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Report to Congressional Requesters

December 2011

PRESCRIPTION PAIN RELIEVER ABUSE

Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness

GAO-12-115

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GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-12-115, a report to congressional requesters

Why GAO Did This Study

The Centers for Disease Control and Prevention has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths, with deaths associated with prescription pain relievers of particular concern. To address this issue, federal agencies are raising awareness by educating prescribers and the general public. In response to your request, GAO (1) described recent national trends in prescription pain reliever abuse and misuse, (2) described how federal agencies are educating prescribers, (3) assessed the extent to which federal agencies follow key practices for developing public education efforts, and (4) identified educational efforts that use similar strategies and assessed how agencies coordinate those efforts.

GAO interviewed officials and reviewed documents and websites from seven agencies involved in federal drug control efforts and analyzed the most recent data from several data sources related to prescription pain reliever abuse and misuse. GAO also assessed the development of public education efforts and federal coordination efforts against key practices from prior GAO work.

What GAO Recommends

GAO recommends that the Director of ONDCP establish outcome metrics and implement a plan to evaluate proposed educational efforts, and ensure that agencies share lessons learned among similar efforts. ONDCP did not explicitly agree or disagree with GAO's recommendations, but noted that it will continue to work for improved coordination of educational efforts and evaluation of outcomes.

View GAO-12-115. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Key measures of prescription pain reliever abuse and misuse increased from 2003 to 2009. The largest increases were in measures of adverse health consequences such as emergency department visits, substance abuse treatment admissions, and unintentional overdose deaths, though increases were not consistent across all measures. Federal officials suggested that increasing availability of prescription pain relievers and high-risk behaviors by those who abuse or misuse the drugs, such as combining prescription pain relievers with other drugs or alcohol, likely contributed to the rise in adverse health consequences, though data about the reasons for the increases are limited.

The Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) use a variety of strategies to educate prescribers about issues related to prescription pain reliever abuse and misuse, but officials told us that more education is needed. The strategies used include developing continuing medical education programs, requiring training and certification in order to prescribe certain drugs, and developing curriculum resources for future prescribers. The Office of National Drug Control Policy (ONDCP) is working to develop a legislative proposal to require education for prescribers registering with the Drug Enforcement Administration (DEA) to prescribe controlled substances. Officials from some agencies said such a requirement would ensure all prescribers were starting from the same baseline of knowledge.

In their efforts to educate the public about prescription pain reliever abuse and misuse, DEA, FDA, NIH, ONDCP, and SAMHSA used almost all of the key practices for developing their consumer education efforts. Agencies varied in how they used the key practices when developing these efforts, which varied in size, scope, and duration. All agencies established metrics to monitor the implementation and functional elements of their educational efforts, but only two agencies have established or are planning to establish metrics to assess the impact of their efforts on audiences' knowledge, attitudes, and behavior. Without outcome evaluations, federal agencies have limited knowledge of how effective their efforts are in achieving their goals—in this case, reducing prescription pain reliever abuse and misuse.

Among federal initiatives to educate prescribers and the public about prescription pain reliever abuse and misuse, GAO found several instances of agencies engaging in similar efforts, directed at similar target audiences and using similar mediums. Officials said that these similarities in public education efforts are beneficial in addressing prescription drug abuse and misuse because having multiple, reinforcing messages about the same subject is valuable in public health communications and because federal agencies provide slightly different perspectives on the issues surrounding prescription drug abuse and misuse. Likewise, the prescriber education programs GAO identified, though similar, are different in content and focus. Though these similar programs have the potential to be duplicative if not effectively coordinated, federal agencies have recently begun to coordinate their educational efforts. Nevertheless, federal agencies have missed opportunities to share lessons learned and pool resources among similar education efforts.

Contents

Tables

Figures

Abbreviations

APQ	aggregate production quota
CDC	Centers for Disease Control and Prevention
CE	continuing education
CME	continuing medical education
DAWN	Drug Abuse Warning Network
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NSDUH	National Survey on Drug Use and Health
NVSS	National Vital Statistics System
ONDCP	Office of National Drug Control Policy
REMS	Risk Evaluation and Mitigation Strategy
SAMHSA	Substance Abuse and Mental Health Services Administration
TEDS	Treatment Episode Data Set

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

December 22, 2011

The Honorable Darrell Issa
Chairman
Committee on Oversight and Government Reform
House of Representatives

The Honorable Mary Bono Mack
House of Representatives

The Honorable Edolphus Towns
House of Representatives

The Centers for Disease Control and Prevention (CDC) has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths, with such drugs involved in more overdose deaths than those involving heroin and cocaine combined. Further, according to CDC, recent increases in prescription drug overdose deaths overall are largely driven by deaths associated with prescription pain relievers, which include such drugs as OxyContin or Vicodin, among others. In 2009, an estimated 12.4 million Americans reported using a prescription pain reliever in the past year without a prescription of their own or simply for the experience or feeling the drug caused, according to the National Survey on Drug Use and Health (NSDUH). Seventy percent of these people reported that they got the drug from a friend or family member, while another 19 percent got the drug from a doctor.[1] Although specific regions of the country have been severely affected by this problem, recent media reports from across the United States suggest it is now a national issue.

Multiple federal agencies have responsibility for addressing the abuse and misuse of prescription pain relievers through prevention, treatment,

[1]According to NSDUH data from 2009, 17 percent of these people reported that they got the drug from one doctor and 2 percent reported that they got the drug from more than one doctor.

and enforcement activities.[2,3] The Office of National Drug Control Policy (ONDCP) assists in setting national drug control priorities and helps to coordinate federal drug control efforts. One prevention activity ONDCP has identified as a focus area is raising awareness of the problem of prescription drug abuse and misuse through the education of parents, youth, patients, and health care providers. Accordingly, the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and ONDCP are engaged in various activities for educating the public and health care providers who prescribe pain relievers about issues related to abuse and misuse of these drugs. These federal agencies and ONDCP (hereinafter collectively referred to as "federal agencies") have assisted in developing and implementing strategies specifically focused on preventing the inappropriate use of prescription pain relievers since the early 2000s, and our prior reports have documented some of their efforts.[4]

You asked us to update our prior work on OxyContin to reflect changes in oxycodone abuse trends and efforts aimed at stemming prescription drug abuse since our 2003 report. In response to that request, we (1) describe recent national trends in prescription pain reliever abuse and misuse,

[2]In this report the term "prescription pain relievers" refers to a class of pain relievers known as opioid analgesics. While multiple classes of pain relievers are used in the United States, opioid analgesics, such as fentanyl, hydrocodone, methadone, morphine, and oxycodone, are the most commonly abused and misused pain relievers. In addition to relieving pain, they can cause feelings of euphoria or a sense of well being among some people who take them, which may lead to their abuse and misuse.

[3]No standard definitions of prescription pain reliever abuse or prescription pain reliever misuse are used by the federal agencies dealing with these issues. In this report, we use the term "abuse and misuse" to collectively refer to the three types of inappropriate use most often included in the agencies' definitions: using a prescription pain reliever with the intent to get high, with or without a prescription of one's own; using a prescription pain reliever for pain relief, but without a prescription of one's own; or using a prescription pain reliever for pain relief, with a prescription of one's own, but in ways other than as prescribed, such as by taking more than prescribed.

[4]GAO, *Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them*, GAO-09-341 (Washington, D.C.: Mar. 26, 2009) and *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (Washington, D.C.: Dec. 23, 2003). For more GAO reports on this topic, see the Related GAO Products page at the end of this report.

(2) describe how federal agencies are educating prescribers about prescription pain reliever abuse and misuse, (3) assess the extent to which federal agencies follow key practices for developing public education efforts about prescription pain reliever abuse and misuse, and (4) identify educational efforts that use similar strategies and assess how agencies coordinate those efforts. At your request, we also provide information on manufacturer-initiated efforts to develop abuse-deterrent formulations of prescription pain relievers (see app. I) and DEA's process for setting quotas for certain substances used in the manufacture of prescription pain relievers (see app. II).

To describe recent national trends in prescription pain reliever abuse and misuse, we interviewed officials from CDC, DEA, FDA, NIH, ONDCP, and SAMHSA; conducted a literature review to identify relevant data sources and explanations for trends in prescription pain reliever abuse and misuse; and analyzed data related to prescription pain reliever abuse and misuse from several data sources representative of the U.S. population aged 12 years and older. We included data in our review from the Drug Abuse Warning Network (DAWN), NSDUH, the National Vital Statistics System (NVSS), and the Treatment Episode Data Set (TEDS). We selected these four data sources because they are the data sources that the responsible agencies use for monitoring trends in prescription pain reliever abuse and misuse, and because they are nationally representative. We analyzed data for calendar years 2003 to 2009, the most recent years for which data from at least three data sources were available. (See app. III for more information about these data sources.) To assess the reliability of these data for our purposes, we reviewed related documentation and conducted interviews with knowledgeable agency officials from CDC and SAMHSA to learn about data collection, quality control, and any limitations of these data sources. We also conducted electronic and manual data testing to ensure the quality of the data. We determined that all data we assessed were sufficiently reliable to provide overall trends for the purposes of our review.

To describe how federal agencies are educating prescribers about prescription pain reliever abuse and misuse, we reviewed documents and interviewed officials from FDA, NIH, and SAMHSA to identify and describe educational strategies used during fiscal year 2011. Because they are involved in federal prevention efforts, we also interviewed officials from DEA, HRSA, ONDCP, and the American Medical Association to gain their perspective on gaps in current prescriber education and efforts to fill these gaps. We excluded agencies that support their own health care systems, such as the Bureau of Prisons,

Department of Defense, Indian Health Service, and Department of Veterans Affairs, from the scope of our review as they serve special populations, rather than the general public. We also excluded educational efforts related to drug abuse treatment, including education about the use of the prescription pain relievers methadone or buprenorphine for the treatment of opioid addiction.

To assess the extent to which federal agencies follow key practices for developing public education efforts about prescription pain reliever abuse and misuse, we reviewed agency websites and interviewed officials from DEA, FDA, NIH, SAMHSA, and ONDCP to identify educational efforts. We then assessed the development of those educational efforts against key practices for developing consumer education efforts identified in our prior work.[5] We limited our scope to efforts that target the general public, rather than special populations, such as educational efforts pursued by the Department of Veterans Affairs, Department of Defense, or Indian Health Service. We also focused on efforts that were being actively revised or disseminated in fiscal year 2011. Finally, we focused on efforts that craft targeted messages about abuse and misuse, rather than efforts that strictly provide factual information, such as a limited number of drug fact websites, since our criteria for developing consumer education efforts are only appropriate for efforts that seek to convey a particular message.

To identify educational efforts that use similar strategies and assess how agencies coordinate those efforts, we first assessed the extent to which agencies targeted similar populations, provided similar information, and used similar educational strategies. We then interviewed officials from DEA, FDA, HRSA, NIH, SAMHSA, and ONDCP and reviewed agency documents in order to assess federal agencies' coordination efforts

[5]GAO, *Digital Television Transition: Increased Federal Planning and Risk Management Could Further Facilitate the DTV Transition*, GAO-08-43 (Washington, D.C.: Nov. 19, 2007).

against key practices for collaboration identified in our prior work.[6] (See app. III for a detailed discussion of our methodology.)[7]

We conducted this performance audit from December 2010 through December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Prescription Pain Relievers

Pain, which affects millions of Americans, can be characterized in terms of intensity—mild to severe—and duration—acute or chronic.[8] While the appropriate medical treatment of pain varies according to these two dimensions, opioid analgesics can provide pain relief for some patients. These prescription pain relievers can be made in either immediate-release or extended-release formulations. Immediate-release pain relievers work for shorter periods of time, while extended-release pain relievers are designed to provide a longer period of drug release so that they can be taken less frequently.[9]

[6]GAO, *Results-Oriented Government: Practices that Can Help Enhance and Sustain Collaboration among Federal Agencies,* GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

[7]Other activities at the federal level are beyond the scope of our review, including prevention activities like supporting state prescription drug monitoring programs—programs that collect information on prescription drugs that are prescribed or dispensed in a state in order to detect and prevent the abuse and misuse of these drugs—and enabling safe disposal of prescription drugs; federal efforts to expand access to addiction treatment; and federal law enforcement activities, such as taking action against "pill mills" where prescription pain relievers can be obtained without a legitimate medical need.

[8]A report from the Institute of Medicine stated that more than 100 million Americans are affected by chronic pain. Institute of Medicine, *Relieving Pain In America: A Blueprint for Transforming Prevention, Care, Education, and Research* (Washington, D.C.: The National Academies Press, 2011).

[9]There are also particular prescription pain relievers, such as methadone, that are referred to as long-acting, rather than extended-release, because they deliver drugs to the body for a longer period of time due to inherent characteristics of the drug substance, rather than because of being specially formulated for an extended period of drug release.

Prescription pain relievers are sometimes used in a manner other than as prescribed—that is, they are abused and misused. While federal agencies' definitions of abuse and misuse vary, they generally incorporate three types of inappropriate use. First, some individuals use prescription pain relievers with the intent to get high, whether or not they were prescribed the drugs. Second, some individuals use prescription pain relievers that they were not prescribed to relieve pain; for example, by borrowing a pill from a friend in order to treat a headache.[10] Third, some individuals, while seeking pain relief, incorrectly use prescription pain relievers that were prescribed to them, such as by taking more than prescribed.

Prescription pain relievers have serious risks when they are abused and misused. Abuse and misuse of prescription pain relievers can lead to addiction and severe respiratory depression, which can cause death. Depending on the amount taken, even a single dose could cause death if taken by an individual who does not regularly use such pain relievers and whose body is not accustomed to their effects. Also, using alcohol or other drugs with prescription pain relievers can increase the risk of dangerous side effects, including death.

Preventing Prescription Pain Reliever Abuse and Misuse

Federal agencies use both regulatory and programmatic approaches in their efforts to prevent prescription pain reliever abuse and misuse.[11] Because of their potential for abuse, prescription pain relievers are regulated under the Controlled Substances Act.[12] Prescribers, such as

[10]Some individuals may also abuse or misuse prescription pain relievers by using pain relievers that were not prescribed to them in order to prevent drug withdrawal symptoms, which may occur if an individual stops or dramatically reduces use of prescription pain relievers after heavy and prolonged use.

[11]DEA officials told us that in addition to federal laws and regulations, state laws and medical practice standards govern the prescribing of prescription drugs. These state laws and standards may include requiring tamper-resistant prescribing pads and restricting who can prescribe controlled substances.

[12]Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified at 21 U.S.C. §§ 801 et seq. as amended). Under the Controlled Substances Act drugs are placed into one of five schedules based on their accepted medicinal uses and potential for abuse and dependence. Schedule I and II drugs have the highest potential for abuse and dependence, and schedules III through V have progressively lower potential for abuse and dependence. *See* 21 U.S.C. §812. All drugs in schedules II through V are available to the public with a prescription. *See* 21 U.S.C. §829. In addition, some schedule V drugs may be available to the public without a prescription, but subject to certain other restrictions.

physicians, physician assistants, nurse practitioners, and dentists, must register with DEA to prescribe drugs regulated under the act, and prescribers serve a key role in reducing prescription drug abuse and misuse.

However, federal agencies have noted gaps in prescriber education about issues related to prescription pain reliever abuse and misuse, including that most prescribers receive little training on the importance of appropriate prescribing and dispensing of prescription pain relievers, on how to recognize substance abuse in their patients, or on treating pain. A recent study on pain education in medical schools found that such education is limited, variable, and often fragmentary.[13] Further, given the recent introduction of new pain relievers to the U.S. market and advances in pain management, prescribers who completed their medical training in prior years may not have received training in prescribing certain types of pain relievers, such as extended-release or long-acting formulations. While continuing education of current prescribers could help address this issue, according to an American Medical Association publication, as of September 2011 medical boards in only nine states had a continuing medical education (CME) requirement related to education on controlled substance prescribing or pain management for certain prescribers.[14] A representative of the American Pain Foundation told us that the organization frequently receives reports from patients that, in some communities, prescribers have stopped prescribing prescription pain relievers because of a lack of knowledge about how to safely prescribe them.

Federal public education efforts seek to educate patients and the general public of all ages about the appropriate use, secure storage, and disposal of prescription drugs, as well as the risks associated with prescription drug abuse and misuse (see app. IV for descriptions of federal efforts to educate the general public about prescription pain reliever abuse and misuse). We have previously identified certain key practices that are

[13]L. Mezei and B.B. Murinson, "Pain Education in North American Medical Schools," *Journal of Pain* (2011).

[14]According to the American Medical Association publication *State Medical Licensure Requirements and Statistics, 2012* the states in which medical boards required CME related to education on controlled substance prescribing or pain management for certain prescribers were California, Florida, Massachusetts (for license renewals after January 1, 2012), Oklahoma, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.

important for the development of educational outreach efforts, motivating a target audience, and alleviating challenges, such as prioritizing limited resources.[15]

Federal Agencies Involved in Preventing Prescription Pain Reliever Abuse and Misuse

Multiple federal agencies play a role in preventing the abuse and misuse of prescription pain relievers. Within the Executive Office of the President, ONDCP establishes policies, priorities, and objectives for a national drug control program. ONDCP also oversees several programs related to curbing drug abuse and misuse, including an educational media campaign.

In addition, Department of Health and Human Services (HHS) agencies, including FDA, HRSA, NIH, and SAMHSA, have various responsibilities and engage in activities related to preventing the abuse and misuse of prescription pain relievers.

- FDA is responsible for ensuring the safety and effectiveness of drugs. FDA can require drug manufacturers to take measures to ensure the safety of their products, such as by providing patient and prescriber education materials. FDA also educates patients and providers about appropriate use and potential risks of drugs, including prescription pain relievers, in order to reduce preventable harm from these drugs.

- HRSA operates the federal Poison Control Program, which provides funds for poison control centers that provide treatment recommendations for poisonings involving prescription drug abuse and misuse. This program also has a campaign that includes public education about the risks of poisoning from prescription pain relievers.

- NIH, primarily through its component NIDA, provides strategic support for and conducts research on drug abuse and addiction. NIH's role also includes translating and disseminating this research into materials for public consumption.

[15]GAO-08-43. These key practices include: define key goals and objectives; analyze the situation; identify stakeholders; identify resources; research target audiences; develop clear, consistent messages; identify credible messenger(s); design a mix of media; and establish metrics to measure success. For further description of these key practices, see app. III.

- SAMHSA seeks to direct substance abuse and mental health services to the people most in need and promote use of evidence-based practices in these areas in the general health care system. In particular, the agency seeks to educate the public and prescribers about issues related to substance abuse in an effort to prevent such abuse and reduce its prevalence.

Finally, within the Department of Justice, DEA is responsible for enforcing the Controlled Substances Act and related regulations. One of DEA's roles is to control the quantity of schedule I and II controlled substances produced or procured each year in the United States, which it does by establishing annual quotas for U.S. manufacturers. (See app. II for a description of DEA's process for setting quotas for controlled substances.) The agency also supports nonenforcement programs aimed at reducing the illicit use of controlled substances, including education about prescription drug abuse and misuse and diversion.[16]

Federal Data Sources Used to Monitor Prescription Pain Reliever Abuse and Misuse

To monitor trends in the extent of prescription pain reliever abuse and misuse, federal agencies rely on data obtained from four nationally representative data sources. Three of these data sources measure adverse health consequences related to abuse and misuse, and the fourth is a national household survey of drug use.[17] Although these data sources do not directly measure abuse and misuse, when used together, they provide a more complete view of the problem of prescription pain

[16]Diversion is the channeling of pharmaceuticals for illegal purposes or abuse. Diversion can involve illegal sales of prescription drugs by physicians, patients, or pharmacists, as well as obtaining controlled substances from Internet pharmacies without a valid prescription. Diversion can also involve such activities as "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, prescription forgery, and pharmacy theft. For more on federal efforts to address the diversion of prescription drugs for illegal purposes or abuse, see GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: Sept. 6, 2011); and *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results*, GAO-11-744 (Washington, D.C.: Aug. 26, 2011).

[17]DEA, NIH, ONDCP, and SAMHSA officials told us that they also use data from Monitoring the Future, an annual national survey supported by a grant from NIH's NIDA and administered to nationally representative samples of public and private secondary school students throughout the United States. (Monitoring the Future also includes surveys following high school students into adulthood.) We did not include this data source in our analysis because it primarily focuses on youth and young adults, and is thus not nationally representative at all age levels.

reliever abuse and misuse than any of the data sources individually. Therefore, we refer to national data from these four data sources as key measures of prescription pain reliever abuse and misuse. The data sources used by federal agencies are:

- DAWN, a public health surveillance system operated by SAMHSA, collects information on emergency department visits in the United States. DAWN staff review emergency department medical records from a nationally representative sample of hospitals to identify and gather information on visits in which drugs were involved, including visits where drugs were a direct cause and visits where drugs were a contributing factor.

- TEDS, compiled by SAMHSA, gathers data from substance abuse treatment facilities in the United States on the demographic characteristics and substance abuse problems of those aged 12 or older admitted for treatment.

- NVSS, operated by CDC, contains vital statistics data, including mortality data, such as causes of death, obtained from death certificates filed for every death from every jurisdiction in the United States.

- NSDUH, an annual household survey sponsored by SAMHSA, gathers self-reported information on the use of illicit drugs (including the "nonmedical use" of prescription drugs), alcohol, and tobacco in the civilian, noninstitutionalized population of the United States aged 12 years old or older.[18]

See appendix III for more information about the data collection methodologies and limitations of these data sources.

[18]NSDUH defines "nonmedical use" of a prescription drug as use without a prescription of the individual's own or simply for the experience or feeling the drugs caused. Such use would be included in our use of the term "abuse and misuse," though it only represents two of the three scenarios within that definition. It does not represent individuals who incorrectly use prescription pain relievers for pain relief, with a prescription of one's own, but in ways other than as prescribed, such as by taking more than prescribed.

Key Measures of Prescription Pain Reliever Abuse and Misuse Have Increased Nationwide

Key measures of prescription pain reliever abuse and misuse increased from 2003 to 2009. The largest increases were in measures of adverse health consequences, though increases were not consistent across all measures. Federal officials suggested that increasing availability of prescription pain relievers and increasing high-risk behaviors by those who abuse or misuse the drugs, such as combining prescription pain relievers with other drugs or alcohol, likely contributed to the rise in adverse health consequences, though data about the reasons for the increases are limited.

Key Measures of Prescription Pain Reliever Abuse and Misuse Increased from 2003 to 2009

Key measures of prescription pain reliever abuse and misuse increased from 2003 to 2009, though increases were not consistent across all measures. All three measures of adverse health consequences that we examined increased substantially in the U.S. population during the period we reviewed (see fig. 1).[19] The estimated number of emergency department visits annually related to prescription pain reliever abuse and misuse increased by 142 percent from 2004 to 2009, an estimated increase of 288,000 visits.[20] Admissions to substance abuse treatment facilities annually for prescription pain reliever abuse and misuse increased by 131 percent, or 133,000 admissions, from 2003 to 2009.[21] The annual number of deaths resulting from unintentional overdoses of prescription pain relievers increased by 83 percent, equivalent to more than 5,000 deaths, from 2003 to 2008.[22]

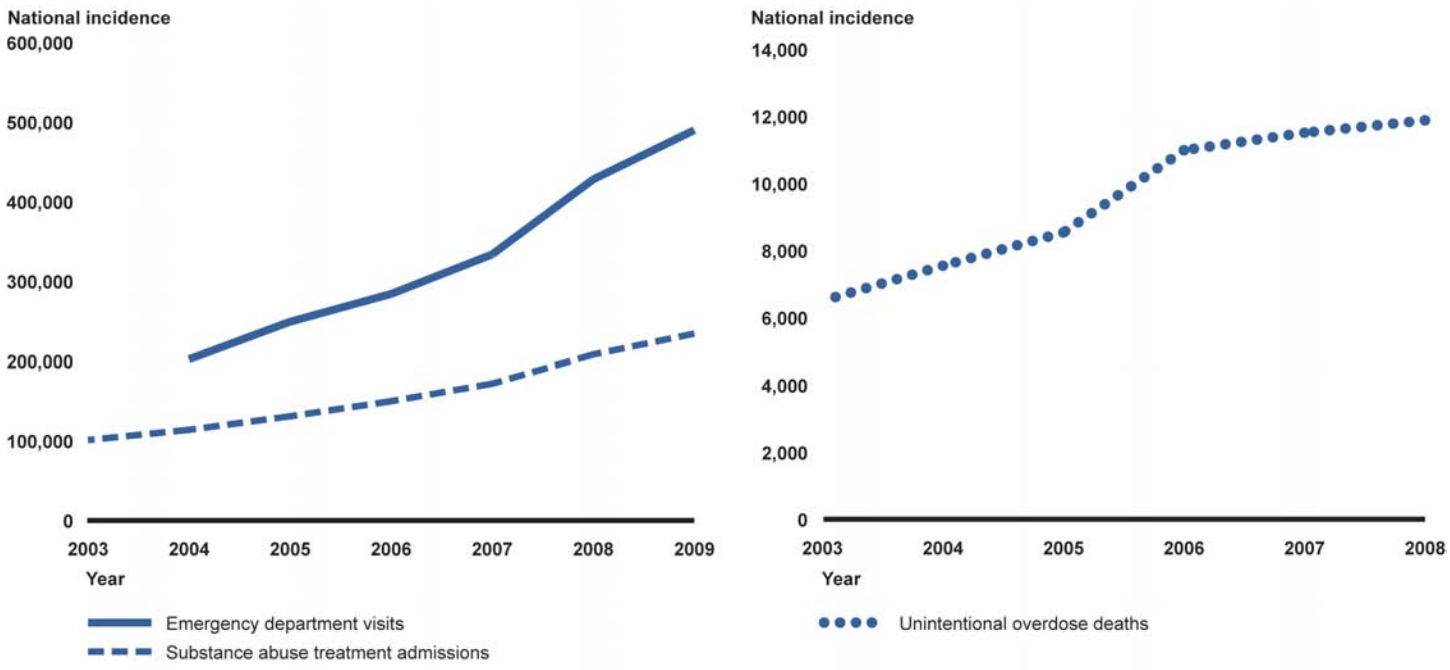
[19]See app. V for the estimated number of emergency department visits, admissions to substance abuse treatment facilities, and unintentional overdose deaths for each year analyzed along with the corresponding confidence intervals, where applicable.

[20]In 2004, according to DAWN, there were an estimated 202,000 emergency department visits related to prescription pain reliever abuse and misuse and an estimated 490,000 such visits in 2009. Comparable emergency department visit estimates are not available for 2003 because changes were made that year to the data collection methodology.

[21]In 2003, according to TEDS, there were about 101,000 admissions to substance abuse treatment facilities for prescription pain reliever abuse and misuse and about 234,000 such visits in 2009.

[22]In 2003 there were approximately 6,500 deaths resulting from unintentional overdoses of prescription pain relievers and approximately 11,900 such deaths in 2008. NVSS unintentional overdose deaths data from 2009 were not published in time for this report. The determination of intentionality in an overdose death is made by the attending physician, medical examiner, or coroner responsible for completing the causes of death section of the death certificate.

Figure 1: Measures of Adverse Health Consequences Related to Abuse and Misuse of Prescription Pain Relievers among the U.S. Population Aged 12 and Older, 2003 to 2009



Source: GAO analysis of SAMHSA and CDC data.

Notes: Comparable emergency department visit estimates are not available for 2003 because changes were made that year to the data collection methodology. Unintentional overdose deaths data from 2009 were not published in time for this report. See app. V for the estimated number of emergency department visits, admissions to substance abuse treatment facilities, and unintentional overdose deaths for each year analyzed along with the corresponding confidence intervals, where applicable.

While these measures of adverse health consequences increased substantially, according to NSDUH survey data, the percent increase in the estimated number of people nationwide who abused and misused prescription pain relievers—another key measure of prescription pain reliever abuse and misuse—was relatively slight during the period we

reviewed.[23] In 2003, an estimated 11.7 million people reported abusing or misusing prescription pain relievers at some point over the past year, and this number increased by 6 percent to 12.4 million people in 2009.[24] Appendix V shows data from the key measures by age group for each year that we reviewed.

Increasing Availability and High-Risk Behaviors Likely Contributed to the Increases in Adverse Health Consequences

Although information about the reasons for the substantial increases in adverse health consequences is limited, agency officials suggested that increasing availability of prescription pain relievers, especially extended-release and long-acting pain relievers, and increasing high-risk behaviors by those who abuse or misuse the drugs were likely contributors to the increased adverse health consequences related to prescription pain reliever abuse and misuse from 2003-2009. Over this time period, the number of prescriptions dispensed from U.S. pharmacies for prescription pain relievers increased by 32 percent—from 195 million prescriptions in 2003 to 257 million prescriptions in 2009—which CDC, FDA, and NIH officials attributed to factors such as an increased focus on pain management.[25] Officials from a number of agencies noted, however, that while most prescription pain relievers are used as prescribed, a fraction of

[23]National estimates of the number of people who abused and misused prescription pain relievers represent only two of the three scenarios that we defined as abuse and misuse. Estimates do not represent individuals who incorrectly use prescription pain relievers for pain relief, with a prescription of one's own, but in ways other than as prescribed, such as by taking more than prescribed. In addition, estimates do not differentiate between individuals who abused or misused a pain reliever with the intent to get high and those who abused or misused a pain reliever to relieve pain.

[24]The increase from 2003 to 2009 in the estimated number of people in the U.S. population aged 12 and older who abused and misused prescription pain relievers as reported in NSDUH is not statistically significant at the 95 percent confidence level. See app. V for the estimates for each year analyzed along with the corresponding confidence intervals.

[25]The estimates represent the number of prescriptions dispensed from U.S. outpatient retail pharmacies for non-injectable opioid analgesics, rounded to the nearest million. These estimates were obtained from FDA, based on its analysis of data from the SDI, Vector One®:National database, which measures retail dispensing of prescriptions based on a sample of retail pharmacies throughout the United States. The data were extracted from the database in June 2010.

all prescribed pain relievers are abused and misused.[26] Available data do not allow officials to determine what fraction of prescription pain relievers are abused and misused.

Officials from multiple agencies suggested that adverse health consequences may also be increasing because more individuals who abuse or misuse prescription pain relievers may be abusing or misusing extended-release and long-acting pain reliever formulations, though data from which to draw this conclusion are limited. Because extended-release and long-acting formulations are designed to release their ingredients and relieve pain over an extended period of time, they may have more pain-relieving ingredients in each dose than immediate-release drugs. Prescriptions dispensed for these extended-release and long-acting formulations increased by 56 percent from 2003 to 2009—an even higher rate than the increase for prescription pain relievers overall.[27] FDA officials said that, because of their potency, when extended-release and long-acting drugs are abused and misused, they are more likely to cause harm than when immediate-release pain relievers are abused. For example, an FDA analysis found that extended-release and long-acting pain relievers are more often involved in emergency department visits than immediate-release pain relievers, when adjusted for number of prescriptions.[28] In addition, a 2009 analysis by a panel of experts associated methadone, a long-acting pain reliever, with a high number of deaths compared with other prescription pain relievers, when adjusted for

[26]According to NSDUH, among persons aged 12 or older in 2009 who abused or misused a pain reliever in the past year, 19 percent got the drug that was most recently abused or misused as a prescription from a doctor. In addition, 55 percent got the drug they most recently abused or misused from a friend or relative for free, 11 percent bought the drug from a friend or relative, and 4 percent took the drug from a friend or relative without asking.

[27]From 2003 to 2009, prescriptions for extended-release and long-acting pain relievers increased from approximately 15 million to 23 million. Estimates of dispensed prescriptions are from FDA's analysis of SDI, Vector One®:National, extracted June 2010.

[28]FDA estimated that in 2008, there were 106.8 emergency department visits involving abuse or misuse of extended-release oxycodone for every 10,000 retail prescriptions, in contrast to 14.3 emergency department visits involving abuse or misuse of immediate-release oxycodone for every 10,000 retail prescriptions. FDA developed these estimates based on an analysis of data from DAWN and SDI, Vector One®: National, extracted June 2010.

the total number of prescriptions dispensed.[29,30] Officials from most of the agencies we interviewed said that they are most concerned about extended-release and long-acting pain relievers, but they noted that immediate-release pain relievers are also abused and misused. Officials from multiple agencies noted, however, that data on what drug formulations are being abused and misused are limited because most measures of abuse and misuse do not gather information on the particular drug formulation involved in a case of an adverse health consequence or self-reported abuse and misuse.

A second factor that officials from several agencies said likely contributed to the increases in adverse health consequences is that more individuals may be engaging in high-risk behaviors when they abuse or misuse prescription pain relievers, though data on the extent of high-risk behaviors are limited. One high-risk behavior officials pointed to was combining prescription pain relievers with other substances, such as another prescription pain reliever, alcohol, or other drugs. Taken together, the interactions of such substances can lead to increased risk of life-threatening conditions. From 2004 to 2009, the number of emergency department visits that involved combining prescription pain relievers with other substances increased by an estimated 200,000 visits, while the number of emergency department visits involving a prescription pain reliever alone increased by an estimated 88,000 visits.[31] However, officials from several agencies told us that their understanding of how drugs are used in combination is limited by the available data. For example, NSDUH, which reports estimates of abuse and misuse based on a nationwide survey, does not ask survey respondents which substances they use in combination. In addition, NVSS data on unintentional overdose deaths are limited by the amount of detail listed on death certificates. Not all substances involved in a death may be listed on

[29]Methadone has unique pharmacological properties that make it different from other opioids, and as a result, when it is used without adequate knowledge or when it is used for a purpose other than that for which it was prescribed, it can lead to adverse health consequences, including death. GAO-09-341.

[30]L.R. Webster et al., "An Analysis of the Root Causes for Opioid-Related Overdose Deaths in the United States," *Pain Medicine,* vol. 12 (2011).

[31]According to DAWN, in 2004, there were an estimated 63,000 emergency department visits involving a prescription pain reliever alone and an estimated 140,000 visits with both a prescription pain reliever and alcohol or other drugs. In 2009 these figures were estimated at 151,000 and 340,000, respectively.

a death certificate, especially when a toxicology report is not used to determine the cause of death. CDC officials said that whether a toxicology report is used to determine the cause of death varies by jurisdiction, and currently, the number of postmortem examinations, which may include toxicology reports, is declining.

Officials from multiple agencies said that another high-risk behavior that may be leading to increased adverse health consequences is inhaling or injecting the drugs, rather than taking them orally as prescribed. From 2003 to 2009, the percentage of admissions to substance abuse treatment facilities where the admitted individual reported usually abusing or misusing prescription pain relievers through inhaling the drugs increased from 9 percent to 16 percent of cases. The percent of admissions where the admitted individual reported using the drugs orally decreased from 72 to 69 percent of cases, while the percent of admissions using the drugs in other ways was stable. NIH has reported that inhaling and injecting drugs is more dangerous than taking them orally as prescribed. Inhaling or injecting the drugs delivers drugs more quickly to the brain and can increase the risk of addiction and overdose.

Federal Agencies Are Using Various Strategies to Educate Prescribers about Issues Related to Prescription Pain Reliever Abuse and Misuse

FDA, NIH, and SAMHSA are using a variety of strategies to fill the gaps federal agencies have identified in prescriber education related to treating pain, prescribing opioids appropriately, and identifying substance abuse in their patients, but officials told us that more education is needed. Strategies that these agencies pursued in fiscal year 2011 include developing CME programs, requiring training and certification in order to prescribe certain drugs, organizing physician mentoring networks, and developing curriculum resources for future prescribers.

First, FDA, NIH, and SAMHSA are using voluntary CME programs to educate prescribers about issues related to prescription pain reliever abuse and misuse. CME programs are educational activities which serve to maintain, develop, and increase the knowledge, skills, and professional performance and relationships physicians use to provide services to patients. Many state medical boards require prescribers to complete a certain number of CME credits for license re-registration. FDA is requiring manufacturers to develop a CME or continuing education (CE) course for prescribers as part of a Risk Evaluation and Mitigation Strategy (REMS)

for extended-release and long-acting prescription pain relievers.[32,33] While completion of the course, which is expected to be implemented in early 2012, will be voluntary, FDA is requiring manufacturers to propose performance goals for the percentage of prescribers who complete it. NIH is undertaking a different approach to using CME programs to educate prescribers about identification of substance abuse in their patients, reaching out to prescribers at medical conferences across the country. Using a live theater CME format, NIH uses a dramatic reading of a portion of the play *Long Day's Journey into Night* that focuses on a character's morphine addiction, an expert panel reaction, and a facilitated audience discussion to highlight issues like incorporating screening, brief intervention, and referral to treatment into primary care settings. Finally, SAMHSA developed a CME course on prescribing opioids for chronic pain and partners with local host organizations, such as local medical organizations and state agencies, to offer it across the United States. The course is targeted at physicians, dentists, and other prescribers and can be modified to reflect the needs of the local host organization.

Another strategy FDA uses is requiring prescribers of certain prescription pain relievers to be trained and certified in order to prescribe them. As of October 2011, all five marketed transmucosal immediate-release fentanyl products had REMS with prescriber training and certification components

[32]According to FDA, the course will be provided by organizations accredited to provide CME to physicians or by organizations that provide CE to health care professionals other than physicians.

[33]*See* Food and Drug Administration Amendments Act of 2007, Pub. L. No., 110-85, § 901, 121 Stat. 823, 922 (codified in pertinent part at 21 U.S.C. §§ 355(p), 355-1) (conditioning authority to market a drug on compliance with an approved REMS, where determined necessary to ensure the benefits outweigh the risks). A REMS is a risk management plan that FDA can require a manufacturer to develop to manage serious risks associated with a drug. Prescription pain relievers subject to the extended-release and long-acting class-wide REMS include extended-release products containing buprenorphine, fentanyl, hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol, and products containing the long-acting prescription pain reliever methadone.

due to unique concerns associated with these products.[34] In order to become certified to prescribe these drugs for outpatient use, prescribers must review written materials, successfully complete a knowledge assessment, and register with the manufacturer of the drug by completing a prescriber enrollment form, which includes a commitment to complete a patient-prescriber agreement with each new patient.[35] Prescribers are required to become recertified every 2 years.

A third strategy NIH and SAMHSA are pursuing is providing funding to develop physician clinical support systems, which provide educational resources and free, nationwide mentoring services related to prescribing prescription pain relievers. As of October 2011, two physician clinical support systems had been funded: one to assist practicing physicians interested in implementing substance abuse screening in their practices and one related to the appropriate use of prescription pain relievers for the treatment of chronic pain.[36] Each system links physicians to trained clinical advisors who can provide telephone or e-mail responses to specific questions and offer support using the educational resources.

The final strategy NIH and SAMHSA are using is developing curricula for future prescribers, including medical students and residents, about issues related to prescription pain reliever abuse and misuse. NIDA's Centers of Excellence for Physician Information, located in eight medical schools, are developing curriculum resources—including lectures, faculty workshops, and web modules—to help train medical students and

[34]As the five products are highly potent and designed for transmucosal absorption they are only indicated for use in adults with breakthrough cancer pain who are already routinely taking another prescription pain reliever around the clock. However, FDA officials told us that in studying the postmarket data, they became concerned that these drugs were being used in patients who were not already routinely taking another prescription pain reliever. Because these products have a very high risk of death if administered incorrectly or if taken by patients who were not already routinely taking another prescription pain reliever, FDA has also placed special restrictions on the dispensing of these products through REMS.

[35]Patient-prescriber agreements are documents signed by the patient and prescriber that outline patient and prescriber responsibilities, including, in the case of transmucosal immediate-release fentanyl products, documenting that the patient is regularly taking another prescription pain reliever and has been counseled on the risks, benefits, and appropriate use of these drugs.

[36]SAMHSA also funds two additional physician clinical support systems related to the use of methadone and buprenorphine in addiction treatment, which are outside the scope of our review.

residents to screen, treat, and refer patients with substance use disorders. As of October 2011, the medical schools had developed 10 curriculum resources, 5 of which are specific to prescription drug abuse and misuse. In addition, NIDA is taking the lead on a project with participation from more than 10 institutes and centers within the NIH to establish the NIH Pain Consortium Centers of Excellence in Pain Education. These Centers of Excellence aim to develop curricula that will educate medical students about best practices in the treatment of pain by fiscal year 2014. SAMHSA is also facilitating the development of curricula for training medical residents. Through its Screening, Brief Intervention, Referral and Treatment Medical Residency Program, medical residency programs are developing curricula and clinical training for identifying substance use disorders, including training about issues related to prescription drug abuse and misuse, and incorporating the curricula and clinical training into 16 residency programs.[37] The curriculum resources for these programs are designed to be transferable to medical schools and residency programs nationwide.

Despite various ongoing strategies to educate current and future prescribers about issues related to prescription pain reliever abuse and misuse, officials from each of the federal agencies we spoke with told us that more prescriber education is necessary. ONDCP officials indicated that they—with technical assistance from DEA, FDA, and SAMHSA—are working to develop a legislative proposal to require that all prescribers who request DEA registration to prescribe controlled substances be trained on the appropriate and safe use, proper storage, and disposal of prescription pain relievers as a precondition of registration. Currently, in order to register with DEA to prescribe a controlled substance, prescribers must hold a valid state license.[38] Officials from many of the agencies we spoke with expressed support for mandatory prescriber education, with some noting that this would ensure that all prescribers were starting from the same baseline of knowledge. Officials from one agency expressed support for promoting the education of all prescribers through other means, such as working with state medical boards. Officials from several agencies explained that more prescriber education is

[37]SAMHSA also provided funding to one additional medical residency program, but officials told us that the curriculum resources that residency program is developing do not include information about prescription drug abuse and misuse.

[38]*See* 21 U.S.C. § 823(f).

necessary because the majority of educational strategies that federal agencies are currently pursuing are voluntary and may not reach the majority of either current or future prescribers. Because training could help prescribers feel more comfortable prescribing these drugs, ONDCP officials also explained that mandatory prescriber education could improve access to prescription pain relievers for patients with a legitimate need for pain relief. Officials from ONDCP also noted that by mandating education for all prescribers, rather than only for those who prescribed extended-release and long-acting prescription pain relievers, they could avoid a possible situation in which some prescribers would be unable to prescribe certain pain relievers because they had chosen not to take the training. Representatives of the American Medical Association told us that they, along with a number of other associations representing prescribers, favored the use of positive incentives—such as a reduction in the $551 fee prescribers pay to DEA when registering to prescribe controlled substances—to encourage prescribers to complete voluntary education about these issues, rather than mandating such education. The American Medical Association representatives noted that the contribution that poor prescribing practices or fraudulent activity on the part of prescribers makes to the supply of prescription pain relievers that are diverted for abuse and misuse is unknown. As a result, they told us that it is unclear whether mandatory prescriber education would have an effect on prescription pain reliever abuse and misuse.

Federal Agencies Generally Followed Key Practices When Developing Public Education Efforts

All federal agencies used almost all of the key practices for developing consumer education efforts, which varied in size, scope, and duration. Agencies also varied in how they used key practices when developing these efforts. All agencies established metrics to monitor the implementation and functional elements of their educational efforts, but only two agencies have established or are planning to establish metrics to assess the impact of their efforts on audiences' knowledge, attitudes, and behavior.

All Agencies Followed Almost All Key Practices; Efforts Varied in Size and Approach

All federal agencies used almost all of the key practices for developing consumer education efforts when developing the efforts that we reviewed to educate the general public about prescription pain reliever abuse and misuse. In fiscal year 2011, five agencies operated nine educational efforts targeted at the general public, ranging from websites to brochures to a museum exhibit (see app. IV for full descriptions of the educational efforts). Our prior work outlines key practices that agencies should engage in when developing public education efforts: define key goals and

objectives of the educational effort; analyze the situation, including identifying competing voices or timing considerations; identify stakeholders and clarify their roles; identify resources; research target audiences, including identifying audience characteristics and motivators; develop clear, consistent messages; identify credible messenger(s); design a mix of media, including method and frequency of delivery; and establish metrics to measure success (for further description of these key practices, see app. III).[39] Our review of initiatives to educate the general public about prescription pain reliever abuse and misuse shows that all of the agencies used almost all of these practices when developing their initiatives (see fig. 2). For instance, FDA relied on seven of nine key practices when developing outreach materials for its *Opioid Public Service Announcements*. Other agencies used more key practices when developing their education efforts; ONDCP relied on all nine key practices for developing consumer education efforts when it developed the prescription drug content for the *National Youth Anti-Drug Media Campaign*.

[39]GAO-08-43.

Figure 2: Agencies' Use of Key Practices for Developing Public Education Efforts

Agency	Education effort	Define goals and objectives	Analyze the situation	Identify stakeholders	Identify resources	Research target audiences	Develop consistent, clear messages	Identify credible messenger(s)	Design media mix	Establish metrics to measure success: Process metrics	Establish metrics to measure success: Outcome metrics
DEA	Just Think Twice[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Get Smart About Drugs[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Take Back Initiative[b]	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Good Medicine, Bad Behavior	✓	✓	✓	✓	✓	✓	✓	✓	✓	
FDA	Opioid Public Service Announcements	✓	✓		✓		✓	✓	✓	✓	
NIH	Heads Up: Real News About Drugs and Your Body[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	NIDA for Teens[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ONDCP	National Youth Anti-Drug Media Campaign[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
SAMHSA	Not Worth The Risk; Even if it's Legal	✓	✓	✓	✓	✓	✓	✓	✓	✓	

Source: GAO analysis of information from DEA, FDA, NIH, ONDCP, and SAMHSA.

[a]Efforts are broader than prescription drugs. We limited our analysis to the prescription drug-related components of these efforts.

[b]According to DEA officials, the primary purpose of the *Take Back Initiative* is to collect and dispose of unwanted and unused prescription drugs. Public education about prescription drug storage and disposal is a secondary goal. We limited our analysis to the public education materials associated with the *Take Back Initiative*.

Agencies varied in how they used the key practices for developing public education efforts. For instance, SAMHSA used the key practice of developing consistent, clear messages by convening Project Advisory Teams composed of external stakeholders and subject matter experts. The teams met several times during the development of two phases of *Not Worth the Risk; Even if it's Legal* and gave input to SAMHSA about effective messaging and distribution channels for the program's target audiences, which include teens, college students, and "student

influencers" (e.g, parents, teachers, health care providers). FDA used a different approach for the same key practice of developing consistent, clear messages for its *Opioid Public Service Announcements*—which include information about appropriate use, storage, and disposal of medications—relying on internal discussions between staff in its Office of Communications and the Office of New Drugs.

Although all agencies used many of the same key practices to develop their educational efforts, the resulting initiatives are different in terms of size, scope, and duration, and agencies dedicated varying amounts of resources to developing their efforts. For instance, NIH's *Heads Up: Real News About Drugs and Your Body* provides classroom materials—including magazine articles, student worksheets, and lesson plans—to students and teachers about a range of topics related to drug abuse and misuse, including but not limited to prescription drugs, and has done so each school year since 2002. By contrast, DEA began collecting and disposing of unused prescription drugs through its *Take Back Initiative* in 2010.[40] The agency developed outreach materials to raise awareness of the event and the materials—including brochures and billboards—are specific to prescription drugs. There is also significant variation in terms of the resources different agencies used for program development. For instance, the budget for the *National Youth Anti-Drug Media Campaign* in fiscal year 2011 was approximately $35 million, whereas *Not Worth the Risk; Even if it's Legal* cost about $80,000 for the last phase of the brochure series.[41] Many programs we reviewed cost less than $150,000 for program development and dissemination in a fiscal year.

[40]In September 2010 DEA conducted a National Prescription Drug Take Back Day to provide a venue for the disposal of unwanted and unused prescription drugs. DEA held a second Take Back Day in April 2011 and a third in October 2011. A DEA official told us that such events are a short-term measure until the agency can implement regulations for the Secure and Responsible Drug Disposal Act of 2010, which will allow for authorized entities to collect and dispose of controlled substances.

[41]The *National Youth Anti-Drug Media Campaign* (the Campaign) is a mass-media campaign, including paid advertising and public communications outreach. In fiscal year 2011, the Campaign targeted parents and teens with messages about prescription drug abuse and misuse on its websites, rather than through paid advertising. The budget for the Campaign includes funding for all aspects of the Campaign. Only a small portion of the overall budget was spent on programming about prescription drug abuse.

All Agencies Followed the Key Practice of Establishing Process Metrics but Most Did Not Assess Program Outcomes

While all agencies established metrics to monitor the implementation and functional elements of their educational initiatives, only two agencies have established or planned to establish metrics to assess the impact of their initiatives on audiences' knowledge, attitudes, and behavior with regard to prescription pain reliever abuse and misuse. The former, known as process metrics, monitor the operational elements of educational efforts, such as the quantity or volume of outreach efforts. The latter, known as outcome metrics, are used to assess the impact of the initiative on the desired health or behavior outcome. Our prior work and other guides for developing consumer education efforts note that establishing both process and outcome metrics are critical elements of program development.[42]

All federal agencies followed the key practice of establishing process metrics for the public education efforts we reviewed. For instance, DEA tracks the amount of activity and use across the different features and content pages on its websites, *Just Think Twice and Get Smart About Drugs*, including the most popular search terms and amount of time spent on the components of the websites. DEA also monitors the number of visitors to its museum exhibit about prescription drug abuse and misuse, *Good Medicine, Bad Behavior*, and records the number of group visits by category (e.g., schools, universities, or senior citizens).

ONDCP and NIH were the only agencies that followed the key practice of establishing outcome metrics for their education efforts. ONDCP measures outcomes from its *National Youth Anti-Drug Media Campaign* (the Campaign) on a weekly basis through ongoing tracking studies. The tracking studies survey 100 teens each week about awareness of the Campaign and their attitudes, beliefs, and intentions regarding drug use, including where and how teens interact with the Campaign's website, and attitudes after interacting with the website.[43] ONDCP also awarded a contract to evaluate the Campaign's contribution to preventing drug abuse among young people in the United States, in particular by assessing the Campaign's impact on knowledge, attitudes, beliefs, and

[42]U.S. Department of Health and Human Services, National Institutes of Health and National Cancer Institute, *Making Health Communication Programs Work: A Planner's Guide* (2004).

[43]The tracking studies also evaluate teen awareness and memory of the Campaign's advertisements. However, there were no advertisements about prescription drug abuse and misuse being broadcast during fiscal year 2011.

behavioral intention about drug use.[44] However, ONDCP indicated that, as of September 2011, the contract was being terminated because the Campaign has not been funded for fiscal year 2012. NIH plans to evaluate outcomes for its *NIDA for Teens* website by surveying students and teachers about students' knowledge acquisition and attitude change after exposure to *NIDA for Teens*, as well as teachers' opinions on the utility of the website. Although officials from agencies that did not establish outcome metrics told us that they recognize the importance of evaluating public education efforts, they cited challenges measuring the impact of such efforts and lack of financial resources as reasons for not assessing program outcomes. For instance, one official explained that an outcome evaluation for his agency's drug education program would cost more than developing and implementing the program itself.

Beyond the key practices for developing public education efforts, our prior work notes that using existing evidence to inform public health communications, such as research on teen messaging or evaluations of related efforts, can also be helpful in analyzing the effectiveness of educational efforts in addition to establishing outcome metrics.[45] When developing their public education efforts, agencies incorporated evidence-based strategies when possible, but limited evidence exists about how to successfully educate the public about prescription pain reliever abuse and misuse. For instance, research shows that teens may mistakenly believe that prescription pain relievers are safer than illicit drugs. As a result, officials from several agencies told us that they seek to dispel this misperception in their educational efforts. In addition, NSDUH data also indicate that most people who abuse or misuse prescription pain relievers get the drugs from a friend or family member. Thus, DEA officials told us that they have sought to educate the public about proper drug storage and disposal in order to limit the amount of drugs that are available to be diverted from medicine cabinets for abuse and misuse.

[44]ONDCP awarded the evaluation contract to Westat, Inc. in July, 2010. We have previously reported on a prior Westat evaluation of the *National Youth Anti-Drug Media Campaign*; see GAO, *ONDCP Media Campaign: Contractor's National Evaluation Did Not Find that the Youth Anti-Drug Media Campaign Was Effective in Reducing Youth Drug Use*, GAO-06-818 (Washington, D.C.: Aug. 25, 2006).

[45]GAO, *Program Evaluation: Strategies for Assessing How Information Dissemination Contributes to Agency Goals*, GAO-02-923 (Washington, D.C.: Sept. 30, 2002).

However, officials from multiple agencies explained that because there are distinct challenges when designing educational efforts about prescription pain reliever abuse and misuse compared to other drug prevention efforts, more research is needed in order to understand how to craft effective messages, particularly for teens. Officials said that education about prescription pain reliever abuse and misuse requires a more nuanced approach because there are legitimate medical uses for these products. In addition, officials from several agencies noted that educational efforts should avoid inadvertently alerting people to the possibility of using these drugs to get high. The motivations for abusing and misusing prescription drugs can also be different than the motivations for using illicit drugs, such as self-medicating for pain relief, and understanding how to effectively target the variety of reasons people abuse and misuse prescription drugs is another area that requires more research, according to agency officials. The Surgeon General, with support from other federal agencies, is currently developing a Call to Action on youth prescription drug abuse that will discuss available evidence to support prevention strategies, including educational efforts.[46] An official from the Office of the Surgeon General told us that the Call to Action, which is anticipated for release in February 2012, will also identify gaps in existing research related to youth prescription drug abuse prevention strategies and call for further research to be conducted to fill these gaps.

Federal Agencies Have Begun Coordinating Similar Public and Prescriber Education Efforts, but Have Missed Opportunities to Share Resources

There are several similarities among agencies' efforts, target audiences, and mediums across the nine public education initiatives and nine prescriber education programs we identified. Officials said that these similarities in public education efforts are beneficial in addressing prescription drug abuse and misuse because having multiple, reinforcing messages about the same subject is valuable in public health communications and because federal agencies provide slightly different perspectives on the issues surrounding prescription drug abuse and misuse. Likewise, the prescriber education programs we identified, though similar, are different in content and focus. Although these similar programs have the potential to be duplicative if not effectively coordinated, federal agencies have recently begun to coordinate their

[46]A Call to Action is a science-based document to stimulate action nationwide to solve a major public health problem.

educational efforts. Nevertheless, federal agencies have missed opportunities to pool resources—a key practice for effective coordination—among similar education efforts, which may have resulted in lost opportunities to obtain additional benefits through coordination.

Federal Agencies Operate Similar Public and Prescriber Education Programs

Among all nine federal initiatives to educate the general public about prescription pain reliever abuse and misuse that we reviewed, there are several instances of agencies engaging in similar efforts (see table 1). Officials told us that it is beneficial to have similar education efforts about prescription pain reliever abuse and misuse because of the complex nature of this problem and the fact that agencies provide different but reinforcing messages about the issue.

Table 1: Public Education Efforts about Prescription Pain Reliever Abuse and Misuse

Primary target audience	Agency	Program	Medium
Teens	DEA	Good Medicine, Bad Behavior	Museum exhibit
		Just Think Twice[a]	Website
	NIH	Heads Up: Real News About Drugs and Your Body[a]	Classroom materials
		NIDA for Teens[a]	Website
	ONDCP	National Youth Anti-Drug Media Campaign[a]	Website
	SAMHSA	Not Worth the Risk; Even if it's Legal	Brochures and posters
Parents	DEA	Get Smart About Drugs[a]	Website
	ONDCP	National Youth Anti-Drug Media Campaign[a]	Website
	SAMHSA	Not Worth the Risk; Even if it's Legal	Brochures and posters
College students	SAMHSA	Not Worth the Risk; Even if it's Legal	Brochures and posters
Teachers	NIH	Heads Up: Real News About Drugs and Your Body[a]	Classroom materials
	SAMHSA	Not Worth the Risk; Even if it's Legal	Brochures and posters
Public	DEA	Take Back Initiative	Posters, brochures, advertisements
	FDA	Opioid Public Service Announcements	Audio, slides

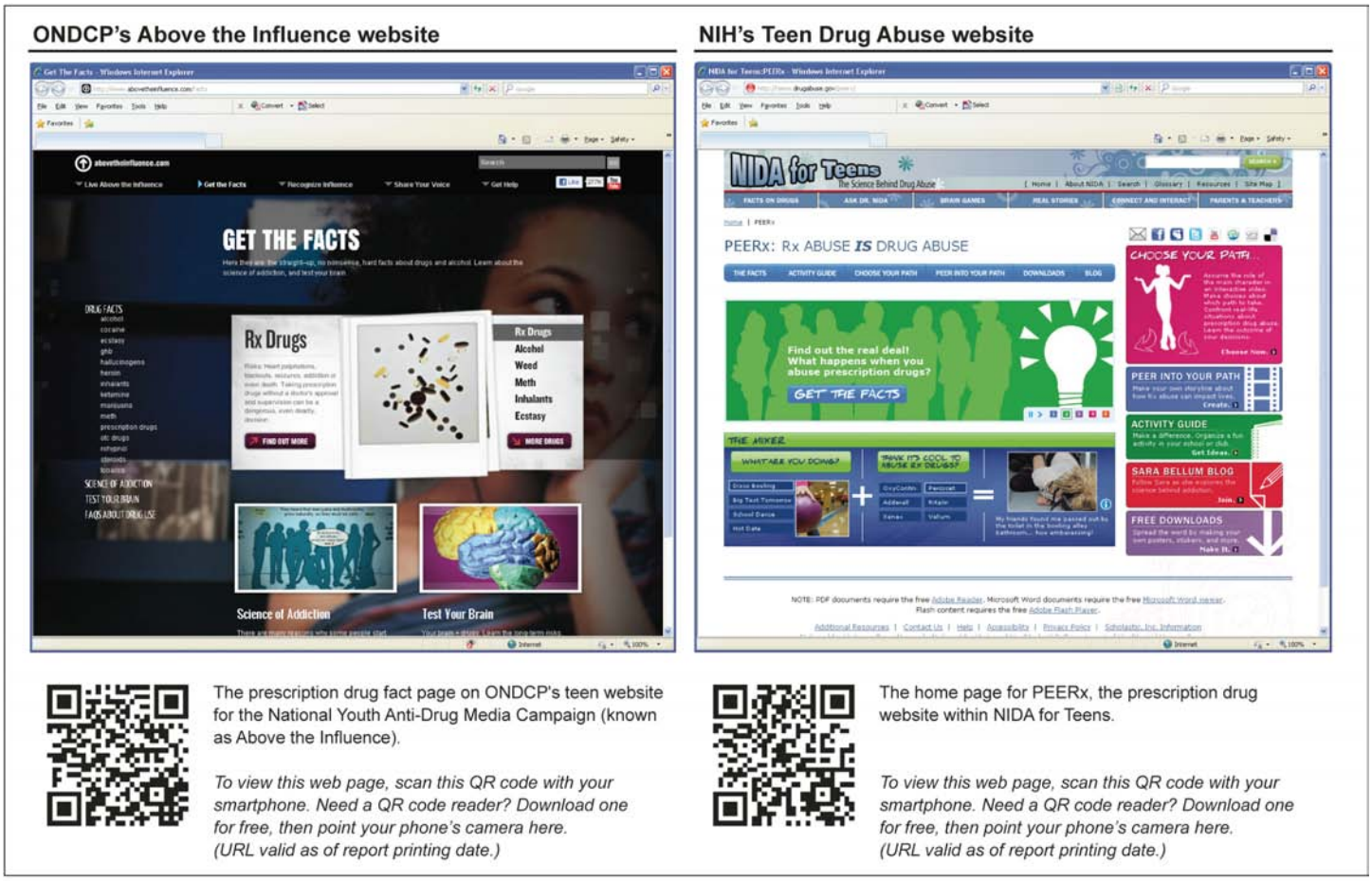
Source: GAO analysis of information from NIH, SAMHSA, FDA, DEA, and ONDCP.

Notes: See app. IV for detailed program descriptions.

[a]Efforts are broader than prescription drugs. We limited our analysis to the prescription drug-related components of these efforts.

For example, three initiatives—*Just Think Twice*, *NIDA for Teens*, and the *National Youth Anti-Drug Media Campaign*—use the same medium to target teens with similar messages about prescription drug abuse and misuse. These efforts provide web-based information and interactive features to educate teens about prescription drug abuse and misuse. (See fig. 3 and fig. 4 for examples of web-based efforts to educate teens about prescription drug abuse and misuse.) Officials working on these efforts noted that they chose to focus on teens because drug abuse typically starts during teen years. NIH officials told us that prescription and over-the-counter medications account for most of the drugs commonly abused by 12th graders as well, after alcohol, tobacco, and marijuana. Teens are also more vulnerable to the negative effects of drug use since their brains are still developing.

Figure 3: ONDCP and NIH Teen Websites



Source: ONDCP, NIH, GAO.

Figure 4: DEA Teen Website

Source: DEA, GAO.

There are also two initiatives—DEA's *Get Smart About Drugs* and ONDCP's *National Youth Anti-Drug Media Campaign*—that use the same medium to target parents with similar messages about prescription drug abuse and misuse. For instance, both use websites that have interactive features that show parents where teens commonly access prescription drugs in the home. Both sites also include tips for parents about how to talk to teens about drugs and about how to identify signs of abuse.

Officials acknowledged these instances of similar goals and similar strategies to reach the same audience among educational efforts. However, officials said that these similarities are beneficial in addressing prescription drug abuse and misuse. Officials from NIH, FDA, DEA, and

ONDCP noted that having multiple, reinforcing messages about the same subject is valuable in public health communications, particularly about an issue as complex as prescription drug abuse and misuse. The National Council on Patient Information and Education also told us that repetition and frequent delivery of information supports message reinforcement. Second, federal agencies have their own constituencies and each approaches prescription drug abuse and misuse from a slightly different perspective. For instance, *NIDA for Teens* provides a science-based perspective and includes information about how prescription drugs affect the brain. Specifically, the "Mind Over Matter" series on the *NIDA for Teens* website explains how prescription drugs mimic neurotransmitters to alter the brain's chemistry. DEA's *Just Think Twice*, on the other hand, provides more information about the legal consequences of abusing drugs, such as losing federal student loans, and the culture of drug abuse, including images of drugs and true stories of youth overdose deaths. NIH officials told us that both perspectives are important as some members of the public may go to NIH's NIDA for information about these issues, while others may go to DEA. Officials also said that they cross-reference each other's information when appropriate. For instance, ONDCP links to publications from NIH's NIDA on one of the *National Youth Anti-Drug Media Campaign* websites.

In addition to the similarities among the nine targeted educational efforts we reviewed, agencies are engaged in additional efforts outside the scope of our review which, taken together, may present areas of potential duplication.[47] These additional efforts include posting materials from retired initiatives online, planning future efforts, and providing factual information about prescription pain relievers. For instance, FDA and SAMHSA have brochures and posters for teens and the elderly with messages about prescription pain reliever abuse and misuse that are no longer actively disseminated, but are still available on their websites. HRSA and, contingent on available resources, DEA are also planning to launch new or update existing educational initiatives in the next fiscal year, targeted at the elderly and parents, respectively. ONDCP is also planning to work with agencies and external stakeholders to develop and

[47]We have previously defined "duplication" as occurring when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries. GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue,* GAO-11-318SP (Washington, D.C.: Mar. 1, 2011).

implement national public education campaigns on prescription drug abuse and misuse and drug storage and disposal, by April 2013. ONDCP officials told us that, as of October 2011, they were still considering various options and working to identify resources for these campaigns. Finally, three federal agencies have prescription drug fact pages on their main websites and FDA oversees the dissemination of drug information to patients through tools such as medication guides that are provided with some prescription drugs. Given the number of agencies involved in educating the public about prescription pain reliever abuse and misuse and the number of efforts currently under way, these additional efforts represent areas where there may be the potential for duplicative programming, if such efforts are not effectively coordinated.

There are also similar target audiences and mediums among the nine prescriber education programs we identified, although the content and focus of these programs is different (see table 2). For example, two CME courses, SAMHSA's Prescribing Opioids for Chronic Pain course and FDA's requirement for prescriber education through its extended-release and long-acting opioid REMS, are both targeted at current prescribers. Though these courses have some similar content about patient selection and monitoring, FDA officials noted that prescriber education through REMS will focus on extended-release and long-acting products, whereas the SAMHSA course includes information on both extended-release and immediate-release pain relievers. They also noted that the SAMHSA course is more focused on addiction and treatment than the REMS materials will be. As a result, prescribers are being educated about the full range of issues related to prescription pain reliever abuse and misuse, including treating pain, appropriate prescribing, and recognizing substance abuse in their patients.

Table 2: Efforts to Educate Prescribers about Issues Related to Prescription Pain Reliever Abuse and Misuse

Target audience	Program (Agency)	Medium	Content of training
Current prescribers	Extended-release and long-acting opioid REMS (FDA)	CME/CE course	Appropriate prescribing[a]
	Addiction Performance Project (NIH)[b]	CME course	Screening, brief intervention, and referral to treatment[c]
	Prescribing Opioids for Chronic Pain (SAMHSA)	CME course	Appropriate prescribing
	Transmucosal immediate-release fentanyl REMS (FDA)	Written materials	Appropriate prescribing
	Physician Clinical Support System – Primary Care (NIH)[b]	Written materials, screening tools, mentoring	Screening, brief intervention, and referral to treatment
	Prescriber's Clinical Support System for the Appropriate Use of Opioids in the Treatment of Pain and Opioid-related Addiction (SAMHSA)	Written materials, mentoring, webinars	Appropriate prescribing[a]
Future prescribers	NIDA Centers of Excellence for Physician Information (NIH)[b]	Curricular resources, including lectures, case studies, and web-based training	Appropriate prescribing; screening, brief intervention, and referral to treatment
	NIH Pain Consortium Centers of Excellence in Pain Education (NIH)	Curricular resources	Treating pain[a]
	Screening, Brief Intervention, Referral and Treatment Medical Residency Program (SAMHSA)[b]	Curricular resources, including lectures, web-based training, and role plays, and clinical training, including practice with simulated patients	Screening, brief intervention, and referral to treatment

Source: GAO.

Notes: The Addiction Performance Project, Physician Clinical Support System—Primary Care, and Centers of Excellence for Physician Information are all part of the NIDAMED physician outreach initiative, designed to provide tools and resources to assist physicians in addressing substance abuse (including prescription drug abuse) in their practices. Another component of this initiative is NIH's Drug Use Screening Tool, a web-based interactive screening tool for use in primary care practices that specifically captures information on patient prescription drug abuse.

[a]Content is anticipated as materials have not yet been developed.

[b]Programs are broader than prescription drugs. We limited our analysis to the prescription drug-related components of these programs.

[c]According to NIH officials, the primary goal of the Addiction Performance Project is to help break down the stigma associated with addiction. Educating prescribers about screening, brief intervention, and referral to treatment is a secondary goal.

Federal Agencies Coordinate Their Educational Efforts through Three Main Mechanisms and Have Increasingly Relied on Key Practices for Coordination

Federal agencies use three main mechanisms—two mechanisms that are overseen by ONDCP, the National Drug Control Strategy and the Prescription Drug Abuse Prevention Plan, and one mechanism within HHS, the HHS Behavioral Health Coordinating Committee's Subcommittee on Prescription Drug Abuse—to coordinate their educational efforts. The agencies have also begun using key practices for coordination that we have identified in prior work on practices that help enhance and sustain collaboration.[48] ONDCP releases the National Drug Control Strategy (the Strategy) on an annual basis and it outlines the administration's goals and priorities for reducing the rate of drug abuse and misuse and the associated consequences. The Strategy, which outlines drug control policies and programs for illicit and prescription drugs, serves as a coordination mechanism for drug control agencies and incorporates several key practices for interagency collaboration. For instance, the Strategy defines and articulates a common outcome by establishing the administration's goals for reducing drug abuse and misuse. The Strategy also provides a means for agencies to agree on roles and responsibilities by listing specific actions for agencies to take, including identifying lead and partnering agencies for each action item. For example, "Enhance Healthcare Providers' Skills in Screening and Brief Intervention" is an action item in the 2010 Strategy and it specifies that SAMHSA is the lead agency, with NIH's NIDA, HRSA, and the Indian Health Service listed as partnering agencies. Finally, the Strategy provides a means to monitor, evaluate, and report on results for collaborative efforts. Agencies developed objectives and 1- and 2-year milestones for the action items in the 2010 Strategy and they submit regular progress reports to ONDCP.

The Prescription Drug Abuse Prevention Plan (the Plan) was recently released by ONDCP and complements the Strategy by outlining the administration's approach to addressing prescription drug abuse and misuse, in particular. As a result, it serves as a second interagency coordination mechanism for agencies addressing prescription drug abuse

[48]These key practices are (1) defining and articulating a common outcome; (2) establishing mutually reinforcing or joint strategies; (3) identifying and addressing needs by leveraging resources; (4) agreeing on roles and responsibilities; (5) establishing compatible policies, procedures, and other means to operate across agency boundaries; (6) developing mechanisms to monitor, evaluate, and report on results; (7) reinforcing agency accountability for collaborative efforts through agency plans and reports; and (8) reinforcing individual accountability for collaborative efforts through performance management systems. See GAO-06-15.

and also reflects the key practices for collaboration that we previously identified. The Plan establishes mutually reinforcing or joint strategies by identifying four priority areas for federal efforts to reduce prescription drug abuse and misuse—education, monitoring, proper disposal, and enforcement—and it aligns agencies' activities around these four areas. For instance, the Plan calls for federal agencies and private stakeholders to work together to develop evidence-based public education campaigns about appropriate use, secure storage, disposal, and abuse of prescription drugs. Like the Strategy, the Plan also provides a means to monitor, evaluate, and report on results. ONDCP asked agencies to submit implementation plans with objectives and 1- and 2-year milestones and to provide progress reports on a quarterly basis. The Plan also calls for the establishment of a Federal Council on Prescription Drug Abuse to coordinate implementation of the Plan.

Finally, the HHS Behavioral Health Coordinating Committee's Subcommittee on Prescription Drug Abuse provides a third coordination mechanism for HHS agencies and demonstrates use of the key practices for collaboration as well. For instance, the Subcommittee defines a common outcome for HHS agencies by identifying five goals related to prescription drug abuse and organizing its activities around these goals.[49] The Subcommittee also provides a means to monitor and report on progress to HHS leadership. Agency officials report on their activities related to prescription drug abuse and misuse to the Subcommittee co-chairs, who then provide updates to HHS leadership.

Agencies have begun using these coordination mechanisms, or augmenting existing coordination efforts, within recent years. Beginning in 2009, ONDCP began using a more collaborative process for developing the Strategy, convening a Demand Reduction Interagency Working Group. The working group brought together subject experts from drug control agencies to provide input on the development of the Strategy and

[49]The five goals are (1) improve the federal surveillance capacity for pharmaceutical abuse; (2) improve clinical outcomes for substance abusers by increasing access to prescription drug monitoring program data by clinicians in a timely manner and across state boundaries; (3) reduce the number of opioid overdose deaths by identifying and implementing effective secondary prevention strategies; (4) collaborate on the development of educational materials for health care providers, patients, parents, and communities at large to address the appropriate use of prescription pharmaceuticals and reduce their misuse and abuse; and (5) implement standards for electronic medical records to increase the identification of pharmaceutical abuse routinely in medical care.

DEA, FDA, HRSA, NIH, and SAMHSA all participated. Officials from multiple agencies indicated that this process was more interactive than in years past. The 2010 Strategy also utilized a new approach by outlining specific action items and developing a system to monitor agency progress toward objectives. ONDCP also released the Plan in April 2011 and agency officials described the process for developing the Plan as collaborative. One official described the amount of brainstorming between ONDCP and agencies in order to develop the Plan as "unprecedented." Finally, the Subcommittee on Prescription Drug Abuse was formed in the summer of 2010. Officials explained that the Subcommittee provides a more regular and formal means of coordination, whereas prior efforts to coordinate within HHS were more irregular and informal. For instance, the Subcommittee helped institutionalize relationships among officials who work on prescription drug abuse and misuse across HHS. Officials noted that although they were previously aware of subject experts at other agencies, they now work together on related tasks through the Subcommittee and therefore have formal working relationships which they can draw on to work through issues. Subcommittee members added that they use their meetings to share programming information. For instance, prior to convening the Subcommittee, NIH officials told us that they were not fully aware of all of the prescriber education efforts across HHS agencies. Now, officials have created a group through the Subcommittee to catalogue related prescriber education programs.

While officials from each agency we spoke with said that these coordination mechanisms were working well, ONDCP and other agency officials indicated that they were aware of the potential for creating too many coordinating bodies. Though the Strategy's Demand Reduction Interagency Working Group, the Plan's new Federal Council on Prescription Drug Abuse, and the HHS Subcommittee on Prescription Drug Abuse may have membership from many of the same agencies, officials said that they felt that they had not reached the point of too much coordination, noting that current coordination efforts were effective in terms of facilitating information sharing and avoiding overlapping programming among agencies.

Federal Agencies Have Missed Opportunities to Leverage Resources among Efforts with Similar Goals

Although agencies have increased their coordination efforts in recent years, they have missed opportunities to leverage resources—a key practice for effective coordination—among similar education efforts targeting teens, which may have resulted in lost opportunities to obtain additional benefits through coordination. At least four teen initiatives—*Just Think Twice*, *NIDA for Teens*, the *National Youth Anti-Drug Media*

Campaign, and *Not Worth the Risk*; *Even if it's Legal*—have obtained feedback from teens and other stakeholders about the features of and messages for educational efforts about prescription drug abuse and misuse that was not shared. For instance, NIH formed a Teen Advisory Group to pretest their messages and also seeks input from local high school students, including groups such as Students Against Destructive Decisions. These focus groups revealed information that could be useful to other teen education efforts, addressing topics such as web and materials design, video content, language and terminology, and messaging. For instance, one focus group revealed that trying to imitate the layout of social networking sites (e.g., MySpace or Facebook) did not make sites more appealing to teen users.

DEA, ONDCP, and SAMHSA also get feedback on their teen education efforts. DEA gets feedback from the Drug Abuse Resistance Education—D.A.R.E.—Youth Advisory Board on content for *Just Think Twice* and also gets feedback from DEA field staff who give presentations to teens about drug abuse. DEA officials told us that the feedback on the website that they received from field staff often varies depending on the part of the country in which the field staff give presentations in schools, with field staff in San Diego reporting different successful approaches than those in Miami. ONDCP also pretests content and features with teens. One lesson derived from ONDCP's pretesting efforts is that teens liked the option to view content posted by their peers on the website, such as photos or stories. Finally, SAMHSA gets input from professional and student groups through its Project Advisory Team for *Not Worth the Risk*; *Even if it's Legal*. For instance, the Project Advisory Team advised SAMHSA on a number of issues related to addressing prescription drug abuse and misuse among teens, including the importance of acknowledging and validating common stressors teens face in order to establish credibility and to create an opportunity to address alternative coping skills.

While each of these agencies obtained feedback on the messages for and features of similar initiatives, agencies did not share the results of their feedback sessions or pretesting efforts with officials from other agencies who work on similar programs. Officials said they did not share the feedback they received for two reasons. First, NIH, DEA, and SAMHSA officials said that they were never asked to do so by other agencies with similar education efforts. Second, ONDCP officials said that they felt that the results of their pretesting would not be useful for other educational efforts. Nonetheless, one official acknowledged that sharing findings from pretesting efforts and other feedback sessions could have

been useful when developing the content and messages for their educational effort.

NIH officials said that there are two coordination mechanisms through which they could share information among agencies involved with educational efforts in the future. In addition to its Subcommittee on Prescription Drug Abuse, the HHS Behavioral Health Coordinating Committee also has a Communications Subcommittee and NIH officials said that they can use the Communications Subcommittee to share information about the development of educational efforts among HHS agencies. NIH officials said that they also have the opportunity to share information with agencies outside of HHS through weekly phone calls that ONDCP facilitates with communications staff from DEA, NIH, ONDCP, and SAMHSA, among other agencies.

Conclusions

Abuse and misuse of prescription pain relievers is a large and growing public health problem in the United States. Although DEA, FDA, NIH, ONDCP, and SAMHSA are engaged in multiple efforts to educate the public about prescription pain reliever abuse and misuse, there is limited evidence about how to craft effective messages about this issue. The agencies agree that education about prescription drug abuse and misuse requires a different approach than other drug prevention efforts, but there is a lack of proven strategies and messages on which agencies can model their own educational efforts to ensure that such efforts will have the desired outcome. In the absence of a strong evidence base, establishing outcome metrics is an especially important key practice to incorporate into the development of educational efforts because outcome metrics provide feedback on the effectiveness of agencies' efforts at preventing prescription pain reliever abuse and misuse. However, seven of the nine public education efforts that we reviewed did not assess program outcomes. This leaves federal agencies with limited knowledge as to whether such efforts are effective.

Given these challenges, there is much to be gained from continued and robust coordination among similar education efforts about prescription pain reliever abuse and misuse. In its role as a coordinating body for federal drug control efforts, ONDCP is uniquely situated to ensure that federal educational efforts are not duplicative and are effectively coordinated. DEA, NIH, SAMHSA, and ONDCP operate similar educational initiatives—including three websites and a brochure series—targeting teens. While agency officials told us that the similar educational efforts we reviewed are reinforcing, it is important that agencies continue

to coordinate their efforts as additional planned educational efforts are implemented in order to avoid duplicative programming. Although agencies involved in educating the public have recently increased their coordination efforts, they have missed opportunities to share the results of teen and stakeholder feedback among similar efforts—a key practice for effective coordination. In developing their educational efforts, DEA, NIH, ONDCP, and SAMHSA obtained feedback from their target audience and other stakeholders that could be useful for other agencies to consider in relation to their own efforts. Although each educational effort has unique features, comments from focus group participants and other stakeholders could produce lessons that other agencies could have drawn on if summaries of those comments had been made available to other agencies to review. As additional public education efforts are developed agencies will need to leverage resources, including sharing lessons learned from the development and implementation of existing educational efforts, to ensure that they make the best use of limited resources.

Recommendations for Executive Action

In order to ensure that federal efforts to prevent the abuse and misuse of prescription pain relievers are an effective and efficient use of limited government resources, we recommend that the Director of ONDCP take the following three actions:

- Establish outcome metrics and identify resources for conducting outcome evaluations for the national education campaigns about prescription drug abuse and safe storage and disposal proposed in the Prescription Drug Abuse Prevention Plan.
- Develop and implement a plan to evaluate outcomes from the proposed national education campaigns.
- Ensure that federal agencies undertaking similar educational efforts leverage available resources and use coordination mechanisms to share information on the development of their efforts.

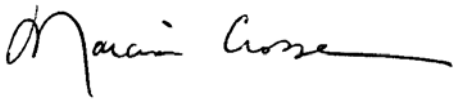
Agency Comments and Our Evaluation

We provided a draft of this report to ONDCP, the Department of Justice, and HHS for their review and comment. In written comments, reproduced in appendix VI, ONDCP did not explicitly agree or disagree with our recommendations, but noted that it will continue to work for improved coordination of prescription drug abuse educational efforts and evaluation of outcomes. ONDCP also stated that the prescription drug abuse

educational efforts that we reviewed target different populations and address different messages, and suggested that we explain the differences among these efforts in our report. We revised our report to include an additional reference to our detailed descriptions of the various educational efforts we reviewed, which explain the scope, target audiences, and mediums used among the educational efforts. We also included additional information about the size and scope of ONDCP's *National Youth Anti-Drug Media Campaign*. ONDCP, DEA, and HHS also provided technical comments, which we have incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time we will send copies of this report to the Director of the Office of National Drug Control Policy, the Attorney General, and the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at 202-512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VII.



Marcia Crosse
Director, Health Care

Appendix I: Abuse-Deterrent Formulations of Prescription Pain Relievers

In order to help address the abuse and misuse of prescription pain relievers, drug manufacturers are developing formulations of these drugs that are specifically designed to deter abuse.[1] We are presenting information on different types of abuse-deterrent formulations of prescription pain relievers, whether they are being used in fiscal year 2011, and challenges related to these products. This appendix is based on our review of scientific literature and Food and Drug Administration (FDA) and manufacturer documents, as well as interviews with FDA officials and representatives of Purdue Pharma L.P., the manufacturer of OxyContin.

Manufacturers of prescription pain relievers have long sought to achieve a balance between creating drugs that are effective for therapeutic use while minimizing their potential for abuse. The scientific articles noted that, in general, abusers seek out drugs that can be smoked, snorted, or taken intravenously, thus providing a more rapid onset of the effects of the drug. Therefore, some manufacturers of prescription pain relievers have focused on making their products tamper resistant, so that the physical or chemical makeup or delivery system of the drug cannot be altered, with the goal of preventing users from accessing and abusing the active ingredient.

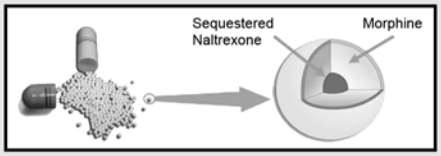
Types of Abuse-Deterrent Formulations

There are five different types of abuse-deterrent formulations manufacturers have developed to reduce tampering and abuse of their products, though some drugs may incorporate multiple types. Some of these abuse-deterrent formulations are already being utilized in prescription pain relievers, others are being incorporated into pain relievers that are in the process of being developed, and others have

[1]Throughout this report we use the term “abuse and misuse” to collectively refer to the three types of inappropriate use that are most frequently incorporated into agencies definitions. However, in this appendix, because the literature we reviewed used the term “abuse,” we use that term alone.

Example of an Abuse-Deterrent Formulation: Embeda

Embeda is a prescription pain reliever that was designed from inception to be abuse-deterrent. Embeda employs an agonist-antagonist combination in which the antagonist—a substance that counteracts the opioid (in this case, naltrexone)—is embedded within the center of the active ingredient, or agonist (in this case, morphine).



Source: Alpharma Pharmaceuticals, LLC, a subsidiary of Pfizer.

When administered orally, as prescribed, the naltrexone remains pharmacologically inert and the morphine provides pain relief for up to 24 hours. If the capsule is chewed, crushed or dissolved, the naltrexone is activated, inhibiting the psychoactive effect of the morphine and thus making it less attractive to abusers.

Source: GAO and Alpharma Pharmaceuticals, LLC.

been used in other types of products, but not prescription pain relievers. In general, the different classifications include:[2]

- Physical/Chemical Barriers – Such barriers impart physical or chemical properties to a drug so that it resists manipulation via chewing, grinding, and mixing with alcohol or other common solvents, thus making extraction of the active ingredient difficult. A reformulated version of the prescription pain reliever OxyContin that is currently marketed uses this type of barrier to deter abuse.

- Agonist/Antagonist Combinations – Combinations of agonists and antagonists, which mitigate, block, or reverse the effect of the agonist (the opioid), if manipulated. Two prescription pain relievers that were marketed in fiscal year 2011 use this barrier to deter abuse: Talwin Nx and Embeda (see sidebar).[3]

- Aversion – A combination of substances designed to produce an unpleasant effect if a tampered form is ingested or a higher dosage than directed is used. For example, one formulation designed in the past added niacin to a prescription pain reliever to dissuade abusers because, in high doses, niacin causes headache, sweating, chills, flushing, and general discomfort. While at least one manufacturer has designed prescription pain relievers using the aversion method of

[2]To develop the list of types of abuse-deterrent formulations, we conducted a literature review. The following articles were particularly useful in defining the five types of abuse-deterrent formulations, and challenges associated with them, referenced here: J.J. Coleman, C.R. Schuster, and R.L. DuPont, "Reducing the Abuse Potential of Controlled Substances," *Pharmaceutical Medicine*, vol. 24, no. 1 (2010); J.J. Coleman, P.B. Bensiger, M.S. Gold, D.E. Smith, R.P. Bianchi, and R.L. DuPont, "Can Drug Design Inhibit Abuse?" *Journal of Psychoactive Drugs*, vol. 37, no. 4 (2005); N. Katz, "Abuse-deterrent Opioid Formulations: Are They a Pipe Dream?" *Current Rheumatology Reports,* vol. 10 (2008); J.P. Schneider, M. Matthews, and R.N. Jamison, "Abuse-Deterrent and Tamper-Resistant Opioid Formulations: What is their Role in Addressing Prescription Opioid Abuse?" *CNS Drugs*, vol. 24, no. 10 (2010); L. Webster, "Update on Abuse-Resistant and Abuse-Deterrent Approaches to Opioid Formulations," *Pain Medicine*, vol. 10, supplement 2 (2009); and N. P. Katz et. al., "Challenges in the Development of Prescription Opioid Abuse-deterrent Formulations," *Clinical Journal of Pain*, vol. 23, no. 8 (2007).

[3]One additional product, Suboxone, uses an agonist/antagonist combination to deter abuse, but this drug is indicated for the treatment of opioid dependence, not the treatment of pain. In addition, though it was marketed earlier in the year, in March 2011 Embeda was voluntarily recalled because a prespecified stability requirement was not met during routine testing. As of October 2011 the recall was still in effect, but Pfizer officials said they hope to return the product to market once the stability issue has been resolved.

abuse-deterrence in the past, FDA officials told us that no such prescription pain relievers are currently marketed.[4]

- Delivery System – The method of delivery or drug release design can be used as an abuse deterrent. For example, a depot injection—an injection that releases its active ingredient over a sustained period—or subcutaneous implant can be more difficult to tamper with. FDA officials told us that they were not aware of any prescription pain relievers currently marketed that were designed to be abuse-deterrent by way of a delivery system.

- Prodrug – Prodrug compounds must undergo biotransformation to activate the active ingredients. For example, they may be formulated so that they are only activated if they are metabolized in the digestive system, so that the drug will not be activated if, for example, it is taken intravenously. FDA officials told us that they were not aware of any prescription pain relievers currently marketed that were designed to be abuse-deterrent by way of a prodrug design.

Challenges Related to Abuse-Deterrent Prescription Pain Relievers

Manufacturers face a number of challenges related to abuse-deterrent formulations of prescription pain relievers. First, there are technical challenges in developing formulations of prescription pain relievers that deter abuse, but still have the intended effect of providing pain relief. For example, it took Purdue Pharma L.P. approximately 9 years to develop a reformulated version of OxyContin that both effectively provided pain relief and displayed abuse-deterrent properties. Another challenge for manufacturers relates to the extent to which they will be allowed to market their new products as reducing or deterring abuse. FDA officials told us that until postmarketing studies demonstrate a product's effectiveness in reducing abuse in the general population, manufacturers cannot market their products accordingly, but they are allowed to make marketing claims based on the product's abuse-deterrent features as demonstrated in clinical trials. For example, Embeda's label includes information on the results of clinical trails testing its abuse-deterrent features, but also states that the abuse-deterrent characteristics of the product "have not been shown to reduce the abuse liability of Embeda."

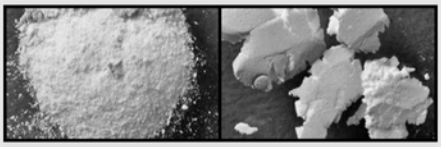
[4]Though no prescription pain relievers that use aversion alone are currently marketed, in June 2011 FDA approved the prescription pain reliever Oxecta, which Pfizer officials said is designed to use a combination of physical/chemical barriers and aversion to deter abuse.

Finally, a manufacturer indicated that insurers may be reluctant to provide coverage for abuse-deterrent formulations of drugs when less expensive, nondeterrent alternatives are available and that this could minimize their usage and ultimately, their impact on abuse in the general population.

FDA faces a number of challenges related to approving and assessing the safety and effectiveness of abuse-deterrent formulations of prescription pain relievers. According to FDA officials, one of these challenges is balancing the abuse-deterrent properties of a drug with its safety in the general patient population. Another challenge for FDA is developing standards and methods for determining if the products are, in fact, abuse deterrent. FDA officials told us that the agency is currently developing guidance for manufacturers on the development of abuse-deterrent formulations and on the postmarket assessment of their performance. However, officials told us that standard guidance is difficult to develop because potential types of abuse-deterrent formulations are so varied that the criteria used to evaluate one drug may not be applicable for another. FDA indicated that it requires manufacturers of prescription pain relievers that want to make abuse-deterrent claims about their products to conduct postmarket epidemiological studies to assess the effectiveness of their drugs in deterring abuse in the general population. However, in developing methods for assessing the effectiveness of a particular drug on deterring abuse, FDA officials told us that they, like manufacturers, are challenged by limitations in available data. FDA officials said that consistent and clear definitions of abuse across data sources are lacking and that most data sources with information on prescription pain reliever abuse do not distinguish between products from different manufacturers, which can make it difficult to assess the effectiveness of a specific drug in deterring abuse. For example, data sources that measure abuse and its consequences may not distinguish between OxyContin and other drugs that contain oxycodone. Further, FDA is challenged in determining what degree of decrease in some measurable outcomes of abuse would be sufficient to label a drug as being able to reduce actual abuse.

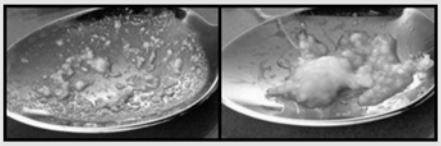
Example of an Abuse-Deterrent Formulation: OxyContin

OxyContin is a prescription pain reliever that was reformulated to be abuse deterrent. The extended-release mechanism of the original formulation of OxyContin could be overcome by crushing the tablet to release a large amount of oxycodone. Purdue Pharma L.P. reformulated OxyContin to use physical/chemical barriers to deter abuse by mixing the active ingredient—oxycodone—with polyethylene oxide, increasing the hardness of the tablet and rendering it more difficult to crush.



Source: Purdue Pharma L.P.

If the tablet is successfully physically altered through crushing and mixing with a liquid, the result is a viscous gel that is difficult to take up in a syringe.



Source: Purdue Pharma L.P.

Note: According to the manufacturer, the reformulated OxyContin on the right cannot be drawn up into a syringe.

FDA officials told us that only limited, preliminary data about the impact of the reformulated OxyContin on abuse are available (the reformulated OxyContin has only been in widespread use since late 2010). These preliminary data have been promising, but officials were uncertain as to whether any decreases in OxyContin abuse would hold over the long term.

Source: GAO and Purdue Pharma L.P.

Finally, there are inherent challenges related to abuse-deterrent formulations of prescription pain relievers and their overall impact on abuse. First, a drug that deters one type of abuse might not necessarily deter another type of abuse. For example, the new formulation of OxyContin is designed to deter abuse via injection or snorting (see sidebar), but is not a deterrent for those who abuse the product via oral ingestion of whole tablets. A related challenge is that while technology may deter the abuse of one particular prescription pain reliever, an abuser may instead seek another prescription pain reliever (either a different formulation of the same pain reliever or a different pain reliever altogether) that is not designed to be abuse deterrent. An abuser may even seek out another opioid, such as heroin.

Appendix II: DEA Quotas for Controlled Substances

As part of its responsibilities related to enforcing the Controlled Substances Act, the Drug Enforcement Administration (DEA) sets limits, called quotas, on the quantity of schedule I and II controlled substances that may be produced in the United States in any given calendar year.[1] Quotas are a component of the closed system of distribution that exists under the Controlled Substances Act. In this appendix, we present an overview of the closed system, as well as information on the three types of quotas: aggregate production quotas (APQ), bulk manufacturing quotas, and procurement quotas. The information in this appendix is based on our review of DEA documents and interviews with DEA officials.

Closed Distribution System

Under the Controlled Substances Act, DEA maintains a closed system requiring any person who manufactures, dispenses, imports, exports, or conducts research with controlled substances to register with DEA (unless exempt),[2] periodically inventory all stocks of controlled substances,[3] provide effective security controls,[4] and maintain records to account for all controlled substances manufactured, imported, exported, received, distributed, or otherwise disposed of.[5] DEA officials said that the closed system, including quotas, is designed to reduce the amount of pharmaceuticals that are diverted for illicit purposes, while also ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical needs. They said that both legitimate and illegitimate users of prescription pain relievers often acquire the drugs from the same source—from doctors or other practitioners who prescribe or dispense them. For example, diversion of prescription pain relievers may occur through methods such as doctor shopping, thefts from medicine cabinets, improper prescribing, and forged prescriptions.

[1]Controlled substances used in the manufacture of prescription pain relievers include codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

[2]21 C.F.R. § 1301.11(a) (2011) (researchers are defined as manufacturers for purposes of this provision) (exemptions, such as institutions operated by the U.S. military, provided for at 21 C.F.R. §§ 1301.22 et seq. (2011)).

[3]*See* 21 C.F.R. §§ 1304.3, 1304.11 (2011).

[4]*See* 21 C.F.R. § 1301.71 (2011).

[5]*See* 21 C.F.R. § 1304.22 (2011).

According to DEA, quotas are a tool used at the beginning of the closed system to manage and prevent diversion of controlled substances, such as the substances used to make prescription pain relievers, during their legitimate scientific, medical, and industrial applications. While DEA is authorized to control the overall amount of controlled substances available, according to DEA officials, it is ultimately for practitioners and their regulating bodies to ensure that these substances are prescribed appropriately. While officials said that they do seek to account for known diversion when setting APQs, they said that establishing quotas based on known diversion for the purpose of reducing the availability of prescribed drugs will not appreciably affect diversion at the retail level and may prevent legitimate patients from having access to medication for legitimate medical needs.

Aggregate Production Quotas

DEA officials said that the APQ is the first type of quota that DEA sets for each year.[6] The APQ specifies the maximum amount of each basic class of controlled substance listed in schedule I or II that can be produced for specified needs in the United States in a given year, thus limiting the amount of bulk raw materials available for use in the manufacture of prescription pain relievers. For example, methadone is a controlled substance that is used in the manufacture of drugs for addiction treatment as well as in the manufacture of the prescription pain relievers Dolophine and Methadose, and multiple generic equivalents. In 2010, DEA set the final APQ for methadone at 20,000,000 grams. Therefore, this is the maximum amount of methadone that could be available for manufacturing addiction treatment drugs and prescription pain relievers that use this substance, as well as for other authorized uses, in the United States in 2010.

DEA officials said that they consider data from many sources when determining the APQ, including estimates of the legitimate medical need for each substance from FDA, estimates of retail consumption based on prescriptions dispensed from IMS Health, companies' production history and forecasts, data from DEA's own internal system for tracking controlled substances transactions, and past quota histories for each

[6]*See* 21 C.F.R. § 1303.11(a) (2011).

substance.[7] DEA officials said that DEA scientists draw on their professional expertise and experience when considering all available data to recommend the appropriate APQ for a substance. DEA then publishes the proposed APQ for each substance for the following calendar year in the *Federal Register*, and, after receiving and reviewing comments, DEA publishes a final order determining the APQ for that year. DEA can revise the APQ midyear if legitimate changes in U.S. manufacturing requirements, such as increased sales or exports, new manufacturers entering the market, new product development, or product recalls, warrant a change. For example, in 2010, DEA revised the APQ for methadone, decreasing it from an initial APQ of 25,000,000 grams to the revised APQ of 20,000,000 grams.

Officials said that when determining the APQ they also consider losses of controlled substances that occur through diversion activities by considering known and reported thefts and losses, case seizures, and information from national databases of drug evidence, such as analysis from DEA and other forensic laboratories and law enforcement entities. DEA can reduce the APQ based on the quantity of seized or diverted material. The APQ may also be decreased because of DEA enforcement actions that impact sales data, such as by shutting down rogue pain clinics, thus reducing the amount of controlled substances purchased by such entities. DEA officials said that because sales data are one factor considered in determining APQ, these actions may ultimately lead to a reduction in the APQ. DEA said that in rare instances the APQ may also be increased as a result of diversion activities. For example, if a large quantity of a controlled substance is stolen from a manufacturer, the APQ may need to be raised to ensure that sufficient quantities of that substance will be available to meet the nation's ongoing legitimate medical needs. When determining the following year's APQ, DEA considers such circumstances to ensure that the APQ remains at an appropriate level to meet legitimate need and may reduce the APQ in relation to the previous year's to account for the known diversion.

[7]DEA obtains data from the IMS Health National Prescription Audit. IMS Health is a private company that provides market information to the pharmaceutical and health care industries.

Bulk Manufacturing Quotas and Procurement Quotas

In addition to the APQ, DEA sets two types of quotas for individual companies: bulk manufacturing quotas[8] and procurement quotas.[9] Bulk manufacturing quotas limit the amount of a basic class of schedule I or II controlled substance that an individual company can extract or synthesize from plant material or other controlled substances. According to DEA officials, once the initial APQ for a substance for a calendar year is set by DEA, individual companies apply to DEA for bulk manufacturing quotas for specific controlled substances to produce the bulk raw materials that are used in prescription pain relievers for that same year. Officials said that separate quotas are issued for each DEA-registered facility that manufactures a controlled substance, even if the same company operates multiple manufacturing facilities. In 2010, five facilities received bulk manufacturing quotas for methadone. The quota levels ranged between 4 grams at the low end and 12,000,000 grams at the highest levels. The sum of the bulk manufacturing quotas for all companies for a particular controlled substance cannot exceed the APQ for that substance in a given year.

DEA officials said that they use a variety of data sources—including internal DEA data, IMS Health data, and data provided by the company—to determine the bulk manufacturing quota for a company. DEA's Office of Diversion Control also reviews the company for any pending administrative, civil, or criminal action. DEA officials said that DEA scientists draw on their professional expertise and experience when considering all available data to recommend an appropriate bulk manufacturing quota, which is then issued to the company by letter. Bulk manufacturing quotas can be revised through a process similar to that used in setting the initial quotas, in that a company submits an application to revise its quota and must include supporting documentation. DEA officials said that DEA does not generally initiate changes to bulk manufacturing quotas on its own.

[8]*See* 21 C.F.R. § 1303.21 (2011). Although this regulation uses the term "individual manufacturing quotas," DEA officials refer to them as "bulk manufacturing quotas." Accordingly, we use the term "bulk manufacturing quotas" throughout our discussion.

[9]*See* 21 C.F.R. § 1303.12 (2011).

DEA also establishes procurement quotas, which limit the amount of a basic class of schedule I or II controlled substance that an individual company can procure from a manufacturer of bulk raw materials in order to manufacture individual dosage units of a medicine, such as a prescription pain reliever. Individual companies must apply to DEA for procurement quotas for each specific basic class of controlled substance, and DEA officials told us that separate quotas are issued for each facility that procures a controlled substance. For example, according to DEA data, 52 facilities received procurement quotas for methadone in 2010. The quota levels ranged between 1 gram at the low end and 9,000,000 grams at the highest levels. Sometimes an individual company may be engaged in both bulk manufacturing and procurement activities for the same controlled substance. In this case, the company will apply for both a bulk manufacturing quota and a procurement quota. DEA officials said they use the same process and data sources, as described above, to determine appropriate levels for procurement quotas as for bulk manufacturing quotas.

Officials said that DEA does not always set a company's bulk manufacturing quota or procurement quota at the level the company requested. For example, if a registrant is suspected of unlawfully diverting controlled substances, DEA will take this factor into consideration when determining whether to grant or deny the quota request. In addition, DEA may set the quota lower than requested if a company has set its quota request based on projected sales figures, which can inflate the quantity of quota requested, rather than on actual sales figures. DEA officials said that the agency uses actual sales and inventory figures in their evaluation of bulk manufacturing or procurement quota applications, and they grant quotas in line with legitimate medical need. In the past, we have reported that DEA cited difficulties in determining an appropriate level for quotas to ensure that adequate quantities are available for legitimate medical need, as there are not direct measures available to establish legitimate medical need. DEA officials said that, based on the available prescription and sales data, there is no method to calculate which prescriptions are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice and which are not. They noted that if DEA were to reduce a quota level by some percentage to account for estimated illegitimate prescriptions or to otherwise reduce a quota by an amount estimating how much of the substance is abused and misused, the action would only reduce the total amount of substance available for dispensing, and would not affect to whom or in what quantities the drugs are prescribed or dispensed. Therefore, DEA officials said that a reduction in the supply of a drug based upon estimated illegitimate

prescriptions or abuse and misuse could result in a shortage of the substance for legitimate purposes, while not affecting illicit demand for the substance at all. As a result, officials said that the agency does not use the quota process as a tool to reduce demand or to help prevent abuse and misuse of prescription pain relievers.

Appendix III: Objectives, Scope, and Methodology

This report (1) describes recent national trends in prescription pain reliever abuse and misuse, (2) describes how federal agencies are educating prescribers about prescription pain reliever abuse and misuse, (3) assesses the extent to which federal agencies follow key practices for developing public education efforts about prescription pain reliever abuse and misuse, and (4) identifies educational efforts that use similar strategies and assess how agencies coordinate those efforts. To conduct this work we interviewed officials and reviewed documents, as described below for each objective. In addition, to gain context on the challenge of addressing the problem of abuse and misuse of prescription pain relievers while ensuring access to these pain relievers for legitimate medical use, we interviewed officials from the American Pain Foundation, and Purdue Pharma L.P., the manufacturer of the prescription pain reliever OxyContin.

To describe recent national trends in prescription pain reliever abuse and misuse, we interviewed officials from the Centers for Disease Control and Prevention (CDC), DEA, FDA, the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA), the Office of National Drug Control Policy (ONDCP), and the Substance Abuse and Mental Health Services Administration (SAMHSA). We also conducted a literature review to identify relevant data sources and explanations for trends in prescription pain reliever abuse and misuse and analyzed data related to prescription pain reliever abuse and misuse from several data sources representative of the U.S. population aged 12 years and older. We included data in our review from the Drug Abuse Warning Network (DAWN), the National Vital Statistics System (NVSS), the Treatment Episode Data Set (TEDS), and the National Survey on Drug Use and Health (NSDUH). We selected these four data sources because they are the data sources that the agencies we interviewed use for monitoring trends in prescription pain reliever abuse and misuse, and because they

are nationally representative.[1] We analyzed data for calendar years 2003-2009, the most recent years for which data from at least three data sources were available.

DAWN, a public health surveillance system operated by SAMHSA, provides annual national estimates of drug-related emergency department visits, including visits involving the abuse or misuse of prescription pain relievers.[2] These national estimates are produced from data DAWN collects from a national sample of general, nonfederal hospitals operating 24-hour emergency departments. For each sample hospital, a trained DAWN reporter conducts a retrospective review of a random sample of emergency department medical records to identify emergency department visits that involved recent drug use. The number of visits may not directly represent the number of individuals who have visited emergency departments in a given year, since some patients may have more than one visit in a year. Emergency department medical records may vary in specificity and detail. For example, prescription pain reliever abuse and misuse may be overreported if the medical record is unclear about whether an individual was abusing or misusing a prescription pain reliever, or taking it as prescribed while abusing or misusing another drug. Conversely, prescription pain reliever abuse and misuse may be underreported if the abuse or misuse of a regularly prescribed prescription pain reliever is not recognized or documented by the clinician. Because of changes to the DAWN methodology for 2004, we were not able to look at trends in DAWN data prior to that year.

[1]Although all of these data sources are nationally representative, they represent slightly different populations. For example, active military personnel are included to different extents in each of the data sources. NSDUH excludes active military personnel from its sample population. NVSS includes deaths of active military personnel, though it does not include overseas military deaths. DAWN and TEDS do not explicitly exclude active military personnel, though emergency department visits and treatment admissions at military-funded facilities are not included in these data sets. A DAWN official said that he therefore expects the number of individuals in the military included in these data to be low because these individuals likely use military-funded services. SAMHSA reports also note that the excluded populations may have different rates of prescription pain reliever abuse and misuse than the general public as a whole.

[2]Data on emergency department visits related to abuse and misuse may include cases of malicious poisoning, which is not included in our definition of abuse and misuse. However, SAMHSA officials told us that there are very few cases of malicious poisoning each year.

NVSS, operated by CDC, receives and compiles data from all death certificates filed in the United States each year, including deaths involving prescription pain relievers. The causes of death section of the death certificates are completed by local medical examiners, coroners, or attending physicians, and the information is then coded by the states, or in some cases by CDC, and submitted to CDC, where it is further processed and coded, if necessary.[3] NVSS data on overdoses includes both the mechanism of injury leading to death (such as poisoning by certain substances) and the manner or intent, including unintentional, suicide, homicide, undetermined, and legal intervention or war. Although CDC sometimes reports on all manners of overdose deaths combined, we focused only on unintentional deaths because it matches most closely with our definition of abuse and misuse.[4] CDC officials said that some jurisdictions may undercount unintentional overdose deaths involving prescription pain relievers because of inconsistent use of toxicological lab tests, which may result in listing a death as a drug overdose death with no drugs specified on the death certificate, and other inconsistencies among jurisdictions, such as how they determine whether deaths are unintentional.[5] NVSS data for 2009 were not published in time for inclusion in this report.

TEDS, compiled by SAMHSA, gathers data on admissions to substance abuse treatment facilities nationwide, including data about the substances being abused by the person being admitted to treatment, such as prescription pain relievers. TEDS does not include all admissions to substance abuse treatment. It includes admissions at facilities that are licensed or certified by the state substance abuse agency to provide substance abuse treatment (or are administratively tracked for other reasons). In general, facilities reporting TEDS data are those that receive state alcohol or drug agency funds (including federal block grant funds) for the provision of alcohol or drug treatment services. Data about

[3]NVSS data are coded in accordance with the International Classification of Diseases, Tenth Revision.

[4]Data on unintentional overdose deaths may include deaths that are not related to abuse and misuse, such as cases of unintentional ingestion of a prescription pain reliever. However, a CDC official said that these cases likely comprise only a small portion of unintentional overdose deaths.

[5]According to CDC analyses, in 2006, more than 20 percent of all drug overdose deaths did not specify the drugs involved.

admissions are initially gathered by the facilities themselves and then collected by states and transmitted to a national data center. The number of admissions does not directly represent the number of individuals who have been admitted to treatment in a given year, because an individual admitted to treatment twice within a calendar year would be counted as two admissions. While treatment facilities included in TEDS account for a significant portion of treatment admissions nationwide, SAMHSA officials told us that no nationwide estimates are available of admissions to private, for-profit facilities or on the number of individuals being treated for substance abuse by physicians who have been approved to independently treat opioid addiction in an office-based setting. Therefore, SAMHSA officials told us that TEDS data underreport the number of individuals seeking treatment for prescription pain reliever abuse and misuse in the United States, especially among populations that have the resources to seek treatment from private facilities or physicians. In addition, the facilities and populations included in the data each state reports to TEDS are affected by state regulations and funding priorities. For example, some states report data from hospital- and prison-based treatment facilities, while others do not. Finally, some states may target certain populations, such as teenagers, with their limited funds for addiction treatment, meaning that these populations may be more heavily represented in the data from those states.

NSDUH, an annual survey sponsored by SAMHSA, provides annual national estimates about the use of illicit drugs, alcohol, and tobacco in the civilian, noninstitutionalized population of the United States aged 12 years old or older, including estimates about the abuse and misuse of prescription pain relievers.[6] These national estimates are produced from data NSDUH collects through a national household survey, which involves in-person interviews with sampled respondents. SAMHSA officials reported that NSDUH may underestimate the extent of drug use, including prescription pain reliever abuse and misuse, both due to underreporting by surveyed individuals and because the sample may not include some individuals at high risk for drug use. We have reported on these limitations in the past.[7] While NSDUH incorporates strategies

[6]Specifically, NSDUH gathers information on the nonmedical use of prescription pain relievers, which it defines as the use of prescription pain relievers without a prescription of the individual's own or simply for the experience or feeling the drugs caused.

[7]GAO, *Drug Use Measurement: Strengths, Limitations, and Recommendations for Improvement,* GAO/PEMD-93-18 (Washington, D.C.: June 25, 1993).

intended to increase respondents' cooperation and willingness to report honestly and accurately, such as use of computer-assisted interviewing methods, it is not possible to know the extent of underreporting within NSDUH data. However, SAMHSA officials told us that when looking at trended data, underreporting is not a problem because it is assumed constant.

To assess the reliability of these data for our purposes, we reviewed related documentation and conducted interviews with knowledgeable agency officials from CDC and SAMHSA to learn about data collection, quality control, and any limitations of these data sources. We also conducted electronic and manual data testing to ensure the quality of the data. We determined that all data we assessed were sufficiently reliable to provide overall trends for the purposes of our review.

To describe how federal agencies are educating prescribers about prescription pain reliever abuse and misuse, we reviewed the 2010 National Drug Control Strategy and interviewed officials involved with federal prevention efforts to identify strategies used to educate prescribers during fiscal year 2011. We then interviewed officials from FDA, NIH, and SAMHSA and reviewed agency websites and documents to describe educational strategies used by these agencies. Because they are involved in federal prevention efforts, we also interviewed officials from DEA, the Health Resources and Services Administration (HRSA), ONDCP, and the American Medical Association about gaps in current prescriber education efforts and efforts to fill these gaps through mandatory prescriber education. We excluded agencies that support their own health care systems, such as the Bureau of Prisons, Department of Defense, Indian Health Service, and Department of Veterans Affairs, from the scope of our review as they serve special populations, rather than the general public. We also excluded educational efforts related to drug abuse treatment, including education about the use of the prescription pain relievers methadone or buprenorphine for use in the treatment of opioid addiction.

To assess the extent to which federal agencies follow key practices for developing public education efforts about prescription pain reliever abuse and misuse, we reviewed the 2010 National Drug Control Strategy and interviewed officials involved with federal prevention efforts to identify efforts to educate the general public during fiscal year 2011. We then interviewed officials from DEA, FDA, NIH, ONDCP, and SAMHSA and reviewed agency websites and documents to gather evidence about how agencies developed public education efforts and then compared the

development of these educational efforts against key practices for developing consumer education efforts from our prior work, *Digital Television Transition: Increased Federal Planning and Risk Management Could Further Facilitate the DTV Transition* (see table 3).[8] We also consulted the Department of Health and Human Services (HHS) publication, *Making Health Communications Programs Work*, for additional information about best practices for developing public education initiatives.[9] We also contacted the National Council on Patient Information and Education to gain information about best practices for public health education.

[8]GAO-08-43.

[9]U.S. Department of Health and Human Services, National Institutes of Health and National Cancer Institute, *Making Health Communication Programs Work: A Planner's Guide* (2004).

Table 3: Key Practices for Developing Public Education Efforts

Key practice	Description
Define goals and objectives	Define the goals of the communications campaign, e.g., to increase awareness or motivate a change in behavior. Define the objectives that will help the campaign meet those goals.
Analyze the situation	Analyze the situation, including any competing voices or messages, related market conditions, and key dates or timing constraints. Review relevant past experiences and examples to identify applicable "lessons learned" that may help to guide efforts.
Identify stakeholders	Identify and engage all the key stakeholders who will be involved in communications efforts. Clarify the roles and responsibilities of each stakeholder, including which entity or entities will lead overall efforts.
Identify resources	Identify available short- and long-term budgetary and other resources.
Research target audiences	Conduct audience research, such as dividing the audience into smaller groups of people who have relevant needs, preferences and characteristics, as well as measuring audience awareness, beliefs, competing behaviors, and motivators. Also, identify any potential audience-specific obstacles, such as access to information.
Develop consistent, clear messages	Determine what messages to develop based on budget, goals, and audience research findings. Develop clear and consistent audience messages; test and refine them.
Identify credible messenger(s)	Identify who will be delivering the messages and ensure that the source is credible with audiences.
Design media mix	Plan the media mix to optimize earned media (such as news stories or opinion editorials) and paid media (such as broadcast, print, or Internet advertising). Identify through which methods (e.g., advertising in newsprint ads), how often (e.g., weekly or monthly) and over what duration (e.g., 1 year) messages will reach audiences.
Establish metrics to measure success	Establish both process and outcome metrics to measure success in achieving objectives of the outreach campaign. Process metrics assure the quality, quantity, and timeliness of the contractor's work. Outcome metrics evaluate how well the campaign influenced the attitudes and behaviors of the target audience(s) that it set out to influence.

Source: GAO.

Note: See GAO, *Digital Television Transition: Increased Federal Planning and Risk Management Could Further Facilitate the DTV Transition*, GAO-08-43 (Washington, D.C.: Nov. 19, 2007).

We limited our scope to efforts that target the general public, rather than specific populations, such as educational efforts pursued by the Department of Veterans Affairs, the Department of Defense, or the Indian Health Service. We also focused on efforts that were being actively revised or disseminated during fiscal year 2011. We focused on programs that craft targeted messages about abuse and misuse, rather than efforts that strictly provide factual information, such as drug fact websites and medication guides that come with prescription drugs, since our criteria for developing consumer education efforts are only appropriate for efforts that seek to convey a particular message.

To identify educational efforts that use similar strategies and assess how agencies coordinate those efforts, we interviewed officials from DEA, FDA, HRSA, NIH, ONDCP, and SAMHSA and reviewed documents about efforts to coordinate public and prescriber education initiatives. We then assessed these coordination activities against key practices for collaboration identified in our prior work.[10] We also assessed the extent to which agencies targeted similar populations, provided similar information, and used similar strategies to educate the general public and prescribers about prescription pain reliever abuse and misuse.

We conducted this performance audit from December 2010 through December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[10]In our prior work, we identified key practices that help enhance and sustain collaboration. These key practices are (1) defining and articulating a common outcome; (2) establishing mutually reinforcing or joint strategies; (3) identifying and addressing needs by leveraging resources; (4) agreeing on roles and responsibilities; (5) establishing compatible policies, procedures, and other means to operate across agency boundaries; (6) developing mechanisms to monitor, evaluate, and report on results; (7) reinforcing agency accountability for collaborative efforts through agency plans and reports; and (8) reinforcing individual accountability for collaborative efforts through performance management systems. See GAO-06-15.

Appendix IV: Public Education Programs

We identified nine efforts in fiscal year 2011 to educate the general public about prescription pain reliever abuse and misuse (see table 4).

Table 4: Summary of Federal Efforts to Educate the General Public about Prescription Pain Reliever Abuse and Misuse

DEA	
Take Back Initiative	To promote DEA's drug collection program (National Take Back Day) and educate the public about drug disposal, DEA created web buttons, posters, brochures, billboards, and banners.
Get Smart About Drugs	A website for parents and caregivers to learn about drug abuse and to give them the tools to talk to their children about drugs. The website includes a downloadable booklet, *Prescription for Disaster: How Teens Abuse Medicine*, and educational PowerPoint presentations for community groups.
Just Think Twice	A website to educate teens about the dangers of drug abuse. It is intended to talk to teens in "their language" and give them the information they need to make informed decisions about drugs. The website also includes a teacher's guide that provides lesson plans and classroom activities about drug abuse.
Good Medicine, Bad Behavior	A museum exhibit that provides information on the history of prescription drug abuse and diversion in the United States and efforts to combat the problem through time, including the effects of prescription drugs on the body and the dangers of misuse.
FDA	
Opioid Public Service Announcements	In-store broadcast announcements and a slide presentation shown in physician waiting rooms over a 4-week period. The announcements and slides contain messages about how to properly use, store, and dispose of prescription medications.
NIH	
Heads Up: Real News About Drugs and Your Body	Heads Up is a drug education series from Scholastic and NIH for teachers and 11- to 15-year-old students with materials about drugs' effects on the brain and body. The series includes inserts in Scholastic magazines and a presence on the Scholastic website and includes materials such as teacher guides and posters.
NIDA for Teens	Launched in 2003, NIDA for Teens provides teens with science-based information about the harmful effects that prescription drug abuse and addiction have on the brain and body through a website and hard copy materials. PEERx is the prescription drug abuse component within the NIDA for Teens website.
ONDCP	
National Youth Anti-Drug Media Campaign	Aims to prevent and reduce youth drug abuse across the nation through a mass-media campaign. The Campaign targets youth, their parents and other caregivers, and community organizations through two primary brands: *Above the Influence* is the Campaign's teen brand and *Parents. The Anti-Drug* is the Campaign's brand aimed at parents, other caregivers, and community organizations. In fiscal year 2011, the Campaign targeted parents and teens with messages about prescription drug abuse and misuse on its websites.
SAMHSA	
"Not Worth the Risk; Even if it's Legal"	A series of posters and brochures released in three phases targeting teens, college students, and teen influencers with information about the dangers of prescription drug abuse.

Source: GAO review of information from DEA, FDA, NIH, ONDCP, and SAMHSA.

Appendix V: Data from Key Measures of Prescription Pain Reliever Abuse and Misuse

To determine recent trends in prescription pain reliever abuse and misuse, we analyzed trends from 2003 to 2009 in four key measures used to monitor prescription pain reliever abuse and misuse. These measures include emergency department visits (see table 5), admissions to substance abuse treatment facilities (see table 6), and unintentional overdose deaths (see table 7) involving prescription pain relievers, as well as the number of individuals who reported abusing or misusing prescription pain relievers in the past year (see table 8).

Table 5: Estimated Number of Emergency Department Visits Related to Abuse and Misuse of Prescription Pain Relievers by Age Groups with Confidence Intervals, 2004-2009

		2004	2005	2006	2007	2008	2009[a]
12-15 years	Estimate	3,517	2,983	3,669	3,967	5,904	3,271
	Confidence Interval[b]	1,980 - 5,054	1,653 - 4,313	2,147 - 5,191	1,974 - 5,961	1,111- 10,696	1,391 - 5,151
16-19 years	Estimate	12,536	13,283	17,401	20,330	23,439	27,385
	Confidence Interval[b]	8,994 - 16,079	9,636 - 16,930	14,117 - 20,685	14,143 - 26,517	16,195 - 30,682	19,923 - 34,846
20-29 years	Estimate	43,912	60,074	70,763	81,318	117,744	134,682
	Confidence Interval[b]	31,501 - 56,322	45,911 - 74,237	56,519 - 85,007	62,892 - 99,744	65,024 - 170,463	79,592 - 189,771
30-39 years	Estimate	50,875	52,656	58,193	68,229	85,801	102,939
	Confidence Interval[b]	40,974 - 60,776	41,247 - 64,064	48,767 - 67,620	53,924 - 82,533	66,713 - 104,889	67,083 - 138,796
40-49 years	Estimate	51,542	63,789	71,742	81,724	95,991	98,454
	Confidence Interval[b]	39,342 - 63,742	50,548 - 77,029	63,385 - 80,099	66,827 - 96,621	74,972 - 117,010	78,221 - 118,686
50-59 years	Estimate	24,827	37,867	39,993	50,778	59,287	77,368
	Confidence Interval[b]	18,353 - 31,301	28,792 - 46,942	33,819 - 46,166	41,885 - 59,670	47,981 - 70,593	63,016 - 91,720
60+ years	Estimate	14,950	18,505	22,310	27,403	39,928	45,852
	Confidence Interval[b]	9,777 - 20,123	12,911 - 24,099	16,812 - 27,809	21,284 - 33,521	30,285 - 49,571	36,776 - 54,929
Total (12+ years)	**Estimate**	**202,159**	**249,156**	**284,071**	**333,748**	**428,092**	**489,951**
	Confidence Interval[b]	**159,527 - 244,791**	**199,241 - 299,070**	**246,132 - 322,011**	**277,696 - 389,800**	**314,570 - 541,614**	**358,177 - 621,724**

Source: Drug Abuse Warning Network (DAWN), Substance Abuse and Mental Health Services Administration (SAMHSA).

Notes: SAMHSA defines emergency department visits related to abuse and misuse of prescription pain relievers broadly to include all visits involving nonmedical use of a prescription pain reliever (such as when a patient exceeded prescribed or recommended dose, used drugs prescribed for another individual, or was administered a drug by another person for a malicious purpose) or use of a prescription pain reliever in combination with alcohol or illicit drugs. DAWN data represent visits, not unique individuals; thus, an individual who visits an emergency department twice within a calendar year would be counted as two visits. Comparable emergency department visit estimates are not available for 2003 because changes were made that year to the data collection methodology.

[a]The change from 2004 to 2009 is statistically significant at the 95 percent confidence level for all age groups except for the 12-15 years age group.

[b]This table presents the lower and upper bounds of a 95 percent confidence level for each estimate.

Table 6: Number of Admissions to Substance Abuse Treatment Facilities for Prescription Pain Reliever Abuse and Misuse by Age Groups, 2003-2009

	2003	2004	2005	2006	2007	2008	2009
12-15 years	1,308	1,406	1,513	1,489	1,847	2,440	2,786
16-19 years	6,653	8,041	8,825	9,717	11,367	15,213	18,322
20-29 years	32,132	39,518	48,882	59,880	71,522	89,485	104,650
30-39 years	28,612	30,250	33,604	37,232	42,251	50,525	56,474
40-49 years	24,575	25,827	27,512	29,402	30,630	33,378	34,059
50-59 years	6,998	7,975	9,500	10,952	12,752	15,170	15,820
60+ years	915	1,047	1,213	1,333	1,556	1,911	2,133
Total (12+ years)	**101,193**	**114,064**	**131,049**	**150,005**	**171,925**	**208,122**	**234,244**

Source: Treatment Episode Data Set (TEDS), Substance Abuse and Mental Health Services Administration.

Note: Admissions for prescription pain reliever abuse and misuse include all admissions where methadone (not prescribed for the individual) or other non-heroin opioids were reported as primary, secondary, or tertiary substances of abuse at the time of admission. TEDS data represents admissions, not unique individuals; thus, an individual admitted to treatment twice within a calendar year would be counted as two admissions.

Table 7: Number of Unintentional Overdose Deaths Involving Prescription Pain Relievers by Age Groups, 2003-2008

	2003	2004	2005	2006	2007	2008
12-15 years	[a]	37	29	32	51	36
16-19 years	207	269	248	350	361	366
20-29 years	1,053	1,341	1,547	2,154	2,314	2,291
30-39 years	1,566	1,633	1,874	2,394	2,464	2,469
40-49 years	2,448	2,777	2,983	3,581	3,519	3,541
50-59 years	1,001	1,217	1,510	2,083	2,338	2,612
60+ years	218	267	343	392	462	562
Total (12+ years)	**6,493**[b]	**7,541**	**8,534**	**10,986**	**11,509**	**11,877**

Source: GAO analysis of National Vital Statistics System multiple cause of death mortality files, Centers for Disease Control and Prevention.

Notes: Deaths resulting from unintentional overdoses of prescription pain relievers are defined as those with an underlying cause of death of poisoning (International Classification of Diseases, Tenth Revision (ICD-10) code of X40-X49) and any mention of ICD-10 codes T40.2, T40.3, or T40.4 as a multiple cause. These data do not include deaths in which drugs are present but the cause of death was determined to be something other than poisoning, such as cancer or motor vehicle traffic crashes. Data represents U.S. residents only. Unintentional overdose deaths data from 2009 were not published in time for this report.

[a]Fewer than 20 deaths. Does not meet standards of reliability or precision.

[b]The total for 2003 does not include deaths of individuals aged 12-15 years, because there were fewer than 20 deaths in this age group.

Table 8: Estimated Number of Individuals Who Reported Abusing or Misusing Prescription Pain Relievers in the Past Year by Age Groups with Confidence Intervals, 2003-2009 (in Thousands)

		2003	2004	2005	2006	2007	2008	2009
12-15 years[a]	Estimate	927	933	797	879	786	750	772
	Confidence Interval[b]	851 - 1,008	855 - 1,017	725 - 875	803 - 963	712 - 868	679 - 829	701 - 850
16-19 years	Estimate	2,152	2,136	2,169	2,151	2,095	1,981	2,005
	Confidence Interval[b]	2,025 - 2,285	2,009 - 2,269	2,044 - 2,300	2,025 - 2,283	1,964 - 2,233	1,853 - 2,116	1,887 - 2,130
20-29 years[a]	Estimate	3,797	3,804	3,943	4,341	4,049	4,136	4,306
	Confidence Interval[b]	3,560 - 4,048	3,563 - 4,060	3,690 - 4,212	4,062 - 4,637	3,802 - 4,309	3,874 - 4,413	4,031 - 4,597
30-39 years	Estimate	2,128	1,923	2,107	2,151	2,293	1,962	2,135
	Confidence Interval[b]	1,869 - 2,421	1,686 - 2,192	1,843 - 2,405	1,897 - 2,437	2,007 - 2,617	1,710 - 2,249	1,870 - 2,436
40-49 years	Estimate	1,815	1,703	1,566	1,974	1,767	1,792	1,645
	Confidence Interval[b]	1,541 – 2,135	1,468 - 1,973	1,329 - 1,843	1,701 - 2,288	1,536 - 2,031	1,552 - 2,067	1,410 - 1,917
50-59 years[a]	Estimate	514	590	876	882	1,070	759	1,193
	Confidence Interval[b]	350 - 754	419 - 830	641 - 1,195	671 - 1,157	796 - 1,435	558 - 1,030	921 - 1,543
60+ years	Estimate	338	167	358	272	406	506	349
	Confidence Interval[b]	192 - 593	97 - 289	221 - 580	159 - 462	258 - 639	337 - 757	225 - 539
Total (12+ years)	**Estimate**	**11,671**	**11,256**	**11,815**	**12,649**	**12,466**	**11,885**	**12,405**
	Confidence Interval[b]	**11,096 - 12,273**	**10,695 - 11,844**	**11,233 - 12,426**	**12,063 - 13,263**	**11,861 - 13,100**	**11,319 - 12,479**	**11,788 - 13,052**

Source: National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration.

Notes: These estimates are based on the number of survey respondents who reported using a prescription pain reliever not prescribed for the respondent or used only for the experience or feeling it caused in the past 12 months prior to the survey being conducted. The survey results are weighted to represent the U.S. civilian, noninstitutionalized population.

[a]The change from 2003 to 2009 is statistically significant at the 95 percent confidence level for only the 12-15 years, 20-29 years, and 50-59 years age groups.

[b]This table presents the lower and upper bounds of a 95 percent confidence level for each estimate.

Appendix VI: Comments from the Office of National Drug Control Policy

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

December 7, 2011

Gene L. Dodaro
Comptroller General
Government Accountability Office
Washington D.C. 20548

Re: Prescription Pain Reliever Abuse - GAO-12-115

Dear Mr. Dodaro:

Thank you for the opportunity to review a draft copy of your report concerning prescription pain reliever abuse and the Administration's coordinated efforts to alleviate the associated problems. I especially appreciate your laudatory comments about the Prescription Drug Abuse Prevention Plan which ONDCP established in 2011 and recognition of the "unprecedented" amount of brainstorming that occurred between ONDCP and other drug control agencies in developing it.

The draft report presents an informative review of the various drug control agencies' prescription drug abuse educational efforts, and describes how these efforts work in concert. Nonetheless, portions of the report suggest that efforts by different agencies are overlapping when they in fact target different populations or address different messages. Most of these agency efforts have very small budgets. As a result, the reader may misperceive that there is greater potential for duplication than actually exists.

I believe the report could benefit from explaining in greater detail the differences between each agency's prescription drug abuse education efforts such as the specific target audiences, the number of people reached, the specific media used, and the amount of money spent on each effort. For example, the $35 million Congress appropriated to the National Youth Anti-Drug Media Campaign funded a generalized message about substance abuse. Two independent, peer-reviewed studies released in 2011 – one in *Prevention Science* and another in the *American Journal of Public Health* – have shown this approach to be effective in reducing the initiation of youth drug use. The draft report did not clearly explain that only a small portion of the Campaign's total funds were directed solely to messages dealing with prescription drug abuse education.

I appreciate the dedication and hard work of your staff, and ONDCP will continue to work for improved coordination of prescription drug abuse educational efforts and evaluation of outcomes.

Sincerely,

R. Gil Kerlikowske
Director

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, 202-512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Thomas Conahan (Assistant Director), Katherine L. Amoroso, Emily Binek, George Bogart, Cathleen Hamann, Regina Lohr, and Leslie Powell made key contributions to this report.

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