IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America, v. NEIL K. ANAND ASIF KUNDI ATIF MAHMOOD MALIK, VIKTORIYA MAKAROVA	Case No. 2:19-cr-00518

DEFENDANT'S REPLY IN SUPPORT OF SECOND MOTION TO CONTINUE SENTENCING

I. INTRODUCTION

The Government's assertion that Dr. Anand "has had four months to gather character evidence" overlooks the fundamental difference between trial preparation and sentencing preparation. The Government's Response fundamentally mischaracterizes the significant issues necessitating a continuance of the sentencing hearing. While the Government correctly notes it takes no position on counsel's Motion to Withdraw (ECF 653), it fails to appreciate the serious consequences of the irreparable breakdown in the attorney-client relationship and the newly discovered evidence that could substantially impact Dr. Anand's sentencing.

II. THE COMPLETE BREAKDOWN OF THE ATTORNEY-CLIENT RELATIONSHIP PRESENTS A GRAVE CONSTITUTIONAL CONCERN

The Government dismisses as insufficient the "irreparable breakdown of the attorney-client relationship with irreconcilable differences" cited in the Motion. However, this is not merely a procedural formality but a fundamental constitutional issue. When an attorney-client relationship has deteriorated to the point where effective representation is impossible, the Sixth Amendment requires that new counsel be appointed and granted reasonable time to prepare.

The specific irreconcilable differences include fundamental disagreements regarding sentencing strategy, communications breakdowns that prevent proper preparation, and loss of confidence in counsel's ability to effectively advocate at sentencing. Proceeding with current counsel under these circumstances would not only violate Dr. Anand's constitutional rights but would also deprive this Court of the benefit of fully prepared and unified advocacy at a critical stage of the proceedings.

The Government's dismissal of the attorney-client breakdown as insufficient minimizes a core Sixth Amendment issue. An "irreparable breakdown" is not mere procedure, it represents a

fundamental failure preventing the "confidence and communication necessary for an effective defense." *United States v. Welty*, 674 F.2d 185, 188 (3d Cir. 1982).

The specific irreconcilable differences center on (Exhibit NA-42):

- Fundamental disagreements regarding sentencing strategy
- Communication breakdowns preventing proper preparation
- Complete loss of confidence in counsel's ability to effectively advocate

Proceeding under these conditions would violate Dr. Anand's constitutional rights and deprive this Court of fully prepared advocacy at this critical stage. This Court has broad discretion to grant continuances when necessary to ensure a fair proceeding. As the Supreme Court has recognized, "the right to the assistance of counsel, guaranteed by the Sixth and Fourteenth Amendments, encompasses the right of a defendant to be represented by an attorney whom he trusts and with whom he can consult in confidence." *Wheat v. United States*, 486 U.S. 153, 159 (1988).

III. NEWLY DISCOVERED SYSTEMIC EVIDENCE UNDERMINES THE RELIABILITY OF DRUG WEIGHT CALCULATIONS

A. The Core Issue: PDMP Data Fundamental Unreliability

Contrary to the Government's assertion that Dr. Anand "neglects to identify any exhibit" showing discrepancies, the problem is not a single exhibit but the **entire foundation** of the drug weight calculation: Pennsylvania's Prescription Drug Monitoring Program (PDMP) data from the ABC-MAP system. Defendant Anand has already identified numerous errors within the Government data set and with patients that Defendant Anand has been convicted for (Exhibit NA-43).

Recent diligent review of the PDMP's own official documentation (Exhibit NA-44) reveals the system is structurally incapable of producing reliable data required for precise sentencing calculations under U.S.S.G. §2D1.1. The Pennsylvania Commonwealth's own materials establish this unreliability through multiple acknowledged error pathways that directly corrupt drug quantity metrics. Defendant identified critical systemic errors in the Pennsylvania PDMP (ABC-MAP) data that was almost certainly used in calculating the Presentence Investigation Report (PSR). These errors directly impact the calculation of drug weight quantities that determine sentencing guidelines under U.S.S.G. §2D1.1. Pennsylvania's own documentation for its ABC-MAP PDMP system explicitly acknowledges multiple categories of errors that render the data fundamentally unreliable for drug weight calculations.

B. The PDMP's Own Error Classifications Invalidate Sentencing Use

1. Catastrophic "Fatal Errors" Corrupt Entire Datasets (Exhibit NA-44)

The PDMP operates under a protocol where if over 10% of records in a file contain fatal errors, the **entire file is rejected**—meaning "no records in it are loaded, including those without any errors." This creates:

- **Wholesale data exclusion**: Entire prescription batches missing through no prescriber fault
- **Unpredictable gaps**: No method to determine which time periods or volumes are absent
- **Cascading undercounts**: Files with 90% accurate data are entirely excluded

2. "Serious Errors" Corrupt Individual Drug Quantities

The system knowingly loads records with "missing or inappropriate data," explicitly **including incorrect drug quantities, dosages, and identification codes.** Specific error codes include:

- "NDC (National Drug Code) Not Found" - corrupting drug identification
- "Dispenser DEA Invalid" - corrupting attribution accuracy
- Missing quantity fields - directly impacting weight calculations

This means prescriptions with fundamentally wrong weight information are included in calculations, artificially inflating or deflating totals unpredictably.

3. Patient Matching Errors Cause Systemic Double-Counting

The PDMP documentation explicitly warns: "Occasionally, 2 people will show up on a single PDMP report. This most often occurs when both parties have the same birth date or same street name or when there are multiple pieces of overlapping information and our computer is unable to isolate one unique patient." This systematic error results in prescriptions being **counted multiple times for a single individual**, directly and unfairly inflating drug weight calculations.

C. Official Disclaimers Confirm Unfitness for Legal Use

Pennsylvania's own disclaimers explicitly warn the data is unsuitable for precise calculations:

- **Attribution Errors**: "The dispensing pharmacy may have erroneously entered into their computer system your name/DEA number as the prescribing physician"
- **Incomplete Data**: "The information reported to the PDMP was incomplete and did not contain all required fields when it was transmitted"
- **Systematic Gaps**: Prescriptions missing due to non-reporting pharmacies, name spelling differences, or reporting delays

IV. LEGAL PRECEDENT COMPELS EXCLUSION OF UNRELIABLE EVIDENCE

A. Constitutional Due Process Requirements

Using data with known systemic errors to calculate drug weight violates fundamental due process protections. As the Supreme Court established in *In re Winship*, 397 U.S. 358, 364 (1970), "the Due Process Clause protects criminal defendants against conviction except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which he is

charged." This principle extends to sentencing, where drug weight determinations must be supported by reliable evidence.

B. Federal Sentencing Guidelines Demand Precision

The Federal Sentencing Guidelines establish specific drug weight thresholds that trigger dramatically different penalties. Using data with known error rates to determine which side of these critical thresholds a defendant falls on violates fundamental fairness principles. As the Third Circuit recognized in *United States v. Kikumura*, 918 F.2d 1084, 1098 (3d Cir. 1990), "the government must prove drug quantities by a preponderance of the evidence, and the evidence must be sufficiently reliable to support the finding."

C. Distinction Between General Admissibility and Specific Reliability

While courts have admitted PDMP data for various evidentiary purposes, as in *United States v. Couch*, this general admissibility does not extend to the specific use of such data for precise drug weight calculations where even minor errors can dramatically impact sentencing outcomes. The *Couch* court recognized that "PDMP data maintained by state agencies pursuant to law also qualifies as a public record," but this general admissibility does not resolve the reliability concerns specific to drug weight calculations where precision is paramount.

D. The Titus Standard Directly Applies

The Government's position ignores established legal precedent regarding the reliability requirements for evidence used in sentencing calculations. As the Third Circuit recognized in *United States v. Kikumura*, 918 F.2d 1084, 1098 (3d Cir. 1990), "the government must prove drug quantities by a preponderance of the evidence, and the evidence must be sufficiently reliable to support the finding."

This principle was recently reaffirmed in *United States v. Titus*, No. 22-1516 (3d Cir. 2023), where the Third Circuit vacated a sentence based on unreliable drug quantity calculations. In *Titus*, the government attempted to extrapolate drug quantities from a sample of 24 patient files to thousands of other prescriptions. The Third Circuit held that "the government must show, and the court must find, that there is an adequate basis in fact for the extrapolation and that the quantity was determined in a manner consistent with accepted standards of reliability." 992 F.2d at 25-26.

The court emphasized that "the government would be well advised to introduce more detailed (and less conclusory) evidence" to support its conclusion that there was a representative sample. Critically, the court found that the district court erred by extrapolating from the sample "without much explanation" and without ensuring the government carried its burden "by presenting reliable and specific evidence." The court noted that the sample size was not "statistically valid" and that the government failed to document proper extrapolation methods.

The *Titus* decision is directly applicable here. The Government's case against Dr. Anand was built almost entirely on a hand-selected sample of just 14 patients, representing a mere 2% of his

total patient population. During trial, Dr. Anand's data analyst, Ryan Vaughn, conducted a comprehensive analysis that proved the probability of this sample occurring randomly was "greater than 1 in 2 million," establishing that the government's selection methodology was deliberately biased toward identifying outliers.

E. The Government's Methodology Violates Titus

Titus directly applies here. The government's case rested on a hand-selected sample of just **14 patients**—a tiny fraction representing 2% of Dr. Anand's practice. Defense analysis proved this sample was not random but deliberately biased toward outliers, with probability of random occurrence "greater than 1 in 2 million."

Comprehensive analysis of Dr. Anand's complete prescribing patterns against national Medicare data showed practices well within mainstream norms:

- Overall Prescribing Volume: 29th percentile among pain specialists
- Opioid Claims Volume: 42nd percentile
- Opioid Prescribing Rate: 77th percentile

This means 77% of pain physicians had more aggressive opioid prescribing than Dr. Anand. The government's selection of extreme outliers from an otherwise conservative practice constitutes exactly the unreliable extrapolation *Titus* condemns.

F. Government's Algorithmic Prosecution Framework Undermines Reliability

1. DEA's Anomaly Detection System

The Government's case relied heavily on the DEA's "Nemesis" Deloitte system and related algorithmic tools designed to identify statistical outliers in prescribing data. These systems employ machine learning techniques, including "Isolation Forest" algorithms, to flag physicians whose prescribing patterns deviate from algorithmic norms.

Most damningly, Dr. King's patent application (US 20200143925A1) explicitly states he "aids in the criminal prosecution of pill mills." This reveals that his methodology was specifically designed to support criminal prosecutions of medical professionals, not to provide objective medical evaluation. This financial incentive structure and prosecutorial alignment create exactly the type of bias that undermines reliability standards required by *Kikumura* and *Titus*.

Dr. King's patent application confirms his role in developing these systems, stating that his methodology "aids in the criminal prosecution of pill mills." This reveals that the Government's approach was not to investigate evidence of actual criminal conduct, but rather to use algorithms to identify statistical anomalies and then build criminal cases around those anomalies.

The fundamental flaw in this approach is that statistical outliers in medical practice are not evidence of criminal conduct. Medicine inherently involves treating patients with varying and complex needs. Some patients legitimately require higher doses or unusual treatment regimens

due to individual medical circumstances. The presence of statistical outliers in any medical practice is normal and expected, not criminal.

2. Conversion of Medical Judgment into Criminal Evidence

The Government's algorithmic approach represents a fundamental transformation of how medical practice is evaluated for potential criminal conduct. Rather than examining whether prescribing decisions were medically appropriate for individual patients, the Government's system:

- **Identifies Statistical Anomalies**: Uses algorithms to flag physicians whose prescribing deviates from predetermined thresholds
- **Assumes Criminal Intent**: Treats statistical deviation as evidence of criminal conduct
- **Ignores Medical Context**: Evaluates prescribing patterns without regard to patient needs or medical appropriateness
- **Reverses Burden of Proof**: Requires physicians to justify statistical outliers rather than proving criminal conduct

This approach violates fundamental principles of both criminal law and medical practice. Criminal law requires proof of intent and actual criminal conduct, not statistical deviation from algorithmic norms. Medical practice requires individualized assessment of patient needs, not adherence to algorithmic thresholds.

3. The Algorithmic Metrics Reveal Prosecutorial Predetermination

The extensive list of metrics used in the Government's algorithmic analysis—including 69+ specific data points ranging from "Trinity" combinations to morphine milligram equivalents—demonstrates that the investigation was designed to find patterns rather than investigate actual criminal conduct. These metrics include:

- Schedule II specific measurements (15+ metrics)
- Morphine Milligram Equivalent calculations (5 metrics)
- "Trinity" combination tracking (12+ metrics)
- Geographic and payment pattern analysis
- Cross-referencing with criminal records

This comprehensive algorithmic framework reveals that Dr. Anand was targeted not based on evidence of patient harm or drug diversion, but because his practice triggered statistical alerts in an automated prosecution system. The Isolation Forest (iForest) algorithm, a tool for anomaly detection, was used by the government in *United States v. Anand* to identify a small, non-representative sample of patient prescriptions as "outliers."

- An outlier is an observation which deviates so much from the other observations as to arouse suspicions that it was generated by a different mechanism.
- Anomalies are instances or collections of data that occur very rarely in the data set and whose features differ significantly from most of the data.

- An outlier is an observation (or subset of observations) which appears to be inconsistent with the remainder of that set of data.
- An anomaly is a point or collection of points that is relatively distant from other points in multi-dimensional space of features.
- Anomalies are patterns in data that do not conform to a well-defined notion of normal behavior.

The government then used this sample as the basis for a criminal prosecution. Isolation Forest is an algorithm for data anomaly detection using binary trees. It was developed by Fei Tony Liu in 2008. The algorithm's primary flaw, as applied in this case, was its reliance on non-clinical data to flag patients. Instead of assessing medical necessity, it identified anomalies based on factors such as:

- Patient travel distance to the pharmacy.
- Payment method (e.g., "private pay").
- Combinations of prescribed medications.
- Their Criminal History of the Patients Including History of Drug Charges

The government used the algorithm as conclusive evidence of criminal intent, a purpose for which it was not designed because of specific algorithmic pitfalls that were exacerbated by the government's use of a biased subsample. The scientific literature on Isolation Forest identifies fundamental limitations that make criminal application inappropriate:

a. Swamping and Masking Effects Technical analysis reveals that when "normal instances are too close to anomalies, the number of partitions required to separate anomalies increases, a phenomenon known as swamping." In medical practice, the line between normal and complex treatment is often subtle, making the algorithm unreliable.

b. High-Dimensional Data Problems Medical prescribing involves high-dimensional data where "every point is equally sparse, so using a distance-based measure of separation is ineffective." The algorithm's performance "can be vastly improved by using feature selection, like Kurtosis, to reduce the dimensionality," but the DEA's implementation uses 50+ factors without proper dimensional reduction.

c. Parameter Sensitivity Requires Domain Expertise The literature emphasizes that "the performance of the Isolation Forest algorithm is highly dependent on the selection of its parameters" and requires" tuning this parameter carefully based on domain knowledge." The DEA lacks medical domain expertise to properly configure these algorithms.

The Government's Application Violates Daubert Scientific Evidence Standards

Under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), scientific evidence must meet reliability standards that the DEA's Isolation Forest implementation fails:

a. Cannot Be Tested for Medical Appropriateness- The Government's algorithm cannot be tested for its ability to distinguish appropriate from inappropriate medical care because it lacks

any training on medical standards. No peer-reviewed studies validate Isolation Forest for determining medical criminality.

b. No Relevant Error Rates for Criminal Applications- While error rates exist for fraud detection (94% false positive rate), no studies establish error rates for distinguishing legitimate from illegitimate medical practice, the central issue in this prosecution.

c. Lacks General Acceptance in Medical Community No medical literature supports using statistical outlier detection to determine medical appropriateness. The medical community relies on clinical judgment, not algorithmic analysis, to evaluate care quality.

4. Additional Systematic Distortions

Beyond the algorithmic targeting, the Government's methodology systematically distorted Dr. Anand's patterns through:

- **Temporal Manipulation**: Using "written date" instead of "fill date" to create artificial prescription "spikes"
- **Expert Financial Bias**: Dr. King earning "millions of dollars" over 15 years ($6,000/day) with clear prosecutorial alignment
- **Selective Evidence**: Expert deliberately kept unaware of Dr. Anand's overall conservative prescribing patterns

This algorithmic prosecution framework, combined with inherently flawed PDMP data, creates compelling grounds requiring time to address these systematic reliability issues and constitutional concerns about due process in algorithmic criminal targeting. The Government's reliance on Isolation Forest algorithms through the DEA's Nemesis system represents a fundamental misapplication of machine learning technology that cannot legally support criminal convictions. Technical analysis reveals multiple scientific failures:

a. Unsupervised Learning Cannot Determine Medical Appropriateness Isolation Forest is an unsupervised machine learning algorithm that identifies statistical outliers without any training on what constitutes "appropriate" versus "inappropriate" medical care. As the technical literature confirms: "Unsupervised anomaly detection techniques assume the data is unlabelled and are by far the most commonly used due to their wider and relevant application." The Government's algorithm has never been trained to distinguish between legitimate medical outliers and criminal conduct.

b. The Algorithm Is Designed to Identify Rarity, Not Criminality The foundational principle of Isolation Forest is that "anomalies are few and different from other data, they can be isolated using few partitions." This assumption directly contradicts medical practice where legitimate treatment often requires statistical outliers for complex patients. The algorithm's core assumption—that rarity equals suspicion is medically invalid.

c. High False Positive Rates Make Criminal Application Inappropriate Technical studies demonstrate Isolation Forest's significant limitations in medical contexts. Credit card fraud

detection using Isolation Forest shows "Precision: 0.06" and "Recall: 0.38," meaning the algorithm incorrectly flags 94% of flagged cases as false positives. This error rate is constitutionally impermissible in criminal prosecutions.

The DEA's Risk Factors Systematically Criminalize Legitimate Medical Practice

The 50+ risk factors used by the DEA's Isolation Forest implementation demonstrate systematic bias against appropriate pain management:

a. MME Thresholds Ignore Medical Literature The algorithm penalizes "Percent of Schedule II Prescriptions with MME Per Day >= 100" and "Count of Prescriptions with MME Per Day >= 100," despite medical literature recognizing that chronic pain patients often legitimately require high-dose opioid therapy. The algorithm treats medical necessity as criminal conduct.

b. Geographic Factors Penalize Access to Specialized Care Risk factors including "Average distance between patient and pharmacy," "Average distance between patient and prescriber," and "# of Out of State Prescribers" systematically discriminate against patients in underserved areas who must travel for specialized pain management. This creates geographic bias in enforcement.

c. Prescription Patterns Reflect Individualized Care, Not Criminal Activity The algorithm flags legitimate medical practices such as:

Trinity combinations (opioid + benzodiazepine + muscle relaxant) which may be medically appropriate

Multiple pharmacy use for insurance, convenience, or medical reasons

Complex prescribing patterns that reflect individualized patient care

V. THE SCOPE OF ADDITIONAL EVIDENCE ISSUES

A. Critical Accounting Discrepancies in Government Exhibits 210 and 211

Government Exhibits 210 and 211 (Exhibit NA-45) reveal a fundamental accounting impossibility that undermines the reliability of the Government's financial calculations. These exhibits show that total pharmacy benefit manager payments were $2,960,583, yet the total amount received in non-pharmacy accounts (TD Bank 5162, TD Bank 7033, and Wells Fargo 7590) was $3,870,273—a discrepancy of $909,690 more received than paid.

This scenario, where Government records and work product show more money leaving pharmacy benefit accounts than entering defendant's accounts, violates basic accounting principles and indicates systematic bookkeeping errors in the Government's financial analysis. In standard double-entry accounting systems, such discrepancies trigger immediate correction through reversing or correcting journal entries, as money cannot be created from thin air. The Government's failure to identify and address this fundamental accounting impossibility suggests

either incomplete financial analysis or the inclusion of funds from sources unrelated to the alleged criminal conduct.

Specifically, Exhibit 210 shows Dr. Anand's TD Bank Account 7033 alone received $3,281,773—approximately $321,190 higher than the total pharmacy payments of $2,960,583. This discrepancy alone exceeds many federal sentencing thresholds and demonstrates that the Government's financial calculations are fundamentally unreliable for determining loss amounts or the scope of alleged criminal activity.

B. Widespread File Inaccuracies

Beyond the accounting discrepancies, defense has identified widespread inaccuracies in government files 309A, 304, 301, 303, and 722, which form the basis of key allegations but contain significant factual errors misrepresenting over $700,000 in alleged payments. These systematic errors include:

1. Government File 309A - Systematic False Claims

- **Quadruple Counting of Claims**: Several insurance claims appear multiple times, artificially inflating alleged billings
- **Claims from Unassociated Physicians**: Numerous claims attributed to doctors with no affiliation to Dr. Anand's practice
- **Factual Impossibilities**: Claims dated prior to IAMS Pharmacy's creation date (1/3/2017), when the pharmacy did not exist and could not have submitted claims
- **False Payment Representations**: Independence Blue Cross payment amounts contradict actual MD Scripts disbursement records

2. Specific Patient Payment Misrepresentations

The Government's files contain demonstrably false payment attributions for specific patients, confirmed through official insurance documentation (Exhibit NA-46):

- **Tamara Gage**: Explanation of Benefits (EOB) from Highmark Blue Cross Blue Shield show Highmark paid all claims from 2015-2019. Independence Blue Cross (“IBC”) fraudulently claims they paid the same claims. Highmark Representative Mia confirmed all Tamara Gage claims were paid by Highmark.
- **Rochelle Morrow**: Independence Administrators actually paid $429.95. IBC fraudulently claims they paid $841.90.
- **Stanley Chmura**: Highmark EOBs for multiple dates (9/12/18 through 6/18/19) clearly show Highmark paid all claims. IBC spreadsheets falsely report IBC paid these claims.
- **Joseph Tinneny**: Highmark EOBs (9/26/18, 12/26/18, 5/22/19, 5/29/19) show claims paid by Highmark. For DOS 1/16/19, Highmark EOB shows $346.17 paid; IBC fraudulently claims they paid $886.17.
- **Thomas Boyd**: Highmark EOBs (7/16/18, 8/15/18, 9/10/18, 10/8/18) show Highmark payments. IBC spreadsheets falsely claim IBC payments.

- **Naikema Good**: Highmark EOBs for 12 separate dates (8/13/18 through 6/17/19) show Highmark payments. IBC spreadsheets falsely report IBC payments.

3. Misattributed Provider Claims Claims actually paid to Dr. Kaplan for patients Joseph Stehel, Joseph Sanoni, and Edward Dillon are fraudulently attributed to Dr. Anand in IBC spreadsheets.

4. Non-Member Fraud Tracy Perfidio: IBC claims payments for four dates in 2017 totaling $586.36. However, Sarah Flynn, Specialist Executive Inquiries, verified that Tracy Perfidio was not an IBC member during the specified dates, making these claimed payments impossible.

5. Additional File Deficiencies

- **File 304**: Falsely attributes payments for services rendered by other providers to Dr. Anand
- **Files 301 & 303**: Include patients never treated by Dr. Anand, duplicate entries, and pre-existence claims
- **File 722**: Contains prescriptions not written by Dr. Anand, including multiple fills from other providers

VI. TIME REQUIREMENTS FOR MEANINGFUL PREPARATION

The Government's case against Dr. Neil Anand fundamentally misrepresents the nature of legitimate medical practice by relying on a statistically manipulated and non-representative sample that transforms ordinary physician conduct into alleged criminal behavior. Through careful selection of just 14 patients, a mere 2% of Dr. Anand's practice, the Government has constructed a false narrative while deliberately ignoring compelling evidence that Dr. Anand's overall prescribing patterns fell well within the mainstream of medical practice (77th percentile nationally for opioid prescribing rates among pain management specialists).

This prosecutorial strategy violates multiple fundamental legal principles:

Statutory prohibition: 42 U.S.C. § 1395's explicit bar against federal interference in medical practice

Constitutional limits: Commerce Clause boundaries established in *United States v. Lopez*, 514 U.S.549 (1995) and *United States v. Morrison*, 529 U.S. 598 (2000)

Criminal law standards: The rigorous evidentiary requirements for prescription drug prosecutions under *United States v. Moore*, 423 U.S. 122 (1975) and its progeny

The Government's approach represents a dangerous departure from established precedent that threatens to criminalize the practice of pain medicine itself. Statistical outliers do not constitute

criminal conduct, particularly when a physician's overall practice demonstrates adherence to accepted medical standards.

This Court should exclude the Government's selectively curated evidence because the Government has failed to establish, and cannot establish based on this record that Dr. Anand's prescriptions were "not for a legitimate medical purpose" and "outside the usual course of professional practice" as mandated by *Moore*. Federal regulation is constitutionally permissible only when it targets "(1) economic activity that substantially affects interstate commerce, or (2) non-economic activity where the jurisdictional nexus is demonstrated on a case-by-case basis." *Lopez*, 514 U.S. at 567. Medical prescribing decisions are quintessentially non-economic activities that fall outside federal regulatory authority:

Non-commercial nature: Physician-patient relationships involve professional medical judgments, not commercial transactions

Local character: Treatment decisions are inherently local, involving individual patient assessment and care

Traditional state authority: Medical practice regulation has historically been a state function under the police power. The Government's Theory Creates Impermissible "Attenuated Chains of Inference". The Government attempts to establish federal jurisdiction through speculative connections between prescribing decisions and interstate commerce, arguing that "inappropriate" prescribing affects commerce through potential "drug diversion." This reasoning suffers from the same constitutional defects the Court rejected in *Lopez* for the following reasons:

Lack of economic activity: Prescribing decisions are medical judgments, not economic transactions.

Speculative effects: The Government provides no evidence of actual diversion in Dr. Anand's specific cases.

Unlimited federal power: The Government's theory would allow federal criminalization of any medical decision by hypothesizing potential downstream effects. As the Court warned in *Morrison*, accepting such "attenuated reasoning" would eliminate meaningful limits on federal power and "obliterate the distinction between what is truly national and what is truly local." 529 U.S. at 615.

This Court should recognize that the Government's prosecution represents an impermissible expansion of federal power into areas traditionally reserved to the states. The proper remedy for prescribing practices that may warrant scrutiny is state medical board oversight, not federal criminal prosecution based on statistical analysis.

Wherefore a continuance is essential to:

1. Resolve constitutional crisis from attorney-client breakdown

2. Conduct forensic analysis of specific PDMP data used in the PSR to identify and quantify systematic errors
3. Prepare motion to exclude unreliable PDMP data or apply statistical reductions for known error rates
4. Fully brief the Court on actual healthcare fraud losses
5. Fully brief the Court on compelling *Titus* implications
6. Investigating file discrepancies in government exhibits (Exhibit NA-47) forming basis of allegations

VII. CONCLUSION

The prosecution in this case violates substantive due process by criminalizing legitimate medical judgment, effectively undermining the rights of both physicians and patients. The Supreme Court has long recognized that the practice of medicine and the receipt of medical care implicate fundamental liberty interests, as seen in *Washington v. Glucksberg* and *Planned Parenthood v. Casey*. By prosecuting medical professionals on the basis of statistical thresholds and algorithmic outlier detection rather than evidence of actual misconduct, the Government imposes a chilling effect on the exercise of these rights. Physicians are forced to weigh the threat of prosecution against their duty to exercise individualized clinical judgment, while patients are deprived of their constitutional right to receive medical care free from arbitrary federal interference. This prosecution does not simply regulate; it substitutes law enforcement metrics for medical expertise, stripping medicine of its professional autonomy.

The Government's use of the DEA's Isolation Forest algorithm exacerbates this constitutional infirmity by introducing a fundamentally flawed and scientifically invalid framework for evaluating medical practice. Isolation Forest is an unsupervised machine learning algorithm designed to identify statistical rarity, not criminality. Its core assumption, that anomalies indicate misconduct, directly contradicts the realities of medical practice, where complex patients often require care outside statistical norms. Technical literature documents false positive rates as high as 94% in non-medical applications, rendering the algorithm constitutionally impermissible in the context of criminal prosecution. Further, the DEA's 50-plus "risk factors" systematically penalize legitimate medical behaviors, such as prescribing high-dose opioids for chronic pain, accommodating patients who must travel long distances for specialized care, or managing complex therapeutic regimens. No peer-reviewed medical studies validate these factors as indicia of misconduct, and under *Daubert v. Merrell Dow Pharmaceuticals*, the Government's algorithm fails every standard for admissible scientific evidence: it cannot be tested for medical appropriateness, lacks known error rates for prescribing decisions, and enjoys no general acceptance within the medical community.

The constitutional violations deepen with the DEA's use of patient criminal history as an input for algorithmic risk scoring, which transforms law enforcement data into de facto medical standards. This practice violates substantive due process, equal protection, and statutory prohibitions against federal interference in medical decision-making. It effectively criminalizes the treatment of vulnerable populations, discouraging physicians from caring for patients with prior convictions and thereby reducing access to medical treatment for underserved communities. Such reliance on criminal history also reintroduces punishment for individuals who have

completed their sentences, perpetuates racial and socioeconomic disparities, and directly contradicts medical ethics that prohibit discrimination in patient care. By embedding criminal history into its evaluative model, the DEA not only skews enforcement outcomes but also transforms medical ethics into prosecutorial liabilities. When coupled with the "black box" nature of machine learning, which prevents meaningful cross-examination under the Confrontation Clause, the Government's evidence is not only scientifically invalid but also constitutionally unreliable. In sum, the prosecution collapses under the weight of its own methodological, ethical, and constitutional flaws, criminalizing medicine while eroding the very protections that substantive due process was designed to safeguard.

Granting this continuance serves justice by ensuring Dr. Anand's sentence rests on reliable evidence and effective counsel assistance. The combination of:

- Widespread factual errors in key government exhibits
- Ensuring the Court has complete information regarding Dr. Anand's character and circumstances

Avoiding potential appellate issues regarding the use of unreliable data in sentencing calculation creates compelling grounds requiring additional preparation time. Proceeding without addressing these issues would compromise this Court's proceedings and create significant appellate vulnerability. The integrity of federal sentencing demands drug weight calculations based on reliable, accurate evidence. Pennsylvania's PDMP data, by the Commonwealth's own admission, fails this fundamental standard.

I thank the Court for its prompt attention to this matter.

Respectfully submitted,

/s/ Neil Anand

NEIL ANAND M.D. Defendant

Dated: September 4, 2025

1313 Cheltenham Drive

Bensalem, Bucks County, PA 19020

Email: cardiacgasman@gmail.com

Phone: 267-934-9784

PROOF OF SERVICE

I hereby certify that on September 4, 2025, I presented the foregoing DEFENDANT'S REPLY IN SUPPORT OF SECOND MOTION TO CONTINUE SENTENCING to the Clerk of the Court through the Pro Se Electronic Document System (EDS) System, submitted in PDF format, to ECF System for filing and uploading to the ECF system, which will send notification of such filing to the relevant attorneys of record.

/s/ *Neil Anand*

Defendant