DuVal CLIENT ALERT

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FDA LETTER TO INDUSTRY:

Data Integrity Concerns from Third-Party Test Labs Jeopardize Medical Device Submissions

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On Tuesday, February 20, 2024, Dr. Jeffery Shuren, Director of CDRH with the U.S. Food and Drug Administration (FDA), issued a "Letter to Industry" reminding sponsors of medical device studies and manufacturers of medical devices to carefully evaluate vendors used to conduct performance testing intended for marketing authorization requests due to an increase in data validity and integrity concerns associated with testing reports from third-party testing laboratories:

> "[FDA] is reminding sponsors of device studies and manufacturers of devices ("device firms") to ***carefully evaluate the third parties they engage to conduct performance testing*** and to ***independently verify all testing results*** before submitting to the FDA. ***It is the responsibility of device firms to qualify third parties*** that generate data ***and to ensure that all information submitted to the FDA is truthful and accurate.***"

Letter to Industry, p.1 (emphasis added) (accessible at https://www.fda.gov/medical-devices/industry-medical-devices/fraudulent-and-unreliable-laboratory-testing-data-premarket-submissions-fda-reminds-medical-device)

This Letter was issued based on recent observations of an increase in premarket submissions containing unreliable, fabricated, duplicated, or inconsistent data generated from third-party testing laboratories located in China and India. In fact, we know of two clients who retained the same Chinese laboratory whose data FDA deemed unusable. In the Letter, FDA explained it has increasingly observed third-party test labs that "are generating data that are ***fabricated, duplicated from other device submissions, or otherwise unreliable.***" *Id.* FDA explains that when it is presented with data integrity concerns in a marketing authorization request, it is unable to reach a favorable substantial equivalence determination or grant a De Novo classification request. *Id.* ("***When such data are submitted to the FDA, the agency is unable to rely on them to grant marketing authorization.***") (emphasis added). Moreover, FDA also notes that data integrity concerns in a marketing authorization request call into question the entire request's integrity.

DuVal & Associates, P.A., is a legal and regulatory law firm that provides legal and regulatory strategies to medical device manufacturers concerning premarket submissions (such as 510(k)s, De Novo requests, and PMAs), and regularly advises and advocates for clients in complex regulatory processes, such as Least Burdensome Flag notifications, AINN/AINE responses, and both 517A and Non-517A appeals. As noted above, we were recently engaged by two different medical device manufacturers after they received Not Substantial Equivalent (NSE) decisions based on unreliable and/or fabricated performance testing data submitted in support of their 510(k) premarket notifications. In each of these instances, those clients, prior to our engagement, selected the same third-party test lab in China to complete performance testing for a 510(k) premarket submission. And, in each instance, the performance testing results provided by the third-party test lab contained substantial and improbable data integrity outcomes, including performance testing results that were identical to data submitted in other, unrelated 510(k) premarket submissions. Fortunately, we were able to effectively and collaboratively engage with FDA representatives to obtain the information necessary for those clients to 1) identify the data in question and to be replaced, and 2) arm our client with enough information to pursue potential recovery and reimbursement of monies paid to and losses incurred from the offending laboratory.

In our experience, and as indicated by FDA's Letter to Industry, the increase in premarket submissions presenting data integrity concerns is a critical challenge that requires a collaborative approach by both FDA and industry. After all, the challenges associated with data integrity issues in marketing authorization requests affect manufacturers, FDA, and the broader healthcare industry. For manufacturers, the

issuance of an unfavorable marketing authorization decision can have devastating impacts, including but not limited to delays in anticipated regulatory clearance/approval and commercialization, adverse effects on funding/investment opportunities, and even the viability of the company itself due to the additional time and expenses associated with preparing, filing, and awaiting FDA's marketing authorization review for a new submission. For FDA, the data integrity concerns unnecessarily complicate and interrupt the regulatory review process and require FDA to implement additional safeguards to ensure the clearance/approval of safe and effective devices. Finally, for the broader healthcare industry, data integrity concerns can slow the innovation of new medical technologies and, therefore, deprive patients of access to critical new therapies.

In its Letter to Industry, FDA calls upon medical device firms to be proactive to stop the tide of data integrity concerns from third-party test labs. Specifically, FDA states that "***it is incumbent on device firms to take proactive steps to qualify third-party test labs and to closely scrutinize all testing data that a firm does not perform itself, especially relating to biocompatibility and other performance testing, that are included in a submission to the FDA.***" Letter to Industry, p.2. While it may be difficult for device manufacturers to answer FDA's call and independently evaluate whether performance testing reports from third-party test labs for pending submissions contain data integrity concerns, DuVal & Associates can help. As mentioned above, DuVal has direct experience in working with medical device manufacturers that have received adverse decisions based on data integrity concerns and, as a result, have professional insights to assist with an evaluation of your company's selection and use of third-party test labs, provide an assessment of your firm's performance testing data for submission in a marketing authorization, or even engage with FDA to discuss how your current submissions may be affected by data integrity concerns.

DuVal & Associates

Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements, and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients with appropriately aggressive, yet compliant, guidance on any FDA-related matter. We pride ourselves not only on our collective legal and business acumen but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

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