

# 07-0453-cv

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

RxUSA WHOLESALE, INC., ET AL.,

Plaintiffs-Appellees,  
v.

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

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR THE APPELLANT AND SPECIAL APPENDIX

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
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BRIEF FOR THE APPELLANT

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**PRELIMINARY STATEMENT**

The decision appealed from was rendered by the Hon. Joanna Seybert, United States District Judge for the Eastern District of New York. The decision is reported at 467 F. Supp. 2d 285 (E.D.N.Y. 2006).

**JURISDICTIONAL STATEMENT**

The district court had subject matter jurisdiction pursuant to 28 U.S.C. 1331. The district court granted a preliminary injunction in an order issued on December 11, 2006 (Special Appendix ("SPA") 1-22). The defendant, the Food and Drug Administration ("FDA"), filed a notice of appeal on February 1, 2007 (Joint Appendix ("JA") A385-A386). That appeal was timely

pursuant to Rule 4(a)(1), Fed. R. App. P. The appeal is from an order granting an injunction, and this Court therefore has jurisdiction pursuant to 28 U.S.C. 1292(a).

### **STATEMENT OF THE ISSUES**

In the Prescription Drug Marketing Act, Congress mandated numerous measures to minimize the risk that substandard, ineffective, and counterfeit prescription drugs will reach American consumers. Crucial among these measures is a requirement that non-authorized wholesalers of prescription drugs provide their customers with a statement identifying "each" prior sale of the drug, language mirrored in FDA's implementing regulation. This requirement for a complete history of prior transactions, contained in both the statute and the regulation, is a direct outgrowth of an extensive Congressional investigation revealing a secondary market in which the true sources of prescription drugs were concealed and problem drugs were therefore easily introduced into the market. At plaintiffs' urging, however, the district court has effectively enjoined FDA's implementation of the statutory scheme, holding that the term "each" (which appears in both the statute and the agency's regulation) does not mean "each" prior sale, but rather only some. The questions presented in this appeal are:

1. Whether the district court's preliminarily injunction barring implementation of FDA's prescription drug "pedigree

regulation" (21 C.F.R. 203.50(a)) must be vacated because, as a matter of law, the regulation properly interprets 21 U.S.C. 353(e) (1) (A) to require non-authorized wholesalers of prescription drugs to provide customers with complete sales histories for those drugs extending back to their manufacturers.

2. Whether, if this Court agrees that FDA properly interpreted the statute, the pedigree provision of the statute comports with equal protection and due process principles.

3. Whether, even if this Court concludes that preliminary relief is appropriate, the district court's injunction is too broad because it extends to provisions of the pedigree regulation that are unrelated to plaintiffs' merits arguments.

#### **STATEMENT OF THE CASE**

This case involves an attack by plaintiffs on a federal statute (and FDA's implementation of it), which was designed by Congress to address the serious public health problem caused by diversion of prescription drugs through a secondary market where the drugs' true sources were unknown and drugs that were substandard or worse could thus easily be sold to witting or unwitting buyers. The district court entered a preliminary injunction against operation of FDA's enforcement regulation, and thereby put on hold a crucial component of the statutory scheme.

Plaintiffs are non-authorized wholesalers of prescription drugs -- that is, they are wholesalers who do not have ongoing

distribution relationships with the manufacturers of the drugs they sell. Docket No. 1 (Complaint) at 4-6 (JA A9-A11). They brought this action in the district court against FDA, seeking a declaratory judgment that the agency's regulation requiring such non-authorized wholesalers to transmit to customers statements ("pedigrees") listing all previous sales of the drugs extending back to the manufacturer erroneously interprets 21 U.S.C. 353(e)(1)(A), and violates the Constitution's guarantees of equal protection and due process. Alternatively, in the event of a determination by the court that the pedigree regulation properly interprets 21 U.S.C. 353(e)(1)(A), plaintiffs sought a declaration that the statute itself violates those two constitutional guarantees. Id. at 22-24 (JA A27-A29).

On November 22, 2006, before FDA had filed its answer, plaintiffs moved in the district court for a preliminary injunction against implementation of the regulation, which was scheduled to become effective on December 1, 2006. Docket No. 4. The motion did not, however, seek to enjoin operation of the underlying statute if the regulation were found to interpret it properly. Id.

The district court referred the motion to a magistrate judge, who issued a report and recommendation on November 30, 2006. RxUSA Wholesale, Inc. v. Dep't of Health & Human Servs., 467 F. Supp. 2d 285, 292-308 (E.D.N.Y. 2006) ("RxUSA Wholesale")

(SPA 9-22). The magistrate judge concluded that plaintiffs had not demonstrated a substantial likelihood that the regulation would be found inconsistent with the statute. Id. at 303 (SPA 18). She nevertheless recommended entry of a preliminary injunction against implementation of the regulation on the ground that plaintiffs had shown a substantial likelihood of success on their claim that the statute itself lacked a rational basis, and was thus unconstitutional. Id. at 305 (SPA 19-20).

Following submission of objections by FDA, the district court preliminarily enjoined implementation of the pedigree regulation, but on grounds quite different from those suggested by the magistrate judge. RxUSA Wholesale, 467 F. Supp. 2d at 285-92 (SPA 1-8). The court rejected the magistrate judge's conclusion that the statute lacked a rational basis. Id. at 290 (SPA 6). Nevertheless, the court determined that plaintiffs had shown a likelihood of success on the merits of their claim of law because, in the court's view, the pedigree regulation undermined the purpose of the statute and was therefore arbitrary and capricious. Id. at 291 (SPA 7). The court also found that issuance of a preliminary injunction would benefit the public interest by preserving the status quo. Id. at 292 (SPA 8).

This appeal followed.

## STATEMENT OF FACTS

### A. Statutory and Regulatory Background.

Prompted by the 1984 discovery, by drug manufacturer G.D. Searle and Company, that nearly two million bogus and ineffective copies of its Ovulen 21 birth control pill had been imported from Panama and offered for sale as genuine to American consumers, a House of Representatives subcommittee embarked upon an investigation that led eventually to enactment of the Prescription Drug Marketing Act of 1987 ("PDMA"), Pub. L. No. 100-293, 102 Stat. 95 (1988). See STAFF OF H.R. COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, 99TH CONG., DRUG DIVERSION 1 (Comm. Print 1985) ("Drug Diversion Report" by "Oversight Subcommittee").

In enacting the PDMA (which amended the Federal Food, Drug, and Cosmetic Act), Congress found that the lack of controls on prescription drug distribution had created an unacceptable risk that "substandard, ineffective, or even counterfeit drugs" would be sold to American consumers. Pub. L. No. 100-293, § 2(2), 102 Stat. 95. Congress further found that the true source of prescription drugs was unknown in a significant number of cases due to the existence of a "wholesale submarket, commonly known as the 'diversion market.'" Id. § 2(3). Congress identified several sources of products fueling this diversion market: American-manufactured drugs reimported into the United States

(which might have become subpotent or adulterated during foreign handling and shipping), foreign counterfeits passed off as reimported American drugs, drug samples provided to physicians through manufacturers' representatives, and resales of large quantities of drugs by healthcare institutions that had purchased them at steep discounts from manufacturers. Id. §§ 2(4)-(7).

As the Oversight Subcommittee investigation revealed, the common element of all of these conduits to the diversion market was that the drugs in question had initially been purchased by wholesalers at steeply discounted prices, which made possible large margins upon resale. Drug Diversion Report at 2; see also Prescription Drug Diversion and Counterfeiting - Part I: Hearings Before the Subcomm. on Oversight & Investigations of the H.R. Comm. on Energy & Commerce ("House Hearings Part I"), 99th Cong. 4-8 ((1985) (statement of Stephen F. Sims, Special Assistant, Oversight Subcommittee).<sup>1</sup> Although not all "diverted" drugs were

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<sup>1</sup>This did not mean lower prices for consumers, however. As the Oversight Subcommittee heard from a federal prosecutor who had conducted a broad criminal investigation into drug diversion:

The low purchase prices obtained by diverters  
\* \* \* are not passed on to the ultimate  
consumers. Instead, the drugs are resold  
through many levels within the secondary  
diversionary distribution system with the  
initial diverter usually doubling his money,  
and subsequent purchasers also making  
substantial profits, until the ultimate  
consumer is given a miniscule discount, if  
there is any discount at all.

(continued...)

substandard or counterfeit, these diversion channels provided a prime gateway for problem products to enter the marketplace and be sold to the public.

To minimize that risk, Congress in the PDMA incorporated a variety of tools, including a requirement that certain wholesalers of prescription drugs provide an identifying statement, known as a "pedigree," prior to each wholesale distribution of prescription drugs.<sup>2</sup> Specifically, as enacted in 1988, the PDMA provided:

Each person who is engaged in the wholesale distribution of drugs \* \* \* and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor.

Pub. L. No. 100-293, § 6, 102 Stat. 98 (emphasis added). This provision expressly exempted "authorized distributor[s] of record" ("ADRs") from the obligation to provide pedigrees to subsequent purchasers. ADRs were defined as "those distributors

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<sup>1</sup>(...continued)  
House Hearings Part I at 300 (statement of Larry D. Thompson, U.S. Attorney for the Northern District of Georgia).

<sup>2</sup>Other provisions of the statute placed limitations on the reimportation of prescription drugs, banned the sale of drug samples and placed controls on their distribution, and prohibited most resales of drugs purchased by healthcare institutions for their own use. Pub. L. No. 100-293, §§ 3-5, 102 Stat. 96-98.

with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products." Id.<sup>3</sup>

Less than four months after the PDMA's enactment, FDA issued a guidance letter to the regulated industry. Docket No. 9 Exhibit A ("1988 guidance letter") (JA A362-A375). The letter announced FDA's intention to engage in notice-and-comment rulemaking to adopt regulations implementing the statute, and provided information to guide regulated entities until that process could be accomplished. Id. at 1 (JA A362). The letter expressly cautioned that it was "not intended to bind FDA should events occur prior to the issuance of a rule that require a change in FDA's policy." Id. With respect to the PDMA's pedigree requirement, the letter included (as relevant here) the following guidance:

5. Statement identifying prior sales. FDA requests that the statement identifying prior sales of prescription drugs by unauthorized distributors be in writing, that it bear the title "Statement identifying Prior Sales of Prescription Drugs by Unauthorized Distributors Required by the Prescription Drug Marketing Act," and that it include all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record.

Id. at 12 (emphasis added) (JA A373).

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<sup>3</sup>Amendments to the PDMA have not altered this definition, which is codified at 21 U.S.C. 353(e)(3)(A).

As FDA has subsequently explained, at the time of the PDMA's enactment and this letter's issuance, most prescription drugs "pass[ed] in a linear manner from a manufacturer to a retail outlet through a primary, or authorized, distributor of record \* \* \*." See DEPARTMENT OF HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMINISTRATION, THE PRESCRIPTION DRUG MARKETING ACT REPORT TO CONGRESS (2001) ("Report to Congress") 20-23 (JA A281-A283).<sup>4</sup> Thus, when the guidance was issued, a drug pedigree that extended back to the manufacturer or the ADR would have provided the purchaser with the protection of knowledge of the product's complete sales history.

In the Prescription Drug Amendments of 1992, Pub. L. No. 102-353, 106 Stat. 941, Congress slightly amended the pedigree provision but did not significantly alter its operative language. As amended there and currently codified, the provision states:

Each person who is engaged in the wholesale distribution of [a prescription drug] and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who

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<sup>4</sup>A link to the report (in "pdf" format) as it was submitted to Congress, with correct pagination, can be found at <http://www.fda.gov/oc/pdma/report2001/>. A differently paginated version of the report was submitted to the district court, and that version is therefore included in the Joint Appendix. For accuracy and for the Court's convenience, we will cite specific portions of the report both by their original page numbers, and by their location in the Joint Appendix.

receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

Id. § 4(e) (21 U.S.C. 353(e)(1)(A)) (emphasis added).

On March 14, 1994, FDA issued a proposed rule implementing certain provisions of the PDMA as amended, including the pedigree provision. 59 Fed. Reg. 11842, 11856-57 (Mar. 14, 1994). The agency subsequently promulgated a final rule, which includes the key statutory text, making no change in the language of the proposed regulation addressing drug pedigrees. 64 Fed. Reg. 67720, 67747 (Dec. 3, 1999). In relevant part, that regulation states:

Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

\* \* \* \* \*

(6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer;

64 Fed. Reg. at 67761 (21 C.F.R. 203.50(a)) (emphasis added).<sup>5</sup>

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<sup>5</sup>Other subsections of the pedigree regulation require the statement provided by non-authorized wholesalers to include the  
(continued...)

In promulgating the final regulations, FDA reported that this provision had provoked only one comment, which recommended that the required pedigree be limited to extend back only to the last previous sale by an ADR. 64 Fed. Reg. at 67747. Rejecting this suggestion, the agency explained that the statute's plain language required information about "each" prior sale, purchase, or trade, and noted that there was no indication that Congress intended to include only transactions following the last handling of the drug by an authorized distributor. Id. Although the regulation departed from the agency's 1988 guidance letter by extending the required pedigree to include the drug's sale by its manufacturer, FDA has explained that this revision was necessary, in light of changed marketing patterns, to achieve what the agency had always viewed as Congress's intent in the pedigree provision of the statute -- that is, a complete transaction history. See Report to Congress at 22 (JA A283).

As we noted previously, the statute defines ADRs as distributors who have an "ongoing relationship to distribute [the] manufacturer's products." 21 U.S.C. 353(e)(3)(A). The implementing regulations as promulgated in final form define

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<sup>5</sup>(...continued)  
proprietary and established name of the drug, its dosage, the container size, the number of containers in the transaction, the drug's lot or control number(s), and the date of each previous transaction. 21 C.F.R. 203.50(a)(1)-(5) and (7). The last of these, the transaction date, mirrors a requirement in the statute itself. See 21 U.S.C. 353(e)(1)(A).

"ongoing relationship" to mean that the distributor has a "written agreement" to distribute the manufacturer's entire product line or specific identified products. 64 Fed. Reg. at 67757 (21 C.F.R. 203.3(u)).

The final regulations were originally scheduled to become effective on December 4, 2000 (see 64 Fed. Reg. at 67721), but FDA postponed the effective date of certain provisions including the pedigree regulation. See 65 Fed. Reg. 25639 (May 3, 2000). The delay was occasioned by numerous comments that followed promulgation of the final rule (from industry, trade associations, and Members of Congress, among others) emphasizing inter alia the practical difficulties of compliance with the pedigree regulation by non-authorized distributors in light of the exemption of ADRs from the statutory obligation to supply drug pedigrees to customers. 65 Fed. Reg. at 25640-41. To allow time for further evaluation of the issues raised, FDA set a new effective date of October 1, 2001. Id. at 25641.

In the next FDA appropriations bill, the House Committee on Appropriations directed the agency to review the pedigree regulation's potential impact on the secondary wholesale industry and to report to Congress. H.R. Rep. No. 106-619, at 119 (2000). FDA then extended the stay of the regulation until April 1, 2002 (66 Fed. Reg. 12850 (Mar. 1, 2001)), and submitted its report to Congress in June 2001. JA A273-A304. In that report, the agency

acknowledged that the statutory exemption of ADRs from the pedigree requirement puts non-authorized distributors at a disadvantage and "undermines the purpose of the pedigree by allowing for potential gaps in the distribution history." Report to Congress at 21 (JA A282). FDA also noted that the prescription drug distribution system had changed significantly since enactment of the PDMA in 1988, when most prescription drugs passed in a linear fashion from the manufacturer to an ADR and then directly to a retail outlet. Id. at 20 (JA A281). FDA stated that by June 2001, it had become common for drugs to be sold through multiple primary and secondary wholesalers before being sold to a retail outlet. Id. (JA A281-A282). The agency concluded, however, that it lacked authority to require ADRs to provide pedigrees because the statute plainly exempts ADRs from the pedigree requirement. Id. at 22 (JA A283).

After submitting its Report to Congress, FDA continued to defer implementation of the regulations to give Congress time to consider the information the agency had provided and to determine whether legislative action was appropriate. See 67 Fed. Reg. 6645, 6646 (Feb. 13, 2002); 68 Fed. Reg. 4912 (Jan. 31, 2003); 69 Fed. Reg. 8105 (Feb. 23, 2004). In announcing the last of these postponements, FDA noted that, as part of its counterfeit drug initiative, it was working to facilitate the voluntary adoption of track-and-trace technology that would create an

electronic pedigree to trace all transactions back to the manufacturer. The agency stated that it believed adoption of this technology would resolve many of the concerns raised about the pedigree regulations. 69 Fed. Reg. at 8106-07.

In June 2006, however, after soliciting more comment and holding a public meeting, FDA announced that electronic tracking technology was developing more slowly than anticipated and that the agency would not delay implementation of the pedigree regulation any longer (after December 1, 2006). 71 Fed. Reg. 34249 (June 14, 2006). The agency further explained its reasoning in a report by its Counterfeit Drug Task Force, noting that complaints about the potential impact of the pedigree regulation were largely absent from the last round of public comments, which had overwhelmingly favored implementation of the regulations. U.S. FOOD & DRUG ADMINISTRATION, COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE ("2006 Update") 6 (JA A319). FDA also stated that its extensive experience with counterfeit and drug diversion cases indicated that much of the illegal activity in this field occurs in the secondary wholesale market. Id. (JA A320). Finally, FDA observed that Congress had not chosen to amend the statute after receiving the agency's 2001 report, which had outlined the concerns about implementation of the regulations raised in earlier public comments. Id.

**B. This Litigation.**

Plaintiffs in this action, a group of non-authorized wholesalers of prescription drugs, sought a declaratory judgment in the district court that FDA's pedigree regulation imposes an arbitrary and unconstitutional requirement not found in the PDMA, and, alternatively, if the regulation properly interprets the statute, that the PDMA itself violates equal protection principles and the Due Process Clause more generally. Docket No. 1 (Complaint) at 14-21 (JA A19-A26). Prior to FDA's answer to the complaint, plaintiffs sought a preliminary injunction against implementation of the regulation. Docket No. 4. They did not, however, seek to enjoin operation of the statute if the regulation were found to interpret it properly. Id.

The matter was referred to a magistrate judge (Docket No. 5), who issued a report and recommendation. RxUSA Wholesale, 467 F. Supp. 2d at 292-308 (SPA 9-22). The magistrate judge concluded that the language of the pedigree regulation "closely mirrors" the relevant language of the statute, and that plaintiffs therefore had not demonstrated a substantial likelihood of success on their claim that "the new Rule, by itself, is inconsistent with the language and intent of the PDMA." Id. at 303 (SPA 18). Despite the fact that plaintiffs had not sought an injunction against enforcement of the PDMA itself, the magistrate judge nevertheless recommended that a

preliminary injunction be granted, concluding that plaintiffs were substantially likely to prevail on their claim that the statute violates equal protection. In particular, the magistrate judge found that the statutory exemption of ADRs from the pedigree requirement made it impossible for non-authorized distributors to comply, that Congress did not intend this result, and that the exemption therefore was not rationally related to the PDMA's purposes of ensuring the integrity of the drug distribution system and preventing the distribution of counterfeit, adulterated, misbranded, or otherwise unsafe drugs. Id. at 304-05 (SPA 18-20). FDA then submitted its objections. Docket No. 15.

The district court took a very different approach from the magistrate judge. RxUSA Wholesale, 467 F. Supp. 2d at 285-92 (SPA 1-8). The court rejected the magistrate judge's determination that the PDMA had no rational basis, focusing instead on plaintiffs' challenge to FDA's pedigree regulation. Id. at 289-90 (SPA 6). Although acknowledging that an agency's interpretation of a statute it administers is normally entitled to considerable deference, the court said that it would review this regulation with "more exacting vigilance" because, in the court's view, the regulation departed from a longstanding position that FDA had taken soon after the PDMA's enactment. Id. at 289 (SPA 6) (internal quotation marks omitted).

Quoting but not analyzing the language of 21 U.S.C. 353(e)(1)(A), the court concluded that the statute -- unlike FDA's regulation -- does not "specifically or expressly require[] unauthorized distributors to provide pedigree information all the way back to the manufacturer." 467 F. Supp. 2d at 290 (SPA 7). The court accepted plaintiffs' representations that they would be unable to comply with this regulatory requirement because they must purchase their inventory from authorized distributors, who refuse to provide pedigree information. Id. at 291 (SPA 7). In the court's view, this impossibility of compliance would "essentially wipe out all the unauthorized distributors." Id. With ADRs exempt by statute from the pedigree requirement, "none of the drugs ultimately going to the American consumer would contain pedigree information," and the PDMA's purpose thus would be thwarted, the court concluded. Id. The court therefore determined that plaintiffs had shown a likelihood of success on the merits of their legal claim that the regulation is arbitrary and capricious.

Based on this determination, and its finding that the public interest would be served by preservation of the status quo, the court preliminarily enjoined FDA from implementing the entire pedigree regulation, 21 C.F.R. 203.50(a). Id. at 292 (SPA 8). The injunction thus not only prohibited FDA from requiring pedigrees that extend back to the manufacturer, but also from

requiring that non-authorized wholesalers include in the statutorily mandated statements provided to their customers information regarding the name, dosage, lot numbers, and containers of the drugs, and the dates of prior transactions.

#### **STANDARD OF REVIEW**

This Court reviews a district court's grant of a preliminary injunction for abuse of discretion. Field Day, LLC v. County of Suffolk, 463 F.3d 167, 181 (2d Cir. 2006). However, critically for this case, this Court has made clear that a lower court abuses its discretion when its decision rests on an error of law. Id. Although "abuse of discretion" is a "species of deferential appellate review," Zervos v. Verizon New York, Inc., 252 F.3d 163, 168 (2d Cir. 2001), this Court reviews the district court's conclusions of law de novo even in the context of an appeal of a preliminary injunction. Disabled Am. Veterans v. Dep't of Veterans Affairs, 962 F.2d 136, 140 (2d Cir. 1992).

A district court properly grants a prohibitory preliminary injunction that stays government action taken in the public interest pursuant to a statutory or regulatory scheme only where the moving party has demonstrated that (1) absent injunctive relief, he will suffer irreparable injury, and (2) there is a likelihood that he will succeed on the merits of his claim. Mastrovincenzo v. City of New York, 435 F.3d 78, 89 (2d Cir. 2006). Where a district court's finding of likelihood of success

on the merits is premised on a legal error, the preliminary injunction will be reversed. Field Day, LLC, 463 F.3d at 182. And this Court has demonstrated that it will not hesitate, at the preliminary injunction stage, to consider with great thoroughness legal issues that are crucial to the merits. See, e.g., id. at 176-91; Mastrovincenzo, 435 F.3d at 90-102. Where it concludes that the district court erred in finding that the moving party has demonstrated a likelihood of success on the merits, this Court will vacate the preliminary injunction, and, in that event, consideration of whether that party will be irreparably harmed absent the injunction becomes unnecessary. Disabled Am. Veterans, 962 F.2d at 144.

A court's review of an agency's construction of a statute that it administers is governed by the framework established in Chevron U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984). "Under this framework, a court defers to the statutory interpretation of an agency authorized to implement the statutory scheme if the interpretation is (1) not contrary to the clear intent of Congress and (2) reasonable." Chauffer's Training Sch. v. Spellings, 478 F.3d 117, 125 (2d Cir. 2007). The first step of the Chevron analysis ("Chevron Step 1") is to determine "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give

effect to the unambiguously expressed intent of Congress.'" Id.  
(quoting Chevron, 467 U.S. at 842-43).

Where the intent of Congress is not clear, the court moves to the second step under Chevron ("Chevron Step 2"), which is "to determine whether deference to the agency's interpretation of the statute is appropriate." Id. Courts will defer to statutory interpretations of an agency charged with implementing a statutory scheme where the agency's interpretation is reasonable. Id.

#### **SUMMARY OF ARGUMENT**

With the pedigree requirement in the Prescription Drug Marketing Act, Congress sought to prevent distribution of substandard, ineffective, or counterfeit drugs through a secondary market in which the true sources of drugs were obscure. This problem was, and remains, most acute with respect to sales by non-authorized wholesalers, who purchase most of their inventory from sources other than drug manufacturers.

Because only a complete history of prior transactions can provide assurance that drugs are genuine, the statute requires the pedigree statements conveyed by non-authorized wholesalers to cover "each" prior transaction. FDA's implementing regulation repeats that requirement, and explains that it includes all transactions, extending back to the sale of the drug by its manufacturer. In rejecting FDA's regulatory interpretation, the

district court ignored the statute's plain terms and its extensive history. The court thereby frustrated Congress's intent and its strategy for addressing an important public health problem.

1. This Court should not look beyond the plain terms of 21 U.S.C. 353(e)(1)(A) to conclude that Congress intended non-authorized wholesalers to provide their customers with pedigree information extending back to the initial sale of the drug by its manufacturer. Dictionary definitions and common usage confirm that the statutory demand for pedigrees covering "each" prior transaction extends to all prior transactions, including the first. Plaintiffs presented no other plausible reading of the statute's plain terms.

The provision's legislative history reinforces the agency's reading. Reports by both the House and the Senate described the required pedigree statement as extending to "all previous sales of the product." H.R. Rep. No. 100-76, at 17 (1988); S. Rep. No. 100-303, at 7 (1988), as reprinted in 1988 U.S.C.C.A.N. 57, 63.

2. The regulation and the statute are entirely consistent with the Constitution's equal protection and due process guarantees. Congress rationally imposed the pedigree burden on non-authorized distributors, but not on authorized distributors. When the statute was enacted, Congress found that non-authorized distributors were the avenue through which most diverted drugs

entered the retail market and created public health dangers. Even now, the risk is greatest with respect to non-authorized distributors, who buy the bulk of their inventory from sources other than drug manufacturers. In contrast, authorized distributors continue to buy the vast majority of their drugs directly from manufacturers, and thus only a small percentage of their sales can potentially involve diverted drugs. Moreover, Congress could rationally have concluded that, because manufacturers have an economic incentive to "police" the conduct of their authorized distributors, imposing a pedigree requirement on those distributors is less crucial to the goal of controlling drug diversion.

3. Even if this Court agrees with the district court regarding the merits of plaintiffs' statutory or constitutional claims, the scope of the preliminary injunction is manifestly too broad. By prohibiting enforcement of the entire pedigree regulation, the injunction prevents FDA not only from requiring the prescription drug pedigrees mandated by the PDMA to extend back to the manufacturer (subsection (6) of the regulation), but also from requiring that those pedigrees include other specific information about the drugs called for in other portions of the regulation (subsections (1) through (5)). Plaintiffs have not, and cannot, claim that it is impossible for them to supply this additional information, as it is readily apparent on the face of

the drugs' labeling. Although easily available to wholesalers, this information is also highly useful to law enforcement and regulatory officials in tracking drugs from illicit sources. Plaintiffs have asserted no claim, much less a meritorious one, that the regulation's separate requirements for this additional information violate any statutory or constitutional provision. The district court, accordingly, abused its discretion by enjoining FDA from requiring that this information be included in drug pedigrees.

#### **ARGUMENT**

##### **I. FDA'S REGULATION MUST BE UPHELD BECAUSE CONGRESS'S INTENT TO REQUIRE PEDIGREES EXTENDING BACK TO THE MANUFACTURER IS CLEAR IN THE PDMA'S LANGUAGE AND ITS LEGISLATIVE HISTORY.**

The starting point in determining whether the pedigree requirement in the FDA regulation is consistent with 21 U.S.C. 353(e) (1) (A) must be the language of the statute. If that language -- which is repeated in the regulation -- is clear, the inquiry ends. Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992) ("When the words of a statute are unambiguous, \* \* \* judicial inquiry is complete.") (internal quotation marks omitted). This is an inquiry that the district court did not even begin, however. Observing only that the statute did not "specifically or expressly require[] unauthorized distributors to provide pedigree information all the way back to the

manufacturer" (RxUSA Wholesale, 467 F. Supp. 2d at 290 (SPA 7)), the district court neglected to analyze or even address the precise terms of the statute.

As amended, the PDMA requires "[e]ach person who is engaged in the wholesale distribution of [a prescription drug] and who is not the manufacturer or an authorized distributor of record of such drug" to provide each wholesale customer with a statement "identifying each prior sale, purchase, or trade of such drug." 21 U.S.C. 353(e) (1) (A) (emphasis added). FDA's pedigree regulation likewise requires non-authorized distributors to "provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug." 21 C.F.R. 203.50(a) (emphasis added). Further, the regulation requires that statement to include "[t]he business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer." Id. at 203.50(a) (6) (emphasis added). FDA thus interprets the statutory demand for information about "each prior sale, purchase, or trade" to mean all prior transactions, including the first.

Plaintiffs insisted below that, had Congress intended the phrase "each prior sale, purchase, or trade of such drug" in 21 U.S.C. 353(e) (1) (A) to include the first sale (that is, sale of the drug by its manufacturer), Congress would have chosen the term "every" rather than "each." See Docket No. 8 at 4-5. Such

a linguistic substitution would not have altered the provision's scope, however. See Black's Law Dictionary 507 (6th ed. 1990) (defining "[e]ach" as "[a] distributive adjective pronoun, which denotes or refers to every one of the persons or things mentioned; every one of two or more persons or things, composing the whole, separately considered"); The Oxford American Thesaurus of Current English 214 (Christine A. Lindberg, ed., Oxford Univ. Press, 1999) (providing "every" and "every single" as synonyms for the adjective "each").

Significantly, plaintiffs made no attempt to explain how Congress's use of the word "each" in 21 U.S.C. 353(e)(1)(A) can be read to exclude any particular prior transaction, and specifically the first sale, from the scope of the required pedigree. Moreover, plaintiffs did not contend that the pedigree obligation that the same provision imposes on "each person" who engages in the wholesale distribution of a prescription drug and who is not an ADR applies to fewer than all non-authorized distributors -- a position that would be linguistically consistent with their argument that "each prior sale, purchase, or trade" excludes some prior transactions. See id. (emphasis added). Plaintiffs would thus apparently construe "each" to mean two different things in the same provision of the statute.

Use of "each" to mean all that are covered by the noun or nouns that follow is commonplace. Thus, for example, an

insurance contract at issue in Interstate Fire & Casualty Co. v. Pacific Indem. Co., 738 F.2d 638, 639 (4th Cir. 1984), provided that "[w]hen used in reference to this insurance: \* \* \* each claim means all claims or suits brought on account of injury sustained by any one person" (internal quotation marks omitted; emphasis altered). Similarly, a jury instruction at issue in Ammesmaki v. Interlake S.S. Co., 342 F.2d 627 (7th Cir. 1965), provided: "If you find \* \* \* that each, meaning all, of these propositions has been proved by the preponderance of the evidence, then your verdict should be for the third party plaintiff \* \* \*." Id. at 633 (Schnackenberg, J., partly concurring and partly dissenting) (internal quotation marks omitted; emphasis added).

FDA's reading of the plain language of the PDMA to require non-authorized distributors to provide customers with information about all prior sales of the drug, including its sale by the manufacturer, is reinforced by the statute's legislative history.<sup>6</sup> The House Report on the PDMA contains the following description of the scope of the pedigree requirement:

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<sup>6</sup>Consideration of legislative history can be appropriate even at Chevron Step 1. See Langhorne v. Ashcroft, 377 F.3d 175, 180 (2d Cir. 2004) ("[U]nder Chevron, courts are not required to read statutes in a vacuum, but rather may employ the traditional tools of statutory construction in determining legislative intent, including review of the statute's legislative history." (internal quotation marks omitted)).

The Oversight Subcommittee's investigation found that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute the manufacturer's product. Thus, the requirement in this section that wholesale distributors must inform their wholesale customers of all previous sales of the product applies only to wholesale distributors who are not authorized distributors for that product. Authorized distributors, as defined, are exempt from this requirement. Unauthorized distributors are those distributors who do not have an ongoing business relationship with a manufacturer to provide wholesale distribution of that manufacturer's products. Unauthorized distributors will be required to certify in writing to drug wholesalers the source and place from which they obtained their drugs. Manufacturers will be required to maintain, for public review, a current list of all authorized distributors of record.

H.R. Rep. No. 100-76 ("House Report"), at 17 (1988) (emphasis added).<sup>7</sup> This language shows unequivocally that (1) non-authorized distributors were the problem Congress was addressing, and (2) Congress concluded that a complete pedigree (extending to "all previous sales of the product") (id.) was necessary to address that problem.

Plaintiffs relied below on a sentence later in the same paragraph of the report: "Unauthorized distributors will be

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<sup>7</sup>The identical description, minus only the first sentence, occurs in the Senate Report on the legislation. S. Rep. No. 100-303 ("Senate Report"), at 7 (1988), as reprinted in 1988 U.S.C.C.A.N. 57, 63.

required to certify in writing to drug wholesalers the source and place from which they obtained their drugs." Id. (emphasis added); see Doc. 8 at 5. Even viewed in isolation from its context (as plaintiffs urged the district court to do), this sentence does not support their position below that the statute requires pedigrees that extend back to the last sale by an authorized distributor (see Docket No. 16 at 19). On its face, the sentence describes a much shorter pedigree, which would include information about only a single transaction -- the last previous sale -- regardless of whether the seller was an authorized distributor. Nothing in the language of the statute, or elsewhere in the legislative history, suggests that Congress intended the scope of the pedigree requirement to be so limited. On the contrary, it was well understood that the proposed (and subsequently enacted) pedigree requirement called for a much more complete history of transactions.

Thus, for example, one witness at the Senate hearings on the legislation who testified in favor of exempting ADRs from the pedigree provision, compared the "audit trail" it would require to "a title search on real property." Prescription Drug Marketing Act of 1987: Hearings on S. 368 Before the Subcomm. on Int'l Trade of the Senate Comm. on Finance ("Senate Hearings"), 100th Cong. 49 (1987) (statement of Ronald J. Streck, Vice President of National Wholesale Druggists Association). The best

reading of the sentence in the House Report upon which plaintiffs rely is that it describes only part of the pedigrees required by the statutory language -- it does not say that "the source from which they obtained their drugs" (House Report at 17) is the only information that unauthorized wholesalers must include in drug pedigrees. And to read this sentence as plaintiffs urge would disregard the House Report's express statement earlier in the same paragraph that pedigrees must inform wholesale customers of "all previous sales of the product" (id.).

The PDMA's legislative history also establishes that Congress was aware of the importance of tracking prescription drug transactions all the way back to the drug manufacturer. While the House Oversight Subcommittee was investigating the drug diversion problem, its staff persuaded FDA to implement an experimental pedigree program for one segment of the diversion market -- reimported American drugs. The Oversight Committee heard testimony that, under that program, FDA required "documentary proof of the custody of the reimported pharmaceuticals back to the original manufacturer." Prescription Drug Diversion and Counterfeiting - Part II: Hearings Before the Subcomm. on Oversight & Investigations of the H.R. Comm. on Energy & Commerce ("House Hearings Part II"), 99th Cong. 6 (1986) (statement of David W. Nelson, Economist, Oversight Subcommittee).

These legislative history materials only underline the intent of Congress that is plain on the face of the statute. The terms of 21 U.S.C. 353(e)(1)(A), which require non-authorized distributors to provide their customers with information on "each prior sale, purchase, or trade of such drug" (21 U.S.C. 353(e)(1)(A)), permit no prior sale to be omitted from the pedigree statement, and they certainly contain no hint that Congress meant to exclude the first sale of the drug. FDA's regulation requiring non-authorized distributors to supply pedigrees that include information about "each prior transaction involving the drug, starting with the manufacturer" (21 C.F.R. 203.50(a)(6)) thus must be upheld under Chevron Step 1.<sup>8</sup>

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<sup>8</sup>In promulgating the pedigree regulation, FDA's exclusive rationale was that a statement of prior transactions extending back to the manufacturer was compelled by the language of the statute. See 64 Fed. Reg. at 67747 (noting that 21 U.S.C. 353(e)(1)(A) requires a statement "identifying each prior sale, purchase, or trade of such drug," and concluding that "[t]here is no indication in [the] PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor"). Therefore, if this Court determines that the statute is ambiguous, the appropriate course would be to remand the matter to the agency to exercise its discretion to interpret and execute an ambiguous statute. See Abbott Labs. v. Young, 920 F.2d 984, 988 (D.C. Cir. 1990) (where statute permits multiple interpretations, choice is for agency charged with its administration, not reviewing court); id. at 989-90 (beyond remanding to the agency, "we may not proceed, since we have no authority to place a construction on the statute that the agency has not offered").

**II. THE PDMA'S PEDIGREE REQUIREMENT IS  
CONSISTENT WITH EQUAL PROTECTION  
AND DUE PROCESS PRINCIPLES.**

Plaintiffs' fundamental complaint about FDA's pedigree regulation is that it imposes a burden on non-authorized distributors from which authorized distributors are statutorily exempt. Because, as we have shown, the regulation properly interprets the statute, plaintiffs' real quarrel is with the statute itself. But the legislative distinction between authorized and non-authorized distributors comfortably passes muster under the Constitution's guarantees of equal protection and due process.

Where, as here, no fundamental right or suspect classification is involved, both of those constitutional guarantees make the same demand: the classification drawn by Congress must be rational. See FCC v. Beach Commc'ns, Inc., 508 U.S. 307, 313 (1993) ("[A] classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification."); Washington v. Glucksberg, 521 U.S. 702, 722 (1997) (where no "fundamental rights \* \* \* deeply rooted in our legal tradition" are involved, substantive due process requires only "a reasonable relation to a legitimate [government] interest"); Rojas-Reyes v. INS, 235 F.3d

115, 123 (2d Cir. 2000) (applying "rational basis review" to a substantive due process claim).

Under the rational basis test, "a legislative choice is not subject to courtroom fact-finding and may be based on rational speculation unsupported by evidence or empirical data." Beach Commc'ns, 508 U.S. at 315. Congress need not have articulated or explained its rationale. Heller v. Doe By Doe, 509 U.S. 312, 320 (1993). Further, "[a] classification does not fail rational-basis review because it is not made with mathematical nicety or because in practice it results in some inequality." Id. at 321 (internal quotation marks omitted). As the Supreme Court has recognized, "[t]he problems of government are practical ones and may justify, if they do not require, rough accommodations." Id. (internal quotation marks omitted). Nor is an economic classification unconstitutional because it completely prohibits a business activity by the regulated class. See City of New Orleans v. Dukes, 427 U.S. 297 (1976) (upholding exemption of street vendors in business for eight years or more at time of enactment of city ordinance otherwise prohibiting street vending in French Quarter of New Orleans).

Here, Congress chose to impose the pedigree burden on non-authorized distributors, but not distributors who had "ongoing relationship[s]" (21 U.S.C. 353(e)(3)(A)) with the manufacturers of the products they sold. This decision was entirely rational

in light of the copious record compiled by Congress, showing that non-authorized distributors were the avenue through which most diverted drugs entered the retail market and created public health dangers.

The PDMA was the outcome of legislative investigation and hearings that began with a report by the staff of the Oversight Subcommittee. See supra at 6-7. That report defined the problem under consideration as the existence of a "'diversion market'" consisting of wholesale transactions involving "brand name product[s] that [are] not obtained directly from the manufacturer or an authorized distributor." Drug Diversion Report at 1-2; see also House Hearings Part I at 28 (statement of Stephen F. Sims, Special Assistant, Oversight Subcommittee). In the extensive hearings that followed, both the House and Senate heard testimony from federal prosecutors who had conducted a major criminal investigation into the diversion market, revealing a "secondary distribution system \* \* \* attractive to those wishing to dispose of stolen, foreign made, counterfeit, or adulterated and misbranded drugs." House Hearings Part I at 300 (statement of U.S. Attorney Larry Thompson); Senate Hearings at 4 (statement of U.S. Attorney Robert L. Barr, Jr.). This secondary distribution system was a market outside the "normal manufacturer-to-wholesaler-to-hospital or retailer system." Id.

The legislative history thus demonstrates that the entire problem Congress sought to address in the PDMA was rooted in the activities of secondary wholesalers, who did not buy their inventory directly from manufacturers. Because there was no required reporting of the source of the drugs distributed by wholesalers, these transactions presented clear opportunities for substandard or ineffective drugs to be introduced into the marketplace. See supra at 6-8. Early bills addressing the drug diversion problem called for pedigree statements by all prescription drug wholesalers. See H.R. 4820, 99th Cong. (1986); S. 2875, 99th Cong. (1986); S. 368, 100th Cong. (1987). A revised bill subsequently introduced in the House, however, exempted ADRs from the pedigree requirement. H.R. 1031, 100th Cong. (1987). The bill eventually enacted by both chambers (H.R. 1207, 100th Cong. (1987)) incorporated this exemption. Pub. L. No. 100-293, § 6, 102 Stat. 95, 98. The reason for its inclusion in the legislation was expressly acknowledged in the House Report: "The Oversight Subcommittee's investigation found that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product." House Report at 17 (emphasis added).

Based on this finding, Congress constitutionally could have -- but did not -- expressly prohibit distribution of prescription

drugs by non-authorized wholesalers. See City of New Orleans v. Dukes, 427 U.S. 297. It was no less constitutional for Congress to impose a pedigree requirement on non-authorized wholesalers that might prove impossible for them to satisfy. Congress could rationally have believed that ADRs would have some economic or other incentive to enter into commercial arrangements with non-authorized distributors to provide pedigree information. That Congress chose to leave this door open, rather than prohibit prescription drug distribution by non-authorized wholesalers, does not undermine the rationality of the requirement that all such wholesalers provide complete pedigrees. In conducting rational basis review, this Court looks for any "'plausible reason[] for Congress' action'" and does not demand that it be articulated in the legislative record. General Media Commc'ns v. Cohen, 131 F.3d 273, 286 n.16 (2d Cir. 1997) (quoting Beach Commc'ns, 508 U.S. at 313-15).

Congress thus acted consistently with equal protection and due process principles in 1988 when it exempted authorized distributors from the pedigree requirement. The constitutional inquiry should stop here. This Court has clearly indicated that it will not second-guess the rationality of legislative judgments in light of subsequent changed circumstances. See United States v. Then, 56 F.3d 464, 466 (2d Cir. 1995). Then involved an equal protection challenge to a federal criminal sentencing guideline

that treated a quantity of crack cocaine as the equivalent of one hundred times as much powder cocaine in determining a defendant's sentence. The Court had previously held that this 100:1 ratio was rational in light of the fact that crack was "the most addictive and destructive form of cocaine" and because its cheaper price made it more widely available and used. United States v. Stevens, 19 F.3d 93, 97 (2d Cir. 1994) (internal quotation marks omitted).

In a concurrence in Then, however, Judge Calabresi observed that, although Congress had acted rationally in adopting the guideline "based on the evidence available at the time," a recent comprehensive report to Congress by the Federal Sentencing Commission had found "that there is scant evidence to support the notion that crack poses a substantially greater threat to drug users or society than does powder cocaine." Id. at 467 (Calabresi, J., concurring). Judge Calabresi acknowledged that courts should not blithely "step in and say that what was rational in the past has been made irrational by the passage of time, change of circumstances, or the availability of new knowledge." Id. at 468. He nevertheless suggested a practice adopted by some European courts of notifying their parliaments that particular laws should be reviewed and that "failure to undertake such a review might in time result in judicial action and perhaps even nullification of the laws." Id. at 468-69. The

majority in Then, however, "decline[d] to accept the invitation by the concurrence" (id. at 466), thus also rejecting the suggestion that rational basis review depends on a factual predicate that can shift over time.<sup>9</sup>

Even if it is current market conditions that provide the proper predicate for the Court's review, however, the statute's pedigree provision should be upheld. As FDA has noted, drugs now sometimes pass through multiple authorized and non-authorized distributors on their way to their "retail destination." Report to Congress at 21 (JA A282). Thus, only a pedigree that lists every sale, including the sale by the manufacturer, will provide the comprehensive transaction history necessary to prevent introduction of problem drugs. Id. at 22 (JA A283)). In addition, however, economic analysis that formed the basis for FDA's Report to Congress demonstrated that authorized distributors continue to purchase "the large majority of their drugs directly from the drug manufacturers." Id., Attachment G at 1-12 (JA A288). This practice means that, although ADRs now pose some risk of introducing diverted drugs into the market,

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<sup>9</sup>Indeed, even Judge Calabresi would not have invalidated the sentencing guideline at issue in Then, and his proposal for judicial warnings to Congress has been the subject of spirited scholarly debate. See Neal Kumar Katyal, Judges As Advicegivers, STAN. L. REV. 1709, 1766 (1998); Abner J. Mikva, Why Judges Should Not Be Advicegivers: A Reponse to Professor Neal Katyal, STAN. L. REV. 1825 (1998); Ronald J. Krotoszynski, Jr., Constitutional Flares: On Judges, Legislatures, and Dialogue, 83 MINN. L. REV. 1 (1998).

this risk exists in only a small percentage of their transactions. The converse is true for non-authorized distributors: they purchase the vast majority of the drugs they sell from sources other than the manufacturers of those drugs. Indeed, this is the whole premise of plaintiffs' suit -- if they and other non-authorized wholesalers bought the goods they distribute directly from drug manufacturers, providing a complete pedigree would pose no difficulty. Thus, exempting ADRs from the pedigree requirement imposed on non-authorized wholesalers was, and remains, entirely rational.

Another reason why Congress -- today -- could rationally decide to require pedigrees from non-authorized distributors but not ADRs is that manufacturers have a business incentive to avoid entering into "ongoing relationship[s]" (21 U.S.C. 353(e)(3)(A)) with wholesalers likely to commit the abuses the statute was designed to prevent (sales of substandard, ineffective, or counterfeit drugs). A manufacturer not only loses revenue directly through these abuses, but indirectly through the damage they are likely to cause to the reputation of the manufacturer's product. Thus, Congress could rationally anticipate that manufacturers would play a "policing" role vis a vis their authorized distributors that would make requiring those distributors to provide pedigrees less crucial to the goal of controlling drug diversion.

Congress may undertake regulation "one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind." Williamson v. Lee Optical of Oklahoma, 348 U.S. 483, 489 (1955); see also Jana-Rock Constr., Inc. v. New York Dep't of Econ. Dev., 438 F.3d 195, 213 (2d Cir. 2006) ("Under rational basis review, '[t]he legislature may select one phase of one field and apply a remedy there, neglecting the others.'") (quoting Lee Optical, 348 U.S. at 489). On today's facts, as well as those prevailing in 1988, the statutory distinction between ADRs and unauthorized distributors is part of a rational attack on the public health and safety problem Congress sought to address in the PDMA.

**III. EVEN IF THE DISTRICT COURT PROPERLY GRANTED PRELIMINARY RELIEF, THE SCOPE OF ITS INJUNCTION IS TOO BROAD.**

The preliminary injunction entered by the district court bars enforcement of the entire pedigree regulation, 21 C.F.R. 203.50(a). RxUSA Wholesale, 467 F. Supp. 2d. At 292 (SPA 8). The court did not enjoin operation of the statutory pedigree provision, however. This means that non-authorized wholesalers remain statutorily obligated to provide pedigree statements to their customers, but those statements need not extend back to the drug manufacturer and need not include other specific information concerning the drug required by FDA's pedigree regulation. In particular, portions of the regulation that plaintiffs never

attacked on any statutory or constitutional ground require that pedigree statements include the proprietary and established name of the drug, its dosage, the container size, the number of containers in the transaction, and the drug's lot or control number(s). 21 C.F.R. 203.50(a)(1)-(5). By enjoining these portions of the regulation, as well as the portion requiring pedigrees to extend back to the manufacturer (21 C.F.R. 203.50(a)(6)), the district court's preliminary injunction is obviously too broad -- even if this Court concludes that the lower court abused its discretion in no other respect.

Injunctive relief is an extraordinary remedy that "should be tailored to restrain no more than what is reasonably required to accomplish its ends. Particularly is this so when preliminary relief on something less than a full record and full resolution of the facts is granted." Consolidated Coal Co. v. Disabled Miners of So. W. Va., 442 F.2d 1261, 1267 (4th Cir. 1971); see also Society for Good Will to Retarded Children v. Cuomo, 737 F.2d 1239, 1251 (2d Cir. 1984) (citing id.); Peregrine Myanmar Ltd. v. Segal, 89 F.3d 41, 50 (2d Cir. 1996) ("injunctive relief should be narrowly tailored to fit specific legal violations") (internal quotation marks omitted). The district court's broad order enjoining enforcement of 21 C.F.R. 203.50(a) in its entirety was inappropriate when narrower relief would have addressed the merits issues raised by plaintiffs.

Plaintiffs challenged only FDA's requirement that pedigrees extend back to the manufacturer -- based on their assertion that they cannot obtain pedigrees from ADRs, and therefore cannot comply with the regulatory requirement. Plaintiffs never asserted that providing the balance of the information required by the regulation is impossible. Nor could they, as the information required by subsections (1) through (5) of the regulation is apparent from the drug's labeling, and is readily available to plaintiffs and other non-authorized wholesale purchasers upon receipt of the drugs. Non-authorized wholesalers are thus able to include this information in the pedigrees they provide to customers, whether or not authorized distributors are willing to supply information on prior transactions.

The fact that the information required by subsections (1) through (5) of FDA's pedigree regulation is readily ascertainable from a drug's labeling does not mean that it is unnecessary in the pedigree or that the overbreadth of the district court's injunction does no harm. Quite the contrary. The information required by these subsections is critical to protecting the public health because it ensures that a pedigree can be matched to a specific lot of drugs. It thereby allows law enforcement and regulatory officials to remove potentially unsafe drugs from the market and trace them back to their potentially illicit source. Without specific identifying information such as lot

numbers, dosage size, and number of containers, an unscrupulous wholesaler could easily purchase one lot of drugs from a legitimate source and use the pedigree that it receives for that lot for other drugs with the same name that were obtained from illegitimate sources. Subsections (1) through (5) of the regulation thus serve an important regulatory function even if subsection (6), requiring the pedigree to extend back to the manufacturer, was properly enjoined.

Subsection (6) is therefore readily severable from the remainder of the regulation. Severability operates according to the same principles in the regulatory context as it does with respect to statutes. See K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 294 (1988) (finding a portion of a regulation severable). A constitutionally flawed statutory provision is severable from the remainder of the statute if the balance of the legislation is capable of "'functioning independently'" and is "consistent with Congress' basic objectives in enacting the statute." United States v. Booker, 543 U.S. 220, 223 (2005) (quoting Alaska Airlines v. Brock, 480 U.S. 678, 684 (1987)). As we have shown, subsections (1) through (5) of FDA's pedigree regulation have an important function, independent of subsection (6)'s requirement that pedigrees extend back to the manufacturer, that advances the goal of the statute and the regulatory scheme.

The PDMA expressly authorizes the Secretary of Health and Human Services (acting here through FDA) to specify the information to be included in drug pedigrees. See 21 U.S.C. 353(e)(1)(A) (requiring the pedigree statements to be "in such form and containing such information as the Secretary may require"). Plaintiffs made no contention below that FDA's requirement for the information specified in 21 C.F.R. 203.50(a)(1)-(5) in any way conflicts with either the PDMA or the Constitution. Accordingly, the district court abused its discretion by extending the preliminary injunction to these provisions of the regulation. Even if this Court agrees with the lower court on the merits of the issues raised by plaintiffs, the scope of the preliminary injunction should be limited to restrain enforcement only of 21 C.F.R. 203.50(a)(6).

#### **CONCLUSION**

For the foregoing reasons, the preliminary injunction entered by the district court should be vacated, and judgment entered for the Government. Alternatively, if the Court determines that plaintiffs are entitled to preliminary relief,

the injunction should be narrowed to prohibit enforcement only of  
21 C.F.R. 203.50(a)(6).

Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE**

Pursuant to Rule 32(a)(7)(C), Fed. R. App. P., I hereby certify that the foregoing brief complies with the type-volume limitation in Rule 32(a)(7)(B). The brief, which uses a monospaced type face with not more than 10.5 characters per inch, contains 9840 words.

s/ Irene M. Solet \_\_\_\_\_  
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**CERTIFICATE CONCERNING VIRUS PROTECTION**

I hereby certify that the foregoing Brief For The Appellant has been scanned for viruses before being digitally submitted to the Court, and no virus has been detected.

s/ Irene M. Solet \_\_\_\_\_  
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**CERTIFICATE OF SERVICE**

I hereby certify that on this 19th day of April, 2007, I caused a copy of the foregoing Brief For The Appellant to be transmitted by electronic mail, and two copies of that Brief with the attached Special Appendix to be served via FedEx next business day delivery on:

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