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ENDORSED  
FILED  
ALAMEDA COUNTY

MAY 09 2014

CLERK OF THE SUPERIOR COURT

By Angela Yamsuan Deputy

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

11 ENVIRONMENTAL RESEARCH CENTER,  
12 a California non-profit corporation

13 Plaintiff,

14 vs.

15 PROFESSIONAL COMPOUNDING  
16 CENTERS OF AMERICA, INC. dba  
17 WELLNESS WORKS and DOES 1-100

18 Defendants.

19 CASE NO.

RG14 724957

COMPLAINT FOR INJUNCTIVE  
AND DECLARATORY RELIEF AND  
CIVIL PENALTIES

[Miscellaneous Civil Complaint (42)]  
Proposition 65, Health & Safety Code  
Section 25249.5 et seq.]

20 Plaintiff Environmental Research Center hereby alleges:

21 I

22 INTRODUCTION

23 1. Plaintiff Environmental Research Center (hereinafter "Plaintiff" or "ERC") brings this  
24 action as a private attorney general enforcer and in the public interest pursuant to Health & Safety  
25 Code section 25249.7, subdivision (d). This complaint seeks injunctive and declaratory relief and  
26 civil penalties to remedy Defendant Professional Compounding Centers of America, Inc. dba  
27 Wellness Works and Does 1-100 (hereinafter "PCCA")'s failure to warn consumers that they have  
28 been exposed to lead from several of PCCA's nutritional health products. Lead is a chemical

1 known to the State of California to cause cancer, birth defects and other reproductive harm. Based  
2 on the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Safety Code section  
3 25249.5 *et seq.*) also known as “Proposition 65,” businesses with ten or more employees must  
4 provide a “clear and reasonable warning” prior to exposing persons to these chemicals.

## 5 II

### 6 PARTIES

7 2. Plaintiff ERC is a California non-profit corporation dedicated to, among other causes,  
8 helping safeguard the public from health hazards by reducing the use and misuse of hazardous and  
9 toxic chemicals, facilitating a safe environment for consumers and employees and encouraging  
10 corporate responsibility.

11 3. Defendant PCCA is a business that manufactures, distributes and/or sells nutritional  
12 health products that have exposed users to lead in the State of California within the relevant statute  
13 of limitations period. PCCA’s business involves distribution of proprietary product formulas to  
14 various independent pharmacies throughout the United States, which subsequently resell these  
15 products to consumers in California under a private label. The products at issue in this case were  
16 purchased through one such independent pharmacy. These “Covered Products” are “Custom  
17 Prescriptions of Lancaster LLC Thyro Support”, “Custom Prescriptions of Lancaster LLC Testo  
18 Support”, “Custom Prescriptions of Lancaster LLC Estro Support”, “Custom Prescriptions of  
19 Lancaster LLC Detox Support”, and “Custom Prescriptions of Lancaster LLC Ultra Joint Forte”.  
20 PCCA is a company subject to Proposition 65 as it employs ten or more persons.

21 4. Defendants Does 1-100, are named herein under fictitious names, as their true names and  
22 capacities are unknown to ERC. ERC is informed and believes, and thereon alleges, that each of  
23 said Does is responsible, in some actionable manner, for the events and happenings hereinafter  
24 referred to, either through said Defendant’s conduct, or through the conduct of its agents, servants or  
25 employees, or in some other manner, causing the harms alleged by ERC in this complaint. When  
26 said true names and capacities of Does are ascertained, ERC will seek leave to amend this complaint  
27 to set forth the same.

## 28 III

1 **JURISDICTION AND VENUE**

2 5. This Court has jurisdiction pursuant to California Constitution Article VI, Section 10  
3 because this case is a cause not given by statute to other trial courts.

4 6. The Complaint is based on allegations contained in a Notice of Violation dated  
5 September 13, 2013, served on the California Attorney General, other public enforcers and  
6 PCCA. A true and correct copy of this Notice of Violation is attached hereto as Exhibit A.  
7 More than 60 days have passed since the Notice of Violation was mailed and no public  
8 enforcement entity has filed a complaint in this case.

9 7. This Court is the proper venue for the action because the causes of action have arisen in  
10 the County of Alameda where some of the violations of law have occurred. Furthermore, this Court  
11 is the proper venue under Code of Civil Procedure section 395.5 and Health & Safety Code section  
12 25249.7.

13 **IV**

14 **STATUTORY BACKGROUND**

15 8. The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute  
16 passed as "Proposition 65" by an overwhelming majority vote of the people in November of 1986.

17 9. The warning requirement of Proposition 65 is contained in Health & Safety Code section  
18 25249.6, which provides:

19 No person in the course of doing business shall knowingly and intentionally expose  
20 any individual to a chemical known to the state to cause cancer or reproductive  
21 toxicity without first giving clear and reasonable warning to such individual, except  
as provided in Section 25249.10.

22 10. Implementing regulations for Proposition 65 define expose as "to cause to ingest,  
23 inhale, contact via body surfaces or otherwise come into contact with a listed chemical." An  
24 individual may come into contact with a listed chemical through water, air, food, consumer products  
25 and any other environmental exposure as well as occupational exposures." (Cal. Code Regs., tit. 27,  
26 § 25102, subd. (i).)

27 11. In this case, the exposures at issue are caused by consumer products. Implementing  
28 regulations for Proposition 65 define a consumer product exposure as "an exposure which results

1 from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of  
2 a consumer good, or any exposure that results from receiving a consumer service." (Cal. Code  
3 Regs., tit. 27, § 25602, subd. (b).)

4 12. Whenever a clear and reasonable warning is required under Health & Safety Code  
5 section 25249.6, the "method employed to transmit the warning must be reasonably calculated  
6 considering the alternative methods available under the circumstances, to make the warning  
7 message available prior to exposure." (Cal. Code Regs., tit. 27, § 25601.) The warning requirement  
8 may be satisfied by a warning that appears on a product's label or other labeling, shelf labeling,  
9 signs, a system of signs, public advertising identifying the system and toll-free information services,  
10 or any other system, that provides clear and reasonable warnings. (Cal. Code Regs., tit. 27, §  
11 25603.1, subd. (a)-(d).)

12 13. Proposition 65 establishes a procedure by which the State is to develop a list of  
13 chemicals "known to the State to cause cancer or reproductive toxicity." (Health & Safety Code,  
14 § 25249.8.) There is no duty to provide a clear and reasonable warning until 12-months after the  
15 chemical was published on the State list. (Health & Safety Code, § 25249.10, subd. (b).) Lead  
16 was listed as a chemical known to the State of California to cause developmental toxicity in the  
17 fetus and male and female reproductive toxicity on February 27, 1987. Lead was listed as a  
18 chemical known to the State of California to cause cancer on October 1, 1992. (Cal. Code Regs., tit.  
19 27, § 27001.)

20 14. The Maximum Allowable Dose Level for lead as a chemical known to cause  
21 reproductive toxicity is 0.5 micrograms per day. (Cal. Code Regs., tit. 27, § 25805.) The No  
22 Significant Risk Level for lead as a carcinogen is 15 micrograms per day. (Cal. Code Regs., tit.  
23 27, § 25705.)

24 15. Proposition 65 may be enforced by any person in the public interest who provides  
25 notice sixty days before filing suit to both the violator and designated law enforcement officials.  
26 The failure of law enforcement officials to file a timely complaint enables a citizen suit to be filed  
27 pursuant to Health & Safety Code section 25249.7, subdivisions (c) and (d).



1           • PCCA has a “database of more than 8,000 proprietary formulas that have been pre-  
2 tested with PCCA’s fine chemicals and are continuously reviewed and updated.”

3           • PCCA has “[m]ore than 60 proprietary bases, each thoroughly tested and evaluated.”

4           • “‘Lives depend on a job well done.’ For PCCA, it’s not just a saying, but the way we  
5 approach Quality. While our members have access to over 4,560 active and non-active chemicals –  
6 more than any other compounding pharmacy supplier – the competitive advantage we bring our  
7 members is the industry’s most comprehensive quality control and assurance program we bring to  
8 those chemicals every day.”

9           • “We do not solely rely upon the USP or manufacturer’s label to ensure the quality of the  
10 Chemicals received.”

11          • “Every lot received is tested using Fourier Transform Infrared Spectroscopy, ultraviolet-  
12 visible analysis, melting point, specific gravity, solubility and chemical identifications.”

13          • “Additional testing of APIs is done using actual formulations.”

14          • “Nine qualitative and quantitative analyses are performed on every incoming chemical  
15 lot before it is released for repacking or sale.”

16          • “Each lot is tested against the certificate of analysis (C of A), including: USP, EP, NF,  
17 FCC, ACS and PCCA standards.”

18          • “After initial testing, all results are reviewed for accuracy by a second QC analyst.”

19          • “Chemicals are tested only by degreed Chemical Analysts.”

20          Given the company’s exacting formulation and production methods, experienced expert  
21 staff, and the extensive testing conducted on its products, PCCA has undoubtedly been aware of the  
22 presence of lead in the Covered Products. Nevertheless, the company’s website touts PCCA’s  
23 commitment to its consumers’ health, and represents to the public that’s its products are completely  
24 pure and of the highest quality. PCCA has been aware of the lead in the Covered Products and has  
25 failed to disclose the presence of this chemical to the public, who undoubtedly believed they have  
26 been ingesting totally healthy and pure products pursuant to the company’s statements.

27          19. Both prior and subsequent to ERC’s Notice of Violation, PCCA failed to provide  
28 consumers of the Covered Products with a clear and reasonable warning that they have been

1 exposed to a chemical known to the State of California to cause cancer, birth defects and other  
2 reproductive harm.

3 **FIRST CAUSE OF ACTION**

4 **(Violation of Section 25249.6 of the Health and Safety Code, Failure to Provide Clear**  
5 **and Reasonable Warning under Proposition 65)**

6 20. ERC refers to paragraphs 1-19, inclusive, and incorporates them herein by this  
7 reference.

8 21. By committing the acts alleged above, PCCA has, in the course of doing business,  
9 knowingly and intentionally exposed users of the Covered Products to lead, a chemical known to  
10 the State of California to cause cancer, birth defects and other reproductive harm without first giving  
11 clear and reasonable warning to such individuals, within the meaning of Health & Safety Code  
12 section 25249.6.

13 22. Said violations render PCCA liable for civil penalties up to \$2,500 per day, for each  
14 violation.

15 **SECOND CAUSE OF ACTION**

16 **(Declaratory Relief)**

17 23. ERC refers to paragraphs 1-22, inclusive, and incorporates them herein by this  
18 reference.

19 24. There exists an actual controversy relating to the legal rights and duties of the parties,  
20 within the meaning of Code of Civil Procedure section 1060, between ERC and PCCA concerning  
21 whether PCCA has exposed individuals to a chemical known to the State of California to cause  
22 cancer, birth defects and other reproductive harm without providing clear and reasonable warning.

23 **VI**

24 **PRAYER**

25 WHEREFORE ERC prays for relief as follows:

26 1. On the First Cause of Action, for civil penalties for each and every violation according to  
27 proof;

1           2. On the First Cause of Action, and pursuant to Health & Safety Code section 25249.7,  
2 subdivision (a), for such temporary restraining orders, preliminary and permanent injunctive orders,  
3 or other orders, prohibiting PCCA from exposing persons to lead without providing clear and  
4 reasonable warning;

5           3. On the Second Cause of Action, for a declaratory judgment pursuant to Code of Civil  
6 Procedure section 1060 declaring that PCCA has exposed individuals to a chemical known to the  
7 State of California to cause, birth defects and other reproductive harm without providing clear and  
8 reasonable warning; and

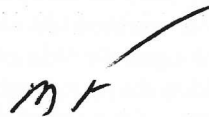
9           4. On all Causes of Action, for reasonable attorneys' fees pursuant to section 1021.5 of the  
10 Code of Civil Procedure or the substantial benefit theory;

11           5. For costs of suit herein; and

12           6. For such other relief as the Court may deem just and proper.

13  
14 Dated: May 9, 2014

15  
16 By



17 \_\_\_\_\_  
18 Michael Freund  
19 Ryan Hoffman  
20 Attorneys for Environmental Research Center  
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**CERTIFICATE OF MERIT**

**Re: Environmental Research Center's Notice of Proposition 65 Violations by Professional Compounding Centers of America, Inc. dba Wellness Works and Custom Prescriptions of Lancaster, LLC**

I, Ryan Hoffman, declare:

1. This Certificate of Merit accompanies the attached 60-day notice in which it is alleged that the parties identified in the notice violated California Health & Safety Code Section 25249.6 by failing to provide clear and reasonable warnings.

2. I am an attorney for the noticing party.

3. I have consulted with one or more persons with relevant and appropriate experience or expertise who have reviewed facts, studies, or other data regarding the exposure to the listed chemicals that are the subject of the notice.

4. Based on the information obtained through those consultants, and on other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiff's case can be established and that the information did not prove that the alleged Violators will be able to establish any of the affirmative defenses set forth in the statute.

5. Along with the copy of this Certificate of Merit served on the Attorney General is attached additional factual information sufficient to establish the basis for this certificate, including the information identified in California Health & Safety Code §25249.7(h)(2), i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons.

Dated: September 13, 2013



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Ryan Hoffman

Notice of Violations of California Health & Safety Code §25249.5 *et seq.*

September 13, 2013

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Service List

District Attorney, Alameda County 1225 Fallon Street, Suite 900 Oakland, CA 94612	District Attorney, Los Angeles County 210 West Temple Street, Suite 18000 Los Angeles, CA 90012	District Attorney, San Diego County 330 West Broadway, Suite 1300 San Diego, CA 92101	District Attorney, Tuolumne County 423 N. Washington Street Sonora, CA 95370
District Attorney, Alpine County P.O. Box 248 Markleeville, CA 96120	District Attorney, Madera County 209 West Yosemite Avenue Madera, CA 93637	District Attorney, San Francisco County 850 Bryant Street, Suite 322 San Francisco, CA 94103	District Attorney, Ventura County 800 South Victoria Ave, Suite 314 Ventura, CA 93009
District Attorney, Amador County 708 Court Street Jackson, CA 95642	District Attorney, Marin County 3501 Civic Center Drive, Room 130 San Rafael, CA 94903	District Attorney, San Joaquin County 222 E. Weber Ave. Rm. 202 Stockton, CA 95202	District Attorney, Yolo County 301 2 <sup>nd</sup> Street Woodland, CA 95695
District Attorney, Butte County 25 County Center Drive, Suite 245 Oroville, CA 95965	District Attorney, Mariposa County Post Office Box 730 Mariposa, CA 95338	District Attorney, San Luis Obispo County 1035 Palm St, Room 450 San Luis Obispo, CA 93408	District Attorney, Yuba County 215 Fifth Street, Suite 152 Marysville, CA 95901
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District Attorney, Colusa County 346 Fifth Street Suite 101 Colusa, CA 95932	District Attorney, Merced County 550 W. Main Street Merced, CA 95340	District Attorney, Santa Barbara County 1112 Santa Barbara Street Santa Barbara, CA 93101	San Diego City Attorney's Office 1200 3 <sup>rd</sup> Avenue, Ste 1620 San Diego, CA 92101
District Attorney, Contra Costa County 900 Ward Street Martinez, CA 94553	District Attorney, Modoc County 204 S Court Street, Room 202 Alturas, CA 96101-4020	District Attorney, Santa Clara County 70 West Hedding Street San Jose, CA 95110	San Francisco, City Attorney City Hall, Room 234 1 Dr Carlton B Goodlett PL San Francisco, CA 94102
District Attorney, Del Norte County 450 H Street, Room 171 Crescent City, CA 95531	District Attorney, Mono County Post Office Box 617 Bridgeport, CA 93517	District Attorney, Santa Cruz County 701 Ocean Street, Room 200 Santa Cruz, CA 95060	San Jose City Attorney's Office 200 East Santa Clara Street, 16 <sup>th</sup> Floor San Jose, CA 95113
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District Attorney, Fresno County 2220 Tulare Street, Suite 1000 Fresno, CA 93721	District Attorney, Napa County 931 Parkway Mall Napa, CA 94559	District Attorney, Sierra County PO Box 457 Downieville, CA 95936	
District Attorney, Glenn County Post Office Box 430 Willows, CA 95988	District Attorney, Nevada County 110 Union Street Nevada City, CA 95959	District Attorney, Siskiyou County Post Office Box 986 Yreka, CA 96097	
District Attorney, Humboldt County 825 5 <sup>th</sup> Street 4 <sup>th</sup> Floor Eureka, CA 95501	District Attorney, Orange County 401 West Civic Center Drive Santa Ana, CA 92701	District Attorney, Solano County 675 Texas Street, Ste 4500 Fairfield, CA 94533	
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District Attorney, Lake County 255 N. Forbes Street Lakeport, CA 95453	District Attorney, San Benito County 419 Fourth Street, 2 <sup>nd</sup> Floor Hollister, CA 95023	District Attorney, Trinity County Post Office Box 310 Weaverville, CA 96093	
District Attorney, Lassen County 220 South Lassen Street, Ste. 8 Susanville, CA 96130	District Attorney, San Bernardino County 316 N. Mountain View Avenue San Bernardino, CA 92415-0004	District Attorney, Tulare County 221 S. Mooney Blvd., Room 224 Visalia, CA 93291	