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CENTER FOR ENVIRONMENTAL HEALTH

ENDORSED
FILED
ALAMEDA COUNTY

JAN - 8, 2015

CLERK OF THE SUPERIOR COURT
BY MARGARET J. DOWNIE
Deputy

9 SUPERIOR COURT OF THE STATE OF CALIFORNIA
10 COUNTY OF ALAMEDA

11 CENTER FOR ENVIRONMENTAL HEALTH,)
12 a non-profit corporation,)

13 Plaintiff,)

14 v.)

15 UNITED MEDICAL DEVICES, LLC; and)
16 DOES 1 through 100, inclusive,)

17 Defendants.)

Case No.

RG15753967

**COMPLAINT FOR INJUNCTIVE
RELIEF AND CIVIL PENALTIES**

Health & Safety Code § 25249.6, *et seq.*

(Other)

1 Plaintiff Center for Environmental Health, in the public interest, based on
2 information and belief and investigation of counsel, except for information based on knowledge,
3 hereby makes the following allegations:

4 INTRODUCTION

5 1. This Complaint seeks to remedy Defendants' continuing failure to warn
6 individuals in California that they are being exposed to n-nitrosodiethylamine ("NDEA"), a
7 chemical known to the State of California to cause cancer. NDEA is a toxic chemical that is
8 often found in latex, including the latex used to make condoms. This Complaint addresses
9 exposures that have occurred, and continue to occur, through the manufacture, distribution, sale,
10 and/or use of Defendants' condoms (the "Products"). Individuals in California are exposed to
11 NDEA when they use the Products, or when their partner does, during sexual activities.

12 2. Under California's Proposition 65, Health & Safety Code § 25249.5, *et*
13 *seq.*, it is unlawful for businesses to knowingly and intentionally expose individuals in California
14 to chemicals known to the State to cause cancer without providing clear and reasonable warnings
15 to individuals prior to their exposure. Defendants introduce Products contaminated with
16 significant quantities of NDEA into the California marketplace, exposing users of their Products
17 to NDEA.

18 3. Despite the fact that Defendants expose individuals to NDEA, Defendants
19 provide no warnings whatsoever about the carcinogenic hazards associated with these NDEA
20 exposures. Defendants' conduct thus violates the warning provision of Proposition 65. Health &
21 Safety Code § 25249.6.

22 PARTIES

23 4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a
24 non-profit corporation dedicated to protecting the public from environmental health hazards and
25 toxic exposures. CEH is based in Oakland, California and is incorporated under the laws of the
26 State of California. CEH is a "person" within the meaning of Health & Safety Code §
27 25249.11(a) and brings this enforcement action in the public interest pursuant to Health & Safety
28 Code § 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group

1 that has prosecuted a large number of Proposition 65 cases in the public interest. These cases
2 have resulted in significant public benefit, including the reformulation of thousands of products
3 to remove toxic chemicals to make them safer. CEH also provides information to Californians
4 about the health risks associated with exposure to hazardous substances, where manufacturers
5 and other responsible parties fail to do so.

6 5. Defendant UNITED MEDICAL DEVICES, LLC is a person in the course
7 of doing business within the meaning of Health & Safety Code § 25249.11. UNITED
8 MEDICAL DEVICES, LLC manufactures, distributes, and/or sells Products for sale or use in
9 California.

10 6. DOES 1 through 100 are each a person in the course of doing business
11 within the meaning of Health & Safety Code § 25249.11. DOES 1 through 100 manufacture,
12 distribute, and/or sell Products for sale or use in California.

13 7. The true names of DOES 1 through 100 are unknown to CEH at this time.
14 When their identities are ascertained, the Complaint shall be amended to reflect their true names.

15 8. Defendant UNITED MEDICAL DEVICES, LLC and DOES 1 through
16 100 are collectively referred to herein as "Defendants."

17 JURISDICTION AND VENUE

18 9. The Court has jurisdiction over this action pursuant to Health & Safety
19 Code § 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant
20 to California Constitution Article VI, Section 10, because this case is a cause not given by statute
21 to other trial courts.

22 10. This Court has jurisdiction over Defendants because each is a business
23 entity that does sufficient business, has sufficient minimum contacts in California or otherwise
24 intentionally avails itself of the California market through the sale, marketing, or use of Products
25 in California and/or by having such other contacts with California so as to render the exercise of
26 jurisdiction over it by the California courts consistent with traditional notions of fair play and
27 substantial justice.

28 11. Venue is proper in the Alameda Superior Court because one or more of the

1 violations arise in the County of Alameda.

2 **BACKGROUND FACTS**

3 12. The People of the State of California have declared by initiative under
4 Proposition 65 their right “[t]o be informed about exposures to chemicals that cause cancer, birth
5 defects, or other reproductive harm.” Proposition 65, § 1(b).

6 13. To effectuate this goal, Proposition 65 prohibits exposing people to
7 chemicals listed by the State of California as known to cause cancer, birth defects, or other
8 reproductive harm without a “clear and reasonable warning” unless the business responsible for
9 the exposure can prove that it fits within a statutory exemption. Health & Safety Code § 25249.6
10 states, in pertinent part:

11 No person in the course of doing business shall knowingly and
12 intentionally expose any individual to a chemical known to the
13 state to cause cancer or reproductive toxicity without first giving
clear and reasonable warning to such individual ...

14 14. On October 1, 1987, the State of California officially listed NDEA as a
15 chemical known to cause cancer. 27 Cal. Code Regs. (“C.C.R.”) § 27001(b). On October 1,
16 1988, one year after it was listed as a chemical known to cause cancer, NDEA became subject to
17 the clear and reasonable warning requirement regarding carcinogens under Proposition 65. 27
18 C.C.R. § 27001(b); Health & Safety Code § 25249.10(b).

19 15. NDEA is a nitrosamine, a class of chemical compounds that form when
20 nitrates and amino acids combine. Nitrosamines such as NDEA can form during the
21 manufacturing process of latex products, including condoms. Defendants’ Products contain
22 sufficient quantities of NDEA such that individuals are exposed to NDEA through the average
23 use of the Products. The primary route of exposure is absorption by individuals through the skin
24 and mucous membranes when individuals use the Products. These exposures occur everywhere
25 throughout California where the Products are used during sexual activity.

26 16. No clear and reasonable warning is provided with Products regarding the
27 carcinogenic hazards of NDEA.

28 17. Any person acting in the public interest has standing to enforce violations

1 of Proposition 65 provided that such person has supplied the requisite public enforcers with a
2 valid 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the
3 action within such time. Health & Safety Code § 25249.7(d).

4 18. More than sixty days prior to naming each Defendant in this lawsuit, CEH
5 provided a 60-Day “Notice of Violation of Proposition 65” to the California Attorney General,
6 the District Attorneys of every county in California, the City Attorneys of every California city
7 with a population greater than 750,000, and to each of the named Defendants. In compliance
8 with Health & Safety Code § 25249.7(d) and 27 C.C.R. § 25903(b), each Notice included the
9 following information: (1) the name and address of each violator; (2) the statute violated; (3) the
10 time period during which violations occurred; (4) specific descriptions of the violations,
11 including (a) the routes of exposure to NDEA from Products, and (b) the specific type of
12 Products sold and used in violation of Proposition 65; and (5) the name of the specific
13 Proposition 65-listed chemical that is the subject of the violations described in each Notice.

14 19. More than sixty days prior to naming each Defendant in this lawsuit,
15 concurrent with sending the Notices described in the preceding paragraph, CEH also sent a
16 Certificate of Merit for each Notice to the California Attorney General, the District Attorneys of
17 every county in California, the City Attorneys of every California city with a population greater
18 than 750,000, and to each of the named Defendants. In compliance with Health & Safety Code §
19 25249.7(d) and 11 C.C.R. § 3101, each of the Certificates certified that CEH’s counsel: (1) has
20 consulted with one or more persons with relevant and appropriate experience or expertise who
21 reviewed facts, studies, or other data regarding the exposures to NDEA alleged in each of the
22 Notices; and (2) based on the information obtained through such consultations, believes that
23 there is a reasonable and meritorious case for a citizen enforcement action based on the facts
24 alleged in each of the Notices. In compliance with Health & Safety Code § 25249.7(d) and 11
25 C.C.R. § 3102, each of the Certificates served on the Attorney General included factual
26 information – provided on a confidential basis – sufficient to establish the basis for the
27 Certificate, including the identity of the person(s) consulted by CEH’s counsel and the facts,
28 studies, or other data reviewed by such persons.

1 20. None of the public prosecutors with the authority to prosecute violations
2 of Proposition 65 has commenced and/or is diligently prosecuting a cause of action against the
3 Defendants under Health & Safety Code § 25249.5, *et seq.*, based on the claims asserted in the
4 Notices.

5 21. Each Defendant both knows and intends that consumers in California will
6 consume the Products, thus exposing them to NDEA.

7 22. Under Proposition 65, an exposure is “knowing” where the party
8 responsible for such exposure has:

9 knowledge of the fact that a[n] ... exposure to a chemical listed
10 pursuant to [Health and Safety Code § 25249.8(a)] is occurring.
11 No knowledge that the ... exposure is unlawful is required.

12 27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final
13 Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2, §
14 12201).

15 23. Each Defendant has been informed of the NDEA in its Products by the 60-
16 Day Notice of Violation and accompanying Certificate of Merit served on each Defendant by
17 CEH.

18 24. Each Defendant also has constructive knowledge that its Products contain
19 NDEA due to the widespread media coverage concerning the problem of nitrosamines in latex
20 products in general and in condoms in particular. The problem of nitrosamines in latex products,
21 including condoms, has been the subject of articles in national newspapers, industry trade papers,
22 scholarly journals, and governmental reports, as well as numerous Internet weblog postings.

23 25. As companies that manufacture, import, distribute, and/or sell Products for
24 use in the California marketplace, each Defendant knows or should know that the Products
25 contain NDEA and that individuals who consumer the Products will be exposed to NDEA.
26 These NDEA exposures are a natural and foreseeable consequence of each Defendant’s placing
27 Products into the stream of commerce.

28 26. Nevertheless, each Defendant continues to expose consumers in California

1 **PRAYER FOR RELIEF**

2 Wherefore, CEH prays for judgment against each Defendant as follows:

3 1. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess
4 civil penalties against each Defendant in the amount of \$2,500 per day for each violation of
5 Proposition 65 alleged herein according to proof;

6 2. That the Court, pursuant to Health & Safety Code § 25249.7(a),
7 preliminarily and permanently enjoin each Defendant from offering Products for sale in
8 California without providing prior clear and reasonable warnings, as CEH shall specify in further
9 application to the Court;

10 3. That the Court, pursuant to Health & Safety Code § 25249.7(a), order each
11 Defendant to take action to stop ongoing unwarned exposures to NDEA resulting from use of
12 Products sold by each Defendant, as CEH shall specify in further application to the Court;

13 4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other
14 applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and

15 5. That the Court grant such other and further relief as may be just and
16 proper.

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18 Dated: January 8, 2015

Respectfully submitted,

19 LEXINGTON LAW GROUP

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22 _____
23 Joseph Mann
24 Attorneys for Plaintiff
25 CENTER FOR ENVIRONMENTAL HEALTH
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