

The Consumer Healthcare Products Association (CHPA) represents the leading manufacturers and marketers of nonprescription, over-the-counter (OTC) medicines and dietary supplements. Through science, education, and advocacy, CHPA works to ensure consumer access to safe, effective, and convenient OTC medicines for the treatment and prevention of many ailments and diseases.

***OTC Drug Review Monograph System Reform: CHPA supports responsible and appropriate reforms to the OTC Drug Review Monograph system.***

The OTC Drug Review Monograph system is the regulatory framework under which the U.S. Food and Drug Administration ensures that older OTC ingredients and products are safe and effective for use by consumers. In recent years, the agency has encountered difficulty in finalizing outstanding monographs, as well as making changes to existing monographs, due to the notice-and-comment rulemaking process required of such changes, no matter how small. CHPA and the agency agree that an administrative order process is more appropriate and better serves the public good by allowing the agency to be more agile in responding to safety concerns or innovations within existing monographs.

***Tax-Preferred Accounts and OTC Drugs: CHPA supports restoring the use of flexible spending arrangements (FSAs) and health savings accounts (HSA) to purchase OTC medicines without having to get a prescription.***

The Affordable Care Act (ACA) requires a prescription in order for OTC medications to be eligible for reimbursement under FSAs, HSAs, and other similar tax-preferred accounts. This provision effectively eliminates the ability of millions of American families to use funds they set aside in their FSAs and HSAs to purchase OTC medicines. CHPA supports the growing movement in Congress to repeal this provision, which went into effect January 1, 2011. CHPA is working closely with a coalition of providers, physicians, pharmacists, pharmacy benefit managers, patient groups, retailers, insurers, pharmacies, employer organizations, and others to change this provision of law and give control of their health dollars back to consumers.

***Pseudoephedrine: CHPA supports the fight against diverting pseudoephedrine while maintaining access to cold and allergy medications.***

Pseudoephedrine (PSE), a safe, effective, and widely-used OTC decongestant, is used by some criminals to manufacture methamphetamine. Federal sales restrictions on pseudoephedrine products, established by the Combat Methamphetamine Epidemic Act (CMEA) in 2006, have significantly reduced the number of domestic methamphetamine labs. In an effort to continue the fight against clandestine meth labs, CHPA member companies have helped establish and pay for the National Precursor Log Exchange (NPLEx), a multi-state electronic, real-time, stop-sale system for PSE transactions. NPLEx prevents individuals from evading the purchase limits on PSE while preserving consumer access and providing law enforcement with tools to help track down meth manufacturers. NPLEx is a real-time, interoperable electronic system that blocks illegal PSE sales and has been adopted or is being considered by more than 30 states. CHPA supports a nationwide electronic system as a tool to enforce purchase limits by preventing the illegal purchase of products containing PSE. The system empowers retailers to block illegal sales that attempt to exceed daily, monthly, and annual gram limits.

***Cough Medicine: CHPA supports federal legislation to help reduce the potential for cough medicine abuse.***

Millions of Americans use OTC cough medicines to safely and effectively relieve coughs due to the common cold or flu. A very small percentage of the nation's teenage population (approximately 3 percent) has abused the active ingredient, dextromethorphan (DXM), in an attempt to get high. CHPA supports federal legislation that would ban the sale of OTC products containing DXM to minors (those under 18 years of age). CHPA also supports provisions that allow only legitimate entities to purchase raw, unfinished dextromethorphan.

***Import Quality: CHPA supports cost-effective measures to ensure the quality of imported drugs***

CHPA supports cost-effective measures to ensure the quality of imported drugs and drug ingredients. CHPA members place a high premium on adherence to federal regulations mandating Good Manufacturing Practices (GMPs) for all of their products. CHPA will continue to work with members of Congress on legislation to address concerns about the safety of drug ingredients manufactured outside the United States.

***Dietary Supplements: CHPA supports full implementation of the Dietary Supplements Health and Education Act (DSHEA)***

CHPA supports full implementation of DSHEA and was pleased by the FDA's implementation of dietary supplement GMPs. CHPA also supports mandatory adverse event reporting for dietary supplements. CHPA and other trade associations representing the supplements industry are concerned about unfounded criticisms leveled against the supplements industry that are baseless or clearly untrue. Supplements are regulated by the FDA under DSHEA, and CHPA encourages FDA to utilize its existing authority to ensure only safe supplements enter into the marketplace.

***Regulation of OTC medicines: CHPA supports a regulatory environment that ensures consumer confidence in the safety and efficacy of the products they purchase***

CHPA supports using the current, robust regulatory process that allows interested parties to conduct new research, submit new information, and inform a transparent decision-making process at FDA. FDA has the tools to act quickly when necessary to protect the public from imminent harm, and CHPA is committed to working closely with FDA to reaffirm the safety and efficacy of OTC medicines.

***FDA Funding: CHPA supports significant increases in funding for FDA***

The U.S. Food and Drug Administration has been chronically underfunded for many years and it is an increasing challenge for the agency to fulfill its myriad responsibilities in ensuring the safety of the nation's food and drug supply. As a founding, active member of the Alliance for a Stronger FDA, CHPA advocates for significant increases in FDA funding.

***CHPA PAC: CHPA supports candidates for federal office who share our business philosophy***

The CHPA Political Action Committee (PAC) was established in 1975 with the goal of supporting candidates for federal office who support our industry, hold key Committee or leadership roles, or represent our members. The Chair of the PAC Advisory Group, the oversight body of the PAC, is Gary Downing, CEO of Clarion Brands, LLC.

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*CHPA is the 136-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements.*