



FDA Perspective on Development of Abuse Deterrent Opioids

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The opinions and information in this presentation are those of the FDA contributor and do not necessarily reflect the views and policies of the FDA

Outline

- Context for the Draft Guidance
 - Larger FDA efforts to improve human abuse liability assessment and regulation
- Abuse-Deterrent Opioids Draft Guidance

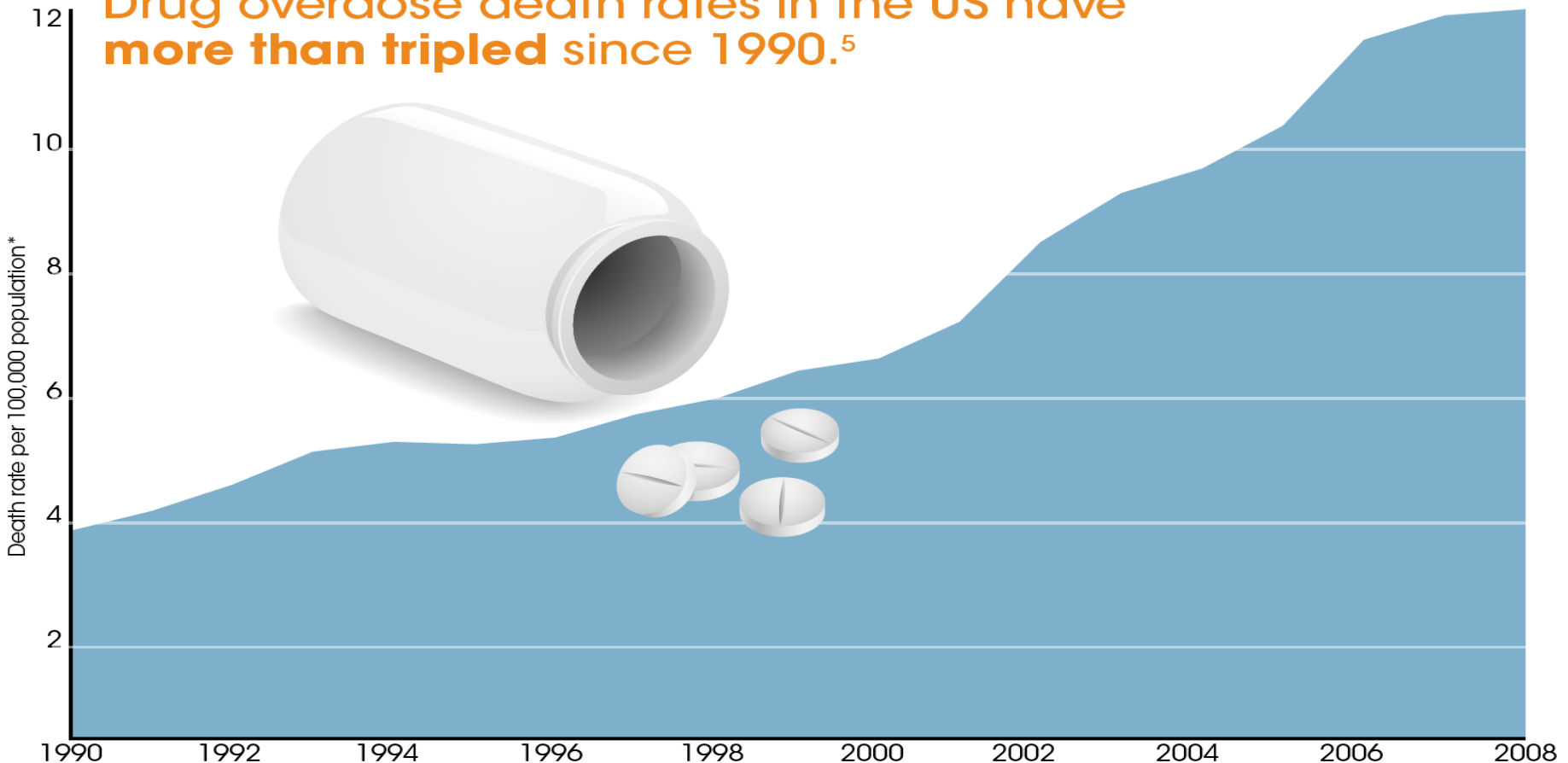
Overall Message

- Incentivizing development and use of successful abuse-deterrent formulations is one important part of ongoing FDA work on opioids abuse
- FDA is committed to taking a flexible approach in this area of emerging science focused on public health
- The determination that a product is abuse-deterrent must be based on substantive scientific data



A Major Public Health Issue

Drug overdose death rates in the US have **more than tripled** since 1990.⁵



*Deaths are those for which poisoning by drugs (illicit, prescription, and over-the-counter) was the underlying cause.

Opioid Deaths Are the “Tip of the Iceberg”

In 2008, there were **14,800** prescription painkiller deaths.⁴

For every **1** death there are...



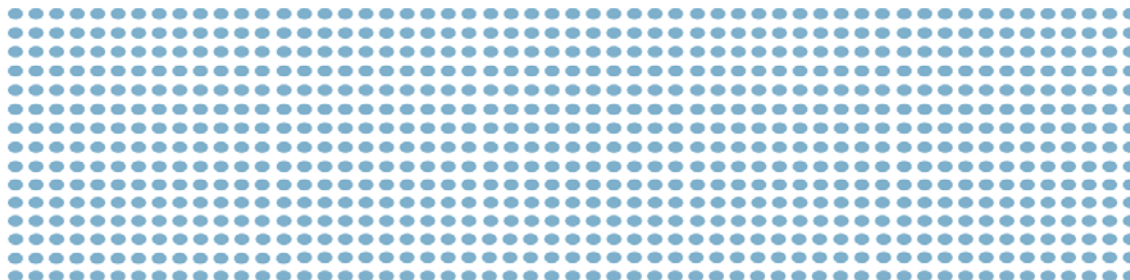
10 treatment admissions for abuse⁹



32 emergency dept visits for misuse or abuse⁶



130 people who abuse or are dependent⁷



825
nonmedical users⁷

Work on Abuse-deterrent Formulations Part of Larger FDA Efforts to Confront Prescription Drug Abuse and Misuse

- Improving the use of opioids through careful and appropriate regulations
- Improving the use of opioid through education of prescribers and patients
- Improving the safe use of opioids through partnership and collaboration
- Improving the use of opioids through improved science



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Attention Prescribers: FDA seeks your help in curtailing the U.S. opioid epidemic

FDA is asking all prescribers of opioids to ensure they have thorough knowledge of the FDA-approved product labeling for the opioids they prescribe, and to ensure they have adequate training in opioid therapy. Below is our Open Letter to prescribers. We encourage all prescribers to help curb our nation's opioid epidemic!

[View and print full article - Attention Prescribers: Curtailing Opioid Epidemic \[PDF - 137KB\]](#)

Summary & Introduction	Take Training	Know Opioid Labels	Key Label Examples	Educate Patients	Conclusion
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Summary

- In light of the expanding opioid epidemic in the U.S., FDA urges prescribers to take advantage of training on opioid prescribing, available as of March 1, 2013. This voluntary training will be provided at little to no cost through accredited continuing education activities supported by independent education grants.
- Taking advantage of training opportunities on opioid therapy, now and in the future, is one of three key roles that FDA sees for prescribers in helping to curtail this pervasive problem. The other two are: knowing the content of the most current drug labels for the opioids they prescribe, and educating patients about the appropriate use of opioids, their potential risks, and proper disposal techniques.
- FDA-approved drug labels are frequently updated based on additional science, new benefit-risk information, or public health implications regarding the medication. Labels of extended release and long-acting opioid drugs were changed in July, 2012.



Introduction

Misuse and abuse of prescription opioids has reached epidemic proportions in the U.S. While much of the problem is attributable to illicit use, appropriate use of medications for pain may also lead to unnecessary adverse events, addiction, and death for some patients. *No group can be more effective in reducing this trend than our nation's front-line health care professionals, especially physicians and other prescribers.*

Other prescribers in reducing this trend are our nation's front-line health care professionals, especially physicians and nurses. Appropriate use of medications for pain may also lead to unnecessary adverse events, addiction, and death for some patients. No group can be more effective in reducing this trend than our nation's front-line health care professionals, especially physicians and other prescribers.

Also Part of Larger FDA Effort to Improve Abuse Assessment

- Draft Guidance: Assessment of Abuse Potential of Drugs, issued January 2010
 - <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf>
- Discusses use of safety information from all areas of the NDA, including brief discussion of abuse deterrence formulations

Goals of Larger FDA Effort to Improve Abuse Assessment

- Improving the science of abuse assessment before a drug is on the market, so that appropriate controls are put in place to reduce the likelihood that a drug will be abused after marketing
- Protecting public health through accurate labeling of drugs that can be abused
- **Recognizing the development of successful abuse-deterrent formulations through labeling to encourage their use**

Developing Guidance on Abuse-Deterrent Formulations

- Advisory Committees
 - Topic at several meetings: 2008 to 2010
 - Tone generally conservative about data needed to conclude a new formulation is abuse-deterrent
- Public/Congressional interest in issue pronounced....

Abuse-Deterrent Opioids Guidance

- Promised as part of ONDCP Rx Drug Abuse Plan (2011)
- Mandated under FDASIA
 - Goal date January 9, 2013

Abuse-Deterrent Opioids

Guidance

- Clear need to lay out road-map for product development as science evolves
 - Lay out standard for testing and assessment
 - Support iterative improvement
- Affirms FDA strong focus on issue
- Support over-arching twin goals:
 - Incentivize new product development and scientific progress
 - Assure appropriate development and availability of generics, reflecting their importance in US healthcare

Abuse-Deterrent Opioids Draft Guidance: Highlights

- Reflect the state of the science of developing abuse deterrent formulations (relatively new), and need to take flexible approach in evaluation and labeling of drugs as data accumulates

Abuse-Deterrent Opioids Draft Guidance: Highlights

- Outline the studies to be conducted for assessing putative abuse-deterrent formulations (4 categories)
- Give advice on conduct of studies
 - Assessment of new formulations
 - Assessment of clinical impact of new formulations
 - Post-marketing evaluation of new formulations

Abuse-Deterrent Opioids Draft Guidance: Highlights

- Outline how FDA will evaluate studies
 - Focus will be on rigor and consistency of studies and analyses
- Outline potential claims in labeling of abuse-deterrence based on data
 - Identify particular areas where advances in science would be particularly valuable to advance the field of human abuse assessment

Areas of Additional Research Needs

- Characterization of the quantitative link between:
 - Changes in the pharmacokinetics of opioids in different formulations,
 - Results of clinical studies using those same formulations, and
 - Differences in abuse in the community
- Characterization of the best methods to analyze clinical data on abuse
- Characterization of the best methods to analyze the impact of formulations on rates of abuse in the community

Issues

- Does not address how FDA will approach assessment of generics with abuse-deterrent features
- Does not set ‘bright line’ standard of what constitutes meaningful ‘abuse deterrence’
 - Will need more experience before we can set such a standard
 - Few examples of well-characterized formulations to date
 - Need more data on the link between non-clinical and pre-market studies and post-market impact on abuse, overdose, and death

Abuse-Deterrent Opioids Draft Guidance: This Meeting

- FDA welcomes opportunity to participate in the discussion
- Highlights (above) reflect:
 - Need for additional scientific exchange
 - Lack of established standards in the area of testing and assessing abuse-deterrent formulations
 - FDA interest in ‘asking’ not ‘answering’

Summary

- Draft Guidance provides an initial framework for the flexible assessment of abuse-deterrent technologies based on available science
- Draft Guidance offers meaningful incentives for companies to develop new technologies
- Draft Guidance identifies areas of needed scientific work
- External discussion and comment like this meeting are key to help inform necessary science and changes to the Guidance