REPORT OF THE CHIEF LEGISLATIVE ANALYST

DATE: May 2, 2014

TO: Honorable Members of the Rules, Elections and Intergovernmental Relations Committee

FROM: Gerry F. Miller
Chief Legislative Analyst

Council File No.: 14-0002-S45
Assignment No.: 14-04-0275

SUBJECT: Resolution (Parks - Koretz) relative to research to develop a pharmaceutical version of a cannabis extract.

CLA RECOMMENDATION: Adopt the attached Resolution (Parks - Koretz) to include in the City's 2013-2014 Federal Legislative Program SUPPORT for any administrative action which would have the Food and Drug Administration (FDA) support pending research to develop a pharmaceutical version of a cannabis extract to treat epilepsy and to select the University of California, Los Angeles (UCLA) as one of the permitted sites to test this product.

SUMMARY

Resolution (Parks - Koretz) states that a British company that is developing a pharmaceutical version of a cannabis extract used to treat epilepsy could be allowed to test its product at UCLA as part of the FDA approval process. The Resolution states that the United Kingdom-based GW Pharmaceuticals received the approval to continue with clinical trials for their product Epidiolex in February and UCLA wants to be on the list of test sites. According to the Resolution, UCLA would treat a small number of patients with Epidiolex and record the results; if the data from UCLA and other test sites is encouraging, GW Pharmaceuticals will move into the next step of the FDA approval process.

The Resolution indicates that the UCLA research center will have to pass an inspection from the FDA because of the federal government's classification of marijuana as a Schedule I drug. According to the Resolution, some parents in states with medical marijuana programs have found success using existing products found in dispensaries and this would be the first time that the correct approach is being followed, especially through the federal government, to declare marijuana derived substances as legitimate medicine.

The Resolution recommends that the City support any administrative action which would have the Food and Drug Administration support pending research to develop a pharmaceutical version of a cannabis extract used to treat epilepsy and to select UCLA as one of the permitted sites to test this medication.

BACKGROUND

According to the Mayo Clinic, epilepsy is a neurological disorder which cause seizures and includes symptoms such as temporary confusion, uncontrollable jerking movements of the arms and legs, and loss of consciousness. Genetics, traumatic injury to the head, prenatal injury, and developmental disorders such as autism are contributing causal factors. The seizures caused by epilepsy can be life-threatening and can cause drowning, car accidents, and permanent brain damage and death. The Mayo Clinic indicates that the condition often develops in early childhood and after age 60 but can occur at any age and in most cases symptoms can be controlled with anti-seizure medications.

The Pediatric Epilepsy Center at the University of California, San Francisco (UCSF) states that it will lead a trial for Epidiolex, a cannabis extract-based anti-epilepsy medication. According to UCSF, treatment for children with uncontrollable seizures is needed because seizures may impact the long-term development of a child's brain. UCSF states that the FDA considers Epidiolex to be a Schedule I substance which is a designation which includes drugs such as heroin; therefore, it is monitored and restricted by the FDA and the United States Drug Enforcement Agency. According to UCSF, Epidiolex does not contain delta-9-tetrahydrocannabinol (THC) which is the main component of cannabis that causes changes in behavior or perception.

UCSF states that the clinical trial will enroll a total of 150 patients across six centers at UCSF Benioff Children's Hospital and at New York University Langone Medical Center. Pending FDA approval, clinical trials will begin at four additional institutions in 2014. Patients will be between one and 18 years of age with severe forms of epilepsy and/or Dravet syndrome, a rare genetic disorder which manifests in early childhood and causes frequent seizures. The FDA indicates that Epidiolex was designated as an "orphan drug" due to its intended use as a drug to treat a rare disease.

On April 9, 2014, the San Gabriel Valley Tribune reported that the Mattel Children's Hospital at the UCLA Medical Center wishes be a test site for the next phase in clinical trials to examine how patients respond to treatment with Epidiolex. The U.S. News and World Report indicates that the UCLA Medical Center is the first-ranked hospital in California and the ninth-ranked hospital in the nation.

The City should continue to take steps to retain its existing advantage in medical research, which in turn will enhance the City's ability to attract and retain high-quality jobs in the medical field. Therefore, we recommend that the City support Resolution (Parks - Koretz).

Departments Notified
None.

Brian Randol
Analyst

Attachment: Resolution (Parks - Koretz)

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RULES, ELECTIONS & INTERGOVERNMENTAL RELATIONS

RESOLUTION

WHEREAS, any official position of the City of Los Angeles with respect to legislation, rules, regulations or policies proposed to or pending before a local, state or federal governmental body or agency must have first been adopted in the form of a Resolution by the City Council with the concurrence of the Mayor; and

WHEREAS, a British company developing a pharmaceutical version of a cannabis extract used to treat epilepsy could be allowed to test its product at UCLA as part of the Food and Drug Administration approval process; and

WHEREAS, United Kingdom-based GW Pharmaceuticals received the approval to continue with clinical trials for their product Epidiolex in February and UCLA wants to be on the list of test sites; and

WHEREAS, the pharmaceutical company is willing to sponsor a small series of patients at half a dozen centers, but they are waiting for clearance by the federal Food and Drug Administration (FDA); and

WHEREAS, Epidiolex will use high concentrations of cannabidiol, a compound found in marijuana, to try to reduce seizures for patients with severe epilepsy, namely children with Dravet's syndrome or Lennox-Gastaut syndrome; and

WHEREAS, as a participant, UCLA would treat a small number of patients with Epidiolex and record the results; if the data from UCLA and other test sites is encouraging, GW Pharmaceuticals will move onto the next step in the FDA approval process; and

WHEREAS, UCLA's research center will have to pass an inspection from the Drug Enforcement Administration because of the federal government's classification of marijuana as a Schedule I drug; and

WHEREAS, some parents in states with medical marijuana programs have found success using existing products found in dispensaries; and

WHEREAS, this would be the first time that the correct approach is being followed, especially through the federal government, to declare a marijuana derived substances as legitimate medicine;

NOW, THEREFORE, BE IT RESOLVED, with the concurrence of the Mayor, that by the adoption of this Resolution, the City of Los Angeles hereby includes in its 2013-2014 Federal Legislative Program support for any administrative action which would have the Food and Drug Administration (FDA) support pending research to develop a pharmaceutical version of a cannabis extract used to treat epilepsy and to select UCLA as one of the permitted sites to test this product.

PRESENTED BY: _____
BERNARD C. PARKS
Councilman, 8th District

SECONDED BY: _____

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ADOPTED
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LOS ANGELES CITY COUNCIL