



NATIONAL CONSUMERS LEAGUE

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February 16, 2005

Re: S. 103/H.R. 314, the "Combat Meth Act of 2005"

Dear Member of Congress:

National Consumers League is concerned about legislation introduced to address the very serious problem of diversion of over-the-counter (OTC) drug products containing pseudoephedrine to the illicit manufacture of methamphetamine. NCL is a national nonprofit consumer advocacy organization representing consumers in the marketplace and the workplace. Founded in 1899, NCL is the nation's oldest consumer organization. Drug safety and affordability have been longstanding concerns of NCL.

S. 103 and its House companion, H.R. 314, would place pseudoephedrine in Schedule V under the Controlled Substances Act and require that pseudoephedrine be dispensed only from behind the pharmacy counter.

NCL is concerned that in the important fight against illicit methamphetamine manufacture, access to primary healthcare products is maintained, including availability of safe, effective, and affordable medicines. Any restrictions that are placed on OTC drug products containing pseudoephedrine must be no more than what would be necessary and practical. To do otherwise will limit therapeutic choices and could increase healthcare costs for consumers.

If sales of OTC drug products containing pseudoephedrine must be restricted because of their misuse, the burden of such restrictions should not be borne by patients who depend on and properly use the products. Pseudoephedrine is a versatile medicine and one which the Food and Drug Administration has determined can be used safely and effectively through self-care of the patient. People need decongestants, not just during cough and cold season, but for treatment of seasonal and other allergies as well. The broad array of OTC products containing pseudoephedrine underscores the fact that large numbers of Americans have come to rely on these products for safe, effective, and affordable relief.

Pseudoephedrine as a decongestant is also often coupled with antihistamines, such as in Sudafed® and Sinutab®. Reformulation of these products without pseudoephedrine, which also has stimulant effects, will leave consumers only with products that may cause drowsiness. This will result either in increased dangers for persons who take these medications, or consumers that must suffer from easily treated conditions because they cannot take the chance of falling asleep.

Moreover, not all OTC pseudoephedrine products are equally amenable to diversion; liquids, liquid capsules and gel capsules, as well as certain products that combine pseudoephedrine with other active ingredients, are much less useful in the illicit manufacture of methamphetamine. S. 103 and H.R. 314 leave these distinctions to a later and uncertain exemption process. In the interim,

there would be an immediate shift of all OTC products containing pseudoephedrine behind the pharmacy counter.

The bills do provide for sales by persons other than pharmacists when the absence of a pharmacy to distribute these products in a community would create a hardship. NCL, however, has significant concerns regarding the implementation of these provisions. Many rural and economically disadvantaged communities in America are underserved by pharmacies or large retail chains with pharmacies. Sometimes it is the local 7-11 or IGA which is the source of OTC drugs for rural populations. Under the proposed legislation, the decision on what constitutes a hardship is left undefined. Consumers should not be limited to safe and effective medicines based on where retailers decide to have a pharmacist on duty.

Conversion of these products to pharmacy-only status would have other direct and indirect effects, all of which would restrict therapeutic choices and raise healthcare costs. Pharmacies are generally served under a different distribution system, often by different distribution companies, than other retailers of OTC drug products. Pharmacy shelf space is limited. Manufacturers and distributors of these OTC drug products would be required to alter their distribution practices, and a significant portion could be effectively forced off the market because of simple lack of room. While decreasing the overall amount of product available may have some small impact on misuse of the product, the more likely effect would be a lessening of competition for these OTC drug products and concomitant price increases.

If restrictions are necessary, they should be tailored to the problem at hand, which is diversion of OTC drug product to illicit methamphetamine manufacture. This criminal activity relies on access to large quantities of OTC pseudoephedrine. NCL believes that retail transactions can be controlled by responsible retailers through a number of means. California, for example, has witnessed a significant reduction in clandestine laboratory seizures after tightening the single retail transaction limit on OTC drug products containing pseudoephedrine. A recently enacted Illinois law, ILL. ANN. STAT. ch. 720, § 647/1 (2004), is another good example of reasonable measures that could be employed. It provides for the following:

- Retail sales are limited to 2 packages or 6 grams per transaction.
- Self-service transactions are subject to special procedures that stop purchases over the retail limit.
- Single active ingredient products may only be displayed for sale
 - behind a store counter (not a pharmacy counter) that is not accessible to consumers;
 - or
 - in a locked case that requires assistance by a store employee for customer access.
- Multi-active ingredient products may
 - be displayed behind a store counter (not a pharmacy counter), not accessible to consumers;
 - be displayed in a locked case that requires assistance by a store employee for customer access;
 - be sold if the retailer requires the customer to show ID and sign a log; or
 - be sold from the sales floor if the retailer adopts at least two of the following four options:

- product must be kept within 30 feet and direct line of sight of a cash register or store counter staffed by one or more store employees;
 - reliable anti-theft devices are used on packages;
 - restricted access shelving is used so that only one package may be removed by a consumer at a time and a delay of at least 15 seconds occurs between package replacement on shelf;
 - affected product is kept under constant video surveillance.
- Liquids, liquid cap, and gel caps product containing pseudoephedrine are exempt.
 - Retail personnel must be trained and certified with respect to special procedures used in the sale of covered OTC drug products containing pseudoephedrine.

The Congress should consider similar features in regulating retail distribution of OTC drug products containing pseudoephedrine.

NCL looks forward to the opportunity to work with you to address the serious problem of illicit methamphetamine manufacture while preserving safe, effective, and affordable medicines for the American consumer.

Sincerely,



Linda Golodner
President