FDA PUBLIC MEETING STATEMENT, OPINION AND RECOMMENDATION

Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting

The meeting will focus on scientific and technical issues related to the development and in vitro assessment of abuse-deterrent formulations, as well as FDA's approach towards assessing the benefits and risks of all opioid medications.

Speaker:
Stephen Marmaras
Manager, State and National Advocacy
Global Healthy Living Foundation

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Disclosure:
I have no disclosures to make regarding my travel here today.

On behalf of the Global Healthy Living Foundation, I want to thank the FDA for its commitment to taking input from a diverse set of stakeholders. GHLF is a 501(c)(3) patient group working to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. We represent approximately 74,000 patients and caregivers nationwide who are in pain.

My name is Stephen Marmaras, the manager of state and national advocacy for GHLF.

We recognize that abuse-deterrent formulations are expensive. The FDA, by charter, is tasked with making decisions based on safety and efficacy. Our patients who battle chronic pain daily, need legitimate access to pain medications, and are NOT abusers. These patients deserve to get the medication their doctors prescribe. Earlier this year, when Attorneys General, and one governor, tried to restrict opioid availability, they were confusing law enforcement with healthcare. Our hope is that ultimately a uniform abuse deterrent formulation opioid policy, for immediate as well as extended release formulations, will eliminate ill-conceived policies such as these.

Today there are many brand-name and generic opioids on the market. Of these, three are considered abuse deterrent. Most insurers only cover the less expensive opioids that are not tamper resistant. This practice prevents companies from investing in the development of abuse deterrent formulations and needs to be addressed. Patients, we think, would be economically penalized because the increased cost would most likely fall to them.

In 1968, despite objections about cost, a Federal law mandated seat belts in cars. Society is willing to pay for safety and efficacy when it is administered uniformly. Today nobody complains about the cost of seat belts.

We believe that the FDA currently stands in a leadership position and should exercise it to implement abuse-deterrent technology.

In the interim, we ask the FDA to overrule as much as it can, attempts to keep certain opioids off the market while favoring others. Only the FDA has the perspective to accurately assess the safety and efficacy of drugs. To allow others to usurp the FDA's scientific judgment and authority is bad government and bad public health policy.

We thank the FDA for emphasizing the value of abuse-deterrent technology through public meetings such as this, and we are ready to mobilize our patient community to create a better life for those who rely on opioids in order to be functioning members of society. We welcome input and collaboration. Thank you for your time and attention.