DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

CHARLES J. GANLEY, M.D.

DIRECTOR

OFFICE OF DRUG EVALUATION IV

CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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INTRODUCTION

Chairman Feinstein, Co-Chairman Grassley, and Members of the Caucus, I am Dr. Charles J. Ganley, Director of the Office of Drug Evaluation IV at the Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). My office is responsible for the regulation of over-the-counter (OTC) drug products. Thank you for the opportunity to discuss the drug pseudoephedrine.

Pseudoephedrine is a drug found in many OTC products and is used to relieve nasal or sinus congestion caused by the common cold, sinusitis, and respiratory allergies. Pseudoephedrine is also found in prescription products, combined with prescription-only drugs. In this testimony, I will discuss how pseudoephedrine products are currently regulated by the Agency, the primary differences between pseudoephedrine and other drugs used to treat nasal congestion, and the potential impact of a change in access to OTC products.

REGULATION OF PSEUDOEPHEDRINE

The regulatory process most familiar to the American public is the New Drug Application (NDA) system in which manufacturers of drug products submit a variety of required information to FDA for review and approval prior to marketing. All prescription pseudoephedrine drug products, and some OTC pseudoephedrine drug products, are subject to the NDA process. However, the majority of OTC pseudoephedrine drug products are regulated under a different regulatory process, the OTC Drug Review.

In January 1972, FDA began the OTC Drug Review, or the "OTC Monograph," a program to regulate OTC products that had been introduced to the marketplace prior to that time. Through scientific review, and a notice-and-comment rulemaking process, this program determines which

OTC drugs can be deemed Generally Recognized as Safe and Effective (GRASE). Products marketed under an OTC Monograph are not subject to FDA approval prior to marketing. The OTC Monograph for nasal decongestants covers several decongestants (including pseudoephedrine) and there are OTC Monographs for many other commonly used OTC products, such as antacids, cold symptom relievers, and analgesics, for relief of minor aches and pains.

Near the outset of the OTC Drug Review, FDA convened an Advisory Panel of clinical experts (the Panel) to evaluate the existing safety and efficacy data for OTC cold, cough, allergy, bronchodilator, and anti-asthmatic drugs, including pseudoephedrine. FDA published the Panel's recommendations on safety, efficacy and use conditions in an Advance Notice of Proposed Rulemaking (ANPR) in September 1976. FDA reviewed comments submitted in response to the ANPR and new scientific data and published a Tentative Final Monograph in January 1985. FDA reviewed submitted comments and other information and published the Final Monograph for nasal decongestant drugs in August 1994. Manufacturers were given an effective date, at which time their products were required to be in compliance with the Final Monograph.

On March 9, 2006, The Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), was signed into law. Congress passed this law in an effort to reduce the illicit manufacture of methamphetamine. The law requires, among other things, that all sellers of pseudoephedrine self certify, confirming that: (1) employees have been trained; (2) records of the training are being maintained; (3) sales limits are being enforced; (4) products are being stored appropriately; and (5) a written or electronic logbook is being maintained. Specifically, the law requires that these retailers must

place pseudoephedrine products where customers do not have direct access to such products before a sale is made. Although the law uses the term "behind the counter" to describe product placement by the retailer, FDA defines pseudoephedrine as an OTC drug in accordance with the monograph and FDA regulations. An OTC drug is a drug whose use does not require oversight by a health care professional.

ALTERNATIVES TO PSEUDOEPHEDRINE

The OTC monograph includes pseudoephedrine and several other nasal decongestants. Nasal decongestants typically act by constricting blood vessels in mucous membranes of the nasal passage. There are several drugs considered GRASE in the OTC monograph that are applied directly to the nose as drops, sprays or inhaled vapors. The OTC decongestant monograph currently includes two GRASE decongestants for oral administration, pseudoephedrine and phenylephrine. Like pseudoephedrine, phenylephrine was subject to the OTC Drug Review Panel review and subsequent notice-and-comment rulemaking process. Data comparing one drug to another are not required to make a GRASE determination for a drug in the OTC Drug Review and no comparative claims are covered by the OTC monographs. However, the proliferation of OTC products formulated by manufacturers with phenylephrine following enactment of The Combat Methamphetamine Epidemic Act of 2005 gave rise to increased public interest in the adequacy of phenylephrine as a more accessible alternative to pseudoephedrine.

In December 2007, FDA held a public advisory committee meeting to review the current safety and efficacy data for phenylephrine. Members of the Nonprescription Drugs Advisory Committee largely agreed that, while additional studies would be useful to evaluate higher doses, the 10 mg phenylephrine dose currently included in the OTC Monograph is effective.

Pseudoephedrine and phenylephrine differ in duration of action so that it is recommended that pseudoephedrine be dosed every 4 to 6 hours, but phenylephrine, with a shorter duration of action, be dosed every 4 hours. FDA considers both pseudoephedrine and phenylephrine as safe and effective for their intended uses.

POTENTIAL IMPACT OF A CHANGE IN ACCESS

Any additional measures restricting the sale of pseudoephedrine to reduce the likelihood of product misuse must be balanced with the need to maintain access for legitimate and safe use. Requiring an allergy or cold sufferer to obtain a prescription may make it more difficult to access safe and effective products that are intended, when used properly, to treat symptoms that can be self-diagnosed by a consumer. Individuals respond differently to medications, some getting more benefit from a specific ingredient than others. Having access to different ingredients without the need for obtaining a prescription from a health care professional allows consumers to obtain medications quickly and will not delay access to symptomatic benefit. Additional consideration should be given to the idea that requiring a prescription could increase health care costs for those who prefer pseudoephedrine. As the Office of National Drug Control Policy Director Gil Kerlikowske has testified, pseudoephedrine continues to be misused to illicitly manufacture methamphetamine and there are important public safety reasons why additional measures restricting the sale of pseudoephedrine may be appropriate.

CONCLUSION

FDA continues to consider NDA-approved and OTC monograph products containing pseudoephedrine as safe and effective for their intended uses. Measures restricting the sale of

pseudoephedrine to achieve important public safety goals that would result from reduced product misuse should be balanced with the need to maintain access for legitimate use.

Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.