UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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RxUSA WHOLESALE, INC., ALDEN SURGICAL CO., INC., ATLANTIC BIOLOGICALS, INC., BELL MEDICAL SERVICES, INC., C.O. TRUXTON, INC., HYGEN PHARMACEUTICALS, INC. and STAT PHARMACEUTICALS, INC.,

Plaintiffs,

- against -

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

Defendants.

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REPORT AND RECOMMENDATION

CV 06-5086 (JS) (AKT)

A. KATHLEEN TOMLINSON, Magistrate Judge:

Before the Court is the Motion for a Preliminary Injunction brought by Plaintiffs RxUSA Wholesale, Inc., Alden Surgical Co., Inc., Atlantic Biologicals, Inc., Bell Medical Services, Inc., Co. Truxton, Inc., Hygen Pharmaceuticals, Inc. and Stat Pharmaceuticals, Inc. (collectively "Plaintiffs") which has been referred to me by District Judge Seybert for a Report and Recommendation. Plaintiffs seek preliminary injunctive relief enjoining Defendants Department of Health and Human Services and the U.S. Food and Drug Administration ("FDA") from making effective § 203.50(a) [21 CFR 203.50(a)] (the "Rule"), an FDA regulation promulgated to enforce § 503(e)(1)(A) of the Prescription Drug Marketing Act of 1987 ("PDMA," 21 U.S.C. § 503 et seq.) and which is presently scheduled to become effective on December 1, 2006.

Based upon Plaintiffs' Memorandum of Law in Support of the Motion, the affidavit of Robert Drucker, sworn to on November 21, 2006, with accompanying exhibits, Defendants'

Memorandum of Law In Opposition To Plaintiffs' Order to Show Cause For A Preliminary Injunction Staying The Effective Date of a FDA Regulation, Plaintiffs' Reply Memorandum of Law In Further Support Of Their Motion For Preliminary Injunctive Relief, the oral arguments presented at the November 29, 2006 hearing and the applicable law, I am recommending that Plaintiffs' motion for a preliminary injunction against the Department of Health and Human Services and the FDA be granted.

I. Factual Background

Plaintiffs are all engaged in the wholesale distribution of pharmaceutical products. Compl. ¶ 12. They purchase pharmaceutical products for resale almost exclusively from authorized distributors and not directly from manufacturers – primarily because manufacturers typically refuse to sell product directly to Plaintiffs. *Id.* ¶ 14 In order to understand fully the nature of the controversy now before the Court, it is necessary to delve into some of the legislative history of the statute at issue as well as the implementing regulations formulated by the FDA.

On April 22, 1988, Congress enacted the Prescription Drug Manufacturing Act 21 U.S.C. § 331, et seq. (Public Law 100-293). That law was modified by the Prescription Drug Amendments of 1992 ("PDA") on August 26, 1992 (Public Law 102-353, 106 Stat. 941). *Id.* ¶ 16. The PDMA, as modified by the PDA, amended sections 301, 303, 503 and 801 of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 331, 333, 353, 381 to establish,

among other things, requirements for the wholesale distribution of prescription drugs by certain entities, including unauthorized[1] wholesaler distributors such as Plaintiffs. *Id.* ¶ 17.

The object of the bill introduced into the U.S. House of Representatives and the Senate, which eventually became the PDMA, was to assure safe and effective distribution of prescription drugs and to minimize risks to consumers from taking counterfeit, adulterated, sub-potent or expired drugs. *See The Prescription Drug Marketing Act Report to Congress June 2001* ("FDA 2001 Report"), annexed as Exhibit 17 to the Affidavit of Robert Drucker;[2] Drucker Aff., ¶ 9. The thrust of the bill was to amend § 503 of the FDCA so as to impose a "pedigree" requirement on wholesale distributors of prescription drugs. Section 6 of the bill set forth in relevant part the following:

> Section 503 [of the FDCA] is amended by adding at the end the following:
>
> (e)(1) 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 sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.

Drucker Aff., ¶ 9.

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[1] It should be noted that "unauthorized" in this context refers only to the fact that these wholesale distributors have not been designated as "authorized distributors" by the manufacturers in this industry. They are so-called "secondary wholesalers" who are not included on a manufacturer's "authorized distributor" list.

[2] All subsequent references to the Affidavit of Robert Drucker are cited as "Drucker Aff., ¶ ___."

In its report of April 30, 1987, the House of Representatives stated that the "pedigree" requirement was "designed to restore accountability to the wholesale sector of the pharmaceutical market. . ." and further noted that "[t]he Oversight Committee'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." *See House Report*, annexed to Drucker Aff., as Ex. 1, at p. 17. The House Report concluded, therefore, that "unauthorized distributors will be required to certify in writing to drug wholesalers the source and place **from which they obtained the drugs**." *Id.* (emphasis supplied) The Senate Report of March 18, 1988 reflected the same language. *See Senate Report*, annexed to Drucker Aff., as Ex. 2, at p. 7. This language remained in both the House and Senate Bills which were ultimately signed into law by President Reagan on April 22, 1988 and came to be known as the PDMA. At that time, based on the foregoing language, the law required unauthorized wholesale distributors to provide pedigree information only so far back as the source from which they obtained the goods. Drucker Aff., ¶¶ 11-13.

On August 1, 1988, the FDA issued a letter that provided guidance on the PDMA for the pharmaceutical industry, pending the issuance of implementing regulations. Compl. ¶ 19. This "Guidance Letter" interpreted the PDMA to require that the pedigree provided by unauthorized wholesale distributors contain the following information, in relevant part:

> 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.

Under the FDA's interpretation of the PDMA at that time, then, an unauthorized wholesale distributor was required to pass along pedigree information relating back to **either** the manufacturer **or** the authorized distributor, depending upon from whom the unauthorized wholesale distributor purchased the drugs (emphasis supplied). Compl. ¶ 20; Drucker Aff., ¶¶ 14-15.

The 1992 amendments which came to be known as the PDA modified several sections of the PDMA, including some of the language of § 503(e)(1). The amendments basically expanded the requirement to provide a pedigree with specific items of information and mandated that the pedigrees be provided to retail pharmacy buyers as well as wholesale distributor purchasers. Drucker Aff., ¶ 18. The language outlining the requirement that an unauthorized wholesale distributor had to pass along pedigree information relating back to either the manufacturer or the authorized distributor did not change. *Id.* Since 1988, the wholesale pharmaceutical products industry – including both authorized and unauthorized wholesale distributors – has been complying with the PDMA by giving pedigree statements back only to the authorized distributor from whom the product was purchased. *Id*. ¶ 19.

The FDA issued proposed regulations to enforce the provisions of the PDMA on March 14, 1994, at which time it requested public comments on those proposed regulations. *Id.* ¶ 20. Section 203.50(a)(6) of the proposed regulations provided, in relevant part, as follows:

> 203.50 – Requirements for wholesale distribution of prescription drugs.
>
> (a) Identifying statement for sales by unauthorized distributors. 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**. . . .

Id. ¶ 20 (emphasis supplied). This proposed rule changed the 1988 Guidance Letter to a regulation which required, for the first time, that unauthorized wholesale distributors provide pedigree information all the way back to the manufacturer, regardless of whether the wholesale distributor purchased the drugs from the manufacturer or from an authorized distributor. *Id.* ¶ 21. This proposed rule placed secondary wholesalers in the position of having to purchase drugs from an authorized distributor who was ***not required*** to convey any pedigree information whatsoever but nevertheless required the secondary wholesaler to provide pedigree information back to the manufacturer – information that was not possible to obtain if the authorized distributor refused to provide it. *Id.* ¶ 23 (emphasis supplied).

After a comment period, the FDA published final regulations in part 203 on December 3, 1999. These were to become effective on December 4, 2000. Compl. ¶ 22; Drucker Aff., ¶ 24. Specifically, § 203.50 stated that

> (a) Identifying statement for sale by unauthorized distributors. 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 transaction involving the drug, **starting with the manufacturer**.

See Drucker Aff., Ex. 7 (emphasis supplied). Therefore, before completion of any wholesale distribution of a prescription drug by an unauthorized wholesale distributor, the seller had to provide to the purchaser pedigree statements showing the entire prior sales history of the drug back to the original manufacturer.

After the final rule was published, the FDA received communications from wholesalers, industry trade associations and members of Congress objecting to this most recent provision regarding the pedigree "identifying statement." Compl. ¶ 23. The FDA met with representatives of the wholesale drug industry and industry associations on March 29, 2000 to discuss their concerns regarding the regulations. As a result of that meeting, the FDA delayed the effective date for those provisions until October 1, 2001 and reopened the administrative record to receive additional comments. Drucker Aff., ¶ 27. In the *Federal Register*, the FDA noted that it was delaying enforcement of the Rule "to address numerous concerns about the provisions raised by effected [sic] parties." Drucker Aff., Ex. 8, p. 25639. In connection with the pedigree requirement, the FDA commented that

> [t]he meeting participants asserted that manufacturers are unwilling to enter in written authorization agreements with the majority of smaller wholesalers so that these wholesalers cannot become authorized distributors of record to the drugs they sell and, hence, must provide an identifying statement for these drugs. The meeting participants also said that the smaller wholesalers can not obtain an identifying statement showing all prior sales of the drugs they purchase for sale because a large portion of these drugs are purchased from authorized distributors who are not required to provide identifying statement and are unwilling to voluntarily provide them. The meeting participants asserted that authorized distributors will not voluntarily provide identifying statements when they sell drugs to unauthorized distributors because it would require them to change their warehouse and business procedures, which would entail additional effort and expense.

> The meeting participants asserted that implementation of the final rule will prevent over 4,000 smaller, unauthorized distributors from distributing drugs to their customers and may put them out of business, at least with respect to their prescription drug wholesale business. They also asserted that because many of their customers are smaller retail outlets that are not served by larger distributors, implementation of the final rule may leave certain markets for prescription drugs, and ultimately consumers for prescription drugs, underserved.

Id. On May 16, 2000, the House Committee on Appropriations stated that it supported "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." The Committee further noted that it "believes the agency should thoroughly review the potential impact of the proposed revisions on the secondary wholesale pharmaceutical industry." Compl. ¶ 25.

On September 19, 2000, the FDA announced that it would conduct public hearings on § 203.50. Jane Axelrod, Associate Director for policy in the Center for Drug Evaluation and Research, in describing events leading up to the hearing, stated that

> After we published the final rule we received a lot of letters and petitions, and had discussions with industry, industry trade associations and even members of Congress objecting to certain provisions of the regulation. As I said, we really didn't have any inkling from the comments we received on the proposed rule what the implications of this were going to be so really we were not quite prepared for the controversy that began almost as soon as we published the regulations.

Drucker Aff., Ex. 10, p. 9. On March 1, 2001, the FDA again delayed the effective date of the provision to April 1, 2002. In the notice announcing the delay, the FDA stated that part of the reason for the delay was to "allow more time" for the agency "to make recommendations to Congress, for Congress to evaluate those recommendations and, if necessary, time for regulatory

or legislative change." Drucker Aff., Ex. 16; Compl. ¶ 26. The notice went on to state that the "FDA acknowledges the concerns of the Pharmaceutical Distributors Association and has decided that, in light of the uncertainty regarding how to resolve the issues involved and the possible adverse consequences that could result from implementation of the relevant provisions of the final rule, it is reasonable and appropriate to delay the effective date" of § 203.50. Drucker Aff., Ex. 16.

On June 7, 2001, the FDA submitted its "Prescription Drug Marketing Act Report" to Congress. The report advised Congress, among other things, of the following:

> The PDMA pedigree exemption for authorized distributors not only puts unauthorized distributors at a disadvantage, but also has the effect of wiping the slate clean each time prescription drugs pass through an authorized distributor. Today under the *status quo*, a large volume of prescription drugs move through the system without pedigrees, or with incomplete pedigrees, because they have passed through an authorized distributor at least once before reaching their retail destination.
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> * * *
>
> The [FDA] believes that, given today's prescription drug distribution system, the PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree undermines the purpose of the pedigree by allowing for potential gaps in the distribution history.
>
> * * *
>
> FDA does not have the authority to require authorized distributors to maintain and pass on a pedigree. Such a requirement would necessitate a statutory change.

Drucker Aff., Ex. 17, pp. 8-9; Compl. ¶ 27. The FDA's report concluded that by revising the regulations, it would be able to address some, but not all, of the concerns raised by secondary wholesalers. Drucker Aff., ¶ 36 and Ex. 17, p. 7. Ultimately, the report noted that "[b]ecause

§ 230.50 reflects the language of the statute, the FDA believes that it cannot revise the regulation to make it consistent with the *status quo*. Such a requirement would necessitate a statutory change." *Id.*, Ex. 17, p. 10.

After submitting its report to Congress, the FDA published a notice on February 13, 2002 that it was further delaying the effective date of § 230.50, until April 1, 2003, because "the delay will allow additional time for Congress and FDA to consider whether legislative and regulatory changes are appropriate." Drucker Aff., Ex. 18, p. 6645; Compl. ¶ 28. A similar notice was published by the FDA on January 31, 2003, further delaying the effective date for the same reasons, namely, to give Congress additional time to determine whether legislative action was appropriate and to "give the agency additional time to consider whether regulatory changes are appropriate, and, if so, to initiate such changes." Drucker Aff., Ex. 19, p. 4912.

Subsequently, as part of its Counterfeit Drug Initiative, the FDA sought comment on the most effective ways to achieve the goals of the PDMA. In light of recent and impending advances in technology at the time, the FDA requested comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree. The majority of comments received as reported by the FDA supported the eventual use of an electronic pedigree for all drug products in the supply chain and indicated that an electronic pedigree should be considered as a long-term solution to fulfilling the PDMA requirements codified at § 230.50. Compl. ¶ 29. On February 23, 2004 (as corrected on March 18, 2004), the FDA published a notice that it was further delaying the effective date of § 230.50 – this time until December 1, 2006. Drucker Aff., ¶ 42; Compl. ¶ 30. In that notice, the FDA explained its reasoning:

> To summarize, FDA has concluded that an electronic pedigree should accomplish and surpass the goals of PDMA and is potentially a more effective solution to tracing the movement of pharmaceuticals than a paper pedigree. As stated previously, it appears that industry will migrate toward and implement electronic track and trace capability by 2007. Therefore, in order to allow stakeholders to continue to move toward this goal, FDA has decided to stay the effective date of . . . § 230.50 until December 1, 2006. Before the effective date, FDA intends to evaluate the progress toward implementation of the electronic pedigree and its capacity to meet the intent of PDMA, and determine whether to further delay the effective date of the regulations or take other appropriate regulatory action.

Drucker Aff., Ex. 20, p. 12795.

The foregoing "electronic pedigree" capability referenced by the FDA is presently operational in the United States. Drucker Aff., ¶ 42. Several software companies offer electronic pedigree systems that are in compliance with the PDMA. *Id.* ¶ 43. Plaintiff RxUSA Wholesale, Inc, as well as several other Plaintiffs here, has e-pedigree system capability through a subscriber service. However, the problem remains that neither manufacturers nor authorized distributors (with few exceptions) have adopted the system and continue to refuse to provide pedigree statements. *Id.*; Compl. ¶¶ 35-36.

On June 14, 2006, the FDA issued an announcement that it did not intend to further delay the effective date of § 230.50 and that it had published a compliance policy guide entitled "Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203" for public comment. Drucker Aff., ¶ 48 and Ex. 22, pp. 34249-34250. The FDA issued another announcement on November 14, 2006 that its final Compliance Policy Guide was available. Drucker Aff., ¶ 49. In addition, during the second week of November, 2006, the FDA released a Guidance comprised of questions and answers, entitled "Prescription Drug Marketing Act

(PDMA) Requirements." *See* Drucker Aff., Ex. 26. Among other things, that document states as follows:

- Manufacturers are not required under the PDMA to provide any specific information to wholesale customers [p. 5, question 9].
- Authorized Distributors are not required to provide a pedigree, whether they obtained the drug directly from a manufacturer, from another authorized distributor, or from a non-authorized distributor [p. 6, question 10].

Based upon the FDA's current interpretation of the PDMA, any inventory of the unauthorized wholesale distributors that exists after December 1, 2006 cannot be sold lawfully in the marketplace and further cannot be returned to the manufacturer or authorized distributor from which it was acquired.

II. Procedural History

On September 20, 2006, Plaintiffs filed a Complaint alleging four causes of action: (1) for a Declaratory Judgment that the FDA Rule at 21 CFR 203.50 is partially unenforceable because it constitutes an equal protection violation; (2) for a Declaratory Judgment that the FDA Rule at 21 CFR 203.50 is partially unenforceable because it constitutes a due process violation; (3) for a Declaratory Judgment that 21 U.S.C. § 503(e)(1)(A) of the FDCA is partially unenforceable because it constitutes an equal protection violation; and (4) for a Declaratory Judgment that § 503 (e)(1)(A) of the FDCA is partially unenforceable because it constitutes a due process violation. *See Compl.* ¶¶ 39-64. On November 22, 2006, Plaintiffs moved the Court for a preliminary injunction under Rule 65 of the Federal Rules of Civil Procedure seeking to stay the effective date of the Rule pending final resolution of this matter. On November 22, 2006, Judge Seybert

referred the issue of preliminary injunctive relief to me for a Report and Recommendation, pursuant to Fed. R. Civ. P. 72. *See* Order dated Nov. 22, 2006 [DE 5].

The parties appeared by telephone for a scheduling conference on November 27, 2006, at which time I set a briefing schedule. *See, e.g., Drywall Tapers and Pointers of Greater N.Y. v. Local 530 of Operative Plasterers and Cement Masons Int'l Ass'n*, 954 F.2d 69, 76 (2d Cir. 1992); *McKenna v. Wright*, No. 01-CV-6571, 2002 WL 338375, at *13 (S.D.N.Y. Mar. 4, 2002). At the November 27 conference, Plaintiffs and Defendants stated their belief that the motion could be resolved on paper submissions and without the need for live testimony. I advised the parties at that time that I would conduct the hearing on November 29, 2006 at 11 a.m. The motion was fully submitted immediately prior to the hearing on the preliminary injunction motion on November 29, 2006. At the conclusion of oral argument on November 29, 2006, I closed the hearing and reserved decision.[3]

III. The Parties' Contentions

Plaintiffs argue that the application of the Rule proposed by the FDA to unauthorized wholesale distributors of prescription drugs, and Plaintiffs in particular, deprives them of equal protection of the laws within the meaning of the Fourteenth Amendment. Pltffs. Memorandum at 17. It is Plaintiffs' position that the Rule requires wholesale distributors who are not authorized distributors to provide a pedigree statement "identifying each prior sale, purchase, or trade of such drug" that shall include "the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer" while at the same time exempting

[3] Because of the imminent implementation date of December 1, 2006, I agreed to render an expedited Report and Recommendation within one day of the hearing, namely November 30, 2006. The parties further agreed to compressed time period to file their objections.

authorized distributors from the pedigree requirement. To the extent that it does so, Plaintiffs maintain, the Rule makes it impossible for the unauthorized wholesale distributors to comply with the regulation as written. That impossibility of compliance, Plaintiffs argue, renders the regulation unconstitutional. *Id.* at 9. Further, Plaintiffs maintain that the Rule as promulgated is inconsistent with the purpose of the PDMA. Plaintiffs also argue that in the event the Rule is found to be a valid interpretation of the PDMA, then certain provisions of the PDMA must be found to be unconstitutional. According to Plaintiffs, when read in conjunction with the Rule promulgated by the FDA, the provision of the PDMA exempting authorized distributors from the pedigree requirement is not rationally related to the purposes of the PDMA, and, therefore, this classification results in disparate treatment of authorized and unauthorized wholesale distributors, in violation of the Equal Protection and Due Process Clauses.

On this motion, Plaintiffs seek to stay the effective date of the Rule promulgated by the FDA to allow the Court the opportunity to rule on the merits of the underlying claims. Plaintiffs have taken the position that staying the effective date maintains what the FDA acknowledges has been the *status quo* in the industry for the past ten (10) years. Defendants counter that the application of the FDA pedigree regulation is consistent with the plain meaning of the PDMA, Defts. Memorandum at 13, and that the regulation is consistent with the PDMA's legislative history. *Id.* at 15. The FDA has not identified any prejudice which might result if the Court were to stay the effective date of this Rule.

IV. **Standard of Review**

The decision whether to grant or deny a preliminary injunction rests within the Court's sound discretion. *Weight Watchers Int'l v. Luigino's, Inc.,* 423 F.3d 137, 141 (2d Cir. 2005);

Sierra Club v. United States Army Corps of Engineers, 732 F.2d 253, 256 (2d Cir. 1984). The grant of a preliminary injunction is reviewed for abuse of discretion. *Hoblock v. Albany County Bd. of Elections*, 389 F.3d 411, 418 (2d Cir. 2004); *Rodriquez v. DeBuono,* 175 F.3d 227, 233 (2d Cir. 1999) (per curiam). A district court abuses its discretion in granting a preliminary injunction "if it applies the wrong legal standard, rests its decision on a clearly erroneous finding of fact, or issues an injunction containing an error of form or substance." *Hoblock,* 422 F.3d at 96; *see also Phillip v. Fairfield Univ.,* 118 F.3d 131, 133 (2d Cir. 1997) (per curiam).

The requirements for a preliminary injunction in this Circuit are typically met when a plaintiff shows "(a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting preliminary relief." *Kaplan v. Bd. of Educ. of the City Sch. Dist. of the City of New York,* 759 F.2d 256, 259 (2d Cir.1985); *see also 1-800 Contacts, Inc. v. WhenU.com, Inc.,* 414 F.3d 400, 406 (2d Cir.), *cert. denied*, 126 S. Ct. 749 (2005); *Federal Express Corp. v. Federal Espresso, Inc.*, 201 F.3d 168, 173 (2d Cir. 2000). Where the moving party seeks to stay governmental action taken in the public interest pursuant to a statutory or regulatory scheme, however, the moving party must show "irreparable injury and a likelihood of success on the merits," *Bery v. City of New York,* 97 F.3d 689, 694 (2d Cir. 1996), not just sufficiently serious questions going to the merits of the action. This higher standard "reflects the idea that governmental policies implemented through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." *Able v. United States,* 44 F.3d 128, 131 (2d Cir. 1995). As Plaintiffs are seeking to enjoin the implementation of a government program intended to protect the public

through the regulation of the distribution of prescription drugs, the application of this higher standard is appropriate here. At oral argument, neither party disputed the application of the higher standard.

A preliminary injunction is a drastic and extraordinary remedy that should not be granted routinely. *See JSG Trading Corp. v. Tray-Wrap, Inc.*, 917 F.2d 75, 80 (2d Cir. 1990); *Patton v. Dole*, 806 F.2d 24, 28 (2d Cir. 1986); *Collagenex v. Ivax Corp*., 375 F. Supp. 2d 120, 123 (E.D.N.Y. 2005). Movants seeking preliminary injunctive relief, therefore, have a "heavy burden" to sustain. *See Robert W. Stark, Jr. v. New York Exch., Inc*., 466 F.2d 743, 744 (2d Cir. 1972); *Dopp v. Franklin Nat. Bank*, 461 F.2d 873, 878 (2d Cir. 1972); *Ringling Bros.-Barnum & Bailey Combined Shows, Inc. v. B.E. Windows Corp.*, 937 F. Supp. 204, 207 (S.D.N.Y. 1996).

Here, the *status quo* in the industry for the past ten (10) years has been to provide a pedigree back to either (1) the manufacturer **or** (2) the authorized distributor. Staying the effective date of the subject FDA Rule does nothing more than maintain what the FDA has already acknowledged is currently the *status quo*. Since 1988, the wholesale pharmaceutical products industry – including both authorized and unauthorized wholesalers – has been complying with the PDMA by giving pedigree statements back only to the authorized distributor from whom the product was purchased. Drucker Aff., ¶ 19. *See, e.g., Building and Constr. Trades Dep't, AFL-CIO v. Donovan*, 543 F. Supp. 1282, 1290 (D. D.C. 1982) (granting preliminary injunction restraining the enforcement of certain regulations issued in implementation of the Davis-Bacon Act where the prior regulations had been the industry standard for many years).

V. Discussion

A. *Irreparable Harm*

The Second Circuit has repeatedly held that the irreparable harm requirement is "the single most important prerequisite for the issuance of a preliminary injunction." *Rodriguez v. DeBuono*, 175 F.3d 227, 234 (2d Cir. 1999) (per curiam) (quoting *Mamiya Co. v. Masel Supply Co.*, 719 F.2d 42, 43 (2d Cir. 1983)); *accord Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005); *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990). Thus, unless Plaintiffs can show an injury that "is neither remote nor speculative, but actual and imminent and cannot be remedied by an award of monetary damages," a motion for a preliminary injunction should be denied. *See Rodriguez,* 175 F.3d at 234.

Irreparable harm may be found where the moving party makes a "strong showing that economic loss would significantly damage its business above and beyond a simple diminution in profits." *See Mylan Pharm., Inc. v. Shalala,* 81 F. Supp. 2d 30, 42 (D. D.C. 2000); *Express One Int'l, Inc. v. United States Postal Serv.*, 814 F. Supp. 87, 91 (D. D.C. 1992) (bidder demonstrated irreparable injury where loss of ten-year $1 billion contract would cause annual loss of $130 million, would impair bidder's relationships with subcontractors and would likely cause capital costs and layoffs).

It is well settled in this Circuit "that the loss of a business" constitutes irreparable harm. *Soap Opera Now, Inc. v. News America Publ'g, Inc.*, No. 90-CV-2631, 1990 WL 124335 at *4 (S.D.N.Y. Aug. 17, 1990); *see also The Arbitron Co. v. Phoenix Broad. Corp.*, No. 97-CV-4355, 1997 WL 452020, at * 4 (S.D.N.Y. Aug. 6, 1997). Thus, where the injunction will prevent damage to the business as a whole, irreparable harm can be established. *See, e.g.*, *GPA Inc. v.*

Liggett Group, Inc., 862 F. Supp. 1062, 1068 (S.D.N.Y. 1994) ("[t]he law requires that the injury to a business necessary to support a grant of a preliminary injunction must be damage to the business as a whole (as opposed to a temporary or partial disruption) and that damage must be immediate"); *Jessup v. American Kennel Club, Inc.*, 862 F. Supp. 1122, 1128 (S.D.N.Y. 1992) (denying motion for preliminary injunction "because the evidence . . . does not reflect loss of goodwill or destruction of business sufficient to support a finding of likelihood of irreparable injury").

Here, the evidence is unrefuted. In his Affidavit filed in support of the motion for preliminary injunction, Plaintiff RxUSA Wholesale's President, Robert Drucker, states that he has attempted for several years to obtain authorized distributor status for his company from virtually every major manufacturer of pharmaceuticals in the United States, to no avail.[4] As evidence, Drucker has supplied refusal letters from major pharmaceutical manufacturers Alcon, Bristol-Myers Squibb, Eisai, GlaxoSmithKline, Inc., Novartis, Pfizer, Schering-Plough, Takeda and Wyeth. Drucker Aff., Ex. 12. The Drucker affidavit goes on to note that "[o]nce the FDA's rule becomes effective . . . neither my company, nor any of the other Plaintiffs will be able to continue in any substantive wholesale distribution business." Drucker Aff., ¶ 66. In addition, Mr. Drucker states that "once our businesses are destroyed and dismantled, it will matter very

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[4] Plaintiff RxUSA Wholesale, Inc. states in its papers – and reiterated at oral argument – that it is an authorized distributor for approximately 30 smaller manufacturers. However, RxUSA Wholesale has been unable to obtain "authorized distributor" status from any of the major drug manufacturers. Although RxUSA Wholesale has invested monies to become completely electronic pedigree-ready, none of the "big three" authorized distributors who purportedly control approximately 95% of the metropolitan and national markets will agree to provide any pedigree information as far back as the manufacturer from whom they purchased drugs. Drucker Aff., ¶ 28.

little whether this Court eventually determines that either the FDA Rule or the underlying statute is unconstitutional." *Id*. ¶ 67. Further, Mr. Drucker points out that the inventory which his company possesses will become worthless since it cannot be returned to the manufacturer or authorized distributor under the new regulations. *Id*. ¶ 68.

At the October 27, 2000 public hearing, the FDA received testimony from several witnesses, including Anthony Young, general counsel to the Pharmaceutical Distributors Association – an association of licensed prescription drug wholesalers that are not authorized distributors of record for the pharmaceuticals they distribute. In his testimony, Mr. Young pointed out that there is no practical way for unauthorized wholesale distributors to obtain pedigree information from authorized distributors since major wholesalers do not voluntarily give pedigree information. Drucker Aff., Ex. 11, p. 37. Young also observed that if the four thousand secondary wholesalers nationwide go out of business as a result of the rule, there will be a serious disruption of drug distribution. *Id*. at pp. 38-39. Citing two economists whose reports were submitted into the record of the hearing, Young stated that the end result of the rule will be higher prices, higher insurance premiums and enhanced ability to charge premium prices. *Id*. at pp. 40-41. Young also referred to a declaration submitted by Steve Simms, former staff person to Congressman Dingell – the author of the PDMA – stating that it was not the intention of Congress to create such an anti-competitive result and upset the system so dramatically, *id*. at p. 46, when the industry had been operating for the prior twelve years under an FDA guidance that interpreted the PDMA to require unauthorized wholesale distributors' pedigree history to go back only to the authorized distributor from whom they purchased the drugs, *id.* at p. 38.

Defendants do not substantively respond to the irreparable harm issue. In opposing the motion, the FDA for example does not address Plaintiffs' claims of loss of business or impossibility of performance. Given my review of all the paper submissions as well as the arguments advanced by both sides during the November 29 hearing, I find that the potential destruction of Plaintiffs' businesses constitutes irreparable injury.

B. *Likelihood of Success on the Merits*

1. The FDA Rule

Plaintiffs assert that the application of the Rule proposed by the FDA to unauthorized wholesale distributors of prescription drugs, and Plaintiffs in particular, deprives them of equal protection of the laws within the meaning of the Fourteenth Amendment. Pltffs. Memorandum at 17. It is Plaintiffs' position that to the extent the Rule (1) requires wholesale distributors who are not authorized distributors to provide a pedigree statement "identifying each prior sale, purchase, or trade of such drug" that shall include "the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer" and (2) at the same time exempts authorized distributors from the pedigree requirement, the Rule makes it impossible for the unauthorized wholesale distributors to comply with the regulation as written. As such, Plaintiffs contend that the regulation is unconstitutional. *Id.* at 9. Defendants counter that the application of the FDA pedigree regulation is consistent with the plain meaning of the PDMA, Def. Memorandum at 13, and that the regulation is consistent with the PDMA's legislative history. *Id.* at 15.

Typically, the FDA's administrative actions are subject to review by the Court under the Administrative Procedure Act ("APA"), and may be disturbed only "if arbitrary, capricious, an

abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (2)(A). When reviewing the FDA's interpretation and application of the PDMA, the Court must apply the two-part test set forth by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837 (1984). The Court first must determine whether Congress has spoken to the question at issue and then determine, if Congress has not addressed the issue, if the agency's regulation is a permissible construction of the statute. *Id*. at 842-43. However, where an agency is attempting, through new regulation, to overturn a position it had originally taken in an order issued contemporaneously with the legislation and allowed to stand without challenge or contradiction for many years, the Court should not simply defer to the agency's conclusion but should make an independent judgment, examining the agency's conclusion "with more exacting vigilance than would otherwise be employed." *Building and Const. Trades Dep't, AFL-CIO,* 543 F. Supp. at 1290 (granting preliminary injunction restraining the enforcement of certain regulations issued in implementation of the Davis-Bacon Act).

On the record before me, Plaintiffs have not demonstrated that there is a substantial likelihood that they will prevail on their claim that the new Rule, by itself, is inconsistent with the language and intent of the PDMA, since the language of the Rule closely mirrors that of the statute. However, as discussed below, this Rule does not stand in isolation, but rather must be viewed in connection with other provisions of the PDMA as enacted by Congress.

2. The PDMA

Plaintiffs' have asserted several challenges to the constitutionality of the PDMA. However, given the time constraints imposed by the filing of this motion roughly a week before the effective date of the statute, I will not rule on all of them since it is unnecessary to do so. For

the reasons stated below, I find that Plaintiffs have demonstrated a substantial likelihood of success on the merits on their claim that when read in conjunction with the Rule promulgated by the FDA, the provision of the PDMA exempting authorized distributors from the pedigree requirement is not rationally related to the purposes of the PDMA, and, therefore, there is a substantial likelihood that the classification resulting in the disparate treatment of authorized and unauthorized wholesale distributors may be found unconstitutional.

Traditional equal protection analysis grants great deference to legislative classifications. If "the distinctions drawn have some basis in practical experience," *South Carolina v. Katzenbach,* 383 U.S. 301, 331 (1966), or if "any state of facts reasonably may be conceived to justify" them, *McGowan v. Maryland*, 366 U.S. 420, 426 (1961), and they are not drawn "on the basis of criteria wholly unrelated to the objective of (the) statute," *Reed v. Reed*, 404 U.S. 71, 76 (1971), then the statute will withstand an equal protection challenge. "But the [Supreme] Court also has refined this traditional test and has said that a statutory classification based upon suspect criteria or affecting 'fundamental rights' will encounter equal protection difficulties unless justified by a 'compelling governmental interest'." *Schilb v. Kuebel*, 404 U.S. 357, 365.

The parties agree that this action neither affects fundamental rights nor involves a traditionally suspect classification. Therefore, we need only determine whether the allegedly discriminatory provisions of the PDMA and the FDA regulation promulgated thereunder can be justified by any reasonable statement of facts supported by the broad purposes of the PDMA. Both sides agree that the purpose of the PDMA is to ensure the integrity of the nation's drug distribution system and to prevent the distribution of drugs that are counterfeit, adulterated, misbranded, or otherwise unsafe. Drucker Aff., Ex. 1, at p. 17. Plaintiffs contend that "it is the

exemption of so-called authorized distributors from [the pedigree] requirement that is claimed to have no conceivable rational relationship to any legitimate government interest." Pltffs.' Reply Memorandum at 10. Plaintiffs point out that the FDA itself specifically stated, in its June 2001 Report to Congress (Ex. 17, pp. 8-9) that "[t]he PDMA provision that exempts authorized distributors from having to maintain and pass on a pedigree undermines the purpose of the pedigree." It is Plaintiffs' position here that the constitutional violation at issue results from the exemption of certain entities from compliance with pedigree reporting requirements, which exemption makes it impossible for the Plaintiffs to comply with the statute as interpreted by the FDA.

Defendants counter that Congress stated its belief that "most" unsafe drugs pass through the hands of the unauthorized wholesale distributors and therefore the exemption of the authorized distributors from the pedigree requirement has a rational basis and should not be disturbed.

Recognizing that "rational-basis review in equal protection analysis 'is not a license for courts to judge the wisdom, fairness, or logic of legislative choices,'" *Heller v. Doe*, 509 U.S. 312, 319 (1993), I nonetheless find that Defendants' argument here falls short. As recognized by the FDA 2001 Report, "the volume of drugs authorized distributors purchase from secondary wholesalers is significant." *See* Drucker Aff., Ex. 17, pp. 8-9. These drugs are then resold by the authorized distributor without a pedigree. *Id.* Even if only a tiny fraction of the suspect drugs pass through the hands of the authorized distributors, it is not rational for the authorized distributors to be exempt from the requirement of providing a pedigree, particularly since the prescription drugs sold may very well have been purchased on the open market.

Moreover, at the October 27, 2000 public hearing, the FDA heard testimony from Ty Kelley, Director of Government Relations for the Food Marketing Institute. The Food Marketing Institute is comprised of members who operate approximately 8,000 pharmacies within major retail stores (Safeway, Giant, Kroger, Albertson's, Publix, etc.). Mr. Kelley stated, among other things, that while the final rule requires authorized distributors to obtain a pedigree, the "Catch-22 here is that the regulations don't require either the manufacturer or an authorized distributor to provide them." Drucker Aff., Ex. 14, p. 99.

"This Court is obligated to seek out other conceivable reasons for validating" the statute at issue. *Powers v. Harris*, 379 F.3d 1208, 1217 (10th Cir. 2004). Having considered all of the arguments advanced by the parties here and having searched for any conceivable precedent akin to the specific circumstances of this case, I am unable to discern a reason to validate the statute with respect to this particular issue. It is not reasonable or rational to believe that Congress intended to create a situation in which it would be impossible for unauthorized wholesale distributors to comply with the regulations of the PDMA. Rather than engage in the convoluted exercise of defining a secondary market, but then making it impossible for entities in the secondary market to actually sell prescription drugs legally, Congress could have much more simply and directly allowed only authorized distributors to distribute prescription drugs. Based on the chronology of events and exhibits submitted detailing the discussions in both the FDA and Congress, however, it seems clear that Congress did not desire that result. At an October 27, 2000 public hearing, the FDA received testimony from several witness, including Anthony Young, general counsel to the Pharmaceutical Distributors Association who referred to a declaration submitted by Steve Simms, former staff person to Congressman Dingell – the author

of the PDMA – stating that it was not the intention of Congress to create such an anti-competitive result. Drucker Aff., Ex. 11, at pp. 37-38. While it is not for this Court to offer suggested legislation, I simply point out that creating such an unworkable situation could not have been Congress' intent and I see no plausible explanation for the creation of a statute that is, in practice, impossible to comply with. Accordingly, I find that Plaintiffs have demonstrated a substantial likelihood of success on the merits of this individual claim.

VI. Laches

Defendants argue that the doctrine of laches precludes the Court from granting Plaintiffs' motion for a preliminary injunction, staying the December 1, 2006 effective date of the Rule, because Plaintiffs unreasonably delayed in making their application until five business days prior to the effective date. *See* Defts. Memorandum at 32. Defendants reason that Plaintiffs had adequate notice since the pedigree requirements set forth in the regulations are not new, but are rather restatements of those contained in the statute, which has been effective in its present form since 1992. *See id*. at 32-33. Additionally, Defendants argue that Plaintiffs have had six months' notice of the impending December 1, 2006 effective date for implementation of the Rule because the FDA published this information in an announcement on June 14, 2006. *See* 71 Fed. Reg. 34250 (June 14, 2006). *See id.* Defendants contend that Plaintiffs' unreasonable delay in bringing this motion "evinces bad faith and undermines any possible good faith contention of imminent, irreparable harm absent a stay." *See* Defts. Memorandum at 32-33.

In rebuttal, Plaintiffs contend that

> the urgent necessity to bring this motion arose because (i) the FDA refused to further delay the effective date of the regulation, notwithstanding that Plaintiffs have challenged the constitutionality

> of the same more than two months ago, and (ii) the FDA announced, for the first time last week, that no inventory could be returned without pedigree information, even though it was purchased before such information was required, and even though Congress clearly did not intend to include returns within the definition of "sales" for pedigree purposes.

Pltfs. Memorandum at 14.

At the November 29, 2006 oral argument, Plaintiffs' counsel argued that it was unfair for Defendants to raise a defense of laches at this juncture since industry representatives were discussing the Rule with FDA representatives as late as this week. This statement was corroborated by Sarah Hawkins, the representative who appeared on behalf of the FDA at the November 29, 2006 oral argument. The Affidavit of Robert Drucker, President of RxUSA Wholesale, Inc. details extensive negotiations between the parties about the implementation of the effective date.[5] In addition, Drucker states that the FDA's requirement, that any inventoried goods to be returned to the originating entity from where they were purchased must be accompanied by a pedigree statement, was "announced for the first time just a week ago." Drucker Aff., ¶ 51. Further, as late as November 20, 2006, counsel for the parties also discussed entering into a possible stipulation consenting to a temporary restraining order. Defendants' counsel ultimately advised Plaintiffs' counsel that "he had no authority to do so." Levine Aff., at ¶ 5.

The doctrine of laches is an equitable defense which bars injunctive relief where a plaintiff unreasonably delays in commencing an action. *See Stone v. Williams*, 873 F.2d 620, 623 (2d Cir.), *cert. denied*, 493 U.S. 959 (1989), *vacated on other grounds*, 891 F.2d 401 (2d Cir.

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[5] These negotiations are set forth in detail in Section II of this Report and Recommendation.

1989), *cert. denied*, 496 U.S. 937 (1990). A party asserting a laches defense must show that "the plaintiff has inexcusably slept on [its] rights so as to make a decree against the defendant unfair." *Prudential Lines, Inc. v. Exxon Corp.*, 704 F.2d 59, 65 (2d Cir. 2003). As an equitable doctrine, laches may not be based on delay alone. *See Tamini v. M/V Jewon*, 808 F.2d 978, 979 (2d Cir. 1987); *Henkind v. Brauser*, No. 87-CV-4072, 1989 WL 54109, at *9 (S.D.N.Y. May 17, 1989). In order to establish a defense of laches and bar the grant of injunctive relief, a defendant must also prove that it has been prejudiced by the plaintiff's unreasonable delay in bringing the action. *See Tri-Star Pictures, Inc. v. Leisure Time Prods., B.V.*, 17 F.3d 38, 44 (2d Cir. 1994).

The Second Circuit has found a defendant to be prejudiced when the assertion of a claim would be "inequitable" in light of the delay in bringing that claim. *See Saratoga Vichy Spring Co. v. Lehman*, 625 F.2d 1037, 1040 (2d Cir. 1980). Specifically, prejudice ensues when a "defendant has changed his position in a way that would not have occurred if the plaintiff had not delayed." *Conoco, Inc. v. Campbell Soup Co.*, 95 F.3d 187, 192 (2d Cir. 1996) (citing *Goodman v. McDonnell Douglas Corp.*, 606 F.2d 800, 808 n. 7 (8th Cir. 1979)). Due to the equitable nature of laches, any resolution must be based on the circumstances peculiar to each case. *See Stone*, 873 F.2d 623-24. The inquiry is a factual one. *See Conoco, Inc.*, 95 F.3d at 192. The determination of whether laches bars a plaintiff from equitable relief is entirely within the discretion of the trial court. *Robins Island Preservation Fund, Inc. v. South Old Dev. Corp.*, 959 F.2d 409, 423 (2d Cir. 1992).

During the November 29, 2006 oral argument, I asked Defendants' counsel at two different times to identify what prejudice would accrue if Plaintiffs' motion were granted and the Rule was enjoined from taking effect on December 1, 2006. Defendants' counsel stated that the

prejudice would be the "message" such a ruling would send to other pharmaceutical companies. I find that even if such a "message" is so perceived in the industry, such outcome does not amount to prejudice warranting the application of the doctrine of laches. Enjoining the effective date of the legislation does nothing more than allow the pharmaceutical distributors to continue to operate in the manner in which the have been for the past ten years. Courts have held that "an additional period of delay while the legality of the regulations is judicially determined with finality cannot significantly harm either the government or others." *Building and Constr. Trades Dep't, AFL-CIO*, 543 F. Supp. at 1292 (citing *Metzenbaum v. Edwards*, 510 F. Supp. 609 (D. D.C. 1981). By comparison, there is no evidence of prejudice demonstrated here by Defendants since "there is no comparably urgent need for allowing the regulations to become effective immediately." *Building and Constr. Trades Dep't, AFL-CIO*, 543 F. Supp. at 1292.

The preliminary injunction will merely be a temporary reprieve of the Rule taking effect while this litigation is decided on the merits. Therefore, based on the lack of any prejudice established by the Defendants and in light of the already lengthy period of time that this Rule has *not* been in effect, I find that the defense of laches should not bar granting the preliminary injunction. *See Sanofi-Synthelabo, Inc. v. Apotex Inc*., No. 02-CV-2255, 2006 WL 2516486, at *27 (S.D.N.Y. Aug. 31, 2006) (because active negotiations between the parties is a legitimate excuse to a delay in bringing suit sufficient to bar a laches defense, Sanofi did not unreasonably delay or inexcusably delay its motion for a preliminary injunction); *see also Merrill Lynch Investment Managers v. Optibase, Ltd*, 337 F.3d 125, 132 (2d Cir. 2003) (laches defense rejected where plaintiff presented evidence that prior to bringing its motion for a preliminary injunction, it pursued its objections to the arbitration).

VII. Conclusion

For all of the foregoing reasons, it is my recommendation that Plaintiffs' motion be GRANTED.

Traditionally, any objection to a Report and Recommendation must be filed with the Clerk of the Court within 10 days of service and failure to file objections within this period waives the right to appeal. *See* 28 U.S.C. § 636(b)(1)(C) (West 2006); Fed. R. Civ. P. 72; *Beverly v. Walker*, 118 F.3d 900, 901 (2d Cir.), *cert. denied*, 522 U.S. 883 (1997); *Savoie v. Merchants Bank*, 84 F.3d 52, 60 (2d Cir. 1996). However, at the November 29, 2006 hearing, I discussed with the parties the fact that the December 1, 2006 effective date of the legislation presented exigent circumstances which seemingly warrant a compression of the 10-day time period provided in 28 U.S.C. 636(b)(1)(C). *See Hispanic Counseling Ctr., Inc. v. Incorporated Vill. of Hempstead,* 237 F. Supp. 2d 284, 290 (E.D.N.Y 2002); *see also United States v. Baney,* 568 F.2d 134, 136 (9th Cir. 1978). Counsel for Plaintiffs agreed on the record during the hearing to reduce the time to one day. Defendants' counsel asked for a short time to confer with his client and get back to the Court. By letter dated November 29, 2006 [DE 10], counsel for Defendants likewise agreed to compress the time to file objections. Therefore, the parties are directed to file written objections, if any, to this Report and Recommendation via ECF no later than noon on December 1, 2006.

SO ORDERED.

Dated: Central Islip, New York
November 30, 2006

/s/ A. Kathleen Tomlinson
A. KATHLEEN TOMLINSON
U.S. Magistrate Judge