



Congress of the United States
House of Representatives
Washington, DC 20515-1705

November 20, 2015

PLEASE RESPOND TO:

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Dear Secretary Burwell,

We write regarding a critical issue we have discussed many times: the epidemic of prescription drug abuse that continues to plague our country. We share your commitment to seeking solutions and today we urge you to utilize the Department of Health and Human Services' (HHS) regulatory authorities to encourage health care providers to consider prescribing abuse-deterrent opioids (ADOs), as appropriate, before prescribing opioids without abuse-deterrent properties, and to increase patient access to ADO options.

As you know, abuse of prescription opioids continues to take a devastating toll on individuals, families and communities across the nation. According to the Centers for Disease Control and Prevention (CDC), every day in the United States, 44 people die as a result of prescription opioid overdose. Deaths from overdose of prescription opioid painkillers have tripled since 2001, killing more than 16,000 in the U.S. in 2013. While we appreciate the efforts of HHS to date to address this crisis, including efforts by the Food and Drug Administration (FDA) to improve safety labeling for extended-release and long-acting (ER/LA) prescription painkillers and to encourage the development of opioid products that are designed to deter abuse, more can certainly be done to help address this public health crisis.

Many of us have long voiced the strong belief that the labeling of opioid products should support and guide appropriate opioid prescribing. We therefore heralded FDA's actions in 2013 to mandate new labeling for ER/LA opioids clarifying that these products should only be used for pain severe enough to require daily, around-the-clock, long-term opioid treatment, and that they should be only prescribed for patients for whom other, lower-risk pain medications are inadequate. These critical labeling changes have proved an important first step to help ensure that providers are fully aware of the risks posed by these products, and ultimately, they will help save lives.

Additionally, we have also followed with keen interest recent strides made in the development of opioid products with abuse-deterrent properties. Since 2010, a number of such products have been approved by FDA. And, in April of this year, FDA issued final guidance establishing a pathway for the development and approval of ADOs, clarifying the types of data required for abuse-deterrent labeling. While it is important to note that no ADO can entirely eliminate the risk of abuse, ADOs are an important part of a comprehensive strategy to reduce prescription opioid-related abuse, misuse and overdose. Continued innovation in this field will be critical to our success in bringing this epidemic to a close.

However, and unfortunately, the medical community has been slow to widely embrace the use of these products intended to deter and mitigate abuse. We urge you to examine the feasibility of implementing labeling requirements for extended release opioids (1) to inform physicians about the availability of abuse-deterrent products, and/or (2) to provide guidance that opioids without abuse-deterrent properties should only be considered when an abuse-deterrent version is not available, or when an ADO is not appropriate for the patient. Similar to the new safety labeling mandated in 2013, we believe such labeling has the potential to make a significant, positive impact on provider knowledge of ADO options, particularly when treating patients at risk for abuse. Of particular note, Medicare Part D plans place greater restrictions on patient access to ADOs than to non-abuse-deterrent generics opioids. We fear that limiting access to these new technologies as they become available could stifle innovation and only perpetuate the prescription drug abuse crisis.

Given the importance of raising awareness of and ensuring patient access to ADOs, we encourage you to review the current labeling of these products in an effort to (1) help ensure that physicians have the guidance they need to prescribe them and (2) ensure that payors, such as Centers for Medicare & Medicaid Services (CMS), are providing access to ADOs. We ask that you provide the signatories below with your views on how your regulatory tools could be utilized to assist in meeting these goals. In addition, we support and encourage a coordinated policy response to ADOs across HHS agencies, including CMS, CDC, the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration. In particular, we would welcome appropriate recognition and incorporation of the important concepts outlined in the FDA final guidance on the evaluation and labeling of ADOs in HHS policy guidance and educational documents addressing opioids, including the Secretarial Initiative announced in March 2015 entitled "Opioid Abuse in the U.S. and HHS Actions to Address Opioid Drug Related Overdoses and Deaths," the CDC's draft "Guideline for Prescribing Opioids for Chronic Pain," and the 2017 CMS Part D Call Letter.

Thank you again for your efforts to address this critical public health threat. We look forward to continuing to work with you to turn the tide of this epidemic.

Sincerely,



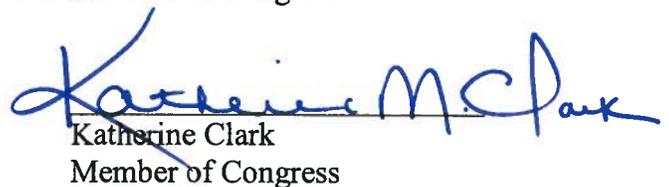
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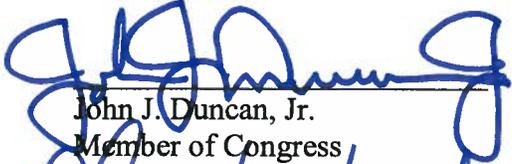
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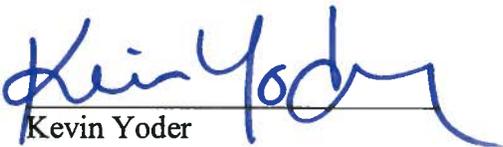
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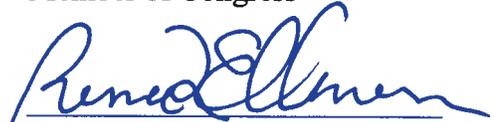
Kevin Yoder
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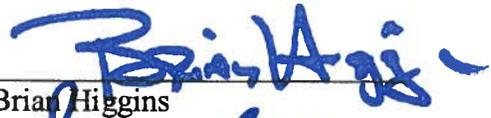
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