United States Congress

WASHINGTON, DC

October 28, 2015

Administrator Howard Shelanski
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Administrator Shelanski:

The Centers for Disease Control and Prevention (CDC) has estimated that prescription opioid abuse costs the U.S. economy tens of billions of dollars each year in lost productivity and health care costs. Sadly, the human cost is much higher—more than 4 million Americans misuse or abuse prescription painkillers, and more than 16,000 individuals die from prescription painkiller overdoses each year. Deaths from drug overdose are now the leading cause of injury-related death in the country—more than from car accidents. While this administration is taking important actions to combat opioid abuse, dependence and overdose, we fear that a policy pending before you could reverse some of the positive steps taken.

We write to express our substantial concerns that the Centers for Medicare & Medicaid Services (CMS) may be poised to finalize a regulation which would mark a significant reversal in the fight against the prescription opioid epidemic. Specifically, we are concerned about the line extension definition included in the February 2012 CMS proposed rule (*Medicaid Program; Covered Outpatient Drugs*, CMS-2345-F). We write to you with some urgency on the matter because it is our understanding that, after over three years of deliberation, the final rule is currently under review by your agency.

We are concerned that unless there are substantial modifications to the proposed rule, under the final rule, manufacturers of medications with abuse-deterrent formulations (ADF) would be subject to additional rebate obligations under the Medicaid program. This policy outcome would be a misunderstanding of Congressional intent. Additional mandatory rebate obligations would also serve as a strong disincentive for industry leaders developing ADF products that can help reduce prescription opioid overdose deaths in our country.

The 2012 proposed rule included in the definition of line extensions those opioids that have been reformulated to have abuse deterrent properties. If this proposal were finalized, we are concerned this requirement would penalize innovation in ADF technologies that have enjoyed broad support amongst Congress, the Administration, industry, and stakeholders. Finalizing the

rule in its current form could significantly stifle the development of these important technologies, which are vital in the fight against prescription drug abuse.

It was not the intent of Congress to include drugs with abuse-deterrent technology in the definition of a line extension. The legislative history clearly demonstrates that Congress intended to close a loophole by subjecting drugs that were merely slight alterations of a pre-existing drug to the line extension alternative rebate calculation. Congress notably raised concerns about prescription drug manufacturers making "slight alterations" to existing products to avoid incurring additional Medicaid rebate liability through numerous Committee reports and legislation.[1]

In addition to the official committee reports and summaries of legislation, even non-partisan summaries of legislation by the Congressional Research Service (CRS) confirm Congressional intent. For example, a CRS report, R40900, dated November 10, 2009, emphasized Congress was focused on closing a loophole under which "drug makers can avoid incurring additional rebate obligations by making slight alterations to existing products." CRS further noted that only "certain extended release versions" reflect a slight alteration.

Unfortunately, CMS's current read of the line extension policy conflicts with the position held by several federal and state agencies engaged in the fight to reduce prescription drug abuse. The White House's Office of National Drug Control Policy (ONDCP), other federal agencies within the Department of Health and Human Services, including at least the Food and Drug Administration (FDA) and the Substance Abuse and Mental Health Services Administration, along with the Drug Enforcement Administration and a broad coalition of State Governors, Attorneys General and elected officials—all encourage the development and adoption of ADFs. So it is disheartening that even as ONDCP and the FDA have been encouraging the development of ADFs, CMS is poised to undercut the policy aims of these agencies by advocating for the inclusion of opioid medication with ADFs in the line extension definition.

Notably, ONDCP's 2011 Prescription Drug Abuse Prevention Plan directed the National Institute on Drug Abuse (NIDA) and the FDA to "[e]xpedite research through grants, partnerships with academic institutions, and priority New Drug Application review by FDA, on the development of treatments for pain with no abuse potential as well as on the development of abuse-deterrent formulations (ADF) of opioid medications and other drugs with abuse potential." It also directed the FDA to "[p]rovide guidance to the pharmaceutical industry on the development of abuse-deterrent drug formulations and on post-market assessment of their performance."

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[1] For example, the House Energy & Commerce Committee's Report (H.R. Report No. 111-299) on H.R. 3200, America's Affordable Health Choices Act of 2009 described the law in effect prior to the ACA as permitting manufacturers to avoid additional rebate requirements "by making slight alterations to existing products." The Senate Finance Committee's Chairman's Mark on the America's Healthy Future Act of 2009 reflected the same concern that "drug makers can avoid incurring additional rebate obligations by making slight alterations to existing products, sometimes called line-extensions, while significantly increasing the price on these products." Similarly, a Senate Finance Committee Report, which accompanied the legislative text to the America's Healthy Future Act of 2009, again emphasized the focus on lawmakers' concern that manufacturers "sometimes can avoid incurring additional rebate obligations by making slight alterations to existing products."

In response to the ONDCP report, FDA issued draft and then final guidance to assist industry in developing opioid prescription drug products with abuse-deterrent properties and to guide the appropriate labeling of these products. In the FDA announcement on the final guidance, Dr. Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research, emphasized that the "development of abuse-deterrent products is a priority for the FDA." She said that it is the hope of the FDA that "this guidance will lead to more approved drugs with meaningful abuse-deterrent properties."

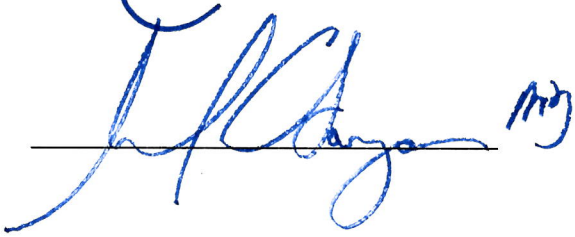
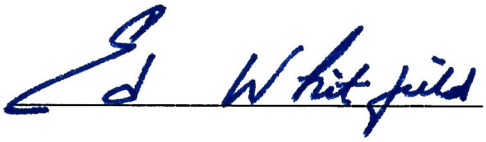
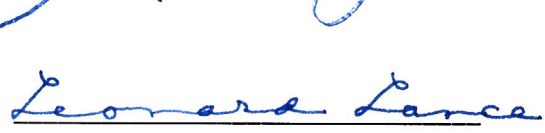
Since the proposed rule was published three years ago, there have been at least four bipartisan Congressional letters to the Administration expressing concern with the line extension definition in the proposed rule. However, at this late juncture, we remain concerned about what decision may be made on this important regulation. Therefore, we ask you to exercise your leadership and commitment to addressing the prescription drug abuse epidemic by excluding ADF technologies from the line extension definition in the final rule.

Thank you for your attention to this critical matter. It is our hope that this issue will be resolved in a way that will encourage the continued development of ADF technologies, which can help prevent prescription drug abuse and the public health and societal challenges that stem from it. We look forward to your prompt response.

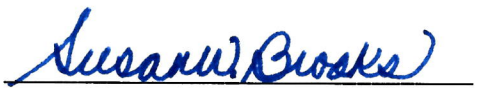
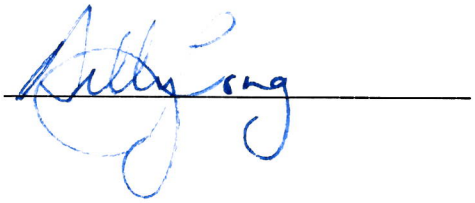
Sincerely,







cc: Mr. Michael Botticelli
Director, Office of National Drug Control Policy

cc: Ms. Sylvia Mathews Burwell
Secretary, Department of Health and Human Services

cc: Mr. Andy Slavitt
Acting Administrator for the Centers for Medicare & Medicaid Services

cc: Dr. Stephen Ostroff
Acting Commissioner of the Food and Drug Administration