qualified the organization is in evaluating the problem," is not sufficient to confer standing. *Morton*, 405 U.S. at 739.

2. Procedural Standing

Intervenors next argue that they have standing to intervene because they have suffered procedural injury, namely, that the judgment directing the FDA to allow Plan B to be marketed without a prescription to 17-year olds "short-circuit[ed] the rulemaking required to remove Plan

B's prescription requirement for seventeen-year olds" (Intervenors' Mem. at 7) and denied intervenors an "opportunity to participate in a rulemaking to oppose the removal of Plan B from the prescription requirements of the Food, Drug & Cosmetic Act" (*id*. at 4). Intervenors' argument fails for two reasons.

First, the Food, Drug, and Cosmetic Act ("FDCA") – and the regulations promulgated under it – do not, as intervenors argue, *require* a rulemaking to switch a drug's status from prescription-only to non-prescription. Indeed, a rulemaking is only required when the FDA, on its own initiative, or after reviewing a Citizen Petition, decides to "promulgate a regulation changing the drug's status." *Tummino*, 603 F. Supp. 2d at 525 (citing 21 U.S.C. § 353(b)(3); 21 C.F.R. §310.200(b); *id*. § 10.25(a)). When the change in the drug's prescription status is proposed by the drug sponsor, however, no rulemaking is required. *Tummino*, 603 F. Supp. 2d at 525 (citing 21 U.S.C. § 355(c)(1); 21 C.F.R. § 310.200(b); *id*. § 314.71). Here, the FDA approved an SNDA – a proposal submitted by the Plan B sponsor – not a Citizen Petition, and, thus, no rulemaking was required. Moreover, the judgment from which intervenors seek to appeal did not "short-circuit" the rulemaking. It merely gave effect to the scientific findings of the FDA that the data submitted with the second SNDA was "'sufficient to support the safe use of Plan B as an OTC [over-the-counter] product . . . for women who are 17 years of age and older.'" *Tummino*, 603 F. Supp. 2d at 535.

Second, even assuming that a rulemaking was required, intervenors still cannot establish sufficient injury-in-fact to confer standing. Indeed, as the Supreme Court recently held in *Summers v. Earth Island Institute*, __ U.S. __, 129 S.Ct. 1142, 1151 (2009), "deprivation of a procedural right without some concrete interest that is affected by the deprivation – a procedural right *in vacuo* – is insufficient to create Article III standing." *See also Ass'n of Am. Physicians*

& Surgeons, 539 F. Supp. 2d at 20 ("'The mere violation of a procedural requirement . . . does not permit any and all persons to sue to enforce the requirement.'" (quoting *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 664 (D.C.Cir. 1996)). On the contrary, to "demonstrate injury sufficient for standing in a procedural rights case, the plaintiff must show that the omission or insufficiency of the procedure had 'demonstrably increased [the] risk of serious . . . harm' that 'actually threatens the plaintiff's particular interests." *Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d at 20 (quoting *Florida Audubon Soc.*, 94 F.3d at 667). "The mere violation of a procedural requirement thus does not permit any and all persons to sue to enforce the requirement." *Florida Audubon Soc*., 94 F.3d at 664 (citing *Defenders of Wildlife*, 504 U.S. at 572-23).

The recent decision of the District of Columbia, *Ass'n of Am. Physicians & Surgeons v. FDA*, which concerned a similar challenge to the FDA's decisions regarding Plan B, is instructive. There, the plaintiffs – CWA, along with a nonprofit physician membership organization, a nonprofit pharmacist membership organization, and a nonprofit pro-life corporation – were, for all practical purposes, identically situated to intervenors here. 539 F. Supp. 2d at 11. They alleged, as one of the bases for their standing to challenge the FDA's approval of Plan B for non-prescription use by women 18 and older, the same procedural injury intervenors allege here. *Id*. at 21 ("plaintiffs argue that they were denied the opportunity to participate in notice and comment rulemakings for the Rx-to-OTC [prescription to over-the-counter] switch for Plan B."). Moreover, they alleged that the plaintiffs, including CWA, "commented on the [FDA's] Advance Notice of Proposed Rulemaking . . . and their members wished to comment and would have commented in subsequent rulemaking proceedings, if [the FDA] had convened them." Amended Complaint at 11 ¶ 27, *Ass'n of Am. Physicians &*

Surgeons, 539 F. Supp. 2d 4 (No. 07-0668). These allegations were not sufficient to establish standing:

> Plaintiffs have not, however, identified a legally protected interest that has been infringed by these alleged procedural shortcomings. Plaintiffs advance no allegations of injury suffered by the organizations themselves, and as explained above, plaintiffs have not demonstrated a concrete injury in relation to their members. Moreover, the Supreme Court "has never freed a plaintiff alleging a procedural violation from showing a causal connection between the government action that supposedly required the disregarded procedure and some reasonably increased risk of injury to its particularized interest," and here, plaintiffs have not demonstrated a sufficient causal connection between a procedural violation and an alleged injury. The allegations in plaintiffs' amended complaint, then, are insufficient to support procedural standing.

Ass'n of Am. Physicians & Surgeons, 539 F. Supp. 2d at 21 (internal citations omitted).

This holding applies with equal force here. Intervenors have not alleged a concrete organizational injury or any injury suffered by their members. Moreover, because it was the FDA that made the decision not to undertake rulemaking, they cannot establish a causal connection between the alleged procedural violation – the judgment directing the FDA to permit Plan B to be marketed without a prescription to 17 year olds – and the alleged injury – the lack of an opportunity to comment and participate in a rulemaking on this change in access. Specifically, in August 2005, "the FDA announced its intention to issue an advance notice of a 60-day public comment on whether rulemaking procedures were necessary to resolve and clarify" issues regarding its authority to approve Plan B for prescription use for one age group and non-prescription use for another and "the logistics of enforcing the age based and point of sale restrictions." *Tummino*, 603 F. Supp. 2d at 535. Nevertheless, after receiving and reviewing 47,000 comments – CWA's among them – the FDA decided that "it was not necessary after all to engage in agency rulemaking before deciding the Plan B sponsor's OTC switch application." *Id*.

3. Pharmacist's Injuries

Intervenors argue that because the judgment "short-circuited" the PREA information requirements and the FDCA rulemaking requirements, their pharmacist members who reside in "states [that] require pharmacists to sell Plan B" (Intervenors' Mem. at 8) will be forced to distribute a "misbranded" drug. Under the FDCA, a drug is "misbranded" if, among other things, it is dispensed without a prescription when not approved for non-prescription use. 21 U.S.C. § 353(b)(1); *see also id.* § 331(a) (distribution of misbranded drug is a prohibited act); *id* § 333(a)(1) (setting out penalties for violating provision of § 331). A drug may be switched from prescription to non-prescription use when the FDA determines that a prescription is not required for its safe use. *Id.* § 353(b)(3) (switch by regulation); *id.* § 355(c) (switch by approving drug manufacturer's application).

Intervenors' compulsion argument is unavailing for a number of reasons. First, the portion of the judgment from which they seek to appeal does not compel them to do anything. The judgment simply directed the FDA to permit the drug manufacturer to market Plan B for sale to 17 year olds on the same basis as it made Plan B available to women over 18. Thus, when the FDA approved non-prescription use of Plan B to women 18 and older, it did so on the condition that the drug sponsor would not sell Plan B to pharmacists unless the pharmacists agreed to sell Plan B only to women who could show valid proof of age. *Tummino*, 603 F. Supp. 2d at 536. The drug sponsor would not distribute Plan to a pharmacist who did not wish to participate in this way.

Second, intervenors have failed to indentify a single state regulation or statute that compels them to dispense Plan B to 17 year olds without a prescription. In their initial papers, intervenors argued, without citation, that certain states required pharmacist to sell Plan B. In

response to a request that they be more specific, they provided citations to two kinds of statutes or regulations: First, they rely on statutes and regulations that apply to pharmacists' dispensation of *prescription* drugs. *See, e.g.,* 68 Ill. Admin. Code § 1330.91(j) ("Upon receipt of a *valid, lawful prescription for a contraceptive,* a retail pharmacy serving the general public must dispense the contraceptive") (emphasis added). The judgment from which they seek to appeal, however, permitted Plan B to be made available to 17 year olds *without a prescription*. Thus, the judgment has not placed pharmacists in danger of running afoul of this type of state regulation.

Intervenors also rely on statutes and regulations that require hospitals and other health care facilities providing services to victims of sexual assault to orally inform victims about emergency contraception and of the option to have it made available upon request. *See, e.g.,* N.M. Stat. § 24-10D-3A; N.J. Stat. Ann. §26.2H-12.6c. These statutes and regulations do not distinguish between prescription and non-prescription emergency contraceptives. Moreover, the setting is for all practical purposes one in which the contraceptive is provided after consultation with a medical intermediary. Such consultation addresses the principal argument against making Plan B available without a prescription to young adolescents, who were said to require the guidance of a medical intermediary. This consideration aside, the statutes and regulations are directed to institutional providers – hospitals and health care facilities – and intervenors have not alleged that any of their member pharmacists would be subject to any penalties under these statutes. In sum, intervenors have not identified a single statue or regulation that compels them to dispense non-prescription Plan B to 17 year olds.

Moreover, even assuming these regulations apply to non-prescription drugs, including Plan B, "it is a stretch to say that a pharmacist could be prosecuted for selling a misbranded drug when there has been no determination that Plan B is misbranded." *Ass'n of Am. Physicians &*

Surgeons, 539 F. Supp. 2d at 19. Indeed, it is even more of a stretch here because, on April 22, 2009, "[i]n accordance with the court's order [the judgment from which intervenors appeal], and *consistent with the scientific findings made in 2005 by the Center for Drug Evaluation and Research*, FDA notified the manufacturer of Plan B . . . that it may, upon submission and approval of an appropriate application, market Plan B without a prescription to women 17 years of age and older." FDA Statement, Updated FDA Action on Plan B (levonorgestrel) Tablets (Apr. 22, 2009) (emphasis added), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149568.htm. Under the circumstances, intervenors' "fears of prosecution here 'are imaginary or speculative,'" and "'are not to be accepted as appropriate plaintiffs [or intervenors].'" *Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d at 19 (internal quotation marks omitted) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 299 (1979)).

4. Physicians' Third-Party Standing

To establish third-party standing, a litigant must satisfy three requirements: "The litigant must have suffered an 'injury in fact,' thus giving him or her a 'sufficiently concrete interest' in the outcome of the issue in dispute; the litigant must have a close relation to the third party; and there must exist some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 411 (1991) (internal citations omitted). As discussed above, neither intervenors nor their members have alleged a concreted injury sufficient to establish standing on their own behalves. Thus, they cannot rely on the legal rights or interests of their patients to substitute for their own lack of standing. Moreover, intervenors have not shown "some hindrance to the third party's ability to protect his or her own interests." On the contrary, intervenors argue "[i]f patients learn about Plan B's unproven safety for repeat use and for young

women, *they simply will avoid it.*" (Intervenors' Mem. at 8 (emphasis added).) This "concession . . . undermines their argument that a genuine obstacle is preventing patients from asserting their own rights." *Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d at 19.

5. Authorization of Illegal Conduct

Finally, intervenors argue that the judgment authorized something which was previously illegal, the distribution of Plan B without a prescription to 17 year olds. They do not, however, argue this change in Plan B's prescription status has harmed them. Instead, they argue that the change itself confers standing. This argument is a nonstarter because the failure to "allege an injury [to them] that fairly can be traced to [the] challenged action" is fatal to standing. *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 45 n.25 (1976) (plaintiffs lacked standing to challenge IRS rule that changed tax treatment of certain nonprofit hospitals, where plaintiffs failed to allege a injury caused by the change in status).

B. Intervenors' Motion to Intervene Is Untimely

Intervenors not only lack standing to intervene, their motion is also untimely. Under Rule 24 of the Federal Rules of Civil Procedure, a prospective intervenor must be permitted to intervene as of right if the applicant claims an interest relating to the subject matter of the case, the disposition of the case stands to impair that interest, and the applicant's interest is not adequately represented by the existing parties. Fed. R. Civ. P. 24(a). Alternatively, an applicant may be permitted to intervene if their claim shares a question of law or fact in common with the underlying action and permitting their intervention will not unduly delay or prejudice the rights of the original parties. Fed. R. Civ. P. 24(b). Under either test, however, the motion to intervene must be "timely." Fed. R. Civ. P. 24(a), (b). "Failure to satisfy *any one* of these requirements is a sufficient ground to deny the application. Thus an untimely motion to intervene must be

denied." *Farmland Dairies v. Comm'r of New York State Dep't of Agric. & Mkts.*, 847 F.2d 1038, 1043 (2d Cir. 1988) (internal citations omitted).

"Among the most important factors in a timeliness decision is 'the length of time the applicant knew or should have known of his interest before making the motion.'" *Catanzano v. Wing*, 103 F.3d 223, 232 (2d Cir. 1996). Here, it is clear that at least one of the intervenors, CWA, knew of its "interest" as far back as April 2007. Indeed, on April 12, 2007, CWA filed its complaint in *Ass'n of Am. Physicians & Surgeons*, which sought to protect the same interest and alleged injuries similar to those CWA allegedly seeks to protect here. *See* Complaint, *Ass'n of Am. Physicians & Surgeons*, 539 F. Supp. 2d 4 (No. 07-0668). There, CWA challenged the FDA's decision to permit Plan B to be sold behind-the-counter without a prescription to women 18 and older; here they challenge the judgment directing the FDA to permit Plan B to be marketed to women 17 and older without a prescription. Nevertheless, intervenors argue that their interest in this litigation only arose with "the new administration's decision to allow" the judgment "to stand without appeal." (Intervenors' Mem. at 13.) This occurred more than a year after the complaint was filed in *Ass'n of Am. Physicians & Surgeons.* Because the motion is untimely in any event, it is not necessary to decide whether intervenors' "interest" arose prior to the FDA's decision not to appeal.

The Second Circuit's decision in *United States v. Yonkers Bd. of Ed.*, 801 F.2d 593 (2d Cir. 1986), is instructive. There, a group of homeowners moved to intervene of right to oppose the siting of public housing on two sites near their homes. *Id*. at 594. In denying their motion to intervene as untimely, the district court found that the homeowners were on notice of the proposed sites approximately three months before they filed the motion to intervene in June 1986. The district judge observed:

> This information was available in the comments of the NAACP and the United States on the City's proposed remedial plan, which comments were submitted to the district court and became page one news in the Yonkers local newspaper published on March 15, 1986, and on page D1 on March 13, 1986. In addition, the issue of sites in eastern Yonkers has been the subject of considerable discussion in Yonkers at least since the district court's opinion finding liability was filed in November 1985.

Id. at 595 (footnotes omitted).

Likewise, this litigation, and particularly the FDA's decision not to appeal, has been the subject of considerable discussion and national media coverage. It is beyond dispute that CWA was aware of the FDA's decision not to appeal, and of its interest in this litigation, on April 22, 2009. *See* CWA, *FDA Caves to Pressure, Plans to Endanger 17-year Olds*, Christian Newswire, April 22, 2009, 3:33 pm. GMT (statement by CWA President criticizing the FDA's decision). Moreover, the other two intervenors, CMDA and CPFI, knew or should have known, of the FDA's decision contemporaneously. Indeed, as discussed above, the announcement was reported by a number of local and national newspapers. Thus, just as in *Yonkers Bd. of Ed*., "any prejudice to [intervenors] resulting from the denial of intervention may be attributed to their own failure to seek intervention when they first had reason to become aware" of their interest in the litigation. 801 F.2d at 595.

Once intervenors became aware that the FDA would not appeal, "it was incumbent upon [them] . . . to take immediate affirmative steps to protect their interests." *Id*. (citing *NAACP v. New York*, 413 U.S. 345, 367 (1973)). More significantly, intervenors seek to intervene after the judgment was entered. Such "[i]ntervention after judgment is unusual and not often granted." *Crown Fin. Corp. v. Winthrop Lawrence Corp.*, 531 F.2d 76, 77 (2d Cir. 1976) (quoting 3B Moore, Federal Practice ¶ 24.13(1), at 24-526). Permitting intervention at this point would force the parties who are directly interested in the subject of the litigation and who do not object to the

final judgment to engage in yet another round of costly and time consuming litigation. As the Second Circuit has observed, "in making the choice between the possibility of harm to the late-arriving prospective intervenors as against the possible harm to parties who have participated diligently during the pertinent portions of this litigation, it does not strike us as unjust that intervention on the part of the late-arrivers must yield under all of the circumstances herein." *Yonkers Bd. of Ed.*, 801 F.2d at 596.

II. Motion for an Extension of Time to Appeal

Intervenors' failure to establish their standing is fatal to their motion for an extension of time to file an appeal. *Official Comm. of Unsecured Creditors of WorldCom, Inc. v SEC*, 467 F.3d 73, 77 (2d Cir. 2006) (recognizing that "[s]tanding is an essential component of our appellate jurisdiction," and permitting party to appeal only after determining that they had met the requirements of Article III standing). Even assuming intervenors had met their burden of establishing standing, their motion must still be denied because it is untimely.

A party seeking to appeal a civil judgment "[w]hen the United States or its officer or agency is a party" must file "the notice of appeal . . . within 60 days after the judgment or order appealed from is entered." Fed. R. App. Proc. 4(a)(1)(B). Intervenors did not file their notice of appeal within 60 days of the entry of judgment on March 24, 2009. Instead, they waited until June 25, 2009. They argue, however, that their appeal is timely pursuant to Fed. R. Civ. App. 4(a)(5), which provides that a district court may extend the time to file a notice of appeal if the party moves within 30 days of the time prescribed in Rule 4(a) and shows that the delay in filing was for "excusable neglect or good cause."

The Second Circuit has "taken a hard line" in "cases addressing when neglect is 'excusable.'" *Silivanch v. Celebrity Cruises, Inc.*, 333 F.3d 355, 368 (2d Cir. 2003). In

evaluating excusable neglect, courts may consider "'[1] the danger of prejudice to the [non-movant], [2] the length of the delay and its potential impact on judicial proceedings, [3] the reason for the delay, including whether it was within the reasonable control of the movant, and [4] whether the movant acted in good faith.'" *Id.* (quoting *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship*, 507 U.S. 380, 395 (1993)). Moreover, "'[w]hile prejudice, length of delay, and good faith might have more relevance in a close[] case, *the reason for delay factor will always be the critical inquiry.*'" *Silivanch*, 333 F.3d at 365 n.7 (emphasis added) (quoting *Graphic Commc'n Int'l Union, Local 12-N v. Quebecor Printing Providence, Inc.*, 270 F.3d 1, 5-6 (1st Cir. 2001)).

Intervenors argue that the reason for delay was due to the difficulty in obtaining "local counsel who would be willing to represent them in this controversial matter." (Intervenors' Letter Reply, dated July 23, 2009, at 8.) But, as the FDA observed in its opposition papers, "[t]here is no reason why the proposed intervenors' Washington Counsel could not have simply sought admission to the Court *pro hac vice* . . . and then filed his own motion papers within sixty days after judgment was entered, as intervenors' letter suggests they were prepared to do." (FDA Letter Resp. at 3.) Indeed, Local Rule 1.3(c), which governs attorney admissions to practice in this District, does not require local counsel. Nevertheless, intervenors argue that their Washington counsel "insisted on CWA's also retaining a local counsel admitted with ECF privileges to the Bar of this Court." (Intervenors' Letter Mot., dated June 25, 2009, at 3.) Intervenors cite no authority for the proposition that a party's failure to file a timely notice of appeal may be excused because their counsel insisted on obtaining local counsel when none was required by the rules of the forum court.

Even were this a proper basis for a finding of excusable neglect in some instances, under the facts and circumstances here intervenors have not provided a "satisfactory explanation" as to why it took them more than two months to find local counsel. *See Silivanch*, 353 F.3d at 366 n.7 (noting that there "'must be a satisfactory explanation for the late filing.'"). As discussed above, the FDA decided not to appeal – and intervenors were aware of this decision – on April 22, 2009. Thus, intervenors had more than 30 days to file a timely notice of appeal after discovering that the FDA "did not adequately represent their interests." Nevertheless, intervenors waited an additional month before filing the instant motions on June 25, 2009. Moreover, intervenors concede that they considered intervening even earlier than April 22, 2009. (Intervenors' Reply Letter at 3 (they "had considered intervening at various points in the process of the action"); *id.* at 6 (when the FDA announced it would not appeal "it truly became a question, *rather than a contingency*, of whether or not Movants' interests were adequately represented.") (emphasis added).) There is simply no satisfactory explanation as to why intervenors were unable to obtain local counsel in time to file a notice of appeal within 60 days of the entry of judgment.

While the contours of the good cause analysis under Rule 4(a) are less well-defined than the excusable neglect analysis, it is clear that the facts and circumstances here do not amount to good cause for intervenors' delay. The "good cause standard may be invoked where the cause for missing the deadline was entirely beyond the control of the moving party, for example, where the Postal Service fails to deliver a notice of appeal." *Myers v. New York City Human Rights Comm'n*, No. 04 Civ. 00543, 2006 WL 2053317, at *1 (S.D.N.Y. July 21, 2006) (citing Fed. R. App. P. 4(a)(5)(A)(ii) advisory committee's note (2002 amendments)); *see also* Fed. R. App. P. 26(a)(3) (excluding the last day of the filing period where the last day is "a day on which the weather or other conditions make the clerk's office inaccessible."). Here, intervenors argue that

they did not control the FDA's decision not to appeal. (Intervenors' Reply Letter at 8.) This argument misses the point. The issue is not whether they had control over the FDA's decision not to appeal, but whether they had control over the factors that caused them to miss the deadline.

Conclusion

Intervenors' motions to intervene and for an extension of time to file a notice of appeal are denied. Moreover, to the extent intervenors seek reconsideration of the judgment, pursuant to Fed. R. Civ. P. 60(b)(4) (*see* Intervenors' Mem. at 21) – a Rule that intervenors merely cite without offering any argument as to why they are entitled to relief under it – that motion is also denied because Rule 60(b) is "not ordinarily . . . available to non-parties to modify [or seek reconsideration] of final judgments." *Dunlop v. Pan Am. World Airways, Inc*., 672 F.2d 1044, 1052 (2d Cir. 1982). While the Second Circuit has recognized a limited exception to this rule where the non-party is "strongly affected" and "sufficiently connected and identified with the . . . suit" at issue, in each case it expressly limited the exception to "the facts of th[e] case" before it. *See Grace v. Bank Leumi Trust Co. of NY*, 443 F.3d 180, 188 (2d Cir. 2006) (non-party movant had standing to invoke Rule 60(b) to vacate judgment enforcing settlement agreement intended to collect from non-party movant); *Dunlop*, 672 F.2d at 1052 (non-party intervenors had Rule 60(b) standing to move to amend stipulation entered into between parties to a federal action that barred intervenors' then-pending related state law action). The "facts of this case" do not permit a finding of standing, because intervenors have not shown that they are "sufficiently connected and identified with" the judgment directing the FDA to permit nonprescription distribution of

Plan B to 17 year olds "to entitle them to standing to invoke Rule 60(b)[]." *Grace*, 443 F.3d at 188.

SO ORDERED.

Brooklyn, New York
August 27, 2009

Edward R. Korman

Edward R. Korman
United States District Judge