

RECOMMENDATIONS

JULY 2017 • PAIN MANAGEMENT AND THE OPIOID EPIDEMIC

RECOMMENDATION 3-1: INVEST IN RESEARCH TO BETTER UNDERSTAND PAIN AND OPIOID USE DISORDER

Given the significant public health burden of pain and opioid use disorder (OUD) in the United States, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the U.S. Department of Veterans Affairs, industry, and other relevant research sponsors should consider greater investment in research on pain and OUD, including but not limited to research aimed at

- improving understanding of the neurobiology of pain;
- developing the evidence on promising pain treatment modalities and supporting the discovery of innovative treatments, including nonaddictive analgesics and nonpharmacologic approaches at the level of the individual patient; and
- improving understanding of the intersection between pain and OUD, including the relationships among use and misuse of opioids, pain, emotional distress, and the brain reward pathway; vulnerability to and assessment of risk for OUD; and how to properly manage pain in individuals with and at risk for OUD.

RECOMMENDATION 4-1: CONSIDER POTENTIAL EFFECTS ON ILLICIT MARKETS OF POLICIES AND PROGRAMS FOR PRESCRIPTION OPIOIDS

In designing and implementing policies and programs pertaining to prescribing of, access to, and use of prescription opioids, the U.S. Food and Drug Administration, other agencies within the U.S. Department of Health and Human Services, state agencies, and other stakeholders should consider the potential effects of these interventions on illicit markets—including both the diversion of prescription opioids from lawful sources and the effect of increased demand for illegal opioids such as heroin among users of prescription opioids—and take appropriate steps to mitigate those effects.

RECOMMENDATION 4-2: IMPROVE REPORTING OF DATA ON PAIN AND OPIOID USE DISORDER

The Substance Abuse and Mental Health Services Administration, the U.S. Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention should collaborate to identify best practices and reporting formats that portray the epidemiology of both pain and opioid use disorder accurately, objectively, and in relation to one another.

RECOMMENDATION 4-3: INVEST IN DATA AND RESEARCH TO BETTER CHARACTERIZE THE OPIOID EPIDEMIC

The National Institute on Drug Abuse and the Centers for Disease Control and Prevention should invest in data collection and research relating to population-level opioid use patterns and consequences, especially nonmedical use of prescription opioids and use of illicit opioids, such as heroin and illicitly manufactured fentanyl.

RECOMMENDATION 5-1: IMPROVE ACCESS TO DRUG TAKE-BACK PROGRAMS

States should convene a public–private partnership to implement drug take-back programs allowing individuals to return drugs to any pharmacy on any day of the year, rather than relying on occasional take-back events.

RECOMMENDATION 5-2: ESTABLISH COMPREHENSIVE PAIN EDUCATION MATERIALS AND CURRICULA FOR HEALTH CARE PROVIDERS

State medical schools and other health professional schools should coordinate with their state licensing boards for health professionals (e.g., physicians, nurses, dentists, pharmacists), the National Institutes of Health's Pain Consortium, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration to develop an evidence-based national approach to pain education encompassing pharmacologic and nonpharmacologic treatments and educational materials on opioid prescribing.

RECOMMENDATION 5-3: FACILITATE REIMBURSEMENT FOR COMPREHENSIVE PAIN MANAGEMENT

Public and private payers should develop reimbursement models that support evidence-based and cost-effective comprehensive pain management encompassing both pharmacologic and nonpharmacologic treatment modalities.

RECOMMENDATION 5-4: IMPROVE THE USE OF PRESCRIPTION DRUG MONITORING PROGRAM DATA FOR SURVEILLANCE AND INTERVENTION

The U.S. Department of Health and Human Services, in concert with state organizations that administer prescription drug monitoring programs, should conduct or sponsor research on how data from these programs can best be leveraged for patient safety (e.g., data on drug–drug interactions), for surveillance of policy and other interventions focused on controlled substances (e.g., data on trends in opioid prescribing, effects of prescriber guidelines), for health service planning (e.g., data on discrepancies in dispensing of medications for treatment of opioid use disorder), and for use in clinical care (i.e., in clinical decision making and patient–provider communication).

RECOMMENDATION 5-5: EVALUATE THE IMPACT OF PATIENT AND PUBLIC EDUCATION ABOUT OPIOIDS ON PROMOTING SAFE AND EFFECTIVE PAIN MANAGEMENT

The nation's public health leadership, including the surgeon general, the Centers for Disease Control and Prevention, and heads of major foundations and professional organizations, should convene a body of experts in communication and in pain and opioid use disorder to evaluate the likely impact (and cost) of an education program designed to raise awareness among patients with pain and the general public about the risks and benefits of prescription opioids and to promote safe and effective pain management.

RECOMMENDATION 5-6: EXPAND TREATMENT FOR OPIOID USE DISORDER

States, with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration, should provide universal access to evidence-based treatment for opioid use disorder (OUD), including use of medication, in a variety of settings, including hospitals, criminal justice settings, and substance use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of OUD. State licensing bodies should require training in treatment for OUD for all licensed substance use disorder treatment facilities and providers.

RECOMMENDATION 5-7: IMPROVE EDUCATION IN TREATMENT OF OPIOID USE DISORDER FOR HEALTH CARE PROVIDERS

Schools for health professional education, professional societies, and state licensing boards should require and provide basic training in the treatment of opioid use disorder for health care providers, including but not limited to physicians, nurses, pharmacists, dentists, physician assistants, psychologists, and social workers.

RECOMMENDATION 5-8: REMOVE BARRIERS TO COVERAGE OF APPROVED MEDICATIONS FOR TREATMENT OF OPIOID USE DISORDER

The U.S. Department of Health and Human Services and state health financing agencies should remove impediments to full coverage of medications approved by the U.S. Food and Drug Administration for treatment of opioid use disorder.

RECOMMENDATION 5-9: LEVERAGE PRESCRIBERS AND PHARMACISTS TO HELP ADDRESS OPIOID USE DISORDER

State medical and pharmacy boards should educate and train their members in recognizing and counseling patients who are at risk for opioid use disorder and/or overdose, and encourage providers and pharmacists to offer naloxone when an opioid is prescribed to these patients or when a patient seeks treatment for overdose or other opioid-related issues.

RECOMMENDATION 5-10: IMPROVE ACCESS TO NALOXONE AND SAFE INJECTION EQUIPMENT

To reduce the harms of opioid use, including death by overdose and transmission of infectious diseases, states should implement laws and policies that remove barriers to access to naloxone and safe injection equipment by

- permitting providers and pharmacists to prescribe, dispense, or distribute naloxone to laypersons, third parties, and first responders and by standing order or other mechanism;
- ensuring immunity from civil liability or criminal prosecution for prescribers for prescribing, dispensing, or distributing naloxone, and for laypersons for possessing or administering naloxone; and
- permitting the sale or distribution of syringes, exempting syringes from laws that prohibit the sale or distribution of drug paraphernalia, and explicitly authorizing syringe exchange.

RECOMMENDATION 6-1: INCORPORATE PUBLIC HEALTH CONSIDERATIONS INTO OPIOID-RELATED REGULATORY DECISIONS

The U.S. Food and Drug Administration (FDA) should utilize a comprehensive, systems approach for incorporating public health considerations into its current framework for making regulatory decisions regarding opioids. The agency should use this approach, in conjunction with advisory committee input, to evaluate every aspect of its oversight of prescription opioid products in order to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, as actually used, the drugs provide benefits that clearly outweigh their harms. When recommending plans for opioids under investigation; making approval decisions on applications for new opioids, new opioid formulations, or new indications for approved opioids; and monitoring opioids on the U.S. market, the FDA should explicitly consider

- benefits and risks to individual patients, including pain relief, functional improvement, the impact of off-label use, incident opioid use disorder (OUD), respiratory depression, and death;
- benefits and risks to members of a patient's household, as well as community health and welfare, such as effects on family well-being, crime, and unemployment;
- effects on the overall market for legal opioids and, to the extent possible, impacts on illicit opioid markets;
- risks associated with existing and potential levels of diversion of all prescription opioids;
- risks associated with the transition to illicit opioids (e.g., heroin), including unsafe routes of administration, injection-related harms (e.g., HIV and hepatitis C virus), and OUD; and
- specific subpopulations or geographic areas that may present distinct benefit-risk profiles

RECOMMENDATION 6-2: REQUIRE ADDITIONAL STUDIES AND THE COLLECTION AND ANALYSIS OF DATA NEEDED FOR A THOROUGH ASSESSMENT OF BROAD PUBLIC HEALTH CONSIDERATIONS

To utilize a systems approach that adequately assesses the public health benefits and risks described in Recommendation 6-1, the U.S. Food and Drug Administration (FDA) should continue to require safety and efficacy evidence from well-designed clinical trials while also seeking data from less traditional data sources, including nonhealth data, that pertain to real-world impacts of the availability and use of the approved drug on all relevant outcomes. The FDA should develop guidelines for the collection of these less traditional data sources and their integration in a systems approach.

RECOMMENDATION 6-3: ENSURE THAT PUBLIC HEALTH CONSIDERATIONS ARE ADEQUATELY INCORPORATED INTO CLINICAL DEVELOPMENT

The U.S. Food and Drug Administration (FDA) should create an internal system to scrutinize all Investigational New Drug (IND) applications for opioids. This review should examine whether public health considerations are adequately incorporated into clinical development (e.g., satisfactory trial design; see Recommendation 6-2). In implementing this recommendation, the FDA should rarely, if ever, use expedited development or review pathways or designations for opioid drugs and should review each application in its entirety.

RECOMMENDATION 6-4: INCREASE THE TRANSPARENCY OF REGULATORY DECISIONS FOR OPIOIDS IN LIGHT OF THE COMMITTEE'S PROPOSED SYSTEMS APPROACH (RECOMMENDATION 6-1)

The U.S. Food and Drug Administration should commit to increasing the transparency of its regulatory decisions for opioids to better inform manufacturers and the public about optimal incorporation of public health considerations into the clinical development and use of opioid products.

RECOMMENDATION 6-5: STRENGTHEN THE POST-APPROVAL OVERSIGHT OF OPIOIDS

The U.S. Food and Drug Administration should take steps to improve post-approval monitoring of opioids and ensure the drugs' favorable benefit-risk ratio on an ongoing basis. Steps to this end should include use of Risk Evaluation and Mitigation Strategies that have been demonstrated to improve prescribing practices, close active surveillance of the use and misuse of approved opioids, periodic formal reevaluation of opioid approval decisions, and aggressive regulation of advertising and promotion to curtail their harmful public health effects.

RECOMMENDATION 6-6: CONDUCT A FULL REVIEW OF CURRENTLY MARKETED/APPROVED OPIOIDS

To consistently carry out its public health mission with respect to opioid approval and monitoring, the U.S. Food and Drug Administration should develop a process for reviewing, and complete a review of, the safety and effectiveness of all approved opioids, utilizing the systems approach described in Recommendation 6-1.

RECOMMENDATION 6-7: APPLY PUBLIC HEALTH CONSIDERATIONS TO OPIOID SCHEDULING DECISIONS

To ensure appropriate management of approved opioids, the U.S. Food and Drug Administration and the Drug Enforcement Administration should apply the same public health considerations outlined in Recommendation 6-1 for approval decisions to scheduling and rescheduling decisions, and study empirically the outcomes of scheduling determinations at the patient and population health levels.

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