Division of Dockets Management

Food and Drug Administration

5630 Fishers Lane

Room 1061, HFA 305

Rockville, MD 2085

Petitioner: Randall Steinmeyer

Respondents : (1)Lab Corporation of America (LabCorp) and (2) DNA Diagnostic Center (DDC) (owned by Eurofins) and (3) American Association of Blood Banks (AABB).

CITIZEN PETITION

The undersigned submits this Petition under the relevant sections of the Food, Drug and Cosmetic Act or any other statutory provisions for which they have been delegated to the Commissioner of the Food and Drugs under 21 CFR Part 809[1] Medical Devices; Laboratory Developed Tests, to request the Commissioner to ban the sale of Respondents lookalike- "forgeries" mislabeled as "DNA paternity tests." This Petition enlarges the presented material in FDA-2022-P-1632-0001[2]

[1] https://public-inspection.federalregister.gov/2024-08935.pdf

[2] https://www.regulations.gov/document/FDA-2022-P-1632-0001/comment

and seeks to provide the Commissioner with additional information for consideration.

I. ACTION REQUESTED

Request for FDA to (a) ban on LabCorp and DDC's (Eurofins) forged tests which are mislabeled[3] and sold to patients as "**DNA paternity tests"**, (b) directly regulate DNA paternity tests , (c) remove the American Association of Blood Banks (AABB) as the paternity test regulator and (d) ban Respondents from participating in the LDT markets.

II,.STATEMENT OF GROUNDS

A.Introduction and Summary

Lab Corporation of America ("LabCorp") and DNA Diagnostic Center ("DDC") control 100% of the "commercial" DNA paternity tests sold in the US. LabCorp

[3] When communicating with FDA, Respondents repeatedly claim thier LDTs are "**forensic"** and based on "**FBI"** standards, and therefore should escape regulation.
However, in June 2024, Respondents would reveal that this too was a lie. See infra.

and DDC's "commercial" DNA paternity tests are regulated by the American Association of Blood Banks (AABB).

These commercial DNA paternity tests are sold directly to patients via CVS, Amazon , LabCorpDNA.com, DNACenters.com. These same tests are also sold indirectly to patients via the family courts where LabCorp and DDC control 100% of the contracts in the United States.

By 2017 and in select markets, LabCorp and DDC began using forgeries in place of paternity tests. To assure themselves of not being caught, in 2017, LabCorp and DDC had their own executives[4] installed as the test regulator (the AABB[5]).

After LabCorp and DDC seized control of the test regulator, LabCorp and DDC began bribing their own newly appointed regulator to "look the other way" as they switched paternity tests with forgeries. LabCorp (and DDC's) "regulators" participated in the scheme from their executive offices at LabCorp (and DDC). Bribing these two executives to participate in the paternity tests forgery scheme

[4] George Maha from LabCorp and Michael Baird from DDC.
[5] AABB Relationship Testing Standards Committee.

was easy. Moreover, the forgeries were a fraction of the cost of the actual paternity tests and made all participants in the scheme more money.

Request for FDA to (a) ban on LabCorp and DDC's (Eurofins) forged tests which are mislabeled as "paternity tests" , (b) directly regulate certain **LDTs claimed to be "paternity tests" but are "forgery-lookalikes,**" (c) remove the American Association of Blood Banks (AABB) as the regulator) and (d) ban Respondents from participating in the LDT markets.

On July 20, 2022, Petitioner filed an FDA Citizens Petition to (1) halt the sale of certain LDT knowing as DNA paternity tests (sold by LabCorp, DDC and AABB) but are actually forgeries (2) remove the AABB as the regulator and directly regulate these tests.

In September 2022 and December 2022, Respondents filed responses to the FDA and which contained fictional citations and phony science claims.

Petitioner submits this Petition which removes all doubt that the FDA should, amongst other things, **immediately (a) halt the sale of these forged tests**

mislabeled as paternity tests and (b) ban Respondents from participating in the LDT markets.[6]

B. FACTS RELATED TO THE TEST FORGERY MISLABELING

From 2017 to present, Respondents LabCorp, DDC (Eurofins) and AABB have been (i) secretly switching court-ordered DNA paternity tests with cheap forgeries and (ii) even replaced, and therefore forged, court-appointed expert's opinions and signatures. For example, in Petitioner's case, the Chairman of the AABB (Maha) was appointed but refused to sign the forgery so Respondents replaced the expert, the expert opinion and signature with a LabCorp employee (Stuhlmiller) who has a reputation for committing DNA test fraud, before the courts.[7]

[6] If Respondents' DNA paternity test can be forged(including those they sell to courts), then what is to stop them from repeating this forgery charade in other tests?

[7] **Paternity Suit Raises Doubts About DNA Tests**: Va. Judge Rejects Results, Questions Lab Work , Washington Post(August 20, 2005) https://www.washingtonpost.com/archive/local/2005/08/21/paternity-suit-raises-doubts-about-dna-tests/7bd15077-582d-4c0e-b16d-7a9354de1ecf/

1.2022 FDA CITIZEN PETITION

In July 2022, Petitioner filed an FDA Citizen Petition to ban the sale of these forgeries to the public and courts.

2.RESPONDENTS USE RESPONSE TO DEFRAUD FDA

In Fall-Winter, 2022, Respondents responded to the Petition ("Response"). In the Response, Respondents (a) denied the test results were forgeries and (b) pretended to provide scientific claims and citations to back up the forgeries denial. However, when the Respondents' scientific claims and citations in the Response were investigated, the citations and scientific claims did not exist.[8]

In addition, to discredit Plaintiff and ensure the FDA would not listen to him , Respondents even used the Response to defame Plaintiff.

[8] There Respondents claim forgered tests are scientific, valid and 99.9999% and cites to the identical fraudulent cites and the exact same way. This reveals a de facto conspiracy. For example, Respondents all cite two papers from 1983. **First**, "1983" predates DNA technology by several years and has nothing to do with DNA paternity tests,**Second**, the "1983 Brenner" paper is not even a real citation (or title). **Third,** both A&B and AABB, cite a "1983 Walker " paper is not even a real citation either. More disturbing, the cited "1983 Walker paper has nothing to do with STRs currently used in forensic and paternity testing, but rather completely outdated technology using "proteins." This has nothing to do with DNA and the development of modern forensic science and the underlying science. **Fourth,** replacing the standard paternity test with a DUO-forgery are not used in any relevant literature in peer-reviewed journals in any 40 years that have passed since 1983, including publications of Respondents.

3.RESPONDENTS PAY A FORMER FDA-COMMISSIONER TO DECEIVE THE FDA ABOUT THE FORGERIES

Defendants also used the Response to leverage a former FDA commissioner's currency with FDA in an attempt to ensure the forgery scheme would not be banned. Specifically,Respondents paid a Former FDA commissioner, (Marc Scheineson) to sign the Response, despite knowing the claims and citations did not even exist and/or contradicted reality.

The Paid for Statements to deceive FDA via Former FDA Commissioner include as follows

PAID FOR CLAIM	V	TRUTH
"Precise".	V	Not precise, a forgery
"99. 99% accurate"	V.	Not accurate, a forgery
"Scientifically validated"	V	Never scientifically validated
"Peer reviewed journals"	V	Never peer-reviewed

4.RESPONDENTS HIRE LAWYERS TO SILENCE PETITIONER:

In July 2023, because of Plaintiff's FDA Citizen petition filings and Respondents scheme to carve out DNA paternity tests from the FDA's regulation of LDTs, Respondents engaged lawyers to silence and threaten him from even asking "questions" about the Respondents' forgeried tests.

5.RESPONDENTS LIE TO FDA AND FALSELY CLAIM THE FORGERIES ARE "FORENSIC FBI " TESTS

In December 2023, Respondents communicated with the FDA again.This time Defendants were attempting to convince the FDA not to regulate its DNA paternity tests in connection with the FDA's regulation of LDTs (or "lab developed tests").Here Respondents made even more outlandish claims and told an even bigger lie to the FDA.

Because Respondents believed that if the FDA believed that Respondents tests were "**forensic**" and based on "**FBI**, " it would not regulate these LDTs, which would therefore allow Respondents to continue with the forgeries.

Accordingly, in Respondents' 2-page December letter to FDA the Respondents, more than 20 times, claimed the tests were "**forensic." In the same letter, Respondents claimed the tests were** also based on "**FBI"** standards. (However, just months later (June 2024), Respondents would reveal that this too was a lie).

THE TRUTH IS REVEALED

6.Respondents shocking admissions

In June 2024, Respondents admitted to material issues, revealing they knew about the forgeries the entities time, but tried to keep it a secret, unsuccessfully:

Specifically, in June 2024, Respondents admitted these tests were document forgeries as they were (a) **not** "forensic" (b) **not** "FBI-based[9]," as Respondents had **falsely** claimed. In addition, a DNA expert testified the lookalike forgery test is a fraud.

7. Respondents forged the signatures of the expert too:

[9] RespondentAABB in Steinmeyer v AABB conceded the forgery was **not** based FBI or and **not** forensic, but based on a hodgepodge of random dictionaries.

In addition to being document forgeries the lookalike forgeries are " signature forgeries" too. That is, the signature of the court-appointed expert is forged too. In fact, in Petitioner's case, the court expert refused to sign the lookalike results and then he secretly replaced his signature of a lab-tech who agreed to participate in the forgeries. That is, in lieu of the authorized, court-ordered expert (George Maha), an individual with a history of fraud (Gary Stuhlmiller) involving these exact tests, pretended to be the court-ordered expert.

8 Robo-Signing forgeries

In addition, Petitioner discovered that Respondents, their counsel, executives were all aware of their **lookalike-forgery** takes only **4 minutes**[10] of a DNA expert's time. Conversely, Respondents admit that a **paternity test,** takes **90 minutes** of a

[10] Maha's employee (**Stuhlmiller) made the following statement in cross-examination** "And then there was Stuhlmiller's workload. He told the judge he personally reviewed 30,000 paternity cases a year, working 10 hours a day with no lunch break, 40 weeks a year, with time away for training and vacation. "**And that would be 15 [reports] an hour, is that right?" Chreky's lead attorney, Glenn C. Lewis, asked him.**

"Correct," Stuhlmiller answered."

Paternity Suit Raises Doubts About DNA Tests: Va. Judge Rejects Results, Questions Lab Work , Washington Post(August 20, 2005)
https://www.washingtonpost.com/archive/local/2005/08/21/paternity-suit-raises-doubts-about-dna-tests/7bd15077-582d-4c0e-b16d-7a9354de1ecf/

DNA expert's time.[11] This is a difference of 23 times. Now in hindsight, this 23x multiplier confirms that Respondents know the lookalikes are forgeries and not paternity testing, but simply robo-signing lookalike forgeries.[12]

Respondents' decisions to use cheap forgeries is motivated by greed. The forgeries can be made to say that any man is the father of "anyone" else. For these reasons the FDA should immediately (a) ban on LabCorp (and DDC) forged tests **mislabeled as paternity tests** and (b) directly regulate these particular LDTs, known as "DNA paternity tests."

[11] Here, in Respondent's own publication it admits a paternity test requires "30 minutes per sample" and at 3 samples per test this equals 90 minutes. https://www.aabb.org/docs/default-source/default-document-library/accreditation/relationship-testing-news-2112.pdf

[12] Respondents DNA expert (Shulmiller) testified they are required to work full-time with no time for breaks or lunch. As such, given the 23X multiplier, legitimate testing would require 22 more DNA experts to perform legitimate paternity tests.. See Id. "30,000 cases, 10 hours a day with no lunch break." To put this in perspective, at Respondent LabCorp where each such DNA expert might cost upwards of $1-million per year, this scheme would save over $22 million per year. And since LabCorp sells over 1 million paternity tests per year (not 30,000), this 23X multiplier is especially attractive. **That is, for 1/23 (or 4%) of the real cost of 23 DNA experts working full time, LabCorp can appear to do 100% the work, but avoid 96% of the cost.** At $22 million per year cost avoided, would allow for creative accounting . For example, if $22 million in costs, per year, are avoided and LabCorp reports this $22 million as earnings, then given LabCorp's current P/E ratio of 42, after just one year this would be material to LabCorp EPS.

In addition, because of the severity of the test forgery and seriousness of lies to FDA , the FDA should ban Respondents from participating in the LDT market. Simply, if Respondesnts will forge the DNA paternity tests, and forge signatures of experts, then what is to stop them from repeating this forgery charade in other LDT's like bird-flu, Cancer or Covid-19? Certainly labs like Respondents that forge LDTs and lie about "biological" paternity can not be trusted.[13]

III. ENVIRONMENTAL IMPACT

Petitioner states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

IV. ECONOMIC IMPACT

Economic impact information will be submitted at the request of the Commissioner.

V. CERTIFICATION

[13] Respondent's counsel was given the opportunity to rebut the factual allegations herein and declined and therefore failed to do so.

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

/s/Randall Steinmeyer

Randall Steinmeyer

(b) (6)

[redacted]

[redacted]