STANFORD LAW SCHOOL
ENVIRONMENTAL AND NATURAL RESOURCES
LAW AND POLICY PROGRAM

SLS Case No. 98-011

Prop 65: Calcium Supplements and Antacids

Introduction

In the late 1980's, a Canadian marine biologist analyzing the chemical make-up of oyster shells made a startling discovery. Oyster shells deposited during the pre-industrial era contained high levels of lead, a known human reproductive toxin. The biologist knew that oyster shells were used to make calcium dietary supplements because his son, who was lactose-intolerant, regularly took these supplements.

The biologist's surprising discovery triggered an investigation of the lead content in calcium supplements and antacids by the California Attorney General's Office, which recognized a gap in the Federal Food and Drug Administration's regulation of these products. A gap that might be filled in California by Proposition 65.

Proposition 65

Section 25249.6 of California's Proposition 65 states that:

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

Cal-EPA's Office of Environmental Health Hazard Assessment had identified lead as a reproductive toxin in 1987 (and had identified lead as a carcinogen in 1992). Prop 65 further states that the warning requirement does not apply to reproductive toxins that will have no

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observable effect at an exposure 1,000 times the level in question. Prop 65 regulations set a "no observable effect level" for lead at 0.5 micrograms per day.

Section 12501 of the Prop 65 regulations provides an additional regulatory exception to the warning requirement, for exposures to naturally occurring chemicals in food. Under the regulation, a Prop 65 chemical is naturally occurring if it is a natural constituent of food or is naturally present in the environment and absorbed or accumulated when food is raised, grown, or obtained. But, the chemical is not considered naturally occurring if it could be avoided by using good agricultural or manufacturing practices. The producer, manufacturer, distributor, or holder of the food must "utilize quality control measures" that reduce the naturally occurring chemical to the "lowest level currently feasible." Chemicals that are present in food due to human activity are not naturally occurring. Addition of chemicals to irrigation water is considered a human activity, but irrigation without added chemicals, sowing, planting, and plowing are not considered human activities. Finally, if the food is used in the manufacture, production or processing of another consumer product, the "naturally occurring" exception applies to the portion of the consumer product made with the food. See attached Exhibit A for the California Health & Safety Code sections codifying Prop 65, and selected Prop 65 implementing regulations.

The California Unfair Competition Act, codified at California Business and Professions Code §§17000 et seq., defines unfair competition as unlawful, unfair or fraudulent business practice. California courts have determined that actions under this statute may "borrow" violations of other laws and treat those violations as independently actionable unlawful practices when committed during business operations. For example, an unfair business practice claim may be predicated on violation of Prop 65.

Prop 65 Enforcement

Section 25249.7(d) of Prop 65 authorizes *private* enforcement actions in the public interest if:

(1) the action is commenced more than sixty days after the person has given notice of the alleged violation to the Attorney General and the district attorney and any city attorney in whose jurisdiction the violation is alleged to occur and to the alleged violator, and

(2) neither the Attorney General nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation.

Civil penalties of $2500 per day per violation are authorized by Health & Safety Code §25249.7(b). Under the Prop 65 "bounty hunter provision" in Health & Safety Code §25192(a)(2), private plaintiffs may retain one-quarter of the penalty amount collected in a private enforcement action. Prop 65 does not authorize a private cause of action for damages or injuries.

Since California voters passed Prop 65 by initiative in 1986, public and private plaintiffs have brought more than 90 enforcement actions. To date, only two Prop 65 cases have been tried rather than settled. Private plaintiffs tried both of these cases. In one case, the Environmental Defense Fund obtained a favorable verdict and a $210,000 civil penalty. In the other, the court awarded a defense judgment against Citizens for a Better Environment, after concluding that the alleged exposure was below the Prop 65 warning level. The appeals court upheld this judgment in *Citizens for a Better Environment and Internat'l Ladies Garment Workers Union v. Sawyer of Napa, Inc*., Napa County Superior Court No. 61687, an unpublished opinion dated April 21, 1994.

Lead: Human Health Effects

The earliest known case of lead poisoning in humans is believed to have been described in the second century B.C. by Greek physician Nikander, who noted the "grave ills" caused by exposure to lead. Since then, lead has been studied extensively. Researchers have identified lead as the cause of many adverse health effects. Even at low exposures, it can cause anemia, kidney and neurological damage, and irreversible reproductive and developmental dysfunction. Researchers have also determined that lead serves no beneficial purpose in the human body. After being ingested, it enters the blood, soft tissues (kidney, bone marrow, liver , and brain), and mineralizing tissues (bone and teeth). For adults, bones and teeth generally contain about 95% of the total lead body burden. But when the body undergoes physiological stress, e.g., pregnancy, breast-feeding, or chronic disease, the stored lead can re-enter the bloodstream.

Experts associate childhood lead poisoning with neurological damage causing decreased intelligence, behavioral disturbances, or developmental delays, and decreased stature, hearing acuity, and balance. Lead presents an especially serious health hazards during pregnancy because pregnant women absorb lead much more readily from the gastrointestinal ("GI") tract than non-pregnant women and because lead easily crosses the placenta. Blood lead levels in pregnant women may increase 15 to 20% and lead levels in fetal blood can be 80-90% as high as maternal levels. Impairment of fetal development, including damage to the brain, major organs, nervous system, and blood cells, have been linked to lead exposure. Researchers have also linked prenatal lead exposure to slower sensory-motor development, delayed early cognitive development, and slower growth.

The Food and Drug Administration ("FDA") estimates that women of child-bearing age in the U.S. have an average daily lead exposure of about 18 micrograms. Food sources account for an estimated 47% of this lead. Other exposure routes for adults include occupational exposures, dust in older homes, and drinking water. Major sources of exposure for children include food, paint, dust and soil, and drinking water. Since low lead exposure is often contributed to by multiple sources, with no single predominant source, the FDA has stated that any single source of exposure should be well below the amount known to cause deleterious health effects. According to the FDA:

> "[r]ecent scientific evidence indicates that lead has deleterious effects on human health at levels that were

> once thought to be innocuous. In fact, there is no known level of lead intake that does not produce adverse effects."
>
> 59 Fed. Reg. 5363, Feb. 4, 1994 (proposed rule on lead in food additives).

The average blood lead level of the typical American has decreased dramatically from 12.8 micrograms of lead per deciliter of blood in 1976, to 2.3 micrograms per deciliter today. The FDA attributes this decrease largely to Federal bans on leaded gasoline and lead-soldered cans. The Centers for Disease Control defines lead poisoning as 10 or greater micrograms of lead per deciliter of blood.

FDA Regulation

The FDA is responsible for monitoring food safety in the U.S., including dietary supplements, under the Federal Food, Drug and Cosmetic Act and related regulations. (21 U.S.C. §300 et seq., and 21 CFR Part 100 et seq.) The FDA definition of dietary supplement includes a broad range of products that are taken by mouth and contain a dietary ingredient such as a vitamin, mineral, herb, organ tissue, or amino acid. Under FDA regulations, labels on dietary supplements must contain enough information about the product composition to allow consumers to make informed choices. Due to limited resources, however, the FDA focuses its resources on public health emergencies and products that may have already caused injury or illness. FDA does *not* analyze dietary supplements before they are sold to consumers. Instead, manufacturers are responsible for ensuring that all ingredients in their supplements are safe.

Since the 1930's, FDA has been attempting to reduce dietary lead exposure by regulating lead-containing pesticides used on fruits and vegetables, ceramic ware, lead-soldered food cans, and tin-lead capsules for wine bottles. No national FDA lead standard for calcium supplements or antacids currently exists. But, the U.S. Pharmacopeia, a compilation of voluntary trade standards and raw material specifications, does limit the concentration of lead in precipitated calcium carbonate used in pharmaceutical grade calcium supplements to three parts per million. Under this trade standard, a thousand milligrams of elemental calcium could contain about 7.5 micrograms of lead. Because no limit on *total* lead exposure exists, a consumer taking a mega dose of calcium (typically 2,000 to 3,000 milligrams) could be exposed to 15.0 to 22.5 micrograms of lead per day.

The Calcium Supplement and Antacid Industry

More than one-third of American households reportedly consume dietary calcium supplements, according to the *1996 Market Share Reporter*. Drug stores, grocery stores and discount stores sell about 60% of the calcium supplements. Health food stores, mail order, and direct sales account for the remaining 40%. The U.S. antacid market has annual sales of about $1 billion. The best selling antacids are Tums, Mylanta, Pepto Bismol, Maalox, and Rolaids.

Product manufacturers obtain calcium from naturally-occurring sources. The major sources of calcium compounds include fossilized oyster shells dredged from the ocean floor,

mined limestone, mined dolomite, and bone meal from cows. Publicly available data on the lead content of these calcium sources indicates that lead levels vary widely from source to source and within source categories. On average, oyster shells reportedly contain more lead than mined sources of calcium. Lead levels in bone meal, once high, appear to have decreased substantially over the last five years for unknown reasons.

Much of the raw calcium-containing materials used to make dietary supplements and antacids undergoes chemical precipitation to purify and concentrate the calcium. Specialty Minerals, Inc., the world's largest manufacturer of precipitated calcium carbonate derived from limestone, manufactures food and drug grades of precipitated calcium carbonate in Auburn, Massachusetts. Another supplier, Oyster Shell Products, an affiliate of Martin Marietta Minerals, dredges oyster shells from Louisiana waters and supplies oyster shell calcium carbonate to tableting companies throughout the U.S.

The web site for General Nutrition Corporation, the largest specialty retailer of nutritional supplements in the U.S., included the following question and answer in its "Top 20 Commonly Asked Questions."

> 8. I've heard a lot about calcium and lead levels. Should I stop taking calcium?
>
> Small amounts of lead are present in all plant and animal tissue; and is naturally present in the earth, and in all the foods we eat. The amounts of lead naturally occurring in calcium supplements is well within the federal standards, put forth by the FDA, for lead in food and drugs. Calcium is known to reduce the body's absorption of lead. The amount of lead absorbed from a 1,000 mg calcium supplement is equivalent to the amount of lead absorbed in a glass of milk. Thus, it is very important to continue to use calcium supplements.
>
> Insufficient amounts of calcium pose a far greater health risk than trace amounts of lead because calcium is an essential to building strong bones and teeth, especially in young adults and teens, and also protects against osteoporosis, a disease which affects 28 million Americans. Calcium has been shown to slow the rate of bone loss and may reduce the risk of osteoporosis.
>
> www.gnc.com/clients/gnc/mor

Another web page for Calcium Plus stated that:

> Calcium protects the bones and teeth from lead by inhibiting absorption of this toxic metal. If there is a calcium deficiency, lead can be absorbed by the body and deposited in the teeth and bones.
>
> www.bodysystem.com/CalciumPlus.htm

Health Benefits of Calcium Supplements and Antacids

No one disputes that calcium is important for forming strong bones and teeth and maintaining healthy gums. Calcium also plays a key role in muscle contraction, blood coagulation, and proper functioning of the immune system. Adequate calcium can be obtained from many foods — milk, yogurt, cheese, sardines with bones, black beans, collard greens, broccoli, tofu, turnip greens, kale, and eggs.

Medical researchers have documented the benefits of calcium dietary supplements and calcium-containing antacids. In studies conducted by the National Institutes of Health, the Johns Hopkins University School of Medicine, and University of California Medical Center, researchers have confirmed that calcium supplements are beneficial in the treatment and prevention of osteoporosis, pregnancy-induced hypertension, pre-term delivery, and steroid-induced osteoporosis. Researchers have also shown that dietary calcium supplements help decrease the risk of colon cancer. Calcium supplements are relied upon to provide adequate calcium levels for lactose-intolerant individuals who do not obtain calcium from milk products. Many pregnant and breast-feeding women also use calcium supplements to ensure adequate calcium in their diets.

The National Institutes of Health's Consensus Panel on Calcium recommends:

- 1000 milligrams of daily calcium for adults over 25
- 1000 to 1500 milligrams of daily calcium to protect against osteoporosis
- 1200-1500 milligrams of daily calcium for pregnant and post-menopausal women, and teenagers.

The Attorney General's Investigation

In 1992, using funds from the California Public Health Trust, the Attorney General's Office began an investigation of lead in calcium supplements, antacids, and multi-vitamins. During the five-year investigation, experts hired by the Attorney General's Office analyzed the lead content in about 100 different calcium products. Attached Exhibit B presents a one-page chronology of key events from 1992 to 1997.

As the Attorney General's investigation proceeded, the calcium product industry began to seek out new calcium sources containing lower lead levels and began developing new technologies for reducing lead in raw materials and final products. In 1995, Deputy Attorneys General Edward Weil and Susan Fiering began discussions with calcium product manufacturers to voluntarily reduce lead levels in products sold in California below the level allowed under Federal law.

NRDC's Investigation and Analyses

The Natural Resources Defense Council ("NRDC"), a national, non-profit environmental organization with more than 350,000 members (including more than 50,000 members in California), began its own investigation in 1995. NRDC purchased over 500

dietary calcium supplement and antacid products marketed in California and hired a leading analytical chemist to analyze the products' lead content. The test results showed a wide disparity in lead levels, from a high of 20.75 micrograms of lead per maximum daily dose to a low of 0.2 micrograms of lead per maximum daily dose. Attached Exhibit C contains NRDC's test results.

On December 10, 1996, NRDC served Prop 65 notice letters on the following companies:

1. General Nutrition Corporation,
2. SmithKline Beecham Consumer Healthcare, LP,
3. Twin Laboratories Inc.,
4. American Home Products Corporation,
5. Pharmavite, Inc., and
6. Perrigo Company.

On December 24, 1996, NRDC served 60-day notice letters on five more companies:

1. Schering-Plough Healthcare Products, Inc.,
2. Source Naturals,
3. Warner-Lambert Co.,
4. Jarrow Formulas, Inc., and
5. Country Life.

During its research and investigation, NRDC evaluated the feasibility of requiring that manufacturers provide lead-free calcium products. NRDC ultimately entered into a settlement with Leiner Health Group, the largest calcium supplement manufacturer in the United States, that limited Leiner's sale of calcium supplements in California, as of February 1, 1997, to those that produce a lead exposure of < 0.5 micrograms per day — the so-called "virtually lead-free" calcium products.

In January 1997, NRDC began a public education campaign to inform the public about the availability of low-lead calcium supplements and antacids, and the importance of avoiding lead. NRDC's public education campaign included news conferences, news releases, and TV and radio announcements. NRDC's web site contained the following advice regarding the taking of calcium supplements:

> 1. Should consumers stop taking calcium supplements?
>
> NO! Calcium is an essential nutrient. Therefore, it is important to continue getting enough calcium either from dietary sources or from low-lead calcium supplements. However, in choosing their source of calcium, consumers should take care to avoid unnecessary exposure to lead, especially during pregnancy. Thus they should consider switching to a brand of calcium supplement that is essentially lead free. In addition, if children or pregnant women have been regularly taking calcium supplements or calcium-containing antacids, they should consider consulting

> their pediatrician to have their child screened for lead. Such medical screening for lead is advisable in any event for all children because of possible exposures to lead from various other environmental sources. Screening involves a routine questionnaire and a possible blood test.
>
> www.igc.org/nrdc/faqs/hecalq.html

The Declaratory Relief Action

On December 17, 1997, the Association for Responsible Calcium Products ("ARCP") and seven individually named plaintiffs filed a complaint in Los Angeles Superior Court against the State of California seeking a declaration of law that marketers of calcium products were currently in compliance with Prop 65, and no warning under Prop 65 was required. The named plaintiffs were: American Home Products Corporation, General Nutrition Corporation, Nutralite Products (a division of Amway Corporation), Perrigo Company, Pharmavite Corporation, SmithKline Beecham Consumer Healthcare, LP, and Twin Laboratories.

The plaintiffs argued that the lead found in calcium products was "naturally occurring," and was therefore excluded from the Prop 65 warning requirement as a food or consumer product containing food under §12501 of the regulations. The declaratory relief action also argued that increasing calcium intake through dietary supplements significantly reduced blood lead levels in pregnant women whose diets were previously deficient in calcium.

NRDC's FDA Petition

On January 27, 1997, NRDC, in conjunction with five other public interest organizations[1], petitioned the FDA under the Food, Drug, and Cosmetic Act to promulgate a rule restricting lead in dietary calcium supplements and antacids. In its petition, NRDC argued that good manufacturing practices and quality control measures could produce supplements and antacids containing less than 0.5 micrograms of lead per maximum recommended daily dose. The petition noted that most major calcium product brands marketed in the U.S. contained lead greatly exceeding this level. NRDC also urged FDA to obtain test data from the major manufacturers that accurately identified lead levels in each product. Pending development of the regulations, NRDC requested that this data be made available to the public, so that consumers could avoid unnecessary lead exposures.

After NRDC submitted the petition, NRDC and FDA experts participated in a telephone conference to discuss the test methods used by the NRDC experts and NRDC's test results. To date the FDA has taken no further action, however, regarding NRDC's petition. An FDA regulation, 21 CFR §10.30(e), states that the FDA Commissioner "shall" furnish a response to a citizen petition within 180 days of receipt of the petition, taking into consideration the agency resources available, the priority of the subject matter presented in the petition, and existing statutory deadlines.

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[1] Alliance to End Childhood Lead Poisoning, Sierra Club, Public Citizen, Physicians for Social Responsibility, and American Public Health Association.

NRDC's Settlement with Leiner Nutritional Health Products Group

Also on January 27, 1997, NRDC entered into a settlement with Leiner Nutritional Health Products Group, Inc. ("Leiner"), the largest manufacturer of calcium supplements in the United States. Under the settlement, Leiner agreed to immediately market only calcium supplements containing less than 0.5 micrograms of lead per recommended daily dose of elemental calcium. Paragraph 16 of the settlement provides that if NRDC enters into an agreement with another company that allows a higher lead level, Leiner may automatically sell products with that same lead level. And, if the Attorney General enters into an agreement with another company that allows a higher lead level, Leiner may nullify its obligation to sell "virtually lead-free" calcium products in California. The Court approved the Leiner consent judgment on January 30, 1997. Exhibit D to this case study contains the settlement agreement between Leiner and NRDC. Exhibit E is a newspaper article regarding NRDC's FDA petition and settlement with Leiner.

NRDC's Complaint and TRO Application

On February 3, 1997, NRDC filed a complaint in San Francisco Superior Court against the following companies that manufacture, market, and sell dietary calcium supplements or antacids in California:

1. Warner-Lambert Co.,
2. SmithKline Beecham Corp.,
3. American Home Products Corp.,
4. Source Naturals, Inc.,
5. Schering-Plough Health Care Products, Inc.,
6. Pharmavite Corp.,
7. General Nutrition Corp.,
8. Perrigo Co., and
9. Twin Laboratories, Inc.

NRDC's Complaint alleged that the companies were violating California Business and Professions Code §§17200 et seq., by failing to comply with the Prop 65 warning requirements. The NRDC Complaint alleged that the failure to provide a Prop 65 warning had resulted in years of unnecessary risk to human health. The NRDC Complaint also alleged that by failing to warn consumers about the lead content in their products, the nine companies had falsely advertised their products. As result, the companies allegedly unfairly profited from the sale of these products to California consumers.

NRDC's Complaint sought to disgorge all monies acquired by the nine companies through unlawful or unfair business practices, to require restitution to all members of the public who had purchased the calcium products, and to establish a fund for medical monitoring of infants exposed in utero to the calcium products produced by the nine companies.

In conjunction with the filing of its Complaint, NRDC also sought a temporary restraining order ("TRO") to immediately enjoin the nine companies from selling and

distributing calcium products in California, unless they provided a Prop 65 warning. The TRO was set for hearing on February 6, 1997. NRDC also requested an order to show cause for granting a preliminary injunction.

Attorney General's Response to the TRO Application

On February 6, 1997, Deputy Attorney General Susan Fiering filed a complaint against the same nine companies sued by NRDC, alleging the companies were violating §25249.6 of Prop 65. At the same time, the Attorney General's Office filed a memorandum *opposing* NRDC's TRO application. In the TRO opposition, Deputy Attorney General Ed Weil argued that NRDC's §17200 unfair business practice claim predicated on violation of Prop 65 was barred because the 60-day notice period had not yet expired and the Attorney General was filing its own Proposition 65 claim. Weil argued that even though NRDC's first cause of action was styled as a violation of the Unfair Competition Act, the organization had no right to proceed in a manner that interfered with the Attorney General's prosecution of Prop 65. On page 1 of the opposition, Weil argued that:

> As the chief law officer of the state, and the statutorily-preferred prosecutor of violations of this law, the Attorney General is entitled to control the prosecution of this matter. The requested temporary restraining order interferes in the Attorney General's ongoing efforts to negotiate a resolution of this matter and to prosecute this case. Moreover, NRDC has investigated this matter for over a year (and the Attorney General for even longer), and there is no apparent reason why a temporary restraining order is suddenly needed. The only recent change is NRDC's recent agreement with Leiner Health Products to market "virtually lead-free" calcium products. Since that agreement specifically provides that Leiner may elect to void its obligation to sell lead-free products if the Attorney General (or NRDC) enter into a settlement that determines that a higher level of lead satisfies Proposition 65, NRDC is hardly in a position to now claim that the Attorney General should not be the primary enforcer of the law in this case.

Weil also noted that the Attorney General's Office was already actively engaged in settlement negotiations with nearly all the defendants identified in the Attorney General's complaint and that NRDC had previously been advised of this.

The Defendants' Response to NRDC's TRO Application

Counsel for six of the defendants in the NRDC Complaint filed a joint opposition to the TRO application. The defendants' Memorandum of Points and Authorities argued that:

- Calcium is critical to maintaining good health and the FDA has deemed calcium supplements on the market today to be "safe and effective" for increasing calcium intake.

- The Attorney General has been conducting its own investigation of calcium products and Prop 65 compliance for more than three years.

- NRDC knows that the six defendants, and other companies, have been negotiating with the Attorney General for several months to resolve Prop 65 compliance issues, and NRDC seeks to disrupt these negotiations just as they are likely to reach fruition.

- NRDC received $225,000 in January of 1997 from a competitor of the six defendants, in exchange for a promise to publicly endorse a calcium product manufactured by that competitor. NRDC is in effect trying to create a virtual monopoly on calcium product sales for its preferred calcium product seller.

- The issue of whether Prop 65 warnings are required for calcium products is already being litigated in a declaratory judgment action filed by the Association for Responsible Calcium Products in Los Angeles Superior Court on December 17, 1996.

The Court's Ruling on the TRO

After brief argument at the February 6, 1997 hearing, San Francisco Superior Court Judge Thomas Cahill issued an order stating that the:

> TRO is denied and request for Order to Show Cause is denied and this case is stayed for 45 days from the date of this order. If there is no settlement of the Attorney General's case w/in the 45 days, an O.S.C. will be set upon proper application.

Settlement Discussions Continue

In the course of the ensuing settlement discussions between the Attorney General's Office and the nine defendants, the companies raised a number of arguments disputing their liability under Prop 65. First, the companies argued that the Prop 65 warning trigger level for lead (an exposure of more than 0.5 microgram per day) was too low. They argued that calcium actually blocks the absorption of lead, and therefore most of the lead contained in the calcium supplement or antacid would not be retained in the body. The defendants also argued that *all* of the lead contained in the calcium supplements and antacids is *naturally occurring* and subject to the §12501 regulatory exception. Finally, the defendants argued that it is infeasible to lower lead levels in calcium products because this would require re-formulation of the products without sufficient information about the performance characteristics of the new calcium sources.

The Attorney General's Settlement Proposal

In April, the Attorney General's Office presented a settlement agreement to Judge Cahill for approval. The proposed settlement included eight of the nine defendants: Warner-Lambert Co., American Home Products Corp., Pharmavite Corp., General Nutrition Corp., Perrigo Co., Twin Laboratories, Inc., SmithKline Beecham Consumer Healthcare, and Schering-Plough Health Care Products, Inc. The Attorney General's Office continued its settlement discussions with Source Naturals and three other companies sued as Doe defendants. The proposed settlement is attached as Exhibit G.

As discussed below and in the correspondence between NRDC and the Attorney General's Office, attached as Exhibit F, key settlement issues involved:

- the assumed daily intake of elemental calcium,
- the assumed amount of "naturally occurring" lead,
- the two-year settlement implementation period, and
- the "reopener" provision that could be used to increase or decrease allowable lead exposures in the future.

The Assumed Daily Intake of Calcium

The proposed settlement submitted to Judge Cahill required a Prop 65 warning for lead exposures greater than 0.5 micrograms *per one thousand milligrams of elemental calcium.* The one thousand milligram level was chosen as the daily exposure (regardless of the recommended dose on the product label) because in 1994 the National Institutes of Health ("NIH") recommended a daily allowance of 1000 milligrams of calcium for most adults over the age of 25. For pregnant women, teenagers, and post-menopausal women, however, NIH recommended a daily allowance of 1200 –1500 milligrams.

For calcium products with a recommended daily dose or maximum daily dose exceeding 1500 milligrams of calcium, the settlement proposed capping the allowable lead exposure at 150% of the level set for 1000 milligrams of calcium. For a mega dose of 3,000 milligrams of calcium, for example, the allowable lead exposure could increase by up to 50% of the level set for 1,000 milligrams of calcium (*not* by three times the 1,000 milligram level).

How much lead is "naturally occurring?"

The proposed settlement allowed the companies to exclude the amount of lead "naturally occurring" in their products from the calculated exposure level, consistent with Prop 65 regulation §12501. The settlement set a level of 3.5 micrograms of naturally occurring lead per thousand milligrams of calcium, effective July 1, 1997. Under the settlement, this amount is reduced to 1.0 microgram of naturally occurring lead per thousand milligrams of calcium, effective April 1, 1999.

The Two Year Implementation Schedule

Under the proposed settlement, as of July 1, 1997, the settling companies must provide a Prop 65 warning on any calcium supplement or antacid sold in California that exceeds 4.0 micrograms of lead per thousand milligrams of elemental calcium. This is equal to the allowable exposure to 0.5 micrograms of lead per day under Prop 65, plus 3.5 micrograms per day of naturally occurring lead. As of April 1, 1999, the companies must provide a warning for any product marketed in California if it exceeds 1.5 micrograms of lead per thousand milligrams of elemental calcium. This is equal to the allowable exposure of 0.5 milligrams of lead under Prop 65, plus 1.0 microgram of naturally occurring lead.

The interim period from July 1, 1997 to April 1, 1999 was intended to allow companies to switch to lower lead calcium sources and to take other steps to reduce the lead level in their final products. The Attorney General's Memorandum of Points and Authorities in support of the proposed settlement noted that all the settling defendants intended to reduce the lead level of their products so that Prop 65 warnings would not be required after the July 1, 1997 and April 1, 1999 deadlines.

The Settlement Reopener

While the proposed settlement set a "naturally occurring" level of lead at 3.5 micrograms per thousand milligrams of elemental calcium, the settlement also allowed any party to seek a modification of this level (up or down) if the party determined that the 3.5 microgram level was incorrect. The Attorney General anticipated using this "reopener" provision to lower the 3.5 microgram amount, after gathering additional information on a possible new supply of low-lead calcium in the Mojave Desert.

Under the proposed settlement, the Attorney General agreed to forego civil penalties. Instead, the proposed settlement required a total payment of $458,000 to California's Public Health Trust for conducting lead-related research and public education projects. The settling companies also agreed to pay the Attorney General's costs, approximately $121,000. The Attorney General planned to use a portion of the recovered costs to replenish the California Public Health Trust funds it had used to analyze the lead content of calcium supplements, antacids, and multi-vitamins.

NRDC's Opposition to the Proposed Settlements

NRDC opposed the proposed settlement and sought to intervene in the Attorney General's enforcement action. (NRDC did not oppose SmithKline Beecham's settlement based on declarations the company submitted to the Court that indicated the company would meet the 0.5 microgram exposure limit in Prop 65.) An NRDC news article regarding the settlement is attached as Exhibit H.

In its opposition memorandum, NRDC argued that Prop 65 requires a clear and reasonable warning if consumers are exposed to more than 0.5 micrograms of lead per day.

NRDC argued that under the §12501 regulatory exception, unwarned exposures in excess of this amount are allowed only if:

1) the entire excess amount is naturally occurring; and
2) the manufacturer can establish that the naturally occurring lead has been removed to the "lowest level currently feasible."

NRDC submitted an expert declaration that concluded "it is highly unlikely that 3.5 micrograms of lead per gram of calcium present in defendants' oyster shell products is solely naturally occurring." The expert further declared: "In my opinion, the lead found in the defendants oyster shell products is not due to contamination of the ancient source naturally but, instead, [is] primarily from the collection and manufacturing process." NRDC also argued that two of the nation's largest manufacturers of calcium products (Leiner and SmithKline Beecham), a large supplier of precipitated calcium carbonate derived from limestone, and a large supplier of oyster shell calcium carbonate were already meeting the 0.5 microgram lead exposure limit in Prop 65. Therefore, NRDC argued, meeting the 0.5 exposure limit was currently feasible and the proposed settlement impermissibly considered the costs of meeting the 0.5 limit in establishing the lead exposure levels allowed.

The Los Angeles Superior Court Rules

On May 13, 1997, the Honorable Paul Boland of the Los Angeles County Superior Court sustained the Attorney General's demurrer to the ARCP complaint filed for declaratory relief, without leave to amend. Judge Boland held that a declaration of law was not necessary or proper because the State had initiated a Prop 65 enforcement action against various ARCP members.

Judge Cahill Rules on the Proposed Settlements

After a hearing on June 20, 1997, the Honorable William Cahill approved the Attorney General Office's proposed settlement over NRDC's objections.

Case Study Exhibits

Exhibit A: Prop 65 code sections and selected implementing regulations
Exhibit B: Chronology of key events
Exhibit C: NRDC Data: Lead Levels in Calcium Dietary Supplements
Exhibit D: NRDC Settlement with Leiner Health Products Group
Exhibit E: The Detroit News, *Clash develops over calcium supplements*
Exhibit F: NRDC correspondence with Attorney General's Office
Exhibit G: Attorney General settlement re: Warner-Lambert Co., et al.
Exhibit H: NRDC News Article, *Lead Levels in Calcium Supplements*