SB-180 Gene therapy kits: advisory notice and labels. (2019-2020)

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Senate Bill No. 180

CHAPTER 140

An act to add Chapter 37 (commencing with Section 22949.50) to Division 8 of the Business and Professions Code, relating to gene therapy kits.

[Approved by Governor July 30, 2019. Filed with Secretary of State July 30, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

SB 180, Chang. Gene therapy kits: advisory notice and labels.

Existing federal law establishes the United States Food and Drug Administration to, among other duties, promote the public health by taking appropriate action on the marketing of regulated drugs, devices, and biological products in a timely manner.

Existing law governs various business practices in this state, including certain laws relating to health and safety, such as a prohibition against the use by a business establishment of polyethylene plastic bags large enough to fit over a child's head as a container for products, as specified.

This bill, except as permitted by federal law, would prohibit a person from selling in this state a gene therapy kit, as defined, unless the seller includes a notice on the seller's internet website in a conspicuous location that is displayed to the consumer prior to the point of sale, and on a label on the package, in plain view and readily legible, stating that the kit is not for self-administration. The bill would also include legislative findings and declarations.

Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature hereby finds and declares all of the following:

(a) CRISPR is a new gene editing technology that is a substantial improvement over other gene editing technologies in the ease of use, efficacy, and, in particular, cost. CRISPR is an acronym for "clustered regularly interspaced short palindromic repeats," which are unique DNA sequences found in some bacteria and other microorganisms. The most-studied CRISPR system is associated with the Cas9 protein and is known as CRISPR-Cas9. During 2012 and 2013, researchers modified CRISPR-Cas9 to serve as an effective and efficient technology for editing the genomes of plants, animals, and microorganisms. Many in the scientific community believe CRISPR-Cas9 (hereafter CRISPR) has revolutionized gene editing with its simplicity, low cost relative to other methods of gene editing, and creation of new research opportunities.

(b) CRISPR has the potential to offer revolutionary advancements in the investigation, prevention, and treatment of diseases, especially those with limited or no effective treatments. There has been significant research using CRISPR to treat diabetes, malaria, and sickle cell disease, among others.

(c) The interest, efforts, and investments of the industrial and financial communities suggest the potential economic benefits are substantial. It is anticipated that the global market for gene editing will reach $8.1 billion by 2025. The potential of CRISPR is further reflected in the rapid increase in CRISPR-related federal research funding and scientific publications. Funding from the National Institutes of Health grew from $5,100,000 in 2011 to $603,000,000 in 2016. Similarly, the number of CRISPR-related publications increased from 86 in 2011 to 2,162 in 2016.

(d) However, there are concerns within the science community on the amateur use of this innovative technology. Currently, there are materials with the capabilities of experimenting with CRISPR technology available for purchase by the public. These “CRISPR kits” have been marketed for self-administration. The affordability and accessibility of these products have benefited educational institutions, but concerns remain about the impact on consumer safety and public health.

(e) Concerns have also been raised as to what can be created through the amateur use of CRISPR technology. There are instances in which research teams have recreated extinct strains of viral diseases from scratch. The use of CRISPR technology has been subjected to regulations in the European Union. The United States Food and Drug Administration has stated that the sale of gene therapy products with the intent of self-administration is against the law, and cites concerns about safety risks.

(f) It is the intent of the Legislature to ensure the safety of the consumer and the public without stifling innovation. Due to the infancy of CRISPR technology, especially for public consumption, more research is needed to ensure safety of the administration of these products. Therefore, it is appropriate to notify consumers that any CRISPR-related gene therapy products for sale are not intended for self-administration.

SEC. 2. Chapter 37 (commencing with Section 22949.50) is added to Division 8 of the Business and Professions Code, to read:

CHAPTER 37. Gene Therapy Kits: Notice

22949.50. Except as permitted by federal law, a person shall not sell a gene therapy kit in this state unless the seller includes a notice on the seller’s internet website in a conspicuous location that is displayed to the consumer prior to the point of sale, and on a label on the package containing the gene therapy kit, in plain view and readily legible, stating that the kit is not for self-administration.

22949.51. For purposes of this chapter, the following definitions apply:

(a) “Gene therapy” refers to the administration of genetic material to modify or manipulate the expression of a gene product, or to alter the biological properties of living cells, for therapeutic use.

(b) “Gene therapy kit” refers to a product that is sold as a collection of materials for the purpose of facilitating gene therapy experiments, including, but not limited to, a system for the targeted cutting of DNA molecules, such as type II clustered regularly interspaced short palindromic repeats (CRISPR), associated proteins (CRISPR-Cas) systems, including CRISPR-Cas9, as described in Regents of University of California v. Broad Institute, Inc. (2018) 903 F.3d 1286.