September 4, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

CC: Poppy Kendall

RE: Docket # 1992N-0297, 1988N-0258, 2006D-0226

Subject: The PDMA (**prescription drug marketing act**) in its current form is unworkable, anti-small business, and will not guarantee drug safety. It will drive the legitimate specialty prescription pharmaceutical wholesalers, some who have been doing business legally and ethically for over 20 years, out of business, along with its thousands of employees. It will leave certain markets for prescription drugs, and ultimately consumers of prescription drugs, significantly underserved.

Petition Request: Eliminate the Authorized Distributor exemption from the PDMA regulations so that ALL pharmaceutical distributors have the same pedigree reporting requirements **or** change the language so that the "non-authorized" distributor is required to pass pedigrees back to the authorized distributor, not the manufacturer.

To Whom It May Concern:

My name is Gene N. Alley, President and CEO, writing you on behalf of STAT Pharmaceuticals, Inc., a California corporation. STAT has served office-based physicians nationwide since 1982, and currently has 25 employees. I am writing you today to express my objections to the PDMA pedigree process that is set to become effective December 01, 2006.

First and foremost, I applaud your efforts in implementing new regulations to track and monitor the movement of prescription drugs in the United States. We too, want a safe and secure supply chain. We are not adverse to providing pedigrees; it will help get rid of the criminal element in this industry. However, the requirement to have the pedigree go back to the manufacturer is not realistic, nor is it effective in adding any additional security to the pharmaceutical supply chain.

The PDMA became law on April 22, 1988 and among other things, it established a pedigree requirement for wholesalers and distributors of prescription drugs (Section 503.50(a)(6). A pedigree is nothing more than a document that identifies each and every sale of a prescription drug, beginning with the manufacturer and concluding with the dispenser (doctor, pharmacy, hospital, veterinarian, etc.).

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Unfortunately, Congress exempted the so called "authorized" distributors (AD) from having to pass pedigrees, which created two distinct categories of drug distributors, an "uneven playing field" in the industry. The word distributor and wholesaler are used interchangeably in this industry.

1. **Authorized (AD),** where the wholesaler buys directly from the pharmaceutical manufacturer.
2. **Unauthorized,** where for a number of reasons the wholesaler cannot purchase directly from the manufacturer and must purchase the same drug from an AD.

Since AD's are exempt from the pedigree requirements and they are unwilling to voluntarily provide pedigrees to the unauthorized distributors, the **implementation of the pedigree provision on December 1, 2006 will effectively shut down the 1000's of legitimate, ethical drug wholesalers and distributors.**

The members of the unauthorized wholesale industry are in competition with the members of the authorized wholesale industry and there is no rational basis for favoring authorized wholesalers over non-authorized wholesalers. Almost every reported case of a conviction (or compensatory penalty) for a reported pharmaceutical counterfeiting violation involved an authorized wholesaler, so to single out one category of distributor over the other makes absolutely no sense.

The only way to remedy the situation would be for the unauthorized distributors to buy directly from the manufacturers. However, history shows that this is not an option as most manufacturers have been unwilling to open new distributor accounts. We are precluded from becoming AD's of these manufacturers because of our size and/or volume, or because we don't purchase a wide enough assortment of their product offering.

STAT Pharmaceuticals is an independent specialty wholesaler and as such, many manufacturers choose not to open up direct accounts with distributors its size, and instead, have referred them to one of their "master" distributors (AD's), a practice that hasn't changed for decades. In fact, in the last 3 years, many manufacturers have been closing many of their direct relationships with the small and medium sized distributors which have been customers of theirs for years, without so much as a "by your leave".

Another problem with the current PDMA language is that it states that there is a "normal" supply chain by which all drugs are delivered in the nation today, which is:

Manufacturer (MFR) > Authorized Distributor (AD) > Dispenser

<u>This is erroneous</u> in that for over 30 years, the supply chain in the physician and dental markets has been as follows:

MFR > AD > Physician Distributor (PD) > Dispenser

The office-based physician, podiatrist, dentist, etc. purchases prescription pharmaceuticals in very small quantities compared to that of a retail or hospital pharmacy. The physician medical/surgical supply distributor, at least those that are licensed as a wholesale drug distributor, fills a vital need in the supply chain. It buys pharmaceuticals in much larger quantities, and is willing to provide

them in the unit size for sale to the physician. It also buys much of its drugs from the AD's for subsequent sale to the physician.

The national billion dollar drug wholesalers, also known as the **Big 3 (Cardinal Health, McKesson, and Amerisource-Bergen)** have stated that they have no interest in servicing the office-based physicians. That is where companies such as STAT Pharmaceuticals provide such a needed service.

The effect of exempting authorized wholesalers from the pedigree requirements of the PDMA results in a complete inability on the part of all unauthorized wholesalers to conduct any business at all because they are unable to obtain pedigree information back to the manufacturer from authorized wholesalers. Absent such information, unauthorized wholesalers can not lawfully resell any products and are, therefore, put completely out-of-business.

Example: The Big 3, authorized distributors of XYZ manufacturer, can sell their drugs to a dispenser OR another Licensed distributor. As noted earlier, most physician supply distributors purchase their drugs from the Big 3 because they cannot buy directly from the manufacturers. I interpret this bill as follows: even though I am licensed in CA, and I am licensed in state X that has no pedigree requirements, I still will be unable to sell to my state X customers any product that I don't buy direct from the manufacturer. I can't sell a drug that I legally bought from the big 3 because I'm 1) not an authorized distributor of the manufacturer, 2) the current law as written requires us to provide a pedigree listing all transactions back to the manufacturer and 3) the Big 3 won't provide a pedigree to us.

On June 7, 2001, the FDA submitted its report to Congress. The report advised Congress, among other things, as follows: "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." **This is a possible weak link in the supply chain where crooks might introduce counterfeit drugs into the market.**

I believe 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. Small businesses (who can least afford it) in the United States will be burdened with the complex record keeping costs associated with this provision. The billion dollar mega distributors (competitors) who are considered AD's will not have these requirements, and the inherent inefficiencies and costs will further burden small businesses in our ability to remain competitive (assuming we are able to find some way to purchase drugs from an authorized distributor who will provide us with a pedigree).

Questions that need answers include:

1. The legislation in its current form stipulates that the largest AD's are secure sources and they don't need to pass a pedigree when they sell directly to the dispenser. Where is the additional risk of counterfeit drugs being introduced into the supply chain if these secure drugs are first sold to a duly licensed ethical drug distributor, who then sells them to the dispenser and also provides a pedigree listing the transactions back to the AD? In other words, what additional security will a pedigree listing transactions back to the manufacturer provide? The answer is none, and there is no additional risk to the supply chain.

2. If there is no additional risk, then shouldn't the distributor who buys directly from the Big 3 (AD) also be exempted from passing a pedigree, or at least only required to pass a pedigree listing transactions back to the last secure source (the AD)?

3. Why couldn't a statement be put on each invoice stating that all products were purchased from AD's? This would be the same policy that the Big 3 follow except the word manufacturer that they use would be replaced with the word authorized distributor.

4. Was it the intention of the legislature to make it harder for its constituents to buy from competitive companies that are duly licensed and purchase their products in an ethical manner, thus having to spend more for the same drug after the December 1st pedigree start date than they did in November?

5. Will there be a grace period for inventory that was purchased prior to 12/1/06? If not, what are we to do with the entire inventory that was LEGALLY purchased without a pedigree?

The following are just some of the negative effects of requiring the "unauthorized distributors" to provide pedigrees back to the manufacturer. Most of these effects would disappear if the pedigree requirement of listing all transactions starting with the manufacturer was changed to listing all transactions starting with the secure authorized distributor, with absolutely NO ADDITIONAL RISK.

1. Implementation of the final rule would leave certain markets for prescription drugs, and ultimately consumers of prescription drugs, significantly underserved.

2. Hospitals will have crisis situations where they will be unable to obtain critical drugs in a timely manner because they will have no options to turn to when their primary wholesaler is out of particular drug.

3. Prices on medications purchased by physicians will increase

4. Reimbursement to physicians will ultimately have to be increased

5. Medical insurance premiums will increase to employers, employees, etc.

6. Tax increases to cover increased Medicare costs will have to be implemented

7. Workmen's Compensation premiums will rise to the employer of all businesses

8. Businesses of all types will have additional expenses to cover

9. Legitimate small businesses (drug distributors) will be forced to close nationwide for NO reason

10. Decreased competition = increased prices

11. Cardinal Health, one of the Big 3, cut off most of their distributor customers in Florida without warning immediately after the July 1 2006 start date of Florida's new pedigree law, which was passed in the dead of night at 11:59pm on the last day of the legislative period. Will history repeat itself?

The correct interpretation of § 503(e)(1)(A) of the FD&C is that a non-exempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back only to the authorized distributor from which it was obtained.

In summary, **the law as written should be changed to either** (i) the exemption to authorized distributors in § 503(e)(1)(A) of the FD&C is unenforceable and authorized distributors must be required to provide pedigree information tracing the product back to the manufacturer, or (ii) the requirement in § 503(e)(1)(A) of the FD&C that a nonexempt wholesaler who acquires pharmaceutical products from an authorized distributor is lawfully required to provide pedigree information on any subsequent sale tracing the product back to the manufacturer is unenforceable and that providing pedigree information back to the authorized distributor from which the product was obtained is in full compliance with the statute.

Bill Hubbard, **former FDA associate commissioner** for policy and planning said in an interview with The Pink Sheet (July 10, 2006 edition) that the AD provision creates an "unlevel playing field" in the industry and **suggests Congress should eliminate the provision**.

If the intent of this law is to drive legitimate small & medium sized drug distributors out of business, and to have only the billion dollar mega drug companies supply doctors a vial of lidocaine and a vial of bacteriostatic sodium chloride along with their order of syringes, cotton balls, and pregnancy tests (which they currently do not do), then this legislation does the trick.

Again, **STAT Pharmaceuticals, Inc. supports the FDA's move to implement a federal pedigree program**. That said, in an effort to ensure that all drugs and medical products get to all the providers and patients that need them, the definition of 'normal distribution' needs to be thoughtfully revised, or the law needs to be the same for all distributors, with no favoritism shown.

For more in depth study on the PDMA, please try any one of the following links.

http://www.rxusa.com/litigation/PDMA%20ACT%20AND%20PEDIGREE%20REQUIREMENTS%20DISCUSSION.pdf

http://www.fda.gov/cber/pdma.htm

http://www.fda.gov/oc/initiatives/counterfeit/cpg.html

http://www.ashp.org/news/ShowArticle.cfm?id=15677

Thank you and your staff for the time and consideration given to this letter.

Sincerely and respectfully,

Gene N. Alley
President & CEO