October 24, 2025

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

CITIZEN PETITION

Request that the Commissioner of Food and Drugs Determine the Unlawful Use of Hair Matrices, Revise Labeling, Issue a Public Advisory to Employers and Law Enforcement, and Coordinate Interagency Action Regarding 510(k) Clearance of Psychemedics Corporation's Cannabinoid Hair Testing Device (K111929)

I. ACTION REQUESTED

Pursuant to 21 C.F.R. § 10.30, Petitioner respectfully requests that the Commissioner of Food and Drugs take immediate regulatory and enforcement action concerning the **unauthorized use of hair-based drug testing methodologies** marketed and performed by Psychemedics Corporation, including but not limited to the Psychemedics Microplate EIA for Cannabinoids in Hair (510(k) K111929) and its predecessor radioimmunoassay of hair (RIAH) assays.

Specifically, Petitioner requests that FDA:

1. **Determine** that use of 510(k) K111929 and predecessor Psychemedics immunoassay methodologies for hair testing lies **outside the device's cleared classification** under 21 C.F.R. § 862.3870.

   The FDA's classification of cannabinoid test systems under 21 C.F.R. § 862.3870 explicitly applies to the measurement of cannabinoids and their metabolites in *human*

body fluids—such as serum, plasma, saliva, and urine—and does not encompass hair as a test matrix. Psychemedics' 510(k) clearance was issued under this classification, and use of this device for hair testing constitutes an off-label use not supported by FDA clearance or classification. A formal determination would provide regulatory clarity and prevent continued misrepresentation of hair testing as "FDA cleared."

2. **Initiate appropriate enforcement action** against Psychemedics for marketing and promotional practices inconsistent with its cleared indications, including consideration of misbranding and adulteration findings under 21 U.S.C. §§ 351–352.

   Psychemedics continues to promote and market its immunoassay methodology as "FDA cleared" for hair testing, despite the fact that 510(k) K111929 was issued under 21 C.F.R. § 862.3870 for cannabinoid testing in *human body fluids* only. Marketing a device for an unapproved use constitutes misbranding under 21 U.S.C. § 352 and, depending on the nature of the representations, may also constitute adulteration under 21 U.S.C. § 351. FDA has clear enforcement authority to address such conduct through warning letters, mandatory labeling revisions, civil penalties, or other appropriate action. A formal enforcement response would prevent further misuse by public employers and law enforcement agencies and safeguard the integrity of the 510(k)-clearance process.

3. **Mandate labeling changes** to include prominent, plain-language disclaimers that the device is **not cleared or validated for hair testing** and **cannot distinguish ingestion from environmental exposure**.

4. **Issue a "Dear Colleague" advisory** or equivalent public communication to employers, law-enforcement agencies, and medical review officers (MROs), clarifying that:
   - The device is **not cleared for use on hair matrices**;
   - 510(k) clearance **does not constitute scientific or legal validation** under Frye or the Uniform Guidelines on Employee Selection Procedures (UGESP); and
   - Hair testing cannot reliably establish ingestion or withstand Frye/UGESP scrutiny in employment contexts.

5. **Coordinate** with the U.S. Department of Justice, the U.S. Equal Employment Opportunity Commission, and other enforcement agencies to address civil-rights and disparate-impact concerns arising from the continued misuse of hair immunoassays.

6. **Expedite review** of the pending HARMS Citizen Petition (filed October 16, 2025)[1] and incorporate the factual record herein, including ongoing disciplinary actions based on this unvalidated testing.

7. **Issue an interim advisory**, in light of the documented September 23–24, 2025 Fogel proceedings and October 17, 2025 termination of Petitioner Frankie F. Palaguachi,

[1] See Exhibit 1 HARM Citizen Petition

clarifying that use of hair testing for employment actions is improper pending final agency resolution.

II. STATEMENT OF INTEREST

Petitioner Frankie F. Palaguachi is a former New York City Police Department officer who was directly and personally subjected to the unlawful and scientifically invalid use of Psychemedics Corporation's hair-based drug testing. During his employment, the Department relied on immunoassay methodologies that were never authorized for use on hair under 21 C.F.R. § 862.3870, which expressly covers **serum, plasma, saliva, and urine, but not hair**.

For nearly three decades, NYPD has relied on Psychemedics' hair testing to make critical employment and disciplinary decisions. From approximately **1996[2] to 2012**, the Department used Psychemedics' **radioimmunoassay of hair (RIAH)** testing. Beginning in 2012, NYPD transitioned to Psychemedics' **enzyme immunoassay (EIA)** methodology under 510(k) K111929. This unauthorized and scientifically unvalidated use of the device has caused direct harm to officers, including Petitioner.

Petitioner Palaguachi was subjected to disciplinary action and ultimately terminated on October 17, 2025, based solely on results from Psychemedics' hair testing, despite the absence of (1) FDA clearance for hair matrices, (2) validation under the Uniform Guidelines on Employee Selection Procedures (UGESP), and (3) general scientific acceptance under Frye v. United States. These actions have caused permanent career harm and collateral employment consequences.

This petition is submitted to protect the civil, employment, and constitutional rights of the Petitioner and similarly situated individuals. Petitioner seeks FDA action to prevent further misuse of a diagnostic device beyond its cleared indications, to ensure proper labeling and advisory communication to employers, and to prompt appropriate interagency coordination with civil-rights enforcement authorities.

III. BACKGROUND

A. Regulatory Classification and Scope of FDA 510(k) Clearance

In 2011, Psychemedics Corporation obtained FDA 510(k) clearance for the Psychemedics Microplate EIA for Cannabinoids in Hair under 510(k) K111929, referencing 21 C.F.R. § 862.3870. That classification—**"Cannabinoid Test System"**—covers in vitro diagnostic devices intended for the **qualitative or semi-quantitative determination of**

[2] Contemporaneous reporting confirms that the New York City Police Department began using Psychemedics Corporation hair testing for drug screening in 1996, under Mayor Rudolph Giuliani. As reported in *NYPD Confidential* on March 11, 1996, the Department 'recently completed its routine end-of-probation drug testing for 2,000 cops hired in 1994,' noting that 'the reason for the increase [in positive tests]' was 'the department's new, more-sensitive hair test.' This contemporaneous account demonstrates that the Department institutionalized the use of Psychemedics' methodology decades before any regulatory framework existed for hair testing — and well outside the scope of FDA's clearance under 21 C.F.R. § 862.3870, which applies only to fluid matrices.

cannabinoids and their metabolites in serum, plasma, saliva, or urine. It **does not authorize use on hair matrices**.

FDA's 510(k) clearance process determines only **"substantial equivalence"** to a predicate device; it does **not validate scientific reliability**, nor does it assess whether a methodology can withstand evidentiary or employment-law scrutiny. As the Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), decision makes clear, "§ 510(k) is focused on equivalence, not safety" and does not constitute an affirmative finding of validity, efficacy, or appropriateness for forensic use.

Despite these clear regulatory limits, Psychemedics and its governmental clients—including the New York City Police Department (NYPD)—have long represented or implied that 510(k) clearance provides federal authorization to use these devices for hair testing in employment contexts. It does not. This practice constitutes a **fundamental misuse of the device**.

B. History of Psychemedics Hair Testing Use in NYPD

The NYPD has relied on Psychemedics hair testing continuously since approximately **1996**, initially through the company's proprietary **radioimmunoassay of hair (RIAH)** and, beginning in **2012**, through its **enzyme immunoassay (EIA)** platform. At no point did the FDA clear these tests for use on hair.

This testing has been used not for voluntary screening but as the basis for serious employment consequences—including **disciplinary action, forced resignation, and termination**. Affected individuals have been denied due process and meaningful avenues to challenge the scientific validity of the results. These consequences have been amplified by the NYPD's reporting of positive test results to other law-enforcement agencies and licensing authorities.

C. Scientific Controversy and Lack of Validation

Unlike urine or blood testing, hair testing for cannabinoids presents well-documented **scientific limitations**:

1. **Environmental contamination** can produce false positives because **THC-COOH is lipophilic** and readily adheres to hair surfaces.
2. Hair testing cannot **distinguish ingestion from passive exposure**.
3. There are **no SAMHSA guidelines**, no **ISO forensic toxicology standards**, and no **SOFT-endorsed protocols** governing cannabinoid hair testing.
4. Psychemedics' **THC cutoff levels are internally generated** and have never been peer reviewed or validated by any independent scientific authority.
5. The **metabolite instability** of THC-COOH further undermines reproducibility and forensic reliability.

These scientific defects are not hypothetical—they have been recognized in administrative and judicial decisions nationwide. Most prominently, federal appellate rulings in

Jones v. City of Boston, 752 F.3d 38 (1st Cir. 2014), and 845 F.3d 28 (1st Cir. 2016), affirmed these findings and held that such testing produced unlawful disparate impact under Title VII and could not withstand scrutiny under Title VII of the Civil Rights Act absent validation and consideration of less discriminatory alternatives. Related administrative findings by the Massachusetts Civil Service Commission in 2013 found the method "a work in progress," unable to prove ingestion. The risks of ignoring UGESP's safeguards are not theoretical—they have already been documented in the Boston Police litigation. In the *Boston Police Drug Testing Appeals* (Massachusetts Civil Service Commission, 2013, pp. 105–114),[3] the Commission rejected Psychemedics' radioimmunoassay of hair (RIAH) for cocaine as proof of ingestion. It found the method plagued by environmental contamination, inconsistent laboratory cutoffs, and a lack of uniform standards. Importantly, the Commission concluded that "a positive hair test, standing alone, cannot establish ingestion," declaring the method "a work in progress" unfit to support discipline without corroboration. That finding applied to cocaine—a metabolite that is chemically more stable in hair than THC. If Psychemedics' immunoassay could not reliably distinguish ingestion from contamination for cocaine, it is even less reliable for marijuana, where THC-COOH is notoriously unstable and highly susceptible to external contamination.

In December 2023, the City of Boston paid **$2.6 million** to resolve nearly two decades of litigation stemming from these tests.

D. UGESP and Employment-Law Implications

Under the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, **employers bear a non-delegable duty** to validate any selection procedure used in employment decisions, including drug testing. This includes maintaining impact data (§1607.4), conducting validation studies (§§1607.5–.6), documenting findings (§1607.15), and discontinuing any test that causes adverse impact without proven job-relatedness (§1607.6(B)).

No such validation exists for Psychemedics hair testing for cannabinoids. The NYPD has **never conducted a UGESP-compliant study**, has produced **no adverse impact analysis**, and continues to rely on the device despite well-documented racial disparities and scientific deficiencies. This creates not only a **scientific and regulatory failure** but also significant **civil-rights exposure** under Title VII.

E. NYPD Case Study: Palaguachi Disciplinary Proceedings (Chronology & Record)

1. **EEOC Charge (April 18, 2025).** Palaguachi filed an EEOC Charge of Discrimination against the City of New York and Psychemedics, challenging reliance on Psychemedics' hair immunoassay in employment actions. *As of this petition, neither respondent has filed a position statement.*[4]

2. **Motion to Strike & Dismiss (August 26, 2025).** Palaguachi moved to (i) strike testimony from Dr. Ryan B. Paulsen (Psychemedics laboratory director) and Sergeant Danny Tse, (ii) preclude the anticipated testimony of Deputy Chief Surgeon/MRO

[3] See Exhibit 2 Boston Police Drug Testing Appeals 022813
[4] See Exhibit 3 EEOC Charge of Discrimination

Dr. Joseph J. Ciuffo, and (iii) exclude Exhibits 1–4 (collection questionnaire; Paulsen CV; "positive" EIA result; MRO documents), and to dismiss the charges. The Motion argues that Psychemedics' **EIA hair methodology** is **inadmissible under Frye** and **unvalidated under UGESP**, and that **510(k) clearance does not establish scientific or employment validation**.[5]

3. **Reply in Further Support (August 30, 2025).** The Reply demonstrates:
   - **No SAMHSA hair standards** or independent professional endorsement;
   - **No UGESP-compliant validation** or disparate-impact analysis by the employer;
   - **Vendor-employee conflict** (Paulsen) and non-independence;
   - Direct relevance of **Jones v. City of Boston** and the **Massachusetts Civil Service Commission** decision rejecting hair immunoassays as proof of ingestion; and
   - Persistent **conflation of 510(k) "equivalence" with scientific/UGESP validation**.[6]
   - Motion Denied.[7]

4. **Fogel Draft Report (September 23, 2025).** The Department circulated a **Fogel** notice attaching a **Draft Report and Recommendation**[8] proposing termination.[9]

5. **Fogel Response / Comments (September 24, 2025).** Counsel submitted **Comments on the Draft** explaining the Draft is **ultra vires**: it substitutes accreditation/licensure/510(k) for **Frye**, **Rule 7.01**, and **UGESP**; ignores **Jones**, the **CSC** ruling, and **Lohr/Riegel/Buckman**; misallocates UGESP's burden to the employee; overlooks collection defects (e.g., body-hair site selection); and treats the MRO as a rubber stamp rather than an independent safeguard. The Response invokes **Fogel**'s requirement that material, record-based legal objections be addressed to avoid an arbitrary or capricious final determination.[10]

6. **HARMS FDA Petition (October 16, 2025).** A related FDA citizen petition was filed challenging employer misuse of Psychemedics' hair immunoassays and seeking labeling and public-advisory action.

7. **Termination (October 17, 2025).** The Police Commissioner **terminated Palaguachi** the day after the HARMS filing—**while** the EEOC Charge remained unanswered by respondents and FDA review was pending—based on Psychemedics' hair EIA results.[11]

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[5] See Exhibit 4 Motion to Strike and Dismiss
[6] See Exhibit 5 Reply in Further Support of Motion to Strike Testimony and Exhibits 1–4, Preclude Testimony, and Dismiss Charges Relating to Psychemedics' Unvalidated EIA Hair Testing
[7] See Exhibit 6 Motion Denied
[8] See Exhibit 7 Trial Transcript Day One – Dr. Ryan B. Paulsen Pages 64 – 153.
[9] See Exhibit 8 Draft Report and Recommendation
[10] See Exhibit 9 Fogel Response
[11] See Exhibit 10 Final Order of Dismissal

IV. LEGAL AND REGULATORY BASIS FOR FDA ACTION

A. FDA Has Clear Authority to Act on Misuse of Cleared Devices

Under the Federal Food, Drug, and Cosmetic Act (FDCA), the U.S. Food and Drug Administration (FDA) have broad authority to regulate the marketing, labeling, and post-market use of medical devices. FDA's 510(k) clearance under 21 U.S.C. § 360(k) authorizes only those uses within the intended use and indications for use contained in the clearance. It does not extend to unapproved matrices such as hair, where clearance was limited to serum, plasma, saliva, or urine.

When a manufacturer or its clients (including government employers) represent or imply that FDA has authorized a use for which no clearance exists, **such representation constitutes misbranding** under 21 U.S.C. § 352(a) and 21 C.F.R. § 807.81. This is particularly true where the unauthorized use carries **high-stakes consequences** for individuals—such as termination of law-enforcement officers—based on test results that lack regulatory or scientific foundation.

FDA has exercised similar authority in other contexts, including enforcement actions, warning letters, labeling clarifications, and public communications to employers and laboratories engaged in misuse of diagnostic devices.

B. 510(k) Clearance Does Not Establish Scientific Validity or Forensic Reliability

The Supreme Court in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), held that the 510(k) process is "focused on equivalence, not safety." It is not a scientific endorsement and does not evaluate reliability in employment or forensic settings. Subsequent cases—Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)—reinforced this point: 510(k) clearance is not evidence of scientific validity.

Despite this, Psychemedics Corporation and its government clients—including the New York City Police Department—have **relied on 510(k) clearance for urine matrices to justify hair testing**, an unauthorized extension. This misuse of regulatory language has created systemic misunderstanding across multiple agencies and employers, effectively transforming a marketing clearance into an instrument of discipline.

C. Employers Relying on Uncleared Use Trigger FDA Oversight

The FDCA applies not only to manufacturers but to any entity that **"causes the introduction or delivery for introduction into interstate commerce"** of a misbranded or adulterated device. By purchasing and using the Psychemedics device for hair testing—despite its lack of clearance for hair matrices—employers are **participating in a use inconsistent with labeling and clearance**.

The legal implications are significant:

- This creates potential **misbranding** liability under 21 U.S.C. §§ 331 and 352.

- It may trigger FDA's **post-market enforcement authority**, including labeling amendments, warning letters, or required public advisories.
- Where the misuse has **systemic employment consequences**, as here, FDA action is appropriate to prevent further harm.

D. Intersection with Civil-Rights and Employment-Law Regimes

While FDA does not directly enforce employment law, its regulatory determinations have **immediate and material consequences** for civil-rights enforcement. Under Title VII and the Uniform Guidelines on Employee Selection Procedures (UGESP), employers bear a **non-delegable duty** to validate any selection procedure they use. If FDA clarifies that Psychemedics' hair testing is **not cleared for hair matrices**, employers cannot plausibly claim reliance on federal authorization to justify their use.

In federal appellate rulings in Jones v. City of Boston, 752 F.3d 38 (1st Cir. 2014), and 845 F.3d 28 (1st Cir. 2016), affirmed these findings and held that such testing produced unlawful disparate impact under Title VII, the First Circuit rejected precisely this kind of defense, finding that Psychemedics' hair immunoassay caused a disparate racial impact and lacked validation. Boston ultimately settled for $2.6 million in 2023 after nearly two decades of litigation. An FDA labeling clarification would **prevent similar harm nationwide** and support coordinated enforcement with the Equal Employment Opportunity Commission (EEOC).

E. FDA Precedent for Regulatory Intervention

FDA has previously acted to correct **misunderstandings about the scope of 510(k) clearances**, including:

- Issuing **Dear Colleague Letters** to clinical laboratories and employers when devices were used beyond cleared indications.
- Requiring **labeling amendments** to clarify limitations of use.
- Taking **enforcement action** against manufacturers and entities for misleading claims about the scope of FDA clearance.

F. FDA Action Here Is Consistent with, Not Preemptive of, Civil-Rights Enforcement

Some employers and vendors have attempted to argue that FDA clearance or oversight of diagnostic devices preempts parallel legal obligations under Title VII of the Civil Rights Act and related state or local statutes. This argument is **legally unsound** and has been squarely rejected by the Supreme Court and multiple federal appellate courts.

In Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), the Court held that 510(k) clearance "does not reflect a determination by the FDA that the device is safe and effective," and thus does not preempt state tort or parallel regulatory claims. The Court emphasized that 510(k) was created to preserve the regulatory status quo, not to erect a shield against other federal or state enforcement regimes. Subsequent decisions—Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)—reaffirmed this

distinction: 510(k) clearance **does not insulate device users or manufacturers from other legal obligations**.

In the employment context, the **civil-rights duty to validate employment testing under Title VII and UGESP is independent** of FDA's limited clearance determinations. An FDA clarification or labeling revision here would therefore **not displace EEOC or private enforcement**. To the contrary, it would provide a **federal regulatory floor** upon which civil-rights enforcement can more effectively stand.

- Employers could no longer claim **good-faith reliance on FDA clearance** to justify an unvalidated, racially disparate practice.
- EEOC investigations and Title VII litigation would have **clear federal guidance** to address the misuse of hair testing.
- Affected employees would have **a documented regulatory record** supporting their statutory claims.

This is precisely the cooperative federalism model envisioned by Congress: FDA ensures scientific integrity and regulatory accuracy, while EEOC and the courts ensure civil-rights compliance. An FDA determination regarding the **uncleared use of Psychemedics' device on hair matrices** would **strengthen**, not preempt, those parallel enforcement mechanisms.

V. NATIONAL, INSTITUTIONAL, AND INTERNATIONAL IMPACT OF THE MISUSE OF PSYCHEMEDICS' HAIR TESTING

The misuse of Psychemedics Corporation enzyme immunoassay hair testing extends far beyond isolated employment disputes. Over nearly three decades, public employers—including the New York City Police Department (NYPD)—have relied on this unvalidated and uncleared testing method to make **irreversible employment decisions**. The consequences are systemic, measurable, and ongoing.

A. Widespread Misuse Based on Misrepresentation

Psychemedics has aggressively marketed its hair testing as a scientifically reliable and FDA-cleared tool for drug screening. In reality, the company's 510(k) clearance applies only to **urine and plasma** matrices—not hair.

This misrepresentation has led numerous public agencies to adopt Psychemedics' testing under the **false assumption** of FDA clearance for hair testing. These agencies include municipal law enforcement departments, transportation employers, and security-sensitive industries across the United States.

B. Employment-Law Consequences and Racial Disparate Impact

For both **sworn officers** and **applicants**, the consequences are profound:

- **Disqualifications, terminations, and forced resignations** based solely on hair test results, with no Frye or UGESP-compliant validation.
- **Collateral consequences** through reporting of "positive" results to law-enforcement databases, affecting licensing, employment, and reputation.
- **Lack of procedural recourse**, especially for applicants, who are afforded no hearing or independent retesting.
- **Chilling effects on recruitment and retention**, particularly in Black and Latino communities disproportionately affected by melanin binding and environmental contamination.
- **Documented racial disparate impact**, as recognized in Jones v. City of Boston (2014, 2016), where Psychemedics' hair testing was found to disproportionately exclude Black officers.

The NYPD has conducted no validation studies, no impact analyses, and no review of less discriminatory alternatives, in violation of the Uniform Guidelines on Employee Selection Procedures (UGESP) and Title VII of the Civil Rights Act.

C. Structural Exclusion of Applicants

Applicants face even **greater vulnerability** than tenured officers:

- They receive no notice of the test's unvalidated status.
- They have no right to a hearing or cross-examination.
- Their results may permanently bar them from law-enforcement careers.
- Their communities bear the cumulative impact of reduced representation in policing.

This structural exclusion compounds existing racial disparities in NYPD recruitment and hiring.

D. Systemic and Institutional Harm Reflected in Petitioner's Case

The misuse of Psychemedics' hair testing methodology does not merely affect individual officers — it distorts institutional structures and workforce composition across law enforcement. Petitioner's termination exemplifies how an unvalidated testing program can have ripple effects far beyond a single case:

- **Erosion of diversity and leadership pipelines.** Discriminatory screening and disciplinary practices disproportionately exclude and remove Black and Latino applicants and officers, narrowing future leadership pools.
- **Loss of institutional trust.** The reliance on scientifically unreliable testing undermines confidence in recruitment and disciplinary systems, particularly among communities of color.
- **Policy and liability exposure.** As demonstrated in the Boston litigation, institutions that rely on Psychemedics' testing face significant legal, reputational, and financial consequences when such practices are challenged.

- **National and international reach.** Because Psychemedics' testing is used not only by the NYPD but also by law enforcement agencies elsewhere in the U.S. and abroad (including Brazil), the institutional impact of misuse extends far beyond New York.

E. National and International Impact

The misuse of Psychemedics' hair testing is **not confined to New York**:

- The Boston Police Department relied on the same methodology from the late 1990s through 2021, ultimately paying $2.6 million to settle claims following nearly two decades of litigation.
- The methodology has been adopted in **transportation and security-sensitive employment sectors** across the country.
- Psychemedics has **exported its testing program to Brazil**, where it has been embedded in commercial driver licensing and law-enforcement screening. Brazilian regulators adopted this testing based on **false assumptions of U.S. regulatory clearance**, further entrenching an unvalidated practice internationally.

This demonstrates the **ripple effect of FDA inaction**: when the agency does not clearly state matrix limitations, vendors exploit the regulatory vacuum, and discriminatory practices spread across jurisdictions and borders.

VI. SCIENTIFIC AND EMPLOYMENT-LAW HARMS

A. Scientific Invalidity and Contamination Risks in Cannabinoid Hair Testing

Psychemedics' cannabinoid hair testing methodology suffers from **inherent scientific defects** that make it unsuitable for employment or disciplinary use:

1. **Environmental contamination** is a primary source of false positives. Cannabinoids, and particularly THC-COOH, are **lipophilic**, binding readily to hair surfaces through passive exposure. Unlike urine or blood testing, hair testing cannot distinguish ingestion from external contact.

2. **No independent standards** exist. Neither Substance Abuse and Mental Health Services Administration (SAMHSA), National Institute on Drug Abuse (NIDA), nor any recognized forensic toxicology body (ISO/IEC, SOFT) has promulgated validated standards for cannabinoid hair testing.

3. **Vendor-created cutoffs.** Psychemedics' internal THC-COOH cutoffs are proprietary and have never been subject to peer review or external validation.

4. **Unreliable detection windows.** Unlike uniform urine testing windows, hair testing varies dramatically depending on hair type, melanin content, and collection site. This

variability is scientifically unpredictable and racially correlated, creating disproportionate impacts.

5. **Scientific consensus rejects reliability.** The Massachusetts Civil Service Commission's 2013 decision found Psychemedics' RIAH methodology "a work in progress" that could not reliably establish ingestion. Subsequent federal appellate rulings in Jones v. City of Boston, 752 F.3d 38 (1st Cir. 2014), and 845 F.3d 28 (1st Cir. 2016), affirmed these findings and held that such testing produced unlawful disparate impact under Title VII.

6. **Recent peer-reviewed research authored in part by Ryan B. Paulsen**—the same laboratory director whom the New York City Police Department presented as its scientific witness in disciplinary proceedings—directly undercuts the Department's reliance on Psychemedics Corporation's EIA hair-testing methodology. In a 2022 study analyzing 4,773 hair samples, Paulsen and co-authors documented wide variability in the relationship between THC and its metabolite THC-COOH, frequent cases of high THC with low or no metabolite, and persistent contamination effects not eliminated by standard washing protocols. They also reported unstable ratios of THCV and CBD to THC, revealing an absence of consistent biochemical signatures of ingestion. These admissions—by the manufacturer's own scientists—demonstrate that EIA hair testing cannot reliably distinguish ingestion from environmental exposure, fails to produce stable interpretive patterns, and therefore does not meet Frye or Rule 7.01 admissibility standards. NYPD nonetheless treats such results as dispositive, compounding scientific unreliability with procedural arbitrariness.[12]

These scientific defects are not isolated concerns—they are structural. They cannot be remedied through mere procedural safeguards or laboratory accreditation, and they persist in both the **RIAH (1996–2012)** and **EIA (2012–present)** methodologies.

B. Employment-Law Consequences and Racial Disparate Impact

The misuse of Psychemedics' hair testing has **far-reaching employment-law consequences** for both **current officers** and **applicants** seeking appointment to the New York City Police Department. Under Title VII of the Civil Rights Act and the Uniform Guidelines on Employee Selection Procedures (UGESP), the Department has clear, non-delegable obligations to:

- Conduct **adverse impact analyses** (§1607.4);

[12] See Exhibit 11 Virginia A. Hill, Michael I. Schaffer, Dr. Ryan B. Paulsen, and G. Neil Stowe of Psychemedics Corporation published a 2022 peer-reviewed article in the *Journal of Analytical Toxicology* (Vol. 46, pp. 487–493) in which they explicitly acknowledged that "not all THC from external contamination may be removed" and that THC to THC-COOH concentration ratios "vary widely." Dr. Paulsen—the same laboratory director who testified in the Palaguachi matter—made these scientific admissions as part of this publication. This acknowledgment by Psychemedics' own personnel directly undermines the reliability of its hair testing methodology as a determinative indicator of ingestion, exposes the instability of its testing protocols, and contradicts the NYPD's reliance on Dr. Paulsen's testimony to assert scientific validity.

- Perform **validation studies** to establish job relatedness (§§1607.5–.6);
- Maintain **validation records** and discontinue any test with adverse impact absent validation (§1607.6(B)).

The Department has done none of these things. For nearly **three decades**, it has relied on Psychemedics' hair testing **without validation**, without adverse impact studies, and without documented analysis of less discriminatory alternatives. This systemic failure has produced **cascading civil-rights consequences**, particularly for Black and Latino candidates and officers.

Consequences include:

- **Disqualifications, terminations, and forced resignations** based solely on hair test results. For applicants, a "positive" result can **permanently bar entry** into law enforcement and related public-safety employment, often with no independent scientific review.
- **Reporting of "positives"** to external law-enforcement databases and agencies, creating **collateral consequences** for professional licensing, security clearances, and future employment opportunities.
- **Lack of procedural recourse**. As shown in the Palaguachi proceedings, the Medical Review Officer (MRO) process functions as a **rubber stamp** rather than a substantive safeguard. Applicants face even fewer protections, as they are not entitled to the same due-process rights as tenured officers.
- **Chilling effects on recruitment and retention**, especially among communities of color. Applicants from Black and Latino communities—who are disproportionately affected by environmental contamination and melanin bias in hair testing—face heightened entry barriers, reinforcing systemic exclusion.
- **Racially disparate impact**. Psychemedics' methodology has already been found to produce disparate racial impact in Jones v. City of Boston, 752 F.3d 38 (1st Cir. 2014), and 845 F.3d 28 (1st Cir. 2016). Boston's $2.6 million settlement confirms that **the liability exposure is real** and falls squarely on the employer.

By failing to meet UGESP obligations and by relying on an **uncleared testing matrix**, NYPD has **institutionalized a racially disparate and scientifically unreliable screening practice** that affects both its workforce composition and its disciplinary system. The harm is not theoretical—it is embedded in every stage of the Department's employment pipeline, from recruitment and background processing to final disciplinary action.

C. Individual Harm: The Palaguachi Proceedings as a Case Example

The ongoing case of Petitioner Palaguachi illustrates the concrete harms caused by misuse of Psychemedics' device:

- **April 18, 2025** — Palaguachi filed an EEOC Charge of Discrimination against the City and Psychemedics challenging the use of hair testing for cannabinoids.
- **August 26, 2025** — Filed a Motion to Strike and Dismiss on Frye, Rule 7.01, UGESP, and FDA misuse grounds.

- **August 30, 2025** — Filed Reply amplifying Boston precedent and contamination risks.
- **September 24, 2025** — Submitted Fogel Response identifying legal and evidentiary errors in the Draft Report and Recommendation, including reliance on vendor testimony, lack of validation, and misapplication of FDA clearance.
- **October 16, 2025** — The HARM Citizen Petition was filed with FDA.
- **October 17, 2025** — NYPD terminated Palaguachi despite the pending EEOC Charge and active FDA petition review.

This sequence demonstrates **the immediacy of the harm**: an officer's career was ended based on a scientifically unreliable and legally unauthorized test **after** the agency was on notice of both the scientific defects and the regulatory challenge pending before FDA.

D. Individual and Systemic Harm: Impact on Employment, Career Trajectory, and Workforce Equity

Petitioner Palaguachi's experience exemplifies how the NYPD's misuse of Psychemedics' hair testing methodology inflicts both **personal harm** and **broader systemic consequences** within law enforcement employment practices. While this petition is filed in his individual capacity, the harms he suffered are not isolated—they reflect patterns that affect applicants, officers, and the composition of the workforce.

1. Direct Harm to Petitioner

- Petitioner was subjected to termination based solely on Psychemedics' scientifically unreliable cannabinoid hair test.
- His termination occurred despite the absence of (1) FDA clearance for hair matrices, (2) validation under UGESP, and (3) general scientific acceptance under Frye v. United States.
- He was denied meaningful due process, including the opportunity to challenge the testing methodology, to cross-examine vendor witnesses, or to seek independent scientific review.
- The termination created permanent collateral consequences, including reputational harm, damage to career prospects in public safety, and reporting of "positive" test results to external entities.

2. Harm to Applicants and Prospective Officers

The same unvalidated testing process affects individuals seeking appointment to the NYPD.

- Applicants face disqualification based solely on hair test results, without procedural safeguards or avenues for independent retesting.
- This system disproportionately affects Black and Latino applicants, who are more likely to test "positive" due to environmental contamination and melanin binding.

- The discriminatory impact mirrors the findings in Jones v. City of Boston, where Psychemedics' methodology was found to produce a disparate impact over nearly two decades.

3. Structural Impact on Workforce Composition

Petitioner's experience underscores how this testing distorts the workforce pipeline:

- Biased screening tools reduce minority recruitment at the entry level.
- Disciplinary removals based on unvalidated testing disproportionately impact officers of color.
- Together, these effects perpetuate systemic underrepresentation in law enforcement and undermine institutional trust.

4. Broader Civil-Rights Implications

Although Petitioner files individually, his case is emblematic of broader systemic violations:

- The Department's failure to comply with UGESP is not a one-off occurrence but a long-standing pattern.
- This pattern impacts hiring, retention, and advancement opportunities for Black and Latino officers and applicants.
- It reinforces institutional inequities and exposes the Department to substantial civil-rights liability.

VII. PROCEDURAL IRREGULARITIES, DUE PROCESS VIOLATIONS, AND THE FAILURE OF SAFEGUARDS

The consequences of relying on an unvalidated and uncleared testing methodology are not limited to technical regulatory errors—they result in **concrete due process violations** that undermine the integrity of employment actions taken against both applicants and officers. The disciplinary proceedings involving Petitioner Palaguachi provide a stark illustration of how NYPD's misuse of Psychemedics' hair testing **bypasses procedural safeguards, disregards evidentiary standards, and produces arbitrary and discriminatory outcomes**.

A. Lack of Independent Scientific Review and Procedural Fairness

In the Palaguachi matter, the NYPD based its entire disciplinary case on a single "positive" Psychemedics enzyme immunoassay (EIA) hair test result. No independent laboratory review was performed. The Department's only scientific witness was **Dr. Ryan B. Paulsen**,[13]

[13] Dr. Paulsen's testimony underscores not only the unreliability of Psychemedics' methodology but also his own lack of credibility. When confronted with two independent negative Psychemedics results and an additional negative result from Omega Laboratories, he attempted to explain the discrepancies as a matter of hair growth rates (3.9 cm versus 3.0 cm). This explanation collapses under scrutiny. The negative samples were collected within weeks of the

Psychemedics' own laboratory director — the same vendor whose test was under challenge. This violates the core evidentiary principles articulated in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), as adopted in People v. Wesley, 83 N.Y.2d 417 (1994): novel scientific evidence must reflect general acceptance in the independent scientific community, not vendor assurances.

The Department made **no effort to present independent toxicological testimony**, and **no Frye hearing was conducted** despite explicit objections. Instead, it treated Psychemedics' marketing claims as legally sufficient proof of validity.

B. The MRO Process Functioned as a Rubber Stamp

The Medical Review Officer (MRO) process, intended to function as an independent safeguard, failed entirely. The MRO:

- Did not reconcile conflicting results (e.g., two independent negative tests).
- Did not assess environmental contamination.
- Did not evaluate the scientific validity of Psychemedics' cutoff thresholds.
- Could not identify any right of the officer to contest or independently retest.

The result was **administrative ratification without substantive review**. This mirrors broader patterns in NYPD's use of Psychemedics' testing for both applicants and officers, where the MRO process functions **not as a check** but as a **conduit for vendor determinations**.

C. Violation of Rule 7.01 and Evidentiary Standards

Under Rule 7.01 of the NYPD Rules of Practice, the Department bears the burden of establishing:

1. That the underlying scientific theory is generally accepted;
2. That the procedure is generally accepted as reliable; and

NYPD's alleged positive, making it scientifically implausible that mere differences in growth rate could account for the absence of detected drug metabolites.

Compounding this inconsistency, Psychemedics' own protocol expressly prohibits forwarding negative samples for gas chromatography/mass spectrometry (GC/MS) confirmation. Yet Dr. Paulsen maintained that only GC/MS confirmation could resolve the conflict—an internally contradictory claim, since Psychemedics' procedures foreclose that very possibility. He ultimately conceded that he could not "know more without further testing," but that such testing was neither performed nor possible once the samples were classified as negative. This circular reasoning demonstrates both methodological unreliability and testimonial inconsistency.

Equally troubling, Dr. Paulsen dismissed Omega Laboratories' independent negative result with little more than conjecture. He offered no peer-reviewed evidence or recognized validation studies to undermine Omega's methodology, but simply inferred that Omega's negative was flawed. Such speculative disparagement of an independent laboratory's results is not science—it is bias in favor of Psychemedics' proprietary and unvalidated methods. As New York courts have held, ipse dixit testimony is insufficient under Frye. See *Wesley*, 83 N.Y.2d at 422 (general acceptance must be established within the relevant scientific community, not by the assurances of a single witness).

These contradictions expose the arbitrary and self-serving nature of Psychemedics' process.

3. That the test in the specific case was conducted in a way likely to yield accurate results.

The Department failed on all three counts. Dr. Paulsen admitted that **no federal agency or professional body** (including SAMHSA, NIDA, ISO, or SOFT) has validated marijuana hair testing. Sergeant Tse admitted to procedural irregularities in sample collection — including allowing the subject to select the body-hair site, deviating from Psychemedics' own protocols. And the Department produced **no documentation** of compliance with any validation or impact-analysis requirement.

D. Fogel Response: Ignoring Material Legal Objections

In formal Fogel comments submitted on September 24, 2025, counsel for Palaguachi identified these fundamental defects, citing controlling authority:

- People v. Wesley and Parker v. Mobil Oil Corp. (Frye)
- Griggs v. Duke Power Co. and Albemarle Paper Co. v. Moody (UGESP compliance)
- Medtronic, Inc. v. Lohr, Riegel v. Medtronic, Inc., and Buckman Co. v. Plaintiffs' Legal Committee (FDA clearance ≠ validation)
- Jones v. City of Boston (racial disparate impact)

Despite these objections, the Department's Draft Report ignored the precedent entirely—**labeling counsel's arguments as "uncorroborated"** rather than addressing them on the merits. This refusal to grapple with controlling law renders the determination arbitrary and capricious under Fogel v. Board of Education, 48 A.D.2d 925 (2d Dep't 1975), which requires a reasoned response to material objections raised in Fogel comments.

E. Termination Despite Pending Federal Matters

On **October 17, 2025**, the Police Commissioner **terminated Palaguachi** notwithstanding two critical pending federal matters:

1. The U.S. Equal Employment Opportunity Commission Charge of Discrimination filed April 18, 2025, against the City of New York and Psychemedics, to which neither respondent has filed a Position Statement; and
2. The Food and Drug Administration Citizen Petition filed October 16, 2025, by HARMS challenging the legality of Psychemedics' use of EIA for hair testing.

This termination despite unresolved regulatory and civil-rights proceedings demonstrates the Department's **institutional entrenchment** of an unlawful testing regime, and its **disregard for procedural fairness**.

F. Broader Due Process Failures Affecting Applicants

These failures are not limited to disciplinary cases involving sworn officers. Applicants subjected to Psychemedics hair testing during pre-employment screening are afforded **no procedural protections at all**:

- No right to challenge or cross-examine vendor witnesses.
- No independent scientific review.
- No opportunity for retesting.
- No meaningful notice of the test's unvalidated status.

This leaves applicants uniquely vulnerable to exclusion based on unvalidated science—a problem with **systemic disparate-impact consequences** for Black and Latino communities.

VIII. REQUESTED FDA ACTIONS

Pursuant to **21 C.F.R. § 10.30**, Palaguachi respectfully petitions the Commissioner of Food and Drugs to take the following actions regarding the Psychemedics Corporation Cannabinoid Hair Testing Device (K111929) and related immunoassay technologies:

1. Issue a Formal FDA Determination Clarifying Matrix Limitations

Clarify that the 510(k) clearance for Psychemedics' Cannabinoid Test System does **not** apply to hair matrices. This determination should:

- Be published in the **Federal Register**;
- Be posted on FDA's website; and
- Clearly state that use of this device on hair is an **uncleared and unauthorized use** under the Federal Food, Drug, and Cosmetic Act (FDCA).

Such a determination will correct pervasive regulatory misrepresentations in the employment, law enforcement, and international drug-testing markets.

2. Require Revised Labeling and Marketing Materials

Direct Psychemedics to amend its labeling and marketing materials to:

- Explicitly state that 510(k) clearance does not cover hair testing;
- Remove or correct any implication of FDA endorsement for hair-based drug testing; and
- Provide clear warnings regarding **matrix limitations** and lack of SAMHSA-recognized hair testing standards.

This is necessary to prevent continued misbranding and misuse by employers and public agencies.

3. Issue a Public Communication to Employers and Law Enforcement Agencies

Publish a **Dear Colleague Letter** or equivalent public communication to:

- Federal, state, and local employers (including law enforcement agencies);
- Federal contractors and regulated industries (e.g., transportation); and
- Relevant foreign regulators (e.g., Brazil), through interagency and international channels.

This communication should explicitly state that **FDA has not cleared Psychemedics' device for hair testing** and that reliance on such testing for employment decisions occurs **outside the scope of federal clearance**.

4. Refer to Appropriate Enforcement Divisions

Refer Psychemedics to FDA's **Office of Regulatory Affairs** for investigation of potential misbranding and unauthorized promotion, including but not limited to:

- Marketing materials that falsely imply FDA clearance for hair matrices;
- Promotional statements made to employers, municipalities, and foreign regulators; and
- Failure to disclose the matrix limitation in materials relied on by public agencies.

5. Coordinate with Civil-Rights Enforcement Agencies

In light of the documented disparate racial impact and due-process harms resulting from this misuse, FDA should **formally coordinate** with:

- U.S. Equal Employment Opportunity Commission (EEOC);
- U.S. Department of Justice Civil Rights Division;
- U.S. Department of Transportation; and
- Other relevant agencies.

This coordination should ensure that FDA action supports and reinforces civil-rights enforcement under Title VII and the Uniform Guidelines on Employee Selection Procedures (UGESP).

6. Consider Rulemaking or Guidance

Consider initiating a **rulemaking or guidance process** to:

- Address the misuse of 510(k) clearances for **uncleared matrices**;
- Establish clearer labeling requirements for immunoassay-based drug testing; and
- Prevent future regulatory gaps that enable discriminatory or scientifically unsound employment practices.

IX. CONCLUSION AND CERTIFICATION

For nearly three decades, the New York City Police Department and other law enforcement agencies have relied on Psychemedics' hair testing under the mistaken belief that

the U.S. Food and Drug Administration authorized this use. In reality, FDA clearance has never covered hair matrices. This regulatory gap has allowed unvalidated science to function as a determinative employment tool, producing documented racially disparate impacts, due-process violations, and international misrepresentation.

The FDA has the authority—and responsibility—to close this gap. By issuing a clear public determination, revising labeling, notifying employers, and coordinating with civil-rights enforcement agencies, the FDA can correct the public record, protect workers and applicants, and restore scientific and regulatory integrity.

This Petition is brought by **former Police Officer Frankie F. Palaguachi**, an individual directly and personally harmed by the NYPD's decades-long reliance on Psychemedics' unauthorized hair testing regime. The harms at issue are not speculative. They are documented in Petitioner's disciplinary proceedings, his pending EEOC charge, federal litigation arising from the Boston Police Department's use of the same methodology, and documented international misuse, including in Brazil.

The FDA's prompt action is necessary to ensure that unvalidated and unauthorized testing does not continue to dictate employment outcomes in law enforcement or other safety-sensitive fields.

X. CERTIFICATION

Under 21 C.F.R. § 10.30(b):

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.

Dated: October 24, 2025

By: /s/Frankie F. Palaguachi
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