

American Institute of Homeopathy



Presenters:

Ronald D. Whitmont, MD

Bernardo Merizalde, MD

David Riley, MD

Michelle Dossett, MD, PhD



American Institute of Homeopathy

- ▶ Established 1844
- ▶ Senator Royal S. Copeland, MD, Past President
- ▶ Licensed physicians (medical, osteopathic, and naturopathic)
- ▶ Dentists
- ▶ Nurse Practitioners
- ▶ Physician Assistants

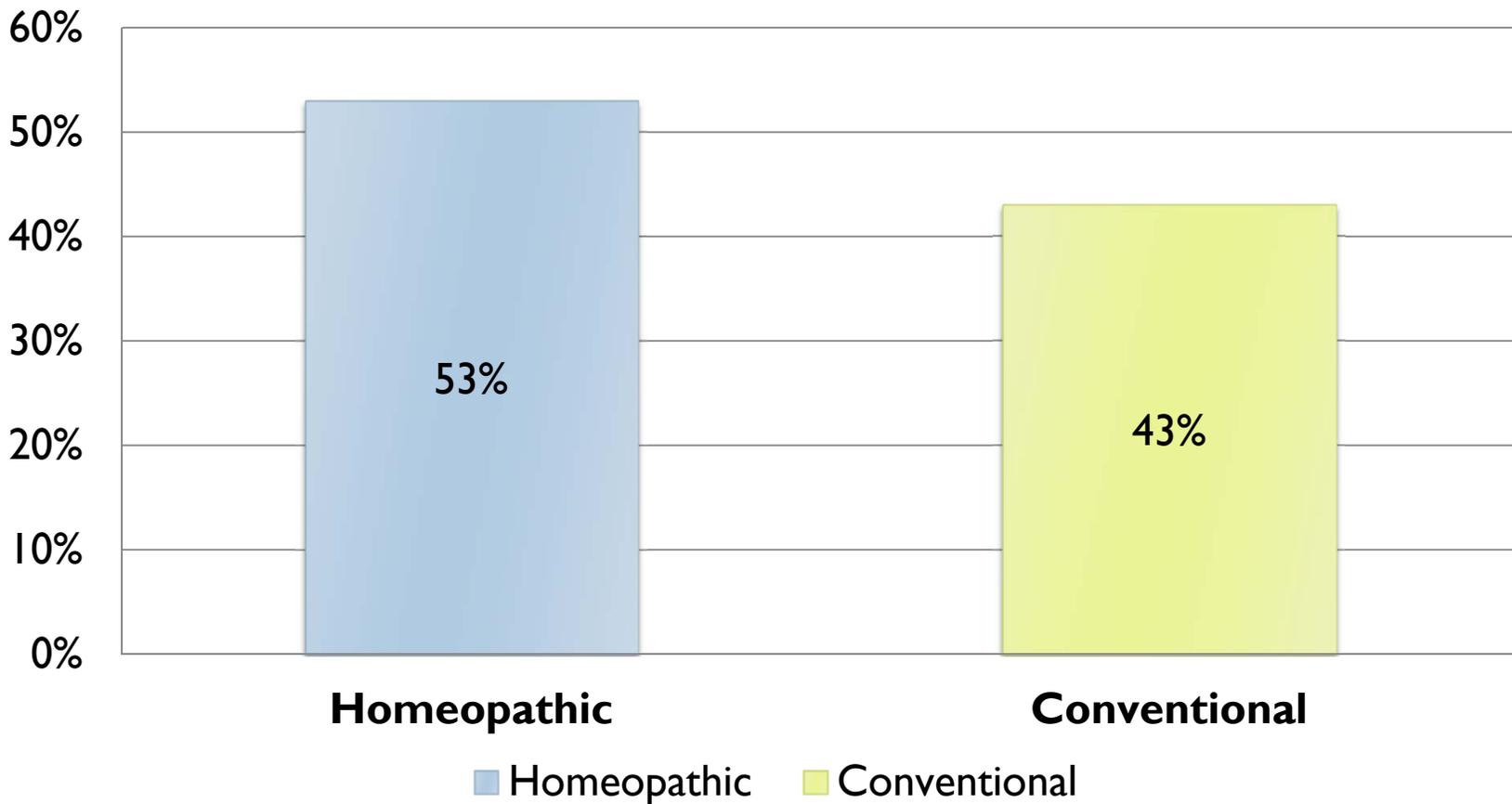


AIH Members

- ▶ Maintain specialty licensing requirements pertaining to their medical specialty
- ▶ Maintain homeopathic continuing medical education
- ▶ Some maintain dual board certifications
 - ▶ conventional medical specialty
 - ▶ homeopathic board certification
 - ▶ integrative medicine specialty

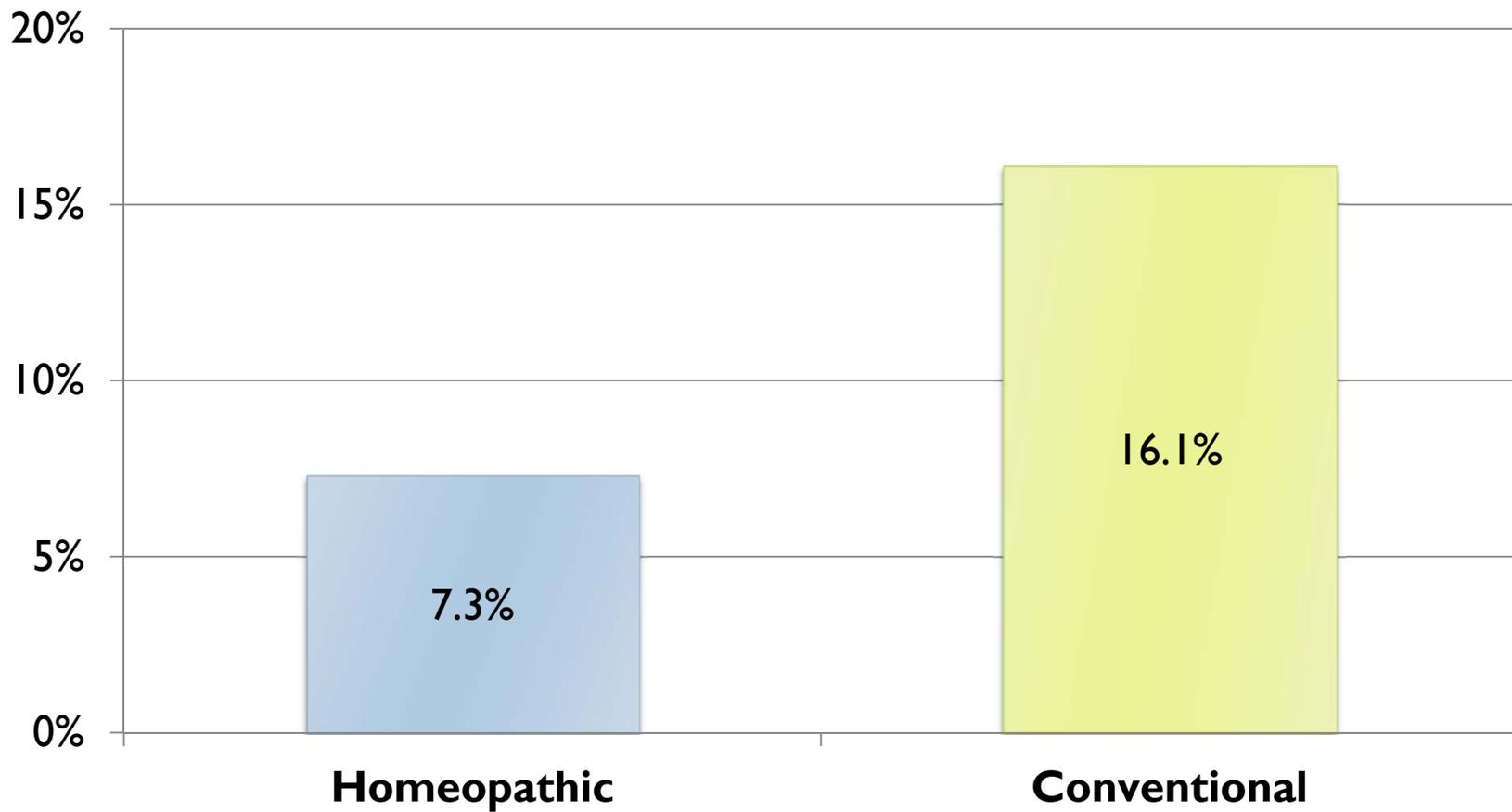


Complete Treatment Satisfaction



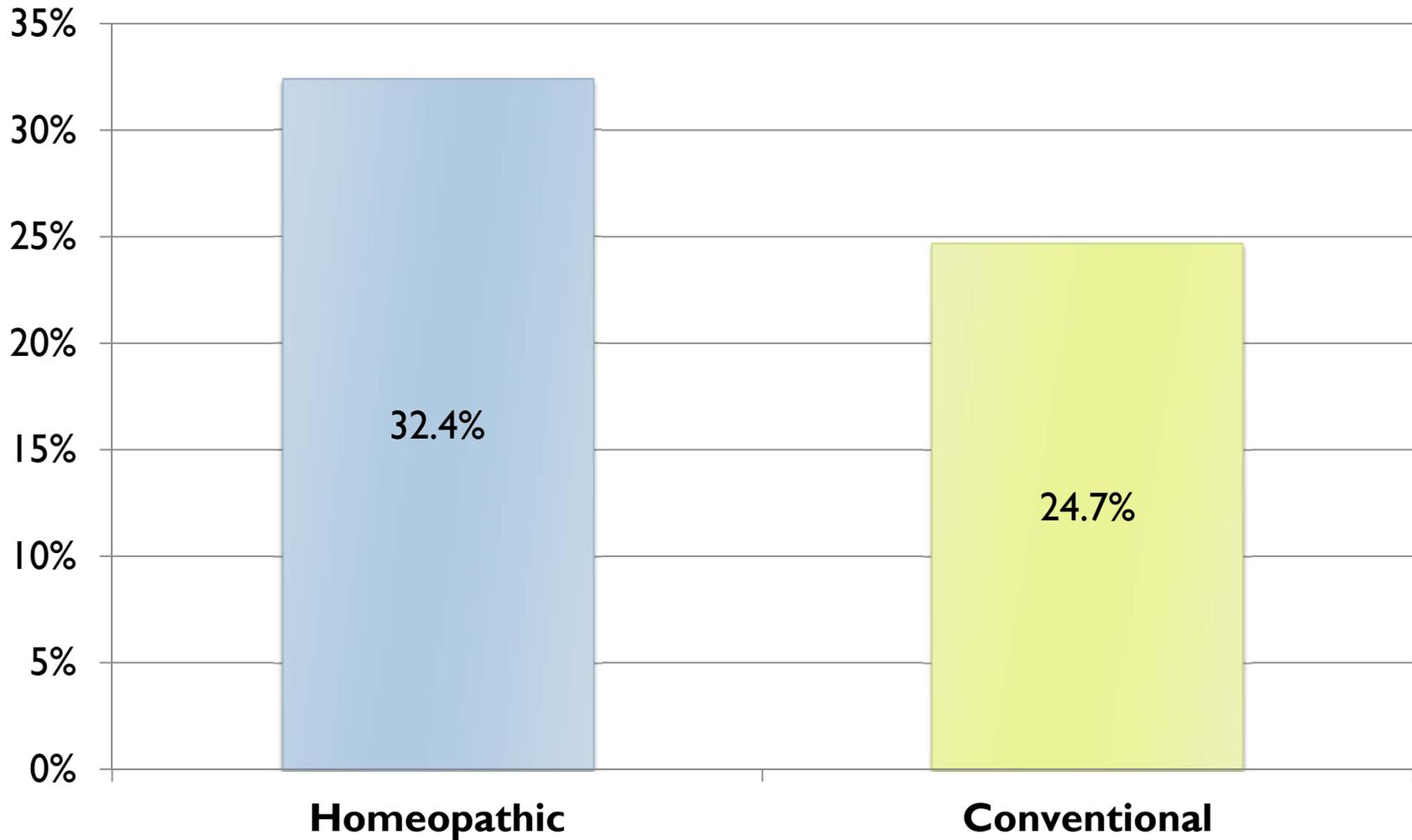
▶ Patient satisfaction and side effects in primary care: An Observational Study. Marian F, Joost K, Saini KD et al. 2008.

Side Effects



► Marian F, Joost K, Saini KD et al. 2008.

Higher Education Status



► Marian F, Joost K, Saini KD et al. 2008.

American Institute of Homeopathy

▶ Homeopathic Data Sources

▶ American Institute of Homeopathy

▶ www.homeopathyusa.org

▶ National Institutes of Health

▶ National Center for Complementary and Integrative Health

▶ <https://nccih.nih.gov/>



Homeopathic Consumers

- ▶ More compliant with their medical care
- ▶ Highly motivated
- ▶ Well educated
- ▶ Conscientious about their lifestyle choices
- ▶ Act responsibly
- ▶ Take their own health care decisions very seriously



American Institute of Homeopathy

- ▶ **Bernardo Merizalde, MD**
 - ▶ Thomas Jefferson University

- ▶ **Michelle Dossett, MD, PhD, MPH**
 - ▶ Massachusetts General Hospital
 - ▶ Harvard Medical School

- ▶ **David Riley, MD**
 - ▶ Arizona Center for Integrative Medicine
 - ▶ New Mexico School of Medicine





Informed Decisions on Homeopathic Medicines – Consumer and Provider Perspectives

Bernardo Merizalde, MD, DHt, ABHIM

Assistant Clinical Professor of Psychiatry and Neurology
Thomas Jefferson University
Philadelphia, PA

Introduction

- ▶ Board Certified in Psychiatry and Neurology
- ▶ Diplomate of the American Board of Homeotherapeutics and the American Board of Integrative and Holistic Medicine
- ▶ Assistant Clinical Professor of Psychiatry and Neurology, Thomas Jefferson University & Hospital, Philadelphia*
- ▶ Private Practice in General Med. & Psychiatry using CAM and Homeopathy for 35 years.

▶ *My views do not necessarily represent those of TJU

My Practice Experience: 35 years

- ▶ Most patients come from community referrals or from colleagues
- ▶ Many know homeopathy and what they are looking for
- ▶ Patients want the choice of including homeopathic medicines in their healthcare
- ▶ Homeopathy is clinically and cost effective



Informed Decisions: Homeopathic Products

- ▶ Homeopathic Product Labelling is sufficient for consumers
- ▶ Improvement always possible
- ▶ Practitioners recommend OTC homeopathic products as options in treatment plans



Searching for Healthcare Online

- ▶ 59% of adults looks up health information online.
- ▶ 35% U.S. adults self-diagnose a medical condition in themselves or for someone they know

Internet Based Health Decisions

- ▶ 46% choose to consult a professional healthcare provider based on internet findings
- ▶ 38% treat their condition at home
- ▶ Homeopathic medicine consumers likely to reflect the general findings

World Health Organization

- ▶ Guidelines provide technical guidance to Member States in developing context-specific and reliable information promoting proper use of TM and CAM

-
- ▶ “Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine” WHO, 2004.

Accurate Information Dissemination

- ▶ FDA provides authoritative guidance
- ▶ Information vacuums can create media confusion
- ▶ HPCUS and AIH can liaison with FDA to help ensure expert and accurate information is available to both media and consumers



Homeopathic Product Marketplace

- ▶ CAM therapies are increasingly popular
- ▶ 65% of the population use CAM (WHO, 2002)
- ▶ Increasing U.S. homeopathic product sales
- ▶ Likely reflects increasing consumer perceived value
- ▶ Increases occurring despite well-publicized claims that homeopathy is not effective.



Areas for Improvement

Role of federal agencies including FDA

- ▶ Provide accurate and reliable information to consumers and healthcare providers
- ▶ Help better distinguish homeopathic medicines from dietary supplements
- ▶ Provide consumers and healthcare providers with more complete information on the production and labeling requirements for homeopathic medicines



Areas for Improvement

Role of federal agencies including FDA

- ▶ Encourage research funding to help document the safety profile of homeopathic medicines for consumers and providers
- ▶ Help ensure availability of current research on homeopathic products



Areas for Improvement

Non-governmental organizations

- ▶ HPCUS should continue to provide more publicly accessible information on the definition and production standards for homeopathic products
- ▶ AIH and NCH should continue to publish available research on homeopathic drug safety and effectiveness



Areas for Improvement

Medical Colleges and Training Programs

- ▶ Increase efforts to educate healthcare providers on homeopathic medicines and other complementary and integrative healthcare therapies
- ▶ A foundational knowledge of these therapies is necessary for healthcare providers to accurately counsel patients and interpret risk when overlapping treatment types occur



Conclusions

1. Use of homeopathic products is increasing
2. Consumers appear readily able to make informed decisions about homeopathic products
3. Patients want freedom to use homeopathic drugs as part of their healthcare solutions
4. Providers utilize homeopathic drugs within the larger context of conventional medicine as a complementary therapy



Conclusions

5. Health care providers utilize homeopathic drugs despite significant paradigm differences inherent in the homeopathic medical model
6. Healthcare providers desire and need unbiased, scientific information on homeopathic drug use and safety
7. Current information available on the internet is often conflicting, incomplete, and inaccurate
8. The AIH membership provides the highest level of expertise in combined knowledge of conventional and homeopathic drugs – potential resource for FDA





Homeopathic Drug Regulation – Consumer and provider perspectives

David Riley, MD

Integrative Medicine Institute
Portland, OR

Homeopathic Regulatory Framework

Homeopathic drug products are governed by:

- ▶ Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15), and the
- ▶ Homeopathic Pharmacopoeia of the United States (HPUS), and
- ▶ Registrations as homeopathic pharmaceutical companies in conformity with Section 510 of the Act and 21 CFR 207



Homeopathic Drug Definition

- ▶ Homeopathic Drugs are listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, and its supplements. The potencies of homeopathic drugs are specified on the label and must contain diluents commonly used in homeopathic pharmaceuticals.
- ▶ Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.



Homeopathic Prescription Drugs

- ▶ Homeopathic drug products categorized as “prescription only” may only be dispensed pursuant to a prescription order.
- ▶ American Institute of Homeopathy members are aware of the benefits and limits of both conventional and homeopathic medicine. The AIH members are trained in conventional and homeopathic medicine and includes those with research regulatory expertise.



Use of Homeopathic Drugs

- ▶ A guide to the use of homeopathic drugs may be found by referring to Homeopathic materia medica texts and the published homeopathic literature.
- ▶ Texts commonly used include but are not limited to *A Dictionary of Practical Materia Medica and Repertory* by John Henry Clarke, MD. These references are commonly reviewed in conjunction with other available literature on these drug substances.



Labeling Regulation

- ▶ **Labeling**
 - ▶ Sections 502 and 503 of Food, Drug & Cosmetic Act (FDCA)
 - ▶ Part 201 Title 21 of CFR
- ▶ **Statement of Ingredients**
 - ▶ Section 502(e) of the Act and 21 CFR 201.10
- ▶ **Statement of quantity and amount of ingredient(s)**
 - ▶ Section 502(b) of FDCA
 - ▶ 21 CFR 201.10
 - ▶ Section 502(e)(1) of FDCA
- ▶ **Established name of product**
 - ▶ Section 502(e)(3) of FDCA
 - ▶ 21 CFR 201.10.



Labeling Guidelines

- ▶ Labeling Guidelines are in Place for both Prescription (Rx.) and Over-the-Counter Medications that appear to be working for both practitioners, patients, and consumers.
- ▶ Homeopathic medicines are generally safe
- ▶ Side effects tend to be mild and adverse drug reactions minimal*
- ▶ Consumers generally use homeopathic medicines for self-limited conditions.

▶ *Jong MC, Jong MU, Baars EW. Pharmacoepidemiol Drug Saf. 2012

10 Year Review of Warning Letters

48 warning letters for homeopathic products
(2005 until present)

Examples include:

- ▶ HCG products (7 letters)
- ▶ Unauthorized H1N1 flu products (6 letters)
- ▶ Misbranding (29 letters)
 - ▶ Rx only products marketed for OTC use
 - ▶ Combining homeopathic and allopathic active ingredients
- ▶ Violation of GMP (10 letters)



Adequacy of Regulatory Framework

- ▶ **The current regulatory process is adequate.**
 - ▶ Defined by the HPUS and CPG 400.400
 - ▶ Informs consumers about OTC use for homeopathic drug products
- ▶ **Consumers and licensed health care providers have adequate information to make informed decisions**





Homeopathy – Safety and Public Perceptions

Michelle Dossett, MD, PhD, MPH

Assistant in Medicine, Massachusetts General Hospital
Instructor, Harvard Medical School
Boston, MA

Safety of Homeopathy

“What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic?”



Anecdotally

- ▶ Homeopathic medicines are safer than conventional medicines
- ▶ Side effects tend to be mild and transient
- ▶ For self-limited conditions, their use may reduce the potential for adverse drug reactions and interactions



Do Homeopathic Medicines Provoke Adverse Effects? A Systematic Review

- ▶ Reviewed literature 1970-1995
- ▶ 19 clinical trials – mean incidence of AEs 9.4 in the homeopathic groups & 6.17 in the placebo groups
- ▶ AEs were mild and transient
- ▶ Case reports – issues with products mislabeled as homeopathic
- ▶ Homeopathic pathogenetic trials, mean incidence of effects of 54.3%, not very different from nocebo effects in phase I RCTs.

Review by the Swiss Government

- ▶ “the use of medium and high potencies is free from toxic and unexpected organ effects.”

Adverse drug reaction to anthroposophic and homeopathic solutions for injection: A systematic evaluation of German pharmacovigilance databases

- ▶ 303 million ampoules sold for injection between 2000-2009
- ▶ 486 case reports, 1180 ADRs total
- ▶ 71.8% (349/486) of reports included ADRs that were listed
- ▶ 27.3% (322/1180) of ADRs were localized reactions
- ▶ 46 of the reports were classified as serious
- ▶ Overall reporting rate of ADRs < 4 per 1 million ampoules sold

Conclusions: “The reporting rate of ADRs associated with anthroposophic and homeopathic solutions for injection is very low.”

Adverse effects of homeopathy: a systematic review of published case reports and case series

- ▶ 1159 patients from 17 countries, 1978-2010
- ▶ “AEs ranged from mild to severe and included 4 fatalities. The most common AEs were allergic reactions and intoxications.”
- ▶ 1070 of the reports are of “unspecified remedies” from a German poison control center and largely represent accidental ingestions by young children with limited or no side effects.

Adverse effects of homeopathy: a systematic review of published case reports and case series

- ▶ Many of the remaining 89 cases
 - ▶ are of unspecified compounds
 - ▶ medicines not traditionally homeopathic
 - ▶ lack documentation of concomitant treatments
 - ▶ low dilution medicines
 - ▶ some AEs are misattributed

2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS)

- ▶ “There were 10,311 reported poison exposure cases related to “Homeopathic Agents,” with 8,788 of those reported cases attributed to children 5 years of age and younger.”
- ▶ “Of the 10,311 reported cases, 697 required treatment in a health care facility.”

Table 22B. Demographic profile of SINGLE-SUBSTANCE Pharmaceuticals exposure cases by generic category

	No. of Case Mentions	No. of Single Exposures	Age				Unknown Child	Unknown Adult	Unknown Age
			≤5	6–12	13–19	≥20			
Homeopathic	10,311	9,704	8,788	303	88	419	20	80	6

	Reason				Treated in Health Care Facility	Outcome				
	Unint	Int	Other	Adv Rxn		None	Minor	Moderate	Major	Death
Homeopathic	9,343	111	3	236	697	1,830	265	47	3	1

▶ Mowry JB, et. al., Clin Toxicol (Phila). 2013.

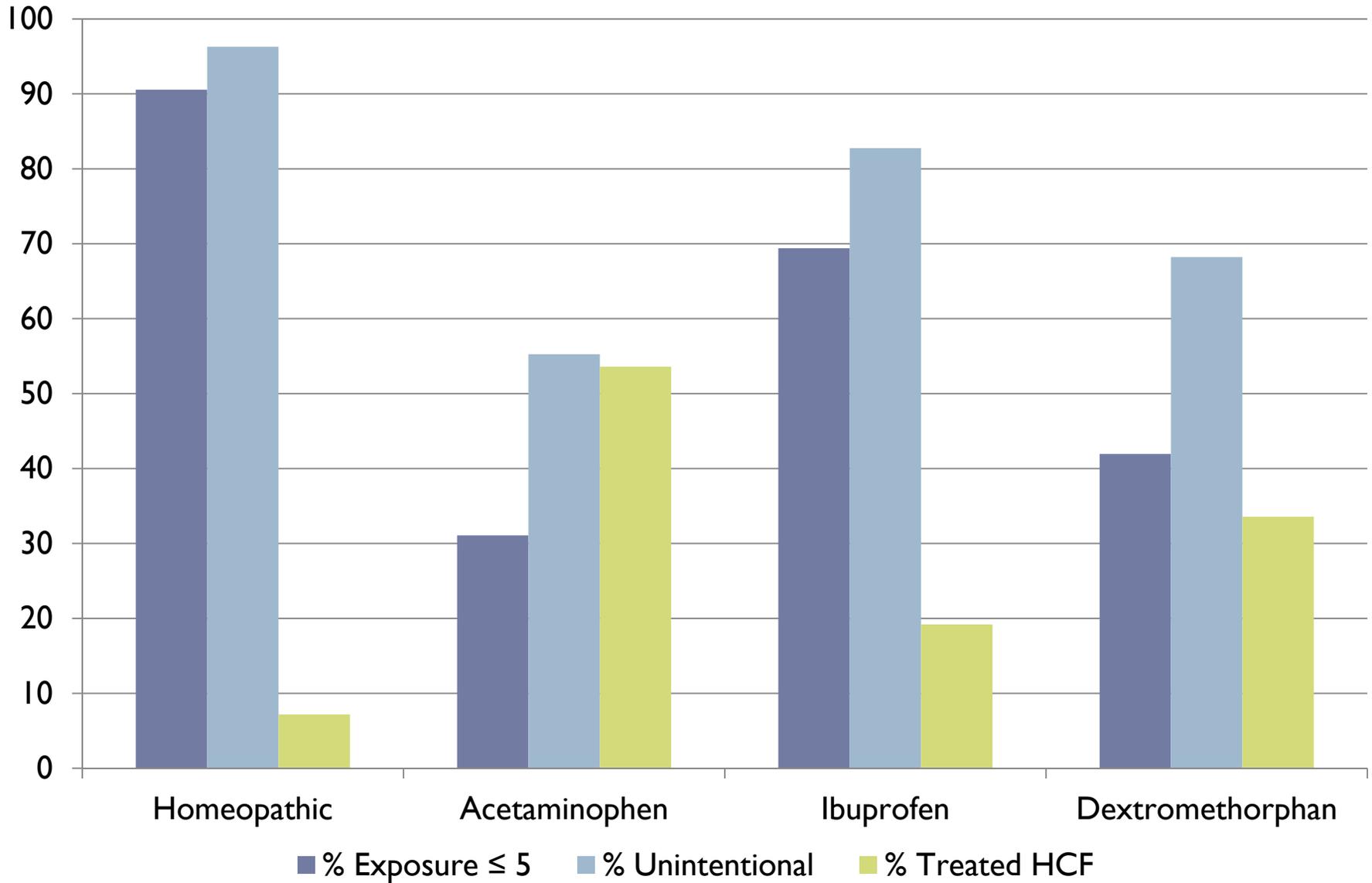
Table 22B. Demographic profile of SINGLE-SUBSTANCE Pharmaceuticals exposure cases by generic category

	No. of Case Mentions	No. of Single Exposures	Age						
			≤ 5	6–12	13–19	≥ 20	Unknown Child	Unknown Adult	Unknown Age
Homeopathic	10,311	9,704	8,788	303	88	419	20	80	6
Acetaminophen Alone, Adult	33,065	21,707	6,745	944	4,267	8,861	15	726	149
Ibuprofen	83,608	66,143	45,909	3,421	6,460	9,169	46	937	201
Other Dex-tromethorphan	13,905	10,745	4,508	1,409	2,074	2,514	10	193	37

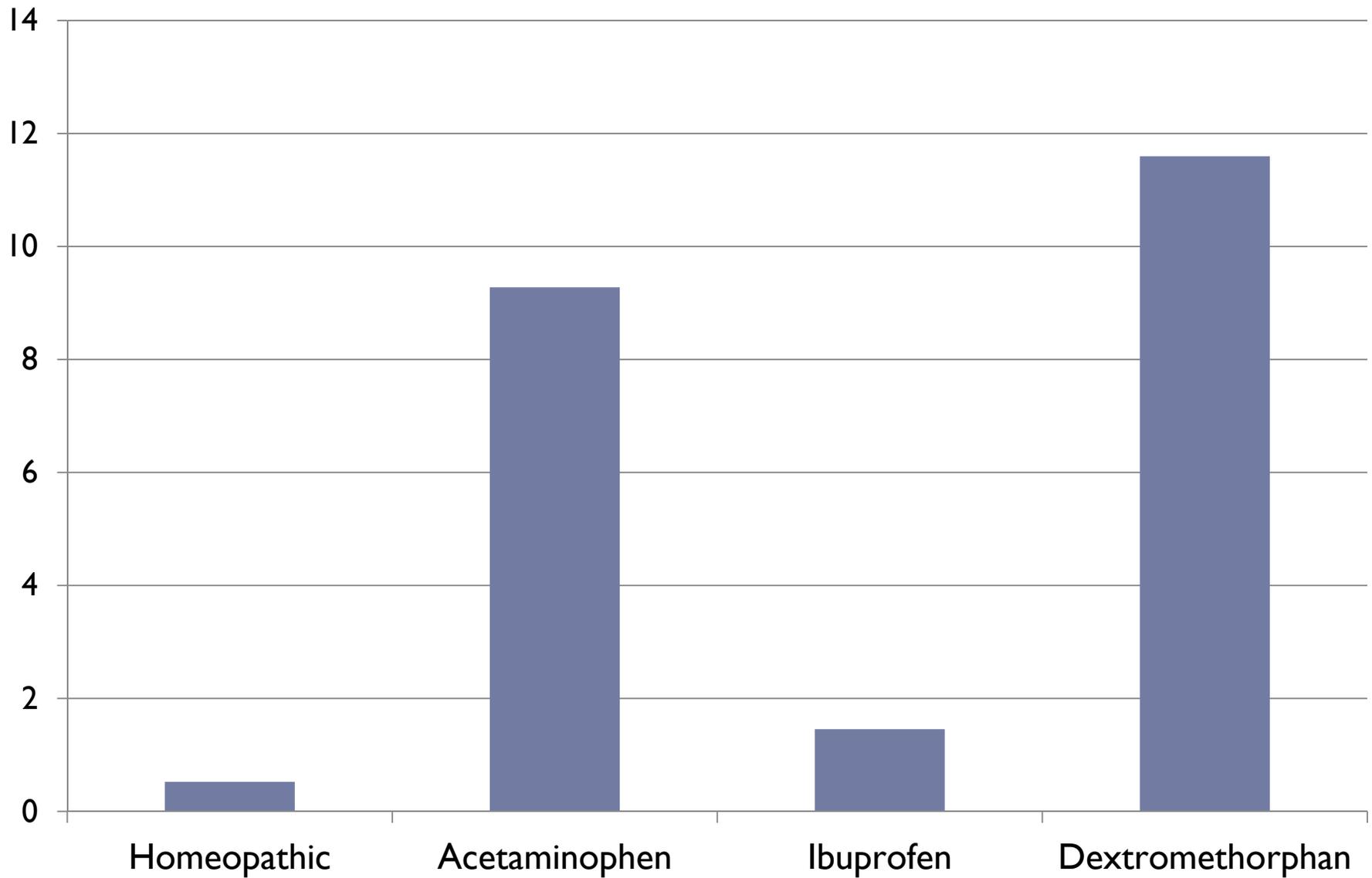
	Reason				Treated in Health	Outcome				
	Unint	Int	Other	Adv Rxn	Care Facility	None	Minor	Moderate	Major	Death
Homeopathic	9,343	111	3	236	697	1,830	265	47	3	1
Acetaminophen Alone, Adult	11,996	9,201	7	265	11,631	5,801	2,472	1,522	443	49
Ibuprofen	54,745	10,531	30	672	12,701	15,188	3,559	890	69	4
Other Dex-tromethorphan	7,330	3,036	14	301	3,608	1,881	1,712	1,208	36	2

► Mowry JB, et. al., Clin Toxicol (Phila). 2013.

Comparison of Different OTC Products



% with Moderate, Major, or Death Outcome



Perceptions of Homeopathy Users

“What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?”



Summary

- ▶ Homeopathic medicines are safe, especially compared to other OTC products.
- ▶ While AEs are reported with homeopathic medicines, the vast majority are mild and self-limited.
- ▶ Use of homeopathic medicines in the U.S. is increasing and users frequently find them to be helpful.



Questions?



Presenters:

Ronald D. Whitmont, MD

Bernardo Merizalde, MD

David Riley, MD

Michelle Dossett, MD, PhD

