THE SANDERS FIRM, PC
30 Wall Street, 8th Floor
New York, NY 10005
212-652-2782
212-652-2783

November 1, 2025

Commissioner Louis A. Molina
New York City Department of Citywide Administrative Services
1 Centre Street, 17th Floor North
New York, NY 10007

FORMAL INVESTIGATORY REFERRAL - MISREPRESENTATION AND UNLAWFUL USE OF ENZYME-IMMUNOASSAY HAIR TESTING IN MUNICIPAL EMPLOYMENT

I. INTRODUCTION AND PURPOSE

This Formal Investigatory Referral is submitted jointly to the New York City Department of Citywide Administrative Services (DCAS), the New York City Department of Health and Mental Hygiene (DOHMH), the New York State Department of Health (DOH), the New York State Office of the Attorney General (Civil Rights Bureau), the New York State Division of Human Rights (DHR), and the New York City Commission on Human Rights (CCHR).

It seeks coordinated investigation and enforcement concerning the misrepresentation, unlawful use, and municipal adoption of radioimmunoassay (RIAH) and enzyme-immunoassay (EIA) hair-testing methodologies manufactured and marketed by Psychemedics Corporation, a Texas-based laboratory services company.

Psychemedics Corporation has repeatedly and falsely represented that its RIAH and EIA devices were *"FDA-cleared for hair testing."* In truth, no such clearance exists under 21 C.F.R. § 862.3870, which governs immunoassay diagnostic devices and limits approved specimen types to serum, plasma, saliva, and urine. Hair has never been authorized as a specimen type for any Psychemedics device under the Federal Food, Drug, and Cosmetic Act (FDCA) or its implementing regulations. Despite this, Psychemedics marketed both methods as validated forensic and employment-screening tools, and the New York City Police Department (NYPD) incorporated them into its hiring, fitness-for-duty, and disciplinary processes.

That reliance culminated in the unlawful termination of former Police Officer Frankie F. Palaguachi, a tenured officer with an unblemished record, following an alleged *"positive"* EIA hair-test result that was scientifically unreliable, forensically inadmissible, and legally unauthorized under federal, state, and municipal law.

A. Standing of Complainant

Palaguachi, through undersigned counsel, respectfully submits this referral as an aggrieved tenured civil servant who was unlawfully terminated on the basis of scientifically

invalid and legally unauthorized evidence. His case exemplifies the intersection of regulatory inaction, vendor misrepresentation, and administrative misuse that has enabled the continued reliance on radioimmunoassay (RIAH) and enzyme immunoassay (EIA) hair-testing methods across municipal employment systems.

The attached exhibits establish that neither RIAH nor EIA testing has ever been validated for forensic or employment screening purposes under the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, nor cleared by the Food and Drug Administration for use on hair matrices under 21 C.F.R. § 862.3870. The continued application of these unapproved and unvalidated methodologies constitutes a pattern of systemic misconduct warranting comprehensive, coordinated investigation by the Department of Citywide Administrative Services, the Department of Health and Mental Hygiene, the New York State Department of Health, the New York State Office of the Attorney General, the New York State Division of Human Rights, and the New York City Commission on Human Rights.

B. Jurisdictional Authority of Receiving Agencies

1. **New York City Department of Citywide Administrative Services (DCAS)**

   DCAS possesses statutory responsibility under the New York City Charter §§ 811–814 to oversee municipal personnel management, establish civil-service standards, and ensure compliance with equal-employment and testing procedures for City agencies. DCAS therefore bears direct oversight responsibility for any testing or qualification mechanism used in hiring, retention, or promotion within the NYPD and other municipal entities.

2. **New York City Department of Health and Mental Hygiene (DOHMH)**

   DOHMH is charged under New York City Health Code §§ 3.01 et seq. with protecting public health and regulating biological testing practices conducted within City limits. Its Bureau of Environmental Sciences and Engineering and its Public Health Laboratory share jurisdiction over laboratory standards applicable to municipal contracts and health-related testing. DOHMH's authority extends to ensuring that laboratories performing analyses for City agencies operate under valid certification and approved methodologies.

3. **New York State Department of Health – Clinical Laboratory Evaluation Program (CLEP)**

   Under Public Health Law §§ 570–580 and 10 N.Y.C.R.R. Part 58, the State Department of Health, through CLEP, regulates and licenses all clinical laboratories performing diagnostic or forensic testing on specimens originating in New York State. CLEP approval is mandatory before any laboratory may use a novel or modified testing procedure in employment, forensic, or clinical contexts. There is no record that Psychemedics' EIA method for hair testing ever received

CLEP validation or permit authorization. Consequently, any use of such testing on NYPD personnel or applicants occurred outside lawful regulatory supervision.

4. **New York State Division of Human Rights (DHR)**

Pursuant to Executive Law § 295, the New York State Division of Human Rights (DHR) investigates and prosecutes unlawful discrimination in employment, housing, and public accommodations. Its jurisdiction under Executive Law § 296 extends to facially neutral selection procedures that lack validation or job-relatedness under the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, and that adversely affect members of protected classes.

For nearly three decades, the New York City Police Department (NYPD) has relied on Psychemedics Corporation's hair-based drug testing to make critical employment and disciplinary decisions. From approximately 1996 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. Both techniques were used without FDA authorization for hair matrices and without validation under any recognized scientific or legal standard.

Contemporaneous reporting confirms that NYPD adopted Psychemedics' testing during the administration of 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 Psychemedics' unapproved 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 such as serum, plasma, saliva, and urine.

Because RIAH and EIA hair-testing methods have never been validated under UGESP § 1607.14 nor cleared by the FDA for use on hair, their continued application in employment screening constitutes an arbitrary, non–job-related selection procedure squarely within DHR's enforcement authority. These methods fail every recognized standard of scientific admissibility—Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), as adopted by the New York Court of Appeals in People v. Wesley, 83 N.Y.2d 417 (1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993); and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness—rendering their evidentiary and employment application legally indefensible.

The Department's violations extend beyond evidentiary inadmissibility to systemic noncompliance with UGESP. Adopted in 1978 and reaffirmed repeatedly by the Equal Employment Opportunity Commission, the Guidelines

are binding federal law, not advisory guidance. They codify the principle that employers bear a non-delegable duty to validate any selection procedure that may affect employment outcomes. As held in Griggs v. Duke Power Co., 401 U.S. 424 (1971), selection devices must be shown to be job-related and consistent with business necessity, with the burden of proof resting squarely on the employer. The Supreme Court reaffirmed this principle in Albemarle Paper Co. v. Moody, 422 U.S. 405 (1975), emphasizing that an employer cannot shift responsibility for validation to a vendor or to the affected employee—the duty is absolute and nontransferable.

UGESP operationalizes this mandate through concrete procedural safeguards: employers must maintain records on racial, ethnic, and gender impact (§ 1607.4); conduct validation studies establishing a demonstrable relationship between test results and job performance (§§ 1607.5, 1607.6, 1607.14); and retain documentation of such studies (§ 1607.15). Critically, UGESP prohibits presuming a test valid without empirical evidence (§ 1607.9) and requires discontinuance of any procedure that produces adverse impact absent validation (§ 1607.6(B)).

The record demonstrates that NYPD made no effort to satisfy these obligations. Testimony by Dr. Ryan B. Paulsen confirmed that Psychemedics has never conducted validation studies consistent with UGESP standards and that no federal or professional body has validated marijuana hair testing for forensic or employment purposes. The Department's own witness, Sergeant Tse, conceded he was entirely unfamiliar with UGESP. The Department produced no validation data, no job-relatedness analysis, and no evaluation of less discriminatory alternatives.

Even more concerning, the Department's internal reasoning attempts to excuse noncompliance by citing the absence of racial data in the individual case. That position is legally untenable. UGESP imposes a structural obligation, not a case-by-case one: every employer using a selection device must ensure its validity and fairness before implementation, regardless of the race or background of a particular applicant or officer. By misallocating this burden and presuming validity from past use, the Department inverted the fundamental rule articulated in Griggs and Albemarle.

Accordingly, this referral requests that the New York State Division of Human Rights initiate a formal investigation into whether the New York City Police Department's reliance on unvalidated RIAH and EIA hair testing constitutes an unlawful employment practice under Executive Law § 296(1)(a) and UGESP, and whether the Department's decades-long use of these unapproved tests represents a systemic violation of state civil-rights law and due-process guarantees. The Division should further coordinate with the New York City Commission on Human Rights and the United States Equal Employment Opportunity Commission to ensure comprehensive enforcement across overlapping

jurisdictional lines and recommend the immediate discontinuance of any hair-testing methodology lacking FDA clearance or UGESP validation.

5. **New York City Commission on Human Rights (CCHR)**

Pursuant to N.Y.C. Administrative Code § 8-101 et seq., the New York City Commission on Human Rights (CCHR) enforces the New York City Human Rights Law (NYCHRL)—the broadest anti-discrimination statute in the nation. Under § 8-107(17), the Commission possesses independent authority to investigate and remedy disparate-impact and pattern-or-practice discrimination, particularly where a public employer utilizes unvalidated or scientifically unreliable selection devices that produce arbitrary or exclusionary outcomes.

For nearly three decades, the New York City Police Department (NYPD) has relied on Psychemedics Corporation's hair-based drug-testing methodologies to make employment and disciplinary determinations. From approximately 1996 to 2012, the Department used Psychemedics' radioimmunoassay of hair (RIAH) testing. Beginning in 2012, the Department transitioned to the company's enzyme immunoassay (EIA) methodology marketed under 510(k) K111929. Both techniques were implemented without FDA authorization for hair matrices and without validation under any accepted professional or legal standard.

Contemporaneous reporting confirms that NYPD adopted Psychemedics' methodology during the administration of 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 shows that the NYPD institutionalized Psychemedics' unapproved testing decades before any regulatory framework existed for hair analysis, and well beyond the scope of FDA clearance under 21 C.F.R. § 862.3870, which authorizes immunoassays only for fluid matrices such as serum, plasma, saliva, and urine.

Because RIAH and EIA hair-testing methods have never been validated under UGESP § 1607.14 nor cleared for hair by the FDA, their use as an employment-screening device constitutes a non-job-related, arbitrary selection procedure within the Commission's jurisdiction under the NYCHRL. These methods fail every recognized standard of scientific admissibility—Frye, as adopted by the New York Court of Appeals in People v. Wesley; Daubert; and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness—rendering their evidentiary and employment application legally indefensible.

The Department's noncompliance with the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, compounds these violations. Adopted in 1978 and reaffirmed by the Equal Employment Opportunity Commission, UGESP carries the force of law, requiring that any employment test

be validated, job-related, and consistent with business necessity. This principle—established in Griggs, and reaffirmed in Albemarle—imposes a non-delegable duty on employers to validate every selection procedure they use, even when developed by outside vendors.

UGESP operationalizes this duty by requiring that employers maintain records of racial, ethnic, and gender impact (§ 1607.4); conduct and document validation studies (§§ 1607.5, 1607.6, 1607.14); and retain such documentation for review (§ 1607.15). Critically, UGESP forbids presuming validity without proof (§ 1607.9) and mandates discontinuance of any test that produces adverse impact without supporting validation (§ 1607.6(B)).

The record shows that the NYPD has never complied with these obligations. Testimony from Dr. Ryan B. Paulsen confirmed that Psychemedics conducted no UGESP-compliant validation studies and that no federal or professional body has recognized marijuana hair testing as valid for forensic or employment purposes. The Department's own witness, Sergeant Tse, admitted complete unfamiliarity with UGESP. The NYPD produced no validation evidence, no job-relatedness analysis, and no evaluation of less-discriminatory alternatives—violations that persist across decades of departmental practice.

More troubling, the Department's reasoning attempts to excuse noncompliance by citing the absence of racial data in individual cases. That rationale is legally and scientifically untenable. UGESP imposes a structural duty—not an individualized one—to ensure that all selection devices are validated *before* implementation. The NYPD's reliance on historical use and vendor assurances in lieu of validation inverts the burden of proof established in Griggs and Albemarle and institutionalizes scientific arbitrariness as policy.

Accordingly, this referral requests that the New York City Commission on Human Rights, acting under § 8-107(17) and § 8-109(a) of the NYCHRL, initiate a formal Commission-initiated investigation into whether the NYPD's continued reliance on unvalidated RIAH and EIA hair-testing methods constitutes a pattern or practice of discrimination and an unlawful employment practice. The Commission should further coordinate with the New York State Division of Human Rights and the United States Equal Employment Opportunity Commission to ensure comprehensive enforcement across overlapping jurisdictional lines and recommend the immediate discontinuance of any hair-testing methodology lacking FDA clearance or UGESP validation.

6. **New York State Office of the Attorney General – Civil Rights Bureau**

Pursuant to New York Civil Rights Law § 40-c(1), all persons within the State of New York are entitled to the equal protection of the laws and to the enjoyment of employment without discrimination based on race, color, national origin, sex, or disability. Under § 40-d, the Attorney General of the State of New York is

expressly empowered to investigate and prosecute violations of § 40-c, to seek injunctive relief, and to recover civil penalties on behalf of the People of the State. The Attorney General's Civil Rights Bureau thus possesses concurrent and independent jurisdiction to investigate systemic discriminatory practices by public employers and to address related misrepresentations that result in the misuse of public resources.

For nearly three decades, the New York City Police Department (NYPD) has relied on Psychemedics Corporation's hair-based drug-testing methodologies in employment and disciplinary decisions. From approximately 1996 to 2012, the Department utilized radioimmunoassay of hair (RIAH) testing; beginning in 2012, it adopted Psychemedics' enzyme immunoassay (EIA) method, marketed under 510(k) K111929. Both techniques were employed without Food and Drug Administration (FDA) authorization for hair matrices and without validation under any recognized scientific or legal standard.

As reported contemporaneously 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 establishes that NYPD institutionalized Psychemedics' unapproved technology decades before any regulatory framework existed for hair testing, and well outside the scope of FDA clearance under 21 C.F.R. § 862.3870, which limits immunoassay use to serum, plasma, saliva, and urine.

Because RIAH and EIA hair-testing methods have never been validated under UGESP § 1607.14 nor cleared by the FDA for hair, their use as a municipal employment-screening tool constitutes an arbitrary and non-job-related selection procedure that directly contravenes the State's public-policy guarantee of equal protection and fair employment. These methods fail every recognized standard of scientific admissibility—Frye, as adopted by the New York Court of Appeals in People v. Wesley; Daubert; and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness—rendering their continued use both scientifically invalid and legally indefensible.

The Attorney General's Civil Rights Bureau is also uniquely positioned to investigate the fraudulent and deceptive aspects of Psychemedics' conduct and the City's reliance upon it. Psychemedics publicly represented—most notably in its 2019 BioSpace statement—that its hair-testing technology was "FDA-cleared" and "forensically proven." These claims were materially false. No immunoassay device has ever been cleared or approved by the FDA for hair analysis. By making such misrepresentations in commercial and governmental contracts, Psychemedics induced the City of New York to expend public funds on an uncleared and scientifically unreliable testing methodology, in violation of Penal Law § 175.35 (Offering a False Instrument for Filing) and Executive Law § 63(12), which prohibit persistent fraud and illegality in the conduct of business.

The Department's violations further encompass systemic noncompliance with the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607. Adopted in 1978 and repeatedly reaffirmed by the Equal Employment Opportunity Commission, these Guidelines have the force of law, not advisory status. They codify the principle that every employer bears a non-delegable duty to validate any selection procedure that affects employment outcomes. As the Supreme Court held in Griggs, and reaffirmed in Albemarle, selection devices must be demonstrably job-related and consistent with business necessity, and employers cannot shift responsibility for validation to vendors or employees.

UGESP operationalizes that mandate by requiring employers to: maintain impact records (§ 1607.4); conduct and document validation studies (§§ 1607.5, 1607.6, 1607.14); and retain supporting data (§ 1607.15). Critically, UGESP prohibits presuming a test's validity without empirical proof (§ 1607.9) and mandates discontinuance of any test that yields adverse impact absent validation (§ 1607.6(B)). The NYPD has met none of these obligations. Testimony from Dr. Ryan B. Paulsen confirmed that Psychemedics never performed UGESP-compliant validation studies, and the Department's own witness, Sergeant Tse, conceded unfamiliarity with UGESP entirely. The Department produced no validation data, no job-relatedness analysis, and no assessment of less discriminatory alternatives—in clear violation of federal, state, and local law.

Accordingly, this referral requests that the Office of the Attorney General, Civil Rights Bureau, initiate a formal statewide investigation into:

1. Whether the New York City Police Department's use of unvalidated RIAH and EIA hair-testing methods constitutes a pattern or practice of discrimination in violation of Civil Rights Law §§ 40-c and 40-d;

2. Whether Psychemedics Corporation engaged in fraudulent and deceptive practices in violation of Executive Law § 63(12) and Penal Law § 175.35 by falsely claiming FDA clearance; and

3. Whether the City of New York, through its procurement and employment practices, knowingly expended public funds on unapproved and scientifically invalid technology in violation of the public-trust doctrine and state law.

The Attorney General is respectfully requested to exercise the Bureau's full statutory and equitable powers, including: issuance of subpoenas; coordination with the **Department of Health, Division of Human Rights, Commission on Human Rights**; and the Equal Employment Opportunity Commission pursuit of injunctive relief and restitution to preclude further use of RIAH, EIA, or any related immunoassay hair-testing methodology in municipal employment.

C. Purpose and Scope of Referral

This referral requests that each addressee exercise its respective statutory authority to:

1. **Investigate** Psychemedics Corporation's false and misleading representations concerning the Food and Drug Administration (FDA) and Clinical Laboratory Evaluation Program (CLEP) clearance of its radioimmunoassay (RIAH) and enzyme-immunoassay (EIA) hair-testing devices;

2. **Determine** whether the New York City Police Department (NYPD) and other municipal agencies procured, relied upon, or enforced employment actions based on unapproved or unvalidated testing methods in violation of applicable federal, state, and local laws, regulations, and administrative rules;

3. **Assess** whether the use of these unvalidated methodologies resulted in discriminatory, arbitrary, or otherwise unlawful employment practices under the New York State Human Rights Law (Executive Law § 296) and the New York City Human Rights Law (N.Y.C. Admin. Code § 8-107); and

4. **Recommend immediate corrective and remedial measures,** including the preclusion of all radioimmunoassay (RIAH), enzyme-immunoassay (EIA), or derivative hair-testing methodologies in any municipal employment, promotional, or disciplinary context.

Further, the referral urges the **reinstatement of Palaguachi** to his former position with full back pay, restoration of seniority, and all attendant benefits, pursuant to the due-process and remedial provisions of **Title VII of the Civil Rights Act of 1964** and **New York Civil Service Law § 75**. These measures are necessary to restore statutory compliance, remedy the continuing effects of unlawful testing, and prevent the recurrence of scientifically unvalidated and legally unauthorized employment practices.

The attached **Exhibits 1–5**—the *BioSpace Press Release*, *EEOC Charge*, *HARMS Citizen Petition*, *Order of Dismissal*, and *Palaguachi Citizen Petition*—collectively document the chronology of misrepresentation, regulatory omission, and resulting harm. They provide a comprehensive factual and legal foundation for joint inquiry, coordinated enforcement, and remedial action across City and State agencies.

II. FACTUAL CHRONOLOGY

1. **BioSpace Press Release (Exhibit 1)** — On October 31, 2019, Psychemedics Corporation publicly issued a statement through *BioSpace* asserting that its hair-based drug-testing methodology was "FDA-cleared" and "forensically proven." In fact, no immunoassay device has ever been cleared by the U.S. Food and Drug Administration for use on hair matrices under 21 C.F.R. § 862.3870. The release marked the beginning of a sustained pattern of misrepresentation that migrated from corporate marketing into municipal practice.

2. **EEOC Charge of Discrimination (Exhibit 2)** — On April 18, 2025, former Police Officer Frankie F. Palaguachi, a tenured member of the New York City Police Department, filed a Charge of Discrimination with the United States Equal Employment Opportunity Commission alleging that his termination was predicated on a false-positive enzyme-immunoassay (EIA) hair-test result. The Charge asserts that the test lacked scientific validity and produced a racially disparate and disability-related impact in violation of Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, and corresponding state and local laws.

3. **HARMS Citizen Petition (Exhibit 3)** — On October 16, 2025, the nonprofit organization *Harmed Americans for Reform in Medical-Device Safety (HARMS)* submitted a Citizen Petition to the U.S. Food and Drug Administration pursuant to 21 C.F.R. § 10.30. The petition documents extensive scientific, regulatory, and enforcement failures surrounding Psychemedics Corporation's enzyme immunoassay (EIA) device, cleared under 510(k) K111929. HARMS establishes that the FDA cleared the device under 21 C.F.R. § 862.3870—a classification limited to serum, plasma, saliva, and urine—and that Psychemedics subsequently marketed it as suitable for hair analysis. This constituted off-label promotion and misbranding in violation of the Federal Food, Drug, and Cosmetic Act.

   The petition requests that the FDA (1) order Psychemedics to revise its "Instructions for Use" to reflect that its EIA device cannot determine marijuana use from hair samples, (2) issue a public communication to employers and law-enforcement agencies clarifying that the device cannot distinguish intentional use from passive exposure, and (3) publish the underlying clearance data to ensure transparency and accountability. These findings underscore that the EIA hair-testing method relied upon by the NYPD has never been scientifically validated, lawfully authorized for hair matrices, or appropriately disclosed to regulators

4. **Final Order of Dismissal (Exhibit 4)** — On October 17, 2025, the subsequent administrative disposition of Palaguachi's employment reflects termination rendered without due-process validation of the underlying test method. The order relied upon an unapproved and scientifically unvalidated testing protocol, whose unreliability precludes it from satisfying the admissibility standards required under Frye v. United States, 293 F. 1013 (D.C. Cir. 1923); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993); and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness.

   Beyond its evidentiary failures, the Department's reliance on this method violated its statutory obligations under the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, which carry the force of law and impose a non-delegable duty on employers to ensure that all selection procedures are valid, reliable, and job-related. Under Griggs v. Duke Power Co., 401 U.S. 424 (1971), and Albemarle Paper Co. v. Moody, 422 U.S. 405 (1975), employers—not employees—bear the absolute burden of proving that any test or

selection device used in employment decisions is consistent with business necessity and demonstrably related to job performance.

UGESP operationalizes this mandate through binding procedural safeguards: requiring employers to maintain data on the racial, ethnic, and gender impact of all tests (§1607.4); to conduct and document validation studies establishing criterion-related or content validity (§§1607.5, 1607.6, 1607.14); and to discontinue the use of any selection device that produces adverse impact absent such validation (§1607.6(B)). Critically, UGESP expressly prohibits presuming a test valid without empirical proof (§1607.9)—a rule the Department wholly ignored.

On this record, the Department made no effort to comply with those requirements. Testimony by Dr. Ryan B. Paulsen confirmed that Psychemedics has never conducted validation studies meeting UGESP standards and that no federal agency or professional body has validated marijuana hair testing for forensic or employment use. Sergeant Tse, the Department's own witness, admitted to being entirely unfamiliar with UGESP. The Department presented no evidence of job-relatedness, no validation studies, and no analysis of less discriminatory alternatives.

Yet the administrative record compounds that failure by suggesting that UGESP noncompliance could be excused due to the absence of racial data in the specific case. That reasoning misconstrues UGESP's structure and purpose. The Guidelines do not hinge on the individual race of an employee; they impose a systemic obligation to validate all employment tests before use. Treating the absence of racial data as an excuse for noncompliance improperly shifts the burden of proof to the employee—precisely the result forbidden by Griggs and Albemarle.

Accordingly, the Final Order of Dismissal not only reflects the use of an inadmissible and unvalidated scientific method but also codifies a systemic failure of statutory compliance under UGESP and Title VII, rendering the termination both procedurally defective and substantively unlawful under federal, state, and local civil-rights law.

5. **Palaguachi Citizen Petition (Exhibit 5)** — On October 24, 2025, filed through counsel before the U.S. Food and Drug Administration, the *Palaguachi Citizen Petition* formally connects the federal regulatory violations established in the HARMS Petition with the individual and institutional harms arising from their downstream implementation in municipal employment. Whereas the HARMS Petition documents the FDA's longstanding non-enforcement regarding Psychemedics' unapproved use of immunoassay devices on hair matrices, the Palaguachi Petition demonstrates the human consequence of that regulatory silence: the wrongful termination of a tenured NYPD police officer based on an invalid, unapproved, and scientifically inadmissible testing protocol.

The Petition presents detailed evidence showing that Psychemedics' radioimmunoassay (RIAH) and enzyme immunoassay (EIA) methodologies were marketed and operationalized by the NYPD beginning on March 11, 1996, despite the absence of any FDA clearance under 21 C.F.R. § 862.3870, which authorizes such devices solely for use on serum, plasma, saliva, and urine. By falsely representing these tests as "FDA-cleared for hair," Psychemedics induced reliance by municipal employers who, in turn, incorporated these unvalidated devices into employment-selection and disciplinary frameworks. This reliance transformed what began as a private act of misbranding under the Federal Food, Drug, and Cosmetic Act into a public act of procedural injustice affecting civil-service employees protected under Title VII of the Civil Rights Act of 1964 and Civil Service Law § 75.

Further, the Palaguachi Petition underscores that the NYPD made no effort to comply with the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607. No validation studies were conducted; no criterion-related or content-validity evidence was produced; and no records were maintained on the racial, ethnic, or gender impact of the test as required under § 1607.4. Instead, the Department presumed validity based solely on vendor marketing representations—a presumption expressly prohibited by § 1607.9. In doing so, the City abdicated its non-delegable duty to ensure job-relatedness and scientific defensibility, a duty recognized in Griggs, and reaffirmed in Albemarle.

The Petition thus establishes a continuum of misconduct: (1) corporate misrepresentation by Psychemedics; (2) regulatory silence and non-enforcement by the FDA; and (3) municipal adoption of an unapproved, unvalidated scientific method as an employment-screening tool. This continuum bridges the gap between federal inaction and local harm, demonstrating how administrative passivity enables pseudoscience to metastasize into public policy.

Taken together, the *Palaguachi Citizen Petition* provides the final evidentiary link in this chronology—transforming what might otherwise appear as an isolated procedural failure into systemic violations of civil rights, due process, and administrative law traceable to both federal regulatory neglect and municipal indifference.

Together, these exhibits form a continuous evidentiary record of corporate misrepresentation, regulatory inaction, and municipal adoption of unvalidated scientific methods as the basis for adverse employment action. Collectively, they establish a clear chain of causation demonstrating how off-label promotion and federal non-enforcement evolved into municipal reliance, producing constitutional, statutory, and civil-rights injury. This evidentiary continuum connects private misconduct with public harm, revealing how regulatory silence permitted an unapproved scientific method to become embedded in government employment policy.

III. FEDERAL VIOLATIONS

A. Violations of the Federal Food, Drug, and Cosmetic Act (FDCA)

Psychemedics Corporation marketed and distributed its enzyme-immunoassay (EIA) devices for hair analysis in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331–333. By promoting a diagnostic device for an uncleared intended use, the company rendered its products misbranded under § 352(a) and (f) and adulterated within the meaning of § 331(a) and (k). The governing regulation, 21 C.F.R. § 862.3870, authorizes immunoassay use only for serum, plasma, saliva, and urine—not hair.

The FDA's failure to delineate scope under its 510(k) clearance for K111929 permitted Psychemedics' false claim of "FDA-cleared for hair testing" to circulate uncorrected for more than a decade, seeding its adoption in public-sector contracts, disciplinary proceedings, and employment screening. This regulatory omission transformed a private act of off-label promotion into a public-law violation implicating due process and civil-service protections.

B. Violations of Title VII and the Uniform Guidelines on Employee Selection Procedures (UGESP)

At the employment-law level, the New York City Police Department's reliance on Psychemedics' unvalidated RIAH and EIA tests contravenes Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-2, and the Uniform Guidelines on Employee Selection Procedures, 29 C.F.R. pt. 1607. Under *Griggs*, and Albemarle, an employer bears a non-delegable duty to ensure that any selection device is job-related and consistent with business necessity.

Because Psychemedics' hair tests were never validated under §§ 1607.5–1607.14, their use constitutes a facially neutral but arbitrary and non-job-related procedure that produces unlawful disparate impact across protected classes. The Department's failure to perform validation studies, maintain adverse-impact records (§ 1607.4), or discontinue unvalidated tests (§ 1607.6(B)) places it in continuing violation of federal employment-testing law.

C. Violations of the Rehabilitation Act and the Americans with Disabilities Act (ADA)

The use of unvalidated biochemical tests to assess fitness-for-duty or continued employment also violates the Rehabilitation Act of 1973, 29 U.S.C. § 794, and the Americans with Disabilities Act, 42 U.S.C. § 12112(d)(4)(A). Both statutes require that any medical or psychological evaluation be scientifically reliable, validated, and narrowly tailored to legitimate business necessity. Psychemedics' immunoassay hair tests—uncleared for their claimed purpose and scientifically unreliable under *Frye*, *Daubert*, and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness—cannot meet this standard.

Accordingly, each administration of such testing constitutes an impermissible medical inquiry and a discriminatory practice under federal law.

IV. STATE LAW VIOLATIONS

A. Public Health Law and CLEP Licensing Violations

Under New York Public Health Law §§ 570–580 and 10 N.Y.C.R.R. Part 58, all laboratories performing diagnostic, forensic, or employment-related testing on specimens collected within New York State must hold a valid permit and operate under methods approved by the Clinical Laboratory Evaluation Program (CLEP). CLEP authorization is a mandatory condition precedent to the use of any novel, modified, or unvalidated testing methodology in a forensic or employment context.

No record exists that Psychemedics Corporation ever sought or obtained CLEP approval for the use of its enzyme-immunoassay (EIA) or radioimmunoassay (RIAH) methodologies on hair matrices. Accordingly, any testing performed on NYPD personnel or applicants using these methods occurred outside the scope of lawful state licensure and oversight, in violation of Public Health Law §§ 576(1)–(2) and 579(1).

Such unauthorized use not only invalidates any resulting test outcome but also constitutes the unlawful practice of clinical laboratory testing under § 579(1), subjecting both the laboratory and any participating agency to administrative sanctions and potential civil liability.

B. Executive Law § 296 and Civil Rights Law § 40-c – Discrimination and Equal Protection

Under Executive Law § 296, it is an unlawful discriminatory practice for an employer to utilize a selection device that lacks validation or job-relatedness and that results in disparate impact upon members of protected classes. The New York State Human Rights Law imposes upon employers a parallel obligation to ensure that all employment-testing methods conform to the Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, as incorporated into state enforcement standards.

The use of RIAH and EIA hair testing—neither validated under UGESP § 1607.14 nor cleared by the FDA for hair matrices—constitutes a facially neutral but arbitrary and non-job-related selection mechanism. Its application produces demonstrable adverse impact and therefore violates Executive Law § 296(1)(a).

Further, under Civil Rights Law § 40-c(1), all persons within the State of New York are entitled to equal protection of the laws and the enjoyment of employment free from discrimination based on race, color, national origin, sex, or disability. The NYPD's continued reliance on scientifically unvalidated and racially correlated testing methods denies officers this statutory guarantee and triggers the Attorney

General's enforcement authority under § 40-d to investigate and seek injunctive relief.

C. General Business Law §§ 349–350 – Deceptive Business Practices and False Advertising

New York General Business Law §§ 349 and 350 prohibit deceptive business practices and false advertising in the conduct of any business within the state. Psychemedics' public claim that its hair-based immunoassay testing was "FDA-cleared" and "forensically proven"—including representations made in the 2019 BioSpace statement—constitutes a materially false and misleading representation.

These misstatements deceived municipal agencies, including the NYPD and the Department of Citywide Administrative Services, into procuring and relying upon an uncleared, unvalidated testing device. Such conduct satisfies each element of a violation under §§ 349 and 350: (1) a consumer-oriented deceptive act; (2) material misrepresentation; and (3) resulting injury to public employees and the integrity of government operations. The City's reliance on such misrepresentations also implicates Executive Law § 63(12), authorizing the Attorney General to investigate persistent fraud and illegality in business practices involving public contracts.

V. LOCAL VIOLATIONS AND MUNICIPAL LIABILITY

A. Violations of the New York City Human Rights Law (NYCHRL)

Under N.Y.C. Administrative Code § 8-101 et seq., the New York City Human Rights Law (NYCHRL) prohibits discriminatory employment practices by both public and private employers, including City agencies. Pursuant to § 8-107(17), an employment practice that produces disparate impact on the basis of race, color, national origin, gender, age, or disability—without demonstrable validation or business necessity—constitutes an unlawful discriminatory act.

The NYPD's continued reliance on Psychemedics' radioimmunoassay (RIAH) and enzyme immunoassay (EIA) hair-testing methods—neither validated under the Uniform Guidelines on Employee Selection Procedures (29 C.F.R. pt. 1607) nor cleared for hair matrices under 21 C.F.R. § 862.3870—violates this provision. Because these unvalidated tests lack any established job-relatedness or scientific justification, their use in employment or disciplinary determinations constitutes a facially neutral practice with unlawful disparate impact within the meaning of § 8-107(17).

B. Municipal Liability under Monell and Chislett

The City's longstanding use of these unapproved methods—despite repeated scientific, judicial, and administrative warnings—demonstrates deliberate indifference within the meaning of Monell v. Department of Social Services, 436 U.S.

658 (1978). In *Monell*, the Supreme Court held that municipalities are liable under 42 U.S.C. § 1983 where an official policy, practice, or custom causes the deprivation of constitutional or statutory rights. The Second Circuit recently reaffirmed this principle in Chislett v. New York City Department of Education, No. 24-972 (2d Cir. 2025), holding that knowledge of an unlawful practice coupled with failure to act constitutes actionable municipal policy.

Here, the City of New York, through its agencies—including DCAS, the NYPD, and the Department of Health—had actual and constructive notice that Psychemedics' testing methods were scientifically unreliable, uncleared for hair, and inconsistent with both federal and state law. Yet it continued to procure, implement, and defend these methods in employment actions. This institutional inertia, sustained over three decades, constitutes deliberate indifference to the rights of municipal employees under both the U.S. Constitution and the NYCHRL.

C. Violations of the New York City False Claims Act

Under the New York City False Claims Act, N.Y.C. Administrative Code § 7-801 et seq., it is unlawful for any person or entity to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval to the City of New York. Liability also attaches to those who knowingly make, use, or cause to be made or used a false record or statement to secure payment or contract approval. Psychemedics' repeated representations that its hair-based immunoassay tests were "FDA-cleared" and "forensically proven"—including those made in its 2019 BioSpace statement—were materially false within the meaning of § 7-803(a). By inducing the NYPD and DCAS to execute and renew contracts based on these misrepresentations, Psychemedics and participating procurement officials caused the submission of false claims for public payment and reimbursement. Each such claim constitutes a separate violation of the Act, subject to treble damages and civil penalties under § 7-804(a).

Collectively, these violations establish a pattern of municipal and vendor misconduct rooted in the same systemic failure: the substitution of marketing for science and the elevation of administrative convenience over legal compliance. The City's knowing reliance on unvalidated methods, despite explicit warnings, converts negligence into deliberate policy, triggering liability under both local and federal law.

VI. COMMON-LAW LIABILITY

Under New York common law, laboratories owe a duty of reasonable care to individuals whose biological samples they analyze. That duty extends not only to the accurate performance of testing but also to the selection and disclosure of scientifically reliable methodologies. Landon v. Kroll Laboratory Specialists, Inc., 22 N.Y.3d 1 (2013), firmly establishes that laboratory negligence can give rise to actionable tort liability when careless testing or misreporting foreseeably causes harm to the subject of the test.

Psychemedics Corporation breached that duty in multiple respects. It employed unvalidated and scientifically unreliable hair-testing methods—both the radioimmunoassay of hair (RIAH) and enzyme immunoassay (EIA)—without FDA clearance for use on hair matrices, without validation under the Uniform Guidelines on Employee Selection Procedures (29 C.F.R. pt. 1607), and without approval by the New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP). These omissions violated the professional and regulatory standards that define the ordinary care owed by a reasonable laboratory under comparable circumstances.

Moreover, Psychemedics' affirmative representations—both in public statements and in contracts with the City of New York—that its tests were "FDA-cleared" and "forensically proven" constituted negligent misrepresentations that foreseeably induced reliance by municipal employers. The resulting injuries to Palaguachi and other affected employees—loss of employment, income, and professional reputation—were the direct and foreseeable consequences of that breach.

These same acts constitute negligence per se, as Psychemedics' conduct violated multiple statutes and regulations specifically designed to protect the class of individuals harmed here, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 331–333), Public Health Law §§ 570–580, and 10 N.Y.C.R.R. Part 58. Under New York precedent, violation of a safety statute intended to prevent the very harm suffered establishes both duty and breach as a matter of law. Accordingly, Psychemedics is civilly liable for damages arising from its negligent and unlawful practices.

VII. EVIDENTIARY CONSEQUENCES

The radioimmunoassay (RIAH) and enzyme immunoassay (EIA) methods employed by Psychemedics fail every recognized standard of evidentiary admissibility under both federal and state law. They lack peer-reviewed validation, known error rates, general scientific acceptance, and demonstrable reliability—all prerequisites to the admissibility of scientific or expert evidence.

Under the Frye standard, as adopted by the New York Court of Appeals in People v. Wesley, a scientific technique must have gained general acceptance in the relevant field before it may be relied upon in judicial or quasi-judicial proceedings. Similarly, the Daubert standard, and Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness, require demonstrable reliability, known error rates, peer review, and methodological transparency. The Uniform Guidelines on Employee Selection Procedures (UGESP), 29 C.F.R. Part 1607, impose a parallel requirement of validation and job-relatedness for employment testing.

Psychemedics' RIAH and EIA methods satisfy none of these criteria. They have never been validated by the FDA, CLEP, or any recognized forensic body; no peer-reviewed studies establish their reliability; and their discriminatory error profile

undermines any claim of scientific acceptance. Accordingly, results derived from such methods are inadmissible in any administrative, civil, or criminal forum.

Reliance upon these test results as the basis for disciplinary or employment action—such as the termination of Palaguachi—constitutes legal error, a violation of due process, and a deprivation of property and liberty interests under the Fifth and Fourteenth Amendments. The continued use of such evidence by municipal entities represents not only scientific malpractice but also a recurring procedural due-process violation under both federal and state law.

VIII. REQUESTED CORRECTIVE ACTIONS

To remedy the ongoing statutory, regulatory, and civil-rights violations documented herein, the undersigned respectfully requests that the receiving agencies take the following coordinated actions:

1. **Immediate Preclusion Order**

   Suspend and prohibit the use of any radioimmunoassay (RIAH), enzyme-immunoassay (EIA), or derivative hair-testing methodology in all municipal employment, disciplinary, or fitness-for-duty contexts. These methods lack Food and Drug Administration clearance under **21 C.F.R. § 862.3870**, Clinical Laboratory Evaluation Program (CLEP) authorization under **10 N.Y.C.R.R. Part 58**, and validation under the Uniform Guidelines on Employee Selection Procedures (UGESP), **29 C.F.R. Part 1607.**

   Moreover, these assays fail every recognized standard of scientific admissibility and reliability. They are inadmissible under the Frye standard, as adopted by the New York Court of Appeals in People v. Wesley; fail the Daubert reliability test; and do not meet the criteria for expert-opinion evidence under Rule 7.01 of the New York Rules of Evidence – Opinion of Expert Witness.

   Because these methods are neither scientifically valid nor legally admissible, their continued use in any employment or disciplinary proceeding is unlawful, unscientific, and contrary to established evidentiary and professional standards. Immediate suspension is therefore required to ensure compliance with governing federal, state, and municipal law and to prevent further due-process and civil-rights violations.

2. **Reinstatement and Restitution of Frankie F. Palaguachi**

   Reinstate Palaguachi to his former civil-service position with full back pay, seniority, benefits, and all attendant rights retroactive to March 2024, consistent with Civil Service Law § 75 and the remedial provisions of Title VII of the Civil Rights Act of 1964.

3. **Regulatory Referral to the New York State Department of Health**

   Refer Psychemedics Corporation to the Clinical Laboratory Evaluation Program (CLEP) for investigation under Public Health Law §§ 570–580 and 10 N.Y.C.R.R. Part 58, to determine whether the company conducted unapproved forensic or employment testing on New York specimens and to impose sanctions or revocation as warranted.

4. **Fraud and Contract Integrity Review**

   Initiate a civil, administrative, and, where appropriate, criminal review under the New York City False Claims Act (Administrative Code § 7-801 et seq.) and Executive Law § 63(12) to determine whether Psychemedics and any municipal procurement officials knowingly made or relied upon false representations of FDA clearance in obtaining or executing City contracts.

5. **Future Procurement and Testing Controls**

   Mandate that all future municipal forensic or employment-screening contracts require independent scientific validation, regulatory clearance, and documented compliance with FDA, CLEP, and UGESP standards prior to award.

   Implement oversight protocols through DCAS and DOHMH to ensure continuous monitoring of vendor compliance and to prevent recurrence of unvalidated or unauthorized testing.

IX. CONCLUSION

This referral exposes a systemic collapse of scientific and administrative oversight. For nearly three decades, a private vendor's marketing narrative supplanted regulatory fact, allowing unvalidated immunoassay methods to be transformed into official policy instruments of employment and discipline. What began as misbranding under the Federal Food, Drug, and Cosmetic Act evolved into institutional misconduct, perpetuated through regulatory silence and municipal adoption.

The consequence has been a pattern of unlawful discrimination, evidentiary unreliability, and deprivation of due process—injuring not only Detective Frankie F. Palaguachi but the integrity of the public institutions charged with protecting fairness and legality in government service.

Federal, state, and city authorities now bear a non-delegable duty to restore scientific and procedural legitimacy to municipal testing practices. Enforcement action, disciplinary review, and regulatory correction are not optional; they are necessary to reaffirm the rule of law and public confidence in the intersection of science, justice, and governance.

Certification

I hereby certify that the foregoing submission and attached exhibits are true and accurate to the best of my knowledge and belief, based on information presently available to counsel. This referral is submitted in good faith pursuant to applicable federal, state, and municipal law for investigatory and enforcement consideration.

Respectfully submitted,

/s/Frankie F. Palaguachi
Complainant

By his Counsel,
/s/Eric Sanders, Esq.

The Sanders Firm, P.C.
30 Wall Street, 8th Floor
New York, NY 10005
Tel: (212) 652-2782

Website: http://www.thesandersfirmpc.com

Exhibit List

1. **Exhibit 1:** BioSpace Press Release – *Psychemedics Corporation Responds to Court Decision* (October 31, 2019)

2. **Exhibit 2:** EEOC Charge of Discrimination – *Frankie F. Palaguachi v. City of New York* (April 18, 2025)

3. **Exhibit 3:** HARMS Citizen Petition – *Harmed Americans for Reform in Medical-Device Safety v. FDA* (October 16, 2025)

4. **Exhibit 4:** Final Order of Dismissal – *NYPD v. Palaguachi* (October 17, 2025)

5. **Exhibit 5:** Palaguachi Citizen Petition – *In re FDA Regulation of Hair-Based Drug Testing* (October 24, 2025)

cc: Distribution

Acting Health Commissioner Dr. Michelle Morse, MD, MPH
New York City Department of Health and Mental Hygiene
42-09 28th Street
Long Island City, NY 11101

Commissioner Dr. James V. McDonald M.D., M.P.H.
New York State Department of Health
Empire State Plaza, Corning Tower
Albany, NY 12237

Commissioner Denise M. Miranda, Esq.
New York State Division of Human Rights
163 West 125th Street
New York, NY 10027

Chair and Commissioner Annabel Palma
New York City Commission on Human Rights
22 Reade Street
New York, NY 10007

Attorney General Letitia James
Office of the New York State Attorney General
The Capitol
Albany, NY 12224-0341

Corporation Counsel Muriel Goode-Trufant, Esq.
New York City Law Department
100 Church Street
New York, NY 10007

Comptroller Brad Lander
Office of the New York City Comptroller
1 Centre Street, Room 530
New York, NY 10007