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Opinion

Commentary: Congress should not micromanage opioid drug labels

By Thomas O. McGarity
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Sen. Joe Manchin, a Democrat from West Virginia, and Sen. Mike Braun, a Republican from Indiana, recently introduced a bill intended to help alleviate the opioid addiction crisis. The bill would prohibit the Food and Drug Administration from approving any label for the use of a long-acting opioid drug in treating chronic pain until the government completes a study on the efficacy of opioid drugs and promulgates "scientifically appropriate" labels for such drugs.

The senators are undoubtedly well intentioned, but their approach is flawed because it tries to solve a problem that begs for medical expertise by taking discretion away from the regulatory agency that is the repository of just such knowledge. In so doing, the bill ignores the very real needs of patients suffering from diseases that cause debilitating chronic pain — that is, people who have good reason to use powerful pain-killing drugs under careful supervision.

Overuse of opioid drugs is a serious problem, and it is keenly felt in West Virginia and Indiana, as well as here in Texas. Every day, more than 130 people in the United States die after overdosing on prescription pain relievers, heroin or illicitly manufactured synthetic opioids such as fentanyl.

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Some patients who are prescribed opioid drugs for pain wind up abusing them and ultimately become addicted to them. A small percentage move on to heroin or fentanyl. In the absence of treatment, find themselves on a treadmill that leads to overdose and its associated risks.

In the past, unscrupulous doctors have run "pill mills" in which they prescribed opioids to people who did not have a legitimate medical need, but most of those operations were shut down by vigilant law enforcement agencies.

The vast majority of doctors are by now well aware of the addictive properties of prescription opioids and therefore limit prescriptions for treating short-term pain following trauma or operations to a small supply to be used within a short timeframe.

But prescription opioids are also effective in treating chronic pain in some patients. In the case of people suffering from conditions such as sickle-cell disease, autoimmune disorders and traumatic injury, use of prescription pain relievers may be the only way to live a normal life. For example, Maria Higginbotham of Pierce County, Washington told NBC News her pain from adhesive arachnoiditis, a rare disease affecting her spinal cord, is "five times worse than childbirth." Since losing access to previously effective pain relief medication, she can no longer work outside her home.

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The Manchin-Braun bill is a brute-force attempt to attack the addiction crisis by taking away FDA's power to approve opioid drugs with scientifically appropriate labels. Scientists are constantly coming up with new formulations and new ways to deliver opioid drugs to reduce the likelihood of abuse. Under the bill, these new formulations and methods would not be available until the Department of Health and Human Services conducts a multi-year study.

The bill contains a narrow exception when the prescribing physician determines that all non-opioid pain management treatments are "inadequate or inappropriate." But given the history of over-prescribing and over-marketing of opioids by irresponsible doctors and pharmaceutical firms, legitimate pain management physicians are not likely to take the risk of having to justify to a law enforcement agency or medical board that other treatments are inadequate or inappropriate. Instead, they will prescribe a less effective drug or tell the patient to grin and bear it.

Rather than micromanaging the FDA, Congress should allow the agency to do its job and trust physicians to assess the risks and benefits of prescribing medications for their patients who suffer from debilitating chronic pain.

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