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U.S. Health Coalition Releases New Resource on Acetaminophen, America's Most Common Drug Ingredient

Report Examines Unintentional Acetaminophen Overdose and Success of Consumer Education Efforts

WASHINGTON, D.C. – The <u>Acetaminophen Awareness Coalition</u> (AAC), a coalition of leading health, healthcare provider, and consumer organizations, today released "<u>Acetaminophen: How It's Used, Preventing Overdose and What We Can Do to Promote Safe Use</u>," a report and educational resource to drive safe and appropriate use of America's most common drug ingredient. The coalition's report reviews the dosing behaviors that can lead to acetaminophen overdose and explores the successful impact of ongoing education campaigns to drive appropriate use and prevent overdose-related liver damage.

"Promoting the safe and responsible use of acetaminophen to healthcare professionals and consumers will help to reinforce its appropriate use and avoid overdoses," said John Whyte, M.D., M.P.H., director of the U.S. Food and Drug Administration's Professional Affairs and Stakeholder Engagement (PASE) in its Center for Drug Evaluation and Research. "We all play an important role in ensuring that the medicines consumers use each day are used as directed and provide the benefits intended."

Each week, more than 50 million Americans use a medicine that contains acetaminophen—found in more than 600 different over-the-counter and prescription medicines including pain relievers, fever reducers, sleep aids and numerous cough, cold and flu medicines. Acetaminophen is safe and effective when used as directed, but there is a limit to how much can be taken in one day: 4,000 milligrams (mg). Taking more acetaminophen than directed and exceeding the maximum daily dose of 4,000 mg is considered an overdose and can lead to severe liver damage. While the <u>vast majority</u> of consumers take acetaminophen appropriately, research highlighted in the report shows that those who exceed the 4,000 mg/day labeled maximum daily dose are making one or more of three common dosing mistakes:

- 1. Taking the next dose too soon (72 percent of those who exceeded 4,000 mg/day);
- 2. Using multiple acetaminophen-containing products at the same time (59 percent of those who exceeded 4,000 mg/day) and/or;
- 3. Taking more than the recommended dose at a single time (34 percent of those who exceeded 4,000 mg/day).

"Educating patients is a key step to promoting safe acetaminophen use and preventing overdose," said Anne Norman, DNP, FNP-BC, Associate Vice President of Education, American Association of Nurse Practitioners, a founding organization of the AAC. "We encourage more pharmacists, healthcare professionals and health-involved stakeholder groups to work together to disseminate safe medicine use education and resources."

Coordinated, comprehensive and robust educational initiatives launched in recent years to promote appropriate acetaminophen use across multiple channels, via multiple stakeholders collaborating together. Over the last three years, acetaminophen safe use educational messages have reached consumers more than one billion times, stemming from aligned acetaminophen education initiatives that include:

- Acetaminophen Awareness Coalition's Know Your Dose campaign
- National Consumers League's <u>Take with Care</u>, <u>Life Smarts</u> and <u>Script Your Future</u> initiatives
- National Council on Patient Information and Education's <u>Be MedWise</u> and <u>MUST for Seniors</u> campaigns
- U.S. Food and Drug Administration's <u>Use Acetaminophen Safely</u> education
- McNeil Consumer Healthcare's <u>Get Relief Responsibly</u> initiative



These efforts are having impact on consumer knowledge and perceptions surrounding acetaminophen safe use. Findings from a recent <u>national survey</u> show that consumer safe use knowledge and risk awareness has increased over a three-year period:

- **Label reading:** More consumers agree that it is "important to check the label to find out the maximum daily dose" of medicines (increased to 98 percent in 2013 from 93 percent in 2010).
- **Following dosing instructions:** More consumers agree it is "important not to exceed the dosing directions on the label" of pain relievers (increased to 96 percent in 2013 from 90 percent in 2010).
- **Awareness of risk:** More consumers understand that "exceeding the recommended daily dose of acetaminophen may lead to liver damage" (increased to 87 percent in 2013 from 78 percent in 2010).
- **Avoidance of "doubling up:"** Knowledge that "acetaminophen can be found in many over-the-counter and prescription pain medicines" increased to 87 percent from 80 percent in 2010, and understanding that "it is possible to exceed the maximum daily dose when taking an OTC acetaminophen product at the same time as a prescription pain medicine" increased to 81 percent from 76 percent in 2010.

"Our collective educational efforts are resonating with consumers and having a positive impact," said Emily Skor, executive director of the Consumer Healthcare Products Association's Educational Foundation, a founding organization of the AAC.

The Acetaminophen Awareness Coalition recommends consumers follow these four simple steps to use acetaminophen-containing medicines safely:

- 1. Always read and follow the medicine label.
- 2. Know if your medicines contain acetaminophen.
- 3. Never take two acetaminophen-containing medicines at the same time.
- 4. Ask your pharmacist or other healthcare professional if you have questions.

The Acetaminophen Awareness Coalition's *Know Your Dose* campaign offers free Spanish- and English-language educational materials for healthcare providers to <u>order for their patients</u>. For more information, and to see a list of some common medicines that contain acetaminophen, visit <u>KnowYourDose.org</u> or follow <u>@KnowYourDose</u>.

ACETAMINOPHEN THE MOST staminophen is a **safe and effective pain reliever and fever reducer** on used as directed. More than 95% of the time, it is taken according directions on the medicine label. **AVOIDING OVERDOSE** EXCEEDING THE OF THOSE MAXIMUM DAILY DOSE WHO EXCEED 4,000 MG IN 1 DAY, of 4,000 mg is MOST DO PROMOTING SAFE USE & EDUCATING CONSUMERS FOLLOW SAFE USE Never take two acetaminophen-containing medicines at the same time KnowYourDose.org ###

The Know Your Dose campaign is an initiative of the Acetaminophen Awareness Coalition (AAC). Coalition members include the Alliance for Aging Research, National Association of Boards of Pharmacy, American Association of Nurse Practitioners, National Association of Chain Drug Stores Foundation, American Academy of Physicians Assistants, National Community Pharmacists Association, National Consumers League, American Pharmacists Association, National Council on Patient Information and Education, and CHPA Educational Foundation. Advisors to the Coalition include the American Academy of Pediatrics, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration.

Sources:

-Kaufman DW, Kelly JP, Rohay JM, Malone MK, Weinstein RB, Shiffman S. "Prevalence and Correlates of Exceeding the Labeled Maximum Dose of Acetaminophen Among Adults in a U.S.-based Internet Survey." *Pharmacoepidemiol Drug Safety*. 21(12):1280-8, 2012 Dec. Abstract accessed at http://www.ncbi.nlm.nih.gov/pubmed/23001694

-Shiffman S, Rohay JM, Kelly JP, Malone MK, Weinstein RB, and Kaufman DW. Acetaminophen Use Patterns Associated with Excess Dosing Abstract of presentation at the 28th International Conference on Pharmacoepidemiology and Therapeutic Risk Management. CCIB, Barcelona, Spain, August 23-26, 2012.