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January 9, 2015

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20552

Re: Docket No. FDA–2014–N–1359, Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting

Dear Sir or Madam:

We are grateful for the opportunity to submit comments regarding the **Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications**.

As a diverse group of stakeholders working together for comprehensive and balanced policies that reduce prescription opioid abuse and promote treatment options, we are committed to working with policymakers, including the leadership and staff of the Food and Drug Administration (FDA), to address this complex and urgent public health challenge. Our comments emphasize core principles that we believe will enable the FDA to establish an effective pathway for both generic and branded products and that will best serve patients.

Core Principles for Abuse-Deterrent Opioid Development

To curb the nationwide epidemic of opioid abuse, every effective tool must be developed. Abuse-deterrent opioids are an essential part of this battle. We believe the FDA must establish clear and reasonable pathways for ***both*** branded and generic products, ensuring doctors and patients have the widest array of abuse deterrent options. Set out below are core principles that we believe are necessary to achieve timely access to these products. These principles reflect our collective understanding that real progress can be achieved with multiple, innovative approaches to abuse-deterrence that accelerate the scientific field.

To best support patients and provide a pathway for both branded and generic products, FDA should:

- **Establish a timely, transparent process to approve abuse-deterrent opioids.** Patients and providers are asking for abuse-deterrent options now, and manufacturers are innovating in response. A clear regulatory approach is needed so that manufacturers will continue to invest in developing abuse-deterrent opioids. FDA must clearly articulate how manufacturers should develop and test abuse-deterrent opioids and define the standards for how FDA will evaluate these new products. Appropriate and reasonable pathways must be developed for both branded and generic opioid medications.
- **Issue final guidance outlining how branded products may demonstrate abuse-deterrence.** Following the October public meetings, FDA should revise existing draft

guidance in light of stakeholder comments and finalize guidance offering a clear path for development and approval of abuse-deterrent opioids. It is critical that this guidance be issued promptly to accelerate the availability of these technologies.

- **Develop and issue guidance for the development of generic abuse-deterrent opioids.** Generic products are essential to ensure widespread access to abuse-deterrent opioids. These products will be hampered without a clear approval pathway. FDA needs to define standards and processes that encourage the rapid development of generic abuse-deterrent opioids. Any delay in this guidance is a significant obstacle to achieving optimal abuse deterrence. The agency must act now to propose and then promptly finalize appropriate guidance in this area. The agency should strive to complete this work in 2015.
- **Balance requirements and scientific advances.** While no product is "abuse-proof," abuse-deterrent technology is evolving rapidly. FDA must recognize that important incremental advances in this area can save lives and implement a regulatory approach that encourages these improvements.
- **Provide physicians with all abuse-deterrence data.** Physicians are searching for medications that will effectively treat an individual patient's pain while reducing the possibility of abuse. When a drug exhibits abuse-deterrence properties that do not meet FDA's full abuse-deterrence standards, FDA should recognize this incremental advance in abuse-deterrence by including information in the product's label stating that, while the drug does not meet the FDA's full abuse-deterrent standards, submitted sponsor data suggest a reduction in human abuse potential which will continue to be analyzed through post-marketing studies. Each patient's pain treatment is unique and physicians need all available information to make the best individualized treatment decision based upon identified levels of risk.
- **Continue appropriate access to generic pain medications as abuse-deterrent formulations are expedited.** As guidance for generic manufacturers to incorporate abuse-deterrent formulations into their products is advanced by the FDA, patients should retain access to appropriate options during this period. Specifically, the FDA should establish ambitious, pragmatic timeframes which allow appropriate access to generic opioid pain medications while manufacturers meet defined benchmarks in the development of abuse-deterrent versions.
- **Pursue consistent implementation and application of the abuse-deterrence guidance.** It is critical that FDA have a consistent approach to its review of these products. Timely and effective guidance for both branded and generic abuse-deterrent formulations of opioid medications will support this goal and encourage additional scientific progress.

Thank you for considering these comments as the agency moves forward in this critical effort. We look forward to continued collaboration with the FDA to confront prescription opioid misuse.

Respectfully submitted,

Trust for America's Health
Community Anti-Drug Coalitions of America
The Honorable Mary Bono
Kentucky Office of Drug Control Policy

Shatterproof
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Center for Practical Bioethics
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