

Solving America's Opioid Crisis

Issue Background

Opioid addiction is plaguing communities across the country, leaving in its wake countless victims, devastated families and economic ruin. Long-term solutions to combating this crisis will depend upon biomedical innovation and the development of novel and safer, next-generation therapies to treat both pain and addiction. To get these new innovations to the patients whose lives depend on them, we must ensure that the policy and regulatory environment keeps pace with advances happening in the lab.

Unfortunately, the reality is that early-stage investments in treatments for pain and addiction are not at the levels of other therapeutic areas because of market and regulatory barriers. In addition, insurance coverage, reimbursement and regulatory challenges are also preventing access to innovative treatments that patients deserve. These barriers are adversely impacting the investment needed to develop safer, next-generation therapies to treat pain and addiction that can help tame the opioid crisis. **The public and private sectors must work together to remove these barriers to investment and unleash the full potential of biomedical innovation to solve the opioid crisis.**

Policy Position

For BIO and its member companies to develop solutions that address America's opioid crisis, a number of reforms are needed to help ensure appropriate access to critical treatments – as well as for the development of next-generation treatments. Recommendations include:

- Eliminating insurance coverage barriers that impede patients' access to the most appropriate treatments.
- Increasing expertise and resources within the FDA to ensure effective and efficient drug development and review processes for innovative treatments for pain and addiction.
- Enhancing and improving the ability to utilize expedited approval pathways for innovative treatments for pain and addiction.
- Partnering with key stakeholders in government, academia and industry to stimulate R&D and advance our understanding of the biology of pain and addiction.

Key Points

- ✓ **Approximately 70** companies are working on novel pain therapies.
- ✓ There are approximately **106 active clinical programs** for novel pain drugs.
- ✓ However, despite the tremendous scope of the opioid crisis, early-stage investment in next-generation pain and addiction treatments lags far behind other areas. For example, over the past 10 years, venture investment in novel oncology R&D was **17 times greater** than investment in pain management programs and even less venture investment goes to developing novel approaches to treat addiction.
- ✓ **Restrictive insurance coverage and reimbursement policies** are preventing access to safer treatments for pain and addiction and **hindering** greater investment in the space. As a recent *New York Times* headline noted: Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers.
- ✓ The United States is spending **nearly \$80 billion annually** in health and social costs to combat this epidemic.
- ✓ Visit www.bio.org to read BIO's new report on the state of innovation in pain and addiction.