CASE NO. A163682

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION 1

CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiff-Appellant,

v.

PERRIGO COMPANY, et al.,

Defendants-Respondents.

Appeal from a Judgment Based on an Order Sustaining Demurrers
Without Leave to Amend

Superior Court of the State of California for the County of Alameda
Case No. RG 20-054985
The Honorable Winifred Y. Smith, Presiding

APPELLANT'S ANSWER TO BRIEF OF THE ATTORNEY GENERAL AS AMICUS CURIAE

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I. INTRODUCTION

Plaintiff-Appellant Center for Environmental Health ("CEH" or "Appellant") forthrightly agrees with the vast majority of the amicus brief submitted by the California Attorney General ("AG") in support of reversal of the trial court's demurrer decision. Most pertinently, the AG correctly concludes that there is no preemption of CEH's Proposition 65 claims. The AG is also correct that "[f]ederal preemption of Proposition 65 is of great concern to the State and its residents," especially given the protective purpose of this voter-enacted initiative. AG Amicus Brief ("AG Br.") at 6. The AG is also correct that the trial court erred by not giving proper effect to the express savings clause for Proposition 65 in the federal Food, Drug, and Cosmetics Act ("FDCA"), which Congress enacted because it believes Proposition 65 to enhance, not hinder, the federal scheme for regulating over-the-counter ("OTC") drugs.

As recognized by the AG, in light of this manifest Congressional intent, a court must find highly extenuating circumstances – akin to those present in *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910 – before it may override the express savings clause. Those circumstances are not present here. To the contrary, the U.S. Food and Drug Administration's ("FDA") formal statements that the cancer risks of consuming ranitidine products containing N-nitrosodimethylamine ("NDMA") are "unacceptable" and subsequent request for market withdrawal on this basis conclusively demonstrate that Proposition 65 and the FDCA are in alignment, and that dual enforcement is proper. Thus, the narrow ground announced in *Dowhal* for invoking implied conflict preemption despite the FDCA's savings clause does not apply.

Despite CEH's overall agreement with the AG, there is one limited aspect of the AG's amicus brief to which CEH takes exception: its attribution to CEH of the view that "Proposition 65 … include[s] a duty to reformulate." AG Br. at 30. In fact, CEH made no such assertion. Rather, CEH's consistent position throughout the briefing below and on appeal is that (1) federal preemption principles (which, as the AG notes, are unmodified by Health & Safety Code §25249.10(a)) demand that a defendant show the "physical impossibility" of compliance with federal and state law by ***any*** means, (2) a defendant may achieve compliance with Proposition 65 either by providing a clear and reasonable warning ***or*** by taking steps to eliminate or reduce the listed chemical such that no warning is required, and (3) since ***either*** of these means of compliance are achievable without violating federal law, impossibility preemption cannot apply here. The AG does not appear to contest the first point, and plainly agrees with the second point (both here and in its earlier amicus brief in *Lee v. Amazon.com, Inc.*). *Compare* AG Br. at 28, *with* Appellant's Request for Judicial Notice ("RJN"), Exh. 5, at 27 n.16. The AG also agrees with CEH that federal law would have allowed a Proposition 65 warning in this case, a fact that is conclusively established by the various public warning statements actually made by several Respondents regarding NDMA in their products. AG Br. at 16-19. However, the AG's brief fails to explain why the availability of certain ***non-warning*** methods of Proposition 65 compliance are not equally relevant to the impossibility analysis.

Instead, in critiquing this single component of CEH's argument, the AG focuses on the premise that "reformulation is not a statutory duty or requirement" under Proposition 65 that a court could even order as a remedy in an enforcement action. AG Br. at 29-30. As CEH explained in

its reply brief, this is an illusory distinction: a court cannot order a company to warn if it has eliminated the exposure any more than a court can order a company to eliminate the exposure if it provides a proper warning. Appellant's Reply Brief ("Reply Br.") at 26-27. The AG's premise is also empirically untrue: courts enforcing Proposition 65 do not, as the AG maintains, "only order the required warning." AG Br. at 29-30. Rather, such courts order the defendant to stop exposing persons to actionable levels of listed chemicals ***without*** providing a warning – a mandate that can just as readily be satisfied by warning or non-warning means. The same is true under the impossibility analysis: if a defendant can warn without violating federal law ***or*** achieve compliance by some non-warning means without violating federal law, there is no impossibility and thus no preemption.

Here, there are several means other than warning by which Respondents concede they could have achieved compliance with Proposition 65 without running afoul of federal law. For instance, they could (1) use cleaner drug ingredients or otherwise adopt better drug manufacturing processes, (2) store the products at lower temperature such that NDMA does not form at dangerously high levels, (3) perform testing on all products and sell only those that contain NDMA at lower levels (or none at all), or (4) adjust the expiration date on the product labels so that consumers ingest the medications at a time before higher NDMA levels can form. Appellant's Opening Brief ("App. Br.") at 40-42. The viability of any one of these options – ***in addition to*** Respondents' ability to provide a Proposition 65 warning – precludes a finding of federal conflict preemption in this action.

II. ARGUMENT

A. The Attorney General Is Correct that *Dowhal* Compels Reversal of the Lower Court's Demurrer Order.

As set forth in CEH's briefing, there can be no preemption where there are numerous means by which Respondents could comply with Proposition 65 that do not conflict with federal law. The AG's brief demonstrates that *Dowhal* provides an independent basis to reverse the trial court's ruling. As the AG explains, "*Dowhal* set forth the governing test for California courts to claims of conflict between Proposition 65 and the FDCA as applied to OTC drugs." AG Br. at 8. There, the source of conflict between state and federal law was an FDA letter specifically relating to the nicotine patches at issue that "established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter." 32 Cal.4th at 929. The California Supreme Court analyzed the effect of the express savings clause in 21 U.S.C. §379r(d)(2) on the preemption analysis, finding "both that Congress did not expressly preempt California law, and that it did not occupy the field of labeling of over-the-counter drugs." *Id.* at 924. On the issue of implied conflict preemption, the Court concluded that: "If the FDA's directive here prohibiting nonidentical labels is to be sustained, it must be ***on a basis relevant to consumer health***, and ***not because the Proposition 65 label would frustrate the FDA's policy favoring national uniformity***." *Id.* at 926 (emphases added). Because the FDA had already made an express finding that warning consumers about the reproductive hazards of nicotine under Proposition 65 would subvert the more nuanced message the agency deemed appropriate for these products to encourage smoking

cessation, the plaintiff's claims were held to be preempted.[1] *Id.* at 927-29. Importantly, the Court took pains to emphasize that "***this is an unusual case***; in most cases FDA warnings and Proposition 65 warnings would serve the ***same purpose*** – informing the consumer of the risks involved in use of the product – and ***differences in wording would not call for federal preemption***." *Id.* at 934 (emphases added).

In the instant case, the AG and CEH agree that the record reflects no cognizable basis to conclude that "consumer health" concerns justify the total preemption of Proposition 65 as to NDMA in OTC antacids containing ranitidine. AG Br. at 16-19; Reply Br. at 16-17. Unlike in *Dowhal*, the FDA has never stated or even implied that providing Proposition 65 warnings on these products (or taking any number of eminently achievable steps to prevent NDMA exposures) would conflict with federal law. (3AA:0940-41 (¶¶28, 31)).[2] To the contrary, upon learning of the NDMA contamination problem from a third-party laboratory, the FDA requested more study on the issue and – when such study confirmed that NDMA levels in these products were "unacceptable" – requested that the products be removed from the U.S. market until such time as the contamination problem was rectified. (1AA:0165-66.) In the meanwhile, several generic manufacturers of ranitidine – including several

[1] The Court had no occasion in *Dowhal* to analyze whether compliance with Proposition 65 by means other than a warning was allowed by federal law, since nicotine was the active ingredient in these products and smokers need this chemical to satisfy their addiction. Thus, there was no way to prevent the exposure at issue.

[2] Factual citations herein to the Appellant's Appendix ("AA") will be provided with the volume number first and the page number last. Accordingly, the cite above is to vol. 3, pp. 940-41 of the AA (and specifically to paras. 28 and 31 of the document cited).

Respondents here – issued public warning statements about NDMA in these products that both preceded and differed from warning statements made by the brand name manufacturer; tellingly, the FDA did not object. (1AA:0135-38; RJN, Exh. 1-4.) Thus, Respondents cannot establish that federal law or the FDA would have blocked any efforts to comply with Proposition 65 as to NDMA in the products at issue. *See Merck Sharp & Dohme Corp. v. Albrecht* (2019) 139 S. Ct. 1668, 1678 (party asserting impossibility preemption must present "clear evidence" that FDA would have rejected state-required warning – "the possibility of impossibility is not enough") (internal brackets omitted).

Respondents are expected to argue, as they did in their merits opposition brief ("Opp. Br."), that the ruling in *Dowhal* applies only to ***obstacle*** preemption, which they characterize as "a more complex, policy-based form of implied conflict preemption, which sometimes preempts actions even when it is not impossible for the defendant to simultaneously satisfy state and federal law." Opp. Br. at 50. This is not correct. Although the ultimate holding in *Dowhal* referred to obstacle preemption and not impossibility preemption, this was only because there was no formal federal law regulating warnings on nicotine patches that could have conflicted with Proposition 65. Both sides in that action – as well as the FDA as an amicus party – argued for or against the application of impossibility preemption as to nicotine patches based on whether a Proposition 65 warning would render these products "misbranded" under 21 U.S.C. §331(a). *E.g.*, 32 Cal.4th at 927, 929. Thus, the Court in *Dowhal* was addressing ***both*** types of implied conflict preemption – impossibility and obstacle – in issuing its ruling. *E.g.*, *id.* at 924 ("Congress has the power to preclude conflict preemption, allowing states

to enforce laws even if those laws are in ***direct conflict*** with federal law or ***frustrate the purpose*** of federal law. … The Court of Appeal here, relying on the language of [21 U.S.C. §379r(d)(2)], concluded that Congress had so exercised its power.") (emphases added); *see also id.* at 927 (framing the legal question as "Is There ***a Direct Conflict*** Between the Warning Required by Proposition 65 and the Orders of the FDA?") (emphasis added).

Any attempt by Respondents to cabin the scope of the *Dowhal* ruling to the obstacle preemption context would be unavailing. Although obstacle preemption may in some instances involve "complex, policy-based" determinations and no actual impossibility of dual compliance (Opp. Br. at 50), the ruling in *Dowhal* was based on a discrete set of FDA letters that explicitly rejected attempts to add a Proposition 65 warning to the products at issue, thus precluding compliance with Proposition 65. 32 Cal.4th at 922, 927-29. Accordingly, subsequent California appellate courts characterize *Dowhal* as a case involving "a ***direct conflict*** between the required Proposition 65 warning and the FDA's mandates because it was ***impossible*** for the manufacturer to comply with both requirements." *Eckler v. Neutrogena Corp.* (2015) 238 Cal.App.4th 433, 449 (emphases added). There is no analytical difference between a formal law or regulation that achieves this effect (such as the so-called "duty of sameness" imposed by 21 U.S.C. §355(j)(2)(A) as to generic drugs) and a formal FDA policy directive that does the same, in terms of applying implied preemption principles. Indeed, the Court's requirement as to "a basis relevant to consumer health" came in discounting a proposal by the U.S. Attorney General that "the savings clause, by nullifying the preemptive effect of 21 [U.S.C. §]379r(a), left ***the law of implied preemption***, so far as Proposition

65 is concerned, as if neither were enacted." *Id.* at 926 (emphasis added). The *Dowhal* ruling thus applies as squarely to the impossibility context as to the obstacle context.

The AG is correct in several further points it makes about *Dowhal*. First, it notes that, unlike in *Dowhal*, "[t]he FDA never opposed a Proposition 65 warning for these products, or stated that providing such a warning would be inconsistent with its own views on the health effects of NDMA exposure." AG Br. at 18. On this point, Respondents earlier argued that, "[u]nlike obstacle preemption, impossibility preemption does not depend on or require an FDA policy statement rejecting a Proposition 65 warning or other evidence that the warning frustrates a federal purpose." Opp. Br. at 51. If Respondents mean to say that the absence of an FDA statement is irrelevant to the impossibility analysis, they are wrong. Although such a statement may not be strictly required before a court may find a direct conflict between federal and state law, the FDA's decision to remain silent or to otherwise acquiesce – under appropriate circumstances – surely sheds some light on how the agency views the legitimacy of the conduct in question. *See, e.g., Carter v. Novartis Consumer Health, Inc.* (C.D. Cal. 2008) 582 F.Supp.2d 1271, 1289 (finding lack of FDA statement on specific risk for which plaintiff sought warnings to counsel against finding of impossibility preemption). Here, the FDA plainly does not believe that there is a conflict between a Proposition 65 cancer warning on Respondents' products and the FDCA, since (1) it has never said so (even though the agency publicly states its position when it deems such conflicts to exist) (3AA:0941 (¶31)); (2) it believes that the levels of NDMA found in these products are sufficiently high that "consumers taking OTC ranitidine [should] stop taking any tablets or liquid they currently have,

dispose of them properly and not buy more" (1AA:0165-66); and (3) it allowed several generic manufacturers of ranitidine to make public warning statements about NDMA in ranitidine without reproach (3AA:0942 (¶32)). This is nothing like the typical cases in which impossibility preemption is found. *E.g.*, *In re Incretin-Based Therapies Prod. Liab. Litig.* (S.D. Cal. Mar. 9, 2021) 2021 U.S. Dist. LEXIS 44596, at *216-*217 (FDA considered and rejected same or similar warning in response to citizen petition).

Second, as the AG notes, the FDA in *Dowhal* had specifically vetted and rejected the exact warning proposed by the Proposition 65 plaintiff during the drug approval process. AG Br. at 13-14. Here, Respondents deprived the FDA of that opportunity by failing to disclose the NDMA issue during the drug approval process. (1AA:0073 (¶¶34, 36); 3AA:0938-39, 0943-44 (¶¶16, 22-23, 39).) It bears emphasis that the "duty of sameness" on which Respondents rely as a shield from liability is entirely a creature of this federal drug approval process; for any issues that were not raised as part of this process (such as NDMA contamination), the FDCA provides no such shield. App. Br. at 13-14.[3] Thus, as the AG concludes: "A Proposition 65 warning that NDMA is a chemical known to cause cancer does not conflict with the FDA-approved label content for these products, for the simple reason that the health effect of NDMA exposure was not within the scope of FDA's consideration in approving the products and the products['] FDA-approved labeling contains no comparable or

[3] Respondents have conspicuously failed to rebut CEH's argument that unintended contaminants like NDMA are addressed by the FDA as "good manufacturing practice issues," and ***not*** as part of the federal drug approval process. App. Br. at 13, 43-44; Reply Br. at 26.

conflicting warning." AG Br. at 17.[4] Again, this distinguishes cases in which the FDA considered and rejected the same warning during the drug approval process. *E.g., Silverstein v. Boehringer Ingelheim Pharms., Inc.* (S.D. Fla. Oct. 7, 2020) 2020 U.S. Dist. LEXIS 188176, at *95, *105, *109.

Lastly, the AG convincingly argues that the *Kordel* and *Leeman* cases on which Respondents rely do not upset the *Dowhal* ruling, for many of the same reasons CEH believes these cases to be inapplicable to the questions presently before this Court. *Compare* AG Br. at 21-22 (distinguishing *Kordel v. United States* (1948) 335 U.S. 345 and *American Meat Inst. v. Leeman* (2009) 180 Cal.App.4th 728), *with* App Br. at 36-40; Reply Br. at 21-22 (same). Indeed, the AG's argument is further supported

[4] Respondents may attempt to argue that the generic drug "duty of sameness" is distinguishable from the "uniformity" concerns animating the passage of the FDCA's express preemption provision in Section 379r (from which Proposition 65 is carved out). This is not so: both serve to ensure consistency among federally regulated drug products in the face of state regulation that may impose requirements that are "different from[,] in addition to, or … otherwise not identical with" the requirements of the FDCA. 21 U.S.C. §379r(a)(2). Ignoring the FDCA's express savings provision simply because this case happens to involve generic drugs rather than brand name ones would impermissibly transform what *Dowhal* deemed an "unusual" case into a common one. Reply Br. at 18-20. Furthermore, whether dealing with consistency between brand name and generic drugs or consistency between federal and state OTC drug regulation, the foundation of any preemptive effect is the federal drug approval process, including the FDA's fully-informed review of the underlying risks and benefits of a drug. Where that process has been subverted (as it was here), there is no reason to allow a generic manufacturer to hide behind a brand name manufacturer that has likewise failed to disclose the pertinent risks. Certainly, there is no indication in the record that Congress or the FDA believe that generic drugs should contain readily preventable levels of dangerous contaminants (especially where the generic version may contain such chemicals in levels that the brand name version does not). Reply Br. at 19 n.11, 26 n.21.

by (1) the crystal-clear distinction in 21 U.S.C. §379r(c)(2) between "labeling" and other public communications by which warnings may be provided; (2) the use of the separate terms "labeling" and "advertising" throughout the FDCA and its implementing regulations; (3) the fact that the FDA does not regulate OTC drug advertising at all; and (4) the *Dowhal* opinion's own parsing out of "product labeling" from other forms of providing warnings (including both "point-of-sale signs" and "public advertising"). App. Br. at 17-18, 31-35, 37-38; Reply Br. at 4, 20-23. All of these points serve to undercut Respondents' argument in favor of an all-encompassing interpretation of "labeling" under the FDCA.

B. The Attorney General Both Mischaracterizes CEH's Position on Whether Proposition 65 Imposes a "Duty to Reformulate" and Misconstrues the Nature of the Impossibility Test.

Although CEH concurs with the AG on most of the points raised in its amicus brief, there is one component on which CEH respectfully disagrees. The AG contends that CEH interprets Proposition 65 "to include a duty to reformulate" products containing listed chemicals, and then criticizes CEH for arguing that "preemption can be avoided by requiring manufacturers to reformulate the products to remove or reduce NDMA so that the warning requirement would no longer apply." AG Br. at 28. The AG believes that this option is not pertinent, since "[n]either Proposition 65 nor its implementing regulations contain any language ***requiring*** reformulation or removal of chemicals, or the reduction or prevention of exposure to chemicals." *Id.* at 28-29. (emphasis in original).

Unfortunately, the AG has misstated both CEH's position and the governing law on impossibility preemption. CEH has never alleged, argued, or maintained that Proposition 65 includes a duty to reformulate. Rather, CEH's position is that a court is authorized to order a defendant to

comply with Proposition 65, which can be accomplished by whatever means the defendant chooses. *Compare* Health & Safety Code §25249.6 (forbidding a putative defendant from "knowingly and intentionally ***expos[ing] 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") (emphasis added), *with* Health & Safety Code §25249.7(a) ("A person who violates or threatens to violate Section … 25249.6 ***may be enjoined*** in any court of competent jurisdiction.") (emphasis added).[5] CEH and the AG appear to be in agreement that a defendant cannot be ordered to take steps to reduce or eliminate listed chemicals in its products if it is providing a compliant warning. *Compare* AG Br. at 30 ("[A]s long as clear and reasonable warning is provided, Proposition 65 does not prevent exposure to listed chemicals, or require reformulation."), *with* Reply Br. at 29 ("[I]f Respondents were unwilling or unable to warn about the NDMA exposures from their Products, they could have and should have reduced or eliminated this undisclosed contaminant."). However, the AG overlooks the necessary corollary to this proposition: a defendant cannot be ordered to provide a warning on any products for which it has eliminated all actionable exposures. Thus, the AG's assertion that "[a] court can only order the required warning" is not accurate. AG Br. at 29.

Indeed, were CEH to prevail at trial on a Proposition 65 claim, it could and would seek a prohibitory injunction preventing the defendant from continuing to expose persons to listed chemicals without a clear and

[5] The plain terms of this injunction provision are ***not*** limited to imposing a requirement to warn.

reasonable warning. The defendant would then have the option of either eliminating actionable exposures or providing the warning. Notably, this is precisely what was ordered in one of the few appellate cases discussing Proposition 65 injunctions. *See Mangini v. J.G. Durand Int'l* (1994) 31 Cal.App.4th 214. In that action, the lower court "enjoined Durand from selling three patterns of leaded crystal stemware unless Durand provided its customers with a notice warning about the danger of exposure to lead." *Id.* at 216. However, the injunction order further provided that "the warning obligation would be vacated and of no force and effect ... upon a showing that the Attorney General of the State of California has determined, after submission of test data by Durand, that one or more of the enjoined patterns do not require a Proposition 65 warning." *Id.* (internal citations omitted). After the imposition of the injunction, "Durand submitted to the Attorney General testing data concerning the three patterns of stemware which had been enjoined"; the AG responded that "two of the three patterns could be sold without a Proposition 65 warning, but that the third pattern … could be sold only if a warning were provided." *Id.* In other words, the defendant could comply with this injunction – and Proposition 65 in general – ***either*** by providing a warning ***or*** taking steps to reduce levels of the listed chemical in the subject products such that no warning was required. The same is true of Respondents here.

The AG's brief also suffers from a larger conceptual flaw about the nature of impossibility preemption. The pertinent question before this Court is not what specific remedies may be awarded under Proposition 65 (or under what circumstances), but ***whether Respondents can achieve compliance with Proposition 65 without violating federal law***. Under binding case authority, impossibility preemption may only be found if a

defendant can establish that "compliance with both federal and state regulations is a physical impossibility." *Wyeth v. Levine* (2009) 555 U.S. 555, 589.[6] The AG concedes here – as it did repeatedly in its earlier amicus brief in the *Lee* case – that Proposition 65 liability "can be avoided or resolved by ensuring that products offered for sale in California do not contain cancer-causing chemicals to begin with" or "by reducing such chemicals to levels below a level considered "no significant risk[.]" AG Br. at 28; *see also* RJN, Exh. 5, at 27 n.16 ("[B]usinesses may comply with Proposition either by warning or by eliminating the exposure.").[7] Accordingly, if Respondents could have "compl[ied] with Proposition 65" by "eliminating" or "reducing" the "exposure" to NDMA ***by any means permitted by the FDCA***, impossibility preemption cannot apply.[8] Since Respondents concede that there are several ways for them to have eliminated the need to warn for NDMA without running afoul of the FDCA

[6] The AG appears to agree, consistent with longstanding canons of statutory construction, that Health & Safety Code §25249.10(a) did not alter the federal test for preemption. AG Br. at 11 (stating that Section 10(a) "incorporates federal preemption principles").

[7] Similarly, one of the Respondents argued to the lower court that it had "effectuated compliance with Proposition 65," *inter alia*, by "eliminating potential exposures requiring warnings" and "seeking returns of existing inventory." (1AA:0095.)

[8] The AG notes in its present brief that "[t]he ballot pamphlet for voters [accompanying the proposed Proposition 65] did not discuss reformulation of products." AG Br. at 29. This is an odd thing to point out, given that (1) the ballot materials repeatedly emphasize the importance of reducing toxicants (as the AG highlighted in the *Lee* brief), and (2) none of the non-warning methods by which Respondents admit they could have complied with Proposition 65 involve product "reformulation." Reply Br. at 24-26, 28-29.

– and since cancer warnings were also a viable option in any event – CEH's Proposition 65 enforcement action may proceed.

III. CONCLUSION

For the foregoing reasons, and for all the reasons set forth in CEH's earlier briefing, the judgment of the trial court should be reversed.

Dated: September 21, 2022

Respectfully submitted,

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CERTIFICATE OF WORD COURT

I, Joseph Mann, hereby certify that this brief was produced on a computer, and that it contains 4,259 words, exclusive of tables, this Certificate, and the proof of service, but including footnotes, as calculated by the word count of the computer program used to prepare this brief.

Executed September 21, 2022, at San Francisco, California.

/s/ Joseph Mann
Joseph Mann

PROOF OF SERVICE

I, Owen Sutter, declare:

I am a citizen of the United States and employed in the County of San Francisco, State of California. I am over the age of eighteen (18) years and not a party to this action. My business address is 503 Divisadero Street, San Francisco, CA 94117 and my email address is osutter@lexlawgroup.com.

On September 21, 2022, I served the following document(s) on all interested parties in this action by placing a true copy thereof in the manner and at the addresses indicated below:

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Please also 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 September 21, 2022 at San Francisco, California.

Owen Sutter

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