

# **Advancing our Understanding of the Safe use of Acetaminophen**

The 3rd Seeking Solutions Stakeholders' Forum  
Executive Summary

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Prepared by Medica Communications, LLC

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## Participants

\* Denotes speaker

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<p><b>Ray Bullman*</b> National Council on Patient Information &amp; Education (NCPPIE) Rockville, MD</p>	<p><b>Angela Landers</b> Acetaminophen Awareness Coalition/GMMB Washington, DC</p>	<p><b>Saul Shiffman, PhD*</b> Pinney Associates Pittsburgh, PA</p>
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<p><b>Paul T. Conway</b> American Association of Kidney Patients Falls Church, VA</p>	<p><b>Jim Moran, MBA</b> Ardelis Group, LLC Alliance for the Rational Use of NSAIDs</p>	<p><b>Charles Vega, MD*</b> University of California –Irvine Santa Ana, CA</p>
<p><b>Barb Cooper</b> Cooper Communications Silver Spring, MD</p>	<p><b>Debra Nelson-Hogan</b> American Academy of Pain Management New York, NY</p>	<p><b>Kevin Volpp, MD, PhD*</b> University of Pennsylvania Philadelphia, PA</p>
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<p><b>Richard Dart, MD, PhD*</b> Rocky Mountain Poison and Drug Center Denver, CO</p>	<p><b>Krista Osterthaler, MPH</b> American Association of Poison Control Centers Alexandria, VA</p>	<p><b>Krystalyn Weaver, PharmD, RPH</b> National Alliance of State Pharmacy Associations Richmond, VA</p>
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<b>McNeil Consumer Health and Johnson &amp; Johnson</b>		
<b>Leslie Bloom, MS</b> McNeil Consumer Health	<b>Rajesh Mishra, MD, PhD</b> Johnson & Johnson	<b>Lynne Szczepaniak</b> McNeil Consumer Health
<b>Lamont Bryant, PhD</b> McNeil Consumer Health	<b>Kristin Recchiuti*</b> McNeil Consumer Health	
<b>Darrel Jodrey, MS</b> Johnson & Johnson	<b>Leily Saadat-Lajevardi</b> McNeil Consumer Health	

## Meeting Objectives and Summary

The 3<sup>rd</sup> Seeking Solutions Stakeholders' Forum on Advancing our Understanding of the Safe Use of Acetaminophen was convened by the National Council on Patient Information and Education (NCPIE), to achieve the following objectives:

- To review the latest research – trend data, adverse event surveillance data, and behavioral surveillance research.
- To leverage new research to inform new solutions for increasing the safe use of acetaminophen.
- To explore – prioritize data gaps, where additional research is needed.
- To discuss – prioritize additional interventions and collaboration opportunities to further reduce acetaminophen overdose and liver injury.

Participants included representatives of national, state, community, consumer, non-profit and other organizations that are involved in supporting public health and safety and that have been involved in promoting the safe use of acetaminophen and over-the-counter (OTC) literacy.

The meeting comprised a pre-meeting dinner presentation on March 18<sup>th</sup> by Dr. Charles Vega looking at critical issues in OTC analgesia. Dr. Richard Dart, MD, PhD from the Rocky Mountain Poison and Drug Center (RMPDC) moderated the March 19<sup>th</sup> meeting. The meeting comprised presentations and breakout sessions. Presentations covered a variety of topics including a brief background and history of the forum (Rick Dart, MD, PhD), updates on behavioral surveillance and icon research, a review of what is currently known about risk factors including the American Association of Poison Control Centers (AAPCC) and RMPDC Adverse Events Surveillance data Jody Green, PhD). Dr. Kevin Volpp presented a model for applying behavioral economics to drive healthy behavior.

Kristin Recchiuti of McNeil Consumer Healthcare summarized program progress and successes to date, future opportunities, and elements of the acetaminophen risk-mitigation plan. Daniel Ramirez, PharmD, RPH, provided the pharmacist perspective and presented NCPDP recommendations for dose accumulation monitoring in the inpatient setting. Cynthia Bens of the Alliance for Aging Research presented results of a survey supported by McNeil Consumer Health to better understand the role of acetaminophen in the lives of older adults.

The presentations are not summarized in detail in this document; however, any actionable item, key insights, comments and questions associated with specific presentations are described. The Breakout Session Recommendations are summarized individually.

## Setting the Stage for Problem Interventions, Saul Shiffman, PhD

Dr. Shiffman reviewed the current status of behavioral surveillance and icon research programs. The data show that using multiple medications is a risk factor for >4 g use and that both prescription and OTC use contribute to the risk.

The data show that for the 650 mg acetaminophen products, the risk of using >4g is associated with the product labeled "Arthritis Relief" (compared to the identical product

with the name “8 hour”) because consumers tended to re-dose every 4-6 hours, rather than follow the label directions for every 8 hours.

On-going consumer focused educational efforts, (such as the importance of reading the directions on the OTC Drug Facts label) have helped increase awareness about the safe and appropriate use of acetaminophen and understanding important differences between prescription and OTC product.

Fifty percent of consumers don't know that acetaminophen is in the prescription or OTC medications they took. This represents an on-going opportunity to educate and help consumers identify those products that contain acetaminophen. It was noted that any icon representing acetaminophen in products currently used in the US would not be useful in areas outside the US where acetaminophen is known as paracetamol.

### **What is Known About Risk Factors, Jody Green, PhD**

Dr. Jody Green of RMPDC reviewed updated data around factors that increase the risk of using >4 g acetaminophen, including new survey data. Dr. Green noted hospitalizations have been going down in all three acetaminophen product categories and that the reduction in the prescription setting has not been accompanied by a concomitant increase in the OTC setting, which would indicate switching behavior. In addition, the following trends were noted:

- All categories of adult acetaminophen exposure are decreasing;
- Intentional exposure cases involving acetaminophen decreased 14.9% - 22.6%;
- Unintentional exposure cases involving acetaminophen decreased 28% from their peak in 2008;
- Sales adjusted rates of reported exposures have decreased 14% from 2009 to 2013; major and death outcomes also decreasing.

Survey data showed the following:

- Patients are unlikely to ask healthcare providers for dosing instructions;
- Most patients will either consult the label or rely on memory to determine their dose;
- Sometimes doses are taken too close together or multiple acetaminophen products are taken concurrently;
- Patients generally think acetaminophen is a safe medication; campaigns may be heard but unsure if behaviors are changed.

### **Applying Behavioral Economics to Drive Healthy Behaviors, Kenneth Volpp, MD, PhD**

Dr. Kenneth Volpp's work is based upon the idea that people behave irrationally, but in predictable ways. One point he made was that immediate losses or benefits are drivers of behavior to a greater extent than are future benefits. He suggested that since loss avoidance and social altruism may not be effective when people are seeking pain relief, it might be useful to develop plans they can commit to. In the pain cycle context, for example, it might be useful to structure plans for pain relief during well-controlled periods. For example, what to do or not do within one hour of taking a pain reliever that contains acetaminophen. It was also suggested that storytelling to reinforce the human-

to-human connection was a bigger driver of behavior than science, data, or brochures. It might be useful to think about what narratives align with the target audience.

### **Review Progress, Successes, and Next Steps in Acetaminophen Safe Use, Kristin Recchiuti**

Kristin Recchiuti pointed to the fact that interventions are working as measured by outcomes, including reduction in adverse event rates and a better understanding of drivers behind exceeding 4 g of acetaminophen. She described multiple packaging, labeling and education interventions that target identified risk factors and are showing an intended effect in changing knowledge, attitudes, and behavior change.

### **NCPDP Recommendations for Dose Accumulation Monitoring in the Inpatient Setting, Daniel Ramirez, PharmD, RPH**

Dr. Daniel Ramirez spoke about industry accomplishments to date including that 80% of the pharmaceutical industry no longer abbreviates “acetaminophen” and the submission of a white paper on recommendations that identify groups that are potential targets for interventions. He noted in the hospital setting, approximately 4% of inpatients exceeded 4 g acetaminophen per day.

Dr. Ramirez identified a gap in healthcare provider (HCP) education around risk factors for acetaminophen overdose and noted many hospitals have not yet integrated current knowledge about acetaminophen risk factors into their systems. Additionally, there is a lack of training in hospitals about how to use the technology that could monitor or track in-patient acetaminophen use.

The question of how and when to implement “hard stops” came up when discussing if there was ever a clinical rationale for exceeding 4 g acetaminophen per day.

### **Breakouts**

Following the didactic presentations, the group was broken up into three smaller groups; each was asked to consider one of the following questions:

1. Using the knowledge gained from the presentations and personal or organizational knowledge and experience, what action(s) would need to be taken to motivate consumers to adhere to the proper use of acetaminophen?
2. What strategies would you recommend, nationally and organizationally, that would propel the meeting’s discussions forward?
3. Using the information from the presentations, what are the key message points and to whom should they be directed (e.g., policymakers, practitioners, patients)? What messages and audiences are missing from the meeting discussions?

### **Group 1**

*Using the knowledge gained from the presentations and personal or organizational knowledge and experience, what action(s) would need to be taken to motivate consumers to adhere to the proper use of acetaminophen?*

This group divided their suggestions into several buckets:

- Education

- Simplify the messaging so that it is accessible to audiences with different educational levels.
  - For example, “Know Your Meds, Know Your Dose”
  - Another comparative example was “lung age” – How do you make the complex simple? How can acetaminophen use be represented as simply as “lung age” with smoking?
  - Feel accountable to a group – can we generate a program of peer mentoring or training for caregivers?
  - \*What You May Not Know # 1... # 2... # 3 (series of factoids.)
- Target specific at-risk groups (e.g., lower literacy, combination users, people with chronic pain conditions)
  - Start with populations at risk and focus on them.
- Focus on the reasons for (safe?) use rather than the risks of use
  - Talk about reasons for using acetaminophen rather than “how” specifically to use it.
- Identify a “WOW” factor to generate interest in the moment
  - Create a series of factoids: “What You May Not Know”
  - Create media buzz; push into news cycles
- Advocate for icon education and industry-wide adoption of the icon because it will improve consumer education at the point of purchase/point of care
- Social norms
  - Individuals are more likely to comply when they feel accountable to a group (these might be peers or caregivers in this case)
  - Peer mentoring: begin with at-risk populations and formulate approaches for messaging to them via peer mentoring
  - If most patients figure out how to use acetaminophen safely, focus consumer attention on the small percentage that doesn’t understand how to use the product.
    - For example, “Don’t be part of the 5%!”
    - Compare the 5% to the small % of people that don’t wear seatbelts or other behaviors that are known to save lives
- Retailers
  - Identify retailer “social norms” and use them to build a message around behavior
  - Shelf-talkers in the aisles (WalMart example)
- Pharmacist visibility
  - There is no visible expert pharmacist in the media; identify someone to fill this role

## **Group 2**

*What strategies would you recommend, nationally and organizationally, that would propel the meeting’s discussions forward?*

This group identified these three items as highest priority:

1. Push the message to pharmacists
2. Confirm messaging with this group
3. Develop social media messaging for specific target groups

- Develop educational materials that Poison Control Centers can use when someone calls to report they've taken one or two extra pills;
- Update current educational materials and messages and work to disseminate and promote usage through the different participating stakeholder organizations.
- Use RMPDC data to identify issues that organizations can address
- Elevate the topic; presentations at pain meetings, websites with links to resources
- Make sure that accurate, vetted messages are at the top of any Google search for acetaminophen
- Expand the OTC Scholastic program beyond the schools and into libraries and other community groups.
- Develop/disseminate accurate messaging on safe acetaminophen use to local and national nurse call-in telephone help lines.(e.g., NurseLine)
- Help organizations understand what the data mean to them
- Draft recommendations for pain relief that include non-medicinal options (e.g., heating pads, movement, diet, exercise, when to see a healthcare professional)
  - Potential challenges: non-pharmacologic options may not be covered by insurance; many primary care providers won't see a patient just for a diagnosis of chronic pain
- Change the conversation within organizations – why we take medicine and when we take it
- Understand how clinicians prioritize patients' risk of overusing acetaminophen in the context of brief patient visits and the need to focus on other conditions
- Pharmacist counseling for consumers beyond “Flag the Bag.” What questions are consumers asking in the real world? What are the answers that pharmacists should provide?

### **Group 3**

*Using the information from the presentations, what are the key message points and to whom should they be directed (e.g., policymakers, practitioners, patients). What messages and audiences are missing from the meeting discussions?*

This group echoed the suggestions made by Group 1.

- They suggested starting with high-risk groups (e.g., patients with limited literacy, patients in chronic pain) and healthcare providers – especially pharmacists
  - Groups that are missing include managed care organizations, men
- Messaging
  - The group identified two key messages:
    - Acetaminophen is safe and effective when used correctly
  - Ensure that messaging extends into the public and social networking spaces (e.g., news cycles, social media, points of sale)
  - Promote the acetaminophen icon
  - Create a message that “an OTC is a REAL medicine”
- Use data gathering devices that are already available to educate the public and consumers, perhaps by using promotions
  - For example, incorporate safe use messaging on coupons to raise awareness
- Share the message that as opioid use is reduced, acetaminophen use increases, therefore education is vital

- Use a Risk Evaluation and Mitigation Strategy (REMS) program for opioids that contain acetaminophen to educate around the safe use of acetaminophen
- Review the FDA docket to see if there is any commentary on opioids that can be applied to acetaminophen
- The Center for Medicare and Medicaid Services (CMS) has expanded counseling payments for chronic conditions. How might coverage for OTC acetaminophen therapy recommended for the treatment of chronic conditions by their healthcare providers be extended to CMS beneficiaries.
- A provision of the "Food and Drug Administration Safety and Innovation Act" authorized the US Access Board to convene a working group (NCPIE was a participant) to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually impaired. The report, entitled, [Access Board Working Group on Accessible Prescription Drug Container Labels](#) was released in July 2013.