UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Petition for the change of DNA Testing regulators and halt the sale of so-called "*motherless* paternity tests."[1]

Docket No. _____

Petitioner: Randall Henri Steinmeyer
Date: July 19, 2022

CITIZEN PETITION

The undersigned submits this petition under CFR Title 21, Chapter I, Subchapter A, Part 10.25 and 10.30 to request the Commissioner of Food and Drugs to **revoke** the Association for the Advancement of Blood & Biotherapies (AABB) authority to regulate DNA commercial DNA testing laboratories pursuant to Re-Approval of AABB 85 Fed Reg 101 (May 28, 2020) forthwith and furthermore halting further the sale of the so-called "motherless paternity test."

[1] Germany banned these "motherless" paternity tests in 2013. However, the version of the so-called motherless test discussed herein is materially more deceptive than even the Germany banned "test."

A. ACTION REQUESTED

This FDA Citizen Petition requests that the Commissioner *remove* the Association for the Advancement of Blood & Biotherapies (hereinafter "AABB") regulatory authority over DNA testing and *transfer* said authority to the American Society of Crime Laboratory Directors (ASCLD).[2] The ACLSD regulates ***forensic*** labs performing DNA testing in ***criminal*** courts; *whereas* the AABB regulates "***commercial***" labs performing DNA tests for ***civil and family courts***. **The Petition also requests that the Commissioner halt the sale of the so-called motherless paternity tests.**

B. STATEMENT OF GROUNDS

1. Summary

LabCorp acquired control of the DNA testing industry in the United States vis-a-vis LabCorp's acquisition of Orchid Cellmark (Orchid). Post-Orchid acquisition, LabCorp enjoyed a monopoly over DNA testing in both public and private markets.

[2]Criminal courts do not use (or allow) motherless paternity testing. Germany banned the sale of "motherless paternity tests.

LabCorp's monopoly also extended to DNA testing in the United States family courts. LabCorp leveraged its monopoly to usurp control of LabCorp's DNA testing regulator, the AABB. Once in control of the AABB, LabCorp switched its DNA paternity test with an artificial test and added fictional math.

LabCorp and its executive responsible[3] have concealed the test switch from the public. LabCorp still maintains that it is using a real paternity test, when it is not. In truth, LabCorp's paternity test is a sham.

The manufacturer of LabCorp's "test" cannot calculate paternity using LabCorp's methods. Neither can the FBI. [4] LabCorp devised a method to make DNA paternity testing incredibly profitable, for LabCorp. Instead of giving alleged fathers authentic DNA paternity tests, LabCorp subjects these alleged fathers to a cheap and artificial test, albeit with a "paternity test" wrapper. LabCorp's inflated profit comes at the expense of these alleged fathers.

On average, about 30% of the alleged fathers have been excluded as biological fathers in US courts while using standardized *scientific* paternity testing (also known as "Trio" tests). LabCorp's artificial tests **wrongfully includes** many of these 30% even though they should be told they were falsely accused. Put another way, if LabCorp conducts

[3] George Maha, Associate Vice President LabCorpDNA
[4]Neither Promega nor PopStats (FBI Statistics) can calculate a CPI with a "motherless" test.

500,000 DNA tests using this method, up to 150,000 men will be **falsely** told that they are the ***biological*** father of a child.[5]

To avoid detection, LabCorp even devised a way around reporting its collective test exclusion rate[6] to the public. Thus, using LabCorp's artificial test all alleged fathers can be told they are the *biological* fathers of children when they are not.

LabCorp's artificial tests create *fictional* **paternal** relationships where no such relationship exists. These *fictional* test results are not scientific, cannot be replicated by independent labs or even the FBI. Instead of performing 20 tests conducted in a paternity test, LabCorp only *pretends* to conduct all 20 such tests. LabCorp's artificial test results are engineered, not the result of biology.

Then, LabCorp *pretends* that 20 out of 20 of the tests revealed 20 separate highly specific "**paternal**" matches. In truth, the artificial test is blind to all 20 different "paternal" matches. The artificial test takes advantage of public naivety and *pretends* it found 20/20 paternal matches, when it cannot positively identify a single one. Labcorp's *artificial* test *fictionalizes* all 20 out of 20[7] matches between the alleged father and child in question.

[5] Over 10 years this number could swell to 1,500,000 false fathers in the United States.
[6] Normally, this rate should be 30%.
[7] 100%.

Then, LabCorp engages in mathematical computations **as if** the artificial test identified not 1 match, not 5, but 20 of 20 **paternal** matches. LabCorp's artificial test cannot identify **paternal** matches, but *pretends* otherwise. Labcorp's artificial test, *pretends* there are matches where there are none, then conducts pointless mathematical calculations. These fictitious calculation *conclusions* adorn the artificial test,
Labcorp was able to engage in this scientific chicanery largely because LabCorp's Associate Vice President and Laboratory Director of the *DNA* Identification Testing Division is ***also*** the head of the FDA regulatory entity controlling the industry, and thus controlling itself.

Previously, the FDA transferred regulatory authority to regulate DNA testing to the AABB. The AABB transferred the authority to the AABB's Relationship Testing Committee ("RTC"). The AABB's RTC is controlled by none other than LabCorp's Associate Vice President and Laboratory Director of the *DNA* Identification Testing Division.[8] **Thus, with regard to DNA testing, LabCorp regulates itself vis-a-vis its own, financially motivated, Vice President.**

Accordingly, LabCorp's current DNA testing regulator, the AABB, is no longer able to effectively regulate DNA testing. Furthermore, a suitable alternative regulator has been identified[9] and transfer of said regulatory authority could occur swiftly and without

[8] Dr. George Maha
[9] The ASCLD regulates ***forensic*** labs performing DNA testing in ***criminal*** courts; *whereas* the AABB regulates "***commercial***" labs performing DNA tests for ***civil and family courts.***

incident. Concurrent with regulator change, the Petition also requests the Commissioner halt the sale of the so-called "motherless paternity test," which as evidenced herein, is plainly an unscientific (and deceptive) test.

2. Labcorp secretly change the definition of "biological father."

A paternity test requires 20/20 matches. LabCorp's motherless paternity test doesn't require a 20/20 match.

Now even 18/20 works.

So does 17/20.

Even 16/20.

Bizarrely, Maha and Labcorp have given themselves through their abuse of the AABB RTC both unlimited discretion and financial incentive to use as few matches as Maha and Labcorp decide is appropriate.

Hence 15/20 will work too.

So will 14/20.

and even 4/20 too.

3. Maha and Labcorp boosted the mathematics in the "test" with a "linkage analysis" which is clearly fictitious

A linked-loci analysis is **not** part of a *scientifically* properly performed paternity test. Nevertheless, Maha and Labcorp added linked-loci analysis to Labcorp's motherless paternity tests.The only paper on linked-loci in paternity was written by Maha.[10] Maha's linked-loci science has **never been** peer-reviewed.[11] Maha's science paper can be found on a **corporate** website[12], ***not a peer-reviewed scientific one.*** In the paper, **Maha admits that this linked-loci analysis is not possible without maternal DNA.** Although lacking the prerequisite maternal DNA, Maha's "analysis" parades itself into the hundreds of thousands of "paternity tests" annually sold by LabCorp[13]. Maha's linked-loci analysis existence in a "paternity" test without **maternal** DNA cannot exist, should not exist, but ***magically*** it appears in Labcorp's current "paternity test" anyway.

Despite the impossibility, the linked-loci analysis parades itself into LabCorp's so-called "motherless paternity tests." **In truth, the linked-loci analysis motherless "paternity" test is actually further evidence of the level of fraud perpetrated.**

4. Test Mechanics

A paternity test does three key things:

Number 1

[10] Gary Stuhlmiller was the co-author and resigned from Labcorp this Spring (2022) after Stuhlmiller (and Maha's) DNA **fraud** became exposed at LabCorp.
[11] Though not peer reviewed, the paper is sponsored by LabCorp and Promega.
[12] Maha's science "paper" is in 1 point type, not 12,
[13] Including the DNA paternity tests used in the civil/family courts

Simultaneously, *Confirms* the mother and determines the child's **maternal** *obligates*[14] alleles ("MOAs").

Number 2

Subtracts the child's **maternal** obligate alleles (MOAs) from the child's DNA to determine the child's **paternal** *obligate*[15] alleles ("POAs").

Number 3.

Compares the alleged father's DNA to the child's POAs. If all POAs match the father's DNA, then a CPI and PoP can be calculated and presented to a court as evidence.

A true "paternity test" can do all 3 (1) confirm the mother (2) identify the father and (3) identify a child as a biological child of the same. LabCorp's so-called "paternity test" does none of these. Most importantly and contrary to popular belief, LabCorp's motherless paternity test **cannot** identify the *biological* father,

The following table illustrates other differences between a real paternity test and Labcorp's so-called "paternity test:"

[14] "Obligate", **not** optional.
[15] Again, obligate, not optional.

	FORENSIC LABS	LABCORP
SELLS MOTHERLESS PATERNITY TESTS	NO	YES
PROHIBITS INDEPENDENT LABS FROM REVIEWING	NO	YES
CALCULATES CPI/POP **WITHOUT** MATERNAL DNA	NO	YES
REGULATES THEMSELVES	NO	YES
SELLS PATERNITY TESTS WITH INSURANCE	NO	YES

5. Fictional Math

A paternity test calculates a POP and CPI[16] if, and only if, all 20/20 of the child's **paternal** markers[17] match the accused. Maha's motherless test cannot identify **paternal**[18] matches.

Maha *pretends* to perform the requisite 20 different tests normally performed in a standard paternity test. Then Maha and LabCorp pretend to derive **paternal**[19] matches, but does so out of vapor, not reality. Maha and LabCorp then calculate numbers with these *pretend* **paternal**[20] matches.

A paternity test mathematics is driven by 20/20 paternal[21] matches (with very defined exceptions and corresponding corrections for a small number of mismatches). The **only** calculations displayed on a true paternity test are the "CPI and PoP."[22] Likewise, Maha and LabCorp's motherless test *pretends* to perform the identical "CPI" and "POP" calculations. Maha and LabCorp's CPI and PoP mathematical calculations based upon purely non-existing POA matches are complete fiction.

In a *scientific* paternity test, the CPI and PoP calculation conclusions are "the test results," and the basis for determining the legal status of a potential father of a child.

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[16] Combined Paternity Index (CPI) and Probability of Paternity (PoP),
[17] Paternal Obligate Allele (POAs). **For a technical discussion of POAs see page 12.**
[18] Paternal Obligate Allele.
[19] Id.
[20] Id.
[21] Id.
[22] Combined Paternity Index and Probability of Paternity.

On Labcorp's and Maha's tests, the calculation *conclusions* for a "CPI" and a "PoP" are present, but meaningless. Maha and LabCorp only *pretends* to calculate the CPI and PoP. Neither the CPI nor POP can exist in a motherless test, but do on Labcorp's motherless self-proclaimed "paternity tests".

Maha and LabCorp's test generates math from random ***similarities*** **between all humans,** not 20/20 paternal[23] matches.**[24]** Maha and LabCorp's motherless test is NOT designed to identify paternal biological relationships. Rather, Maha and LabCorp's test is designed only to illuminate these similarities and pawn off these "similarities[25]" as discrete **paternal**[26] matches.

These similarities, and not 20/20 paternal[27] matches, steer the motherless test "mathematical results." **In truth, the mathematical results[28] on each of the motherless paternity tests are fictitious**.[29]

[23] Paternal Obligate Allele.
[24] Maha's motherleles test computations suggest discrete biological meaning where truly none exists. If Maha's "science" was executed in the 8th Century, it might look like "If the sun comes up tomorrow, you are the biological dad."
[25] Within Maha's professional circle, Maha's "tests" are also known as "*similarity* tests."
[26] Paternal Obligate Allele (POA)
[27] Paternal Obligate Allele (POA)
[28] Both CPI and PoP.
[29] Maha's results are not scientific or even replicable by an independent lab.
Maha's results are not evidence.

6. Confession by Maha

George Maha was confronted with the core issues plaguing Maha's tests including the 1) the maternal DNA omission, (2) the definition for "biological" father switch and (3) the fictional linked-loci analysis.[30] During the interview, Maha confessed that the "**biological** evidence" in the "tests" had been switched with "**social** science evidence."

7. Resignations to Date

Maha's employee, Dr. Gary Stuhlmiller, LabCorp scientist responsible for "*signing*" *some* of the fake paternity tests, recently resigned from LabCorp in response to damaging claims made about LabCorp's motherless tests. [31]

As the director of LabCorp DNA, Maha is responsible for "*all*" of LabCorp's DNA paternity tests. To preempt Maha's "disbarment," Maha directed the North Carolina Bar to remove Maha's name from the North Carolina Bar. Ironically, Maha still uses the name Dr George Maha "**JD**", PhD including in **legal** cases where Maha parades as a "*legal* DNA *expert*" where Maha also *pretends* to be a member of the North Carolina Bar, even though Maha clearly is **not**. Nevertheless, Maha parades as the **legal** DNA evidence[32] expert with no law license, but *pretends* otherwise.[33]

[30] The confrontation occurred vis-à-vis a telephone interview of Dr. Maha
[31] Stuhlmiller and Maha worked side by side for decades at LabCorp.

[32] Worse, in each of the motherless (POA-less) tests, Maha has "**no evidence"**, not a single POA match, not 1, not 20,
[33]' No license is required to practice magic in North Carolina.

8. Maha's abuse of the AABB is material.

Each year, hundreds of thousands DNA paternity tests are "**AABB**" stamped[34] by Maha. As a matter of law, the "AABB" stamp (or seal) on the bottom of the test, is a condition precedent to a paternity test being monetized in civil or family court. Maha controls the AABB stamp. *Without* Maha's **AABB** stamp, the test results could not parade as "paternity" evidence in either public[35] or private markets.[36] The **AABB** stamp is on the bottom of **each** of LabCorp's **fictional** "*motherless*" paternity tests. The word "**fictional**" cannot be stressed enough.

There is no such thing as a "motherless" paternity test. Rather a "motherless" paternity test is actually a 2 person "kinship" or generic "relationship" test. A kinship test involves **two** people.

A paternity test involves **three** people. If an alleged father is not excluded via a "kinship test, maternal DNA is added to the 2-person "**kinship"** test, transforming it into a 3-person "**paternity**" test.

If the mother's DNA is not available, it is simply reconstructed by obtaining DNA from close relatives of the missing mother. Maha admits the same in his own 2018 article entitled "The UPA 2017: The Science of It All":

[34] Robo-signed.
[35] Civil and family courts.
[36] The same fraudulent activities Labcorp perpetrates outside of the courts, on consumers purchasing DNA tests over the Internet via LabCorpDNA.com

"The biological relatives ideal for testing are both of the missing [mother's] alleged biological parents (the alleged grandparents), as they will contain all the biological material their child has. When both of the alleged grandparents are not available, other relatives can be used. The greater the number of relatives tested, the more likely an expert is to be able to reconstruct the genetic material in the missing [mother]." [37]

Thus, when selling "motherless" tests, Maha contradicts not only science and his own publications, but also the law. Maha should know since Maha actually was instrumental in writing the very law.

The Uniform Parentage Act (UPA) was written in part by Maha. **The UPA requires Maha to identify a child's paternity using maternal DNA.**[38] Maha induced all 50 States to adopt the UPA as the law. In truth, LabCorp and Maha are now, and have been, breaching that very law Maha helped pass.

8. A particular case where Maha and LabCorp were Court appointed as expert witness and laboratory, respectively, illustrates their scheme

[37] https://www.americanbar.org/groups/family_law/publications/family-advocate/2018/spring/4spring2018-maha/n See also George C. Maha, Determining Paternity After Death: Genetic Testing When a Party is Not Available, in Disputed Paternity Proceedings (N. M. Vitek, ed., Mathew Bender & Co.) (1999).

[38] Or recreate the maternal DNA

In that case, the alleged father denied having any procreative conduct between himself and the alleged mother. Nevertheless, Maha, the expert witness, switched the paternity test to the infamous "motherless" test.

The results were shocking. Despite no sexual conduct, the so called "test" results claimed a 99.99% certainty that the alleged father was the biological father.

Coincidentally, the same day the results were issued, the alleging mother **sold** the legal right[39] to collect **money** from the alleged father to Maha's client.Thereafter, Maha's client garnished the alleged fathers wages. With garnished funds, Maha's client paid[40] for the so-called "test."

9. Maha and Labcorp's science scheme

LabCorp and Maha are engaging in a scheme to change the paternity testing market in favor of their own benefit but to the detriment of **falsely** alleged fathers. In addition, to cover up this elaborate scheme,LabCorp and Maha worked with lawmakers and state regulators to limit competitor's access to the market and prevented the reporting of court

[39]In this circumstance, no legal right exists **but for** a **paternity test** identifying "alleged father" as "biological " father.
[40] County of San Diego.

decisions to the public. LabCorp and Maha have done all this in contrast to existing science, and in contrast to forensics experts in the field.

In summary, LabCorp and Maha abolished a solid system of paternity testing (so-called Trio testing), where the tests are performed to give evidence of potential paternity by an alleged father which is then weight by experts to evaluate the probability of fatherhood of a given child and have displaced this system with a testing system (so-called " motherless" or "Duo" testing), where non such evidence is generated. Instead, LabCorp and Maha are using calculations for the probability of even having evidence (without demonstrating that they in fact do have evidence), and they are representing the probability of having evidence misleading in a way the strength of evidence has been presented in the proper Trio testing system.

LabCorp and Maha effectively built a system which misleads courts, judges, and the public by pretending to have generated evidence where in fact there is none.

A. Paternity testing science

Since the development of molecular biology-based DNA technologies, DNA testing has become an important element of forensic investigations. Following the necessary scientific and mathematical rules to evaluate DNA-based evidence is necessary to present

these forensic findings to the courts. Once performed properly, DNA-based evidence can be highly reliable evidence and very specific and important to a specific case.

Besides criminal investigations – like rape or murder cases – the testing and comparison of multiple sources of DNA has become an important part of relationship or kinship testing. Here, a substantial portion of investigations are used as paternal testing, a method to identify the potential father of a child.
In general, paternity testing is based on the fact that every child has inherited two sets of chromosomes:

One form its mother (maternal set of 23 chromosomes, 22 autosomes and one X chromosome, a single chromosome set present in the egg at conception) and one from its father (paternal set of 23 chromosomes, 22 autosomes and one X or Y chromosome, a single chromosome set present in the sperm at the time of conception). Maternal and paternal DNA is similar, but never identical. By identifying these differences one can determine the origin of specific DNA. By using very specific stretches of DNA located on a pair of chromosomes (called markers or loci), one can now determine which two alleles (the specific version of a marker or locus) are present in a child after a DNA sample is taken.

Doing this for multiple loci produces a genetic profile of the child. Following the same procedure for the mother and the alleged father, specific markers present in the mother and in the alleged father are identified. Comparing the child's profile of specific alleles to the one of the mother, one can determine the exact set stemming from the mother ("Obligate Maternal Alleles" or "OMA"). By subtracting that set from the child's profile the set of markers belonging to the real father can be generated ("Obligate Paternal Alleles" or "OPA").Simply comparing this set of OPAs to the DNA profile of an alleged father can answer the question if an alleged father can be excluded as a potential father. Illustration of generating an OPA by determining the OMAs, subtracting it from the child's allele pattern to generate an OPA and determining the match to a potential, alleged father.

An example of determining matches or mismatches in standard paternity testing (TRIO test) for a single marker (or locus) follows: In this case the locus or marker has three alleles, namely 10, 11 and 12.

	Case 1	**Case 2**
Child	10 : **11**	10 : 11
Mother	10 : 12	10 : 12
OMA	10	10
OPA	**11**	**11**
Alleged Father	**11** : 12	10 : 12
Potential Father?	**YES**	**NO**

If the alleged father's profile is a perfect match to the child's OPAs, the person can usually not be excluded as a potential father. Since different alleles at a specific locus on a chromosome have very different distribution patterns and frequency of occurrence within the human population, a simple match of one allele alone does not present strong enough evidence for paternity of a child. For example, an allele match for an allele that is present in 50% of a population would result in a random match in 25% of randomly compared DNA, or 1 in 4 cases.

On the other hand, a marker match for an allele which is present in only 1% of the population would result in only 0.01% of randomly compared DNA, or 1 in 10.000 cases – a much stronger indicator of potential fathership. To account for this phenomenon, following the determination of alleles in 20 loci to generate a specific DNA profile of child, mother and alleged father, the strength of the evidence that an alleged father is the

real father is determined. Once the alleged fathers DNA pattern matches the child's OPAs, the so-called Combined Paternity Index is calculated, which takes the strength of evidence of each individual matched allele into account, each individually depending of the frequency of occurrence of each matched allele.

The stronger the indicative strength of each allele pair in the matched DNA samples are (in reality the less common the matched alleles are in a population), the larger the calculated CPI will be. Using this CPI, a Probability of Paternity can be calculated. The courts currently consider a PoP of 99.99% or more as sufficient to conclude that an alleged father is the biological father. This correlates to CPI of 10.000 or more.

All of the above is based on the fact that an alleged father's DNA profile represents a perfect match to the child's Obligate Paternal Alleles, which were derived by subtracting the mother's Obligate Maternal Allele set from the child's two sets of alleles for each locus. But what if the father's DNA profile is not a perfect match to the child's OPA? Here, scientists, forensic experts and the courts allow for a correction in specific cases considering the following assumptions. DNA can mutate, and in fact it does so every day.

Many of these mutations do not have any impact on the cells or the tissue surrounding it. But in other cases, single mutations in a cell can lead to severe changes in our bodies, for example the development of cancer. However, a changed allele from a father manifesting itself in a possible child's DNA can only have happened at the time of sperm production

by the father, since the child's mismatching allele is not found in the alleged father's DNA derived from a sample taken from him. To account for this extremely rare event, paternity testing allows for a mismatch to be included in the calculation of a CPI. This requires a corrective factor to be included in the calculation of the CPI to account for the low probability of this event really to have occurred in reality.

The inclusion of a mismatch into the calculation of the CPI usually lowers the CPI as compared to a perfect match of the same compared DNA profiles. This can cause an otherwise perfectly matched DNA pattern to produce a CPI resulting in a PoP below 99.99% and excluded an alleged father. On the other hand, it also will include alleged fathers as potential fathers, if the resulting PoP is above 99.99%. With a requirement for a perfect match between the child's OPAs and the father's DNA profile, these alleged fathers would have been excluded.

By testing child, mother, and father (also called a trio test), proven fathership with more than one mismatch between the child's OPAs and the alleged father's DNA do to our knowledge practically not exist. Legally the courts allow for two mismatches to potentially still consider an alleged father a potential father of a child. For cases with any more mismatches a CPI is not calculated, and the alleged father is automatically excluded as a potential father. **Using the extensively studied and evaluated trio method, between ¼ and 1/3 of all alleged fathers turn out to NOT be the father of the child in question.**

In summary, all statistical calculations, allele frequency used in calculations, the selection of the specific marker set used, and calculations of CPIs including the rare events of germ cell mutations resulting in mismatches are based on the correct determination of the Obligate Maternal and Obligate Paternal Alleles in a child's DNA profile, as it is done in correctly performed trio testing.

The determination of the probability of a given alleged father to be the father of a specific child is complex. It requires the proper performance of sample collection, the determination of all three DNA profiles, and the exact application of the mathematical rules used to calculate a CPI and PoP based on methodology developed for a trio test.

B. Technical analysis of the science scheme

Courts usually base their decision purely on the resulting PoP, and detailed explanation on how the samples were taken, the analysis was performed and the numbers were calculated are not discussed.

However, by applying changed methodologies in analyzing markers, determining DNA profiles, including or excluding samples taken for the tests, and applying mathematical methods not specifically developed for a potentially changed protocol, one can now – out of sight of the court system – manipulate individual elements of the system to generate "fictitious" CPIs and PoPs without having to explain the validity of such changes to the courts. This is exactly what LabCorp and Maha have done.Contrary to science, the

basics and prerequisites for calculating a CPI for a paternity test, and against the opinion of the AABB and other experts in the field, including Maha himself, LabCorp and Maha introduced a so-called DUO or motherless test into the field of paternity testing.

LabCorp and Maha developed an elaborate scheme to exclude competitors, including to control regulatory bodies regulating the industry, introduced scientifically questionable methods to generate "false" evidence [matching alleged father's alleles to OMAs, using linkage analysis where none were performed] and withhold systematically DNA evidence [the mother's DNA] to artificially inflate CPIs and thus convince courts of alleged father ships under false assumptions, while effectively covering up their tracks from the public eye [no publications of testing results in paternity cases].

Before explaining the way LabCorp and Maha corrupted system of paternity testing, first, a short overview of some of the elements used to achieve their goals:

• By using a Duo test and not including the DNA profile of the mother, they are matching alleged father's alleles to maternal alleles and including such matches in the calculation of CPIs and PoPs they are generating "false" evidence to inflate or even generate CPIs.

• By withholding maternal obligate DNA, they avoid to identify potential mismatches between the alleged father's DNA and the OPAs of the child, thus withholding evidence

that could drastically reduce the CPI or even bring it to zero, again effectively inflating CPIs and calculating PoP where there are none.

• By using a linkage analysis derived element of the CPI calculations to increase the CPI in a Duo test, without demonstrating that the child's allele pairs are in fact linked as maternal and paternal allele pairs, again producing "false" evidence to effectively increase the CPI and PoP.

• Obtaining an exemption from antitrust laws to exclude competitors and open market scrutiny of their practices.

• Taking effective control of the industry regulating body.

• Convincing regulatory bodies and states to stop publishing results of paternity testing in court to effectively hide their activities from (meanwhile not any more existing) competitors and the public.

LabCorp and Maha have developed an elaborate scheme using multiple elements of DNA based paternity testing to manipulate the outcome of court based paternity testing, all to the disadvantage of alleged fathers.

LabCorp and Maha introduced a Duo or motherless testing system, testing only the child's (and NOT the mother's DNA) and the alleged father's DNA.

This process does not allow for the determination of the OMA derived from the mother, and consequently does not allow for the determination of the child's OPA.

As a main consequence, the alleged father's DNA profile cannot be directly compared to the child's OPA, and the real number of mismatches or matches between the Child's OPA and the alleged father's DNA cannot be determined. By comparing the results of Trio vs Duo testing, a South African research group found, that this change in methodology lowers the number of detected mismatches in almost 90% of all cases investigated, and by this included a higher number of alleged fathers being considered potential fathers by apparently and falsely lowering their exclusion level below the allowed exclusion level, or even to zero. As one consequence, the switch from Trio to Duo results in a higher probability of the father to match the child's allele by a factor of two. This is caused because now an alleged father's allele can either match the paternal allele (with a correct matching result) OR the maternal allele of the child which represents a false positive match. This would otherwise have been considered a mismatch and represent one element of exclusion of the alleged father as the real father.

Disregarding this potential exclusion, LabCorp and Maha have used the matches to obligate maternal alleles as part of their CPI calculations, where in reality the value for this match would be 0.

This can be easily demonstrated using the example from above.
Here we can see an exclusion of an alleged father for an allele mismatch using the scientifically correct TRIO method and the inclusion of the same father using Labcorp's and Maha's fraudulent Duo "motherless paternity" test.

Example of determining matches or mismatches in standard paternity testing (TRIO test) as compared to a fictional Duo motherless "paternity test" for a single marker (or locus). In this case the locus or marker has three alleles, namely 10, 11 and 12.

	Trio test		**Duo test**	
	Case 1	Case 2	Case 1	Case 2
Child	10 : 11	10 : 11	10 : 11	10 : 11
Mother	10 : 12	10 : 12	(10 : 12)	(10 :12)
OMA	10	10	n. d.*	n. d.
OPA	**11**	**11**	n. d.	n. d.
Alleged Father	**11** : 12	10 : 12	11 : 12	10 : 12
Potential Father?	YES	NO	YES	YES**

* n.d. not determined

** By not determining the POA, the father's alleles are "matched" to an obligate **maternal** allele (OMA) of the child, thus falsely generating a paternal match which does not exist

This is done by LabCorp and Maha even though a match between an alleged father's allele and a maternal allele of the child is under no circumstances evidence of paternity – the allele is simply not derived from the alleged father.

By including these matches in court ordered paternity testing, LabCorp and Maha are in fact generating false evidence, and by calculating mathematical CPIs where in reality none exists – as would be shown in a properly performed Trio test.

By allowing these undetected mismatches to be included into the CPI calculations, LabCorp and Maha not only artificially lowered and changed the number of exclusions in about 90% of all investigated cases in the above cited study, they are also in effect increasing the probability of determining a random man as a potential father of a child be the factor of up to 100,000-fold **See Exhibit A.**

Furthermore, LabCorp and Maha have introduced rules which ignore evidence in support of excluding an alleged father as the real father of the child. In a Trio test, the maximal number of mismatches (or exclusions) between a child's OPAs and an alleged father's

DNA pattern is 2, with almost no known cases of an alleged father being determined the real father with more than one mismatch.

Labcorp and Maha switched the definition of a biological father. **Contrary to science or forensic practices, LabCorp and Maha routinely allow for the calculation of CPIs in the presence of "4 or more" mismatches or exclusions, even though in these cases alleged fathers should have been excluded based on the exclusion limitations.**

Given the fact that in properly performed paternity testing the Probability of Paternity is set to zero after detecting more than two mismatches, LabCorp and Maha– without any scientific basis and against the opinion of the scientific and forensic community – calculates CPIs and PoPs where, in reality, they do not exist or are equal to zero.Thus, again presents "false" evidence to the courts by calculating CPIs and withholding evidence by ignoring the existence of mismatches or exclusions which otherwise could outright exclude alleged fathers from being determined as potential fathers.

Lastly, by introducing a "novel" combinatorial analysis of alleles on specific chromosomes (a so-called "linkage analysis" or "linked-loci ") LabCorp and Maha uses high CPI contributing analyses to increase the CPI.

LabCorp and Maha uses the fact that two of the 20 loci used in paternity testing are located on the same chromosome – they are physically linked on the same strand of DNA. Having the same set of two alleles for the two loci linked on the same chromosome in the child and the alleged father presents a strong piece of evidence for potential paternity. However, the fact that potential alleles are linked in reality can **only** be demonstrated in a trio test, where the Obligate Maternal Alleles of the child have been determined, and consequently a link between such alleles has been confirmed. As a result, a link between the remaining two Obligate Paternal Alleles can be assumed and presented as evidence.

Here an illustration of the Trio test analysis, including potential alleles 10, 11 and 12 for locus 1 and alleles 6, 7, and 8 for locus 2

	Locus 1	**Locus 2**
Child	11 : 12	7 : 8
Mother	10 : 11	6 : 7
OMA (linked 11&7)	11	7
OPA (linked 12&8)	12	8
Alleged Father	10 : 12	6 : 7
Potential Father (linked 12&8)?	NO	

The mother matches allele 11 in locus 1 and allele 7 in locus two, resulting in a linkage of allele 12 in locus 1 and allele 8 in locus two being considered linked as part of the OPAs. However, by intentionally withholding **maternal** DNA evidence, the LabCorp and Maha Duo test allows for the inclusion of all men with potential marker combinations that are random permutations of the parental alleles present at the two loci in the child (L1: 11;12 L2: 7;8).

By not determining the real OMAs linked marker combination (here 10&7) and correctly deducting the real OPAs linked (here 11&8), LabCorp and Maha allow for the inclusion of all four combinations of the child's alleles to be included as matches in the calculations, here (11&7 , 11&8 , 12&7 , 12&8).
This would result in the fact that the alleged father in the above example (he carries allele combination 12, 7 would NOT be excluded based on the fictional lineage analysis, even though these alleles are NOT linked in the child.

In reality, only one of these combinations is the real OPA linked combination which only then can be used to calculate a CPI. However, LabCorp and Maha without any scientific basis includes all four scenarios into matching CPI calculations. **In fact, LabCorp and**

Maha is including 4 out of four individuals as being potential fathers, even though only one out of four has the potential to be the father.

All three other individuals would be excluded based on the facts and a CPI calculation for the linked alleles would not be possible. Using the above example of an alleged father NOT matching the linked OPAs, it becomes clear that Labcorp's and Maha's *pretended* linkage analysis does not exist in reality, and that an alleged father would be included in a testified court document as matching the child's alleles:

	Locus 1	**Locus 2**
Child	11 : 12	7 : 8
Mother	(10 : 11)	(6 : 7)
OMA (linked 11&7)	n. d.*	n. d.
OPA (linked 12&8)	n. d.	n. d.
Alleged Father	10 : 12	6 : 7
Potential Father	YES**	

* n.d. not determined

** By not determining the OMAs and POAs, the father's alleles are "matched" to an obligate **maternal** allele (in this case allele 7 in locus 2) of the child, thus falsely generating a paternal match which does not exist. Here, in addition Maha and Labcorp

not only assign a wrong maternal match to the alleged father, but also pretend to have performed a so-called linkage analysis while they have not done so.

Here, LabCorp and Maha *pretend* to have performed a "linkage" analysis by calculating CPIs, where in fact they have not done so at all. In doing so they are actively misleading the courts by generating false evidence and then presenting it as evidence, where in reality this evidence does not exist.

In summary, LabCorp and Maha have developed an elaborate scheme to systematically generate and present to courts **false evidence, withhold evidence, and fabricate evidence** all with the goal to present inflated and or fabricated CPIs where none exist – all to the detriment of falsely accused fathers. **By implementing all elements of this scheme, LabCorp and Maha allow for the calculation of an alleged father's CPI in the range of multiple millions, resulting in PoP far exceeding the 99.99% threshold, without the father alleles matching a single OPA of the child**.
This is only possible because LabCorp and Maha allow for matching alleged father's alleles to either OPAs or OMAs without discrimination and without detecting which is which. This case would be based on 100% false evidence, and the alleged father would incidentally match most or all of the maternal alleles of the child. **See Exhibit B**.

In conjunction with all other doings, has abandoned the color-coding system used in Trio testing with colors specific for child, mother, and alleged father to avoid switching of

samples. The sample collection has been switched to mono color system, allowing for undetected switching of samples and resulting potentially in exactly the scenario described as above. In a further twist of these unscientific and forensically unacceptable practices, by omitting the maternal DNA, it cannot even be shown that the alleging mother of the child is in fact the real mother. [41]]

[41] In truth, LabCorp and Maha's practices open the door to fraud, including presenting a baby other than the mothers in an attempt to match a potential father, or claiming a child as their own which in fact is someone else's child.

EXHIBIT. A

Appendix A

[needs statistician confirmation]

Multiple of randomly matching an alleged father to a child Trio vs Duo

Locus	Average
Trio calc prob 2 alleles of father vs OPA	0.355917618
Duo calc prob 2 alleles of father vs 2 child alleles	0.620860375

Trio test average probability that a father is determined randomly as father, matching a random pattern:
Using 20 known average probabilities of alleles

# Mismatch	0
P=	5.30806E-10
1 in	1883928406

Duo test average probability that a father is determined randomly as father, matching a random pattern
Using 20 known probabilities of alleles
Each probability is doubled, since two alleles can be randomly match at each locus

# Mismatch	0
P=	4.27407E-05
1 in	23396.89872

Multiplier of random match from trio to duo probability

M=	**80520**

EXHIBIT. B

Alleged Father is the Father

Marker	Father		Mother		Child		Alleged Father		Mother of All. Fath	
CSF1PO	12.0	13.0	13	12.0	13	13.0	12.0	13.0	13	9
D13S317	11.0	12.0	9.0	10.0	9.0	11.0	11.0	12.0	12	8
D16S539	12.0	12.0	10.0	13.0	10.0	12.0	**12.0**	**12.0**	12	9
D18S51	14.0	17.0	11.0	16.0	11.0	14.0	14.0	17.0	17	12
D21S11	29.0	30.0	28.0	30	30	30.0	29.0	30.0	30	31.2
D3S1358	14.0	17.0	15.0	18.0	15.0	14.0	14.0	17.0	17	17
D5S818	10.0	13.0	11.0	11.0	11.0	13.0	10.0	13.0	13	12
D7S820	9.0	12.0	11.0	8.0	11.0	9.0	9.0	12.0	12	10
D8S1179	13.0	13.0	14.0	15.0	14.0	13.0	**13.0**	**13.0**	13	11
F13A01	3.2	7.0	12.0	5.0	12.0	3.2	3.2	7.0	7	6
F13B	10.0	10.0	8	10	10	10.0	**10.0**	**10**	10	9
FESFPS	11.0	12.0	10.0	12	12	11.0	11.0	12.0	12	8
FGA	22.0	24.0	21.0	24	24	24.0	22.0	24.0	24	23
LPL	9.0	11.0	12.0	13.0	12.0	9.0	9.0	11.0	11	14
Penta_C	11.0	11.0	13.0	9.0	13.0	11.0	**11.0**	**11.0**	11	12
Penta_D	9.0	13.0	11.0	10.0	11.0	9.0	9.0	13.0	13	12
Penta_E	10.0	12.0	7.0	13.0	7.0	12.0	10.0	12.0	12	5
TH01	6.0	9.0	7.0	9.3	7.0	6.0	6.0	9.0	9	8
TPOX	10.0	11.0	9.0	9.0	9.0	11.0	10.0	11.0	11	12
vWA	14.0	16.0	14	18.0	14	14.0	14.0	16.0	16	15

Trio analysis

Formula used	Allele Targeted	PI
1/2a	13	6.11864
1/2a	11	1.53617
1/a	**12**	3.18062
1/2a	14	3.72165
1/2a	30	1.76961
1/2a	14	4.68831
1/2a	13	3.50485
1/2a	9	2.98347
1/a	**13**	3.03361
1/2a	3.2	7.84783
1/a	**10**	2.56940
1/2a	11	1.21549
1/2a	24	3.72165
1/2a	9	12.89286
1/a	**11**	2.53333
1/2a	9	2.25625
1/2a	12	2.50694
1/2a	6	2.12353
1/2a	11	1.98352
1/2a	14	5.38806
Combined Paternity Index		11198330927
Probability of Paternity		99.99999999107%

Duo Analysis

Formula used	Allele Targeted	PI
		1.889394706
1/(4a)	13	3.05932
1/(4a)	11	0.76809
1/(2a)	**12**	1.59031
1/(4a)	14	1.86082
1/(4a)	30	0.88480
1/(4a)	14	2.34416
1/(4a)	13	1.75243
1/(4a)	9	1.49174
1/(2a)	**13**	1.51681
1/(4a)	3.2	3.92391
1/(2a)	**10**	1.28470
1/(4a)	11	0.60774
1/(4a)	24	1.86082
1/(4a)	9	6.44643
1/(2a)	**11**	1.26667
1/(4a)	9	1.12813
1/(4a)	12	1.25347
1/(4a)	6	1.06176
1/(4a)	11	0.99176
1/(4a)	14	2.69403
Combined Paternity Index		10680
Probability of Paternity		99.9906%

Alleged Father is the Father, mother of alleged FATHER claims CHILD is FATHER's father

Marker	Father		Mother		Child		Alleged Father		Mother of All. Fath	
CSF1PO	12.0	13.0	13	12.0	**13**	**13.0**	12.0	13.0	13	9
D13S317	11.0	12.0	9.0	10.0	9.0	11.0	11.0	12.0	12	8
D16S539	12.0	12.0	10.0	13.0	10.0	12.0	12.0	12.0	12	9
D18S51	14.0	17.0	11.0	16.0	11.0	14.0	14.0	17.0	17	12
D21S11	29.0	30.0	28.0	30	**30**	**30.0**	29.0	30.0	30	31.2
D3S1358	14.0	17.0	15.0	18.0	15.0	14.0	14.0	17.0	17	17
D5S818	10.0	13.0	11.0	11.0	11.0	13.0	10.0	13.0	13	12
D7S820	9.0	12.0	11.0	8.0	11.0	9.0	9.0	12.0	12	10
D8S1179	13.0	13.0	14.0	15.0	14.0	13.0	13.0	13.0	13	11
F13A01	3.2	7.0	12.0	5.0	12.0	3.2	3.2	7.0	7	6
F13B	10.0	10.0	8.0	10	**10**	**10.0**	10.0	10.0	10	10
FESFPS	11.0	12.0	10.0	12	12	11.0	11.0	12.0	12	8
FGA	22.0	24.0	21.0	24	**24**	**24.0**	22.0	24.0	24	23
LPL	9.0	11.0	12.0	13.0	12.0	9.0	9.0	11.0	11	14
Penta_C	11.0	11.0	13.0	9.0	13.0	11.0	11.0	11.0	11	12
Penta_D	9.0	13.0	11.0	10.0	11.0	9.0	9.0	13.0	13	12
Penta_E	10.0	12.0	7.0	13.0	7.0	12.0	10.0	12.0	12	5
TH01	6.0	9.0	7.0	9.3	7.0	6.0	6.0	9.0	9	8
TPOX	10.0	11.0	9.0	9.0	9.0	11.0	10.0	11.0	11	12
vWA	14.0	16.0	14	18.0	**14**	**14.0**	14.0	16.00	16	15

Trio analysis

Formula used	Allele Targeted	PI
1/a	**mis**	#DIV/0!
1/2a	11	1.53617
1/2a	12	1.59031
1/2a	14	3.72165
1/a	**mis**	#DIV/0!
1/2a	14	4.68831
1/2a	mis	#DIV/0!
1/2a	9	2.98347
1/2a	13	3.03361
1/2a	3.2	7.84783
1/a	**10**	2.56940
1/2a	11	1.21549
1/a	**mis**	#DIV/0!
1/2a	9	12.89286
1/2a	11	2.53333
1/2a	9	2.25625
1/2a	mis	#DIV/0!
1/2a	6	4.19767
1/2a	mis	#DIV/0!
1/a	**14**	10.77612
Combined Paternity Index		#DIV/0!
Probability of Paternity		#DIV/0!

Duo Analysis

Formula used	Allele Targeted	PI
1/(2a)	**13.00000**	6.11864
1/(4a)	11.00000	0.76809
1/(4a)	12.00000	0.79515
1/(4a)	14.00000	1.86082
1/(2a)	**30.00000**	1.76961
1/(4a)	14.00000	2.34416
1/(4a)	13.00000	1.75243
1/(4a)	9.00000	1.49174
1/(4a)	13.00000	0.75840
1/(4a)	3.20000	3.92391
1/(2a)	**10.00000**	1.28470
1/(2a)	11.00000	0.60774
1/(2a)	**24.00000**	3.72165
1/(4a)	9.00000	6.44643
1/(4a)	11.00000	0.63333
1/(4a)	9.00000	1.12813
1/(4a)	12.00000	1.25347
1/(4a)	6.00000	1.06176
1/(4a)	11.00000	0.99176
1/(2a)	**14.00000**	5.38806
Combined Paternity Index		21359
Probability of Paternity		99.9953%

C. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exemption from environmental assessment under 21 C.F.R. § 25.34.

D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30, petitioner will provide data concerning the economic impact of the action requested should such information be requested by the FDA.

E. CERTIFICATION

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.

Randall Henri Steinmeyer

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