



***By Electronic Delivery***

February 16, 2018

Senator Orrin G. Hatch, Chairman  
Ron Wyden, Ranking Member  
United States Senate  
Committee on Finance  
Washington, DC 20510-6200

**RE: BIO Response to Senate Finance Committee Request for Input on How to Address the Opioid Epidemic**

Dear Chairman Hatch and Ranking Member Wyden,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide feedback to the Senate Finance Committee (the Committee) on activities and policy solutions to address America's opioid crisis. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO commends the Committee's and Congress' continued efforts to address the opioid crisis. BIO and our members are committed to developing solutions to combat the opioid crisis. To this end, we have established a working group, composed of representatives from more than 27 of BIO's member companies, in order to identify ways in which the biotechnology industry can assist in mitigation of the opioid crisis and serve as a strong partner to other stakeholders involved in these efforts. The working group has established priorities that outline how BIO and our members can help mitigate the crisis, focused under three key pillars: (1) advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction, and ensuring appropriate and optimal use of existing therapies; (2) ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma; and (3) stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse.

As detailed through our pillars, BIO believes that the Committee and Congress must prioritize access to innovation in addressing the opioid crisis. To this end, BIO has developed a comprehensive approach for addressing the opioid crisis through the advancement of novel and safer treatment options for pain as well as current and new treatments for addiction. While some of our recommendations may fall outside of the Committee's jurisdiction, we find it is important to detail our recommendations across all

areas in order to inform the broader efforts in addressing America's opioid crisis. BIO's recommendations are based on actions across agencies engaged on solutions to the opioid crisis – the National Institutes of Health, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration – and rooted in our three priority areas:

***(1) Advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction and ensure appropriate and optimal use of existing therapies:*** Under this pillar BIO recommends the National Institutes of Health (NIH) establish an Opioid Research Steering Committee to prioritize and support research at the appropriate institutes and in academia focused on improving our understanding of the neurology of pain and addiction, and advancing preclinical modeling and development of better measurements of pain and addiction in the clinical setting. BIO supports increasing appropriated funds to the NIH to advance priorities outlined by this Steering Committee and the ability of the NIH to use "other transactional authority" to distribute such funds for research. Additionally, BIO supports the NIH's recommendations to the Drug Enforcement Agency (DEA) regarding research exemptions for controlled substances, as this can help advance scientific discoveries in pain and addiction treatment.

Further, the NIH should collaborate with stakeholders, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services and other agencies as appropriate to convene meetings focused on how to best collect, analyze, and apply data that answers important questions about quality, patient-centered pain and addiction treatment, and publish a report of meeting outcomes and recommendations for implementation.

***(2) Ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma:*** To support these ends, BIO recommends that the Centers for Medicare and Medicaid Services (CMS) develop an Opioid Action Plan, building on the Opioid Misuse Strategy, focused on removing coverage and reimbursement barriers that prevent patient-centered decisions about and access to the most effective treatments for pain and addiction, and further strengthens activities that have already been underway at CMS for addressing the opioid crisis. The proposed Action Plan would include an extensive review of coverage regulations and calls for broad stakeholder collaboration to update coverage and reimbursement policies and inform innovation models. In addition, implementation of laws and regulations that protect and promote access to comprehensive pain and addiction treatment must be reported upon to ensure success, and enhancements must be made to advance patient access to appropriate treatments across pain and addiction.

***(3) Stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse:*** Stimulation of research and development of novel treatments for pain and addiction is critical to ensuring an America free of addiction in the future. BIO recommends that the Food and Drug Administration (FDA) expand their Opioid Action Plan to include activities to better enable effective and efficient drug development and review for novel and safer

treatments for pain and innovative treatments for addiction, including enhancing and improving drug developers' abilities to utilize expedited approval pathways.

Most consistent with the Committee's focus and areas of jurisdiction are our priorities and recommendations related to ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma. BIO finds that the Committee can drive concerted efforts at CMS and within the Medicare and Medicaid programs that will help address the opioid crisis and ensure that patients suffering from pain and addiction are able to access the most appropriate form of treatment. Our response to the Committee's request and questions, detailed further in the balance of this letter, emphasizes policy priorities in Medicare and Medicaid for mitigating and preventing opioid use disorder and improving access to high-quality, patient-centric care for pain and addiction. The areas highlighted below are consistent with the recommendations outlined in BIO's proposed CMS Opioid Action Plan. We believe that through strong, focused actions in Medicare and Medicaid, policies and recommendations can stimulate changes across the healthcare marketplace that will help address the crisis.

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**Committee Questions:**

- ***How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?***
- ***How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?***

**BIO Response:** Medicare and Medicaid are central to healthcare coverage for Americans, covering over 55 million and 74 million lives respectively.<sup>1</sup> BIO believes that Medicare and Medicaid play a critical role in ensuring and expanding access to currently available and innovative non-addictive and/or abuse-deterrent pain medications, as well as existing and novel treatment options for addiction, and future innovations in medications for pain and addiction. BIO encourages the Committee to require updates to payment regulations and coverage policies that prioritize patient access to innovative medications and treatment options across the continuum of care for pain and addiction.

Coverage policies in Medicare and Medicaid should prioritize access to FDA approved pain treatments that reduce, mitigate, or prevent addiction in the first place (e.g. abuse-deterrent formulations), and medication assisted treatments (MAT) for patients with addiction. This includes elimination of coverage barriers that may preclude timely patient access to the most appropriate care, such as step-therapy, fail first requirements, burdensome cost-sharing, or care limitations on substance use disorder treatments and related services. For instance, the guidelines governing benefit design for the Medicare Advantage and Medicare Part D programs can ensure plan benefit structures provide

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<sup>1</sup> Kaiser Family Foundation, [Total Number of Medicare Beneficiaries](#), 2015; [Medicaid and CHIP Enrollment Data Highlights](#), November 2017 (includes CHIP enrollment).

sufficient coverage for novel and safer pain treatments as well as existing and new addiction treatments.

Additionally, Medicare payment regulations should facilitate rapid uptake of new medications through timely issuance of healthcare payment codes for the outpatient setting, accurate reflection of costs of care and associated services in the inpatient setting, use of quality measures that prioritize the highest standard of care and innovative treatment options, and by ensuring that reimbursement based on route of administration or site-of-service for care does not serve as a barrier to access. Providing patients with novel and safer pain treatments is central to mitigating future addiction, and providing patients suffering from addiction with the most appropriate, quality care is critical to reduce the risk of relapse or death.

**Committee Question:**

- ***Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?***

**BIO Response:** Policies in the Medicare and Medicaid prescription drug program rules play a pivotal role in patient access to care. Strategies in these programs can mitigate opioid overutilization and addiction potential, while also ensuring patients have access to novel and safer medicines for pain and innovative treatments for addiction. BIO asks the Committee to institute updates to Medicare and Medicaid prescription drug policies that advance patient access to timely and appropriate treatment for pain and addiction.

In Medicaid, state preferred drug lists should not preclude or hinder access to pain treatments that either are abuse-deterrent or prevent addiction altogether, and should ensure those suffering from addiction have access to the most appropriate course of MAT for their given condition. Further, use of state Medicaid waivers under Section 1115A should not make it more difficult for our most vulnerable populations to access innovative treatment options, particularly for pain and addiction. BIO has serious concerns with waivers that have been proposed that fail to prioritize access to the most appropriate course of treatment for a particular patient, but rather place arbitrary restrictions on access to certain medications, failing to prioritize the most appropriate course of treatment for each patient's given health need.

Waivers that take a narrow focus based on cost considerations, instead of focusing on patient-centric, quality care, have significant negative impacts for patient access to both current and new innovative treatment options. Such types of waivers would be particularly concerning where they may impact patient access to novel and safer pain treatments as well as current and new addiction therapies, thereby impeding efforts to address the opioid crisis. BIO believes that states can use Section 1115A authority in an effective and efficient manner to positively benefit patients suffering pain or addiction, and we ask that this be considered when guiding Medicaid program activities.

In the Medicare Advantage (MA) and Part D prescription drug programs, BIO applauds the implementation of policies in the Comprehensive Addiction and Recovery Act (CARA) to address opioid overutilization in the Medicare Drug Utilization Review (DUR) and Opioid

Monitoring System (OMS) programs. We believe appropriate identification of beneficiaries “at risk” for OUD is a critical tool for combatting the crisis, but also that expanding access to novel and safer treatments in the Medicare prescription drug program will serve as a key component in addressing the crisis.

The recent Medicare Advantage and Part D program proposed rule estimated that more than 319,000 beneficiaries could potentially be at risk for opioid overutilization. In addition, the Department of Health and Human Services Office of the Inspector General notes that although many beneficiaries may receive opioids for legitimate uses, the high number raises concern. Novel and safer medicines can play a central role in reducing these risks, while still providing necessary treatment in appropriate cases for Medicare beneficiaries. BIO believes the Committee should consider how such innovations in treatment for pain can play a role in the DUR and OMS. Required use of novel and safer pain treatments for beneficiaries who have been identified as “at risk” under the parameters of the DUR and OMS should be considered, where appropriate.

Furthermore, appropriate formulary placement for novel and safer pain treatments can help minimize risk of OUDs and prioritize patient access to the most effective course of care. Currently, many plan sponsors place a variety of utilization management tools or cost-sharing requirements on therapies that represent an advance in innovation, limiting provider choice and patient access. We urge the Committee to acknowledge the role novel and safer analgesic therapies can play, by ensuring MA and Part D plans provide adequate access and do not place inappropriate utilization management or cost-sharing obligations on such products. By advancing access to formulations of pain treatments that have abuse-deterrent properties as defined and approved in FDA labeling, the Medicare and Medicaid programs can prevent risk not only to beneficiaries but also others who may have access to their medications in the home.

For individuals with Medicare Advantage or Part D plans who find themselves in the grips of addiction, it is imperative that all treatment options are equally accessible. Echoing our comments concerning access under Medicaid, current and novel therapies for addiction should be no less available under MA and Part D plans. Allowing plan sponsors to implement restrictive utilization management, site-of-service or cost-sharing policies can have potentially dire consequences. Especially in a patient population where the window for entrance into treatment can be short before an addicted individual decides to return to their drug of choice, access to the right treatment at the right time can mean the difference between life and death.

Prescription drug policies across the Medicare and Medicaid programs should also consider substitution or withdrawal of coverage for non-abuse deterrent formulations when an abuse-deterrent or non-addictive formulation with identical bioequivalence and patient outcomes becomes available. Such substitution and withdrawal considerations should be made as science advances a better understanding of the biology of pain and addiction, including patient outcomes and response to treatments. Application of such a policy should not hinder access for patients who require a specific type of pain treatment based on their condition, nor should it be considered appropriate beyond the space of therapies with addiction potential.

**Committee Question:**

- ***How can Medicare and Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?***

**BIO Response:** In Medicare and Medicaid's pivotal role in supporting healthcare services across the country, these programs can be instrumental in facilitating provider education to assist in mitigating and solving the opioid crisis. BIO believes that efforts to better inform healthcare professionals should not solely focus on high prescribing patterns, an important first step, but also on advancing the understanding of the treatment of pain and addiction for all prescribers. For this reason, BIO's policy proposals integrate considerations for updates to provider education and treatment guidelines.

Activities to educate providers should be continually updated to emphasize the highest standard of care and treatment, based on better scientific understanding of the biology of pain and addiction and FDA-approval of new therapies for the treatment of pain and addiction. It is imperative that providers who in any capacity have responsibility for the treatment of pain or addiction are armed with the most up-to-date information in combating the opioid crisis, including availability of innovative medications for pain and addiction, and how they can be appropriately integrated into a patient's overall treatment plan and the broader continuum of care for pain and addiction. Parameters across Medicare and Medicaid programs can help address barriers in providing the most accurate and relevant information to healthcare professionals.

Through partnership with provider organizations and other organizations that serve as thought leaders in the space of guidelines development, CMS can help disseminate and distribute new recommendations and advance access to innovative standards of treatment through applicable quality measures, coverage regulations, and communications with providers. Quality measures across the Medicare program should prioritize integration of new guidelines and pathways in treatment that reduce or mitigate addiction in treating pain, and that generate better patient outcomes in the treatment of addiction. Coverage and payment policies should correlate to advances in treatment and new standards of care, ensuring that site-of-service, cost-sharing obligations, or utilization management tools do not create a barrier to access.

**Committee Question:**

- ***What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?***

**BIO Response:** State and Medicaid innovation activities through the Centers for Medicare and Medicaid Innovation (CMMI) can also play a role in addressing the opioid crisis. BIO believes that CMS should serve as a convener of stakeholder ideas for innovative approaches to addressing the opioid crisis across the Medicaid and Medicare programs, through open forum discussion of ongoing activities and proposed new ideas. The Agency should collect and report on the discussion and considerations for potential recommended innovative policies. Consistent with our proposed CMS Opioid Action plan, we call upon the



Committee to stimulate collaborative engagement with stakeholders at the Agency to develop innovative policies that can address the epidemic and drive high quality patient care for pain and addiction.

In the development of any innovative policies or innovation models, key themes must be considered to ensure such activities are appropriate, measurable, and repeatable in other settings. BIO believes that the agency must delineate a clear stakeholder engagement strategy and process for collection and incorporation of feedback as models are being considered, implemented, and evaluated; assure that models are appropriately assessed before expansion or use in other areas; and use patient protection guardrails to ensure quality, patient-centric care is being delivered. We note that it is imperative that any innovative policies or models prioritize and preserve patient access to existing and new innovative therapies for the treatment of pain and addiction.

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BIO appreciates the opportunity to provide feedback to the Committee on policies to address the opioid crisis, and we again commend the Committee for its continued efforts toward an America free of addiction. We look forward to continuing to work with the Committee to discuss the proposals and policies raised in this letter. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is stylized with a large, looping initial "J".

James C. Greenwood  
President and CEO  
Biotechnology Innovation Organization

ATTACHMENTS: Biotechnology Innovation Organization, Policy Principles to Address the Opioid Crisis