

We, the undersigned organizations, seek to reduce opioid misuse, abuse, addiction, and overdose while ensuring that people with pain have access to high quality health care.

Our concerns:

1. Pain affects nearly 100 million Americans at an estimated annual cost of \$560-635 billion.ⁱ
2. Between 11 percent and 40 percent of the U.S. population report some level of persistent pain, with millions suffering from daily, severe, and disabling pain.ⁱⁱ
3. Opioids have been demonstrated to help manage pain when other treatments have not provided enough pain relief. For some individuals, opioids are the best treatment for their pain.ⁱⁱⁱ
4. Individuals seeking to abuse opioid analgesics often alter the route of administration to intensify the effect or overcome a tolerance to the substance.^{iv}
5. Individuals who abuse opioid analgesics typically follow the same trajectory—starting with oral ingestion of pills, moving to crushing and snorting of pills, continuing to snorting of heroin, and finally, injecting prescription opioids and heroin—as tolerance to opioids develops, and it becomes more costly to maintain their abuse patterns.^v
6. Individuals who use altered routes of administration are at an increased risk for overdose and the development or exacerbation of substance use disorders.^{vi}
7. Opioid abuse is a public health epidemic in the United States.^{vii} An estimated 4.3 million Americans abuse opioids each year.^{viii}
8. Over 24,000 Americans died from opioid-related overdoses in 2013, with 16,235 deaths involving prescription opioid medications and 8,257 deaths involving heroin.^{ix}
9. An estimated 517,000 people had a heroin use disorder in 2013, compared with 189,000 in 2002.^x

Our Position:

1. Abuse-deterrent formulations (ADFs) of opioids reduce the attractiveness or drug-liking qualities of an opioid by hindering the extraction of active ingredients, limiting their bioavailability, preventing administration through alternative routes, or making abuse of the manipulated product less attractive or rewarding while simultaneously preserving access to vital medications for individuals with legitimate medical needs.^{xi}
2. For a new drug to obtain an “abuse-deterrent” label from the U.S. Food and Drug Administration (FDA), the agency requires scientifically rigorous studies that demonstrate how the product reduces known or expected routes of abuse.
3. Some drugs have been reformulated to incorporate abuse-deterrent features but have not sought or received abuse-deterrent labeling from the FDA.
4. Evidence shows that ADFs can reduce prescription drug abuse and its consequences.^{xii}
5. ADFs help prevent inexperienced substance users from successfully taking controlled substances via altered routes of administration, thereby preventing associated overdoses and escalation of substance use.^{xiii}
6. Even an incremental reduction in abuse can have a significant impact on the nation by reducing the costly social, physical, mental, and public health problems resulting from abuse.^{xiv}

7. Every time an abuse-deterrent medication enters the market, it enhances the quality of health care, spurs competition, and funds additional research and development to eventually provide patients with effective treatments that pose minimal risk of addiction and overdose.
8. Health care providers should prescribe opioids with FDA-approved abuse-deterrent labeling, when medically necessary and appropriate, rather than opioids without abuse-deterrent properties.
9. Policy should support an eventual transition of all Schedule II controlled-prescription medications, including opioids, to ADFs.
10. Private, federal, and state insurance plans should cover FDA-labeled ADFs, and coverage should be in parity with non-abuse deterrent opioids. “Fail-first requirements” and unreasonable patient cost-sharing should not be employed to restrict access to such medications.





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- ⁱ *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, INST. OF MED., (June 2011) <https://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research/Pain%20Research%202011%20Report%20Brief.pdf>.
- ⁱⁱ *National Pain Strategy*, U.S. DEP'T OF HEALTH & HUMAN SERVS, (Mar. 18, 2016), <https://iprcc.nih.gov/docs/draftHHSnationalpainstrategy.pdf>.
- ⁱⁱⁱ *Id.*
- ^{iv} April M. Young, et al., *Route of Administration for Illicit Prescription Opioids: A Comparison of Rural and Urban Drug Users*, 7 HARM REDUCTION J 24 (Oct. 2010).
- ^v William Compton, et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, NEW ENG. J OF MED. (Jan. 14, 2016).
- ^{vi} H. Surratt, et al., *Alternative Routes of Administration and Risk for HIV Among Prescription Opioid Abusers*, 30(4) J ADDICTIVE DISORDERS 334 (2011); S. McCabe, *Motives, Diversion and Routes of Administration Associated with Nonmedical Use of Prescription Opioids*, 32 ADDICTIVE BEHAVIORS 562 (2011).
- ^{vii} *The U.S. Opioid Epidemic*, U.S. DEP'T OF HEALTH & HUMAN SERVS, (Apr. 8, 2016); <http://www.hhs.gov/opioids/about-the-epidemic/#us-epidemic>.
- ^{viii} *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., (Sept. 2015), <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>.
- ^{ix} *Overdose Death Rates*, NAT'L INSTIT. ON DRUG ABUSE, (July 7, 2015), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.
- ^x Rachel N. Lipari & Arthur Hughes, *Trends in Heroin Use in the United States: 2002 to 2013*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN, (Apr. 23, 2015), http://www.samhsa.gov/data/sites/default/files/report_1943/ShortReport-1943.pdf.
- ^{xi} S. Budman, et al., *Can Abuse Deterrent Formulations Make a Difference? Expectation and Speculation*, 6 HARM REDUCTION J 8 (2009).
- ^{xii} S. Severtson, et al., *Reduced Abuse, Therapeutic Errors, and Diversion Following Reformulation of Extended-Release Oxycodone in 2010*. 14 J PAIN 1122 (2013); P. Coplan, et al., *Changes in Oxycodone and Heroin Exposures in the National Poison Data System after Introduction of Extended-Release Oxycodone with Abuse-Deterrent Characteristics*, 22 PHARMACOEPIDEMIOLOGICAL DRUG SAFETY 1274 (2013).
- ^{xiii} Michael C. Barnes, et al., *Abuse-Deterrent Formulations: Transitioning the Pharmaceutical Market to Improve Public Health and Safety*, 6(2) THERAPEUTIC ADVANCES IN DRUG SAFETY 67 (2015).
- ^{xiv} *Substance Abuse*, OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, <https://www.healthypeople.gov/2020/topics-objectives/topic/substance-abuse> (last visited June 16, 2016).