

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CORRECTED SUMMARY ORDER

Rulings by summary order do not have precedential effect. Citation to summary orders filed after January 1, 2007, is permitted and is governed by this court's Local Rule 32.1 and Federal Rule of Appellate Procedure 32.1. In a brief or other paper in which a litigant cites a summary order, in each paragraph in which a citation appears, at least one citation must either be to the Federal Appendix or be accompanied by the notation: "(summary order)." A party citing a summary order must serve a copy of that summary order together with the paper in which the summary order is cited on any party not represented by counsel unless the summary order is available in an electronic database which is publicly accessible without payment of fee (such as the database available at <http://www.ca2.uscourts.gov/>). If no copy is served by reason of the availability of the order on such a database, the citation must include reference to that database and the docket number of the case in which the order was entered.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 24th day of July, two thousand and eight.

PRESENT:

JOSÉ A. CABRANES,
RICHARD C. WESLEY,
J. CLIFFORD WALLACE*,
Circuit Judges.

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DEPARTMENT OF HEALTH AND HUMAN
SERVICES, U.S. FOOD AND DRUG ADMINISTRATION,

Defendant-Appellant,

-v.-

No. 07-0453-cv

RxUSA WHOLESALE, INC., et al,

Plaintiffs-Appellees.

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* The Honorable J. Clifford Wallace, United States Court of Appeals for the Ninth Circuit, sitting by designation.

APPEARING FOR APPELLANT:

IRENE M. SOLET, Attorney (Peter D. Keisler, Assistant Attorney General, Douglas N. Letter, Attorney, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC; Roslynn R. Mauskopf, United States Attorney, Vincent Lipari, Assistant United States Attorney, United States Attorney's Office for the Eastern District of New York, Brooklyn NY; Daniel Meron, General Counsel, Sheldon T. Bradshaw, Chief Counsel Food and Drug Division, Eric M. Blumberg, Deputy Chief Counsel for Litigation, Jennifer Caruso, Attorney, United States Department of Health and Human Services, Rockville, MD, *of Counsel*), Appellate Staff, Civil Division, United States Department of Justice, Washington, DC.

Arthur Y. Tsien, (Richard L. Frank, Philip C. Olsson, Jonathan M. Weinrieb, *of Counsel*) Olsson Frank & Weeda PC, Washington, DC, *for Amicus Curiae Healthcare Distribution Management Ass'n.*

APPEARING FOR APPELLEES:

MICHAEL L. LEVINE, Scarsdale, NY.

Richard W. Cohen, (Peter D. St. Phillip, Jr., *on the brief*), Lowey Dannenberg Bemporad Selinger & Cohen, P.C., White Plains, NY, *for Amicus Curiae Nat'l Coalition of Pharmaceutical Dist., Inc.*

Appeal from an order of the United States District Court for the Eastern District of New York (Joanna Seybert, *Judge*).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the District Court's preliminary injunction is **AFFIRMED**.

Defendant-Appellant, the U.S. Food and Drug Administration (FDA), appeals from an order of the District Court entering a preliminary injunction enjoining the FDA from implementing 21 C.F.R. § 203.50(a). *See RxUSA Wholesale, Inc. v. Department of H.H.S.*, 467 F.Supp.2d 285 (E.D.N.Y. 2006). We assume the parties' familiarity with the underlying facts, the procedural history, and the issues on appeal.

To succeed on its motion for preliminary injunction, RxUSA Wholesale, Inc. (RxUSA) was required to demonstrate "(i) irreparable harm absent the injunction and (ii) a likelihood of success on the merits." *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005). On appeal to our Court, the FDA has not directly challenged the District Court's holding on irreparable harm.

To succeed on the merits of its claim, RxUSA must demonstrate that the FDA's implementation of 21 C.F.R. § 203.50(a) is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Because this case came before the District Court in the context of a preliminary injunction, the court was not required to determine with certainty whether the FDA's actions were arbitrary or capricious, but merely whether RxUSA had a "better than 50 percent" chance of proving them so. *Mohammed v. Reno*, 309 F.3d 95, 100-01 (2d Cir. 2002) (quotation marks omitted). The factual findings and conclusions of law made by the District Court in granting a preliminary

injunction are not binding in subsequent proceedings before the Court. *See, e.g., Irish Lesbian and Gay Org. v. Giuliani*, 143 F.3d 638, 644 (2d Cir. 1998) (“Ordinarily, findings of fact and conclusions of law made in a preliminary injunction proceeding do not preclude reexamination of the merits at a subsequent trial”); *see also University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (“The findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits . . . [because] a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits”). Our review of the District Court’s order, accordingly, does not render any of its conclusions of law or factual findings binding in later proceedings. We review the District Court’s order for an abuse of discretion. *Alleyn v. New York State Educ. Dept.*, 516 F.3d 96, 100 (2d Cir. 2008).

In deciding whether the FDA’s actions were arbitrary or capricious, the District Court began by examining the underlying statute in order to determine “whether Congress has directly spoken to the precise question at issue.” *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842 (1984). As amended, the Prescription Drug Marketing Act (PDMA) requires that each person engaged in the wholesale distribution of a prescription drug must provide a statement “identifying each prior sale, purchase, or trade of such drug.” 21 U.S.C. § 353(e)(1)(A). The statute does not specifically state whether this identification must extend back to the manufacturer, or whether it must only extend to the last authorized distributor. The parties offer differing textual interpretations, but we agree with the District Court that for purposes of preliminary injunction the statute’s language does not unambiguously compel one interpretation over another.

Because it concluded Congress has not unambiguously spoken on the issue, the District Court next considered whether the FDA’s interpretation was “arbitrary and capricious” under the Administrative Procedures Act. *See New York Pub. Interest Research Group, Inc. v. Johnson*, 427 F.3d 172, 179 (2d Cir. 2005). The District Court did not abuse its discretion when it held that RxUSA had demonstrated a likelihood of success on this question.

Under the PDMA, all authorized distributors are exempted from the statute’s pedigree requirements. 21 U.S.C. § 353(e)(1)(A). Thus, if the FDA’s regulation were put into effect as written, all lower-level distributors would be required to provide pedigree information that is currently held only by authorized distributors. The court determined that this would effectively make it impossible for lower-level distributors to comply with the law. Moreover, the FDA’s regulation is inconsistent with the position taken by the agency in its original 1988 guidance letter, and it runs directly counter to the 20-year history of industry reliance on the FDA’s initial position. For these reasons, the District Court held that RxUSA had a fifty-percent or greater chance of showing that the regulation was arbitrary and capricious. This was not an abuse of discretion.

The District Court concluded that, for the purposes of the preliminary injunction, the statute survived rational basis review, *see RxUSA*, 467 F.Supp.2d at 290. The Court also construed RxUSA’s challenge to the regulation as a question of whether the FDA’s regulation is potentially arbitrary and capricious in light of the PDMA’s exemption of authorized distributors and the current practice in the industry and concluded that RxUSA had demonstrated a likelihood of success on the merits of this argument. We find no reason to disturb these conclusions.

Finally, the FDA argues that the District Court’s preliminary injunction is overbroad because it enjoins the implementation of even those innocuous subsections of 21 C.F.R. § 203.50(a) that RxUSA does not specifically challenge. On appeal, the FDA makes the factual assertion that the first five subsections of 203.50(a) call for information that is “apparent from the drug’s labeling, and . . . readily available to plaintiffs and other non-authorized wholesale purchasers upon receipt of the drugs.”

The drug distribution industry has been operating for the past 20 years on the basis of guidelines issued by the FDA in 1988. Under those guidelines, each wholesale drug transaction already requires disclosure of “(a) the business name and address of the source from which the drug was purchased, (b) the date of the sale, and (c) the identity, strength, container size, number of containers, and lot number(s) of the drug.” FDA Guidance Letter, Aug. 1, 1988, No. 88N-258L. These requirements are very similar to those contained in subsections (1) through (5) of the enjoined regulation. Therefore, given the District Court’s intention of merely “maintaining the status quo” until it could determine the constitutionality of the regulation, it was not an abuse of discretion for the court to refuse a piecemeal enforcement of the FDA’s regulation in favor of reliance on the prevailing industry practice.

The District Court’s preliminary injunction is **AFFIRMED**.

FOR THE COURT,

Catherine O’Hagan Wolfe, Clerk of Court

By _____