***VIA ELECTRONIC SUBMISSION TO THE DOCKET***

January 8, 2018

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-4182-P

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, MD 21244-1859

**RE: File code CMS-4182-P; RIN 0938-AT08**

**Comments regarding Proposed Rule: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program**

Dear Administrator Verma:

Collegium Pharmaceuticals appreciates this opportunity to provide its comments on the Proposed Medicare Part D Rule, and supports the efforts of the Centers for Medicare & Medicaid Services (CMS), and the Department of Health and Human Services (HHS), to combat drug addiction and the opioid crisis. We offer our comments specifically on the proposed regulations to implement the Comprehensive Addiction and Recovery Act (CARA). In aggregate, the provisions in the proposed rule that are intended to establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse (at-risk beneficiaries) have the potential to limit prescription opioid abuse or misuse and enhance the safety and effectiveness of the use of prescription opioids by beneficiaries. To be clear, Collegium condemns in the strongest terms the abuse of prescription opioid medications and is dedicated to working with the federal government and the private sector to eradicate the current opioid abuse crisis. However, we are writing to call your attention to and suggest modifications of certain provisions in the proposed rule that are scientifically unsound and which may inappropriately burden physician prescribers and cripple the access of beneficiaries with a medically appropriate need for a prescription opioid.

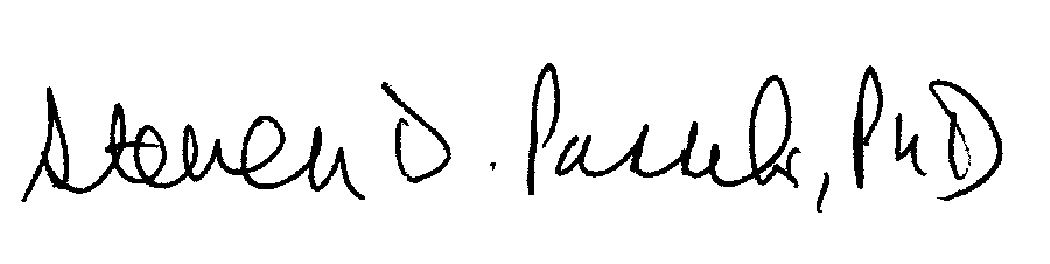
Collegium Pharmaceuticals, based in Canton, MA, is committed to the responsible and safe use of opioid therapy for people who have tried and failed other modes of pain management. Collegium believes that every patient with pain severe and chronic enough to require opioid therapy should be treated with the safest possible product in the lowest effective dose with sufficient monitoring and use of safeguards to attempt to protect against the development of abuse and addiction and their many, often deadly, complications. Our DETERx technology platform used in our extended release, long acting oxycodone product, Xtampza ER, is innovative and we believe has the potential to deter - not absolutely prevent - oral, nasal and intravenous abuse as well or better than existing abuse deterrent formulations. We also recently acquired the rights to market immediate release and extended release Nucynta (tapentadol) from Depomed. Tapentadol is an atypical opioid with weaker activity at the mu opioid receptor and norepinephrine reuptake activity and this dual mechanism is thought to be the basis of the provision of pain relief and its unique safety profile. At Collegium we are dedicated to attempting to bring the safest technology and molecules to the pain community to supplant less safe alternatives, not grow the overall opioid market.

The approach to dosing, monitoring, and concomitant use of other pharmacologic and non-pharmacologic interventions for pain should be delivered in a highly individualized way to accommodate to each patient’s unique needs for pain relief and safety. People with chronic pain have highly divergent medical, genetic and psychological profiles and opioid therapy cannot be effectively delivered to this diverse populations in a “one size fits all” fashion. The proposed rule change, instituting a 90 MMSE limit is, in our view, unfortunately just such an approach. It may be argued that an atypical opioid such as tapentadol is a particularly problematic case for the application of MMSE limits, but we are concerned about the use of any approach that places a universal limit on any opioid meant to apply to all patients thereby short circuiting the individualized clinical assessment and management of people with pain. There are multiple factors that interact with opioid dose – concomitant use of benzodiazepines and other centrally acting sedatives; renal function; history of obesity and/or sleep disordered breathing; history of aberrant use of prescription or illicit opioids and alcohol, to name a few – and thus, a single upper limit is likely to poorly serve a large segment of the population of opioid therapy patients. There is a danger to under dosing people with chronic pain as well, whether it be that poor pain control can lead to the loss of hope, despair and suicidal thinking on the one hand, or the forcing of people to improvise with other substances and medications to their ultimate peril on the other. A survey of over 3000 chronic pain patients and almost 300 health care providers conducted by Pain News Network and the International Pain Foundation found that the CDC guidelines and corresponding dose limits had a negative impact on patient care.  These include a worsened quality of life and pain, suicidal thoughts, and patients obtaining opioids illegally for pain relief (1).

The rule implies that the 90 MMSE level is not an ultimate limit but in the real world such rules are often treated as if they are and little is said about what will be required for additional titration beyond this level. Will abuse deterrent formulations be supported for higher dose patients? Pharmacogenetic testing? Psychological support? Urine drug testing? We certainly would support the more intensified use of safeguards in people treated with higher doses but as written now it seems that doses are likely to be limited without providing additional services for people who are unable to obtain relief and maintain psychosocial functioning at acceptable levels.

We therefore respectfully request that CMS reconsider this rule change and if the decision to go forward is taken to make provisions for patients and their doctors who need to titrate to higher doses so as to attempt to provide greater safety in such cases. People living with the scourge of chronic pain deserve no less.

Sincerely,



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Reference

1. <https://www.painnewsnetwork.org/stories/2017/3/13/survey-finds-cdc-opioid-guidelines-harming-patients>