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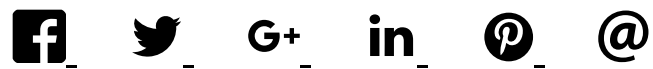
EDITOR'S PICK

FEATURED

Judge Goodwin: DEA had no evidence to support Oak Hill pharmacy suspension

By Erin Beck Register-Herald Reporter Nov 1, 2019

Charleston – A federal judge found this week that the federal Drug Enforcement Administration provided no proof Oak Hill Hometown Pharmacy was endangering patients before it stripped the pharmacy of its permission to sell controlled substances. Instead, Judge Joseph Goodwin, of the United States District Court for the Southern District of West Virginia, wrote in his decision that the pharmacy was filling prescriptions for a legal addiction medication, Subutex, in an area of West Virginia where many doctors and pharmacies refuse to provide the medication due to the stigma of addiction.



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Instead, Judge Joseph Goodwin, of the United States District Court for the Southern District of West Virginia, wrote in his decision that the pharmacy was filling prescriptions for a legal addiction medication, Subutex, in an area of West Virginia where many doctors and pharmacies refuse to provide the medication due to the stigma of addiction.

"The DEA has not pointed to a single instance of violation of the law," Goodwin wrote, in a decision rendered Wednesday. "The DEA does not even contend that a specific patient abused or diverted Subutex or Suboxone. The DEA simply offers what it sees as a suspicious pattern of the filling of lawful prescriptions for medication designed to treat opiate addiction."

On Aug. 8, DEA agents had served the pharmacy with an Immediate Suspension of Registration, blocking it from filling prescriptions for controlled substances. U.S. Attorney for the Southern District of West Virginia Mike Stuart held a press conference to announce that the DEA had suspended the Oak Hill pharmacy's registration on an emergency basis, saying that the pharmacy's sales of more than 2,000 prescriptions for Subutex over more than two years "in the face of obvious red flags of drug abuse and diversion" constituted an "imminent danger to public health or safety."

Subutex, a partial opioid, is prescribed to prevent symptoms of opioid withdrawal. Research shows that it can prevent death by overdose among patients with opioid use disorder. When taken as directed, the Substance Abuse and Mental Health Services Administration (SAMHSA) says Subutex, also known by its generic name buprenorphine, is only likely to cause a high among inexperienced users. However, some users crush and snort or inject the drug to create euphoric effects similar to heroin and sell the drug on the street.

Goodwin's order dissolved the Immediate Suspension of Registration, meaning the pharmacy is no longer blocked from filling prescriptions for controlled substances, at least for now. But the DEA is still seeking to revoke the pharmacy's registration on a more permanent basis. Oak Hill Hometown Pharmacy will be given the opportunity to make its case in a hearing

Judge Goodwin said that Uttam Dhillon, acting administrator of the DEA, had offered no proof that Subutex purchased at the pharmacy was being sold on the street, offering only "red flags." He also noted that the law dictates the DEA must show "imminent danger" before suspending a pharmacy's registration on an emergency basis.

"This standard requires more than mere surmise of abuse and diversion of a controlled substance," Goodwin wrote.

Stuart had said over half the prescriptions came from an out-of-state clinic located almost 200 miles away from Oak Hill, and that in some cases, patients drove more than 600 miles. Stuart said about 96 percent of the prescriptions were paid for in cash.

The DEA had argued Subutex is more likely to be diverted and abused than Suboxone, a similar medicine that also contains naloxone. Most people know naloxone, brand name Narcan, as the drug that can reverse opioid overdoses. But when combined with buprenorphine to make Suboxone, it makes the medication less susceptible to abuse because it brings on effects of withdrawal when the medication is injected or snorted. However, the FDA still recommends Subutex for patients who can't tolerate naloxone, include patients with an allergy to naloxone and pregnant women.

Goodwin, meanwhile, countered that the DEA had "not pointed to a single law or regulation that forbids prescribing Subutex to patients for whom the use of naloxone is safe."

In a memorandum submitted to the court, Oak Hill Hometown Pharmacy responded that they had told DEA agents that their patients traveled because there weren't enough doctors who would prescribe Subutex in West Virginia, and many pharmacies refused to fill those prescriptions, due to the stigma surrounding the medication. They also told them that patients were requesting partial prescriptions because when insurance wouldn't cover it, they couldn't afford to pay the full amount. They said that low-income patients couldn't afford Suboxone, but could afford Subutex, because it comes in a generic version.

They wrote that Oak Hill Hometown Pharmacy "has been a staple of the Oak Hill community since its inception in 2012."

"As a locally owned, family business, OHHP serves patients from Oak Hill and its surrounding areas," they wrote. "In short, OHHP was the fulfillment of a longtime goal of its part owner and head pharmacist, Martin Njoku, who has lived and worked as a pharmacist in that area for nearly thirty years. And shortly after its inception, OHHP's patient base soon began to grow.

In 2016, historic and catastrophic floods left much of Greenbrier and Nicholas Counties underwater and its businesses closed. As a result, patients from those and other affected counties began filling their prescriptions at OHHP. Like many businesses in West Virginia, especially those in the southern part of the State, the opioid epidemic also began to affect OHHP's business. In response to the epidemic, and in an effort to help remedy the deep scars that it has left on the community, OHHP filled prescriptions for a common medication, called Subutex, which was specifically approved by the FDA to treat patients with opioid use disorder."

Goodwin also wrote that he found it "important to keep in mind that Suboxone and Subutex are to be used to treat addiction."

"Access to effective treatment is of course essential. Yet in West Virginia—as well as many other parts of the country—access is limited," he wrote. "Many clinics in West Virginia have reached patient capacity, forcing prospective patients seeking treatment onto long waitlists. Additionally, many West Virginian pharmacies refuse to participate in MAT therapy because of the stigma of addiction or their fear of wholesalers declining to engage in business with them. I am personally familiar with the effect of opioids on this community from my decades of work with defendants on supervised release who desperately need treatment."

Goodwin also noted that the Controlled Substances Act's purpose is: "[t]o deal in a comprehensive fashion with the growing menace of drug abuse in the United States."

"The DEA was designed in part to enforce this statute, tackling head-on the criminal abuse of controlled substances. Although buprenorphine is a controlled substance, I cannot ignore the purpose of Subutex and Suboxone. These medications play an essential role in addressing the "menace of drug abuse in United States."

We cannot solve addiction to opioids solely through criminal law enforcement. This epidemic also requires medical intervention. When the government uses tools that were chiefly developed to crackdown on illegal drugs to impede the lawful prescription of substances for MAT therapy, it may erect barriers to that necessary medical intervention."

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MD **Margaret drumheiser** 15 HRS AGO

This is outrageous!! We need to die away with the DEA!! Now first attacking millions of us with disabling intractable chronic pain by going after innocent Dr just trying to do their jobs and treating thrif pts effectively with pain meds, then cutting manufacturing of the meds and how much pharmaceutical companies can distribute to pharmacies, hospitals, hospice programs causing widespread shortages throughout, now artcacking pharmacies just for filling these scripts and now their attacking pharmacies for filling addiction treatment meds. Yet the drug cartels continue to manufacture and distribute the real reason for this crisis illegal drugs (illicit fentanyl, herion, meth, cocaine and fake pills made to look like pain meds and benzos laced with illicit fentanyl and herion) why are they not doing their actual job and stopping the real reason for this crisis??? A lot easier to chase down and go after innocent Dr and pharmacies. ??? Does the DEA truely want to end this crisis!!! Then stop attacking those trying to treat addiction!! Dis they check to see if these pts had legitimate scripts?? If so then back off, they are not educated to treat either chronic pain or addiction. Makes me furious this drug subutex is not easily diverted because their monitored closely , urine tested, pill counts, their are many who can't take suboxone due to issues from the narcanmy niece is allergic to narcan documented by her Dr and she has to get pregnant authorized every 3 months (fight with her ins companies just to get it filled) then that's if like us with chronic pain can even get it filled) due to again guess who DEA restrictions on manufacture . Way to go judge it's about time someone stops the DEA with their outrageous witchhunting against the innocent while drug cartels continue

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