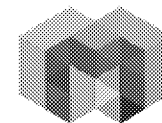


# Mallinckrodt Pharmaceuticals – Advocacy Initiatives

February 24, 2015

Confidential – Not for Public Disclosure

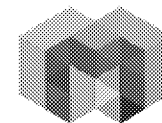




# Key Programs

- ▶ Collaborative for Effective Prescription Opioid Policies (CEPOP)
- ▶ Alliance for Balanced Pain Management
- ▶ Medication Inactivation Pouches (Medsaway)

# Mallinckrodt Advocacy Objective: Engage in National Dialogue



- I. Assure Appropriate Pain Management and Patient Access
- II. Address Societal Epidemic of Abuse, Misuse & Diversion

## Policy; Legislative

Policy/Legislative platform to address opioid abuse, misuse and diversion while ensuring patient and provider access to necessary pain medications

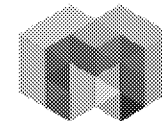
## Societal Burden

Societal platform to balance maximizing access for appropriate pain management with responsible opioid use, storage & disposal

## Mallinckrodt Initiatives

Position Mallinckrodt as a responsible company developing & implementing innovative solutions to address patient pain and supporting efforts to end misuse and abuse

# Collaborative for Effective Prescription Opioid Policies



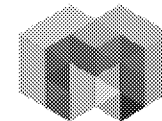
## Co-Conveners



## Objective

Collaborative to engage a diverse group of stakeholders interested in the manufacture, distribution, and appropriate use of opioid medications behind a comprehensive and balanced policy strategy to reduce abuse and promote treatment options, both for those living with chronic pain and confronting addiction

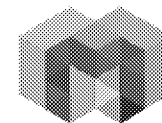
# CEPOP Structure and Members



Policy Priorities (Work streams)		
Prevention	Education	Treatment & Recovery
Technology & Manufacturing	Monitoring & Deterrence	Visibility & Awareness

- |   |   |  |
|---|---|--|
| ▶ AIT Labs                                | ▶ Cardinal Health                                     | ▶ National Association of State Alcohol and Drug Abuse Directors |
| ▶ AmerisourceBergen Corporation           | ▶ CareFirst (BC/BS)                                   | ▶ National Governor's Association                                |
| ▶ American College of Preventive Medicine | ▶ Hazelden (Betty Ford Foundation)                    | ▶ National Hospice and Palliative Care Organization              |
| ▶ American Pharmacists Association        | ▶ Johns Hopkins Center for Injury Research and Policy | ▶ PAINS Action Alliance  |
| ▶ American Society of Addiction Medicine  | ▶ Kentucky Office of Drug Policy Control              | ▶ Shatterproof   |
|   | ▶ Mallinckrodt Pharmaceuticals                        | ▶ Walgreens  |

# Alliance for Balanced Pain Management

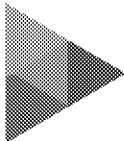


## Mission:

Represent the rights of people with pain to receive appropriate pain management while striving for restoration of function balanced with misuse deterrence

### Patient Pain Alliance

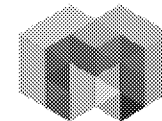
*Alliance of  
patient advocacy groups, medical  
associations, industry and employers  
committed to ensuring availability  
of appropriate medications for  
the treatment of pain management  
and restoration of function, and  
shared responsibility in  
safeguarding  
medications*

- 
- ▶ Align a disparate group of key stakeholders to coalesce around a core set of principles which will help drive the narrative and action in this national debate
  - ▶ Through public education campaign(s), drive awareness of the need to balance legitimate pain management needs with shared responsibility in safeguarding medications
  - ▶ Further propagate Alliance message(s) through the Alliance membership and to the constituents of each respective organization



ALLIANCE FOR

# Balanced Pain Management



## Goals of the Alliance

▶ Ensure people with or affected by pain have access to appropriate, integrated pain management

▶ Reinforce the critical need to safely prescribe, dispense, take, store and dispose of prescription medications with an aim to reduce abuse, misuse and diversion.

▶ Create tools and messaging for its members to educate their constituents and the public about integrated pain management strategies and responsible use of medicine.

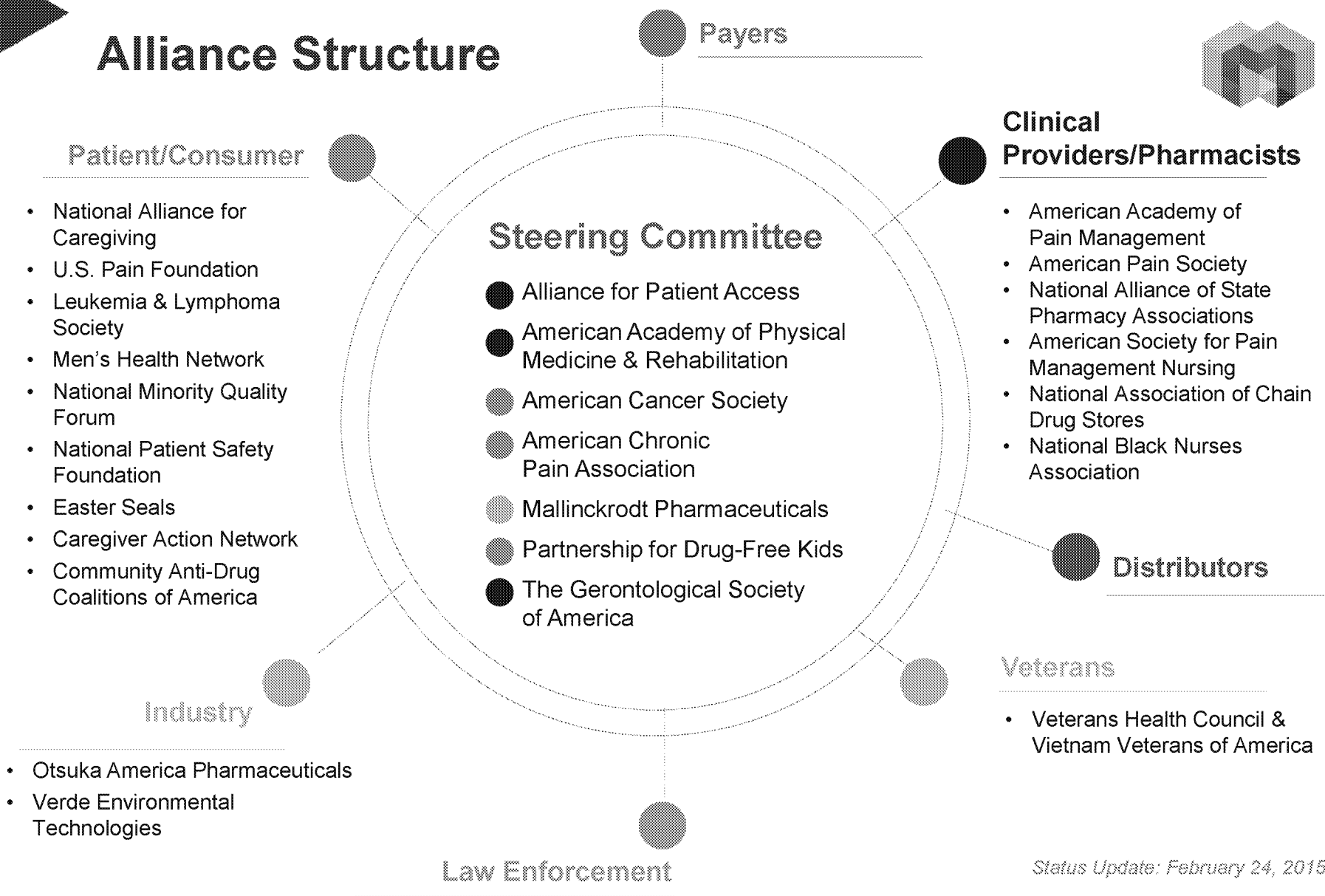
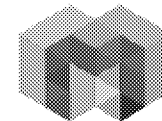
## How is the Alliance Different?

▶ Focus on societal burden of ensuring access and safe use (not policy/legislative agenda)

▶ Focus is limited to 2-3 actionable initiatives

▶ Members agree to speak with one voice and pull through messaging with their respective constituents

# Alliance Structure

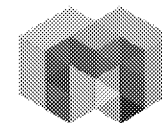


Status Update: February 24, 2015

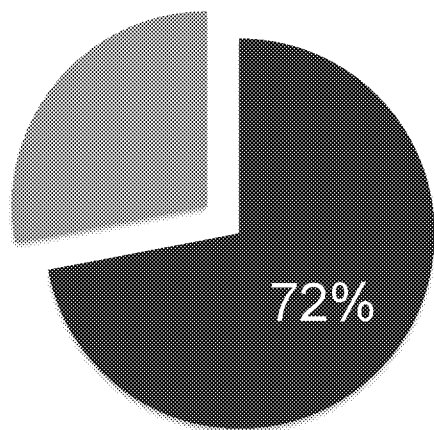
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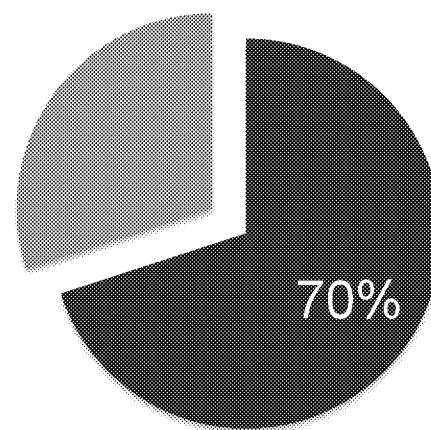
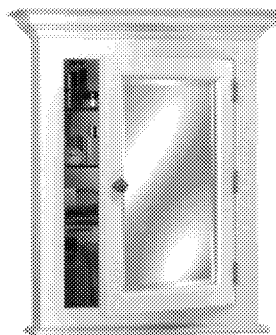
# Opioid Misuse Is A National Concern



Mallinckrodt is committed to taking an active role in addressing prescription opioid misuse, abuse and diversion



72% of patients that were prescribed opioids reported having leftover amounts<sup>1</sup>



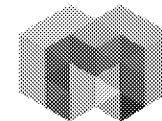
More than 70% of people who abused prescription pain relievers got them from friends or relatives<sup>2</sup>

An important first step is to begin disposing of unused medications

1. Morbidity and Mortality Weekly report Vol 59, No. 6. Center for Disease Control and Prevention Feb 19, 2010

2. 2009 National Survey on Drug Use and Health (NSDUH): National Findings, SAMHSA (2010)

# Mallinckrodt Offers Safe Disposal Method

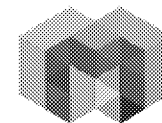


- ▶ Mallinckrodt has a partnership with Verde Environmental Technologies, the makers of the Medsaway® SP home medication inactivation pouches<sup>1</sup>
  - ▶ Sole distribution channel to clinicians
  - ▶ Pouches help customers simply and safely dispose of any unused medication
  - ▶ Minimizes potential for diversion or accidental exposure
- ▶ Patient Safety Awareness Week (March 8-15)
  - ▶ Mallinckrodt will distribute over 120,000 pouches to Ambulatory Surgery Centers



<sup>1</sup> Pouch was developed with the support of the National Institute on Drug Abuse (NIDA), a branch of the National Institutes of Health (NIH)

# Medsaway Pilot



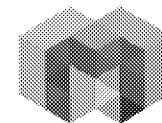
Objective: Implement pilot program designed to identify patient education message and tools which result in a change in behavior to dispose of unused prescription medications

Key Collaborators		
Mallinckrodt	Verde	PhRMA

Pilot Groups				
Rx Drug Activist	VA	Physician	Environmental	Pharmacy
CADCA	Dayton, OH (proposed)	24 Ortho Clinics (Minneapolis-St. Paul)	American Illinois Water	CVS

Outcomes Data (Survey Measurement)		
Control Group	Patient Education Material	Patient Ed Material + Pouch

# Research: Safe Use, Storage & Disposal Not A Priority



**Audience**

**Opiate Providers**

**Opiate Patients**

**Survey Type**

**15 Minute Online Survey**

**15 Minute Online Survey**

**Field Dates**

**December 30<sup>th</sup> 2014 to January 3<sup>rd</sup> 2015**

**December 30<sup>th</sup> 2014 to January 13<sup>th</sup> 2015**

**Sample Size**

**N=360 Doctors who have  
prescribed opiates in the past 30  
days**

**N=705 Adults Aged 18+ who  
have filled an opiate  
prescription in the past 60 days**

**Sample  
Design**

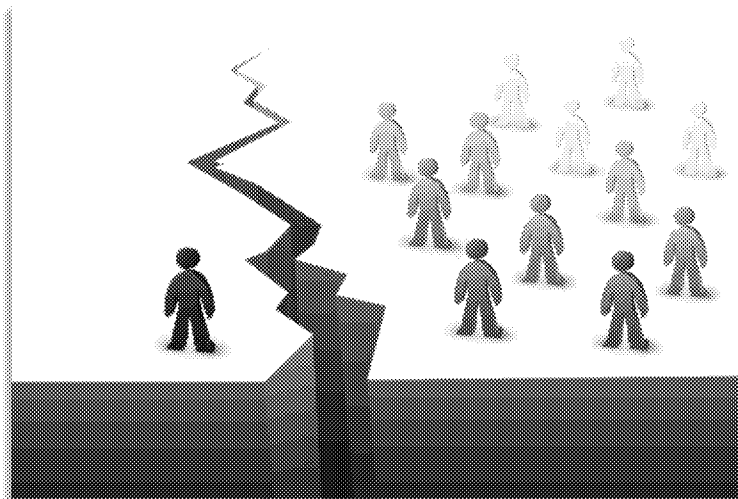
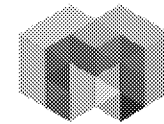
**N=360 Doctors**

- N=205 Primary Care Physicians
- N=51 Pain Management Specialists
- N=53 Oncologists
- N=51 Surgeons

**N=705 Pain Patients**

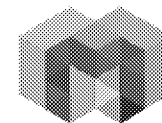
- N=401 Chronic Pain Patients
- N=304 Acute Pain Patients
- N=145 Cancer-Related Pain Patients (acute or chronic)

# Executive Summary – Safe Storage & Disposal

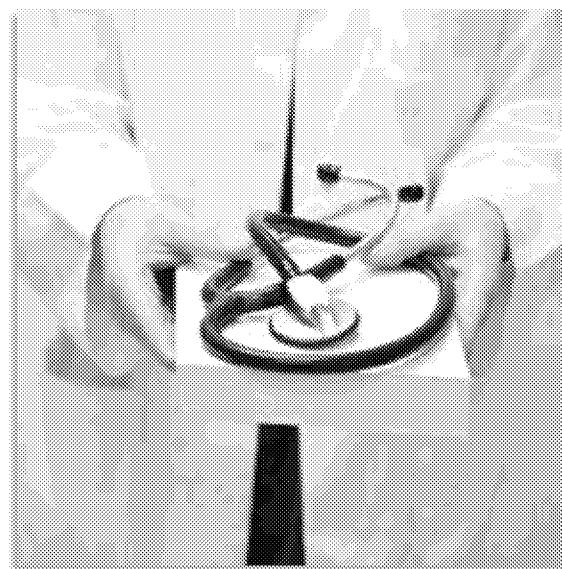


- ▶ There is a large communications gap between physicians and patients around the storage and disposal of opiates
  - ▶ This disconnect is driven by a lack of communication rather than miscommunication
  - ▶ One of the key drivers behind this is that doctors simply don't see instructions around storage and disposal as very important
  - ▶ PMS are more attentive towards providing these instructions - but these are still dwarfed by other opiate concerns

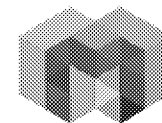
# Executive Summary – Identifying Misusers



- ▶ Only 1 in 4 doctors feel very well prepared to identify opiate misusers who are seeking medication, and fewer than 1 in 10 say medical school prepared them well in this manner



# Opportunities for Improvement



- ▶ American Board of Medical Specialties
  - ▶ Partner with medical community to educate health care providers regarding prescription medication abuse, misuse, diversion and disposal through the development of a Patient Safety Module which physicians would need to review to receive their annual specialty certification
- ▶ Red Flags Video
  - ▶ Education video that helps HCPs identify red flags which could alert the provider to the suspicious activity of a potential abuser
- ▶ Medication Disposal Pilot
  - ▶ Identify patient education message and tools which result in a change in behavior to dispose of unused prescription medications