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Committee on Energy and Commerce
Subcommittee on Health
Hearing on

“Improving Predictability and Transparency in DEA and FDA Regulation”

Testimony Submitted by the Global Healthy Living Foundation
April 7, 2014

Thank you for the opportunity to submit written testimony for the record of the hearing on “Improving Predictability and Transparency in DEA and FDA Regulation.” We applaud the Subcommittee for having today’s hearing and bringing attention to the complex issue of prescription drug abuse.

The Global Healthy Living Foundation is a 501(c)(3) non-profit advocacy organization, based in New York, with the mission to improve the quality of life for people with chronic illness. GHLF accomplishes its mission by advocating for improved access to care and by educating the community about the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement, and therapeutic compliance. Through our CreakyJoints webpage, we advocate on behalf of more than 60,000 patients living with arthritis who experience severe, chronic pain every day.

Zohydro is a new, FDA-approved time-release opioid for the 115 million people in the US dealing with debilitating pain who need medications like this to stay productive and attain some measure of quality of life. These people are not abusers, but their access to pain medications for their clinically diagnosed medical conditions is being methodically taken away by frustrated law enforcement officials.

The FDA did its job correctly by approving a treatment based on its safety and efficacy data. Despite what was said, this particular pill isn’t any more powerful than others on the market. It appears stronger because its ingredients are released over 12 hours, not four, as with other opioids. So instead of taking two 10mg pills every four hours for a total of 60mg every 12 hours, this pill is 50mg and lasts 12 hours. Any opioid can be abused by taking one or several pills in many different available doses.

Diversion of licit drugs to the street is a very real problem with devastating consequences for our communities. However, restricting legitimate patients’ access to needed medications is not the answer. There are many proven, evidence-based options for stemming prescription drug abuse, including one national program authorized by this Committee. The National All Schedules Prescription Electronic Reporting (NASPER) Act, sponsored by Congressman Whitman and Ranking Member Pallone,

established a grant program to assist states with creating prescription drug monitoring programs. Since its passage in 2006, 29 states now have an active prescription drug-monitoring program. These programs allow physicians and pharmacists to check a database before writing a prescription to easily identify an abuser who is doctor shopping for drugs, already received prescriptions for pain management, or has tried to fill multiple prescriptions at several different pharmacies.

GHLF supports the use of prescription drug monitoring programs and urges Congress to reauthorize and fully fund NASPER this year to enable the remaining states to establish monitoring programs and/or enhance the ones they currently have in place.

Another successful tactic at reducing prescription drug abuse is the use of abuse-deterrent formulations of highly addictive drugs. This makes drugs useless when they are crushed or cooked, preventing abusers from getting a lethal super-dose. However, because abuse-deterrent formulations are more expensive, health insurance companies usually won't pay for them. Just as seat-belts were considered too expensive in the 60s, health insurance companies are saying abuse deterrence is too expensive; however GHLF believes they must be the standard of care if we care about our public health. We need to address these reimbursement challenges and create incentives for the development of abuse-deterrent formulations.

As the Committee considers policy solutions for prescription drug abuse, we ask that you also focus on the very real challenges that patients living with chronic pain face day after day. Patients need access to safe and effective medications approved by the FDA and that includes Zohydro. Prescription drug monitoring programs and abuse-deterrent formulations of scheduled drugs provide sufficient options for stemming prescription drug abuse. Let's not force patients to suffer and instead, find a balanced evidenced-based solution to this public health crisis.

