



**U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
Substance Abuse and Mental Health
Services Administration
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Data Summary

METHADONE MORTALITY: A 2010 REASSESSMENT

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Substance Abuse and Mental Health
Services Administration

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- Seddon R. Savage, M.S., M.D., Director, Dartmouth Center on Addiction Recovery and Education (DCARE), and Pain Consultant, Manchester VA Medical Center, and Associate Professor of Anesthesiology, Dartmouth Medical School, Hanover, NH.

DISCLAIMER

The views, opinions, and content of this document are those of the individual authors and other referenced sources, and do not necessarily reflect the views, opinions, or policies of SAMHSA or any other part of the U.S. Department of Health and Human Services (HHS).

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Dear Colleague:

This report provides a brief summary of the presentations and discussions at the July 29-30, 2010 meeting, "Methadone Mortality: A 2010 Reassessment," which was sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). The meeting brought together more than 90 epidemiologists, clinicians, educators, regulatory and enforcement officials, patient advocates, and policymakers for an in-depth reassessment of the current knowledge base on methadone-associated deaths and a review of progress in addressing the situation.

Methadone has a long, successful history as a potent analgesic and a highly effective medication for reducing the morbidity and mortality associated with opioid addiction. However, diversion, abuse, and deaths associated with many opioid medications, including methadone, have become a significant public health concern.

As the Federal agency tasked with oversight of the Nation's opioid treatment programs, SAMHSA is concerned about these developments. Accordingly, in May 2003, SAMHSA convened a meeting entitled "National Assessment of Methadone-Associated Mortality." Participants were tasked with reviewing the available data on methadone-associated deaths; determining whether and to what extent the reported increase in such deaths might be related to the clinical practices of SAMHSA-monitored opioid treatment programs; and formulating recommendations to address the problem. A follow-up meeting on the same topic was held in July 2007.

For the 2010 meeting, SAMHSA convened a group of experts to reassess the situation, review the progress made to date, and provide advice and guidance on needed modifications or additions to the strategies currently being pursued. This document summarizes the information presented and conclusions reached, as well as strategies and action plans endorsed by the participants.

Those of us at SAMHSA found this to be a very valuable session and trust that this summary and the full report (which is posted on the SAMHSA website) capture both the content and the collaborative spirit that marked the session.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM

Director
Center for Substance Abuse Treatment

GOALS OF THE REASSESSMENT

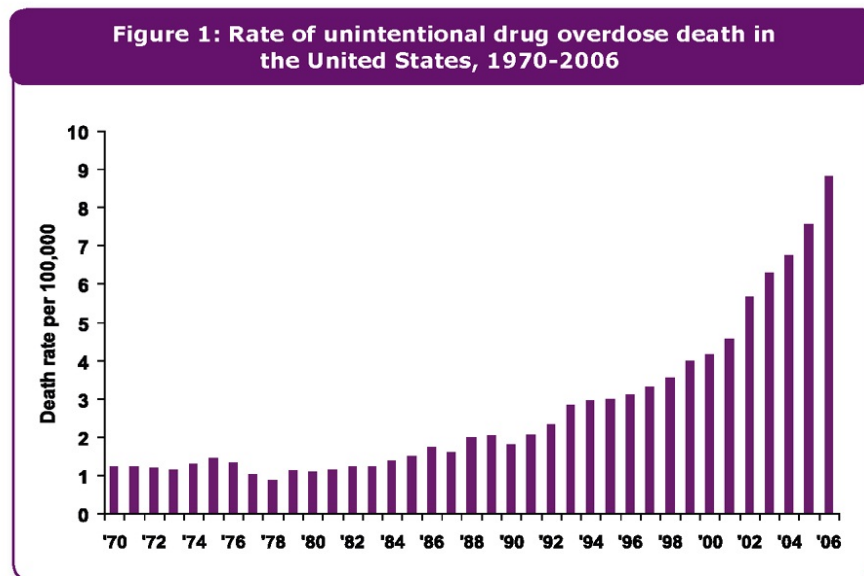
Methadone is an important medication for the treatment of opioid use disorders and chronic pain. It is a well-studied, safe, and powerful medication when prescribed and consumed properly. As a result, methadone has been used for more than 40 years to treat opioid addiction and its use in the treatment of pain has increased in the past 10 years.

Understanding the Problem

Methadone is life-saving, yet it presents special challenges. Some pharmacologic and pharmacokinetic properties of methadone can lead to harm if the drug is misused or used for nonmedical purposes. Methadone's short duration of analgesic effect, coupled with a significantly longer elimination half-life, increase the risk of toxicity. Methadone can cause fatalities among individuals who have not developed tolerance to opiates; for example, deaths have occurred among children and adults who accidentally ingest methadone. Fatal intoxications also have occurred during the first weeks of medically supervised treatment and at the time of dose adjustments.

Additional difficulties are caused by the absence of a common nomenclature and uniform case definitions for use in distinguishing between deaths caused by methadone and deaths in which methadone is a contributing factor or merely present. These difficulties make it difficult to determine the true number and nature of methadone-involved deaths. However, it is clear that the number of methadone-associated deaths has continued to rise since the first National Assessment meeting in 2003 (Figure 1). The increase in methadone-associated deaths has occurred in the context of rising death rates for all prescription opioids, such as oxycodone and hydrocodone.

Figure 1.



Source: National Vital Statistics System

Despite what we do know, the precise causes of the increase in methadone-associated deaths remain unclear. There is substantial agreement that patients are at elevated risk of methadone-associated mortality if they: (1) engage in concurrent use of other CNS depressants, such as benzodiazepines, other opioids, and alcohol; (2) have risk factors for adverse cardiac events, such as prolonged QT syndrome and Torsades de Pointes; (3) are given too large induction doses or are not adequately monitored during induction; or (4) engage in deliberate misuse or abuse of methadone.

The increased scrutiny of methadone that has attended the increase in fatalities requires exploration of the benefits of methadone as a medication, the risks associated with its use, and the need to take timely and effective action to reduce harm to individuals who use methadone to treat addiction or pain.

A Focus on Solutions

SAMHSA's role in monitoring adverse events related to methadone is embedded in both its statutory authority and the agency's commitment to promoting the public health. In 2001, the Secretary of Health and Human Services delegated to SAMHSA the responsibility for regulation and oversight of the Nation's opioid treatment programs (OTPs).

SAMHSA's current actions to address methadone-associated deaths began in 2002, spurred by reports of drug diversion, abuse, and deaths involving many opioid medications, including methadone. SAMHSA already was collaborating with other Federal agencies and with agencies in some of the States most directly affected by rising methadone mortality rates. Their reports, coupled with an increase in requests for consultation and assistance from State authorities and practitioners in the field, created added urgency for SAMHSA to evaluate and address the causes of the increase.

To assist it in developing a comprehensive plan and priorities, SAMHSA acted in July 2010 to convene a multidisciplinary group of more than 90 experts – including representatives of various Federal and State agencies, researchers, epidemiologists, pathologists, toxicologists, medical examiners, coroners, pain management specialists, addiction medicine experts, and others – to re-evaluate and update the findings of the 2003 National Assessment and the 2007 Reassessment. Participants were tasked with:

- Evaluating the best available data on methadone-associated overdoses and deaths.
- Determining whether and to what extent such deaths might be related to the clinical practices of SAMHSA-monitored OTPs as well as to the use of methadone to treat chronic pain.
- Reviewing current activities of SAMHSA and other Federal agencies to address the problem.
- Formulating strategies and action steps to enhance the effectiveness of existing activities and to describe potential new activities and areas of opportunity.

The information presented by the speakers, as well as the discussions and conclusions reached by this distinguished group of experts, are summarized here.

UNDERSTANDING THE PROBLEM: CURRENT DATA AND TRENDS

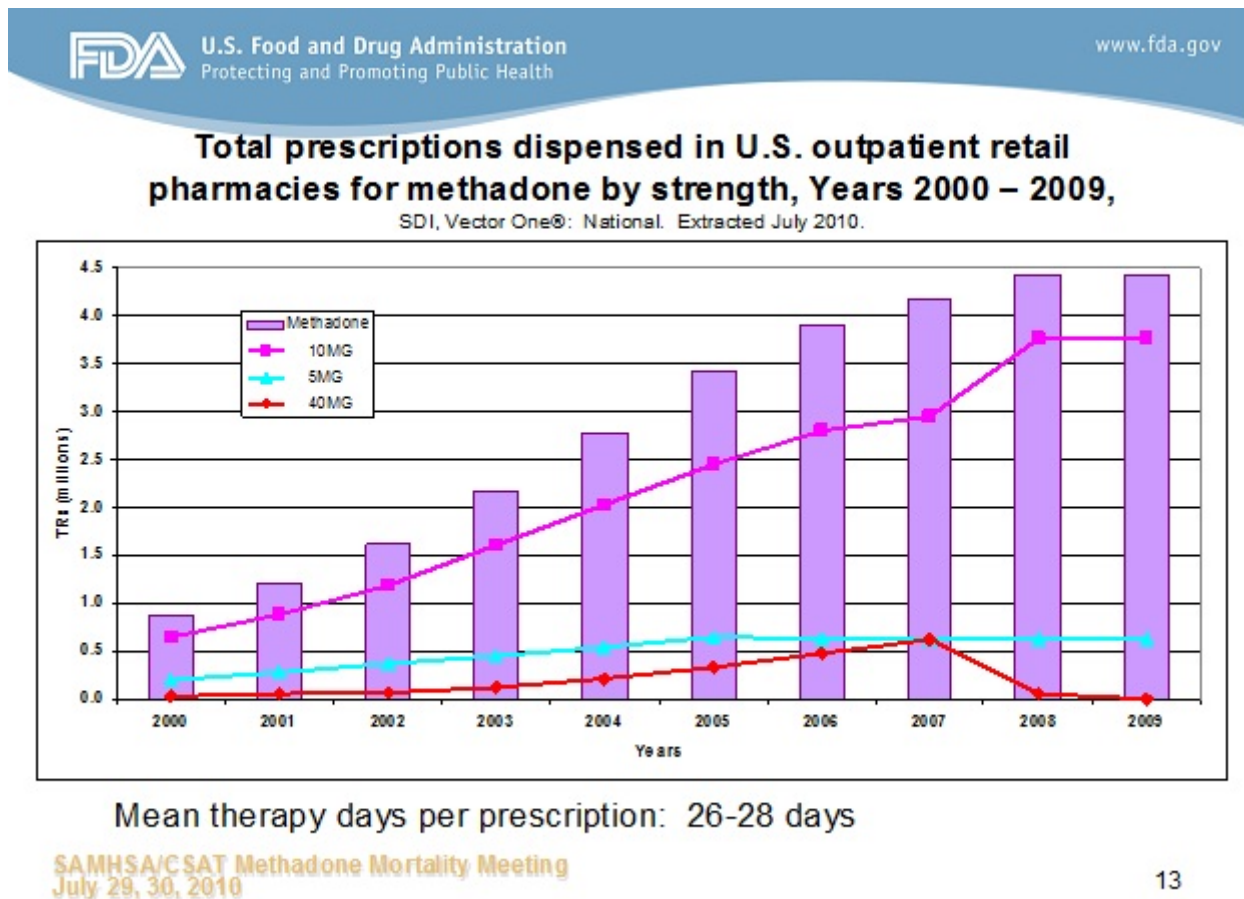
FDA Data on Methadone

Laura Governale, Pharm.D., M.B.A., Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration

The Food and Drug Administration (FDA) purchases access to drug utilization data through a number of commercial drug utilization data vendors. From these data sources, FDA can track the amount of methadone sold by manufacturers.

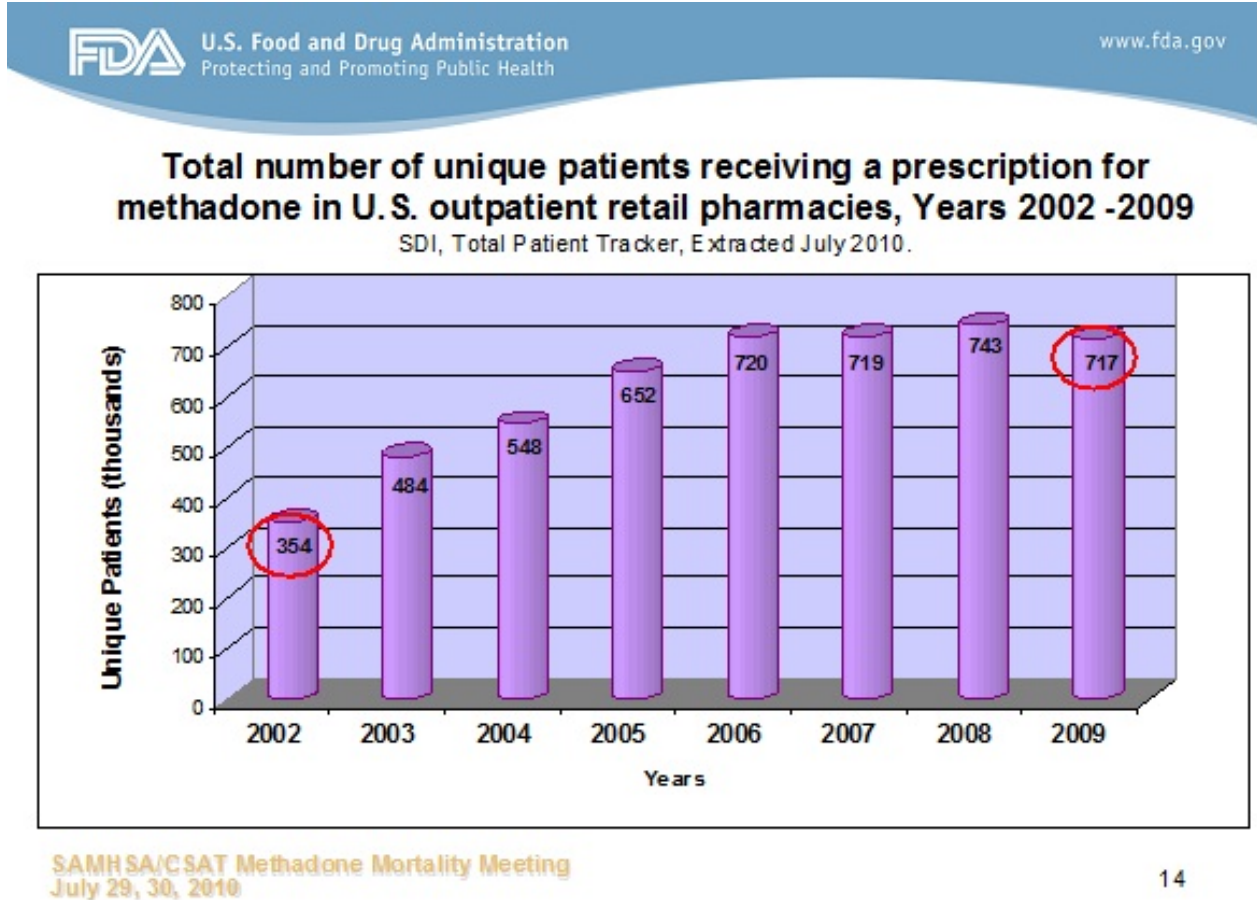
Drug utilization data show that, in general, the wholesale distribution and outpatient use of methadone have leveled off in recent years. In 2009, methadone constituted approximately 2% of all prescriptions for opioids, at about 4.4 million prescriptions. The 10 mg tablets, which are used to treat pain, have been the most widely dispensed methadone formulation over the past 10 years (Figure 2).

Figure 2.



The number of unique patients receiving a prescription for methadone from 2002 to 2009 increased by 103 percent, from about 354,000 patients in 2002 to about 717,000 patients in 2009 (Figure 3).

Figure 3.

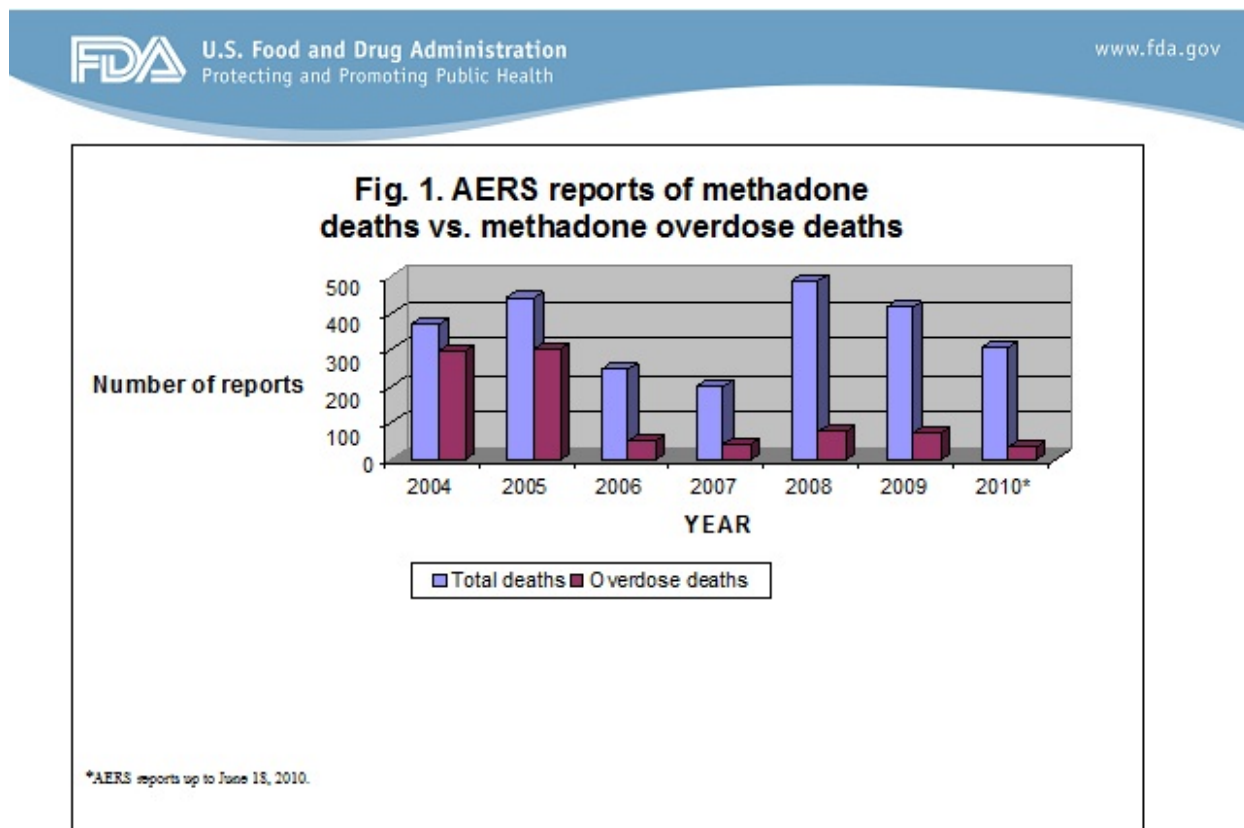


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In 2009, the majority of prescriptions for methadone were written by primary care physicians and physician extenders. The indications for which methadone was prescribed included pain associated with musculoskeletal disorders (46%), headaches and nerve pain (17%), and cancer-related pain (11%).

Between 2004 and June 2010, FDA received 2,500 reports of deaths and 989 reports of overdoses associated with methadone from the Adverse Events Reporting System (AERS; Figure 4).

Figure 4.



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DEA Data on Drug Distribution (ARCOS)

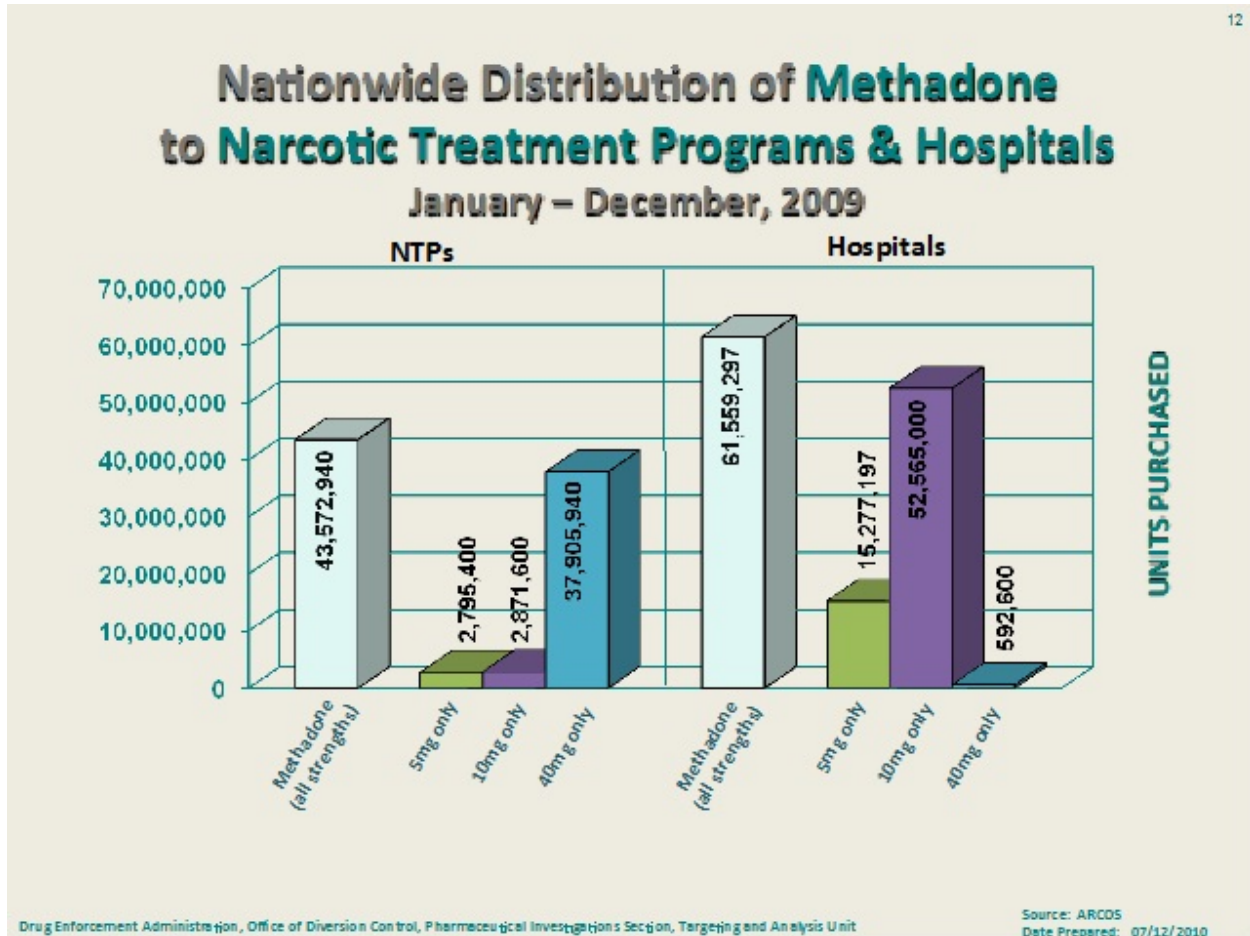
June E. Howard, Chief, Targeting and Analysis Unit (ODPT), Pharmaceutical Investigations Section, Drug Enforcement Administration

Every entity that manufactures or distributes prescription drugs is required to report that activity to the Drug Enforcement Administration (DEA). The DEA's Automation of Reports and Consolidated Orders System (ARCOS) captures information on drug inventories, acquisitions, dispositions, and manufacturing activities. Methadone data are included in ARCOS, although the data on distribution are somewhat limited.

ARCOS data for the period January 2006 through June 2010 show that 150 to 200 million dosage units of methadone (at all strengths and in all formulations) were distributed in each quarter, leveling off to 125 million units in the second quarter of 2010.

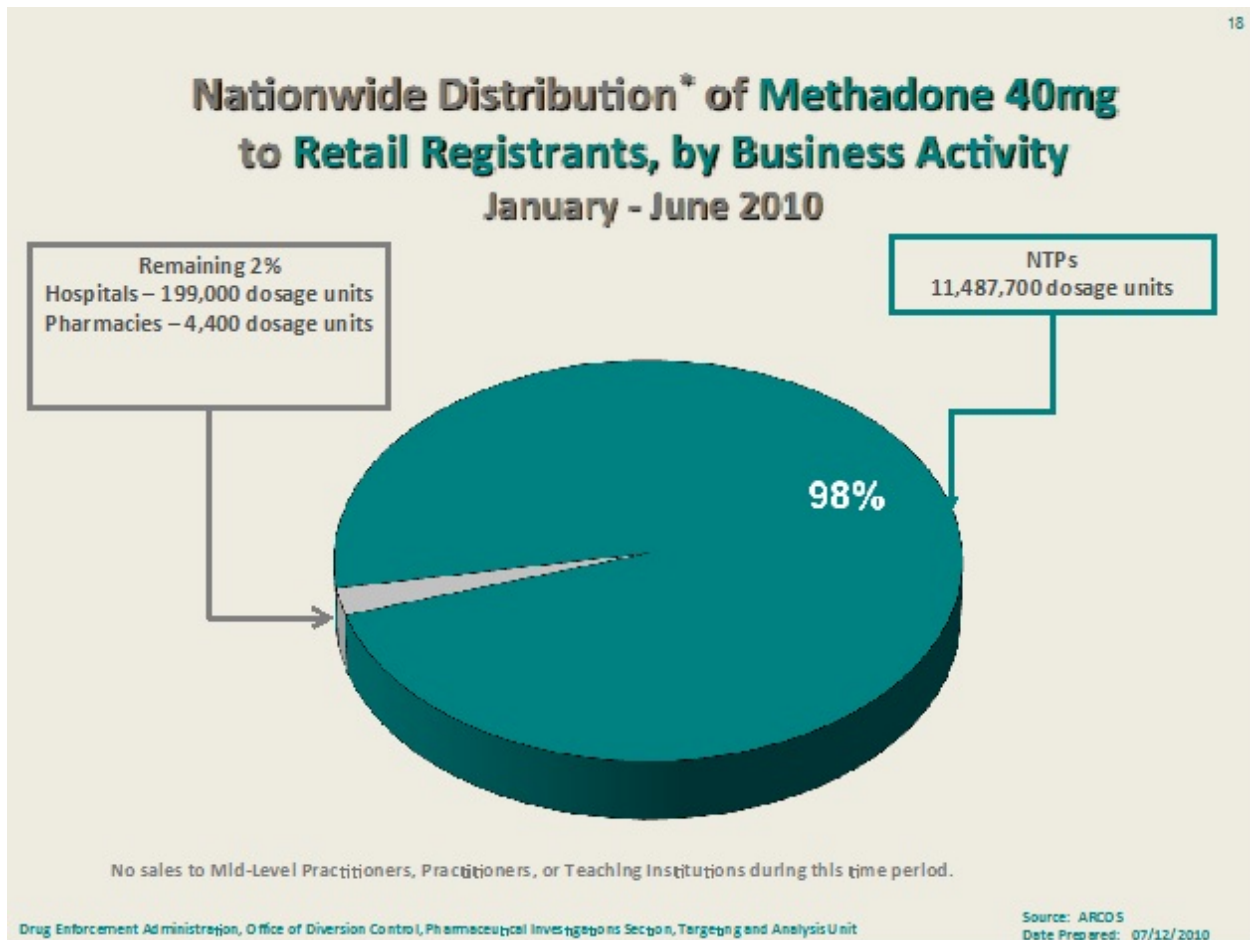
In 2009, 98% of methadone in the 40 mg formulation (about 38 million units) was distributed to OTPs (also known as Narcotic Treatment Programs or NTPs). The remaining 2% was distributed to hospital pharmacies (Figure 5).

Figure 5.



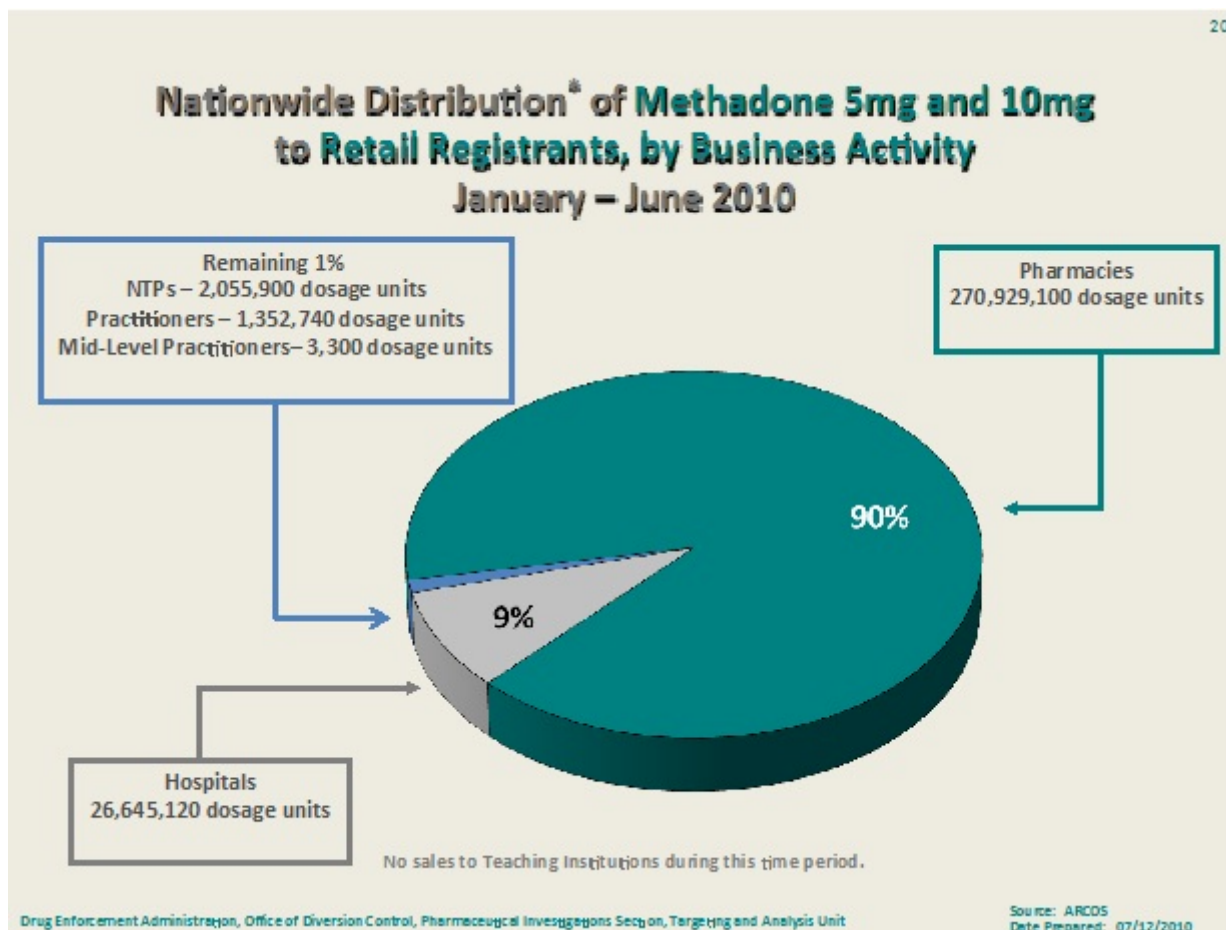
Individual practitioners received approximately 4.5 million dosage units of methadone in 2009 and about 1.3 million units in the first six months of 2010. The patterns of distribution seen in 2009 also were observed in 2010, with the vast majority of the 40 mg formulation going to OTPs/NTPs (Figure 6).

Figure 6.



In contrast, ARCOS data show that a large majority (90%) of the 5 mg and 10 mg formulations of methadone (commonly used for pain treatment) were distributed to retail pharmacies. Of the rest, 9% was distributed to hospitals and 1 percent to OTPs/NTPs (Figure 7).

Figure 7.



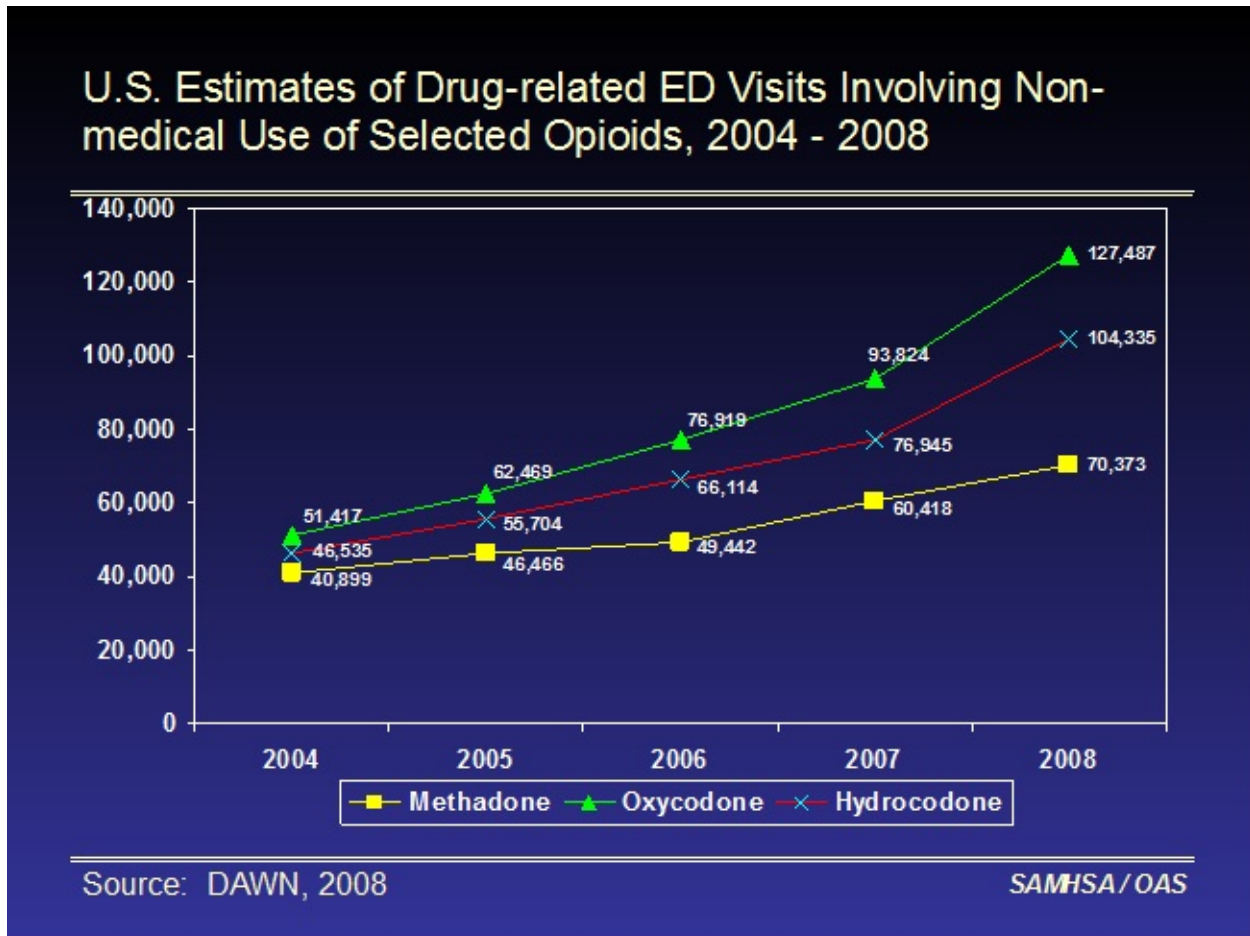
SAMHSA Data on Emergency Department Visits (DAWN)

David J. Skellan, B.S., Drug Abuse Warning Network, Center for Behavioral Health Statistics and Quality [formerly Office of Applied Studies], Substance Abuse and Mental Health Services Administration

The Drug Abuse Warning Network (DAWN) is a public health surveillance system, which collects data from selected emergency departments and medical examiners/coroners. Using DAWN case criteria, reporters in participating institutions classify deaths as drug-related and attempt to determine the motive for drug use. All types of drugs, including illicit, prescription medications, and over-the-counter products--are included in DAWN. Twelve States report data on drug-related deaths.

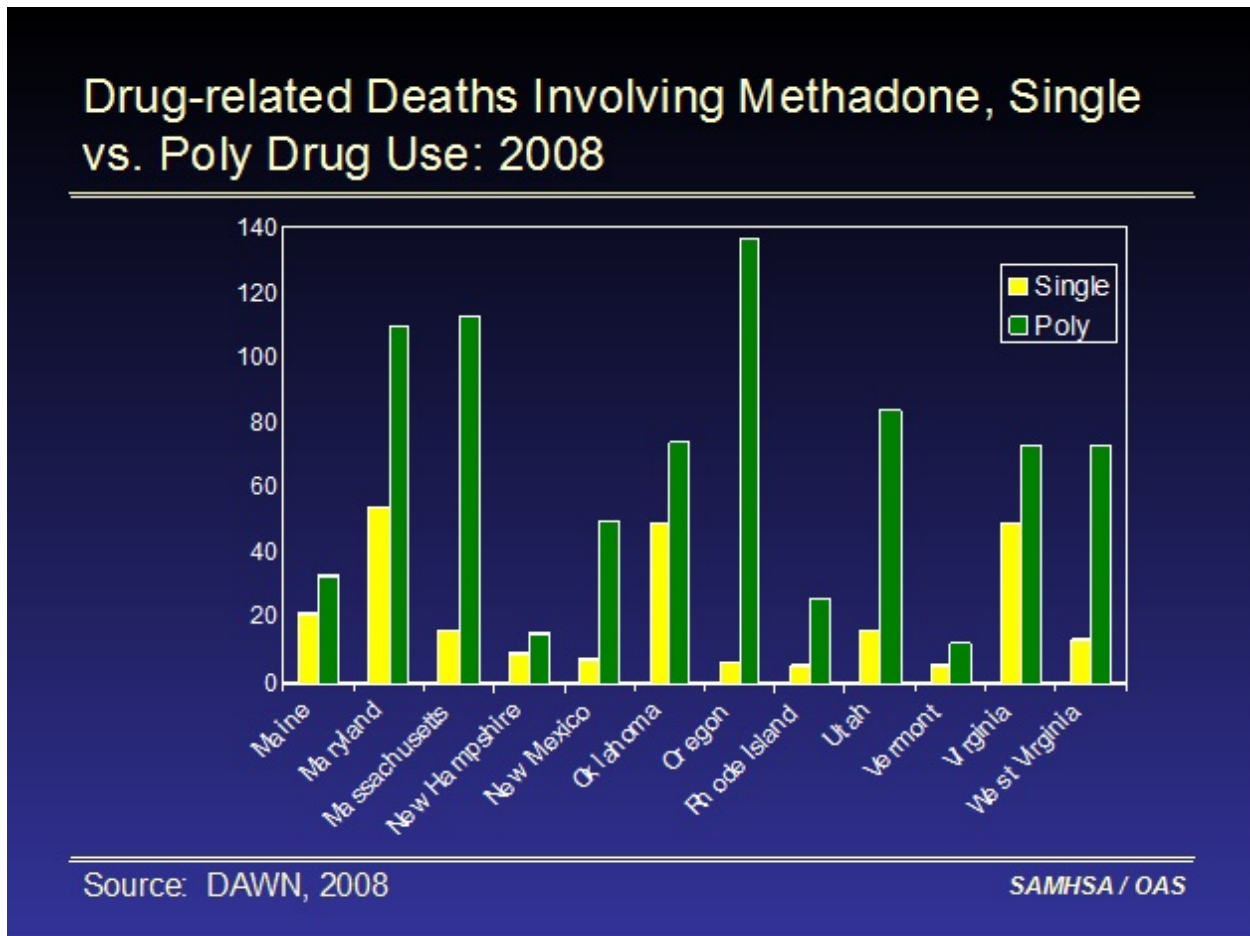
Overall, the number of emergency department (ED) visits resulting from nonmedical use of opioids increased in the period 2004–2008. Visits related to oxycodone and hydrocodone increased by an estimated 36% in 2008 over 2007, while ED visits related to methadone increased by 16% in the same period (Figure 8).

Figure 8.



In the States that currently report death data to DAWN, the number of deaths involving methadone in combination with other drugs is approximately three times the rate of deaths associated with use of methadone alone. In 2008, there were 800 polydrug deaths, compared with 250 methadone-only deaths (Figure 9).

Figure 9.



CDC National Data on Drug-Related Deaths

Margaret Warner, Ph.D., Injury Epidemiologist, National Center for Health Statistics, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) maintain the National Vital Statistics System (NVSS) to capture data on deaths from numerous causes, based largely on death certificates. Poisonings also are coded by cause.

NVSS data show that, in 2007, there were 5,692 deaths in the U.S. involving methadone. This represented an increase over 1999, when 826 deaths were reported (Figure 10). The largest portion of these deaths occurred in persons aged 45 to 54.

Figure 10.

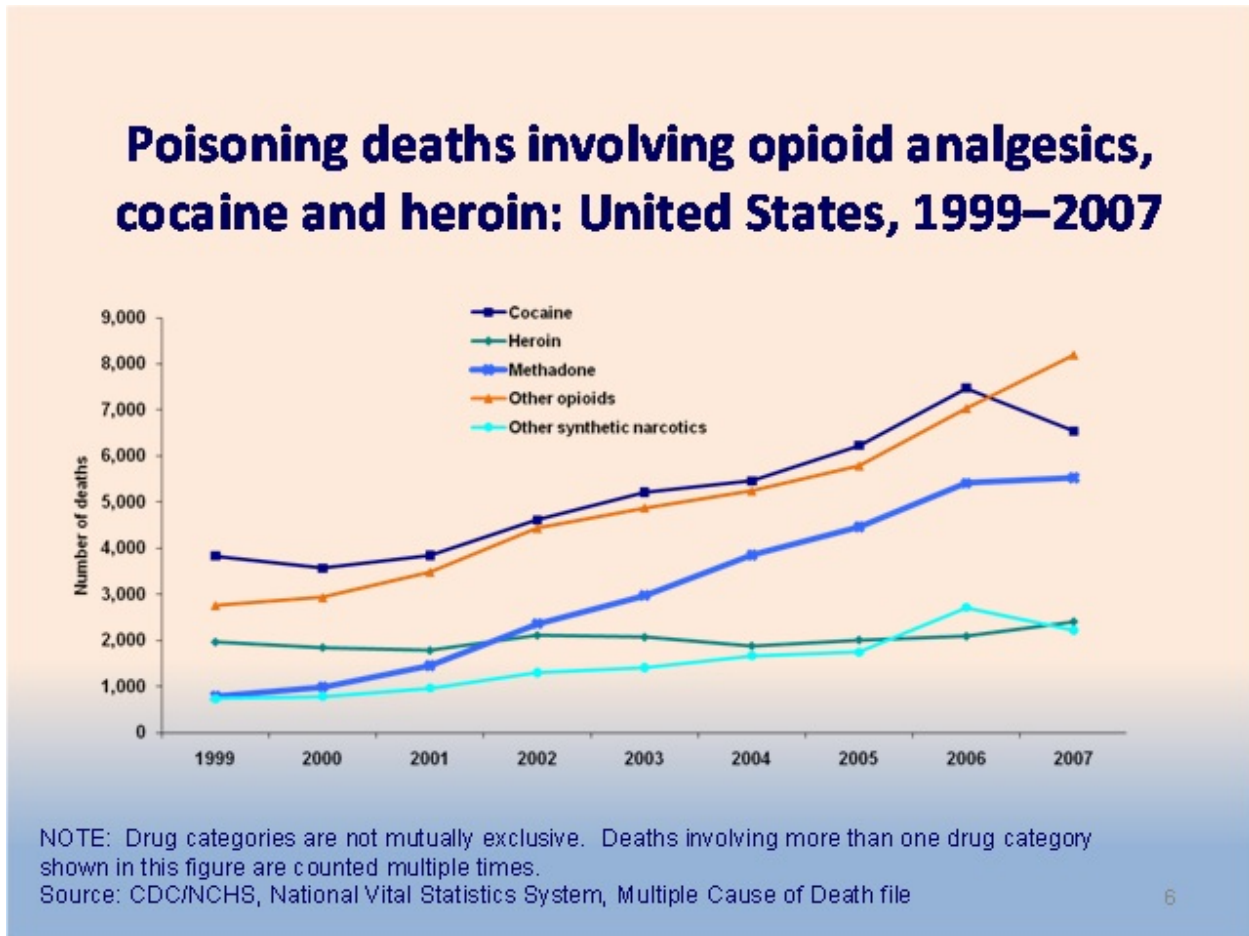
Deaths involving methadone: United States, 1999–2007

	1999	2000	2001	2002	2003	2004	2005	2006	2007
Poisoning unintentional	623	778	1,158	1,911	2,452	3,202	3,701	4,552	4,706
Poisoning undetermined	105	138	186	295	370	441	523	598	591
Poisoning Suicide	56	72	111	149	146	195	232	254	225
Disease	42	62	88	96	125	153	152	187	136
Other Injury	-	-	-	-	-	29	24	30	34
Poisoning homicide	-	-	-	-	-	-	-	-	-

- Less than 20 deaths.
 Source: CDC/NCHS, National Vital Statistics System, Multiple Cause of Death

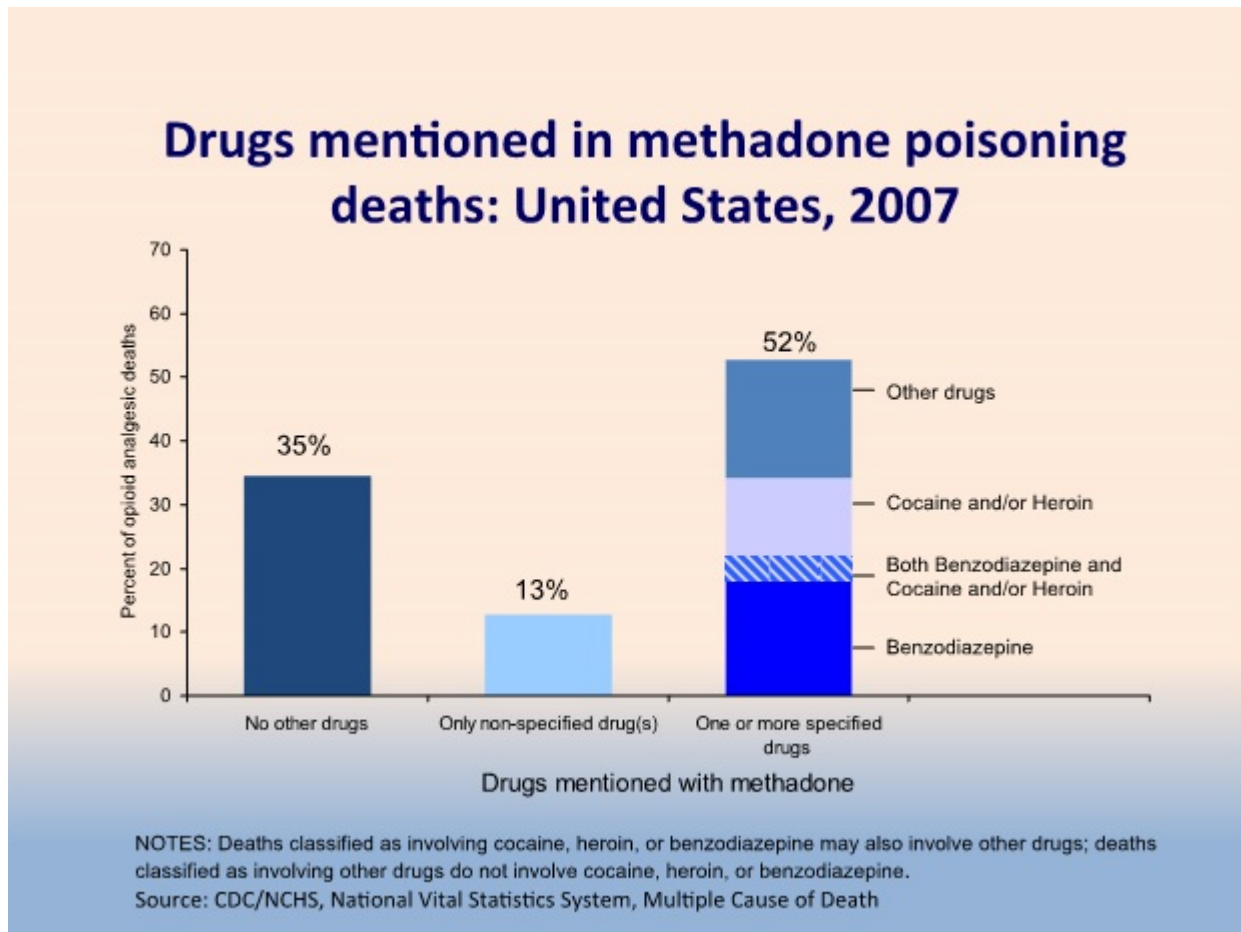
NVSS data show that methadone deaths increased by 2% from 1999 to 2007, while other opiate-related deaths increased by 16% and deaths related to cocaine decreased by 12% (Figure 11).

Figure 11.



Of all methadone-associated deaths, 35% involved methadone alone. In 52% of the cases, methadone was used in combination with another known drug. In 13% of the cases, an unspecified drug was involved (Figure 12).

Figure 12.



CDC State-Level Data on Drug-Related Deaths

Leonard J. Paulozzi, M.D., M.P.H., Medical Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention & Control, Centers for Disease Control and Prevention

According to CDC data in the National Vital Statistics System (NVSS), most States reported fewer than 2 methadone-related deaths per 100,000 population in 2007. The most commonly reported death rate was 1 to 2 per 100,000 (Figure 13). However, the data are based on coding on death certificates, and there is a great deal of variability regarding how medical examiners arrive at those codes.

Figure 13.

Rates of Poisoning Death Related to Methadone by State, 2007	
Crude Death Rate per 100,000	States in rank order
<1	SD, AK, ND, NE, IL, TX, CA, NJ
1-<2	PA, DC, MS, MN, CO, IA, IN, AZ, WY, SC, MO, NY, MI, ID, HI, KS, CT, OH, VA, AL, MA
2-<3	DE, AR, LA, WI, TN, NM, VT, RI, MT
3-<4	FL, UT, ME, MD, OR, NC, KY
4-<5	WA, NV, NH
5+	OK, WV

Source: National Vital Statistics System, National Center for Health Statistics, CDC

Ten State-level studies conducted between 1987 and 2008 show that, overall, patients in OTPs account for a fairly small percentage of methadone-associated deaths; however, the percentage varies widely from one State to the next, ranging from 4% to 50% (Figure 14). Another 10 State studies suggest that methadone was the leading cause of death in overdoses involving opioids. In some states, methadone has been replaced by oxycodone as the opioid most often involved in overdose deaths. In those states, methadone remains the second most frequently cited opioid.

It should be noted that, in a large number of these deaths, the actual source of the methadone is not reliably known.

Figure 14.

Information on Sources of Methadone Among Drug Overdose Deaths				
State/Author	Year of Deaths	Number	Pct in OTP	Pct w Rx
Texas/Barrett	1987-92	54	9%	na
Minnesota/Gagajewski	1992-2002	31	42%	6%
Maryland/Anon	1998-99	8	50%	na
North Carolina/Ballesteros	1997-2001	198	4%	37%
New Mexico/Shah	1998-2002	143	22%	19-26%
Oregon/DOH	2002	103	~25%	33%
Kentucky/Shields	2000-04	95	10%	48%
Maryland/Anon	2004-05	52	15%	2%
West Virginia/Paulozzi	2006	87	12%	32%
North Carolina/Harmon	2007-08	18	na	17%

RADARS Methadone Study

Richard C. Dart, M.D., Ph.D., Director, Rocky Mountain Poison & Drug Center, and Executive Director, RADARS System

The Researched Abuse, Diversion, and Addiction Related Surveillance (RADARS) System captures data from six sources: drug diversion datasets, surveys of key informants, poison control centers, OTPs, programs that treat impaired health professionals, and college surveys. Each source has its own strengths and weaknesses; together, they identify unique aspects of prescription drug abuse and diversion and the medical consequences thereof.

RADARS data show that deaths associated with oxycodone, buprenorphine, and methadone are increasing substantially. RADARS' poison center research data, which include all intentional exposures among children and adults, show that oxycodone ranks first in terms of deliberate abuse, but that methadone is abused at higher rates given its relatively limited availability.

Methadone is more likely to be diverted than oxycodone or buprenorphine, even though fewer prescriptions are written for methadone than for oxycodone. While all formulations

of methadone are diverted, tablets (which are prescribed for pain) are the most likely to be involved.

Children under the age of 6 were disproportionately involved in unintentional deaths after ingesting methadone, as compared to other prescription opioids. For example, in 2009, 1,105 children under age 6 were exposed to buprenorphine and no child died; 1,655 children under age 6 were exposed to oxycodone and one child died; and 316 children under 6 were exposed to methadone and two children died. This may be because methadone liquid formulations (typically take-home doses) are absorbed quickly, leading to rapid metabolism and death.

SAMHSA Data on Methadone Deaths in OTPs

Jane C. Maxwell, Ph.D., Senior Research Scientist, Gulf Coast Addiction Technology Transfer Center (ATTC), University of Texas at Austin

In late 2008, SAMHSA launched an initiative to collect standardized data on deaths involving patients in OTPs through use of a Mortality Report form. Data submission was voluntary. The data collected were entered into an online database.

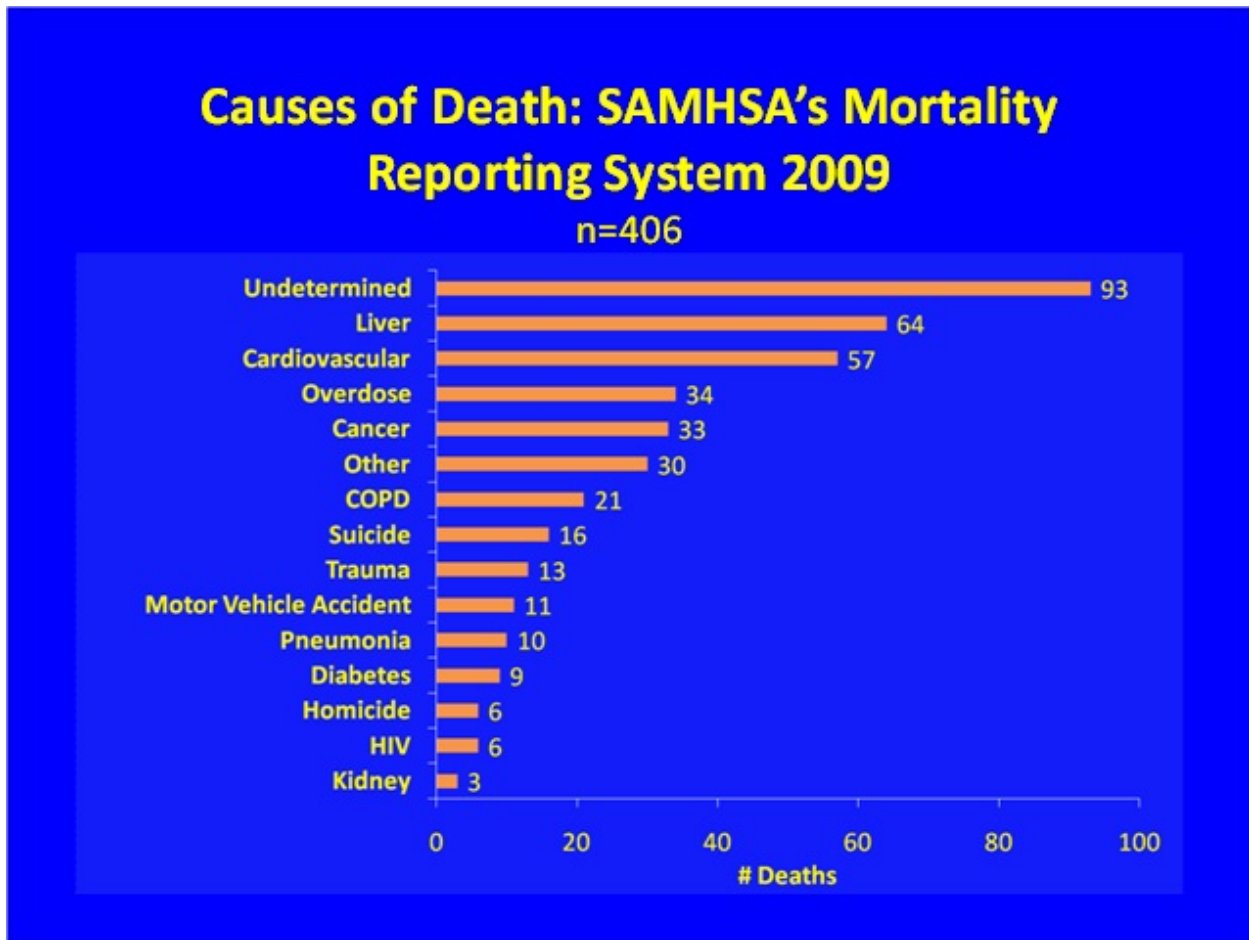
A number of problems were encountered in interpreting the data. For example, the report provided within 48 hours of death is subjective, as it uses information collected from family and friends. As a result, the preliminary certificate issued immediately after death frequently is amended as much as 6 to 8 months later when a coroner or medical examiner issues a final ruling as to cause of death.

In 2009 (the first full year for which data were collected), 406 deaths were reported. Of these, 27% occurred in the first two weeks of treatment. Although the data on cause of death are preliminary, they indicate that persons who died of methadone overdose were more likely to have a history of depression. Also, 32% of the death reports cited the presence of benzodiazepines in addition to the methadone.

According to the data gathered, 67% of methadone decedents were male, with an average age of 49.8 years. The average length of treatment was 4.5 years and the average number of days of “take-home” doses dispensed at the last visit was 5. The average dose was 91.8 mg.

Deceased patients had an average of 1.5 comorbid medical or psychiatric conditions, including mental disorders, depression, or anxiety; liver problems, including hepatitis; cardiopulmonary disorders, including circulatory problems, high blood pressure and COPD; metabolic disorders, particularly diabetes; musculoskeletal disorders; kidney problems; and traumatic injuries. Given the rate of co-occurring disorders, it is not surprising that a large number of deceased patients had been using at least one prescription drug (most frequently a benzodiazepine) in addition to methadone (Figure 15).

Figure 15.



SAMHSA's next steps are to ask the expert panel to consider revisions to the current Mortality Report form and to refine the definitions used.

A FOCUS ON SOLUTIONS: PROPOSED STRATEGIES AND ACTION STEPS

After evaluating the data, participants in the 2010 Reassessment met in a series of working groups to develop strategies and action steps to address specific problems.

Group 1: Improving the Reporting of Methadone-Associated Deaths

Group 2: Improving the Use of Methadone in Addiction Treatment

Group 3: Improving the Use of Methadone in Pain Treatment

Group 4: Research Needs

Group 5: Data and Trend Monitoring

Group 6: Legislation, Accreditation and Administrative Actions

Each group reported its findings, strategies and action steps to the larger meeting. A considerable degree of consensus was noted across the six groups, as exemplified by their agreement that highest priority should be assigned to the following strategies:

1. Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.
2. Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.
3. Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).
4. Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.
5. Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.
6. Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.

The reports of the Action Planning Groups, with suggested action steps, are summarized below.

STRATEGY 1: Take steps to enhance the knowledge of all physicians and other health care professionals about the nature and safe management of chronic pain and addiction.

- 1-1. Integrate training about addiction and pain management into the core curriculum for undergraduate and graduate education of all physicians, mid-level providers, and dentists. Focus on specific knowledge and skills, such as those needed to conduct screening and brief intervention.
 - a. Include specific instruction in prescribing controlled drugs as part of the undergraduate and graduate curricula.
 - b. Increase attention to the core competencies of caring for addicted patients, including the risks of drug interactions with methadone and those inherent in the concurrent use of methadone and other sedative drugs such as the benzodiazepines.
 - c. Focus initially on primary care practitioners.
 - d. Employ contextual approaches to training practitioners in specialty care (e.g., emergency physicians, Ob-Gyns, oral surgeons, et al.).

- 1-2. Continue to sponsor continuing education and mentoring programs on the management of pain and addiction for physicians, oral surgeons and dentists, and midlevel professionals.
 - a. Target content to the specific needs of primary care practitioners.
 - b. Develop a cadre of experts at the community level, including peer mentors to provide assistance and peer monitors for physicians with prescribing issues (similar to the system employed by Physician Assistance Programs).

- 1-3. Leverage the success of the SAMHSA opioid prescribing courses to reach even more prescribers and other health care professionals.
 - a. Develop virtual resources such as web modules to expand the number of physicians and other health professionals who can access this valuable resource.
 - b. Find ways to increase awareness of the courses, as by partnering with various State agencies, academic institutions, and private sector organizations.
 - c. Make the courses available to medical schools and residency training programs.
 - d. Continue to develop specialized courses to meet the specific needs of the VA, the Indian Health Service, and other groups serving defined populations.

STRATEGY 2: Develop and disseminate educational messages to patients and the public about the hazards of prescription drug misuse, as well as specific steps to assure safe use of methadone and other controlled drugs.

- 2-1. Enhance patient education about the safe use of methadone.
 - a. Work with groups such as the National Council on Patient Information and Education to develop educational materials.
 - b. Employ peer support to encourage safe methadone use.
- 2-2. Improve public understanding of the safe use of methadone and other opioid analgesics.
 - a. Launch a public awareness campaign about safe use of prescription opioids (including safe disposal of unused medications), in partnership with other Federal agencies and private-sector organizations.
 - b. Work with leading medical organizations to develop materials on safe medication use for distribution in medical offices.
 - c. Develop public service announcements and other public information vehicles in partnership with other private-sector groups such as the Partnership for a Drug-Free America.

STRATEGY 3: Encourage and support studies to fill voids where current knowledge is not adequate to assure patient safety (for example, on the cardiac effects of methadone).

- 3-1. Analyze available data and encourage additional studies to develop strategies to prevent, identify and safely manage interactions between methadone and the following:
 - a. Benzodiazepines
 - b. Antiretroviral medications
 - c. HCV medications
 - d. Tuberculosis medications
 - e. Psychotropics (antidepressants, antipsychotics, and anticonvulsants).
- 3-2. Encourage and support studies to identify risks that are highly predictive of poor clinical outcomes, including morbidity and mortality, in patients treated with methadone for pain or addiction.
- 3-3. Conduct a systematic examination of the costs and benefits of implementing the recommendations contained in the report of the SAMHSA Expert Panel on Cardiac Effects of Methadone.

- 3-4. Support a prospective study of patients being treated with methadone for pain or addiction who have QTc prolongation (defined as ≥ 500 msec) to determine whether they develop arrhythmias over a specified period of time.
- 3-5. Encourage studies of chronic pain patients to determine the safety of methadone induction in opioid-naïve versus opioid-experienced patients. (This is highly relevant to the common practice of opioid rotation.)

STRATEGY 4: Use all appropriate legislative, regulatory, and administrative tools to incentivize the desired changes in treatment systems and individual clinical practice.

- 4-1. Use available legislative and regulatory frameworks to reduce the toll of methadone induction deaths.
 - a. Employ quality improvement initiatives (such as those conducted by NIATx) to develop program standards and practices that reduce patient risk. Link adoption of the resulting evidence-based standards and practices to accreditation or reimbursement.
 - b. Consider making naloxone available to patients and/or family members during the induction period and whenever take-home doses are prescribed.
- 4-2. Encourage the adoption of evidence-based practices for methadone induction and stabilization, as by making use of approved guidelines part of the standards for OTP accreditation.
- 4-3. Urge the Accreditation Council on Graduate Medical Education to require core competencies related to safe prescribing of opioids as part of all accredited residency training programs. Similarly, agencies that accredit training programs for allied health professionals should require evidence of competency in safe use of opioids where relevant to the scope of practice.
- 4-4. Require every physician to demonstrate competency in the safe prescribing of opioids in order to obtain or renew his or her DEA registration.
- 4-5. Educate health care professionals and policymakers about the value of prescription monitoring programs (PMPs) and take steps to enhance the usefulness of PMPs in preventing and identifying nontherapeutic use of methadone and other controlled drugs.
 - a. Work with the NASPER-funded PMPs and State licensing boards to develop and apply consistent standards as to what constitutes opioid “use” and “misuse.”
 - b. Increase the use of PMPs to identify patients who are using prescribed benzodiazepines concurrently with methadone or other opioids.
 - c. Enhance physician access to the data PMPs contain.

- d. Support legislation that enables pharmaceutical companies to contribute to State pools to fund PMPs in a transparent way. (This was suggested by a pharmaceutical company representative.)
 - e. Expand PMPs to all States, and take steps to assure interoperability across State borders.
 - f. Expand data collection to include controlled drugs in all schedules. Leverage electronic resources to identify knowledge deficits in individual prescribers and provide remediation as needed.
 - g. Provide information and mentoring on the management of challenging patients through the PCSS or a similar network.
- 4-6. Support the development and implementation of Risk Evaluation and Mitigation Strategies (REMS).
- 4-7. Collaborate with organizations that develop health professions curricula, that accredit educational programs, that write questions for specialty board exams, and that support faculty training and development to assure that the knowledge and skills needed to assess and safely manage or refer patients with pain or addiction are included in health professions training.
- 4-8. Develop a system for certifying the competency of OTP clinical staff, similar to the DATA 2000 requirements for physicians who would prescribe buprenorphine for addiction treatment.
- 4-9. Develop pain management competency standards for accreditation programs other than pain medicine (e.g., for ambulatory care, hospitals, and long term care).
- 4-10. Approach professional liability insurers about the possibility of rate adjustments for physicians practicing in States that adopt prescribing guidelines or PMPs, or for individual physicians who complete continuing medical education programs on safe prescribing of opioids and other controlled drugs.

STRATEGY 5: Increase collaboration among Federal and State agencies and between government agencies and private-sector organizations.

- 5-1. Encourage greater coordination between OTPs and providers of general medical care.
- a. Provide primary care in OTPs, thus making them the patient’s “medical home.”
 - b. Establish satellite OTPs in Federally Qualified Health Centers (FHQCs).
 - c. Address the expansion of treatment capacity needed to meet the increased demand expected to result from health care reform. For example, expand treatment options by offering medical maintenance with methadone in office-based settings.

- d. Identify a mechanism to observe patients at peak methadone effect in OTPs or at other sites (e.g., pharmacies, FQHCs, primary care settings).
 - e. Find ways to allow communication between OTPs and outside providers, without violating the confidentiality requirements of 42 CFR Part 2.
- 5-2. Work with DEA, pharmacy organizations and State and local officials to encourage the expansion of drug take-back programs and to increase public awareness of their value in limiting unauthorized access to unused opioids and other controlled drugs.
- 5-3. Reach out to agencies and organizations at the State and Federal levels to identify problems and work with them to craft solutions.

STRATEGY 6: Enhance the quality, timeliness, and usefulness of data as a key step in executing the foregoing strategies.

- 6-1. Convene a meeting of epidemiologists, technical experts, and data users to reach agreement on ways to synthesize data from multiple sources to address the need for:
- a. More complete and accurate data on methadone deaths;
 - b. Access to proprietary data (AAPCC, SDI, IMS);
 - c. Better ethnographic data;
 - d. Adding opioids to arrestee drug testing (ADAM);
 - e. Better support of the existing data infrastructure;
 - f. Expanded State-level capacity for surveillance; and
 - g. An assessment of data needs for prevention activities.
- 6-2. Improve the reporting of deaths among OTP patients (particularly those that involve concurrent use of benzodiazepines).
- a. Identify barriers to voluntary reporting.
 - b. Develop better methods of collecting data on patient deaths.
 - c. Educate OTP administrative staff about the need for reporting.
 - d. Consider making reporting an accreditation standard.
- 6-3. Improve surveillance of methadone-associated deaths by medical examiners and coroners.
- a. Work toward greater standardization of case definitions by medical examiners and coroners.
 - b. Provide medical examiners and coroners with reports and other feedback on the uses and consequences of the data they provide.
- 6-4. Develop more detailed and focused analyses of data from all sources.

- 6-5. Study the characteristics of all deaths of patients receiving opioids for the treatment of pain or addiction.
- 6-6. Examine the incidence, prevalence and patterns of concurrent opioid and benzodiazepine use and abuse in opioid-maintained addiction treatment populations and chronic pain populations.
- 6-7. Encourage and facilitate the linkage of data from PMPs with medical examiner/coroner data and OTP death records.
- 6-8. Encourage comparative effectiveness studies, such as those that establish an evidence base for the use of longitudinal opioids in the treatment of pain or addiction.
- 6-9. Pursue a special issue of a peer-reviewed journal on data related to methadone or opioid morbidity and mortality.
- 6-10. Work with DEA and stakeholder groups to enhance the dissemination of geographically targeted data.

CLOSING REMARKS BY DR. H. WESTLEY CLARK

Since the initial 2003 National Assessment meeting in response to the increasing number of methadone-associated deaths, data show that these deaths, as well as all opioid-related deaths, continue to rise. By reconvening experts and representatives of Federal and State agencies, practitioners, patient advocates, and pharmaceutical industry representatives knowledgeable about the issues surrounding methadone mortality, we have reaffirmed our commitment to understand and address these critical issues. The data, clinical challenges, and stakeholder perspectives examined during the 2010 Reassessment meeting were assessed through the prism of the work groups to ensure that our next steps are informed by current research findings, clinical experience, and patient and family viewpoints.

SAMHSA will continue to work collaboratively with our Federal partners, as well as with the States, with medical societies and organizations, with patient advocacy groups, and with other interested parties to develop and implement practical strategies and action steps that will reduce the toll of methadone-associated deaths. Meeting participants have offered many suggestions for consideration by SAMHSA and others. Some of these suggestions reinforce or expand on those made by meeting participants in 2003, while others reflect our expanded knowledge and take us in new directions.

SAMHSA is particularly interested in taking a balanced approach to reducing methadone-associated deaths and values the input provided by the full spectrum of stakeholder groups. Through this approach, we intend to focus on key issues and avoid unintended consequences from the policies and actions we pursue. We are now better equipped than in 2003 to recognize the complexity represented by methadone-associated deaths and to understand the need to engage patients, medical professionals, health professions organizations, and Federal and State agencies in a mutual effort to achieve our goals.

Multiple initiatives are already under way, but there is much more to be done to gain an accurate understanding of the circumstances that lead to these unfortunate deaths and that will enable us to limit the human losses they represent.

This reassessment effort has provided critical information and guidance to SAMHSA as we work to find the best solutions for patients, their families, and the public, and to meet our regulatory and public health responsibilities.

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