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November 25, 2013

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Division of Dockets Management,FDA
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Citizen Petition to add drug-abuse deterrent technology to all hydrocodone schedule II products and to implement standards of practice and corresponding responsibilities for pharmacists

Dear Divisions of Dockets Management,

Pharmacists Planning Services, Inc. (PPSI) a 501 C(3) nonprofit public health consumer pharmacy education organization in conjunction with National Coalition Against Prescription Drug Abuse (NCA-PDA), Marin County Pharmacists Drug Abuse Task Force (MCPDATF), and Marin County Pharmacists Association (MCPhA) submits this Citizen's Petition to add drug-abuse deterrent technology to all hydrocodone schedule II products and to implement standards of practice and corresponding responsibilities for pharmacists.

The undersigned submits this petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food Drug and Cosmetic Act (FDA) or any other statutory provision which authority has been delegated by the Commissioner of Food and Drug to request the Commissioner of FDA to add drug-abuse deterrent technology to all hydrocodone schedule II products and to implement standards of practice and corresponding responsibilities for pharmacists.

This petition requests the FDA Commissioner to issue a federal regulation to make regulatory decisions regarding the reformulation with abuse-deterrent technology of the two opioid drug products, hydrocodone bitartrate ER and hydrocodone/acetaminophen as well as implementing a standard of practice (SOP) for prescription monitoring programs, which are discussed below in our statement of scientific basis for petition.

STATEMENTS OF SCIENTFIC BASIS FOR PETITIONS IS SPELLED OUT AS FOLLOWS:

1. Misuse, abuse, addiction, hyperalgesia, overdose, and death from prescription medications are a public health epidemic. According to the CDC, in 2010 prescription opioids were involved in more than 75 percent of all prescription drug related overdose deaths.
2. Public Health advocates have become increasingly focused on the mortality and illness that results from inappropriate use of controlled substances, especially opioid analgesics due to the increase in opioid prescriptions.
3. According to the New England Journal of Medicine, these prescriptions have increased 300% between 1999 and 2010. There has also been an increase in overdose from these medications from 4000 in 1999 to 16,600 in 2010.

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4. Over-dose is now the second-leading cause of accidental death in this country. It is estimated that 2.4 million people abuse opioids in the U.S. in 2010
5. One of the causes of the increase in prescriptions is that health advocates began promoting clinicians to be more liberal with pain management in 1990s because chronic pain was undertreated. At the same time, new and stronger formulations of opioids became available.
6. The growth in prescription drug abuse has increased due to inappropriate prescribing where licensed physicians with DEA numbers are willing write larger quantities of opioids for younger patients.
7. An FDA panel had earlier voted 11 to 2 against approval of the drug Zohydro ER (hydrocodone bitartrate) for the management of pain because it was not formulated to deter abuse as is Oxycontin.
8. Hydrocodone bitartrate (Zohydro ER) is a scheduled II controlled substance with high potential for abuse similar to fentanyl, methadone, morphine, oxycodone, and oxymorphone.
9. Hydrocodone/APAP is the number one drug prescribed in the U.S. with over 140 million prescription dispensed by pharmacists per year. Painkillers like Vicodin (hydrocodone/acetaminophen) are the most abused because they are relatively easy to obtain. The International Narcotics Control Board reported that in 2010 the US accounted for more than 99 percent of the world's consumption of hydrocodone and American doctors prescribed far more daily doses per million people than doctors in any other country.
10. PPSI in conjunction with the MCPDATF, NCA-PDA, and MCPhA has encouraged the FDA to reschedule this hydrocodone/apap to schedule II. Pure hydrocodone should also have opioid abuse deterent technology.
11. Pharmacists who fill the prescriptions have a "corresponding responsibility" to ensure that controlled substances are only dispensed for a legitimate medical purpose under 21 CFR 1306.04.
12. In a letter written to PPSI by Virginia Herold (CEO of the Board of Pharmacy) on November 6th 2013, she stated : "corresponding responsibility means that pharmacists must determine that before dispensing a drug, that it is appropriate for the patient (see Health and Safety Code section 11153). This is a presentation we do with the Drug Enforcement Agency (DEA). It is related to our precedential disciplinary decision we adopted at the last meeting on drug diversion and a pharmacist's corresponding responsibility".
13. Courts have interpreted this rule as to require pharmacists to exercise professional judgment prior to dispensing controlled substances.
14. Walgreens, CVS/Caremark, Costco, Omnicare SNF, SF general Hospital, and PPSI have issued standards of practice for prescription monitoring programs (PMPs), which require professional judgment on controlled substance agreements for patients, physicians, and

health care providers to require rational prescribing and pharmacy dispensing. Attached are 5 SOPs for prescription monitoring programs to this Citizen's Petition for prevention of prescription medication abuse. These standards should be adopted by the FDA, National Boards of Pharmacies, and the DEA as a standard of practice for all schedule II prescriptions.

15. The intent of the PMP is to be a primary source of information for prescribers and pharmacists to use in the care of patients and as a tool to help deter, detect, and appropriately respond to drug diversion and abuse for prescription controlled substances. It is not intended to prevent patients from obtaining their necessary medications.
16. Schedule II drugs include, oxycodone, methadone, hydromorphone, morphine, fentanyl, oxymorphone, hydrocodone bitartrate ER,and the proposal of hydrocodone/apap along with other drugs of abuse including the amphetamine combinations and ADHD prescription drugs.
17. PPSI, MCPDATF, NCA-PDA, and MCPhA propose in this Citizen's Petition that no schedule II drug be allowed, either brand or generic, before the abuse deterrent technology is implemented into the product before FDA approval.

PPSI believes there is ample amount of scientific evidence and information available to request the FDA Commissioner to hold public hearings and open up a Federal Registry to establish standards to add drug-abuse deterrent technology to all hydrocodone schedule II products and to implement standards of practice and corresponding responsibilities for pharmacists.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

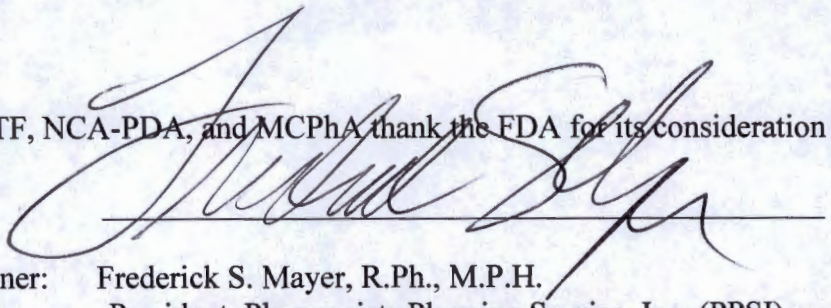
There is no economic impact involved with this Citizen's Petition. We encourage the FDA to undertake this issue for public hearings immediately in the interest of public health, safety, and harm.

Finally, FDA has most recently made regulatory decisions regarding the reformulations of two opioid drug products OxyContin Controlled-Release Tablets (oxycodone hydrochloride) and Opana ER (oxymorphone hydrochloride Extended-Release Tablets). The sponsoring groups of this Citizen Petition are **ONLY** asking the FDA to do the same for the hydrocodone schedule II Drugs.

The undersigned certified, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

It is our sponsoring groups' understanding that both of these two products, hydrocodone bitartrate ER and hydrocodone/acetaminophen may be eligible for one or more of the FDA's expedited review and approval programs, including fast track designation and priority review timelines, if the applicable statutory and regulatory criteria are met.

PPSI, MCPDATF, NCA-PDA, and MCPhA thank the FDA for its consideration of this proposal.

Signature 

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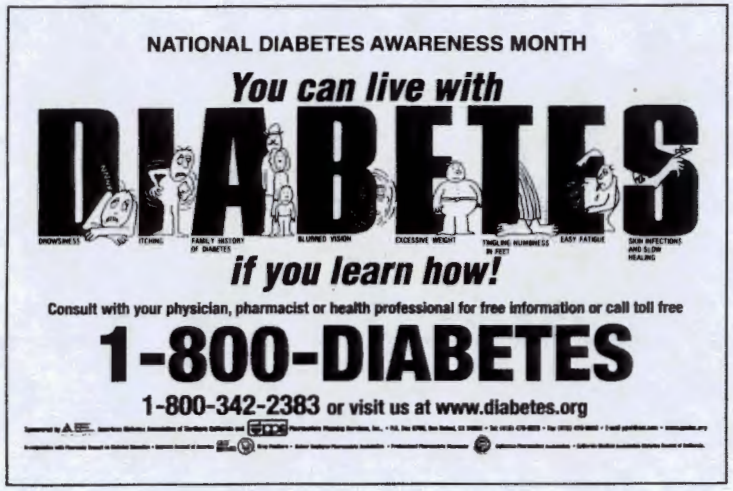

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