

Pharmaceutical Company Sues FDA for Rejecting New Opioid Abuse-Deterrent

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Pharmaceutical Manufacturing Research Services, Inc., or PMRS, has filed a petition asking the US Court of Appeals for the District of Columbia Circuit to overturn the US Food and Drug Administration?s refusal to approve a new deterrent for drug abuse. This new opioid capsule is intended to limit abuse through a novel combination of physical properties and labeling changes.

?We presented a product that updates the opioid Roxicodone with a useful indication for limited dosing and acute pain,? said PMRS. ?We are working hard to manage the risks associated with effective pain management. Our updated product and label respond to findings from the Centers for Disease Control that FDA-approved labeling of opioids for the treatment of 'chronic' pain is one of the drivers of the opioid crisis.?

The company asked the FDA for an opportunity to address the current opioid epidemic ?with a new product and more appropriate labeling,? said the PMRS, ?but the FDA wouldn't even give us a hearing?.

Addiction experts agree that the opioid crisis can be traced to 2001 when the FDA labeled opioids for long-term treatment of chronic pain. Click the link to see Stockton's top rehab placement programs.

The FDA previously said that the abuse deterrence language in PMRS?s label was ?false and misleading? because the company did not supplement its laboratory tests with clinical studies. The PMRS was testing the effects of adding dye to discourage intravenous misuse of the drug. However, there are no clinical studies that support the claim that the dye?s unattractive color would actually discourage drug abusers. The FDA has also refused to consider PMRS?s new label as a means of deterring abuse.

?The FDA fixated on the dye we added to our formula as defining the product's ability to deter abuse,? PMRS said. ?But that makes no sense for two reasons. First, intranasal and intravenous abuse are peripheral concerns for our product, which is limited in dosing and duration. Second, the clinical studies the FDA demanded are not required by the federal statute for new drug approval and have never reliably predicted real-world abuse scenarios.?

The PMRS also insists that the dye is ?the tail, not the dog? on the issue of abuse deterrence. The PMRS hopes to address the issue through both its product?s formulation as well as new labeling that removes the indication that it could help with chronic pain. The company explained the importance of labeling, saying that it limits a prescription opioid?s indication and dosing, which means it can prevent abuse and addiction.

?Once people become addicted, they will take great risks to defeat abuse-deterrent properties of prescription drugs or turn to even more dangerous sources, which is why we need to approach abuse-deterrence from the standpoint of prevention, starting with the labeling.?

The PMRS?s court filings say that the FDA?s refusal to even consider this approach ignores current science and the public interest. The company further stated that this is unlawful and should be overturned.

?If FDA has a problem with specific language in our proposed label, it should modify the label, not disapprove the drug altogether. That is the approach the FDA has taken to other opioids with the 'chronic pain' indication. This country desperately needs a product that has the therapeutic properties of Roxicodone, but without the chronic pain indication that is still driving an ongoing national health emergency. This is no time to ignore novel solutions allowed by law and supported by science in order to protect a flawed regulatory regime built around the chronic use indication.?

If someone in the family is struggling with opioid or alcohol addiction, it is important to seek help. A combination of medical detox and behavioral therapy can go a long way in the fight against drug abuse. But because every individual is affected by addiction differently, a comprehensive program tailored to their specific needs is necessary. Look for a nearby addiction treatment facility today and find out how drug

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