CLAAD Center for Lawful Access and Abuse Deterrence

March 3, 2016

Andy Slavitt, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2345-FC
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via www.regulations.gov

Dear Administrator Slavitt:

As not-for-profit and commercial organizations that share the Obama Administration's goals of reducing prescription drug abuse and improving access to high-quality health care, we would like to provide our comments on the final rule with comment period issued by the Centers for Medicare & Medicaid Services (CMS), entitled *Medicaid Program: Covered Outpatient Drugs* ("the Final Rule"). Specifically, we continue to oppose including abuse-deterrent formulations (ADFs) of controlled prescription medications in the line extension definition.

Controlled prescription medications are often necessary to treat conditions like pain, anxiety, ADHD, insomnia, and addiction. Lawful access to them requires careful examinations of medical need, precautions to prevent harm to the patient and the public, and ongoing vigilance to ensure their appropriate use, safe storage, and responsible disposal. Along with counseling tools, prescription drug monitoring program data checks, and therapeutic urine drug testing, the use of ADFs may be part of a prescriber's plan to meet a patient's medical need without exposing the patient, his or her family, and community to unnecessary risks.

The Obama Administration actively supports the development and use of ADFs. The White House Office of National Drug Control Policy, Food and Drug Administration (FDA), Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, National Institute on Drug Abuse, and Drug Enforcement Administration are all working in support of Administration policy on abuse-deterrent medications. FDA's April 2015 guidance entitled "Abuse-Deterrent Opioids — Evaluation and Labeling Guidance for Industry" provided additional regulatory clarity to advance research and development into ADFs. FDA will release similar guidance covering generic products this year and announced earlier this month that applications for the approval of opioid pain relievers that do not have abuse-deterrent properties will be subject to the additional scrutiny of an expert advisory committee.

Present-day ADFs can hinder the extraction of active ingredients, prevent administration through alternative routes, or make abuse of the manipulated product less attractive or rewarding.[1] FDA has approved and granted abuse-deterrent labeling to six abuse-deterrent opioid analgesics sponsored by four companies since 2013 (approval is tentative in one instance). More than 30 active Investigational New Drug applications are under discussion with FDA, and research has already begun on abuse-deterrent medications that would provide protection against overdose by excessive oral

[1] Laurence Greene, *Pain Management 2010: New and Emerging Abuse-Deterrent Technologies*, http://primeinc.org/downloads/38PR092.pdf (last visited 6 January 2015).

ingestion.

Including ADFs in the line extension definition would hinder or even halt the U.S. market transition to less readily abused controlled prescription medications by reducing the incentives necessary for private-sector funding of the development of new ADFs. Given that companies that invest in the extensive research required to obtain approval and labeling of ADFs would have to pay additional Medicaid rebates, the ability to recoup medication development costs and finance further research into next-generation abuse-deterrent technologies would be significantly diminished. President Obama's 2017 budget recognizes this reality by noting that exempting ADFs from the definition of line extension would "encourage the development of abuse-deterrent formulations."

It is puzzling and troubling that CMS's proposed line extension policy does not support and, in fact, would seriously undermine market incentives to research, develop, and obtain approval and labeling of ADFs. This CMS policy is inconsistent with Obama Administration policy and disregards the important scientific, regulatory, and market advances that have resulted under President Obama's leadership to expand consumer access to ADFs.

We commend CMS for taking additional time to consider the definition and identification of line extension drugs prior to issuing further regulations applicable to outpatient drugs. Again, we request that controlled prescription medications that include abuse-deterrent technology not be included in the line extension definition. We appreciate your consideration of our comments and would be pleased to discuss this matter in greater detail with you.

Sincerely,

Center for Lawful Access and Abuse Deterrence
Abuse Deterrent Coalition
Acura Pharmaceuticals
Alliance for the Adoption for Innovation in Medicine
Alliance for Aging Research
American Society for Pain Management Nursing
Atlantic Pharmaceuticals, Inc.
Chronic Pain Research Group, Univ at Buffalo School of Pharmacy and Pharmaceutical Sciences
Collegium Pharmaceutical, Inc.
Community Anti-Drug Coalitions of America
Egalet Corporation
Elysium Therapeutics
Endo Pharmaceuticals
Gatekeeper Innovation, Inc.
Grünenthal USA, Inc.
Healthcare Distribution Management Ass'n.
Inspirion Delivery Technologies, LLC
Intellipharmaceutics
Interstitial Cystitis Association
Kem Pharm
Nat'l Association of Directors of Nursing Administration/Long Term Care, Inc.
Nat'l Council of Certified Dementia Practitioners
Nat'l Fibromyalgia & Chronic Pain Association
National Hospice and Palliative Care Organization
Pain Connection-Chronic Pain Outreach Center, Inc.
Partnership for Drug-Free Kids
Pernix Therapeutics
Project Lazarus
Purdue Pharmaceuticals
Teva Pharmaceuticals
The Pain Community
U.S. Pain Foundation
Wisconsin Pain Initiative

Copy: The Honorable Sylvia Burwell
Secretary of Health and Human Services