Attachment K

LEXSEE 2005 U.S. DIST. LEXIS 5710

RAY ANDREWS, and GAYLEE ANDREWS, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.

Civil Action No. 04-0307 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2005 U.S. Dist. LEXIS 5710

March 31, 2005, Filed

COUNSEL: [*1] For RAY ANDREWS, individually and as representatives of similarly situated persons, GAYLEE ANDREWS, individually and as representatives of similarly situated persons, Plaintiffs: Richard Talbot Seymour, LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP, WASHINGTON, DC; Barry R. Himmelstein, Elizabeth J. Cabraser, LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP, San Francisco, CA; George S. Bellas, Robert A. Clifford, CLIFFORD LAW OFFICES, P.C., Chicago, IL.

For DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, TOMMY G. THOMPSON, Secretary, U.S. Department of Health and Human Services, Defendants: Alan Phelps, Gerald Cooper Kell, U.S. DEPARTMENT OF JUSTICE, Washington, DC.

JUDGES: JAMES ROBERTSON, United States District Judge.

OPINION BY: JAMES ROBERTSON

OPINION:

MEMORANDUM

In this case, citizen plaintiffs bring a challenge to provisions of the Federal Food, Drug & Cosmetic Act (FDCA), *21 U.S.C. §§ 301-397*, and the Medicare Prescription Drug, Improvement, and Modernization Act (MPDMA), *21 U.S.C. § 384*, that prohibit the reimportation of prescription drugs from Canada by consumers. The complaint fails to state a claim upon which [*2] relief can be granted, and it will be dismissed.

Background

Plaintiffs Ray and Gaylee Andrews allege that they are a married couple residing in Chicago; that they are both 75 years old; that they take prescription drugs for arthritis, asthma, diabetes, emphysema, high blood pressure and replaced hips; that these drugs cost them about $ 1,100 per month; that they have almost depleted their life savings in order to pay for the prescription drugs they need; that they have both begun to work again to supplement their retirement and Social Security incomes and in order to qualify for health care benefits; that at some time in the future they will be forced to choose between purchasing medications and purchasing food or other essentials; that if they could buy their medications from Canada, they would save about $ 400 - $ 500 per month; that if it were lawful, they would purchase their medications from Canada; but that because it would be unlawful they have never done so.

The Andrews seek a declaratory judgment that the statutory prohibition on the reimportation of prescription drugs by consumers, *21 U.S.C. § 381(d)(1)*, violates their substantive due process [*3] rights under the *Fifth Amendment*. They also challenge, as arbitrary, capricious, and contrary to law, *5 U.S.C. § 706(2)(A)*, the refusal of the Secretary of Health and Human Services to issue the certifications to Congress under *21 U.S.C. § 384(l)* that would be necessary to trigger certain waivers of the reimportation ban.

The government moves to dismiss pursuant to *Rule 12(b)(1)* for lack of subject matter jurisdiction and, alternatively, pursuant to *Rule 12(b)(6)* for failure to state a claim on which relief can be granted.

On a motion to dismiss, all facts, and all inferences drawn from those facts, are "liberally construed ... in the plaintiff's favor." *Andrx Pharms., Inc. v. Biovail Corp. Int'l, 347 U.S. App. D.C. 178, 256 F.3d 799, 805 (D.C. Cir. 2001)*. "'However, the court need not accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations.'" Id. (quoting *Kowal v. MCI Communications*

Corp., 305 U.S. App. D.C. 60, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

Article III [*4] Standing

When their standing to sue is challenged, as it has been here, the plaintiffs must demonstrate they have suffered an injury in fact, that the injury is traceable to the defendants' conduct, and that there is a likelihood that this court may redress the injury. *Bhd. of Locomotive Eng'rs v. United States, 322 U.S. App. D.C. 45, 101 F.3d 718, 723 (D.C. Cir. 1996).* The injury must be "'concrete and particularized and actual or imminent, not conjectural or hypothetical.'" *Flynt v. Rumsfeld, 359 U.S. App. D.C. 402, 355 F.3d 697, 702 (D.C. Cir. 2004)* (quoting *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 119 L. Ed. 2d 351, 112 S. Ct. 2130 (1992)).* It may either be current and actual, or threatened to occur in the near future. *Northwest Airlines v. FAA, 254 U.S. App. D.C. 150, 795 F.2d 195, 201 (D.C. Cir. 1986).*

These plaintiffs plead present injury. They claim that they are currently deterred from purchasing more affordable medicines from Canada. They claim that, if they were to purchase their medications from Canada and if those medications were seized as other medications have been seized in the past, Second Am. Compl. [*5] P 28; Mot. Dismiss 10 n. 3; Pl. Resp. Ex. A (in "blitz" seizures conducted by U.S. Customs at postal facilities), they could not afford to purchase substitute medicines. They allege -- and their allegation must be taken as true for purposes of the instant motion -- that the current statutory scheme prohibiting the reimportation of prescription medications deters them from purchasing drugs from Canada and thus injures them by requiring them to pay more than they otherwise would. Second Am. Compl. P 28.

Economic injury may amount to injury-in-fact for standing purposes. *National Rifle Ass'n of America v. Magaw, 132 F.3d 272, 282 (6th Cir. 1997)* ("'economic injury which is traceable to the challenged action' satisfies the requirements of Article III standing") (citing *Linton v. Commissioner of Health & Environment, 973 F.2d 1311, 1316 (6th Cir. 1992)).* Citing *Brotherhood of Locomotive Engineers, 322 U.S. App. D.C. 45, 101 F.3d 718 (D.C. Cir. 1996),* plaintiffs allege that the defendants' policies "impose substantial, unrecoverable financial losses on them." Id. at PP 17, 19. Union members in that case were held to have shown [*6] injury from the loss of job protections even without evidence that any union member would actually lose his job. Just so, the Andrews need not order medications, have them seized, and then forego either their prescription medications or other basic necessities in order to demonstrate injury sufficient for standing purposes. Their allegation of injury is sufficiently current, particularized, and actual to meet the requirements of Article III. n1

n1 I have also considered whether the issues plaintiffs present are ripe, that is, whether they are fit for judicial resolution and what hardships the Andrews would suffer if the court withheld its consideration. *Village of Bensenville v. FAA, 363 U.S. App. D.C. 78, 376 F.3d 1114, 1119 (D.C. Cir. 2004).* The Andrews are senior citizens working in their retirement years and struggling financially to pay domestic prices for their prescriptions. They have gone on record to say they want to purchase cheaper drugs from Canada and have inquired at Canadian pharmacies about doing so, but that they are unwilling and unable to break the law. The issues the plaintiffs present are legal in nature and may be decided without further factual development. *Nuclear Energy Institute, Inc. v. EPA, 362 U.S. App. D.C. 204, 373 F.3d 1251, 1313 (D.C. Cir. 2004).* The hardship they suffer is real, and would continue if the court postponed its review.

[*7]

Substantive Due Process Claim

The scrutiny a court employs to test a statute or regulation's validity under the *due process clause* depends on whether or not that statute or regulation implicates a fundamental right. Fundamental rights recognized under *Fifth Amendment* jurisprudence receive the strictest scrutiny, requiring proof that the statute or regulation is narrowly tailored to further a compelling state interest. *Troxel v. Granville, 530 U.S. 57, 65, 147 L. Ed. 2d 49, 120 S. Ct. 2054 (2000); Washington v. Glucksberg, 521 U.S. 702, 720-21, 138 L. Ed. 2d 772, 117 S. Ct. 2258, 117 S. Ct. 2302 (1997).* If a statute implicates no fundamental right, the court considers only whether the law is rationally related to furthering a legitimate government interest, and the government is granted much more deference. *Glucksberg, 521 U.S. at 766* (Souter, J. concurring) (rational basis test presumes constitutionality).

The right to purchase drugs from a preferred source or at a preferred price -- if there is such a right at all -- is not fundamental. Many courts have held that there is no fundamental right to choose a particular medical treatment. Eg. *Rutherford v. United States, 616 F.2d 455, 456-57 (10th Cir. 1980)* [*8] (no privacy right to access drugs not approved by the FDA); *Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980)* (same); *Garlic v. FDA, 783 F. Supp. 4, 5 (D.D.C. 1992)* (same). Certain rights pertaining to health-related and medical choices are protected by the Constitution, eg. *Roe v. Wade, 410 U.S. 113, 35 L. Ed. 2d 147, 93 S. Ct. 705 (1973),*

Carey v. Population Services International, 431 U.S. 678, 52 L. Ed. 2d 675, 97 S. Ct. 2010 (1977), *Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990)*, but the plaintiffs' argument for extending constitutional protection to the rights they assert is unsupported. See *Glucksberg, 521 U.S. at 720* (Supreme Court reluctant to expand rights protected under substantive due process); *Dronenburg v. Zech, 239 U.S. App. D.C. 229, 741 F.2d 1388, 1396 (D.C. Cir. 1984)* (lower courts should not "freely create new constitutional rights").

The reimportation ban easily withstands rational basis scrutiny. The FDA's interest in ensuring the safety of prescription medications is a legitimate governmental interest. The statutory scheme of which [*9] plaintiffs complain reasonably furthers this legitimate interest by shielding the public from reimported drugs that may be adulterated or otherwise unsafe. The plaintiffs make no point that requires a response when they argue that a prohibition on drug reimportation also prevents access to safe and unadulterated medications. The reimportation ban implicates no fundamental interest and the government is under no duty to tailor its regulation more narrowly.

APA Claim

The plaintiffs' Administrative Procedure Act claim is that the Secretary's refusal to make the certifications necessary to trigger *§ 384 of the MPDMA* is arbitrary and capricious and contrary to law. *Section 384* provides that the Secretary may waive the prohibition on reimportation of drugs from Canada for certain groups and individuals, but the section does not become law until the Secretary certifies that its implementation would "pose no additional risk to the public's health and safety" and "result in a significant reduction in the cost of covered products to the American consumer." n2 The fact that the Secretary has not made these certifications does not constitute reviewable final agency action.

> n2 "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." *21 U.S.C. § 384(b)*. "Waiver authority ... The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate." *21 U.S.C. § 384(j)(2)(A)*. "This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will - (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." *21 U.S.C. § 384(l)(1)*.

[*10]

The Secretary has not refused to issue a *§ 384* certification in response to a citizen petition, an adjudicatory decision, or as part of a rulemaking. He has only stated in response to a letter signed by sixteen United States Senators that he was "unable to make the determinations" Congress required to trigger the MPDMA's waiver provisions. A response to a senatorial inquiry is not final agency action reviewable under the APA. See *Indep. Equipment Dealers Ass'n v. EPA, 362 U.S. App. D.C. 53, 372 F.3d 420, 427 (D.C. Cir. 2004)* (term "agency action" not so broad to authorize review of every agency action) (citing *Hearst Radio Inc. v. FCC, 83 U.S. App. D.C. 63, 167 F.2d 225, 227 (D.C. Cir. 1948))*.

Since the Secretary's response to the senatorial inquiry the FDA has rejected citizen petitions from several states requesting waivers under the MDMA, but those actions are not final agency action either. The MPDMA prohibits the Secretary from making a *§ 384* certification: "The Secretary shall not submit a certification under subparagraph (A) unless," "after a hearing on the record," he makes a series of findings as outlined in the statute. *21 U.S.C. § 384(l)(2)(B)* [*11] . Thus, in its written response to the petition of Governor Blagojevich of Illinois for a waiver of the FDA reimportation ban, the agency stated it had no choice but to deny the request for waiver because drug reimportation was still illegal under the law, see *Indep. Equipment Dealers, 372 F.3d at 427* (agency's expression of its view of what the law requires not reviewable), and informed the Governor that Secretary Thompson had created a task force to address the required certifications and was still evaluating whether he could make them. Letter from Thompson to Jeffords, Second Am. Comp. P 19. See *Barrick Goldstrike Mines Inc. v. Browner, 342 U.S. App. D.C. 45, 215 F.3d 45, 48 (D.C. Cir. 2000)* (final agency action is neither tentative nor interlocutory). The denial of this and other states' petitions for waivers was required under the law of the MPDMA, and does not constitute a refusal by Secretary Thompson to make the certifications necessary to trigger *§ 384*'s waiver authority. See *Indep. Equipment Dealers, 372 F.3d at 427* (EPA letter response that is informational in nature and does not announce a new interpretation [*12] or effect change in regulations is not reviewable agency action).

Even if the FDA's denials of the states' petitions was final agency action, the Andrews have no standing to litigate the states' claims. *Powers v. Ohio, 499 U.S. 400,*

411, 113 L. Ed. 2d 411, 111 S. Ct. 1364 (1991) (litigant bringing claim on behalf of third party must show injury in fact, close relation to third party, and hindrance to third party's ability to protect its own interests).

The parties have discussed a theoretical APA claim for unreasonable delay that is not found in plaintiffs' second amended complaint. It will not be addressed. An appropriate order accompanies this memorandum.

JAMES ROBERTSON

United States District Judge

ORDER

For the reasons stated in the accompanying memorandum, the defendants' motion to dismiss the second amended complaint [# 28] is **granted**. Defendants' first motion to dismiss [# 14] and motion for clarification [# 21] are **denied as moot**.

JAMES ROBERTSON

United States District Judge