New York to Hold Clinical Trials for Marijuana

JOSEFA VELASQUEZ, Associated Press

ALBANY, N.Y. (AP) — New York state is partnering with a British company to hold clinical trials for marijuana-based medication for children who have seizures that are resistant to their medicine.

An agreement was signed on Sunday between Gov. Andrew Cuomo's administration and GW Pharmaceuticals. The state health department and the company will develop the framework for a clinical trial for a marijuana-based drug for people under the age of 18.

It will involve Epidiolex, an investigational medication that uses cannabidiol, a marijuana extract that doesn't get users high. It could help children with rare forms of epilepsy such as Dravet and Lennox-Gastaut syndromes.

Dravet syndrome is a rare genetic disorder typically untreatable by anti-epileptic drugs. It can be fatal. Lennox-Gastaut syndrome, another rare form of childhood-onset epilepsy, is characterized by different types of seizures multiple times a day and cognitive dysfunction. To be eligible for the trial, the children would have to show signs that their current medication is not working.

The health department is working on the framework for the protocol, which needs to be approved by the Food and Drug Administration before it is enacted. A state official with knowledge of the agreement told The Associated Press on Monday they expect FDA approval relatively quickly. The official spoke on condition of anonymity because the official was not authorized to speak publicly about the agreement.

In Colorado, the Charlotte's Web strain of marijuana, which is high in cannabidiol content, has received international attention for its effect on children with severe seizures. It also is low in the chemical responsible for most of marijuana's psychological effects. The Realm of Caring, a non-profit organization which produces the strain, currently has 206 people on its waiting list in the United States and separate waiting lists worldwide.

The announcement of the agreement with GW Pharmaceuticals comes as medical marijuana legislation is being pushed into the forefront of New York state politics.

In January, Cuomo, a Democrat, proposed a pilot program to allow 20 hospitals statewide to administer medical marijuana to seriously ill patients under the health department's guidelines.

The Legislature also is considering two medical marijuana bills. One called the "Compassionate Care Act" is making its way through the Republican-led Senate. It would allow patients with one of 20 serious illnesses to use the drug. The bill would bar anyone under the age of 21 from smoking marijuana, but would allow the drug

to be administered through a vaporizer, oil or something edible.

Another measure would prohibit smoking the drug in its entirety, but legalize medical marijuana use in vaporizer, oil or edible form for seriously ill patients.

Source URL (retrieved on *10/13/2015 - 5:07am*):
http://www.pharmpro.com/news/2014/06/new-york-hold-clinical-trials-marijuana