January 10, 2025

Randall Henri Steinmeyer

Sent via email: [redacted]

Re: Docket Numbers FDA-2022-P-1632 & FDA-2024-P-3357

Dear Mr. Steinmeyer:

This letter is a final response to your first citizen petition (hereinafter "2022 Petition"), dated July 19, 2022, associated comment to your 2022 Petition (hereinafter "Comment"), dated April 28, 2023, and undated second citizen petition (hereinafter "2024 Petition"). The 2022 Petition requested that the Food and Drug Administration (FDA or the Agency) "revoke the Association for the Advancement of Blood and Biotherapies (AABB) authority to regulate … commercial DNA testing laboratories," "transfer" AABB's authority to the American Society of Crime Lab Directors (ASCLD), and "halt the sale of the so-called motherless paternity tests." The 2024 Petition repeated the requests[1] in the 2022 Petition and additionally requested that FDA "directly regulate DNA paternity tests" and "ban Respondents[2] from participating in the LDT markets." Your petitions were received and processed under 21 CFR 10.30. FDA sent you an acknowledgement letter regarding the 2022 Petition on July 21, 2022, an interim response to the 2022 Petition on January 4, 2023, and an acknowledgment letter regarding the 2024 Petition on July 17, 2024.

FDA has carefully reviewed the 2022 Petition, the 2024 Petition, your Comment, other public comments to your petitions, and other information already available to the Agency, and for the reasons outlined below, we deny your petitions in accordance with 21 CFR 10.30(e). Below we summarize your petitions and provide the bases for FDA's decision.

I. Actions Requested

Your 2022 Petition and Comment appear to present information intended to support two requests: that FDA (1) "halt the sale" of "motherless paternity tests," and (2) "revoke the [AABB's] authority to regulate . . . commercial DNA testing laboratories pursuant to Re-Approval of AABB 85 Fed Reg 101 (May 28, 2020)" and "transfer said authority to the

[1] The 2024 Petition includes a request to ban a certain type of paternity tests manufactured by two identified firms. FDA considered this request sufficiently similar to the request in the 2022 Petition to "halt the sale" of certain paternity tests, which we interpret below as a request to ban such tests.

[2] In your 2024 Petition you refer repeatedly to "Respondents." We note that citizen petitions to FDA do not have respondents in the sense of an adversarial court action.

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[ASCLD]" (emphasis omitted).[3] In your 2022 Petition, you included a variety of information[4] that appears to allege that a paternity test accomplished solely through comparing a child's DNA to a potential father's DNA (what you refer to interchangeably as a "motherless paternity test" or "duo test") is less accurate than a paternity test which also incorporates comparison to the DNA of the known mother (what you call a "trio test"). Your 2022 Petition also includes statements that appear to allege an inappropriate relationship between LabCorp and the AABB. In your Comment, you reiterated the 2022 Petition's requests and included a declaration from an individual named Sheila Gentile that you note "reveals the [motherless paternity test] is a complete fraud."[5]

You therefore argue FDA should "halt the sale" of duo tests, which FDA interprets as a request to ban these products under section 516(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[6] Additionally, you request that FDA "**revoke** the [AABB's] authority to regulate … commercial DNA testing laboratories pursuant to Re-Approval of AABB 85 Fed Reg 101 (May 28, 2020)." FDA interprets this as a request to revoke AABB's ability to accredit clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[7] Additionally, you request that the authority you have requested be revoked from AABB be transferred to the American Society of Crime Laboratory Directors (ASCLD).

Your 2024 Petition appears to contain two additional requests beyond those included in the 2022 Petition. First, you request that FDA "directly regulate DNA paternity tests," which FDA interprets as a request to state that paternity tests are regulated by FDA as devices or to take enforcement action against these paternity tests. Second, you request that FDA "ban respondents from participating in the LDT markets."[8] In support of the requests in your 2024 Petition, you allege that these tests are forgeries of various types and "mislabeled" as "DNA paternity tests,"[9]

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[3] 2022 Petition at 1, 2. FDA notes that the citation offered in your petition does not relate to any material relevant to the AABB's authority. For the purposes of this response, FDA assumes the Federal Register document to which you were referring to be Announcement of the Re-Approval of AABB (Formerly Known as the American Association of Blood Banks) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988, 85 FR 31509 (May 26, 2020).

[4] This includes, but is not limited to, your contentions that motherless paternity tests "create fictional paternal relationships," that the analyses associated with such tests are "not part of a scientifically properly performed paternity test," and that the "mathematical results on each of the motherless paternity tests are fictitious." 2022 Petition at 4, 7, 11.

[5] Comment at 2.

[6] 21 U.S.C. § 360f(a). FDA's interpretation of this request is further supported by the requests made in the 2024 Petition, which do not include a request to "halt the sale" of duo tests but do include a similar request to ban duo tests that are manufactured by certain identified firms.

[7] CLIA mandates accreditation for laboratories that perform laboratory testing (not including research) on humans in the United States. See 42 CFR part 493.

[8] 2024 Petition at 2.

[9] 2024 Petition at 2. See also 2024 Petition at 10–11 (discussing "document forgeries," "signature forgeries," and "robo-signing forgeries").

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and you reiterate statements that appear to allege an inappropriate relationship between LabCorp, DNA Diagnostic Center, and the AABB. You also allege that comments submitted by LabCorp and the AABB to your 2022 Petition contain "fictional citations and phony science claims," as well as false claims that these tests are "forensic" and "FBI-based."[10]

II. Request to Ban the Sale of Duo Paternity Tests

As an initial matter, FDA interprets your request to "halt the sale" of motherless paternity tests as a request to ban these products under section 516(a) of the FD&C Act.[11] While your 2022 Petition and 2024 Petition make many references to LabCorp, they fail to clearly identify a specific test which you believe should be banned and which received premarket approval[12] or 510(k) clearance[13] from FDA or is exempt from premarket notification. As such, FDA interprets this portion of your petition as a request to ban *all* such paternity tests.

Section 516(a) of the FD&C Act authorizes FDA to ban a "device" or an intended use or uses of a "device" in certain circumstances. Under section 201(h)(1) of the FD&C Act, products are "devices" when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or when they are intended to affect the structure or any function of the body, and they do not achieve their primary intended purposes through chemical action and are not dependent upon being metabolized for the achievement of their primary intended purposes. FDA's device regulations specify that the term "intended use" or similar words "refer[s] to the objective intent of the persons legally responsible for the labeling of an article (or their representatives)."[14] That intent "may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article."[15]

While FDA regulates certain types of tests as devices,[16] based on the information you submitted, and other information available to the Agency, it is unclear that the motherless paternity tests you reference in your petitions meet the definition of a device under the FD&C Act. Specifically, there is no evidence that these tests are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or any function of the body. FDA is therefore unable to determine from your petitions whether these motherless paternity tests are devices.

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[10] 2024 Petition at 4, 8–9.
[11] 21 U.S.C. § 360f(a).
[12] See 21 CFR part 814.
[13] See 21 CFR part 807, subpart E.
[14] See 21 CFR 801.4.
[15] Id.
[16] See 21 CFR 809.3; https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation. We note that FDA has adopted several enforcement discretion policies for certain categories of IVDs, including tests intended solely for forensic (law enforcement) purposes. See 89 FR 37286.

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Even assuming that these motherless paternity tests are devices in this context,[17] based on the information you submitted, and other information available to the Agency, FDA concludes that there is a lack of information to support FDA's initiating proceedings to ban the tests under section 516(a) of the FD&C Act. Specifically, there is insufficient information to support a finding that motherless paternity tests present a substantial deception or an unreasonable and substantial risk of illness or injury under the FD&C Act and its implementing regulations.

Under the FD&C Act, FDA "may," but is not required to, promulgate a regulation banning a device where, on the basis of all available data and information, FDA finds that the device "presents substantial deception or an unreasonable and substantial risk of illness or injury," where such deception or risk cannot be or has not been "corrected or eliminated by labeling or change in labeling."[18] In determining whether a "deception or risk of illness or injury is substantial," FDA "will consider whether the deception or risk posed by continued marketing of the device … is important, material, or significant in relation to the benefit to the public health from its continued marketing."[19] "In determining whether a device is deceptive, [FDA] will consider whether users of the device may be deceived or otherwise harmed by the device."[20]

FDA has carefully reviewed the information you submitted and finds it insufficient to support a finding that these tests present a substantial deception or an unreasonable and substantial risk of illness or injury, as required under section 516(a) of the FD&C Act. First, we find that you did not provide sufficient information to determine whether there is a substantial risk of deception with these tests. Your assertions that motherless paternity tests are "forgeries" because they are claimed to be, or "mislabeled as," paternity tests by the manufacturers despite the tests not being sufficiently accurate are addressed elsewhere in this response[21] or are outside the scope of this response.[22] You also appear to contend in your 2022 Petition and Comment that motherless paternity tests are not as accurate as trio tests and that the odds of a motherless paternity test falsely identifying a random man who submits to such a paternity test as a father are 1 in 23,396. As an initial matter, it is not clear that less accuracy than trio tests or this figure supports a finding of "substantial deception." Moreover, this figure does not appear to be supported by any

[17] As noted above, FDA makes no final determination in this petition response regarding whether any duo or trio paternity test is or is not a device as defined in Section 201(h)(1) of the FD&C Act. (21 U.S.C. § 321(h)(1)).
[18] Section 516(a) of the FD&C Act.
[19] 21 CFR 895.21(a)(1).
[20] 21 CFR 895.21(a)(2).
[21] To the extent you assert that the tests are forgeries because they were claimed to be "forensic" and based on "FBI standards," those arguments seem to be related to jurisdictional issues, which are addressed elsewhere in this response, as well as accuracy issues, addressed above.
[22] Your 2024 Petition also includes assertions that the test manufacturers, among others, engaged in fraudulent behavior, for example, related to court-ordered actions (e.g., "secretly switching court-ordered DNA paternity tests with cheap forgeries") and expert opinions submitted to the court (e.g., "replaced and therefore forged court-appointed expert opinions and signatures"). Any alleged fraud committed on the court or forged documents submitted to the court are matters beyond the scope of this response.

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scientific evidence and is substantially different than the figures LabCorp presents,[23] and you have not provided evidentiary support for your assertions in your Comment responding to LabCorp's submission to FDA or in your 2024 Petition to explain this discrepancy.[24]

Second, we find that you did not provide sufficient information to support a finding that these tests pose an unreasonable and substantial risk of illness or injury. Specifically, the evidence presented in your petitions is not sufficient for FDA to determine how patient populations would be impacted by these tests or the results derived from them.[25] FDA at this time is also not aware of other scientific evidence indicating such risks. Because you have provided insufficient information to support a finding of substantial deception or an unreasonable and substantial risk of illness or injury, we do not reach the question of whether labeling may correct or eliminate such deception or risk.

Accordingly, we find that there is insufficient information in your petitions to conclude whether the paternity tests referenced in your petitions are devices subject to the FD&C Act and its implementing regulations. Further, even if these tests are devices, there is insufficient information to support a finding by FDA that these tests present a substantial deception or an unreasonable and substantial risk of illness or injury, and FDA declines to initiate rulemaking to ban these tests. Therefore, your request to ban the sale of duo paternity tests is denied.

III. Request to Revoke AABB's Authority to Accredit Clinical Laboratories under CLIA and Transfer the Authority to ASCLD

In your 2022 and 2024 petitions, you request that FDA revoke AABB's authority to accredit laboratories under CLIA. FDA does not grant deeming authority to accreditation organizations under CLIA and FDA did not publish this notice in the Federal Register. The Centers for Medicare and Medicaid Services (CMS) published this notice and is the agency tasked with regulating accreditation programs for clinical laboratory testing performed on humans in the United States under CLIA. FDA does not have the authority to revoke AABB's deeming authority under CLIA. As such, FDA denies your request to revoke such authority. For the same reasons, FDA denies your request to transfer AABB's deeming authority under CLIA to ASCLD. Questions regarding CMS' CLIA program can be directed to LabExcellence@cms.hhs.gov.

[23] See Response to Citizen Petition of Randall Steinmeyer, Esq. (FDA-2022-P-1632), FDA-2022-P-1632-0004, (Dec. 7, 2022), available at https://www.regulations.gov/comment/FDA-2022-P-1632-0004 at 5.
[24] An example of your failure to present evidence to support your claims is that you claim in footnote 8 of your 2024 Petition that certain works cited by LabCorp as scientific evidence do not exist, when the works do exist.
[25] See 81 FR 91722 (Dec. 19, 2016) for an example of devices for which sufficient evidence existed to demonstrate an unreasonable and substantial risk of illness or injury.

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IV. Request for FDA to Directly Regulate DNA Paternity Tests

In your 2024 Petition you request that FDA "directly regulate DNA paternity tests." FDA interprets this as a request to state that paternity tests are regulated by FDA as devices. As noted in section II above, whether or not a paternity test should be regulated by FDA as a device depends on whether that test meets the definition of a device in section 201(h)(1) of the FD&C Act. Based on the information provided in the petitions, FDA does not have sufficient evidence to determine that all paternity tests are devices. As such, FDA is denying your request to state that DNA paternity tests are regulated by FDA as devices.

To the extent that your request may be interpreted as a request for FDA to take specific enforcement action against DNA paternity tests, we note again that the 2024 Petition does not clearly identify a specific test or tests which you believe should be subject to such enforcement action. Even assuming that any such paternity test is a device, requests for the agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures. *See* 21 CFR § 10.30(k). Such matters are within the discretion of the agency. Therefore, we are also denying your request under 21 CFR § 10.30(e).

V. Request for FDA to ban Respondents from Participating in the LDT Markets

In your 2024 Petition you request that FDA "ban Respondents from participating in the LDT markets." As discussed in Section II, there is insufficient information before the Agency to make a determination that all duo paternity tests are devices, and thus it is not clear that these products or manufacturers are in violation of the FD&C Act. In such circumstances, FDA has no authority to "ban" or otherwise prohibit a firm from offering its products. As such, FDA is denying your request to ban these companies from "the LDT markets."

If you have any questions about this response, please contact Daniel Schieffer in our Office of Policy at daniel.schieffer@fda.hhs.gov or 301-796-3350.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
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Deputy Center Director for Policy
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