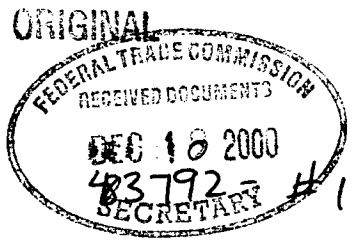
NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



December 18, 2000

Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Generic Drug Study - FTC File No. V000014

Dear Secretary:

I write on behalf of the National Association of Chain Drug Stores to voice our strong support for the Federal Trade Commission's plan to collect documents regarding anticompetitive practices of drug manufacturers. Founded in 1933 and based in Alexandria, Virginia, the National Association of Chain Drug Stores (NACDS) membership consists of nearly 170 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 20,000 traditional chain drug stores, 7,800 supermarket pharmacies and 5,300 mass merchant pharmacies. The NACDS membership base operates over 33,000 retail community pharmacies with annual sales totaling over $400 billion. Chain operated community retail pharmacies fill over 60% of 3 billion prescriptions dispensed annually in the United States.

The FTC plans to collect documents from approximately thirty brand name drug manufacturers and ninety generic drug manufacturers. The FTC is investigating the extent to which brand manufacturers have paid generic manufacturers not to market competing generic drug products. The FTC also plans to investigate brand manufacturers' abusive patent listings and patent litigation, which stalls generic competition whether or not the listed patents are valid.

The FTC seeks comments on "[w]hether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility." *See* 65 Fed. Reg. 61335 (Oct. 17, 2000). The document collection is necessary because the practices at issue are anticompetitive. As the FTC knows, under the 180-day exclusivity provisions of the Hatch-Waxman Act -- which were intended to encourage generic competition -- the agreements between brand and generic manufacturers have the effect of preventing all other generic manufacturers from marketing generic competitors. Similarly, brand manufacturers list newly-patented products in the FDA's Orange Book, and then file patent infringement lawsuits against generic manufacturers, which prevents generic competition under the Hatch-Waxman

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Act's 30-month rule even if the brand manufacturers' patents are invalid or have not been infringed. The FTC is already investigating several well known examples of these practices, so a full recitation of the facts is unnecessary.

The FTC needs to collect relevant documents to discover new examples of these antitrust violations. The existence of an anticompetitive agreement is rarely if ever publicized by the manufacturers. Likewise, manufacturers do not voluntarily admit that they filed a patent or a lawsuit primarily for the purpose of delaying generic competition. Unless the FTC collects the documents they may never be discovered.

There can be no doubt that these anticompetitive practices have an enormous impact on NACDS members and society in general. Generic drug prices are much lower than brand name drug prices, and market entry by generic competitors lowers the price of a drug by as much as ninety percent. When generic drug products are kept off the market, prices remain artificially inflated for pharmacies, government payors, private payors, and uninsured citizens. Under the Supreme Court's *Illinois Brick* decision NACDS members are often precluded from litigating against these antitrust violations. Therefore, the FTC needs to take the lead on this issue.

The FTC also asks for comments on ways to enhance the quality and utility of the information collection. We recommend that the FTC expand the collection to include other anticompetitive activities of drug manufacturers. For example, the FTC should investigate the extent to which brand name drug manufacturers file baseless citizens petitions with the Food and Drug Administration that challenge the FDA's approval of a generic drug product. The FTC should seek disclosure of documents that discuss whether the citizens petitions were filed primarily for the purpose of delaying legitimate competition by generic manufacturers. The FTC should also collect information regarding the unlawful pricing strategies of some drug manufacturers.

Conducting the document collection will be an important first step toward fully assessing facts presently hidden from the public. But the collection alone will not solve the anticompetitive affects of drug manufacturers' practices. After the FTC studies the documents, we recommend implementation of a four stage strategy with the goal of preventing such anticompetitive practices in the future. First, the FTC should immediately halt all anticompetitive practices it discovers. Second, the FTC should issue new rules or guidances preventing such anticompetitive arrangements in the future. Third, the FTC should work closely with the Food and Drug Administration to revise the FDA's policies regarding citizens petitions, the 180-day exclusivity rule and the 30-month stay rule. Fourth, the FTC should recommend revisions to the relevant provisions of the Hatch-Waxman Act to permanently eliminate the ability of brand and generic drug manufacturers to conspire to restrain competition.

In conclusion, we urge the FTC to complete the proposed document collection with all deliberate speed. The FTC should then use the resulting study as a springboard for enforcing the antitrust laws against drug manufacturers' anticompetitive practices.

Thank you for considering our comments. If you have any questions, please contact me or NACDS Assistant General Counsel Don Bell at (703) 549-3001.

Sincerely,

S. Lawrence Kocot
Senior Vice President, Government Affairs
and General Counsel