



ASAM American Society of
Addiction Medicine

Public Policy Statement on Ethical Promotion of Addiction Treatment Medications

Background

Significant and rapid progress has been made in both the scientific understanding of the disease of addiction and the medical interventions available to treat it. There has been especially notable expansion in the number of prescription pharmacotherapies available to treat patients with addiction, with the pharmaceutical arsenal of addiction medicine physicians nearly doubling since 2000. For example, approvals over the past 15 years by the Food and Drug Administration (FDA) of medications to treat addiction include:

- Buprenorphine (2002) and extended-release injectable naltrexone (2010) for opioid use disorder
- Acamprosate (2004) and extended-release injectable naltrexone (2006) for alcohol use disorder
- Varenicline (2006) for tobacco use disorder

Many of these prescription medications are currently sold under brand names by major pharmaceutical companies. Since addiction treatment was long characterized by nonpharmacological interventions and the use of generic medicines, the approval of these new brand-name products has introduced new questions about the role that pharmaceutical companies play in influencing treatment decisions and policy for addiction treatment. Many aspects of the role of pharmaceutical companies merit thoughtful debate, such as how they develop and test their products, how they interact with academic medicine, and how they interact with clinicians, prescribers, and regulators. This public policy statement focuses on guiding principles for pharmaceutical companies' ethical marketing, advertising, information sharing, and advocacy practices related to addiction medications (collectively referred to as "promotion" of addiction medications).

Because addiction is a highly stigmatized disease that disproportionately affects vulnerable populations (e.g. persons who have experienced adverse childhood events) and uniquely can lead to adverse social consequences due to illness (e.g., involvement with the criminal justice system), pharmaceutical companies should adhere to the highest ethical standards when promoting addiction treatment medications.

Recommendations:

The American Society of Addiction Medicine recommends pharmaceutical companies that manufacture addiction treatment medications should:

1. Comply with FDA's regulations governing direct-to-consumer advertising, and should apply these principles to their marketing and information sharing with all consumer groups. This includes clinicians, payers, legislators, family and patient groups, and the criminal justice system. The FDA requires all direct-to-consumer communications to be (1) accurate and not misleading; (2) only include information that is supported by strong evidence; (3) balance the risk and benefit information; and (4) be consistent with the prescribing information approved by FDA.
2. Avoid language that stigmatizes patients or disparages other evidence-based treatment options in all promotional and advocacy communications.
3. Engage in no significant activity that may result in legislative or regulatory action limiting access to competitors' approved products.
4. Use accurate terminology and presentation of data that aligns with the scientific understanding and accepted definitions of substance use disorders.

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