

Mass. sued over restrictions on painkiller Zohydro

By Philip Marcelo | ASSOCIATED PRESS JUNE 09, 2014

BOSTON (AP) — A federal judge on Tuesday will consider whether Massachusetts' latest attempt to restrict a powerful new painkiller violates the U.S. Constitution.

Zogenix, the San Diego-based manufacturer of Zohydro, is asking the court to temporarily halt enforcement of the restrictions until the case is decided on its merits.

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Zohydro is a hydrocodone-based prescription drug that comes in higher doses than Vicodin and other comparable drugs. Some restrictions on the drug took effect mid-April and others in early May.

The company argues that the restrictions are pre-empted by federal law because they represent a “de-facto ban” on a drug

already approved by the U.S. Food and Drug Administration for use in cases of severe and chronic pain. It also claims that the rules improperly single out Zohydro.

State Attorney General Martha Coakley's office, meanwhile, wants U.S. District Court Judge Rya Zobel to dismiss the case entirely, arguing that states have the right to regulate the medical and pharmacy professions within their borders.

State public health officials have said the new regulations, which are similar to ones already in place in Vermont, do not run counter to the FDA approval process. They allow qualified patients to access the drug, but help prescribers better evaluate a patient's likelihood of abuse, officials say.

Gov. Deval Patrick already has declared a public health emergency around prescription drug abuse and has said he does not want Zohydro to exacerbate the epidemic. A federal judge has ruled the state's previous attempt to ban the drug outright was likely unconstitutional.

Under the new rules, doctors, dentists and other prescribers are required to examine a patient's substance abuse history and current medications before submitting a "letter of medical necessity" to a patient's pharmacist explaining the diagnoses and treatment plan. Pharmacists, meanwhile, cannot dispense the drug if they do not receive the medical need letter. They

also must go over the drug's precautions and warnings with the patient.

Judge Zobel is expected to consider one or both of the requests Tuesday — either temporarily blocking the state's restrictions or dismissing the lawsuit entirely.