



General Assembly

Amendment

February Session, 2010

LCO No. 5721

SB0042805721SD0

Offered by:

SEN. HARRIS, 5th Dist.

REP. RITTER, 38th Dist.

To: Subst. Senate Bill No. 428

File No. 379

Cal. No. 271

"AN ACT CONCERNING REVISIONS TO THE PUBLIC HEALTH RELATED STATUTES."

1 After the last section, add the following and renumber sections and
2 internal references accordingly:

3 "Sec. 501. (NEW) (*Effective October 1, 2010*) As used in sections 501
4 and 502 of this act:

5 (1) "Biologic" means a "biological product", as defined in 42 USC
6 262(i), as amended from time to time, that is regulated as a drug under
7 the federal Food, Drug and Cosmetic Act, 21 USC 301 et seq.;

8 (2) "Department" means the Department of Consumer Protection;

9 (3) "Medical device" means an instrument, apparatus, implement,
10 machine, contrivance, implant, in vitro reagent or other similar or
11 related article, including any component, part or accessory, that is: (A)
12 Recognized in the official National Formulary or the United States
13 Pharmacopeia or any supplement thereto; (B) intended for use in the

14 diagnosis of disease or other conditions or in the cure, mitigation,
15 treatment or prevention of disease, in persons or animals; or (C)
16 intended to affect the structure or function of the body of a person or
17 animal, and that does not achieve its primary intended purposes
18 through chemical action within or on such body and that is not
19 dependent upon being metabolized for the achievement of its primary
20 intended purposes; and

21 (4) "Pharmaceutical or medical device manufacturing company"
22 means any entity that: (A) Is engaged in the production, preparation,
23 propagation, compounding, conversion or processing of prescription
24 drugs, biologics or medical devices, either directly or indirectly, by
25 extraction from substances of natural origin or independently by
26 means of chemical synthesis or by a combination of extraction and
27 chemical synthesis; or (B) is directly engaged in the packaging,
28 repackaging, labeling, relabeling or distribution of prescription drugs,
29 biologics or medical devices. "Pharmaceutical or medical device
30 manufacturing company" does not include a health care provider,
31 physician practice, home health agency, hospital licensed in this state,
32 wholesale drug distributor licensed in this state or a retail pharmacy
33 licensed in this state.

34 Sec. 502. (NEW) (*Effective October 1, 2010*) (a) On or before January 1,
35 2011, each pharmaceutical or medical device manufacturing company
36 shall adopt and implement a code that is consistent with, and
37 minimally contains all of the requirements prescribed in, the
38 Pharmaceutical Research and Manufacturers of America's "Code on
39 Interaction with Healthcare Professionals" or AdvaMed's "Code of
40 Ethics on Interactions with Health Care Professionals" as such codes
41 were in effect on January 1, 2010.

42 (b) Each pharmaceutical or medical device manufacturing company
43 shall adopt a comprehensive compliance program in accordance with
44 the guidelines provided in the "Compliance Program Guidance for
45 Pharmaceutical Manufacturers" dated April, 2003 and issued by the
46 United States Department of Health and Human Services Office of

47 Inspector General.

48 (c) Upon complaint, the department may investigate an alleged (1)
49 violation of subsection (a) of this section, or (2) failure to conduct any
50 training program or regular audit for compliance with the code
51 adopted pursuant to subsection (a) of this section by a pharmaceutical
52 or medical device manufacturing company. The Commissioner of
53 Consumer Protection may impose a civil penalty of not more than five
54 thousand dollars for any violation of the provisions of this section."