October 6, 2020

VIA ECF

The Honorable Jacqueline Scott Corley
United States District Court for the
Northern District of California
450 Golden Gate Avenue
San Francisco, CA 94102

Re: *In re Juul Labs, Inc., Mktg., Sales Prac. & Prods. Liab. Litig.,* 19-md-02913

Dear Judge Corley,

Pursuant to Case Management Order No. 6 (ECF No. 357), Defendant Juul Labs, Inc. ("JLI") and Plaintiffs (together, the "Parties") respectfully submit this Joint Letter Brief concerning Plaintiffs' requested discovery regarding JLI's Premarket Tobacco Product Applications ("PMTA" or "PMTAs"). The Parties' respective positions for the Court's consideration are set forth below.

BACKGROUND

The Family Smoking Prevention and Tobacco Control Act ("TCA") prohibits companies from bringing new tobacco products to market unless the manufacturer can prove to the FDA that those products are "substantially equivalent" to those already available, or that permitting their sale would be "appropriate for the protection of the public health." 21 U.S.C. § 387j. To make this showing, the manufacturer must submit a comprehensive application to the FDA, detailing all relevant aspects of its products, from technical features to marketing practices. This obligatory process is referred to as "premarket review" and the associated application is a premarket tobacco product application, referred to in shorthand as a PMTA.

On May 8, 2020, Plaintiffs served JLI and Altria with a request for "[a]ll draft and final Premarket Tobacco Product Applications relating to JUUL, whether or not actually submitted." *Plaintiffs' Fourth Set of RFPs*, No. 127 at p. 20, Ex. A. On July 23, 2020, JLI objected "on the grounds that it seeks information prepared or compiled in connection with JLI's forthcoming PMTA" and that "production of information would impair or interfere with the FDA's exclusive jurisdiction to consider JLI's forthcoming PMTAs. *JLI's Responses to Plaintiffs' Fourth Set of RFPs*, at p. 79, Ex. B. On July 29, 2020, JLI submitted its PMTAs to the FDA.

PLAINTIFFS' POSITION

Throughout these proceedings JLI has represented to the Court that the premarket PMTA it submits to the FDA will "substantially affect this litigation" because it relates to "all relevant aspects of the design, manufacturing, risks, benefits, and marketing of the

products at issue." *Joint Case Management Conference Statement*, Dkt. No. 368 at 13-14; *see also JLI's Motion to Dismiss*, Dkt. No. 626 at 13-17 (detailing how its PMTA materials address each of Plaintiffs' claims). JLI now contends that its PMTA is non-discoverable. Plaintiffs conferred with JLI and sought to understand the basis of its objections. JLI asserted variously that its PMTA (and its drafts) were irrelevant or that production was unduly burdensome. In an effort at compromise, Plaintiffs agreed to proceed step-wise: limiting its initial request to JLI's final PMTA, in hope that a review of the submitted application might aid or eliminate negotiations over draft versions. In response, JLI anchored at the position that its final PMTA is non-discoverable—*full stop*—and would not be produced absent a laundry-list of restrictions that ignore the Court's prior rulings, infuse confusion, and frustrate the schedule. While Plaintiffs have offered several accommodations, the threshold dispute has made further negotiation futile and Plaintiffs seek an order requiring JLI to produce its PMTA application (with all supporting materials) within seven days.

ARGUMENT

Plaintiffs have filed multiple complaints in this MDL proceeding, on behalf of injured minors, consumers and government entities, asserting a variety of claims, including consumer protection claims, fraud, RICO, breach of the implied warranty of merchantability (CAC ¶¶ 631-703), product liability, failure-to-warn, design and manufacturing defects, negligence, wrongful death (PIC, ¶¶755-1068), public nuisance and deceptive practices (PEC, ¶¶ 622-753). Nearly all of these claims are predicated on a core set of allegations that starting in 2015, JLI set a public health crisis in motion, inflicting widespread injuries by: (1) engineering its JUUL product to initiate and deepen nicotine addiction; (2) deceiving consumers about the dangers associated with its product; and (3) aggressively targeting young people. Plaintiffs may take discovery of any non-privileged matter that is relevant to these claims. Fed.R.Civ.P. 26(b)(1).

It is hard to imagine documents more relevant to Plaintiffs' claims than JLI's PMTA materials. According to JLI, its PMTA overflows with details apprising the FDA about (1) "all design features;" (2) "the addictiveness, abuse, and misuse potential" from nicotine exposure and consumption "during product use;" and (3) all marketing including "the impact of the flavoring on consumer perception … especially given the attractiveness of flavors to youth and young adults." *JLI's Motion to Dismiss*, at 13-14. This information goes directly to Plaintiffs' claims regarding JLI's product's design, addictiveness and deceptive marketing.[1] Indeed, a few months ago, JLI itself argued the FDA's review of its PMTA "will inform ***all claims in this MDL***, including Plaintiffs'

[1] JLI has been working on its PMTA for years (with Altria's help) and has accumulated thousands of iterative drafts. Each of these drafts is relevant for all the same reasons, but they are also relevant as direct evidence of JLI and Altria's knowledge at the time each was drafted. Nevertheless, to dispense with the burden and privilege issues JLI has cited regarding production of its drafts, Plaintiffs seek only the final PMTA at this stage.

claims that JUUL products are too addictive, that their labeling and advertising lacks necessary warnings, and that, all things considered, they are a public nuisance that JLI should be ordered to abate." *Id*. at 14 (emphasis added).

JLI does not dispute that the PMTA they submitted is relevant, nor does JLI raise any privilege objection or quantify any purported burden associated with its production. Rather, JLI's objection—"on the grounds that it seeks information prepared [for] JLI's forthcoming PMTA"— is not valid under the Federal Rules and serves no useful or enforceable purpose. Applications and other materials submitted to the FDA are not privileged or otherwise protected from discovery as a matter of course. *See, e.g.*, *In re Incretin-Based Therapies Prod. Liab. Litig.*, 721 F. App'x 580, 583 (9th Cir. 2017) (district court erred in circumscribing discovery on data produced to the FDA, where plaintiffs brought state common law failure-to-warn claims); *Chembio Diagnostic Sys. v. Saliva Diagnostic Sys.*, 236 F.R.D. 129, 137 (E.D.N.Y. 2006) (ruling FDA "application for premarket approval" discoverable); *Tria Beauty, Inc. v. Radiancy, Inc.*, C-10-05030, 2011 WL 13152740 at *4–5 (N.D. Cal. Sept. 23, 2011)(ruling documents submitted to FDA discoverable). Nor are materials related to regulatory application preparation. *See, e.g. Narayan v. EGL, Inc.*, 2006 WL 3050851, at *2 (N.D. Cal. Oct. 24, 2006) (research made in preparation of SEC filing discoverable); *see also Merix Pharma. Corp. v. Glaxosmithkline Corp.*, No. 05-1403, 2006 WL 2931260, at *2 (N.D. Ill. Oct. 11, 2006) (ordering production of defendant's New Drug Application submitted to the FDA and other related "documents generated by defendants, or anyone on their behalf").

Apparently conceding that the PMTA is discoverable, JLI now seeks a stay on discovery. But the Court has already denied JLI's request that "discovery [] be phased in accordance with the PMTA review process" and stayed until the FDA is finished. *Joint Case Management Conference Statement*, Dkt. No. 368 at 4; *compare* Ex. C, *Transcript of Proceedings, Case Management Conference,* February 14, 2020, at X (Judge Orrick explaining that "with respect to scheduling, ***I am not inclined to wait for the FDA to act***, as was discussed in the joint case-management conference statement"). The Court should not provide JLI with an end-run around Judge Orrick's instruction.

But even if the Court was inclined to address this request again, JLI has not carried its "heavy burden of making a strong showing" that there is a "particular and specific need" for a stay. *Gray v. First Winthrop Corp.*, 133 F.R.D. 39, 40 (N.D. Cal. 1990) (citation omitted). JLI cites no case law supporting its position. At most, JLI offers vague and conclusory assertions (without any evidence) that materials produced in litigation "might interfere with, and potentially impact" the FDA's review. This is insufficient. *Id*. (explaining that "stereotyped or conclusory statements" will not do). JLI does not explain how this interference might occur, given that Plaintiffs' handling of these materials would be subject to a rigorous Protective Order (Dkt. No. 308) that the parties negotiated with the forthcoming PMTA materials in mind. Further, Plaintiffs are not seeking to second-guess the FDA or asking the Court to rule on whether JLI's PMTA should be approved. Rather, they the seek the PMTA because it likely contains evidence

relevant to their state common law claims, which is entirely consistent with the Ninth Circuit's guidance in *In re Incretin-Based Therapies Prod. Liab. Litig.*, that materials submitted to the FDA are properly discoverable to support failure-to-warn claims. 721 F. App'x at 583.

JLI also offers no basis for tethering its prompt production of the PMTA to onerous, unworkable and unnecessary conditions. For example, JLI seeks to delay deposition questions regarding scientific studies it submitted with the PMTA until 60 days before Plaintiffs' expert reports are due. This proposal would postpone discovery on core scientific issues beyond the close of fact discovery, require scheduling multiple depositions for the same witnesses in an already compressed schedule, and unfairly jam Plaintiffs' experts into a rushed analysis. Additionally, JLI seeks a pass on producing otherwise responsive ESI communications, merely because they were somehow related to the PMTA. Despite requests for clarification, Plaintiffs have no idea what JLI means when it says it won't produce communications except those relating to "certain aspects of the science behind JLI's PMTA", and have grave concerns that broad swaths of relevant material will be held back under these vague terms. Finally, whether an Attorney General's Office has agreed to JLI's proposed conditions is irrelevant. This multi-faceted litigation stands apart from the various state litigations—pursuing different claims on behalf of different plaintiffs under different circumstances and on different timelines.

For these reasons, Plaintiffs respectfully request an Order requiring JLI to produce the PMTA within seven days.

JLI'S POSITION

In 2009, Congress passed the Tobacco Control Act ("TCA"), which grants to the FDA wide-ranging and exclusive authority to regulate many aspects of "tobacco products." 21 U.S.C. §387a(a). In the TCA, Congress explained that it was delegating this authority to the FDA because of the agency's "scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health." TCA § 2(44), Pub. L. No. 111-31, 123 Stat. 1776, 1780.

The TCA requires "premarket authorization" of any "new" tobacco product prior to its sale. *See generally* 21 U.S.C. § 387j. In 2016, the FDA deemed e-cigarettes "tobacco products" subject to the TCA and the FDA's comprehensive regulatory authority, *see* 81 Fed. Reg. 28973-76, but established a compliance period in which it would not seek to prevent sales of certain e-cigarettes (including JLI's JUUL products) for which a PMTA had not yet been submitted or authorized, *see* 81 Fed. Reg. 28977, 29011, 29014. JLI submitted its PMTAs on July 29, 2020, and the FDA is currently

reviewing those applications, after which it will issue a decision regarding whether JLI may continue to market and sell its JUUL products. JLI's PMTAs are more than 125,000 pages and represent the work of hundreds of employees and tens of thousands of employee hours.

A Limited Stay of PMTA Discovery Is Appropriate

Many of the issues in Plaintiffs' Complaint—such as nicotine content, product formulation, labeling, and the safety of JUUL products relative to combustible cigarettes—are the subject of the FDA's review of JLI's PMTAs.

Allowing unfettered discovery into JLI's PMTAs while the FDA's review is underway would interfere with the premarket review process that Congress assigned exclusively to the FDA. For example, permitting Plaintiffs' counsel and experts to assess and comment on the PMTA in parallel with the FDA not only would create scientific and logistical confusion, but would allow Plaintiffs to litigate (and invite this Court to adjudicate) JLI's PMTAs when Congress has said that the FDA is the exclusive authority over them. Moreover, JLI expects to receive follow-up questions from the FDA about its PMTAs and may be asked to submit additional information as part of the agency's review. Given the FDA's jurisdiction over the PMTA and overall premarket approval process, Plaintiffs' discovery requests (and any PMTA-related depositions) should not be allowed to interfere with, and potentially impact, this process.

Unrestricted discovery into JLI's PMTAs also would impose undue burdens on JLI. The PMTAs were drafted over the course of years, with numerous employees and others involved in drafting various aspects of the documents. There are numerous potential document custodians whose files would need to be searched to identify an unknown number of drafts, each of which may contain privileged comments given the nature of the PMTA process and requirements. The document collection, review, and privilege logging that would be required far outweighs any need in this case, particularly in light of JLI's compromise offer below.

JLI's Offer Regarding PMTA-Related Discovery

While JLI believes it has grounds to object to any discovery into its PMTAs while the FDA's review is ongoing, JLI nevertheless has offered to compromise with Plaintiffs on access to certain PMTA-related materials in ways that will not impose undue burdens on JLI or the FDA's review process. Indeed, two State Attorneys General already have agreed to many of the proposals JLI made to Plaintiffs, including:

- JLI will produce, during the ordinary course of fact discovery, its as-filed PMTAs (and any supplements of those PMTAs submitted to the FDA);

- JLI will produce, during the ordinary course of fact discovery, all reports of final research studies cited in its PMTAs and underlying data for such studies, whether

or not sponsored by JLI, to the extent that such studies and data are in JLI's possession, custody, or control;

- JLI will produce, during the ordinary course of fact discovery, and subject to the Parties' agreement on search terms and custodians, communications about certain aspects of the science behind the design and use of JUUL products and JLI's age-verification and youth-prevention measures, as described in its PMTAs.

In exchange, JLI asked Plaintiffs to agree to the following provisions:

- JLI will not be required to produce (or log for privilege) any drafts or unfiled versions of its PMTAs;

- JLI will not be required to produce communications except those relating to certain aspects of the science behind JLI's PMTAs; and

- Certain PMTA-related fact depositions may be taken out of time, including during the expert discovery period or not before the earlier of the FDA's decision on JLI's PMTAs or 60 days before the Plaintiffs' expert reports are due.

Plaintiffs have rejected these compromises, most notably concerning drafts of the PMTAs.[2] Plaintiffs have not articulated a sound basis to demand production of drafts, risking an MDL that litigates the merits of JLI's PMTAs—not the merits of this case—through extensive discovery into the PMTA drafting process. Although Plaintiffs state that they do not seek drafts of JLI's PMTAs "at this stage," *supra* note 1, Plaintiffs maintain that drafts are relevant—which JLI strongly disagrees, as drafts do not represent JLI's final positions on its PMTAs—and they provide no assurance against seeking drafts soon after receiving the final documents. As part of any order on discovery into JLI's PMTA, the Court should establish now that JLI will not be required to produce drafts of its PMTAs.

JLI—and two State Attorneys General—agree that the above compromises strike an appropriate balance between JLI providing certain PMTA-related discovery while also not infringing on JLI's ongoing PMTA-related work or invading the FDA's exclusive authority over the standards for marketing and labeling of JUUL products. Plaintiffs have not articulated any basis as to why they are differently situated than State Attorneys Generals litigating similar issues with similar case schedules. The Court therefore should adopt JLI's proposals regarding the production of PMTA-related documents and the limitations on the timeframe for depositions.

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[2] Plaintiffs' Request for Production No. 127 seeks "All draft and final Premarket Tobacco Product Applications relating to JUUL, whether or not actually submitted."

Dated: October 6, 2020

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