

[Warning on Cough and Cold Medicine for Infants and Young Children Ordinance.]

Ordinance amending the San Francisco Health Code by adding Article 36, sections 3601 through 3609, to: (1) require businesses located in the City and County of San Francisco to post point-of-sale warnings on administering cough and cold medicine to infants and children younger than 2 6 years, and (2) provide penalties for violations.

Note: Additions are single-underline italics Times New Roman;
deletions are ~~strikethrough italics Times New Roman~~.
Board amendment additions are double underlined.
Board amendment deletions are ~~strikethrough normal~~.

Be it ordained by the People of the City and County of San Francisco:

Section 1. Findings.

(a) The City and County of San Francisco has a duty to protect the health of its citizens.

(b) Cough and cold medications have not been shown to be beneficial in reducing symptoms or duration of illness and are associated with significant harm (and in rare cases death) in infants and young children. The US Food and Drug Administration (FDA) has advised healthcare professionals to exercise caution when administering cough and cold medications to infants and children younger than 2 years. A Food and Drug advisory committee has recommended against use of the medications in children under six.

(c) No well-controlled scientific studies support the efficacy and safety of narcotics or dextromethorphan as antitussives (cough suppressants) in infants and ~~young children~~ under the age of 2 6 years. Indications for their use in infants and young children under the age of ~~two~~ six have not been established. In a systematic review of randomized controlled trials evaluating the efficacy of cough and cold medications in children, antitussives, antihistamine-

1 decongestant combinations, and antihistamines alone showed no difference in effectiveness
2 compared to placebos.

3 (d) Suppression of coughing in pulmonary airway diseases may be hazardous and
4 contraindicated. According to a January 2007 Center for Disease Control Study, in 2004-
5 2005, three infant deaths occurred due to administration of over-the-counter (OTC) or
6 prescription cough and cold medications.

7 (e) There are no FDA-approved dosing recommendations for OTC cough and cold
8 medications to children younger than 2 years. Dosage guidelines for children are
9 extrapolated from adult data and clinical experience, and thus are imprecise for children.

10 (f) Adverse effects and overdose associated with administration of cough and
11 cold preparations in children have been reported.

12 (g) Coughing due to acute viral airway infections is short-lived and may be treated
13 with fluids and humidity. A rubber suction bulb may be used to clear congestion from the
14 nose and saline nose drops should also be considered as an alternative to medication for
15 infants and young children.

16 (h) Education of patients and parents about the lack of proven antitussive effects
17 and potential risks of cough and cold medications in infants and *small* children under the age of
18 2 6 years is needed.

19 Section 2. The San Francisco Health Code is hereby amended by adding Article 36,
20 Sections 3601 through 3609, to read as follows:

21 **SEC. 3601. SHORT TITLE.**

22 *This Ordinance shall be entitled the "Child Cough and Cold Medicine Warning Ordinance."*

23 **SEC. 3602. DEFINITIONS.**

24 *For the purposes of this Ordinance, the following words shall have the following meanings:*
25

1 (a) "Business" means a fixed location within the City and County of San Francisco, whether
2 indoors or outdoors, at which merchandise is offered for sale at retail and that is required to obtain a
3 valid San Francisco business registration certificate from the San Francisco Tax Collector's office.

4 (b) "Cough or Cold Medicine" means drugs available "over the counter" or "OTC" and
5 without a doctor's prescription that are used to suppress coughs and/or reduce symptoms associated
6 with colds and includes nasal decongestants, antitussives, and antihistamines ingested orally.

7 (c) "Department" means the Department of Public Health.

8 (d) "Director" means the Director of the Department of Public Health.

9 (e) "Marketing for use in children" means cold and cough medications contained in
10 packaging that promotes the use of the product in children and that contains the words "child"
11 or "children" and/or includes a picture of a child on the packaging.

12 (f) ~~(e)~~ "Person" means an individual, trust, firm, joint stock company, corporation,
13 cooperative, partnership, or association.

14 **SEC. 3603. WARNING REQUIRED AT POINT OF SALE.**

15 All owners, managers, and proprietors in charge of businesses selling, or displaying for the
16 purpose of marketing for sale use in children, cough or cold medicines, shall post a warning sign in
17 a manner that is prominent and accessible at the point of product selection. Such sign shall be printed
18 on a white background with black text and in a legible manner with a depiction of a baby's face inside
19 a circle with a slash through it next to the following: "0-2 0-6". Such sign shall be in English, Spanish,
20 and Chinese conveying the following warning:

21 "WARNING: Based on a Federal Health Advisory Panel's recommendation to the
22 FDA... Not recommended for children under 2 6 years. When misused, these products have
23 caused illness and death in children under 2 6 years. -BEFORE USE, talk to your child's doctor
24 first."

1 The warning must be legible and easily readable by the average person to the naked eye.

2 **SEC. 3604. IMPLEMENTATION.**

3 The Director, after a public hearing, may adopt and may amend guidelines, rules, regulations,
4 and forms to implement this Ordinance. When businesses post a warning sign, they do so to comply
5 with City law and are not offering health care advice. Therefore, such businesses are not responsible
6 for the consumers' actions regarding the purchase of cold or cough medicines.

7 **SEC. 3605. ENFORCEMENT AND PENALTIES.**

8 (a) The Director may enforce the provisions of this Ordinance against violations by serving
9 notice requiring the correction of any violation within a reasonable time specified by the Director.
10 Upon the violator's failure to comply with the notice within the time period specified, the Director may
11 request the City Attorney to maintain an action for injunction to enforce the provisions of this
12 Ordinance and for assessment and recovery of a civil penalty for such violation.

13 (b) Any person that violates or refuses to comply with the provisions of this Ordinance shall
14 be liable for a civil penalty, not to exceed \$500 for each day such violation is committed or permitted to
15 continue, which penalty shall be assessed and recovered in a civil action brought in the name of the
16 people of the City and County of San Francisco, by the City Attorney, in any court of competent
17 jurisdiction. Any penalty assessed and recovered in a civil action brought pursuant to this Section shall
18 be paid to the Treasurer of the City and County of San Francisco.

19 (c) Any person who violates or refuses to comply with the provisions of this Ordinance shall
20 be guilty of an infraction, and shall be deemed guilty of a separate offense for every day such violation
21 or refusal shall continue. Every violation is punishable by (1) a fine not exceeding \$100 for a first
22 violation; (2) a fine not exceeding \$200 for a second violation within one year; (3) a fine not exceeding
23 \$500 for each additional violation within one year.

1 (d) In undertaking the enforcement of this Ordinance, the City and County of San Francisco
2 is assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing
3 on its officers and employees, an obligation for breach of which it is liable in money damages to any
4 person who claims that such breach proximately caused injury.

5
6 **SEC. 3606. OPERATIVE DATE.**

7 This Ordinance shall become operative on January 1, 2008. This ordinance shall go
8 into effect February 1, 2008, January 1, 2008, upon a determination that the FDA has failed
9 to require that labels on cold and cough medicine reflect that the product is dangerous to
10 children under 2-6 years. In the event that the FDA does require such warnings by
11 February 1, 2008, January 1, 2008, this ordinance shall be repealed in its entirety. The
12 determination as to whether the FDA has required such warnings shall be made by the
13 Board of Supervisors.

14 **SEC. 3607. SEVERABILITY.**

15 If any section, subsection, sentence, clause, or phrase of this Ordinance is for any reason held
16 to be invalid or unconstitutional by a decision of any court of competent jurisdiction, such decision
17 shall not affect the validity of the remaining portions of the Ordinance. The Board of Supervisors
18 hereby declares that it would have passed this Ordinance and each and every section, subsection,
19 sentence, clause, or phrase not declared invalid or unconstitutional without regard to whether any
20 portion of this Ordinance would be subsequently declared invalid or unconstitutional.

21 **SEC. 3608. NO CONFLICT WITH FEDERAL OR STATE LAW.**

22 Nothing in the Ordinance shall be interpreted or applied so as to create any requirement,
23 power, or duty in conflict with any federal or state law.

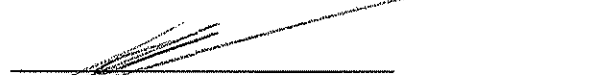
24 **SEC.3609. UNDERTAKING FOR THE GENERAL WELFARE.**

1 In adopting and implementing this Ordinance, the City and County of San Francisco is
2 assuming an undertaking only to promote the general welfare. It is not assuming, nor is it imposing on
3 its officers and employees, an obligation for breach of which it is liable in money damages to any
4 person who claims that such breach proximately caused injury.

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6
7 APPROVED AS TO FORM:

8 DENNIS J. HERRERA, City Attorney
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10 By:

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12 Aleeta M. Van Runkle
13 Deputy City Attorney
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City and County of San Francisco

City Hall
1 Dr. Carlton B. Goodlett Place
San Francisco, CA 94102-4689

Tails Ordinance

File Number: 071089

Date Passed:

Ordinance amending the San Francisco Health Code by adding Article 36, Sections 3601 through 3609, to: (1) require businesses located in the City and County of San Francisco to post point-of-sale warnings on administering cough and cold medicine to infants and children younger than 6 years, and (2) provide penalties for violations.

October 23, 2007 Board of Supervisors — RE-REFERRED: City Operations and Neighborhood Services Committee

Ayes: 10 - Alioto-Pier, Ammiano, Daly, Dufty, Elsbernd, Chu, Maxwell, Mirkarimi, Peskin, Sandoval
Excused: 1 - McGoldrick

December 11, 2007 Board of Supervisors — AMENDED

Ayes: 11 - Alioto-Pier, Ammiano, Chu, Daly, Dufty, Elsbernd, Maxwell, McGoldrick, Mirkarimi, Peskin, Sandoval

December 11, 2007 Board of Supervisors — PASSED ON FIRST READING AS AMENDED

Ayes: 10 - Alioto-Pier, Ammiano, Chu, Daly, Dufty, Elsbernd, Maxwell, McGoldrick, Mirkarimi, Sandoval
Noes: 1 - Peskin

January 8, 2008 Board of Supervisors — FINALLY PASSED

Ayes: 10 - Alioto-Pier, Ammiano, Chu, Daly, Dufty, Elsbernd, Maxwell, McGoldrick, Mirkarimi, Sandoval
Noes: 1 - Peskin

File No. 071089

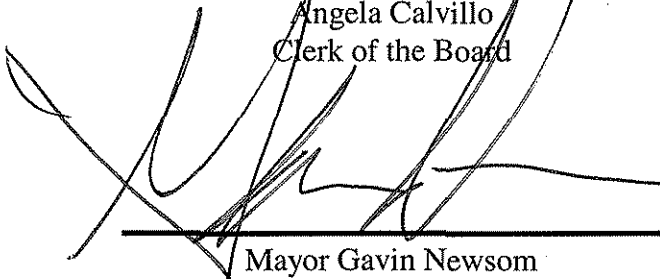
I hereby certify that the foregoing Ordinance
was **FINALLY PASSED** on January 8, 2008
by the Board of Supervisors of the City and
County of San Francisco.



Angela Calvillo
Clerk of the Board

1.14.08

Date Approved



Mayor Gavin Newsom