

## State Legislation

# Opioid Tax Bills

**It is critical that we combat the misuse and abuse of prescription medication while maintaining legitimate, uninterrupted access to medicine by patients in need. Generic drug manufacturers play a key role in producing affordable FDA-approved therapies and believe that patient safety is of the utmost importance. It is a public health imperative that patients take medicines as prescribed and adhere to the instructions of their health care providers.**

### Patients need effective treatment for pain.

- Chronic pain is real and affects 30-60 million Americans. Improper pain treatment leads to higher utilization of health care and increased societal costs.
- Most patients taking opioids do not abuse their medicines. Millions of patients who suffer acute trauma, undergo surgery, or suffer from pain as the result of chronic disease such as cancer, rheumatoid arthritis, and other ailments rely on effective pain treatment.
- Appropriately treated pain allows patients to perform basic daily activities - walking, bathing, working, and can reduce the likelihood of lower self-esteem, depression, and suicide.<sup>1</sup>
- Legislation to prevent opioid abuse should be carefully crafted to avoid the unintended consequence of denying patients with legitimate pain access to low cost generic medications.
- Enhanced prescriber training, prescription adherence, safe storage, and proper disposal can help prevent medication abuse and ensure that patients get the full benefit of safe, effective, and affordable generic medicines.

### Misuse of prescription opioids is a public health challenge.

- The Centers for Disease Control and Prevention (CDC) estimates that the total 'economic burden' of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.<sup>2</sup>

### The production of opioid medicines is tightly controlled by federal authorities.

- FDA employs a rigorous process for opioid approval that requires that the benefits outweigh the risks of any product. The process also includes validation of safety and product medical need and appropriate labeling that informs physicians of known associated risks.
- The Drug Enforcement Administration (DEA) requires that all opioid manufacturers register and certify effective diversion controls, technical capabilities, and prior experience handling controlled substances.
- The DEA sets strict quantity limits on opioid manufacturing and uses its authority to set standards for prescribers and manufacturers that limit total annual opioid sales. Generic manufacturers cannot exceed these quotas.

**The DEA reduced opioid quotas for three straight years, most recently by 25% for 2019.**

- Manufacturers must report to the DEA (at least quarterly) inventories, acquisitions, and disposition of all Schedule II and III substances.

## Generic manufacturers do not engage in advertising or detailing.

- Generics simply enter into existing markets rather than creating new prescribing habits, thus, they are simply providing the supply to meet existing demand.
- Generic drug makers do not promote drugs to physicians or directly to patients. Generics are FDA approved as identical products and compete on price without the marketing typically used by brand manufacturers.
- Generic products, including opioids, can be automatically substituted at the pharmacy counter. There is no need for generic manufacturers to promote products because they rely on physicians to maintain responsible prescribing habits, and trust that their products will reach patients when substituted at the pharmacy counter.

## Proposals to tax opioids would undermine generic competition and increase prices for patients.

- Many generic products operate on razor-thin profit margins, which are extremely susceptible to minor market changes, including new regulatory requirements.
- Because generic products, including opioids, function on such low margins, new taxes or regulatory burdens would significantly increase costs for generic manufacturers.
- Manufacturers of affordable opioid medications may find there is no possibility of providing affordable products that can exist in a competitive market. As manufacturers are forced to deal with these realities, it is not unlikely that some will exit the market, reducing competition and increasing costs for patients and the system.
- Fewer generic competitors will result in higher generic prices and increased reliance on higher cost brand drugs.

For instance, the price of a prescription for Percocet is \$1,849.97, while the average generic equivalent is only \$41.80.

## Policymakers should consider the role of other supply chain entities that benefit from the sale of opioids.

- Any legislation should consider and evenly distribute responsibility on all stakeholders who take part in the distribution of such medicines to

patients (all of whom are regulated by DEA).

- Generic drug makers do not typically promote drugs to physicians or directly to patients, as do brand companies.
- Today, three large purchasing consortiums control 90% of the generic medicines sold in the US. Once a generic company sells its medicines to a wholesaler, the manufacturer no longer controls the further sale of the medicine.

## Strong policies can help reduce the opioid crisis but must ensure access to pain treatment for those who need it.

- Short-sighted policies like manufacturer opioid taxes and stewardship fees will decrease investment in lower cost opioids and will ultimately result in unintended consequences including:

The inability to exempt certain diseases/ conditions treated by opioids from being impacted by a tax that will result in reduced access by patients with the most severe pain.

Increased disparity of treatment for lower income patients.

Increased prices on drugs to treat other diseases/conditions.

Increased costs to state programs including Medicaid.

## State of play in the States:

- States are actively engaged in finding sound policy solutions to address the opioid crisis without reducing access to needed therapies through programs and policies including:

- 1) Prescription Drug Monitoring Programs (PDMP);
- 2) Script Limits;
- 3) Electronic prescribing for controlled substances;
- 4) "Lock-in" programs;
- 5) Proper disposal of unused or unwanted prescription drugs through the national U.S. Drug Enforcement Agency Take Back days; and
- 6) Prescriber Education.