

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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March 31, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Acting Administrator Slavitt:

On January 21, 2016, the Centers for Medicare & Medicaid Services' (CMS) released the Covered Outpatient Drugs Final Rule with Comment (CMS-2345-FC) that addresses key areas of Medicaid drug reimbursement and changes made to the Medicaid Drug Rebate program by the Affordable Care Act.<sup>1</sup> We write to applaud CMS's decision to continue to seek input on the definition of line extension in the final rule under the Medicaid Drug Rebate program.

At a time when so many of us are working together to identify and adopt targeted solutions to curbing our drug abuse crisis, we believe CMS's decision to seek further definition of line extension is a responsible measure. We support CMS' prudent decision to solicit new input from industry and stakeholders and we believe the comment period will yield updated and innovative comments that reflect advances made in technology since the rule was originally proposed in February 2012.<sup>2</sup>

One of the most promising technologies to come to market in recent years has been the development of abuse-deterrent formulations (ADF) of drugs. FDA took an important step forward in promoting the adoption of ADF in recent years by issuing its guidance.<sup>3</sup> In its Opioids Action Plan, FDA recognized the important role that ADFs play, setting a goal to "expand access to abuse-deterrent formulations discourage abuse." The goal, FDA noted, was to "spur innovation and generic ADF product development."<sup>4</sup> More recently, we were pleased to see FDA Commissioner Califf's commitment to ADF with his statement that FDA would do "everything possible under [FDA] authority to prevent abuse, save lives and treat dependence."<sup>5</sup>

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<sup>1</sup><https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs>

<sup>2</sup><https://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf>

<sup>3</sup><http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf>

<sup>4</sup><http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm>

<sup>5</sup><http://www.sfgate.com/news/medical/article/New-FDA-chief-cites-promise-of-harder-to-abuse-6863596.php>

We note with interest that the nation's governors recently called on the administration to "improve access to and encourage the manufacture and evaluation of abuse-deterrent formulations of opioid painkillers." As the governors noted, "ADFs can help balance appropriate access to opioids with efforts to prevent opioid addiction."<sup>6</sup>

Since CMS is taking additional comment on the issue of ADF related to the line extension definition, we would also like to reiterate strong Congressional concerns that were previously outlined last fall in an October 28, 2015 letter to Administrator Shelanski of the Office of Management and Budget.<sup>7</sup> As that letter noted, there is strong concern that subjecting manufacturers of ADFs to additional rebate obligations under the Medicaid program would not only be a problematic dampener on ADF research and development, it would contravene the intent of Congress. It was not the intent of Congress to include drugs with abuse-deterrent technology in the definition of a line extension.

Moreover, the statute is clear that CMS has the authority to exclude products that are reformulated to include ADF from the definition of "line extension drug" added by the Patient Protection and Affordable Care Act to Social Security Act § 1927(c)(2)(C). As the statute notes, "the term 'line extension' means, with respect to a drug, a new formulation of the drug, such as an extended release formulation. A plain reading of the "such as" clause in the statute leads us to conclude that not all new formulations of existing products will meet the definition of line extension. By contrast, "such as" extended release formulations indicates that some, but not all, extended release formulations are an example of a type of line extension.

We also note that in an Energy & Commerce committee report describing this provision, lawmakers explained that the law in effect prior to the ACA permitted manufacturers to avoid additional rebate requirements "by making slight alterations to existing products, sometimes called line-extensions[.]" (H.R. Rep. No. 111-299, Pt. 1 at 635 (2009)). Therefore, CMS would be going beyond the statute and legislative history if it interpreted all "extended release" formulations as a "line extension," especially since there has been significant research and continued efforts to improve on existing ADF technologies since that time.

We hope that CMS's decision to accept additional comments is a positive step towards a final rule that excludes ADFs from the line extension definition. It is imperative that we continue to support improvements in drug ADF technology in order to combat prescription drug abuse and the public health and societal challenges associated with it. Thank you for your attention to this critical matter.

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<sup>6</sup> <http://www.nga.org/files/live/sites/NGA/files/pdf/2016/1602PrioritiesOpioidCrisis.pdf>

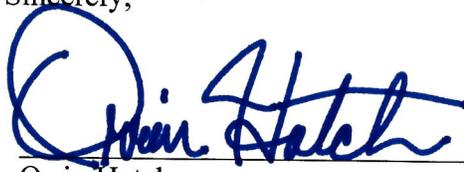
<sup>7</sup> <http://www.finance.senate.gov/imo/media/doc/Republicans%20Call%20on%20Administration%20to%20Halt%20Harmful%20Opioid%20Rule.pdf>

Sincerely,



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Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives



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Orrin Hatch  
Chairman  
Committee on Finance  
U.S. Senate



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Joseph R. Pitts  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives