

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

LEXINGTON LAW GROUP
Mark N. Todzo (State Bar No. 168389)
Joseph Mann (State Bar No. 207968)
503 Divisadero Street
San Francisco, CA 94117
Telephone: (415) 913-7800
Facsimile: (415) 759-4112
mtodzo@lexlawgroup.com
jmann@lexlawgroup.com

Attorneys for Plaintiff
CENTER FOR ENVIRONMENTAL HEALTH

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

CENTER FOR ENVIRONMENTAL HEALTH,
a non-profit corporation,

Plaintiff,

v.

PERRIGO COMPANY, *et al.*,

Defendants.

Case No. RG 20-054985

**FIRST AMENDED COMPLAINT
FOR INJUNCTIVE RELIEF AND
CIVIL PENALTIES**

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

(Other)

FILED BY FAX
ALAMEDA COUNTY
November 06, 2020
CLERK OF
THE SUPERIOR COURT
By Joanne Downie, Deputy
CASE NUMBER:
RG20054985

1 Plaintiff Center for Environmental Health, in the public interest, based on information and
2 belief and investigation of counsel, except for information based on knowledge, hereby makes the
3 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-nitrosodimethylamine ("NDMA"), a
7 chemical known to the State of California to cause cancer. Such exposures have occurred, and
8 continue to occur, through the manufacture, distribution, sale, and use of over-the-counter acid
9 reducing medications containing ranitidine (the "Products"). Individuals in California are
10 exposed to NDMA when they use the Products.

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

16 3. Despite the fact that Defendants expose individuals to NDMA, Defendants provide
17 no clear and reasonable warnings about the carcinogenic hazards associated with NDMA
18 exposure. Defendants' conduct thus violates the warning provision of Proposition 65, Health &
19 Safety Code § 25249.6.

20 **PARTIES**

21 4. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH ("CEH") is a non-profit
22 corporation dedicated to protecting the public from environmental health hazards and toxic
23 exposures. CEH is based in Oakland, California and incorporated under the laws of the State of
24 California. CEH is a "person" within the meaning of Health & Safety Code § 25249.11(a) and
25 brings this enforcement action in the public interest pursuant to Health & Safety Code §
26 25249.7(d). CEH is a nationally recognized non-profit environmental advocacy group that has
27 prosecuted a large number of Proposition 65 cases in the public interest. These cases have
28 resulted in significant public benefit, including the reformulation of thousands of products to

1 remove toxic chemicals and to make them safer. CEH also provides information to Californians
2 about the health risks associated with exposure to hazardous substances, where manufacturers and
3 other responsible parties fail to do so.

4 5. Defendant PERRIGO COMPANY is a person in the course of doing business
5 within the meaning of Health & Safety Code § 25249.11. Defendant PERRIGO COMPANY
6 manufactures, distributes, and/or sells the Products for sale and use in California.

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

10 7. Defendant APOTEX CORP. is a person in the course of doing business within the
11 meaning of Health & Safety Code § 25249.11. Defendant APOTEX CORP. manufactures,
12 distributes, and/or sells the Products for sale and use in California.

13 8. Defendant GRANULES PHARMACEUTICALS, INC. is a person in the course of
14 doing business within the meaning of Health & Safety Code § 25249.11. Defendant
15 GRANULES PHARMACEUTICALS, INC. manufactures, distributes, and/or sells the Products
16 for sale and use in California.

17 9. Defendant GRANULES USA, INC. is a person in the course of doing business
18 within the meaning of Health & Safety Code § 25249.11. Defendant GRANULES USA, INC.
19 manufactures, distributes, and/or sells the Products for sale and use in California.

20 10. Defendant 7-ELEVEN, INC. is a person in the course of doing business within the
21 meaning of Health & Safety Code § 25249.11. Defendant 7-ELEVEN, INC. manufactures,
22 distributes, and/or sells the Products for sale and use in California.

23 11. DOES 1 through 20 are each a person in the course of doing business within the
24 meaning of Health & Safety Code § 25249.11. DOES 1 through 20 manufacture, distribute,
25 and/or sell the Products for sale and use in California. Defendants PERRIGO COMPANY;
26 TARGET CORPORATION; APOTEX CORP.; GRANULES PHARMACEUTICALS, INC.;
27 GRANULES USA, INC.; 7-ELEVEN, INC.; and DOES 1 through 20 are collectively referred to
28 herein as “Defendants.”

1 12. The true names of DOES 1 through 20 are either unknown to CEH at this time or
2 the applicable time period before which CEH may file a Proposition 65 action has not run. When
3 their identities are ascertained or the applicable time period before which CEH may file a
4 Proposition 65 action has run, the Complaint shall be amended to reflect their true names.

5 **JURISDICTION AND VENUE**

6 13. The Court has jurisdiction over this action pursuant to Health & Safety Code §
7 25249.7, which allows enforcement in any court of competent jurisdiction, and pursuant to
8 California Constitution Article VI, Section 10, because this case is a cause not given by statute to
9 other trial courts.

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

16 15. Venue is proper in Alameda County Superior Court because one or more of the
17 violations arise in the County of Alameda.

18 **BACKGROUND FACTS**

19 16. The People of the State of California have declared by initiative under Proposition
20 65 their right “[t]o be informed about exposures to chemicals that cause cancer, birth defects, or
21 other reproductive harm.” Proposition 65, § 1(b).

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

27 No person in the course of doing business shall knowingly and
28 intentionally expose any individual to a chemical known to the state to

1 cause cancer or reproductive toxicity without first giving clear and
2 reasonable warning to such individual

3 18. On October 1, 1987, the State of California officially listed NDMA as a chemical
4 known to cause cancer. 27 Cal. Code Regs. (“C.C.R.”) § 27001(b). On October 1, 1988, one
5 year after it was listed as a chemical known to cause cancer, NDMA became subject to the clear
6 and reasonable warning requirement regarding carcinogens under Proposition 65. 27 C.C.R. §
7 27001(b); Health & Safety Code § 25249.10(b).

8 19. NDMA is a nitrosamine, a class of chemical compounds that form when nitrates
9 and amino acids combine. NDMA is used in laboratory research to induce tumors in
10 experimental animals. Nitrosamines such as NDMA can also form during the manufacturing
11 process of certain drug products, such as those containing ranitidine.

12 20. The U.S. Food and Drug Administration (“FDA”) performed a root cause analysis
13 to determine how and why nitrosamines, including NDMA, form in ranitidine and other drug
14 products. FDA’s analysis determined that NDMA formation can occur in ranitidine through the
15 use of contaminated materials and ingredients, the application of inferior drug manufacturing
16 processes, and improper drug storage after manufacture. Thus, Defendants can reduce or
17 eliminate NDMA from the Products by using cleaner ingredients and manufacturing processes
18 and more careful storage techniques.

19 21. Defendants’ Products contain sufficient quantities of NDMA such that individuals
20 are exposed to NDMA through the average use of the Products. The primary route of exposure is
21 through ingestion when individuals use the Products. These exposures occur everywhere
22 throughout California where the Products are used.

23 22. No clear and reasonable warning is provided with the Products regarding the
24 carcinogenic hazards of NDMA.

25 23. The Products are popular over-the-counter medications for treatment of heartburn.
26 They are part of a class of acid reducing products known as H2 blockers, because they block the
27 formation of acid in the stomach. There are a number of other H2 blockers available for over-the-
28 counter sale that do not contain ranitidine. The failure to provide warnings regarding the

1 carcinogenicity of NDMA in Ranitidine Products is of particular concern in light of evidence that
2 ingestion of NDMA causes cancer and the alternative products on the market that do not contain
3 NDMA.

4 24. Any person acting in the public interest has standing to enforce violations of
5 Proposition 65 provided that such person has supplied the requisite public enforcers with a valid
6 60-Day Notice of Violation and such public enforcers are not diligently prosecuting the action
7 within such time. Health & Safety Code § 25249.7(d).

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

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

1 for the Certificate, including the identity of the person(s) consulted by CEH's counsel and the
2 facts, studies, or other data reviewed by such persons.

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

7 28. Defendants both know and intend that individuals will use the Products, thus
8 exposing them to NDMA.

9 29. Under Proposition 65, an exposure is "knowing" where the party responsible for
10 such exposure has:

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

13 27 C.C.R. § 25102(n). This knowledge may be either actual or constructive. *See, e.g.*, Final
14 Statement of Reasons Revised (November 4, 1988) (pursuant to former 22 C.C.R. Division 2,
15 § 12601).

16 30. As companies that manufacture, import, distribute, and/or sell the Products for use
17 in the California marketplace, Defendants know or should know that the Products contain NDMA
18 and that individuals who use the Products will be exposed to NDMA. The NDMA exposures to
19 individuals who use the Products are a natural and foreseeable consequence of Defendants'
20 placing the Products into the stream of commerce.

21 31. Defendants have also been informed of the NDMA exposures caused by their
22 Products pursuant to the 60-Day Notice of Violation and accompanying Certificate of Merit
23 served on them by CEH.

24 32. Defendants have also been informed of the NDMA exposures caused by their
25 Products by a series of widely-publicized recalls of Products from the national marketplace due to
26 the presence of NDMA, which commenced in September 2019. These recalls were based on
27 findings of significant quantities of NDMA by an independent laboratory in Products that were
28 already made available for sale to consumers. Following up on these recalls, FDA issued a public

1 alert that (1) set forth the results of the agency’s testing in Products, which also found NDMA in
2 all Products tested, (2) instructed companies selling Products to perform their own testing for
3 NDMA in Products, and (3) advised such companies to recall their Products if testing confirmed
4 the presence of NDMA above certain federal levels.

5 33. Nevertheless, Defendants continued to expose individuals to NDMA without prior
6 clear and reasonable warnings regarding the carcinogenic hazards of NDMA even after the
7 publicity and recalls.

8 34. CEH has engaged in good-faith efforts to resolve the claims alleged herein prior to
9 filing this Complaint.

10 35. Any person “violating or threatening to violate” Proposition 65 may be enjoined in
11 any court of competent jurisdiction. Health & Safety Code § 25249.7. “Threaten to violate” is
12 defined to mean “to create a condition in which there is a substantial probability that a violation
13 will occur.” Health & Safety Code § 25249.11(e). Proposition 65 provides for civil penalties not
14 to exceed \$2,500 per day for each violation of Proposition 65.

15 **FIRST CAUSE OF ACTION**
16 **(Violations of Health & Safety Code § 25249.6)**

17 36. CEH realleges and incorporates by reference as if specifically set forth herein
18 Paragraphs 1 through 35, inclusive.

19 37. By placing the Products into the stream of commerce, Defendants are each a
20 person in the course of doing business within the meaning of Health & Safety Code § 25249.11.

21 38. NDMA is a chemical listed by the State of California as known to cause cancer.

22 39. Defendants know that ordinary use of the Products will expose users of their
23 Products to NDMA. Defendants intend that the Products be used in a manner that results in
24 exposures to NDMA.

25 40. Defendants have failed, and continue to fail, to provide clear and reasonable
26 warnings regarding the carcinogenicity of NDMA to users of the Products.

27 41. By committing the acts alleged above, Defendants have at all times relevant to this
28 Complaint violated Proposition 65 by knowingly and intentionally exposing individuals to

1 NDMA without first giving clear and reasonable warnings to such individuals regarding the
2 carcinogenicity of NDMA.

3 **PRAYER FOR RELIEF**

4 Wherefore, CEH prays for judgment against Defendants as follows:

- 5 1. That the Court, pursuant to Health & Safety Code § 25249.7(a), preliminarily and
6 permanently enjoin Defendants from offering Products for sale in California without providing
7 prior clear and reasonable warnings, as CEH shall specify in further application to the Court;
- 8 2. That the Court, pursuant to Health & Safety Code § 25249.7(a), order Defendants
9 to take action to stop ongoing unwarned exposures to NDMA resulting from use of Products sold
10 by Defendants, as CEH shall specify in further application to the Court;
- 11 3. That the Court, pursuant to Health & Safety Code § 25249.7(b), assess civil
12 penalties against each of the Defendants in the amount of \$2,500 per day for each violation of
13 Proposition 65 according to proof;
- 14 4. That the Court, pursuant to Code of Civil Procedure § 1021.5 or any other
15 applicable theory, grant CEH its reasonable attorneys' fees and costs of suit; and
- 16 5. That the Court grant such other and further relief as may be just and proper.

17
18 Dated: November 5, 2020

Respectfully submitted,

19 LEXINGTON LAW GROUP

20 

21
22

Mark N. Todzo
23 Attorneys for Plaintiff
24 CENTER FOR ENVIRONMENTAL HEALTH