AGN. NO._____

MOTION BY SUPERVISOR MICHAEL D. ANTONOVICH NOVEMBER 18, 2014

In October 2013, Mikaela was diagnosed at age 24 with renal cell carcinoma, a deadly form of kidney cancer that migrated into her bones. She exhausted all approved treatments in just a matter of months – but the disease did not abate. The Knapp's learned about a new medicine being developed by three companies, but under the archaic rules of the U.S. Food and Drug Administration (FDA), the companies could only provide the medicine to patients enrolled in a clinical trial. The FDA denied Mikaela entry to every trial because of the advanced stage of her cancer.

Two years into their marriage, Keith launched a social-media campaign to convince the FDA to relax its rules enough to give Mikaela a fighting chance. It wasn't enough. The FDA wouldn't budge. Mikaela died on April 24, 2014.

The sad story of Mikaela and Keith, unfortunately, is not a rarity. The plight of dying patients was recently recognized by the World Health Organization as a result of the Ebola outbreak in West Africa, when its Ethics Committee declared the use of experimental drugs is an ethical exercise of clinical judgment. Some chance is better than none.

While the FDA has a program called "Compassionate Use" that allows dying patients to obtain experimental drugs, the process is so daunting that fewer than 1,000 people

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were able to obtain such drugs last year. The FDA's process is a bureaucratic nightmare for terminally ill patients who may only have weeks to live. These patients should not be forced to run an obstacle course to the treatment that might save their lives.

In an attempt to address the treatment needs of terminally ill patients and allow these individuals to take advantage of these experimental treatments without having to go through an arduous FDA process, several states have enacted bipartisan legislation or approved ballot initiatives to establish "Right to Try" laws. These states include Colorado, Louisiana, Missouri, Michigan, and Arizona, which was the first state in the nation to approve a "Right to Try" measure via a ballot initiative. With these legislative and voter-approved actions, terminally ill patients in these states can use experimental drugs or treatments not yet fully approved for consumer use by the FDA, as long as the treatment has: 1) successfully passed an initial safety trial; 2) received a recommendation from a doctor to access the treatment; and 3) received approval from a supplying drug company to offer the treatment.

Terminally ill patients who have exhausted their options in finding a cure and who have identified both a physician and a drug company willing to assist them in their pursuit of an experimental treatment, deserve the right to take advantage of these potentially life-saving opportunities.

I, THEREFORE, MOVE that the Board of Supervisors direct the Chief Executive Office and the Sacramento advocates to pursue or support State legislation, similar to the measures passed in other states, to allow the use of experimental drugs and/or biological products, which have passed the initial FDA safety trial, to be made available to terminally ill patients.

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