



## **National Call for Commitment Statements on Reversing the U.S. Opioid Epidemic**

The Biotechnology Innovation Organization (BIO) and our member companies are committed to unleashing the power of scientific innovation to develop solutions that will allow for an America free of prescription opioid addiction by:

- 1. Advancing our 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.**
  - BIO supports efforts including research to investigate potential therapeutic targets with increased receptor/intracellular signaling selectivity, identification and validation of biomarkers that identify subsets of pain and more accurately predict treatment response for both pain and addiction that can more accurately identify subsets of pain or risk for addiction, identification and utilization of more effective drug screening models and assays that better translate to therapeutic outcomes for patients, elucidation of the underlying biological mechanisms of different types of pain and addiction, as well as differences in pain perception, development of a more comprehensive set of objective tools for assessing pain that take into account acute versus chronic pain, the possible neurobiological and psychosocial mechanisms underlying pain, individual differences in pain perception, and distinctions between somatic and psychic pain, development of diagnostic tools that enable the identification of specific causes of pain, expansion of clinical trial registries and clinical trial networks for pain and addiction to help develop, validate, refine, and deliver new treatment options to patients, research to further the development of approaches for determining risk or susceptibility for individual patients, and associate outcomes with the basic neurobiology and/or pharmacological alterations, research to further develop multi-disciplinary approaches for treating pain and addiction by enabling approaches for determining risk or susceptibility for an individual.
  
- 2. Ensuring patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma.**
  - BIO supports actions that ensure patient access to novel and safer treatment options for pain and addiction, including:

- Removing coverage and reimbursement barriers that are preventing patient-centric decisions about and access to the most effective treatment for pain and addiction across Medicare, Medicaid, and commercial health insurance.
- Advancing implementation of and adherence to laws and regulations protecting and promoting access to resources for comprehensive pain and addiction treatment.

### **3. Stimulating research and development (R&D) of innovative treatments that effectively treat pain and opioid addiction and prevent abuse.**

- BIO supports activities that can help streamline the regulatory process for novel and safer treatments for pain and addiction, including:
  - Improved mechanisms for comprehensively evaluating pain including how to better enable the utilization of biomarkers and novel endpoints. Following the stakeholder meeting, the FDA should update or develop relevant guidance documents.
  - Use of innovative clinical trial designs, including master protocols, platform trials, extrapolation and interpolation across indications, and real-world evidence in order to help mitigate issues with pain and addiction drug development.
  - The use of expedited approval pathways for novel and safer treatments for pain.