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## Prop 65: Calcium Supplement and Antacids Teaching Note

### Synopsis

In this case study, the students retrospectively evaluate the effectiveness of California's Proposition 65 in regulating lead content in calcium supplements and antacids. After tests conducted by the Natural Resources Defense Council ("NRDC") and the California Attorney General's Office revealed lead levels higher than expected in some calcium supplement and antacid products, a rift developed between the two groups on how best to reduce lead exposures. Acknowledging that many people need to take these products to ensure good health, and seeking to avoid a consumer scare, the Attorney General's Office chose to negotiate with major product manufacturers to voluntarily reduce their products' lead content over time. NRDC chose to file a lawsuit seeking to use California's Prop 65's warning requirement to inform consumers *immediately* that certain calcium supplement and antacid products contained excessive amounts of lead.

The case study discussion generally takes place during two class periods. During the first discussion, students evaluate NRDC's tactical decision to proceed with a private enforcement action based indirectly on Prop 65. During the second class discussion, students evaluate the tactical approach taken by the Attorney General's Office, focussing on its factual investigation, negotiations with manufacturers, and response to the lawsuit filed by NRDC.

### Positioning

This case study was developed for use in Law 603, Environmental Law, Policy and Process at Stanford Law School. Law 603, an introductory environmental course, covers regulatory approaches, waste management, toxics regulation, administrative issues, the

Mary J. Decker prepared this note, under the editorial guidance of Barton H. ("Buzz") Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law, Stanford Law School, for the sole purpose of aiding classroom instructors in the use of SLS Case No. SLS 98-011. It provides analysis and questions intended to present alternative approaches to meeting the learning objectives of the case and stimulating class discussion. Copyright © 1998 by the Board of Trustees of the Leland Stanford Jr. University.

Federal Clean Air Act, and enforcement. The students discuss this case study towards the middle of the course, after the teacher has lectured on FIFRA, TSCA, and other approaches to regulating risk.

## Learning Objectives

**Part 1:** The students will gain substantive knowledge of Prop 65's warning requirement provision, an approach to regulation of toxic substances that encourages manufacturers to reformulate their products to avoid consumer exposures to toxic substances. From the perspective of NRDC, a national environmental organization, the students will learn to formulate a strategic course of action to deal with the difficult problem of lead in calcium supplements, considering both legal and non-legal arguments.

**Part 2:** The students will develop the ability to examine the same problem from a different perspective, that of a governmental enforcement agency. The students will learn to evaluate the strength of the potential legal challenge under Prop 65 from the government's perspective, and will gain experience in formulating a fair and reasonable settlement agreement.

## Case Study Exhibits

### List of Case Study Exhibits

- A Prop 65 code sections and selected regulations
- B Chronology of key events
- C NRDC data on lead levels
- D NRDC settlement with Leiner Group
- E Detroit News newspaper article
- F Correspondence between counsel
- G Attorney General's proposed settlement
- H NRDC news article on settlement

- A Prop 65 code sections and selected implementing regulations

For easy reference, attached to the case study are the Prop 65 sections (codified as California Health & Safety Code §25249.5 et seq.) containing the discharge prohibition, the warning requirement, the enforcement provision, chemical listing and exemption provisions, and the penalty and bounty hunter provisions. (Under Prop 65, private enforcers can keep 25% of the penalty amount collected.) The two Prop 65 regulations attached for easy reference cover the naturally occurring chemical in food warning exemption and the no observable effect level for lead (0.5 micrograms per day).

- B Chronology of key events

This chronology presents some key facts starting with the initiation of the Attorney General's investigation of lead in calcium products in 1992. The chronology ends with Judge Cahill's June 1997 order approving the Attorney General's proposed settlement agreement with eight companies.

C NRDC data on lead levels

Used with NRDC's permission in this case study, this exhibit contains the copyrighted data that NRDC submitted to the FDA in January 1997, as Appendix A to its petition for a rulemaking on lead in dietary calcium supplement and antacids. The data also appears on NRDC's web site. Table 1 shows lead levels in 21 calcium supplement products. Table 2 shows lead levels in five antacid products.

D NRDC settlement with Leiner Health Care Group

On January 27, 1997, NRDC entered into a settlement with the Leiner Health Care Group, the largest manufacturer of calcium supplements in the United States. Under the settlement, Leiner agreed to *immediately* market only calcium supplement that contain less than 0.5 micrograms of lead per recommended daily dose of elemental calcium. This is the lead exposure level permitted under Prop 65 without a prior warning. NRDC argues that Leiner's willingness to market virtually lead-free supplements is evidence that all calcium product makers could, if required, immediately reduce the lead content of their products to the Prop 65 level.

E Detroit News newspaper article

This one page January 28, 1997 newspaper article titled *Clash develops over calcium supplements*, reports on NRDC's petition to the FDA requesting a rulemaking on lead in calcium products. In the article, the National Osteoporosis Foundation accuses NRDC of using "scare tactics" and describes NRDC's data as "scientifically inappropriate." The Council for Responsible Nutrition also opposes NRDC's FDA petition, saying there is no cause for concern about the safety of calcium products. The article misquotes NRDC scientist, Dr. Gina Solomon, as saying "Just pick them carefully; you *can't* get the calcium without the lead." The newspaper later issued a retraction correcting the quote to: "Just pick them carefully; you *can* get the calcium without the lead." [emphasis added]

F Correspondence between counsel

In these two letters, attorneys for the Attorney General's Office and NRDC discuss various provisions in the Attorney General's proposed settlement with eight calcium product manufacturers. In the first letter, NRDC's attorney questions the two-year implementation period for the proposed settlement, noting that a company called Specialty Minerals has informed NRDC that it can supply the entire California market with low-lead precipitated calcium carbonate "virtually immediately." The letter from Deputy Attorney General Susan Fiering provides a point by point response to the

issues raised in NRDC's letter, and notes that the Attorney General has no way of confirming or disproving Specialty Mineral's statement that it can supply the entire California market.

#### G Attorney General's proposed settlement

This exhibit is the settlement proposed by the Attorney General's Office. The caption shows the settlement involves eight manufacturers. Paragraph 2.2 of the proposed settlement sets out the timeframes by which the manufacturers must provide warnings on their products. The negotiated lead levels that will trigger the warning requirement are described in Paragraphs 2.3 and 2.4. In summary, the proposed settlement requires that the settling companies provide Prop 65 warnings as of July 1, 1997 on any calcium products sold in California, if the products contain more than 4.0 micrograms of lead per thousand milligrams of elemental calcium. The parties based this number on the 0.5 microgram exposure level acceptable under Prop 65, plus a negotiated "naturally occurring" lead level of 3.5 micrograms. As of April 1, 1999, the settlement requires warnings on products that contain more than 1.5 micrograms of lead per thousand milligrams of elemental calcium. The parties calculated this number by adding 1.0 micrograms of "naturally occurring" lead to the 0.5 microgram exposure level acceptable under Prop 65.

#### H NRDC news article on settlement

This one-page article appeared on NRDC's web site. The article states that the Attorney General's settlement allows companies to sell "calcium products for the next two years, without warning labels, with exposures of up to 6 micrograms for supplements and up to 9 micrograms for antacids." NRDC's article lists calcium products that currently meet the Prop 65 standard for lead.

### Teaching Plan

Law 603 meets for 65 minutes at a time. Two class periods are devoted to this case study discussion. The teaching plan assumes that a class guest will participate in each of the classes. For the first day, Part 1, a lawyer representing NRDC will attend as a guest. For the second day of discussion, a lawyer from the Attorney General's Office will attend.

<b>Teaching Plan</b>	
(1) Opening	1 minute
(2) Student Discussion	40 minutes
(3) Class Guest	20 minutes
(4) Closing	4 minutes
Total Class Time	65 minutes

## Discussion: Part 1

### (1) Opening — 1 minute

Here is one possible opening for Part 1:

In the late 1980's a Canadian marine biologist discovered, quite by accident, that some types of calcium dietary supplements contain higher levels of lead than expected. The California Attorney General's Office, and a national environmental organization, the Natural Resources Defense Counsel, began to analyze the lead content in a wide variety of dietary calcium products for sale in California. Under California's Prop 65, companies could arguably be required to place warnings on their products if consumers using the products would be exposed to more than 0.5 micrograms of lead per day. Acknowledging that many persons need to take calcium supplement to ensure good health and prevent disease, and seeking to avoid a consumer scare, the Attorney General's Office entered into negotiations with manufacturers aimed at reducing the lead content of calcium supplements without filing a Prop 65 enforcement action. NRDC, on the other hand, felt that consumers should be notified *immediately* of the lead content in the calcium products they were using. NRDC believed that ample alternative sources of low-lead calcium existed, and manufacturers would quickly switch to these supplies if a Prop 65 warning was required.

Today we'll be discussing this situation from the perspective of NRDC. Did NRDC make the right choice in filing a lawsuit demanding immediate product warnings under Prop 65? Was their approach successful? What did NRDC gain or accomplish? What are the potential downsides to the approach NRDC took?

### (2) Possible Discussion Questions — 40 minutes

The first class discussion should focus on the strategy adopted by NRDC and the results achieved. The following questions may help stimulate the students' discussion.

- Assume you are an attorney at NRDC and the Attorney General's Office has taken no interest in calcium supplement lead levels. Would you recommend filing a Prop 65 private enforcement action? How strong is your legal case? What non-legal concerns do you have? Was NRDC's lawsuit barred by the 60-day notice requirement in Prop 65, as the Attorney General argued?
- Why do you believe NRDC, on February 3, 1997, filed a complaint under the California Unfair Business Practices Act and an application for a TRO? Do you believe NRDC made the correct decision? Was there any downside to filing this action and a TRO application?
- Is exposure to lead in calcium products significantly different than, for example, exposure to toluene in correction fluid? What about exposures to lead from ceramic dishes or glassware?

- The “naturally occurring” chemical exception to Prop 65 was added by regulation. Should this provision apply to calcium supplements and antacids? How does this regulatory exemption fit with the Prop 65 initiative itself?
- Assume you are an NRDC attorney and have received an advance copy of the Attorney General Office’s proposed settlement. What is your opinion of the settlement? Would you challenge the settlement in court (as NRDC did)? What changes would you demand before lending NRDC’s public support to the agreement? Before agreeing not to challenge the settlement?
- How effective is Prop 65’s approach to regulating toxic substances? Would you recommend that other states adopt this type of provision? Massachusetts is currently considering the adoption of a Consumer Right to Know Act similar to Prop 65. What arguments would you make to Massachusetts legislators in favor of such legislation? Against?

### **(3) Class Guest — 20 minutes**

The class guest, an attorney representing NRDC in this matter, should use most of their allotted time to respond to whatever analytical points the students raise. The teacher should tell the guest ahead of time to take notes during the student discussion and be prepared to respond to, expand on, critique, or clarify the points the students raise. The class guest should reserve a few minutes for a general question and answer session with the students. An update covering subsequent events, including a status report on the FDA petition and current lead levels in calcium dietary products, including multi-vitamins, would be useful.

### **(4) Closing — 4 minutes**

The teacher may close the discussion session by briefly summarizing, and clarifying as needed, the most important points that emerged from the discussion.

## **Discussion: Part 2**

### **(1) Opening — 4 minutes**

Here is one possible opening for Part 2:

Today, we’ll be looking at the Prop 65 calcium supplement case study from the perspective of the Deputy Attorney General that handled the case for the State of California. As you recall, the Attorney General’s Office opposed NRDC’s request for a TRO that would have required calcium supplement manufacturers to immediately place Prop 65 warnings on their products. The Attorney General’s Office also filed its own Prop 65 lawsuit, effectively barring any private enforcement action by NRDC. This action contrasts markedly with other Prop 65 actions in which the Attorney General’s Office and NRDC have cooperated in enforcing Prop 65. For example, in Prop 65 lawsuits filed against manufacturers of faucets containing lead, both public and private enforcement actions were brought; NRDC’s action

covered residential faucets, while the Attorney General's action covered non-residential faucets. Here, Judge Cahill stayed NRDC's action under the California Unfair Practices Act. While the stay was in place, the Attorney General negotiated its own settlement with the leading calcium product manufacturers. Judge Cahill then approved this settlement over NRDC's objections.

## **(2) Possible Discussion Questions — 40 minutes**

The second class discussion should focus on the strategic decisions made by the Attorney General's Office and the results achieved. The following questions may help stimulate the students' discussion.

- How, if at all, do you believe the goals and interests of the Attorney General's Office differ from the goals and interests of NRDC in this matter?
- If you were the Deputy Attorney General handling this matter, would you recommend filing a Prop 65 enforcement action against the calcium product manufacturers? How strong do you believe your legal case under Prop 65 is? What, if any, non-legal concerns so you have about proceeding with a Prop 65 enforcement action involving calcium products?
- If you had been the Deputy Attorney General handling this matter and were involved in on-going settlement discussions with manufacturers of calcium supplements, what would have been your reaction to:
  - (1) NRDC's 60-day notice letters, and
  - (2) NRDC's February 3, 1997 complaint and application for a TRO?

How would you have responded to both?

- Why do you believe that the Association for Responsible Calcium Products filed a declaratory relief action against the State on December 17, 1996? As the Deputy Attorney General, how would you have responded to this tactic?
- If you had been the Deputy Attorney General, would you have agreed with the provisions in the proposed settlement agreement? How would you have responded to NRDC's objections to the settlement?
- What about other calcium product manufacturers not named in the Attorney General's enforcement action? Are those manufacturers free to market products containing lead levels greater than that allowed under the settlement? What lead levels do their products contain? How, as Deputy Attorney General, would you decide which manufacturers to name in your enforcement action? What action could be taken to address lead levels in the products of non-defendants?

**(3) Class Guest — 20 minutes**

The class guest, an attorney from the Attorney General's Office that handled this matter, should respond to the analytical points the students raise. The teacher should tell the guest ahead of time to take notes during the students' discussion and be prepared to respond to, expand on, critique, or clarify the points the students raise. The class guest should reserve a few minutes for a question and answer session with the students. An update covering subsequent events, including the Attorney General's continuing investigation of other over the counter products such as multi-vitamins, and industry compliance with the settlement provisions, would be useful.

**(4) Closing — 4 minutes**

As for Part 1 of the case study, the teacher may close the discussion session by briefly summarizing, and clarifying as needed, the most important points that emerged from the discussion. Summarizing the key provisions in Prop 65 or offering additional clarification at the beginning of the *next* class period may also help reinforce the learning objectives.