

# 07-0453-CV

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

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RxUSA WHOLESALE, INC., et al.,

Plaintiffs-Appellees,

v.

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

Defendant-Appellant.

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

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BRIEF FOR *AMICUS CURIAE* HEALTHCARE DISTRIBUTION MANAGEMENT  
ASSOCIATION IN SUPPORT OF DEFENDANT-APPELLANT IN URGING  
REVERSAL

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**CORPORATE DISCLOSURE STATEMENT**

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure, *amicus curiae* Healthcare Distribution Management Association does not have a parent corporation, and does not have any corporate stock.

April 27, 2007

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**TABLE OF CONTENTS**

I. INTEREST OF *AMICI CURIAE* .....1

II. ARGUMENT .....3

    A. The District Court Erred In Concluding That The Exemption For ADRs  
    “Would Completely Defeat The Purpose Of The PDMA.” .....3

        1. The PDMA Provides A Rational And Consistent Framework For  
        Supply Chain Accountability .....4

        2. The PDMA’s Legislative History Demonstrates That Congress  
        Clearly Intended To Treat ADRs And Non-ADRs Differently  
        Because Of Congressional Concerns That Drug Diversion Was  
        Pervasive In The Secondary Market For Prescription Drugs .....6

        3. Counterfeiting And Diversion Of Prescription Drugs Continue  
        To Be Significant Problems .....12

    B. The District Court Erred In Concluding That The ADR Exemption  
    “Would Essentially Wipe Out All The Unauthorized Distributors.” ..... 15

III. CONCLUSION.....20

CERTIFICATE OF COMPLIANCE

CERTIFICATE CONCERNING VIRUS PROTECTION

**TABLE OF AUTHORITIES**

**Cases**

*RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, No. 06-CV-03447 (DRH)  
(E.D.N.Y. filed July 14, 2006).....18

*RxUSA Wholesale, Inc. v. Dep’t of Health and Human Servs.*,  
467 F. Supp. 2d 285 (E.D.N.Y. 2006) .....3, 15

**Statutes**

21 U.S.C. § 353(c)(1).....8

21 U.S.C. § 353(c)(2).....8

21 U.S.C. § 353(c)(3).....8

21 U.S.C. § 353(d) .....8

21 U.S.C. § 353(e) .....4

21 U.S.C. § 353(e)(1)(A) .....4

21 U.S.C. § 353(e)(1)(B) .....17

21 U.S.C. § 353(e)(3)(A) .....6, 16

21 U.S.C. § 381(d)(1) .....8

21 U.S.C. § 381(d)(2) .....8

**Regulations**

21 C.F.R. § 203.50(a).....4

21 C.F.R. § 203.50(d) .....17

59 Fed. Reg. 11,842, 11,857 (Mar. 14, 1994).....11, 12

64 Fed. Reg. at 67,751 (Dec. 3, 1999) .....13-14

71 Fed. Reg. 34,249 (June 14, 2006) .....13

**Legislative Materials**

H.R. REP. NO. 100-76 (1987) .....10-11

S. REP. NO. 100-303, at 7 (1988), *reprinted in* 1988 U.S.C.C.A.N. 57 .....11

*Prescription Drug Diversion and Counterfeiting – Part 1: Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 99th Cong. (1985) (“Hearings – Part 1”)* .....8, 9

*Prescription Drug Diversion and Counterfeiting – Part 2: Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 99th Cong. (1986) (“Hearings – Part 2”)* .....7, 9, 10

H.R. SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE COMM. ON ENERGY AND COMMERCE, 99th Cong. REPORT ON DANGEROUS MEDICINE, THE RISK TO AMERICAN CONSUMERS FROM PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING (Comm. Print 1986) .....7

STAFF OF H.R. SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE COMM. ON ENERGY AND COMMERCE, 99TH CONG., REPORT ON DRUG DIVERSION, PRESCRIPTION DRUG DIVERSION AND THE AMERICAN CONSUMER: WHAT YOU THINK YOU SEE MAY NOT BE WHAT YOU GET (Comm. Print 1985) (“DRUG DIVERSION REPORT”) .....7, 9

**Administrative and Executive Materials**

DEPARTMENT OF HEALTH AND HUMAN SERVS., U.S. FOOD AND DRUG ADMINISTRATION, THE PRESCRIPTION DRUG MARKETING ACT REPORT TO CONGRESS (2001), *available at* <http://www.fda.gov/oc/pdma/report2001/4228rpt.pdf> .....13

STATEMENT OF RANDALL W. LUTTER, PH.D. BEFORE THE H.R. SUBCOMM. ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES OF THE COMM. ON GOV’T. REFORM (2006), *available at* <http://www.fda.gov/ola/2006/counterfeit0711.html> .....14-15

Statement by President Ronald Reagan Upon Signing H.R. 1207, 24 WEEKLY COMP. PRES. DOC. 519 (April 25, 1988), *reprinted in* 1988 U.S.C.C.A.N. 71 .....11

**Miscellaneous**

STATEMENT OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) RE: DOCKET NO. 92N-0297, at 4 (Oct. 27, 2000).....12

Merck & Co., Inc's Designated ADRs, <i>available at</i> <a href="http://www.merck.com/product/distributors">http://www.merck.com/product/distributors</a> (accessed Apr. 27, 2007).....	17
Millenium Pharmaceuticals Inc's Designated ADRs, <i>available at</i> <a href="http://www.millennium.com/products/velcade/adr.asp">http://www.millennium.com/products/velcade/adr.asp</a> (accessed Apr. 27, 2007).....	17
Pfizer, Inc's Designated ADRs, <i>available at</i> <a href="http://www.pfizer.com/pfizer/subsites/counterfeit_importation/mn_pharmacist_wlist.jsp">http://www.pfizer.com/pfizer/subsites/counterfeit_importation/mn_pharmacist_wlist.jsp</a> (accessed Apr. 27, 2007).....	17
Sandoz's Designated ADRs, <i>available at</i> <a href="http://www.us.sandoz.com/site/en/company/news/pool/ADR_LISTING.pdf">http://www.us.sandoz.com/site/en/company/news/pool/ADR_LISTING.pdf</a> (accessed Apr. 27, 2007).....	17
Wyeth's Designated ADRs, <i>available at</i> <a href="http://www.wyeth.com/products/authorized_distributors">http://www.wyeth.com/products/authorized_distributors</a> (accessed Apr. 27, 2007).....	17

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**I. INTEREST OF THE *AMICUS CURIAE***

*Amicus curiae* Healthcare Distribution Management Association (“HDMA”) is the national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors. These healthcare distributors deliver lifesaving products and services, ensuring that 300 million U.S. consumers have continuous access to prescription drugs and other important products. Prescription drugs are rarely shipped from the manufacturer straight to the pharmacy or other healthcare provider. Rather, most prescription drugs are sold by manufacturers to distributors that ensure that nine million products are safely and efficiently delivered to 144,000 pharmacies, hospitals, clinics, physician offices, nursing homes, government providers, and others each and every day.

HDMA has 38 distributor members. What they have in common is they predominantly buy prescription drugs directly from manufacturers and predominantly distribute them directly to healthcare providers. These distributor members have a wide range of business models, including national and regional firms, and publicly traded and family-owned businesses. They include specialty distributors, for example, firms that distribute only “biologics” (such as vaccines) or oncology drugs, firms that service only physician offices, and firms that distribute only generic products. While all HDMA members are authorized distributors of record (“ADRs”) for most products they distribute, some HDMA members are non-ADRs for some products they distribute.

HDMA’s members have an important stake in maintaining the integrity of the prescription drug supply chain and with preventing counterfeit and otherwise unsafe prescription drugs that endanger the public health from entering the supply chain. The public health dangers associated with counterfeit and otherwise adulterated drugs have been well-recognized over the years by Congress, the Food and Drug Administration (“FDA”), and others.

HDMA’s members are one of the principal groups of businesses affected by Congress’ and FDA’s efforts to regulate the wholesale distribution of prescription drugs. The controlling statute and FDA’s final rule at issue in this lawsuit require that a non-ADR distributor provide each customer with a statement showing the product’s detailed distribution history and chain of custody, going back to the original manufacturer (commonly known as a “pedigree”). HDMA does not agree with all aspects of FDA’s challenged pedigree rule,<sup>1</sup> and the rule creates extra costs and burdens for HDMA’s members, regardless of their ADR status. Nevertheless, on balance, HDMA supports FDA’s rule, as it implements both the plain statutory language and the intent of Congress. The

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<sup>1</sup> However, HDMA’s points of disagreement with FDA are not relevant to this lawsuit.

requirement that a non-ADR provide its customer with a pedigree going back to the manufacturer is designed to further protect the integrity of the supply chain and the safety of U.S. prescription drugs.

HDMA respectfully submits that the district court's preliminary injunction should be vacated, so that FDA's rule can take effect. HDMA is submitting this *amicus* brief because of the importance of the issues involved, both to HDMA's members and the public health.

HDMA sought the consent of the parties to file this *amicus* brief. FDA consented. Plaintiffs (collectively "secondary distributor appellees") did not. Therefore, this brief is accompanied by a motion for leave to file an *amicus* brief.

## II. ARGUMENT

HDMA supports FDA's positions and legal arguments on the pedigree rule in question. This *amicus* brief presents additional information for the Court's information and use.

### A. The District Court Erred In Concluding That The Exemption For ADRs "Would Completely Defeat The Purpose Of The PDMA."

The district court's holding, that "[i]f the Rule were to go into effect while the exemption for authorized distributors existed, the result would completely defeat the purpose of the PDMA," *RxUSA Wholesale, Inc. v. Dep't of Health and Human Servs.*, 467 F. Supp. 2d 285, 291 (E.D.N.Y. 2006), cannot withstand scrutiny. What the district court is saying is that the provision that exempts ADRs from having to provide a pedigree somehow defeats the purpose of the Prescription Drug Marketing Act of 1987 ("PDMA"). To the contrary, the PDMA's statutory exemption for ADRs is part of a carefully considered congressional plan to provide accountability for prescription drug distribution and to address the problem of counterfeit and otherwise adulterated drugs in the secondary market.

## **1. The PDMA Provides A Rational And Consistent Framework For Supply Chain Accountability.**

The PDMA established requirements for prescription drug distribution to help safeguard the safety and integrity of the prescription drug supply. It was enacted to combat the sale of counterfeit, adulterated, misbranded, subpotent, and expired prescription drugs and passed in response to the development of a secondary wholesale submarket (known as the “diversion market”) for prescription drugs. The PDMA, as it was signed into law in 1988, amended the Federal Food, Drug, and Cosmetic Act (“FDC Act”) and created the original statutory pedigree requirement. In 1992, Congress passed and the President signed into law the Prescription Drug Amendments of 1992 (“PDA”) to clarify and strengthen the pedigree requirement. The PDA modified the statutory provision to read as it currently does:

(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) [namely, 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 receives the drug ***a statement (in such form and containing such information [FDA] 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).***

(e)(1)(B) Each manufacturer of a drug subject to subsection (b) of this section shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

21 U.S.C. § 353(e) (emphasis added). In practice, the statutorily required “statement,” or pedigree, is provided in either written or electronic form.

The FDA rule that was enjoined by the district court, 21 C.F.R. § 203.50(a), would implement this express statutory language, which is self-executing and is not dependent upon FDA rulemaking, *see* 21 U.S.C. § 353(e)(1)(A).

The district court's conclusion that FDA's rule would somehow defeat the purpose of the statute is contradicted by the clear language of the statute itself. The PDMA and PDA provide that each distributor with whom a manufacturer has established an ongoing relationship to sell a particular prescription drug may sell that product to healthcare customers, such as pharmacy chains, without providing to its customer a pedigree that would permit the customer to engage in further wholesale distribution of the product. In this way, the PDMA and PDA prevent a healthcare customer from reselling product into the secondary market unless it receives from its ADR supplier a pedigree going back to the manufacturer, which includes the transaction date(s) of the ADR's original purchase(s) from the manufacturer and other required information.

Secondary distributor appellees argue that manufacturers and ADRs will sell prescription drugs to secondary distributors, but will not provide an accompanying pedigree, and that such a sale would be of no value to them. This argument is nothing but a strawman. An ADR is exempt from having to provide a *statutory* pedigree. But, under secondary distributor appellees' argument, an ADR who wishes to sell product to a secondary distributor will of necessity need to provide a *de facto* pedigree with the product that contains the information required by statute.

Secondary distributor appellees argue that a non-ADR distributor should only have to provide a pedigree going back to the ADR distributor. This is inconsistent with the language and purpose of the statute. Under the provisions of the PDMA and PDA, as implemented by FDA's enjoined rule, a secondary wholesaler that wishes to purchase and resell product in the secondary market must obtain a pedigree from and through its supplier back to the manufacturer. That may not always be easy, but it is the law.

The statutory scheme of the PDMA and PDA relies upon a manufacturer and its ADRs, who are the distributors with whom it maintains ongoing relationships, to provide their own

accountability as the originators of authentic, non-counterfeit, unadulterated product. A distributor must work closely with a drug's manufacturer to become an ADR. Each manufacturer makes its own individual business decision about the distributor or distributors with which it wishes to (in the terms of the statutory language, 21 U.S.C. § 353(e)(3)(A)) "establish[ ] an ongoing relationship to distribute such manufacturer's products."

Where there are transactions in the secondary market – where this accountability does not exist because the secondary distributor does not have an "ongoing relationship" with the manufacturer – the statute instead requires a pedigree to document the product's transaction history going back to the manufacturer. Thus, the statute only requires pedigrees where they are needed and avoids the burdens and costs of creating pedigrees when they are unnecessary. The statute is clear in distinguishing between ADRs and non-ADRs, expressly requiring only non-ADRs to provide pedigrees.

**2. The PDMA's Legislative History Demonstrates That Congress Clearly Intended To Treat ADRs And Non-ADRs Differently Because Of Congressional Concerns That Drug Diversion Was Pervasive In The Secondary Market For Prescription Drugs.**

If the clear language and statutory pattern of the PDMA itself were not sufficient, its intent is confirmed by the PDMA's ample legislative history. This legislative history makes clear that Congress, in addressing the problems posed by counterfeit and diverted drugs, intended to create a legal distinction between different types of distributors.

When Congress first addressed concerns with the integrity of the prescription drug supply in the mid-1980s, much of the attention focused on specific *sources* of potentially counterfeit or otherwise adulterated prescription drugs. These included non-profit hospitals and similar entities

that purchased prescription drugs at discount prices and resold them at a profit,<sup>2</sup> the reimportation of prescription drugs manufactured in the United States and exported to foreign countries,<sup>3</sup> and the

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<sup>2</sup> Particular sources of diverted pharmaceuticals identified for the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce included secondary sources such as nonprofit associations, hospitals, clinics, and nursing homes, STAFF OF H.R. SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE COMM. ON ENERGY AND COMMERCE, 99TH Cong., REPORT ON DRUG DIVERSION, PRESCRIPTION DRUG DIVERSION AND THE AMERICAN CONSUMER: WHAT YOU THINK YOU SEE MAY NOT BE WHAT YOU GET, at 15 (Comm. Print 1985) [hereinafter DRUG DIVERSION REPORT], with much of the early focus on hospitals:

An entire industry has sprung up whose sole purpose appears to be to solicit nonprofit hospitals to purchase excess pharmaceuticals using their special discount, which products are then immediately resold to the broker or wholesaler for ultimate resale to a retailer. The current head of the California Board of Pharmacy told the Subcommittee staff that it was his guess that hospital diversion was the leading source of products for the diversion market in his state.

*Id.* at 23; accord H.R. SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE COMM. ON ENERGY AND COMMERCE, 99th Cong. REPORT ON DANGEROUS MEDICINE, THE RISK TO AMERICAN CONSUMERS FROM PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING, at 18 (Comm. Print 1986) (“Drugs diverted from health care institutions, especially hospitals, are another important source of merchandise for the secondary market.”).

<sup>3</sup> Congress uncovered substantial evidence that reimportation of pharmaceuticals from a vast array of foreign countries contributes substantially to the secondary diversion market. See *Prescription Drug Diversion and Counterfeiting – Part 2: Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 99th Cong., at 4-7 (1986) [hereinafter *Hearings – Part 2*] (testimony of David W. Nelson, Economist, Subcomm. on Oversight and Investigations). Testimony revealed that, during a six-month period between September 1985 and March 1986, drugs from 29 countries totaling in excess of \$10 billion re-entered the United States pharmaceutical supply chain. See *id.* at 4.

repackaging for resale of free samples of prescription drugs provided to physicians.<sup>4</sup> Congress addressed the specific problems associated with prescription drugs resold by hospitals and reimported prescription drugs by expressly prohibiting both practices. *See* 21 U.S.C. § 353(c)(3) (prohibition against public and private hospitals from reselling prescription drugs, with very limited exceptions for transfers between related entities and for medical emergencies) and § 381(d)(1) and (2) (except for medical emergencies, only the manufacturer of a prescription drug manufactured in the U.S. and exported may reimport the drug into the U.S.). Congress also imposed strict controls on the distribution of prescription drug samples and prohibited their sale. *See* 21 U.S.C. § 353(c)(1) – (2) and (d).

Regardless of the *source* of prescription drugs in the secondary market, much of the information brought before congressional investigators revolved around the *activities of secondary wholesalers themselves*. Through a variety of mechanisms, “[a]dulterated, mislabeled, and expired drugs were being widely distributed within the secondary market and ultimately sold to the consuming public.” *Hearings – Part 1, supra* note 4, at 304 (testimony of Hal N. Helterhoff, Chief of the White-Collar Crimes Section of the Criminal Investigative Division at the Federal Bureau of

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<sup>4</sup> Testimony showed that individuals were repackaging “outdated sample and stolen products under less than sanitary conditions,” where those “contaminated pharmaceuticals were then sold to corner drugstores for ultimate delivery to the unsuspecting public.” *Prescription Drug Diversion and Counterfeiting – Part 1: Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 99th Cong.*, at 303 (1985) [hereinafter *Hearings – Part 1*] (testimony of Hal N. Helterhoff, Chief of the White-Collar Crimes Section of the Criminal Investigative Division at the Federal Bureau of Investigation (FBI)). Indeed, along with hospital- and import-related diversion, misappropriated samples accounted for a major segment of the secondary market and, consequently, significant congressional concern. *See, e.g., id.* at 472-82 (1985) (testimony and statement of Bruce J. Brennan, Senior Vice-President, Pharmaceutical Manufacturers Ass’n).

Investigation). The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (“Subcommittee”) also noted that theft and domestic counterfeiting were also “obvious source[s] of goods for the diversion market,” recognizing that because “there are a number of wholesalers who buy pharmaceuticals with no questions asked, disposing of the stolen merchandise does not appear to be a problem.” DRUG DIVERSION REPORT, *supra* note 3, at 25-26.

Congress had ample information regarding the risks posed by counterfeit and otherwise suspect drugs and their entry through the secondary market, and this provided the basis for its distinction between ADRs and non-ADR in the PDMA, as amended by the PDA. The Subcommittee recognized more than 20 years ago the profound problem facing the industry:

American consumers can no longer purchase prescription drugs with the certainty that the products are safe and effective ... [because] the integrity of the distribution system is insufficient to prevent the introduction of substandard, ineffective or counterfeit pharmaceuticals.... Specifically, the existence and method of operation of a wholesale submarket, herein referred to as the “diversion market,” prevents effective control over or even routine knowledge of the true sources of merchandise in a significant number of cases.

*Id.* at 1-2; *see also generally Hearings – Part 2, supra* note 3, at 118-63 (describing secondary wholesaler syndicate responsible for large-scale prescription drug diversion scheme in south Florida during the 1980s).

Testimony before the Subcommittee specifically diagrammed the “fraudulent activity and theft that [gave] rise to a secondary market for legitimate medicines.” *Hearings – Part 1, supra* note 4, at 303 (testimony of Hal N. Helterhoff, Chief of the White-Collar Crimes Section of the Criminal Investigative Division at the Federal Bureau of Investigation).

As one witness before the Subcommittee summarized, there exists

overwhelming evidence of a thriving, multi-billion dollar market in drugs which are removed from normal channels of distribution through theft or fraud, routed through numerous companies, delivered to ports around the United States and the world, and finally sold to wholesalers and retailers at huge profits. These drugs are no longer able to be recalled and may be stored or handled improperly. Yet, those who purchase and sell them ask no questions. Only the ultimate, and unwitting consumer is forced, without his knowledge or consent, to take the risks. Ironically, the consumer reaps no discernable benefit for this risk – the prices he pays are not significantly reduced, although each buyer and seller has “beat the market” by dealing in diverted drugs.

*Hearings – Part 2, supra* note 3, at 190 (statement of Hon. Fred J. Eckert, Member, Subcomm. on Oversight and Investigations).

The legislative history of the PDMA clearly shows that section 353(e) was added to address serious abuses in this secondary, non-ADR market for prescription drugs. The Committee on Energy and Commerce’s Report explains the language adopted by the House that subsequently became the PDMA:

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. Thus, the requirement ... 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.

H.R. REP. NO. 100-76, at 17 (1987). The House Report concluded, therefore, that “[u]nauthorized distributors will be required to certify in writing to drug wholesalers the source and place from which they obtained the drugs” and “[m]anufacturers will be required to maintain, for public review,

a current list of all authorized distributors of record.” *Id.*; accord S. REP. NO. 100-303, at 7 (1988), *reprinted in* 1988 U.S.C.C.A.N. 57 (reflecting same language).

Therefore, in focusing on the diversion activities of the non-ADRs, the PDMA’s primary purpose “is to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals, which are being dispensed under existing law and practice, and to restore competitive balance in the marketplace.” H.R. REP. NO. 100-76, at 6.

That legislative goal was confirmed by President Reagan in his 1988 signing statement: “I support the expressed goal of this legislation, which is to reduce potential public health risks that may result from the distribution of mislabeled, subpotent, counterfeit, or adulterated prescription drugs in the secondary source market, the so-called ‘diversion market.’” Statement by President Ronald Reagan Upon Signing H.R. 1207, 24 WEEKLY COMP. PRES. DOC. 519 (April 25, 1988), *reprinted in* 1988 U.S.C.C.A.N. 71.

Moreover, the PDMA’s amendments to the FDC Act regarding wholesale drug distribution were subsequently tightened by the PDA, resulting in current 21 U.S.C. 353(e). As characterized by FDA:

The PDA amendments to the PDMA significantly tightened the drug pedigree requirement.... Passage of PDA thus gave added emphasis to Congress’ intent, as stated in the legislative history of PDMA, to restore accountability to the wholesale sector of the pharmaceutical market and to regulate the wholesale distribution of prescription drug products.

59 Fed. Reg. 11,842, 11,857 (Mar. 14, 1994).

### 3. Counterfeiting And Diversion Of Prescription Drugs Continue To Be Significant Problems.

Reasons to be concerned about counterfeit prescription drugs have not diminished over time.<sup>5</sup>

Since the enactment of PDMA and PDA, FDA has continued to amass information that supports the PDMA's pedigree requirements. Indeed, as FDA recognized shortly after passage of the PDA in its 1994 proposed rulemaking:

Soon after the enactment of PDMA, the terms "secondary" and "unauthorized" distributors became common to describe persons who are not authorized distributors of record, and the term "drug pedigree" became popular to describe the required statement of origin. In order to make it possible to distinguish between authorized and unauthorized distributors, section [353(e)] also required each manufacturer to maintain at its corporate offices a current list of its authorized distributors. This requirement was not altered by PDA, which otherwise amplified the pedigree requirement. When Congress adopted section [353(e)(1)], it was responding to information uncovered by the Oversight Subcommittee of the House Committee on Energy and Commerce. *The Committee found that most counterfeit, stolen, expired, or fraudulently obtained drugs entering commercial channels had been handled by distributors who were not authorized to distribute the manufacturer's product, rather than by the manufacturer's authorized distributors.* Accordingly, Congress imposed a more stringent reporting requirement on distributions by unauthorized distributors, requiring them to inform their wholesale customers of all previous sales of the drug product.

59 Fed. Reg. at 11,856 (emphasis added) (*citing* H.R. REP. 100-76, at 17).

FDA has continued to receive comments confirming the need for non-ADRs to provide pedigrees. *See, e.g.*, STATEMENT OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) RE: DOCKET NO. 92N-0297, at 4 (Oct. 27, 2000) ("PhRMA Statement") ("If the act were amended by Congress to delete the requirement for provision of a drug pedigree *by unauthorized distributors*, [there would] be an increased risk of distribution of counterfeit, expired,

adulterated, misbranded, or otherwise unsuitable drugs to consumers and patients.”) (emphasis added).

Based on the nature of prescription drug distribution and the pervasiveness of the diversion and counterfeit problems stemming from the secondary market, FDA stood firm in its 2001 report to Congress:

FDA believes that maintaining and passing on a pedigree on prescription drugs provides a valuable tool – even if this is required of only those secondary distributors unable to attain authorized distributor status. The pedigree requirement is a deterrent to the introduction and retail sale of substandard, ineffective, and counterfeit drugs. Although a pedigree can be, and sometimes is, falsified to disguise the true source of prescription drugs, FDA believes that requiring a pedigree makes it more difficult for someone planning to introduce counterfeit or diverted drugs into commerce. Requiring a pedigree also facilitates the efforts of law enforcement personnel seeking to identify the source of a counterfeit or diverted drug shipment and take action against those responsible.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION, THE PRESCRIPTION DRUG MARKETING ACT REPORT TO CONGRESS (2001) at 21, *available at* <http://www.fda.gov/oc/pdma/report2001/4228rpt.pdf>.

These conclusions led FDA to promulgate its final rule and to lift the stay of its effective date as of December 1, 2006. 71 Fed. Reg. 34,249 (June 14, 2006). In its final rule, FDA has established procedures and requirements implementing the PDMA that are “consistent with Congress[ional] intent,” and that are designed to prevent “the sale of subpotent, adulterated, counterfeit, or misbranded prescription drugs and drug samples to the American public.” 64 Fed. Reg. at 67,751

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<sup>5</sup> For example, anyone who has access to the Internet knows that it is flooded with promotional material for pharmaceutical products of potentially suspect origin.

(Dec. 3, 1999). Specifically, FDA stated the final rule's wholesale distribution requirements

will permit the distribution chain of prescription drugs to be traced, and will make unauthorized wholesale distributors more accountable. In sum, the final rule establishes controls over the distribution of prescription drugs and drug samples that will help to ensure that drugs are safe and effective not only when they leave manufacturers, but also when they reach consumers.

*Id.*

The reasons that led to enactment of the PDMA – the need to keep counterfeit and otherwise adulterated prescription drugs out of distribution – continue to be valid today. Just last year in addressing Congress, FDA's Associate Commissioner for Policy and Planning reiterated FDA's findings regarding the depth of the problem in the non-ADR market:

FDA is committed to minimizing opportunities for counterfeiters and diverters to infiltrate our nation's drug supply with counterfeit drugs. Our extensive experience with counterfeit and drug diversion cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Based on our recent fact-finding effort, we can no longer justify continuing the stay. Many supply chain stakeholders told FDA that the regulations should go into effect. In addition, some states are moving forward with their own pedigree laws. Allowing the stay to expire will provide clarity in the prescription drug supply chain by distinguishing who is an ADR, and would therefore be exempt from providing a drug pedigree, from non-ADRs who must provide a pedigree.

STATEMENT OF RANDALL W. LUTTER, PH.D. BEFORE THE H.R. SUBCOMM. ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES OF THE COMM. ON GOV'T. REFORM (2006), *available at* <http://www.fda.gov/ola/2006/counterfeit0711.html>.

Congress and FDA have been grappling with how best to combat counterfeit drugs, drug diversion, and similar concerns for more than 20 years, while also balancing competing interests (including several stays of the pedigree final rule because of concerns about the economic interests of secondary distributors). Because of heightened concerns with counterfeit prescription drugs,

however, FDA decided in 2006 it could not stay the final rule any longer. *E.g., id.* In HDMA's view, FDA got it right.

The FDA final rule that was enjoined by the district court clearly and fairly implemented the statutory language of the PDMA, as amended by the PDA, and the plain language of that statute is supported by the legislative history of the enactment of the PDMA. The district court's conclusion that the statute's "exemption for authorized distributors" would somehow "defeat the purpose of the PDMA," 467 F. Supp. 2d at 291, is an unsupportable interpretation of the statute and should be overturned.

For the foregoing reasons, there is an ample rational basis for Congress and for FDA to distinguish between ADRs and non-ADRs. Therefore, the district court erred in concluding that FDA's rule is arbitrary. The same reasons establish that neither FDA's rule nor the statutory scheme itself constitutes a denial of equal protection, as alleged by secondary distributor appellees.

**B. The District Court Erred In Concluding That The ADR Exemption "Would Essentially Wipe Out All The Unauthorized Distributors."**

The district court concluded that "the Rule would essentially wipe out all the unauthorized distributors, leaving only authorized distributors who are exempt from the pedigree requirement." *Id.* The district court's conclusion appears to follow from secondary distributor appellees' factually incorrect characterization of the prescription drug distribution industry.

Secondary distributor appellees' underlying assumption, that the prescription drug distribution industry pits a few of the largest distributors against all other distributors, is patently incorrect. Contrary to secondary distributor appellees' fallacious characterization, the primary wholesale distribution industry includes firms with a wide variety of business models, large and small, public and private, each with a varying degree of activity in particular areas of the healthcare

distribution landscape. These entities include national, full-service firms; regional, full-service firms; and smaller specialty firms that concentrate on a narrower market, such as firms that only distribute “biologics” (*e.g.*, vaccines, because of their special handling and storage requirements) or oncology products, distributors that only service medical offices and clinics, or distributors that only handle generic products. These primary distributors may or may not be ADRs for any particular manufacturer and drug product, but they are ADRs for most products they distribute.

Secondary distributor appellees have also misrepresented the nature of the secondary market for prescription drugs, portraying it as a “linear” business, where secondary wholesalers are wholly dependent upon ADRs for inventory. ADRs are only one source of product for secondary wholesalers, and as the foregoing discussion of legislative history demonstrates, the initiative for passage of the PDMA and the PDA resulted from secondary wholesalers purchasing from a variety of secondary market sources, one of which (non-profit hospitals) was so prone to abuse that they were banned from continuing to sell product into the secondary market.

Regardless of the type of distributor, nothing prevents any of those firms from serving as an ADR for any particular manufacturer, for any product or any class of products. A distributor must work closely with a drug’s manufacturer to become an ADR, which typically entails convincing the manufacturer that it is a firm of integrity as well as a good business match with that manufacturer’s needs. ADR status is an individual business decision and is granted by each manufacturer to the distributor or distributors with which it wishes to (in the terms of the statute, 21 U.S.C. § 353(e)(3)(A)) “establish[ ] an ongoing relationship to distribute such manufacturer’s products.” Each manufacturer makes its own decision on how many ADRs it will have and which wholesale distributors it will designate as ADRs.

Pursuant to 21 U.S.C. § 353(e)(1)(B) and 21 C.F.R. § 203.50(d), each manufacturer is required to maintain a current written list of all its ADRs and (if applicable) to specify which products those ADRs are authorized to distribute. Even a cursory glance at several such lists that are available on the Internet<sup>6</sup> disproves secondary distributor appellees' claim that only a few very large distributors are being designated by the manufacturers as ADRs. Quite to the contrary, a review of Wyeth's list of ADRs, for example, is illustrative of a large prescription drug manufacturer. Wyeth has designated about 50 different business entities as ADRs. *See* [http://www.wyeth.com/products/authorized\\_distributors](http://www.wyeth.com/products/authorized_distributors) (accessed Apr. 27, 2007).

Likewise, Pfizer, Inc., the largest pharmaceutical manufacturer in the market, has a similarly diverse list of ADRs, some of which do not have ADR status for the entire product line. *See* [http://www.pfizer.com/pfizer/subsites/counterfeit\\_importation/mn\\_pharmacist\\_wlist.jsp](http://www.pfizer.com/pfizer/subsites/counterfeit_importation/mn_pharmacist_wlist.jsp) (accessed Apr. 27, 2007). Merck & Co., Inc., another well-known major prescription drug manufacturer, lists 36 ADRs on its website. *See* <http://www.merck.com/product/distributors> (accessed Apr. 27, 2007). Sandoz, a major generic drug manufacturer, lists over 50 different business entities that have ADR status, some of which only have that status for specific products. *See* [http://www.us.sandoz.com/site/en/company/news/pool/ADR\\_LISTING.pdf](http://www.us.sandoz.com/site/en/company/news/pool/ADR_LISTING.pdf) (accessed Apr. 27, 2007).

In comparison, other manufacturers may designate only one or two ADRs. For example, manufacturer Millenium Pharmaceuticals, Inc. has chosen to have only two ADRs for its product, but has authorized a diverse group of approximately 30 non-ADRs to place orders for that product through its ADRs. *See* <http://www.millennium.com/products/velcade/adr.asp> (accessed Apr. 27, 2007).

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<sup>6</sup> There is no requirement that a manufacturer make its ADR list available on the Internet.

As these references clearly demonstrate, the wholesale distribution market is far more open, diverse, and competitive than secondary distributor appellees would have the Court believe. There is substantial diversity of ADRs within most manufacturers' ADR lists (many small and medium-sized firms are listed), but there also exists robust variability *between* manufacturers that is equally damaging to secondary distributor appellees' factual assertions. In short, there is simply no evidence supporting the notion that all (or even most) manufacturers somehow confine their ADR designations to a few large distributors, or that the distribution market is otherwise wholly occupied by a few large distributors. Moreover, the prescription drug distribution marketplace is highly competitive. HDMA members and non-HDMA distributors actively compete with each other to provide a safe, efficient, and reliable source of prescription drugs and other products to the nation's healthcare providers.<sup>7</sup>

As noted, each manufacturer decides for itself, on a product-by-product basis if it so desires, how many and which distributors will be its trading partners with ADR status. In addition, each manufacturer always has discretion to sell to non-ADRs, so that every distributor to whom a manufacturer sells its products will not necessarily be on its published list of ADRs.

Secondary distributor appellees' objection here is really that secondary wholesalers will no longer be able to buy prescription drugs from other distributors and create their own pedigrees in concert with each of these suppliers. Until now, non-ADRs have only had to provide a pedigree

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<sup>7</sup> The lead plaintiff in this case (RxUSA Wholesale, Inc.), represented by the same counsel, has a pending private antitrust lawsuit against HDMA, five prescription drug distributors that are HDMA members, and 16 prescription drug manufacturers. *RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, No. 06-CV-03447 (DRH) (E.D.N.Y. filed July 14, 2006). In that antitrust lawsuit, RxUSA Wholesale, Inc. claims that it has been injured by the allegedly "monopolistic" business practices of prescription drug manufacturers and distributors.

going back to the last ADR. Now they have to trace the product's history back to the manufacturer. This may be difficult, but it is exactly what Congress intended the law to do.

The PDMA is intended to eliminate counterfeit and otherwise adulterated products that tended to originate in the secondary market. To achieve this goal, Congress provided two options. A manufacturer may form a publicly disclosed, ongoing ADR relationship with a distributor, where the manufacturer has made an affirmative decision to rely on the distributor to handle its products. A manufacturer of course could terminate a distributor's ADR status. Thus, ADRs have an incentive not to abuse their ADR status. Alternatively, a distributor without ADR status must provide a pedigree with a documented chain of custody going back to the manufacturer to prevent counterfeit, diverted and substandard product from reaching consumers.

Secondary distributor appellees and other secondary distributors may seek to become ADRs. For its own business reasons, each manufacturer may or may not choose to grant ADR status to all distributors desiring it, and may or may not choose to have only a limited number of ongoing ADR relationships. Secondary distributor appellees and other secondary distributors can also seek to purchase products from ADRs, but they may not always be successful in doing so, since each ADR will make its own decisions as to its customers.

Secondary distributor appellees and other secondary distributors can continue to purchase in the secondary market, but the pedigree will now have to go all the way back to the manufacturer and cannot be created entirely by the secondary wholesaler, in concert with its direct, non-ADR supplier. Some secondary wholesalers may lose business or have to alter existing business relationships as a result of this change, but this is what Congress put into law, because the uncertain origin of prescription drugs in the secondary market had resulted in counterfeit and otherwise adulterated products.

For these reasons, the very diverse and competitive nature of the prescription drug distribution industry are at odds with the district court's conclusion that FDA's pedigree rule will put all non-ADRs out of business.

### III. CONCLUSION

For the reasons discussed above and in FDA's brief, this Court should reverse the district court's December 11, 2006 judgment and vacate the preliminary injunction.

April 27, 2007

Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE WITH RULE 32(a)**

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 5,748 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2000 (9.0.2720) in Times New Roman (12 point).

Dated: April 27, 2007

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