



General Assembly

**Amendment**

February Session, 2010

LCO No. 4881

**\*SB0027004881SD0\***

Offered by:

SEN. HARRIS, 5<sup>th</sup> Dist.

REP. RITTER, 38<sup>th</sup> Dist.

To: Subst. Senate Bill No. 270

File No. 468

Cal. No. 333

**"AN ACT CONCERNING THE PROHIBITION OF CERTAIN GIFTS FROM PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING COMPANIES TO HEALTH CARE PROVIDERS."**

1 Strike everything after the enacting clause and substitute the  
2 following in lieu thereof:

3 "Section 1. (NEW) (*Effective October 1, 2010*) As used in sections 1  
4 and 2 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. 2. (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."

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2010</i>	New section
Sec. 2	<i>October 1, 2010</i>	New section