



County of Los Angeles CHIEF EXECUTIVE OFFICE

Kenneth Hahn Hall of Administration
500 West Temple Street, Room 713, Los Angeles, California 90012
(213) 974-1101
<http://ceo.lacounty.gov>

SACHI A. HAMAI
Interim Chief Executive Officer

Board of Supervisors
HILDA L. SOLIS
First District

MARK RIDLEY-THOMAS
Second District

SHEILA KUEHL
Third District

DON KNABE
Fourth District

MICHAEL D. ANTONOVICH
Fifth District

March 20, 2015

To: Mayor Michael D. Antonovich
Supervisor Hilda L. Solis
Supervisor Mark Ridley-Thomas
Supervisor Sheila Kuehl
Supervisor Don Knabe

From: Sachi A. Hamai
Interim Chief Executive Officer

SACRAMENTO UPDATE

Executive Summary

This memorandum contains pursuits of County positions on the following legislation related to the Right to Try Act:

- **Pursuit of County Positions to Support AB 159 (Calderon) and SB 715 (Anderson).** These measures would establish the Right to Try Act which would permit a manufacturer of an investigational drug, biological product, or device, which has successfully completed Phase 1 of a clinical drug trial approved by the U.S. Food and Drug Administration, to make the product available to eligible patients with terminal illnesses. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that allows for the use of experimental drugs and/or biological products which have passed the initial U.S. Food and Drug Administration's safety trial, to be made available to terminally ill patients, **the Sacramento advocates will support AB 159 and SB 715.**
- **Pursuit of County Position to Support SB 149 (Stone), if Amended.** This bill would establish the Right to Try Act; however, SB 149 does not contain specific requirements to provide written, informed consent for terminally patients who

"To Enrich Lives Through Effective And Caring Service"

**Please Conserve Paper – This Document and Copies are Two-Sided
Intra-County Correspondence Sent Electronically Only**

would be eligible to receive investigational drug, biological product, or device, which has successfully completed Phase 1 of a clinical drug trial approved by the U.S. Food and Drug Administration under the Right to Try Act. Therefore, **the Sacramento advocates will support SB 149, if amended to provide specific requirements for written, informed patient consent.**

Background

Federal law requires a drug company to seek FDA-approval to sell a drug. This process includes conducting FDA-approved clinical trials on humans to determine if the drug is safe and effective for its intended use. The clinical trials are usually conducted in three phases.

Phase 1 clinical trials are typically limited to 20 to 80 healthy volunteers and are used to determine a drug's most frequent side effects. Phase 2 clinical trials involve hundreds of participants with the goal of determining the effectiveness of the drug for people who have a certain disease or condition. At the end of Phase 2, the FDA and the drug manufacturers may begin large-scale patient studies in Phase 3 trials. This phase typically includes thousands of patients during which researchers gain more information about the safety and effectiveness of the drug. When the Phase 3 clinical trials show that a new drug is more effective and/or safer than the current standard treatment, the drug company must submit a new drug application to the FDA for patient use. Even after obtaining FDA approval, new drugs are closely monitored for safety and effectiveness.

In addition to the clinical trials, the FDA has established compassionate use exemptions to help ensure broader and more equitable access to investigational drugs for terminally ill patients. 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. However, this process is complicated and burdensome for patients.

In an attempt to increase access to experimental drugs and treatments for terminally ill patients and to avoid the FDA's lengthy process for obtaining a compassionate use exemption, five states; Colorado, Louisiana, Missouri, Michigan, and Arizona have recently enacted bipartisan legislation or voter-approved ballot initiatives to establish "Right to Try" laws. These laws are essentially similar to the three measures introduced by members of the California Legislature, **AB 159 (Calderon)**, **SB 149 (Stone)** and **SB 715 (Anderson)**.

Overview of the Proposed Right to Try Bills

AB 159 (Calderon), which as introduced on January 21, 2015; **SB 149 (Stone)**, as introduced on January 29, 2015; and **SB 715 (Anderson)** as introduced on February 27, 2015, would permit a manufacturer of an investigational drug, biological product, or device, which has successfully completed Phase 1 of a clinical drug trial approved by the U.S. Food and Drug Administration, to make the product available to eligible patients with terminal illnesses. Specific provisions of these measures are described below.

Patients seeking Right to Try treatment must meet certain criteria which includes: 1) having a terminal illness attested to by his or her treating physician; and 2) giving written, informed consent for the treatment. AB 159 and SB 715 define written, informed consent to mean a document that is signed by the eligible patient, parent, or their legal guardian or legally authorized representative which does all of the following:

- Explains the currently approved products and treatments for the terminal illness from which the patient suffers;
- Attests to the fact that the patient, or his or her legal guardian or legally authorized representative, concurs with the patient's physician that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;
- Identifies the specific proposed investigational drug, biological product or device that the patient is seeking to use;
- Describes the best and worse outcomes from using the investigational drug, biological product or device, including the possibility that new, unanticipated, different or worse symptoms and that death could be hastened by the proposed treatment;
- States that the patient's health plan, or health provider are not obligated to pay for the treatment;
- States that the patient's eligibility for hospice may be withdrawn; and
- States that the patient understands that he or she is liable for all expenses related to the use of the investigational drug, biological product or device, and that this liability extends to the patient's estate or as otherwise provided in the patient's health care plan or the contract between the patient and the drug manufacturer.

SB 149 does not include specific requirements for written, informed patient consent.

All of the bills would prohibit a State regulatory board from revoking, failing to renew or taking any other disciplinary action against a physician's license based solely on the physician's recommendation or prescription for a patient to participate in the Right to Try.

AB 159 and SB 715 specifically provide that no cause of action is created against any person or entity involved in the care of an eligible patient using the investigational drug, biological product or device in the event any harm results, unless there was a failure by the person or entity to exercise reasonable care. SB 149 would also prohibit a State regulatory board from taking any action against a health facility's license based solely on the facility's treatment by or use of an investigational drug.

Conclusion

On November 18, 2014, the Board of Supervisors approved a motion which directed the Chief Executive Office and the Sacramento advocates to pursue or support State legislation, similar to measures passed in other states, to allow the use of experimental drugs and/or biological products, which have passed the initial Food and Drug Administration safety trial, to be made available to terminally ill patients. In the motion, the Board noted that 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.

As reported in November 2014, the Department of Health Services indicated that it would be supportive of Right to Try legislation which ensures that a patient is fully informed and provides consent. County Counsel concurs that this legislation should include significant protections to help ensure patient safety through a robust written, informed consent process. AB 159 and SB 715 contain such provisions. SB 149 does not.

This office and the Department of Health Services support AB 159 and SB 715. Therefore, unless otherwise directed by the Board, consistent with existing policy to support legislation that allows for the use of experimental drugs and/or biological products, which have passed the initial United States Food and Drug Administration's safety trial, to be made available to terminally ill patients, **the Sacramento advocates will support AB 159 and SB 715.**

AB 159 is scheduled for a hearing in the Assembly Health Committee on April 7, 2015. Currently, there is no registered support or opposition on file for this measure.

SB 715 is awaiting referral to the Senate policy committees.

Each Supervisor
March 20, 2015
Page 5

As noted above, SB 149 does not contain specific requirements to provide written, informed consent for terminally patients who would be eligible to receive investigational drug, biological product, or device, which has successfully completed Phase 1 of a clinical drug trial approved by the U.S. Food and Drug Administration under the Right to Try Act. Therefore, **the Sacramento advocates will support SB 149, if amended to provide specific requirements for written, informed patient consent.**

SB 149 has been referred to the Senate Committees on Health and Business, Professions and Economic Development. The committees have not yet scheduled hearings on this measure. SB 149 is sponsored by the Goldwater Institute.

We will continue to keep you advised.

SAH:JJ:MR
VE:lm

c: All Department Heads
Legislative Strategist
Local 721
Coalition of County Unions
California Contract Cities Association
Independent Cities Association
League of California Cities
City Managers Associations
Buddy Program Participants