Pharmaceuticals & Medical Surgical Supplies
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September 18, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Re: Docket #2003N-0361

Dear Sirs:

The FDA's special emphasis and task force on counterfeit drug distribution is an important initiative to maintain the integrity of the U.S.'s drug supply. PSI supports this effort.

We submit these comments as a small distributor. The DEA audit files and audits done by state drug regulators will show that a small drug distributor, that is ethical and follows established FDA/DEA procedures, can supply its customers while maintaining the necessary controls to protect against counterfeit drugs. The smaller distributor operates efficiently and markets its drugs at prices that keep the larger distributors honest.

The Healthcare Distribution Management Association, which is reported to support expensive technology to track drug shipments, is a trade association of larger wholesalers. It does not represent the many smaller distributors. This Association and its members continue to push the consolidation of large wholesalers, which has significantly lessened competition in the industry.

Improved packaging and regulation at the manufacturer's level is the answer to most of these problems. Increased monitoring and regulation of the re-packagers may be necessary, but those of us who do not alter the packaging are not a weak link in the drug supply chain. Do not burden the small distributor with unnecessary requirements for scanning electromagnetic chips, etc., in drug packaging. The counterfeitors are obtaining drugs either legally and then altering them or by illegal means. The FDA/DEA have existing authority to audit and trace the legally obtained drugs. If obtained illegally, no rules or scanning devices can prevent this. Your inspection and seizure at the Local Repack/Phil & Kathy's situation clearly shows your existing regulations are adequate.

We are not opposed to technological improvements. In fact, through small business technology, we operate at better margins than our larger wholesaler competitors. Most of us operate in a PC environment with internet/email capabilities. We can readily increase or revise our reporting to the necessary drug regulators through this network.

Please consider carefully the cost-to-benefit ratio for any regulations the FDA may propose to control counterfeit drugs. Thank you.

2003N-0361 C2

Sincerely,

E. M. Behnken

E. M. Behnken, Treasurer