

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO

FILED
Superior Court of California
County of San Francisco

OCT 31 2022

CLERK OF THE COURT

BY: *Sam Kozlowski*
Deputy Clerk

LABORATORY CORPORATION OF
AMERICA HOLDINGS and MYRIAD
GENETICS, INC.,

Case No. CPF-22-517872

Plaintiffs/Petitioners,

**ORDER GRANTING MOTION
FOR PRELIMINARY
INJUNCTION**

vs.

CALIFORNIA DEPARTMENT OF
PUBLIC HEALTH, et al.,

Defendants/Respondents.

Plaintiffs' motion for a preliminary injunction in this writ of mandate action is granted.¹

Prenatal cell-free DNA testing for genetic disorders has been used in California for over a decade. (Writ Pet. 5:19-20.) Frequently screened syndromes are Down, Edwards and Patau – trisomies 21, 18 and 13.

¹Plaintiffs/petitioners are Laboratory Corporation of America Holdings and Myriad Genetics, Inc.; defendants/respondents are the California Department of Public Health (CDPH) and its director, Tomas Aragon.

Last month, the Department of Public Health amended a key regulation to read: “Only Department approved birth defects screening laboratories shall offer or provide prenatal screening for fetal autosomal trisomies or prenatal screening for neural tube defects that are included in the Department’s Prenatal Screening [PNS] Program to California residents.” (Kiernan Dec. Ex. D at p. 13: CCR, tit. 17, §6523(e).) The effect, plaintiffs say, is to bar laboratories like them from the California market in favor of prenatal screening providers that have joined defendants’ PNS program. (Memo. 15:14-22.) Plaintiffs filed a petition for writ of mandate and this preliminary injunction motion.

Two “interrelated factors” are weighed “when deciding whether to grant a plaintiff’s motion for preliminary injunction: (1) the likelihood that the plaintiff will prevail on the merits at trial, and (2) the relative interim harm to the parties from the issuance or nonissuance of the injunction.” (*SB Liberty, LLC v. Isla Verde Assn., Inc.* (2013) 217 Cal.App.4th 272, 280.)

Plaintiffs are likely to prevail on the merits at trial – at a minimum – on their second cause of action for “violation of rulemaking requirements.” (Id.; Writ Pet. 21:12-23:2, 3:4-5, 4:19-22, 12:13-15, 13:21-14:19; Memo. 14:22-15:13, 16:21-17:12.) In this gating claim, defendants plead that plaintiffs failed to consult the public and experts before adopting amended regulations and instead opted for

unauthorized “emergency” regulation. (Writ Pet. 21:12-23:2; Health & Saf. Code §§124980(a),² 124975(h).³)

Defendants effectively concede they did not comply with §124980(a) or §124975(h); their opposition does not dispute plaintiffs’ assertions that defendants failed to provide “notice to the public, seek input from potentially interested individuals, hold public hearing, make findings or otherwise conduct any meaningful rulemaking.” (Opp. 13:21-24.)⁴

Instead, defendants point to statutes allowing them to adopt “emergency regulations.” (Opp. 14:5-28; §§124977, 125055.) However, defendants’ opposition posits no emergency; indeed, cfDNA screening has been conducted for over a decade in California and the opposition cites no crisis.

Defendants are left with the argument that *all* their regulations are “emergency.” (Opp. 14:5-28.) This is contrary to §124977(d)(1), which provides that “emergency regulations” are those “necessary for the *immediate* preservation of the public peace, health and safety, or general welfare.” Defendants’ argument also runs headlong into the requirement that statutory language be read in harmony with other statutes in the same code. (*Jurcoane v. Sup. Ct.* (2001) 93 Cal.App.4th

² The statute reads: “The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted *before* any regulations and standards are adopted by the department.”

³ All statutory references herein are to the Health & Safety Code, all emphasis is added and unnecessary capitalization and quote marks are deleted.

⁴ The opposition notes a public hearing this week (*id.* at 14:28-15:3), but it is *after* the regulations’ effective date, not – as per §124980(a) – “*before* any regulations...are adopted.”

886, 893.) Section 124980(a)'s admonition that the "public...should be consulted before any regulations...are adopted by the department" cannot be squared with the notion that all of defendants' regulations are "emergency," so they never need consult anyone before adopting regulations.⁵

Absent a foundation of proper rulemaking, plaintiffs' other claims need not be reached at this time.

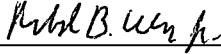
The "relative interim harm to the parties" also weighs in plaintiffs' favor. (*SB Liberty*, 217 Cal.App.4th at 280.) Plaintiffs show that barring them from the California market for cfDNA screening of trisomies 21, 18 and 13 would cause harm in the form of lost revenue, goodwill and innovative momentum. (Memo. 24:1-5.) In contrast, defendants fail to show significant harm from maintaining the pre-September 2022 status quo for the relatively short time it should take to adjudicate this writ.

Disposition: Until this writ proceeding is resolved, defendants are enjoined from enforcing and/or implementing amended California Code of Regulations, title 17, section 6523(e) and from taking any action to prohibit or restrain otherwise licensed laboratories from providing cfDNA prenatal laboratory screening services, and from taking any steps to prohibit or restrain any California patients or

⁵ Also noteworthy is plaintiffs' pleading that, before amending the same regulation in 2020, defendants published notices, held a public hearing, explained the amendments, held a public comment period and published a statement of reasons. (Writ Pet. 14:3-12.)

healthcare providers from obtaining cfDNA screening services from any non-CDPH-contracted, otherwise licensed, laboratories. This does not preclude the PNS Program from offering, providing information about and making cfDNA and other prenatal screening available to prospective participants who may choose to obtain screening through the PNS Program.⁶

Dated: October 29, 2022



Richard B. Ulmer Jr.
Judge of the Superior Court

⁶Plaintiffs' unopposed motions to seal are granted.

CPF-22-517872

LABORATORY CORPORATION OF AMERICA HOLDINGS ET AL VS.
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH ET AL

I, the undersigned, certify that I am an employee of the Superior Court of California, County Of San Francisco and not a party to the above-entitled cause and that on October 31, 2022, I electronically served the foregoing Order Granting Motion for Preliminary Injunction on the following counsel of record by causing a copy thereof to be sent by email to the email addresses indicated below.



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