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225 Broadway, Suite 1900
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October 24, 2024

Via Certified Mail

Ossur Americas, Inc. c/o C T Corporation System 330 N Brand Blvd Glendale, CA 91203	Current Chief Executive Officer Ossur Americas, Inc. c/o Sveinn Solvason 200 Spectrum Center Dr #700 Irvine, CA 92618
DME Direct c/o Andrew C. Everett 25574 Rye Canyon Road, Unit A Valencia, CA 91355	Current Chief Executive Officer DME Direct c/o Andrew C. Everett 28082 Bridlewood DR Castaic, CA 91384

Re: Proposition 65 Notice of Violation

To Whom It May Concern:

We represent Environmental Health Advocates, Inc., an organization in the State of California acting in the interest of the general public. This letter serves as notice that the parties listed above are in violation of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, commencing with section 25249.5 of the Health and Safety Code (“Proposition 65”). In particular, the violations alleged by this notice consist of types of harm that may potentially result from exposures to the toxic chemical Di(2-ethylhexyl) phthalate (DEHP). This chemical was listed as a carcinogen on January 1, 1988 and as a developmental/reproductive toxin on October 24, 2003.

The specific type of product that is causing exposures in violation of Proposition 65 are braces, including but not limited to:

<u>Product Name</u>	<u>Manufacturer</u>	<u>Distributor/Retailer</u>
Ossur Airform Universal Inflatable Stirrup Ankle Brace	Ossur Americas, Inc.	DME Direct

The routes of exposure to the chemical(s) in violation include dermal absorption, ingestion, and inhalation by consumers. These exposures occur through the reasonably foreseeable use of the product. The sales of this product have been occurring since at least May 2024, are continuing to this day and will continue to occur as long as the product subject to this notice is sold to and used by consumers.

Proposition 65 requires that a clear and reasonable warning is provided with these products regarding the exposures to Di(2-ethylhexyl) phthalate (DEHP) caused by ordinary use of

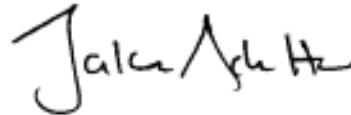
the product. The Parties are in violation of Proposition 65 by failing to provide such warning to consumers and as a result of the sales of this product, exposures to Di(2-ethylhexyl) phthalate (DEHP) have been occurring without proper warning.

Pursuant to Proposition 65, notice and intent to sue shall be provided to violators 60-days before filing a complaint. This letter provides notice of the alleged violation to the parties listed above and the appropriate governmental authorities. A summary of Proposition 65 is attached.

EHA identifies Fred Duran as a responsible individual within the entity, 12245 Carmel Vista Road, Unit 193, San Diego, CA, 92130; 915-312-2577. Mr. Duran requests all communications be sent to EHA's attorneys.

If you have any questions or wish to discuss any of the above, please contact me at jake@entornolaw.com and include clerks@entornolaw.com in the email.

ENTORNO LAW, LLP

A handwritten signature in black ink that reads "Jake Schulte". The signature is written in a cursive, slightly slanted style.

Jake Schulte

Noam Glick
Craig M. Nicholas
Janani Natarajan

Enclosures

CERTIFICATE OF MERIT

I, Jake Schulte, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged the parties identified in the notice have violated Health and 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 has reviewed facts, studies, or other data regarding the alleged exposure to the listed chemical that is the subject of the action.

4. Based on the information obtained through those consultations, and on all 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 plaintiffs' case can be established and the information did not prove that the alleged violator will be able to establish any of the affirmative defenses set forth in the statute.

5. The copy of this Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including the information identified in Health and Safety Code section 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: October 24, 2024

A handwritten signature in black ink that reads "Jake Schulte". The signature is written in a cursive, slightly slanted style.

Jake Schulte, Attorney at Law

CERTIFICATE OF SERVICE

I, Mia Conti, declare that I am over the age of 18 years, and am not a party to the within action. I am employed in the County of San Diego, California, where the mailing occurs; and my business address is 225 Broadway, 19th Floor, San Diego, California 92101.

On October 24, 2024, I served the following documents: **(1) 60-DAY NOTICE OF VIOLATION SENT IN COMPLIANCE WITH HEALTH & SAFETY CODE SECTION 25249.7(d); (2) CERTIFICATE OF MERIT; (3) PROPOSITION 65: A SUMMARY; and (4) CERTIFICATE OF MERIT ATTACHMENT (served only on the Attorney General)** on the parties listed below by placing a true and correct copy thereof in a sealed envelope, addressed to each party and depositing it at my business address with the U.S. Postal Service for delivery by Certified Mail with the postage thereon fully prepaid:

Via Certified Mail

Ossur Americas, Inc. c/o C T Corporation System 330 N Brand Blvd Glendale, CA 91203	Current Chief Executive Officer Ossur Americas, Inc. c/o Sveinn Solvason 200 Spectrum Center Dr #700 Irvine, CA 92618
DME Direct c/o Andrew C. Everett 25574 Rye Canyon Road, Unit A Valencia, CA 91355	Current Chief Executive Officer DME Direct c/o Andrew C. Everett 28082 Bridlewood DR Castaic, CA 91384

On October 24, 2024, I served the California Attorney General (via website Portal) by uploading a true and correct copy thereof as a PDF file via the California Attorney General’s website.

On October 24, 2024, I transmitted via electronic mail the above-listed documents to the electronic mail addresses of the City and/or District Attorneys who have specifically authorized e-mail service and the authorization appears on the Attorney General’s web site.

See Attached Service List

On October 24, 2024, I served the following persons and/or entities at the last known address by placing a true and correct copy thereof in a sealed envelope and depositing it at my business address with the U.S. Postal Service for delivery with the postage thereon fully prepaid, and addressed as follows:

See Attached Service List

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on October 24, 2024, at San Diego, California.

Mia Conti

Mia Conti

APPENDIX A

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65): A SUMMARY

The following summary has been prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as "Proposition 65"). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. The reader is directed to the statute and OEHHA implementing regulations (see citations below) for further information.

FOR INFORMATION CONCERNING THE BASIS FOR THE ALLEGATIONS IN THE NOTICE RELATED TO YOUR BUSINESS, CONTACT THE PERSON IDENTIFIED ON THE NOTICE.

The text of Proposition 65 (Health and Safety Code Sections 25249.5 through 25249.13) is available online at: <http://oehha.ca.gov/prop65/law/P65law72003.html>. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 27 of the California Code of Regulations, sections 25102 through 27001.¹ These implementing regulations are available online at: <http://oehha.ca.gov/prop65/law/P65Regs.html>.

WHAT DOES PROPOSITION 65 REQUIRE?

The "Proposition 65 List." Under Proposition 65, the lead agency (OEHHA) publishes a list of chemicals that are known to the State of California to cause cancer and/or reproductive toxicity. Chemicals are placed on the Proposition 65 list if they are known to cause cancer and/or birth defects or other reproductive harm, such as damage to

¹ All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated. The statute, regulations and relevant case law are available on the OEHHA website at: <http://www.oehha.ca.gov/prop65/law/index.html>.

female or male reproductive systems or to the developing fetus. This list must be updated at least once a year. The current Proposition 65 list of chemicals is available on the OEHHA website at: http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html.

Only those chemicals that are on the list are regulated under Proposition 65. Businesses that produce, use, release or otherwise engage in activities involving listed chemicals must comply with the following:

Clear and reasonable warnings. A business is required to warn a person before “knowingly and intentionally” exposing that person to a listed chemical unless an exemption applies. The warning given must be “clear and reasonable.” This means that the warning must: (1) clearly make known that the chemical involved is known to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed to that chemical. Some exposures are exempt from the warning requirement under certain circumstances discussed below.

Prohibition from discharges into drinking water. A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Some discharges are exempt from this requirement under certain circumstances discussed below.

DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. You should consult the current version of the statute and regulations (<http://www.oehha.ca.gov/prop65/law/index.html>) to determine all applicable exemptions, the most common of which are the following:

Grace Period. Proposition 65 warning requirements do not apply until 12 months after the chemical has been listed. The Proposition 65 discharge prohibition does not apply to a discharge or release of a chemical that takes place less than 20 months after the listing of the chemical.

Governmental agencies and public water utilities. All agencies of the federal, state or local government, as well as entities operating public water systems, are exempt.

Businesses with nine or fewer employees. Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees. This includes all employees, not just those present in California.

Exposures that pose no significant risk of cancer. For chemicals that are listed under Proposition 65 as known to the State to cause cancer, a warning is not required if the business causing the exposure can demonstrate that the exposure occurs at a level that poses “no significant risk.” This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. The Proposition 65 regulations identify specific “No Significant Risk Levels” (NSRLs) for many listed carcinogens. Exposures below these levels are exempt from the warning requirement. See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of NSRLs, and Section 25701 *et seq.* of the regulations for information concerning how these levels are calculated.

Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause reproductive toxicity, a warning is not required if the business causing the exposure can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words, the level of exposure must be below the “no observable effect level” divided by 1,000. This number is known as the Maximum Allowable Dose Level (MADL). See OEHHA's website at: <http://www.oehha.ca.gov/prop65/getNSRLs.html> for a list of MADLs, and Section 25801 *et seq.* of the regulations for information concerning how these levels are calculated.

Exposures to Naturally Occurring Chemicals in Food. Certain exposures to chemicals that naturally occur in foods (i.e., that do not result from any known human activity, including activity by someone other than the person causing the exposure) are exempt from the warning requirements of the law. If the chemical is a contaminant² it must be reduced to the lowest level feasible. Regulations explaining this exemption can be found in Section 25501.

Discharges that do not result in a “significant amount” of the listed chemical entering any source of drinking water. The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a “significant amount” of the listed chemical has not, does not, or will not pass into or probably pass into a source of drinking water, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A “significant amount” means any detectable amount, except an amount that would meet the “no significant risk” level for chemicals that cause cancer or that is 1,000 times below the “no observable effect” level for chemicals that cause reproductive toxicity, if an individual were exposed to that amount in drinking water.

² See Section 25501(a)(4).

HOW IS PROPOSITION 65 ENFORCED?

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys. Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. The notice must comply with the information and procedural requirements specified in Section 25903 of Title 27 and sections 3100-3103 of Title 11. A private party may not pursue an independent enforcement action under Proposition 65 if one of the governmental officials noted above initiates an enforcement action within sixty days of the notice.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court to stop committing the violation.

A private party may not file an enforcement action based on certain exposures if the alleged violator meets specific conditions. For the following types of exposures, the Act provides an opportunity for the business to correct the alleged violation:

- An exposure to alcoholic beverages that are consumed on the alleged violator's premises to the extent onsite consumption is permitted by law;
- An exposure to a Proposition 65 listed chemical in a food or beverage prepared and sold on the alleged violator's premises that is primarily intended for immediate consumption on- or off-premises. This only applies if the chemical was not intentionally added to the food, and was formed by cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination;
- An exposure to environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises;
- An exposure to listed chemicals in engine exhaust, to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking non-commercial vehicles.

If a private party alleges that a violation occurred based on one of the exposures described above, the private party must first provide the alleged violator a notice of special compliance procedure and proof of compliance form.

A copy of the notice of special compliance procedure and proof of compliance form is included in Appendix B and can be downloaded from OEHHA's website at: <http://oehha.ca.gov/prop65/law/p65law72003.html>.

FOR FURTHER INFORMATION ABOUT THE LAW OR REGULATIONS...

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900 or via e-mail at P65Public.Comments@oehha.ca.gov.

Revised: May 2017

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.7, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

E-Mail Service List

<p>The Honorable Pamela Price Alameda County, District Attorney 7677 Oakport Street, Suite 650 Oakland, CA 94621 CEPDProp65@acgov.org</p>	<p>The Honorable Barbara Yook Calaveras County, 891 Mountain Ranch Rd. San Andreas, CA 95249 Phone: 209-754-6330 Prop65Env@co.calaveras.ca.us</p>	<p>The Honorable Stacey Grassini Contra Costa County, Deputy District Attorney 900 Ward Street Martinez, CA 94553 sgrassini@contracostada.org</p>
<p>The Honorable James Clinchard El Dorado County, Assistant District Attorney 778 Pacific Street Placerville, CA 95667 EDCDAPROP65@edcda.us</p>	<p>The Honorable Lisa A. Smittcamp, Fresno County, District Attorney 2100 Tulare Street Fresno, CA 93721 Phone: (559) 600-3141 consumerprotection@fresnocountyca.gov</p>	<p>The Honorable Thomas L. Hardy Inyo County, District Attorney 168 North Edwards Street Independence, CA 93526 Phone: 760.878.0282 inyoda@inyocounty.us</p>
<p>The Honorable Michelle Latimer Lassen County, Program Coordinator 220 S. Lassen Street Susanville, CA 96130 Phone: 530-251-8284 mlatimer@co.lassen.ca.us</p>	<p>The Honorable Lori Frugoli Marin County, District Attorney 3501 Civic Center Drive, Room 145 San Rafael, CA 94903 consumer@marincounty.gov</p>	<p>The Honorable Walter W. Wall , Mariposa County, District Attorney P.O. Box 730 Mariposa, CA 95338 Phone: (209) 966-3626 mcda@mariposacounty.org</p>
<p>The Honorable Kimberly Lewis, Merced County, District Attorney 550 West Main Street Merced, CA 95340 Phone: (209) 385-7381 Prop65@countyofmerced.com</p>	<p>The Honorable Jeannine M. Pacioni, Monterey County, District Attorney 1200 Aguajito Road Monterey , CA 93940 Prop65DA@co.monterey.ca.us</p>	<p>The Honorable Allison Haley Napa County, District Attorney 1127 First Street, Suite C Napa , CA 94559 CEPD@countyofnapa.org</p>
<p>The Honorable Clifford H. Newell Nevada County, District Attorney 201 Commercial Street Nevada City , CA 95959 DA.Prop65@co.nevada.ca.us</p>	<p>The Honorable Morgan Briggs Gire Placer County, District Attorney 10810 Justice Center Drive Roseville, CA 95678 Phone: 916-543-8000 prop65@placer.ca.gov</p>	<p>The Honorable David Hollister Plumas County, District Attorney 520 Main St. Quincy, CA 95971 Phone: (530) 283-6303 davidhollister@countyofplumas.com</p>
<p>The Honorable Paul E. Zellerbach Riverside County, District Attorney 3072 Orange Street Riverside, CA 92501 Prop65@rivcoda.org</p>	<p>The Honorable Anne Marie Schubert Sacramento County, District Attorney 901 G Street Sacramento, CA 95814 Prop65@sacda.org</p>	<p>The Honorable Summer Stephan San Diego County, District Attorney 330 West Broadway San Diego, CA 92101 SanDiegoDAProp65@sdcda.org</p>
<p>The Honorable Alexander Grayner San Francisco County, Asst. District Attorney 350 Rhode Island Street San Francisco, CA 94103 alexandra.grayner@sfgov.org</p>	<p>The Honorable Tori Verber Salazar San Joaquin County, District Attorney 222 E. Weber Avenue, Room 202 Stockton, CA 95202 DAConsumer.Environmental@sjcda.org</p>	<p>The Honorable Eric J. Dobroth San Luis Obispo County, Deputy District Attorney County Government Center Annex, 4th Floor San Luis Obispo, CA 93408 Phone: 805-781-5800 edobroth@co.slo.ca.us</p>
<p>The Honorable Christopher Dalbey Santa Barbara County, Deputy District Attorney 1112 Santa Barbara St. Santa Barbara, CA 93101 Phone: 805-568-2300 DAProp65@co.santa-barbara.ca.us</p>	<p>The Honorable Bud Porter Santa Clara County, Supervising Deputy District Attorney 70 W Hedding St San Jose, CA 95110 EPU@da.sccgov.org</p>	<p>The Honorable Jeffrey S. Rosell Santa Cruz County, District Attorney 701 Ocean Street Santa Cruz, CA 95060 Phone: 831-454-2400 Prop65DA@santacruzcounty.us</p>
<p>The Honorable Jill Ravitch Sonoma County, District Attorney 600 Administration Drive Santa Rosa, CA 95403 Jeannie.Barnes@sonoma- county.org</p>	<p>The Honorable Phillip J. Cline Tulare County, District Attorney 221 S Mooney Blvd Visalia, CA 95370 Prop65@co.tulare.ca.us</p>	<p>The Honorable Gregory D. Totten Ventura County, District Attorney 800 S Victoria Ave Ventura, CA 93009 daspecialops@ventura.org</p>
<p>The Honorable Jeff W. Resig Yolo County, District Attorney 301 Second Street Woodland, CA 95695 cfepd@yolocounty.org</p>	<p>The Honorable Mark Ankcorn City of San Diego, Deputy City Attorney 1200 Third Avenue San Diego, CA 92101 CityAttyProp65@sandiego.gov</p>	<p>The Honorable Henry Lifton City of San Francisco, Deputy City Attorney 1390 Market Street, 7th Floor San Francisco, CA 94102 Prop65@sfcityatty.org</p>
<p>The Honorable Nora V. Frimann City of Santa Clara, City Attorney 200 E. Santa Clara Street, 16th Floor San Jose, CA 96113 Proposition65notices@sanjoseca.gov</p>		

MAIL SERVICE LIST

<p>The Honorable Robert Priscaro Alpine County, District Attorney P.O. Box 248 Markleeville, CA 96120</p>	<p>The Honorable Todd Riebe Amador County, District Attorney 708 Court Street, #202 Jackson, CA 95642</p>	<p>The Honorable Michael L. Ramsey Butte County, District Attorney 25 County Center Drive - Administrative Building Oroville, CA 95965</p>
<p>The Honorable Brenden Farrell Colusa County, District Attorney 310 6th Street Colusa, CA 95932</p>	<p>The Honorable Katherine Micks Del Norte County, District Attorney 450 H Street, Room 171 Crescent City, CA 95531</p>	<p>The Honorable Dwayne Stewart Glenn County, District Attorney P.O. Box 430 Willows, CA 95988</p>
<p>The Honorable Stacey Eads Humboldt County, District Attorney 825 5th Street Eureka, CA 95501</p>	<p>The Honorable George Marquez Imperial County, District Attorney 940 West Main Street, Suite 102 El Centro, CA 92243</p>	<p>The Honorable Cynthia Zimmer Kern County, District Attorney 1215 Truxtun Avenue Bakersfield, CA 93301</p>
<p>The Honorable Sarah Hacker Kings County, District Attorney 1400 West Lacey Blvd. Hanford, CA 93230</p>	<p>The Honorable Susan Kronos Lake County, District Attorney 255 N. Forbes Street Lakeport, CA 95453</p>	<p>The Honorable George Gascon Los Angeles County, District Attorney 211 W. Temple Street, Suite 1200 Los Angeles, CA 90012</p>
<p>The Honorable Sally O. Moreno, District Attorney 300 South G Street, Suite 300 Madera, CA 93637</p>	<p>The Honorable C. David Eyster Mendocino County, District Attorney P.O. Box 1000 Ukiah, CA 95482</p>	<p>The Honorable Cynthia Campbell Modoc County, District Attorney 204 S. Court Street, Room 202 Alturas, CA 96101</p>
<p>The Honorable David Anderson Mono County, District Attorney P.O. Box 2053 Mammoth Lakes, CA 93546</p>	<p>The Honorable Todd Spitzer Orange County, District Attorney 300 N. Flower Street Santa Ana, CA 92703</p>	<p>The Honorable Joel Buckingham San Benito County, District Attorney 419 4th Street Hollister, CA 95023</p>
<p>The Honorable Jason Anderson San Bernardino County, District Attorney 303 W. Third Street San Bernardino, CA 92415</p>	<p>The Honorable Stephen M. Wagstaffe San Mateo County, District Attorney 400 County Center, Third Floor Redwood City, CA 94063</p>	<p>The Honorable Stephanie A. Bridgett Shasta County, District Attorney 1355 West Street Redding, CA 96001</p>
<p>The Honorable Sandra Groven Sierra County, District Attorney 100 Courthouse Square Downieville, CA 95936</p>	<p>The Honorable James Kirk Andrus Siskiyou County, District Attorney P.O. Box 986 Yreka, CA 96097</p>	<p>The Honorable Krishna A. Abrams Solano County, District Attorney 675 Texas Street, Suite 4500 Fairfield, CA 94533</p>
<p>The Honorable Jeff Laugero Stanislaus County, District Attorney 832 12th Street, Suite 300 Modesto, CA 95353</p>	<p>The Honorable Jennifer Dupre Sutter County, District Attorney 463 2nd Street, Suite 102 Yuba City, CA 95991</p>	<p>The Honorable Matthew Rogers Tehama County, District Attorney P.O. Box 519 Red Bluff, CA 96080</p>
<p>The Honorable David Brady Trinity County, District Attorney P.O. Box 310 Weaverville, CA 96093</p>	<p>The Honorable Cassandra Jenecke Tuolumne County, District Attorney 2 S. Green St. Sonora, CA 95370</p>	<p>The Honorable Clint Curry Yuba County, District Attorney 215 Fifth Street, Suite 152 Marysville, CA 95901</p>
<p>The Honorable Mike Feuer City of Los Angeles, City Attorney 200 N. Main Street Los Angeles, CA 90012</p>		