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November 17, 2014

To: Supervisor Don Knabe, Chairman
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Supervisor Michael D. Antonovich

From: William T Fujioka
Chief Executive Officer

MOTION TO PURSUE OR SUPPORT STATE LEGISLATION TO ALLOW TERMINALLY ILL PATIENTS TO USE EXPERIMENTAL DRUGS AND/OR BIOLOGICAL PRODUCTS UNDER SPECIFIED CIRCUMSTANCES (ITEM NO. 89-C, AGENDA OF NOVEMBER 18, 2014)

Item No. 89-C on the November 18, 2014 Agenda is a motion by Supervisor Antonovich 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 United States Food and Drug Administration (FDA) safety trial, to be made available to terminally ill patients:

Background

Over the years, terminally ill patients suffering from fatal diseases and illnesses, such as cancer, acquired immune deficiency syndrome, and Parkinson's disease have been limited in finding a cure to their illness to the drugs and/or treatments approved by the FDA. Unfortunately, FDA-approved drugs or treatments do not always offer a cure to a disease or illness, and in some cases, while one individual may respond positively to an approved drug, another individual with the same illness may not respond as positively despite using the same medication. While the FDA has sought to address the need for some patients to use yet-to-be-approved experimental drugs and/or treatments through the availability of the "Compassionate Use Exemption," the amount of time and effort needed for a terminally ill patient to receive approval of this exemption has been labeled by some critics as cumbersome, complicated to navigate, and mired in paperwork.

Compassionate Use Exemption

In 1987 the FDA established rules allowing patients to, under specified circumstances, obtain and use drugs that were still in their developmental phase. These rules, referred to as "expanded access" rules and also known as compassionate use, were amended in 2009 to ensure broader and more equitable access to investigational drugs. Under the Compassionate Use Exemption, individuals with a terminal illness and who are not responding to available FDA-approved medications/treatments, may seek permission from the FDA to be included in a clinical trial of a drug or procedure that has passed its initial safety testing.

According to the FDA, prior to requesting a Compassionate Use Exemption, a patient and their healthcare provider must: 1) search for a clinical trial that they may qualify for; 2) search for specific expanded access programs; 3) contact drug companies to ask about their policies; 4) contact patient advocacy organizations to obtain information on expanded access programs; 5) identify a physician willing to provide drug therapy oversight for a drug that he/she may not be familiar with; and 6) work with the identified drug company and the FDA to obtain the desired medication. According to Prevention.com, a total of 550 Compassionate Use Exemption requests were received by the FDA in 2013 and all received approval to proceed from the FDA.

Right to Try Laws Approved by States

In an attempt to address the experimental drug and/or treatment needs of terminally ill patients and avoid the FDA's lengthy and sometimes controversial process for obtaining a Compassionate Use Exemption, a number of states enacted legislation with bi-partisan support in 2014 establishing "Right to Try" laws. The first state to legislatively pass a "Right to Try" law was Colorado promptly followed by Louisiana, Missouri, and Michigan. In addition to the four states that have enacted "Right to Try" laws via the legislative process, Arizona became the first state in the nation to approve a "Right to Try" measure via a ballot initiative.

These legislative and voter-approved actions allow terminally ill patients in these states to use experimental drugs or treatments not yet fully approved for consumer use by the FDA on the conditions that: 1) the drug/treatment has successfully passed an initial safety trial; 2) the individual has received a recommendation from a doctor to access an unapproved drug or treatment; and 3) the individual has received approval from a supplying drug company to offer the drug/treatment for their use.

It is important to note that these "Right to Try" laws do not expand required coverage by health insurers, or require health plans, third party administrators, or governmental agencies to provide coverage for costs related to experimental treatment.

County Impact

Based on our research California has yet to consider any similar legislative or ballot initiative proposals. However, because of the momentum surrounding this issue nationwide and the enactment of "Right to Try" laws in five states, it would not be unexpected to see similar proposals introduced at some point during the 2015-16 Legislative Session.

Upon reviewing the Board's proposed motion and the related issue, the Department of Health Services has indicated that they would be supportive of "Right to Try" legislation so long as it ensures a fully informed and consenting patient. The Office of County Counsel notes that while the Federal government has yet to challenge these laws, it is possible that we may see these challenges in the future. County Counsel further notes that the constitutionality of these laws may be questionable and could be litigated at some point.

Conclusion

Because there is currently no Board-approved policy to pursue or support State legislation that allows for 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, **approval of this motion is a matter of Board policy determination**.

We will continue to keep you advised.

WTF:RA
MR:RM:lm

c: Executive Office, Board of Supervisors
County Counsel