EDMUND G. BROWN JR.
Attorney General

State of California
DEPARTMENT OF JUSTICE

1515 CLAY STREET, 20TH FLOOR
P.O. BOX 70550
OAKLAND, CA 94612-0550

Public: (510) 622-2100
Telephone: (510) 622-2149
Facsimile: (510) 622-2270
E-Mail: Ed.Weil@doj.ca.gov

March 3, 2008

JL Sean Slattery
Del Mar Law Group, LLP
322 8th Street, Suite 101
Del Mar, CA 92014

David Lavine
Laralei Paras
Hirst & Chanler
2560 Ninth Street
Parker Plaza, Suite 214
Berkeley, CA 94710

RE: Proposition 65 Claims Concerning Lead in Lipstick

Dear Mr. Slattery, Mr. Lavine, and Ms. Paras:

The release of a report titled "A Poison Kiss: The Problem of Lead in Lipstick," by the Campaign for Safe Cosmetics in October of 2007 ("CSC Report"), has raised public concern about whether the presence of lead in lipstick violates Proposition 65. On January 22, 2008, Christine Deubler, represented by Del Mar Law Group, served notices of violation under Proposition 65 alleging that L'Oreal USA, Maybelline, LLC, Parfums Christian Dior, Procter & Gamble, Inc., and Peacekeeper Cause-Metics, have violated Proposition 65 by failing to warn of the presence of lead in certain lipsticks. In the latter half of 2007, the Attorney General also received approximately ten notices of violation from Whitney Leeman, represented by Hirst & Chanler, alleging that various companies have failed to warn concerning lead in various cosmetics, some of which are lipsticks. Some of those notices pre-date the CSC Report, but raise many similar issues. Ms. Leeman has served additional notices raising similar claims as recently as February 19, 2008.

Over the past few weeks, we have exchanged information concerning the merits of these claims with the law firms representing the noticing parties. Del Mar Law Group has today advised us that they will not proceed with claims raised in their notices, which we consider an appropriate and responsible decision. Hirst & Chanler has indicated that they intend to continue pursuing these claims.

As you may know, the Attorney General has brought numerous actions enforcing Proposition 65 with respect to lead in consumer products, including imported candies, soft drink bottles, toys, jewelry, tableware, drinking water faucets, and calcium supplements. Thus, he is committed to protecting California consumers from products containing lead in excess of legal requirements, and vigorously enforcing Proposition 65.

Ordinarily, when the Attorney General declines to pursue a proposed private Proposition 65 enforcement matter, it should not be considered a rejection of the claim on the merits. Nor does the Attorney General typically make a public statement concerning the merits of the matter. In a few instances, however, where an issue is of great concern to the public, it is appropriate to explain that we have concluded that no action is warranted based on the facts of the case. We believe that this is one of those instances.

Accordingly, this letter sets forth why, after thorough analysis, we have concluded that lead in lipstick at the levels identified in the CSC Report, and up to 5 parts per million lead, does not raise a reasonable claim of a Proposition 65 violation and ought not to be pursued.

A. Analysis

1. Lead Contents.

The CSC report tested 33 samples of lipstick and found 13 with no detectable lead (at a detection limit of 0.02 ppm), 9 with less than 0.1 ppm, and 11 within a range of more than 0.1 to as much as 0.65. This data is consistent with what has been found on previous occasions. In other instances, higher levels, in the 1-3 ppm range, have been reported.

2. Proposition 65 Requirements.

Proposition 65 requires that a business that "knowingly and intentionally" exposes persons to chemicals known to the state to cause cancer or reproductive harm must provide a "clear and reasonable warning," unless the business can prove that the exposure would have "no observable effect assuming exposure at one thousand (1,000) times the level in question," for reproductive toxicants, or pose "no significant risk" for carcinogens. (Health & Saf. Code, §§ 25249.6, 25249.10, subd. (c).) Designation of chemicals as known to cause cancer or reproductive toxicity, and regulatory standards for compliance, are implemented by the designated lead agency, the Office of Environmental Health Hazard Assessment ("OEHHA").

Lead is listed as a reproductive toxicant and a carcinogen under Proposition 65. (Cal. Code Regs., tit. 22, § 12000, subd. (a), (b).) For a number of reproductive toxicants, OEHHA

has adopted a "safe-harbor" Maximum Allowable Dose Level (MADL). Where such a level is adopted, "[e]xposure to a chemical at a level which does not exceed the level set forth in [the regulation] for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level." (Cal. Code Regs., tit. 22, § 12805, subd. (a).) In other words, if the exposure is less than the safe-harbor level, no warning is required. If the exposure exceeds the safe-harbor level, the business still has the option of attempting to prove a different (presumably higher) Maximum Allowable Dose Level, but must do so in compliance with scientific standards set forth in the regulations. (Cal. Code Regs., tit. 22, § 12801.) The adopted safe-harbor MADL for lead is 0.5 micrograms per day. (Cal. Code Regs., tit. 22, § 12805, subd. (b).)[1]

This daily dose does **not** directly correspond to the concentration of lead in the product, however. To determine whether a warning is required, one must analyze whether the "reasonably anticipated rate of intake or exposure for average users of the consumer product" would be less than 0.5 micrograms per day. (Cal. Code Regs., tit. 22, § 12821, subd. (d)(2).) This requires a determination of how much lipstick people use.[2]

The meaning of "average users" is not fully settled. The only reported case on the issue upheld a trial court decision finding no violation where the 75th-85th percentile of users were below the warning level as an acceptable definition of average users. (*DiPirro v. Bondo Corporation* (2007) 153 Cal.App.4th 150, 190.) In other instances, courts have focused on the mean or the median.

3. Exposure Analysis.

a. Available Evidence.

There is some information available concerning average users of lipstick in the peer-

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[1]We think it is unlikely that a defendant could successfully prove a higher MADL for lead. In addition, although lead also is listed as a carcinogen, it is far less potent as a carcinogen than as a reproductive toxin, with a safe-harbor No Significant Risk Level of 15 micrograms per day. (Cal.Code Regs., tit. 22, § 12705, subd. (b)(1).) Thus, if the product does not require a warning for reproductive toxicity, it clearly will not require one for cancer.

[2]The CSC report suggested that a concentration of lead of 0.1 ppm is an appropriate standard under Proposition 65. That standard was borrowed from another case brought by the Attorney General concerning candy contaminated with lead, and was based on a variety of factors, most importantly concerning the amount of candy ingested by children. Since people do not eat lipstick the way children eat candy, the two analyses of exposure are quite different.

reviewed literature. The first is a report prepared in 2001 by the Cosmetic, Toiletry, and Fragrance Association ("CTFA"). This data was admitted into evidence in 2004 in a trial of a private Proposition 65 enforcement case in which the trial court found that lipstick did not require a warning. (*DiPirro v. J.C.Penney*, San Francisco Superior Ct. No. 407150 [Statement of Decision filed February 9, 2005, pp. 37-47, 113-117].)[3] (The products at issue in that case included lipstick, make-up, and leaded glassware, and the private plaintiff prevailed on the glassware issue.) The study subsequently was published in peer-reviewed literature. ("Exposure data for cosmetic products: lipstick, body lotion, and face cream," *Food and Chemical Toxicology* v. 43, pp. 279-291 (2005).)

The study estimated exposure by getting 311 women to participate, giving them lipstick, having them come back in two weeks, asking how many times per day they used it, and actually measuring the difference in the net weight of the lipstick. (Measuring the amount actually used has a significant advantage over simply asking the respondents how much they use, because it is not subject to memory error.) The study was reasonably well done given the inherent limitations involved, although there are some valid criticisms (e.g., some of the respondents apparently did not like the product, and therefore may not have used as much of it as they ordinarily would).

The study found that the mean number of applications was 2.4 times per day, with 11% of users applying it 4 or more times per day, and a median of 2.1 times per day. The mean amount of lipstick applied per application was 5 milligrams, with 12% of users applying 20 milligrams or more per application. Thus, using the means, the daily use of lipstick is 24 milligrams. Someone in both the top 11% of frequency of use and the top 12% of amount per application would use 80 milligrams each day.

Recently, two more studies were published in peer-reviewed literature, based on surveys conducted in Europe.[4] These studies combined some large existing European databases in which thousands of persons kept diaries and answered questionnaires concerning cosmetic use, in combination with another study in which the actual use of lipstick in milligrams is measured. In this study, the arithmetic mean of use was 24.6 mg/day, the median was 17.1, the 80th percentile

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[3]The plaintiff appealed, but the matter was settled while the appeal was pending.

[4]The two studies are "Probabilistic modeling of European consumer exposure to cosmetic products," *Food and Chemical Toxicology* 45 (2007) 2086-2096, and "European consumer exposure to cosmetic products, a framework for conducting population exposure assessments," *Food and Chemical Toxicology* 45 (2007) 2097-2108.

was 39.7, and the 90th percentile was 56.5 mg/day.[5]

In the *DiPirro v. J.C.Penney* case referenced above, the plaintiff relied on an expert who calculated exposures based on an average number of applications per day of six times, taken from a figure presented in the U.S. EPA's Exposure Factors Handbook, and estimated the amount of lipstick applied through an estimate of the surface area of the lips and the depth of the application at 53 milligrams per application. This results in exposure of 318 milligrams per day. The court in that case rejected the expert's testimony, mostly for reasons not directly related to this aspect of her opinions. In any event, the expert's method of estimating offered in that case does not seem to be supported by any other data.

While not a matter of formal evidence, it is worth considering whether these exposure parameters seem to fit with ordinary understanding of the consumption of the products. An average tube of lipstick weighs about 0.14 ounces (about 4 grams, or 4,000 milligrams). At 24 milligrams a day, it would take about 5 ½ months to use a tube, if that is the only tube used. If we assume the use is 100 milligrams per day, it would take 40 days to use a tube, if that is the only tube used. If one assumes the use is 300 milligrams per day, a tube would be consumed in less than two weeks. On that basis, consumption estimates of up to 100 milligrams per day seem consistent with common experience.

b. Likely Exposure Estimate.

The above-referenced data suggests that the highest use supportable by the facts and the regulation would be about 100 milligrams per day. (Indeed, this figure exceeds the 90th percentile as indicated in any of the published studies.) Comparing this to the 0.5 microgram per day Safe-harbor level, this means that the lipstick would need to contain 5.0 ppm lead to require a warning.

The analysis above estimates the total amount of lead the user comes into contact with, i.e., gets on the lips. Under the statute and regulations, any contact with the body constitutes an "exposure," which is sufficient to make the prima facie case. (Cal. Code Regs., tit. 22, § 12102, subd. (i); *Consumer Cause v. Weider Nutrition* (2001) 92 Cal.App.4th 363.) Attempting to prove under the statute that the exposure has "no observable effect . . . at the level in question," a

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[5]These studies computed "daily averages" of use. For a reproductive toxicant such as lead, the usage on a given day is considered the appropriate measure of exposure, not the long-term daily average. In these studies, however, the product was used every day, and there was no evidence that the usage varied significantly from day-to-day. Thus, in this case there is little practical difference in the two numbers.

defendant can attempt to prove that the substance in question is not actually absorbed by the body, which would affect the level at which the warning exemption would apply. In this instance, defendants may try to prove that in fact much of the lipstick is never actually absorbed by the body, because relatively little of it is actually absorbed through the lips (lead is not well-absorbed through skin), or swallowed and ingested. We have seen no reliable data on how much lipstick is actually ingested, although reason suggests that it is some fraction of the total amount applied. Thus, if the matter were to proceed to litigation, it seems likely that some allowance would have to be made for the fact that not all of the product is ingested or absorbed. In this analysis, we have not eased the standard to account for any claim that lead is not absorbed, which effectively applies a stricter and more health-protective standard than might be applied by a court after trial.[6]

B. Conclusion

The above analysis indicates that lipstick with lead concentrations at the levels found in the CSC report could not plausibly be considered to trigger a duty to warn under Proposition 65. Indeed, it appears that a reasonable claim that there is a duty to warn would not arise until concentrations reached 5 ppm lead. We have not seen any publicly-available, reliable data showing significant amounts of lipstick with lead concentrations above those levels. Accordingly, based on the data we have reviewed, we do not think Proposition 65 actions would be warranted for lipstick with lead levels less than 5 ppm. If data showing higher concentrations of lead in lipstick are provided, the matter would need to be evaluated in the light of that information.

In addition to the public concern about the matter, we are concerned about the potential

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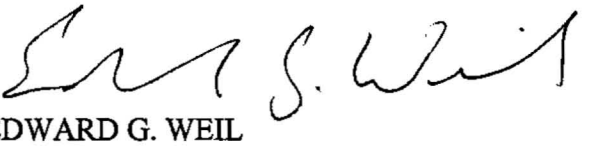
[6]A defendant seeking to raise this issue may not be able to rely on the 0.5 microgram per day MADL, however. The regulations allow a defendant to establish the "no observable effect" defense in one of two ways, either "(1) By means of an assessment that meets the standards described in Section 12803" or "(2) By application of a specific regulatory level for the chemical in question as provided in Section 12805." (Cal. Code Regs., tit. 22, § 12801, subd. (b).) The safe-harbor MADLs provided in section 12805 by their terms apply to the amount of "exposure" to the chemical (Cal. Code Regs., tit. 22, § 12805, subd. (a)), which in this instance is the amount of lipstick applied. If the exposure exceeds the safe-harbor level, but the defendant argues that there will be no actual effect because of a lack of absorption or ingestion, the defendant is no longer proceeding under safe-harbor provision, but must establish the No Observable Effect defense under section 12801(b)(1), by means of an independent assessment. Of course, the evidence that led OEHHA to establish the safe-harbor MADL would be considered as part of the defense, and, depending on the facts, could lead to the same result.

use of this claim by plaintiffs to pursue matters in a manner that does not promote the public interest. (*Consumer Defense Group v. Rental Housing Industry Members* (2006) 137 Cal.App.4th 1185.) Lipstick is sold in literally thousands of stores throughout the state. In the past, some plaintiff groups have pursued Proposition 65 litigation against large numbers of small businesses, with little evidence of whether the retailer has knowledge of the presence of the listed chemical in the product or on the premises. If this were to occur here, many of those stores would find it more practical to pay a small settlement to the plaintiff than to contest the case. Those stores also might post warnings for products that clearly do not require warnings, which is not in the public interest. Nor would such proceedings result in the "enforcement of an important right affecting the public interest" or confer a "significant benefit" on the general public as those terms are used in Code of Civil Procedure section 1021.5.

We hope this objective review of the merits of the issue will discourage your client and any other private plaintiffs from pursuing these matters. If such cases are brought, we will carefully review them in order to determine whether it is appropriate for the Attorney General to take any action.

Sincerely,



EDWARD G. WEIL
Supervising Deputy Attorney General

For EDMUND G. BROWN JR.
Attorney General

cc: Linda Katz, M.D. (Director, Office of Cosmetics and Colors, FDA/CFSAN)
Elizabeth Anderson, Personal Care Products Council