

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

Neil Anand, et al.,	:	
	:	
Plaintiffs,	:	CASE NO. 21-1635-CKK
	:	
Barbara Doyle Marino	:	
	:	
Intervenor	:	
	:	
v.	:	
	:	
U.S. Department of Health	:	
	:	
And Human Services et al.,	:	
	:	
Defendants	:	

**Urgent Second Motion For Intervention By Right And Permissive
Intervention Pursuant to Federal Rules of Civil Procedure 24(a) and 24(b)**

Intervenor Barbara Doyle Marino (“Intervenor”), moves Pro-Se, opposed by Defendants, and requests Motion to Intervene based on rights and permission pursuant to F.R.C.P. Rule 24. The Intervenor seeks to provide a clear basis for relation to the Plaintiffs. The issues are: 1) suitable for judicial resolution, 2) the withholding judicial review would cause undue hardship, and impair rights to the Intervenor, 3) Intervenor and the Plaintiffs Anand and Pompy have a common nucleus of operative facts resulting in damage and harm to Intervenor and her

second upcoming criminal trial (*U.S. v Marino*, B, case# 4:19-cr-00602, TX, SD) which can be resolved through Judicial Relief by the Court, 4) Intervenor requests that the Honorable Judge allow the intervention by right and permission for purposes of judicial economy, 5) Intervenor Marino needs the requested pertinent information to assist in her criminal trial as it pertains to the Government's expert, Dr. Timothy King, testifying against Intervenor by using Government data, algorithms and/or artificial intelligence.

I. INTRODUCTION AND OVERVIEW

The government seeks to introduce risk scores, anomaly flags and other “black box” outputs generated by patented algorithms (e.g., Dr. Timothy Earl King's patent application (US 20200143925A1), fraud detection graphs) as evidence of a criminal defendant's wrongdoing. Absent disclosure of the underlying metrics, thresholds, confidence intervals, ontologies, and statistical validation, such “evidence”: (1) violates due process by denying notice and a fair opportunity to challenge its reliability; (2) infringes the Sixth Amendment's Confrontation Clause; (3) runs afoul of *Brady v. Maryland and Giglio's* requirement to reveal impeachment and exculpatory material; and (4) contravenes Federal Rule of Criminal Procedure 16's discovery mandates. For these reasons, the government must be compelled to produce full disclosure of the algorithms' outputs and their inner workings, etc.

This case involves critical Freedom of Information Act (FOIA) requests for documents that bear directly on Intervenor Marino's constitutional rights in her pending criminal prosecution (*United States v. Marino*, Case No. 4:19-cr-00602 (S.D. Tex.)). The requested materials including data analytics algorithms used in the "Pill Mill Doctor Project," contracts with Qlarant Corporation, and reports from Blue Cross Blue Shield to HHS-OIG which constitutes potentially exculpatory and impeachment material that the government has improperly withheld in violation of *Brady v. Maryland*, the *Jencks* Act, and Federal Rule of Criminal Procedure 16.

Intervenor Marino's upcoming second criminal trial mandates expedited FOIA disclosure under *Brady* [(*Brady v. Maryland*, 373 U.S. 83, 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963))]. A Government's failure to disclose the requested *Brady* information that a respondent could have used to conduct an effective cross-examination impairs a respondent's right to confront adverse witnesses. "In *Davis v. Alaska*, ...the Supreme Court held that the denial of the 'right of effective cross-examination' was "constitutional error of the first magnitude" requiring automatic reversal." 719 F.2d, at 1464 (quoting *Davis v. Alaska*, 415 U.S. 308.318. 94 S.Ct. 1105 1111, 39 L.Ed.2d 347 (1974)).

It is Intervenor's grave concern that no meaningful documents will be released to Intervenor which are critical for Intervenor to receive prior to my

upcoming trial (Case #4:19-cr-00602, SD TX) as both Defendants appear to be “stonewalling” Intervenor and obstructing fulfilling Intervenor’s request for information which is entitled to Intervenor by law, causing prejudice. An agency may meet its burden solely on the basis of affidavits or declaration, see *Valencia-Lucena v. U.S. Coast Guard*, 180 F.3d 321,326 (D.C. Cir 1999), as long as they “describe the documents and the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record [or] by evidence of agency bad faith,” *Military Audit Project v. Casey*, 656 F.2d 724m 738 (D.C. Cir. 1981)

Intervenor’s upcoming criminal trial mandates expedited FOIA disclosure under *Freeman v. Dep’t of Justice*, No.92-0557 (D.D.C.Oct.2,1992) (“exceptional circumstances”/ ”due diligence”: vacate, in part, court’s May 22, 1992 order; because of the limited scope of plaintiff’s FOIA request and because plaintiff has demonstrated that the information will assist him in his defense against state criminal charges for securities fraud where discovery of these records would not be available, orders the defendant to comply with plaintiff’s FOIA request by December 31, 1992; and also, by that date, to file a Vaughn Index of those documents or document portions for which it invokes exemptions).

Intervenor Marino's situation presents exceptional circumstances warranting immediate judicial intervention:

1. Her second criminal trial is scheduled for June 16, 2025;
2. The prosecution's case relies on algorithmic evidence similar to that being withheld in this FOIA action;
3. Intervenor has made repeated, good faith efforts to obtain these materials through proper FOIA channels, only to face improper denials and agency stonewalling;
4. The information sought goes to the heart of Intervenor's ability to confront witnesses and present a complete defense.

II. FACTUAL BACKGROUND

1. On June 11, 2021, pro se Plaintiffs Neil Anand and Lesly Pompy (collectively, "Plaintiffs") filed the instant Freedom of Information Act ("FOIA"), 5 U.S.C. 552, action against the U.S. Department of Health and Human Services ("HHS") and the U.S. Drug Enforcement Administration ("DEA"). The genesis of their case concerns FOIA request submitted by the Plaintiff on April 17, 2021, to HHS- Office of Inspector General ("HHS-OIG") seeking a number of records, including records on "data analytics algorithms used in the Pill Mill Doctor Project; statement of work and official contract of Qlarant Corporation; all reports from Blue Cross Blue Shield Corporation to OIG concerning improper prescribing of opiates by specific

physicians and all reports of OIG concerning Neil Anand or Institute of Advanced Medicine and Surgery.” See Compl. Ex. B.

2. Additionally, Intervenor Marino filed FOIA requests on May 5, 2022 to Drug Enforcement Agency and HHS-OIG seeking a number of records including records on “data analytics algorithms use in the Pill Mill Doctor Project; statement of work and official contract of Qlarant Corporation; all reports from Blue Cross Blue Shield Corporation to OIG concerning improper prescribing of opiates by specific physicians and all reports of OIG concerning Barbara Marino” (See Exhibit 1).
3. On 5/5/2022 Intervenor Marino submitted two different FOIA requests to the USDOJ at MRUFOIA.Requests@USDOJ.gov both by email and by postal service (See Exhibit 2) On 5/31/2022, the U.S. Department of Justice, Drug Enforcement Administration/ Freedom of Information and Privacy Act Unit—C, Freedom of Information Group, Case Number: 22-00600-F sent Barbara Marino at 417 Redfish Drive, Freeport, Texas 77541 and via e-mail at bdmarino@marinomd.com, Ms. Davis wrote:”Regarding Case Number:22-00600-F, Subject: All information regarding the arrest of HCP and targeting patients needing LTOT (1/1/1990 through 5/5/2022.) We have determined that your requests should be aggregated for fee purposes. Please be advised that the Department of Justice regulations provide for the aggregation of

requests where “a component reasonably believes that a *requester* or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees. . . .” 28.C.F.R. 16.10(h)(2019) Your requests as written do not meet the requirements of the FOIA, 5 U.S.C. 552(a)(3)(A), since they do not reasonably describe records.”

4. Intervenor Marino has now received two responses from Douglas Hibbard, Chief, Initial Request Staff, Office of Information Policy (OIP): 6/13/2022 he stated that OIP was the incorrect department and she should send her request to the USDOJ, stating that her second request was duplicative of her first request, so his department closed her second request seen in Exhibits (See Exhibit 3). Intervenor has attached communications Intervenor has had with Mr. Hibbard and with Ms. Yvette Davis (See Exhibit 4). Intervenor also requested expedited processing of my requests pursuant to the USDOJ’s standard involving the “loss of substantial due process rights.” See 28 C.F.R.16.5(e)(1)(iii) (2018). Based on the information Intervenor provided, the Defendants/OIP determined that Intervenor’s request for expedited processing under this standard should be denied. The Defendants/OIP stated that Courts are reluctant to grant expedited processing unless a requester can show (1) “that she is facing grave punishment [in a criminal proceeding], and (2) that there is reason to believe information will be produced to aid the

individual's defense.” *Freeman v United States Department of Justice*, No. 92-0557, slip op. At 4 (D.D.C. Oct. 2, 1992).

5. The Defendants seek to unlawfully control the practice of medicine in violation of 42 U.S. Code § 1395 through computerized decision making of Artificial Intelligence (AI) as well as data and predictive analytics. (See Exhibit 5)
6. Intervenor argues that the Defendants seek restitution, which is a profiteering scheme under criminal, but not contract law. (See Exhibit 6)
7. The Defendants are partnered with private healthcare payors in a Joint Enterprise known as the Healthcare Fraud Preventive Partnership (HFPP) which includes Medicare contractors and Blue Cross Blue Shield insurance companies that seeks anticipatory repudiation and proprietary pecuniary gains. (See Exhibit 7)
8. The HFPP Joint Enterprises' process is designed, largely through automated computer processes, to categorically and systematically, without human input, eliminate, abate, and/or reduce first-party benefits coverage for which the insured has paid a separate premium. (See Exhibit 8)
9. Defendants utilize artificial intelligence to determine violations by healthcare professionals of complex and constantly shifting healthcare guidance and regulations. (See Exhibit 9)

10. The amount HFPP insurance pays for its insured's health care expenses are based upon its handling of arbitrary, constantly changing, various, vague, and ambiguous medical codes which occurs due to the progress of science, business, and other human, non-artificial, thoughtful activity.
11. The HFPP Joint Enterprise utilizes computer algorithms, mathematical equations, and artificial intelligence which is able to categorize and analyze the constantly fluctuating: 1) International Classification of Diseases ("ICD"; there have been 10 versions and 68,000 codes in the most recent version with flexibility as a living document for expansion), 2) American Medical Association ("AMA") Current Procedural Terminology ("CPT"; the AMA first developed and published CPT in 1966 with the CPT codebook remaining a living document that undergoes annual updates, where for example the 2016 edition offered over 350 code changes, 140 of which were new, 134 revised, and 93 deleted), as well as 3) the Prescription Drug Monitoring Program ("PDMP"; a database containing all medication information of every U.S. Citizen) to determine and categorize all confidential medical diagnoses and treatments of U.S. citizens.
12. The Government employs an algorithmic fraud detection system, referred to here as HFPP, which functions as a "black box", its internal methodology,

logic, and error rates are not disclosed to the public, criminal defendants, or the courts.

13.HFPP equates statistical outliers or deviations from normative behavior with intentional criminal conduct, regardless of available alternatives or legitimate explanations. (See Exhibit 9)

14.The HFPP system reduces complex human behavior to data points and statistical patterns, without accounting for individual context or intent, thereby contravening the foundational legal principle of *actus non facit reum nisi mens sit rea* (that an act alone does not establish guilt without a culpable mental state).(See Exhibit 10)

15.The Defendants' algorithm lacks the capacity to differentiate between deliberate fraud (*mens rea*) and innocent or circumstantial deviations in behavior, thus violating the intent requirement fundamental to fraud prosecution. (See Exhibit 11)

16.The Defendants' algorithmic system fails to recognize or apply the Principle of Alternate Possibilities (PAP), which holds that a person is responsible only if they had the ability to choose otherwise. (See Exhibit 12)

17.The Defendants employs proprietary algorithms that purport to assess inter-rater reliability and related statistical measures.

18. Defendants' algorithms do not disclose how they calculate Cohen's Kappa or any alternative measure of inter-rater agreement. (See Exhibit 12)
19. Criminal defendants cannot independently verify whether the reported levels of agreement between the Government's and its experts algorithms or artificial intelligences account for chance-corrected concordance, as required by standard statistical methodology. (See Exhibit 12)
20. The absence of transparency by Defendants prevents any meaningful evaluation of the validity or reliability of the Defendants algorithm's outputs, particularly in contexts where subjective classifications or categorizations significantly affect individual outcomes.
21. The outputs of the HFPP system are neither peer-reviewed, empirically validated, nor accepted as reliable within the relevant scientific or legal communities. (See Exhibit 10)
22. The Department of Justice and related executive agencies deploy HFPP outputs as de facto definitions of fraud, absent congressional authorization. This practice constitutes executive overreach, allowing the executive branch to enforce algorithmic criteria as if they were duly enacted statutory law, in violation of President Donald Trump's Executive Orders on May 9, 2025, "FIGHTING OVERCRIMINALIZATION IN FEDERAL REGULATIONS".

23. The use of HFPP undermines due process, as courts risk treating algorithmically flagged behavior or "fraud scores" as conclusive evidence of criminal conduct without independent judicial scrutiny or adversarial testing.
24. Judicial acceptance of HFPP-generated outputs without examining their legal foundation constitutes a judicial bypass, wherein courts abdicate their constitutional role to independently interpret and apply the law. (See Exhibit 13)
25. The Defendants and HFPP operates beyond the scope of legislative oversight or judicial review, effectively establishing a parallel, shadow legal regime determined by proprietary algorithms.
26. The delegation of legal decision-making to opaque algorithmic systems such as HFPP poses a direct threat to the separation of powers, transferring core constitutional responsibilities from elected legislators and appointed judges to unelected technology vendors and administrative agencies. (See Exhibit 12)
27. Judicial intervention is necessary to prevent the erosion of constitutional governance and to restore proper checks and balances among the legislative, executive, and judicial branches.
28. In *United States v. Neil Anand et al.* 19-518, Dr. Timothy Earl King testified to the usage and filing of a patent titled, "Forensic System and Method for

Detecting Fraud, Abuse, and Diversion in the Prescriptive Use of Controlled Substances” (Patent No.: US 2020/0143925 A1). (See Exhibit 14)

29. Dr. Timothy King’s patented system also references four other patented criminal forensic systems including: 1) Method, System, and Computer Program Product for Determining a Narcotics Use Indicator (Narcotics Use Indicator System Patent No.: US 8,688,477 B1); 2) Opioid + Device Combination Products with Improved Safety and Efficacy Profiles (JP 2019-513504 A); 3) Identification and Analysis of Copied and Pasted Passages in Medical Documents (Patent No.: WO 2015/167852 A1); 4) System for Detecting Health Care Fraud (Patent GB 2514239 A). (See Exhibit 5)
30. The patents at issue implement a triadic framework of metrics/red flags, ontology, and metaphysics to detect alleged misuse, fraud, and non-compliance within healthcare data systems. (See Exhibit 5)
31. First, mathematical models such as statistical analysis, graph theory, and natural language processing are used to convert subjective behaviors into quantifiable metrics, e.g., computing opioid risk scores based on percentile rankings or identifying text similarity through cosine metrics and other similar algorithms.

32. Second, ontological structures organize this data into structured relationships, such as linking patients, providers, and pharmacies via labeled edges to detect suspicious clusters or non-compliant documentation.
33. Third, the patents embed metaphysical assumptions that human intent and complex behaviors can be reduced to measurable proxies, for example, assuming high morphine milligram prescriptions causally indicate misuse.
34. Together, these three elements operationalize human behavior into Government algorithmic outputs. Dr. King testified to these methodologies in *United States v. Neil Anand et al.* 19-518: (See Exhibit 14) (excepted below)
- a. Dr. King offered testimony concerning government recruitment (pp. 700, 2222): Dr. King admitted under oath: "I'm getting paid \$6,000 a day for testimony for my time in court" (Testimony p. 700).
 - b. When asked about total earnings over 15 years of consulting: "Over the course of those 15 years, your total compensation would be into the millions of dollars if we added it all up; is that correct?" Dr. King responded: "I have not added it up... But it's a matter of record. Whatever it is, it is" (p. 2222). This financial relationship with the Government creates an inherent bias, as noted when Dr. King acknowledged the patent application's statement about "practitioners... willing to provide opinions for hire" (pp. 2228-2232).

- c. Dr. King offered testimony concerning *Government Duration & Compensation*: "I was approached approximately 15 years ago to assist in reviewing cases... I'm getting paid \$6,000 a day for testimony for my time in court." (p. 700). "Over the course of those 15 years, your total compensation would be into the millions of dollars... Whatever it is, it is." (p. 2222)
- d. Dr. King offered testimony concerning *Volume of Cases*: "I've testified for the Government approximately 38 to 40 times previously... Over the course of many years." (p. 2222)
- e. Dr. King offered testimony concerning DEA Publications (pp. 728-729)
- f. Dr. King offered testimony concerning *Standard of Care Claims and Contradictory Knowledge*: "They're a standard of care... a doctor would be outside the standard of care if a physical exam were not performed." Q: "Does the DEA require a physical exam every time a patient gets an opioid?" A: "I'm reviewing in my mind DEA publications... my memory isn't that good. I can't answer that specifically." (p. 729)
- g. Dr. King offered testimony concerning medical records (pp. 738-739 and *Absolute Reliance on Charts*: "The medical chart is supposed to represent the complete... history of the patient such that an outside observer will garner a complete picture." (p. 738)

- h. Dr. King offered testimony concerning admitted limitations of medical record review: Q: "You don't get to look them in the eye as you're manipulating their shoulder?" A: "No, but that's not necessarily the same thing... The chart is where the story is expected to be told in its fullness." (p. 739)
- i. Dr. King offered testimony concerning "Map Is the Terrain" concept (p. 757) *Circular Documentation Logic*: (Repeats verbatim from p. 739 medical records testimony, suggesting interchangeable use of these concepts)
- j. Dr. King offered testimony concerning his patented criminal forensic methodology (pp. 2223-2232, 2272-2291) *Methodology Disclosure and Contradictions*: "The forensic chronology is... my notes... a compilation of various points put forth in peer-reviewed literature and by statute." (p. 2228) Q: "Is your patent application accurate?" A: "It is the one that I have stated is inaccurate." (p. 2272) "If [doctors] ignored biosocial issues... they should be scored as not prescribing for legitimate medical purpose." (p. 2291) Q: "The purpose of the patent was to collect royalties?" A: "No... I allowed other individuals to use it... no royalties required." (p. 2291)(See Exhibit 14)

- k. Dr. King offered testimony concerning reliance on Government-Selected, Limited Patient Samples: "The Government chose [the patient files]; right?...Correct...They appeared to be fairly consistent in terms of what I was looking for...I had no concerns [about selection bias]" (pp. 758, 2235-2236).
- l. Dr. King offered testimony concerning lack of need in requesting additional files: "Did you ever ask them for more patients to review?...No" (p. 758).
- m. Dr. King offered testimony concerning Medical Records Completeness: "The medical chart is supposed to represent the complete and thorough history of the patient such that an outside observer will be able to garner a complete picture" (p. 738). But conceded limitations when pressed: "You don't get to talk to the person?...No, but that's not necessarily the same thing" (p. 739).
- n. Dr. King offered testimony concerning his "Forensic Chronology" system admitting his team (including wife and daughter), perform critical work: "Some of the data from the medical chart is put into an Excel spreadsheet. That's the portion that they do...I'm the one who overviews it at the end and then adds probably the last 50 percent or so to it" (pp. 2223-2227).

- o. Dr. King offered testimony concerning adopting potential errors: "If there are any mistakes made by your team, you've adopted those mistakes by signing off on the work...correct?...That is correct" (pp. 2272-2291).
- p. Dr. King offered testimony concerning his patent (US 20200143925A1), where he admitted portions were inaccurate: "Did you sign a federal patent application that you did not agree with?...Yes...So there are things in that patent application that are...inaccurate; correct?...Correct" (pp. 2272-2291). But affirmed core premises about "biosocial factors" affecting prescribing decisions (pp. 2272-2291).(See Exhibit 15)
- q. Dr. King offered testimony concerning his "Forensic Chronology" system where he contradicted himself on scientific basis: "You have no peer-reviewed articles on pain management published, do you?...Correct...You've never submitted one?...Correct" (p. 2291).

35.The Defendants utilized these numerous patents in *United States v. Neil Anand et al.* 19-518, where mathematics is the operational backbone of these patents, serving as the primary mechanism for human abstraction, human standardization, and human scoring.

36.The Defendants goal is to take qualitative, socially embedded phenomena (like medical decision-making or fraud) and flatten them into numeric scales that appear neutral, objective, and actionable.

37. The Defendants measure Statistical Norms and Deviations (Method, System, and Computer Program Product for Determining a Narcotics Use Indicator (Narcotics Use Indicator System Patent No.: US 8,688,477 B1)) where prescription patterns are ranked via percentiles (e.g., morphine milligram equivalents above the 95th percentile) and weighted averages give more influence to certain metrics (e.g., overlapping prescriptions, early refills) creating a risk continuum where *statistical outliers* are flagged, regardless of context. (See Exhibits 11,12)
38. The Defendants utilize graph theory and network metrics (System for Detecting Health Care Fraud (Patent GB 2514239 A)) to construct social-medical networks using nodes (patients, providers, pharmacies) and edges (interactions). (See Exhibit 9)
39. The Defendants utilize centrality scores or unusually dense clusters that are treated as red flags (e.g., one pharmacy dispensing for 50+ doctors), which is derived from social network analysis, where abnormal connectivity implies potential coordination or collusion.
40. The Defendants utilize similarity metrics in natural language processing (Patent No.: WO 2015/167852 A1) and uses algorithms like cosine similarity, Jaccard index, or Levenshtein distance to detect textual repetition where a

similarity score above a threshold (e.g., 90%) may trigger audit or review, regardless of whether the duplication was clinically appropriate.

41. The Defendants utilize rule based scoring systems (Patent No.: US 2020/0143925 A1) and employs checklists where each medical standard is binary-scored (✓/X) and generates a "compliance index" to quantify adherence to best medical practices, potentially to be used in retrospective peer reviews or litigation.
42. The Defendants utilize mathematics here which is not merely descriptive but is prescriptive by constructing what counts as "normal" by setting thresholds, norms, and cutoffs.
43. The Defendants redefines clinical deviation as risk in violation of 42 U.S. Code § 1395.
44. The Defendants utilize ontological structures from these patents to map human concepts into machine-readable categories, allowing Government artificial intelligence and algorithms to make inferences about real-world entities.
45. The Defendants utilize entity-attribute models or ontological frameworks that define core objects (e.g., patients, providers, drugs) and their attributes (e.g., dosage, frequency, NPI) and where relationships are codified (e.g., "provider X prescribed opioid Y to patient Z").

46. The Defendants utilize hierarchical taxonomies and ontological frameworks where medical actions are classified into multi-level hierarchies (e.g., from “diagnosis” → “clinical note” → “ICD code”) and where this structured hierarchy allows scoring mechanisms to track omissions or inconsistencies.
47. The Defendants utilize risk ontologies for categories like "doctor shopping," "pharmacy hopping," and "concurrent prescriptions" that are given formal definitions.
48. The Defendants calculate composite risk indices based on inclusion or exclusion from these ontological buckets.
49. The Defendants Ontology creates epistemic boundaries where what the system can "know" is limited to what it has been taught to recognize and anything outside this structured world is epistemologically invisible to the algorithm.
50. The Defendants utilize patents that encode a specific worldview which equates data patterns with truth, correlation with causation, and statistical rarity with criminal risk.
51. The Defendants utilize patents where causal determinism assumes that human behaviors such as early refills or high morphine equivalents are causally linked to future misuse, even though these are probabilistic, not deterministic, indicators.

52. Similarly, medical text duplication is assumed by Defendants to increase the likelihood of clinical error or fraud, a dangerous leap from syntax to intent.

53. The Defendants utilize patents where reductionism reduces the complex socio-medical act of prescribing medical treatment into a vector of numbers, and ignores patient nuance (e.g., chronic pain, cancer, end-of-life care), reducing human experience to measurable computerized tokens.

54. The Defendants utilize patents that ignore abstract concepts like human and/or patient agency, cognition, or intent. (See Exhibit 5)

55. The Defendants utilize patents that encode normative judgments about what constitutes deviance, responsibility, and risk. (See Exhibit 5)

56. The Defendants utilize patents where computerized algorithmic systems do not just observe human behavior but reinterpret it through a pre-structured moral and logical lens. (See Exhibit 5)

57. The Defendants utilize patents that create closed epistemic loops where data is structured ontologically, measured mathematically, interpreted metaphysically, and then used to justify real-world actions (e.g., audits, arrests, license revocations).

58. The Defendants utilize patents that can punish legitimate outliers, such as patients with severe chronic pain or rare diseases. (See Exhibit 5)

59. The Defendants utilize patents where algorithms can entrench confirmation bias, flagging those previously flagged. (See Exhibit 12)
60. The Defendants utilize patents where ontologies often lack cultural or contextual sensitivity (e.g., racial disparities in prescribing aren't modeled).
61. The Defendants utilize patents where hierarchies are often static, failing to adapt to emergent clinical practices or medical standards of care.
62. The Defendants ultimately utilize patents that assume that correlation implies causation, turning probabilistic risk into actionable judgments.

III. DIRECT RELEVANCE TO UNITED STATES V. MARINO

The Intervenor represents to the Court that an identical methodology is expected in *United States v. Marino* Prosecution as the Government has hired Dr. Timothy King, who will likely: 1) Rely on government-selected patient files without independent verification; 2) Apply his proprietary "forensic chronology" system; 3) Use the same biosocial risk factors cited in King's patent application.

The requested FOIA materials are essential for effective cross-examination in *United States v. Marino* where the withheld documents would reveal: 1) Algorithmic Bias; 2) Full details about the "Pill Mill Doctor Project" algorithms, that Dr. King's methods mirror; 3) Financial Connections including contracts

between agencies and paid experts like Dr. King; 4) Selection Bias and how the government targets U.S. physicians (including Intervenor Marino).

Dr. Timothy King testimony in *United States v. Anand* necessitates release of all FOIA evidence possessed by Defendants to allow Intervenor to effectively cross examine Dr. King's methodology at trial: "If there were issues with regard to the way the PDMP was put together...I would take it at face value" (pp. 2272-2291, Exhibit 14); testimony demonstrating systemic Government reliability problems.

IV. LEGAL IMPLICATIONS

If the Defendants cannot produce the raw data, source code, or decision logic, the Government's evidence is functionally indistinguishable from junk science. Intervenor argues that there are constitutional violations if FOIA materials remain withheld, including *Brady/Giglio* Violations as the Government documents likely contain impeachment material about Dr. King's methodology and potential biases. Intervenor argues that there are Confrontation Clause issues because without algorithmic and data details, Intervenor Marino cannot meaningfully cross-examine Dr. King about his and/or the Government's analytical framework. Intervenor also argues Due Process concerns as Dr. King testified about his patent in *United States v. Anand*: "The social part of the biopsychosocial model requires that all these things be considered...individually"

(p. 2291, Exhibit 14) - a standard impossible to challenge without full FOIA disclosure by Defendants.

Dr. Timothy King's testimony from *United States v. Anand* revealed:

1. Financial Conflicts: \$6k/day testimony fee with millions earned (pp. 700, 2222, Exhibit 14) and financial dependence on government prosecutions;
2. Selective Reliance: Only reviewed government-provided records (pp. 758, 2235-36, Exhibit 14) and reliance on cherry-picked evidence;
3. Documentation Gaps: Admits Electronic Medical Records are incomplete yet treats medical charts as definitive (pp. 738-39, 2246-49, Exhibit 14)
4. Methodological Contradictions: Disavows patent while using its framework (pp. 2272-91, Exhibit 14)-use of an unvalidated, self-contradictory analytical system.

Dr. King's testimony (Exhibit 14) directly impacts Intervenor Marino's case by demonstrating: 1) The Government prosecution expert's financial incentives, 2) Systemic flaws in Government evidence collection methods, 3) Unreliable Government analytical frameworks being applied to Intervenor's criminal case. Intervention is necessary because only through judicially compelled FOIA disclosure by Defendants can Intervenor Marino:

1. Expose these flaws in Dr. King's anticipated testimony at criminal trial;
2. Effectively exercise Intervenor's Sixth Amendment confrontation rights;
3. Prevent criminal convictions based on unreliable expert evidence.
4. Verify Dr. Timothy King's claims about standard medical practices
5. Examine potential Government selection bias in patient medical records
6. Challenge the validity of Dr. Timothy King's and/or the Government's patented methodology

A. Intervenor's Pending Criminal Case and Trial

Intervenor Marino, a physician, faces a superseding indictment alleging illegal prescription of controlled substances after her first criminal trial resulted in acquittal on prescribing charges and a hung jury on conspiracy charges. The government's case relies heavily on: 1) Algorithmic "risk scores" generated from prescription data; 2) Expert testimony based on undisclosed analytical methodologies; 3) Evidence and data developed through the very "Pill Mill Doctor Project" that is the subject of Plaintiffs' FOIA requests.

B. FOIA Requests and Agency Obstruction

On May 5, 2022, Intervenor submitted two FOIA requests to USDOJ seeking:

1. All information regarding the arrest of healthcare providers and targeting of patients needing long-term opioid therapy (1/1/1990-5/5/2022);
2. Specific records related to data analytics algorithms, Qlarant contracts, and BCBS reports (mirroring Plaintiffs' requests).

The agencies responded with improper denials:

1. USDOJ aggregated requests and claimed they failed to reasonably describe records;
2. OIP improperly closed one request as duplicative;
3. Expedited processing was wrongly denied despite showing "exceptional circumstances" under 28 C.F.R. § 16.5(e)(1)(iii).

V. LEGAL ARGUMENT

A. Intervention as of Right Under Rule 24(a)(2)

1. Protectable Interest: Intervenor has a direct, substantial interest in the requested FOIA materials that goes beyond mere curiosity. As recognized in *United States v.*

Presser, 844 F.2d 1275 (6th Cir. 1988), these materials constitute compulsory process essential for Intervenor's criminal defense.

2. Impairment of Liberty Interest: Without intervention, disposition of this action may practically impair Intervenor's ability to protect her liberty interest. The Supreme Court's recent decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022), heightens the need for these materials to challenge the prosecution's scienter arguments.

3. Inadequate Representation: While Plaintiffs share some interests, they cannot adequately represent Intervenor's unique needs because their FOIA requests, while overlapping, lack Intervenor's urgent trial deadline. Furthermore, Plaintiffs have no mechanism to compel production of materials specifically relevant to *U.S. v. Marino*.

B. Permissive Intervention Under Rule 24(b)(1)(B)

Intervenor satisfies permissive intervention standards because:

1. Intervenor's claims share common questions of law and fact with the main action, particularly regarding:

- a. The propriety of agencies withholding algorithm-related documents;
- b. The public interest in disclosing healthcare enforcement methodologies;
- c. Constitutional implications of secret evidence in criminal cases.

2. Intervention would promote judicial economy by consolidating related challenges to agency FOIA practices.

C. The Requested Materials Are Critical to a Fair Criminal Trial

1. *Brady v. Maryland* and *Giglio* Require Production of Exculpatory and Impeachment Material

2. The Proprietary Nature of These Systems Conceals Potential Exculpatory Data.
3. Intervenor has a right to challenge Defendants' algorithms false positive rate, margin of error, or alternative interpretations of the data which are currently hidden, including its validity. For example a "high-risk" score may be skewed by legitimate medical needs (e.g., cancer pain), but without access to confidence intervals or training data, the Intervenor cannot demonstrate this.
4. *Brady* requires disclosure of all material that could undermine the government's criminal case, including algorithmic biases or errors.
 - a. Exculpatory Value of Error Rates and Confidence Intervals
Under *Brady v. Maryland*, 373 U.S. 83 (1963), the Government must disclose material favorable to the defense. Knowledge of an algorithm's false-positive rate, confidence intervals, or population-norm deviations may show that a particular "red-flag" was statistically insignificant or within expected variation—information critical to a criminal defendant's rebuttal.
 - b. Impeachment Material Under *Giglio*
Any internal critiques of the algorithm (e.g., known biases, failure-mode reports, conflicting expert opinions) are impeachment materials that must be disclosed under *Giglio v. United States*, 405 U.S. 150 (1972). Without disclosure, the defense cannot effectively challenge the credibility of the Government's "evidence."
5. Defendants must disclose exculpatory evidence about algorithm error rates.

(*United States v. Bagley*, 473 U.S. 667 (1985))
6. Defendants must disclose impeachment material regarding prosecution experts. (*Giglio v. United States*, 405 U.S. 150 (1972))
7. Defendants must disclose evidence of investigative bias. (*United States v. Starusko*, 729 F.2d 256 (3d Cir. 1984))

The FOIA documents requested by Intervenor Marino also constitute compulsory and timely materials denied to physician criminal defendants nationwide violating the due process of criminal trials particularly against physicians. See *United States v Presser*, 844 f 2d 1275, 1283 (6th Circuit 1988). Furthermore, Fed R Crim P 16(a)(1)(E)(i-iii) mandates disclosure of compulsory and timely materials “in time for its effective use at trial.” The Supreme Court has defined impeachment material as ‘evidence favorable to an accused...so that, if disclosed and used effectively, it may make the difference between conviction and acquittal.’ *United States v Bagley*, 473 U.S. [667], 105 S.Ct. 3375, 3380 [87 L.Ed.2d481](1985). Impeachment evidence need not be exculpatory in the traditional sense of tending to negate guilt. Rather, such material deals with the credibility of witnesses. The Third Circuit stated in *Higgs*, 713 F.2d 39 (3rd Cir. 1983), and also in *United States v Starusko*, 729 F.2d 256 (3rd Cir. 1984), that it believes the *Brady* Doctrine is not violated if *Brady* material is disclosed in time for its “effective” use at trial. See *Starusko*, 729 F.2d at 262; *Higgs*, 713 F.2d at 44. In *Starusko*, however, the Third Circuit did indicate that in its view, there may be special circumstances when the *Brady* doctrine may require the disclosure of Jencks Act material before trial. In the Third Circuit’s view, the situation could arise when the Jencks’s Act material truly is exculpatory of the charge against the defendant. See *Starusko*, 729 F.2d 262-265. The court implied however, that the

Brady doctrine may require pre-trial disclosure in such a situation because of the due process foundation of the doctrine, that is, that it is fundamentally unfair of the prosecution to withhold from the defendant until trial, material which seemingly does prove innocence and therefore, which could obviate the need for a trial altogether. The Third Circuit noted that a prosecutor who withholds such material most likely violates professional ethical canons. However, the court did not state that it was establishing the rule that if exculpatory material is disclosed in time for use at trial, but that the material could have been disclosed earlier, a violation of constitutional law has occurred.

D. The Sixth Amendment's Confrontation Clause Compels Disclosure

The Government's reliance on algorithmic "risk scores" or "fraud indicators" constitutes hearsay if the underlying methodology is not disclosed. Testimonial evidence must be subject to cross-examination. Under *Crawford*, the criminal defendant has the right to confront the actual basis of the accusation not just a summary output. If the Government cannot produce the developers, statisticians, or data scientists who designed the Government's artificial intelligence models, the evidence is inadmissible. Under *Crawford v. Washington*, 541 U.S. 36 (2004), any "testimonial" statement not subject to cross-examination is inadmissible. A Government risk-score report generated by an computerized algorithm, especially one effectively authored by human designers or "statistical experts" is testimonial,

as it communicates findings intended for use in legal proceedings. Intervenor has a right to confront the Government’s designers, explore their methods, and expose any flaws.

In *Melendez-Diaz v. Massachusetts*, 557 U.S. 305 (2009), and *Bullcoming v. New Mexico*, 564 U.S. 647 (2011), the Court held that forensic lab reports cannot be introduced without the opportunity to cross-examine the scientists who certified them. By parity, any Government algorithmic “certification”, a narcotics risk score or fraud-flag, cannot be introduced unless the Government produces the code, the data sources, the weighting schema, and the error-rate studies so that criminal defense attorneys and/or their experts can cross-examine the Government’s methodology and its reliability. Under *Crawford v. Washington*, 541 U.S. 36 (2004), and *Melendez-Diaz v. Massachusetts*, 557 U.S. 305 (2009), Intervenor cannot properly cross-examine algorithmic “witnesses” without access to the complete codebase and weighting formulas, validation studies and error rates, and documentation of known biases.

E. Due Process Requires FOIA Disclosure of the Defendants’ Algorithms Methodology and Validation

The Fifth Amendment guarantees that no one shall “be deprived of ... liberty ... without due process of law.” A core component of due process is “notice of the evidence against [the defendant]” and an opportunity to test its reliability. In

Moore v. Illinois, 408 U.S. 786 (1972), the Supreme Court held that defendants must have access to “the underlying reasons and data” for scientific evidence if they are to meaningfully confront it. Here, the Government’s reliance on undisclosed red-flag thresholds and undisclosed weightings of computerized indicators deprives criminal defendants of any ability to test their validity, error rate, or applicability to the facts.

Although *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993), governs civil cases, its underlying principle, that expert testimony based on novel methods must be shown reliable reflects due-process values equally critical in criminal trials. A reclaimed “patented” algorithm does not gain automatic credibility; the proponent must demonstrate, through validation studies and known error rates (e.g., confidence intervals), that its results are generally accepted and reliable. Absent production of validation data, the Court cannot perform its gatekeeping function.

Many Government proprietary systems lack independent validation. If the Government refuses to disclose how often their algorithmic systems falsely flags legitimate prescriptions, it cannot be deemed reliable. Transparency is crucial to ensure the fairness and legitimacy of government methodologies, especially those used in the criminal justice system. Hiding the details of how decisions are reached

prevents criminal defendants from exercising their right to due process and defending themselves against potential flaws in the process.

F. Federal Rule of Criminal Procedure 16 Demands Full Inspection

- i. Rule 16(a)(1)(E): Reports of Examinations and Tests.
This provision requires the government to produce, upon request, “any results or reports of ... examinations and tests” in its possession or control. An algorithm’s risk scores are the product of “tests” on prescription, PDMP, ICD, CPT data; its internal datasets, codebase, statistical models, and ontology are therefore discoverable.
- ii. Rule 16(a)(1)(G): Expert Witness Disclosures.
If the government intends to call any person to present the algorithmic results as expert testimony, Rule 16(a)(1)(G) mandates production of “a written summary” of the expert’s opinions, “the bases and reasons for them,” and “the data or other information considered.” Withheld metrics and model specifications constitute precisely the “information considered” and must be disclosed by the Defendants.
- iii. Consequences of Non-Compliance.
Under Rule 16(d)(2), if the government fails to comply, the court “must” order appropriate relief, including excluding the non-compliant evidence.
- iv. Secret evidence violates the Fifth Amendment (*Moore v. Illinois*, 408 U.S. 786 (1972)), particularly when, as here the government relies on patented algorithms (Dr. King’s US 20200143925A1, Exhibit 5).
- v. Criminal defendants cannot test the methodology’s reliability (*Daubert v. Merrell Dow*, 509 U.S. 579 (1993));
- vi. The materials could obviate the need for trial (*Starusko*, 729 F.2d at 262-65).

G. Supporting Legal Precedents: *Williams v. Illinois* and *State v. Loomis*

Due process trumps corporate secrecy. If the state chooses to wield a patented algorithm as a sword in a criminal trial, it cannot simultaneously shield that sword from scrutiny (Citing Brady and Rule 16)

In *Williams v. Illinois*, 567 U.S. 50 (2012), the Supreme Court grappled with whether an expert could rely on a forensic DNA report prepared by a non-testifying analyst without violating the Confrontation Clause. Although the plurality upheld the conviction, the fractured decision highlighted critical due process concerns including the right to cross-examine the underlying data. Justice Alito's plurality opinion suggested that an expert's independent analysis of raw data (rather than mere parroting of a report) might avoid Confrontation Clause issues. However, Justice Thomas's concurrence (decisive in the 4-1-4 split) emphasized that unsworn, un-cross-examined forensic reports are inadmissible unless the defendant can challenge their basis. If the government's algorithmic risk scores rely on undisclosed data or proprietary models, the criminal defense cannot meaningfully cross-examine their validity, rendering them inadmissible under *Williams*. Although the government may argue that algorithmic outputs are merely "basis evidence" for an expert's opinion (not for their truth), as Justice Kagan's dissent warned, this creates an end-run around the Confrontation Clause by allowing untested, machine-generated accusations to sway a jury.

In *State v. Loomis*, 881 N.W.2d 749 (Wis. 2016), the Wisconsin Supreme Court upheld the use of the COMPAS risk assessment tool in sentencing but imposed strict transparency requirements where the court ruled that defendants must be informed of how COMPAS calculates risk scores and be allowed to challenge its scientific validity. The proprietary nature of COMPAS was criticized, yet the court allowed its use only because the defendant received a detailed explanation of its inputs and limitations.

If Defendants DEA and HHS continue to withhold its FOIA documents, algorithms, training data, and/or error rates, it violates *Loomis* core due process principle: "A defendant cannot rebut evidence they do not understand." The *Loomis* court warned that risk algorithms risked "masking human bias" under a veneer of objectivity. If the criminal defense cannot probe whether a system overweights certain factors (e.g., race, zip codes, or past prescriptions), it cannot ensure fairness or due process pursuant to the 5th and 14th Constitutional Amendments.

Under *Williams*, the Government cannot introduce algorithmic outputs unless the defense can cross-examine their creators and inspect their raw data. Under *Loomis*, even if such evidence is admitted, the criminal defense must be given full access to the methodology not just a numerical output. Neither case

permits "trust us, the algorithm is reliable" as a substitute for transparency. "Under *Williams* and *Loomis*, the government's reliance on opaque, proprietary algorithms to establish criminal liability violates the criminal defendant's rights. If the state cannot or will not disclose how its systems calculate 'risk' or 'fraud,' then those systems are indistinguishable from the unfronted lab reports in *Williams* and the criticized 'black box' of COMPAS in *Loomis*. Courts should exclude this machine generated evidence unless the Government provides full discovery via FOIA of its models, data, and error rates underlying its accusations.

VI. CONCLUSION

The Government's use of proprietary, opaque algorithmic systems to establish criminal liability violates the Intervenor's constitutional and procedural rights. Without full transparency, these Government criminal forensic tools function as unaccountable, unchallengeable accusations, precisely the kind of evidence the Confrontation Clause, *Brady*, and Rule 16 were designed to prevent.

Resolving the truth or falsity in this context is a more challenging endeavor, and a criminal conviction cannot lie on the basis of a healthcare professionals' subjective understanding of the regulations alone, in the absence of evidence showing that that interpretation was objectively unreasonable. See *United States of America v. Ron Elfenbein*, CRIMINAL NO. JKB-22-0146; See also *United*

States v. Harra 985 F.3d 196 (3d Cir. 2021) which involved ambiguous reporting requirements regarding reporting past due loans. *Id.* at 205–06. The court held that “to prove falsity beyond a reasonable doubt” in the context of an ambiguous reporting requirement, “the Government must prove either that its interpretation of the reporting requirement is the only objectively reasonable interpretation or that the defendant’s statement was also false under the alternative, objectively reasonable interpretation.” *Id.* at 204. In so doing, the court rejected the government’s argument that “the Government’s burden as to falsity is simply to prove that a defendant understood an ambiguous reporting requirement to mean what the Government says it means and, in light of that meaning, intended to lie.” *Id.* at 211. “In the false statement context, because falsity and knowledge are distinct elements, this means the Government must prove a statement was false beyond a reasonable doubt, regardless of the defendant’s subjective intent to lie.” *Id.* The court explained that it was “guided by [a] due process principle: the requirement that potential defendants be given ‘fair warning’ of what conduct could give rise to criminal liability” and that such principles “apply with equal force when a defendant is criminally charged as a result of noncompliance with agency regulations or guidance.” *Id.* at 212–13.

The Court should exclude such evidence unless the Government provides complete discovery of the underlying metrics and methodologies. The indictments

in this case against Intervenor Marino (*U.S. v. Marino*, Case Number 4:19-cr-00602 (TX SD)) asserts, inter alia, that Intervenor Marino illegally prescribed and distributed various commonly “abused” opioids. Intervenor Marino, acquitted on both illegally prescribing charges as of April 2024, endured a vindictive superseding indictment of 4 additional illegally prescribing charges as well as the original conspiracy charge which previously resulted in a hung jury. Trial is now set for June 16, 2025 and the prosecutorial witness is known to use the same or similar algorithms to fraudulently prove guilt or innocence of indicted physicians as are utilized by the DEA, Qlarant and BCBS in cooperation with the HHS/OIG. Intervenor Marino is presumed innocent for the second time and has elevated status to obtain FOIA information from the Defendants and Government for impeachment purposes. The outcome of criminal proceedings for Intervenor Marino would be different without the release of the information and documents from Defendants as requested by Intervenor Marino via FOIA. The refusal of the Defendants/OIP to release the information would lead to a finding of cumulative error. The Defendants/OIP’s denial of release of the documents requested in an expedited rolling process will be prejudicial to Intervenor Marino in her upcoming second criminal trial *United States v. Marino*. In this case, the failure of Defendants/ OIP to release the requested FOIA information will reduce the chance of Intervenor Marino to defend each element of the charged crime in *United States*

v. Marino. The Defendants/OIP's error and failure to process Intervenor Marino's FOIA requests in an expedited rolling process would not be harmless.

Intervenor Marino makes the instant claim that she must intervene in the current FOIA action to protect her interest in information critical to her in light of the recent legal rulings of the United States Supreme Court, *Xiulu Ruan v United States*, No. 20-1410. Argued March 1, 2022- Decided June 27, 2022, in order to aid her criminal defense in *U.S. v Marino*, Case Number 4:19-cr-00602 (TX SD.) Intervenor Marino is requesting a waiver of all search and duplication fees, since the purpose of this Intervenor's FOIA request is simply to advance the public interest and for her criminal defense. Intervenor's first trial resulted in acquittal on illegally prescribing charges but a hung jury on the conspiracy charge. It is Intervenor's strong belief that the USDOJ, DEA, HHS, OIG and OIP all egregiously withheld the information she requested and that had the information been available, the outcome of the trial would have gone completely in Intervenor's favor. It is crucial for Intervenor to receive these documents ahead of her trial on June 16, 2025.

Because the Government refuses to disclose their patented algorithms' inner workings, metrics, thresholds, confidence intervals, ontologies, validation studies, and related impeachment material it denies criminal defendants due process,

violates the Confrontation Clause, breaches *Brady/Giglio* obligations, and flouts Rule 16. This Honorable Court should therefore (a) compel complete disclosure of all underlying Government data, code, and validation materials; and (b) exclude any algorithm-generated evidence for which the Government cannot justify full and constitutionally required disclosure.

RELIEF REQUESTED

Intervenor respectfully requests that the Court:

1. Grant Intervention under both Rule 24(a) and 24(b);
2. Order Expedited Production of all requested FOIA materials on a rolling basis, including:
 - c) Complete algorithmic methodologies used in the Pill Mill Doctor Project;
 - c) All Qlarant Corporation contracts and deliverables;
 - c) BCBS reports to HHS-OIG regarding prescribing patterns.
3. Waive Fees under 5 U.S.C. § 552(a)(4)(A)(iii), as the requests are made in the public interest and for criminal defense purposes;
4. Provide Judicial Oversight to prevent further agency obstruction, including:
 - c) Requiring *Vaughn* indices for withheld documents;
 - c) Setting strict production deadlines before June 16, 2025 trial date;
 - c) Retaining jurisdiction to resolve disputes.
5. Hold an evidentiary hearing to evaluate Defendants' and Dr. Timothy King's methodologies.

Respectfully Submitted,

/s/ *Barbara Marino*

Barbara Doyle Marino

5/21/2025

Date

Appendix A of Government Patents' References (Legend)

1. NarxCare (Narcotics Use Indicator System)

- Patent No.: US 8,688,477 B1
- Title: Method, System, and Computer Program Product for Determining a Narcotics Use Indicator
- Assignee: National Association of Boards of Pharmacy
- Key Features:
 - Generates a numerical "risk score" for prescription drug misuse based on patient history.
 - Compares individual prescription patterns to population data using weighted metrics (e.g., morphine equivalents, prescriber counts).
- Relevance:
 - Used to flag "high-risk" patients or prescribers.
 - Opaque weighting algorithms and lack of disclosed error rates violate Daubert and Brady .

2. Opioid + Device Combination (Biometric Dispenser System)

- Patent No.: JP 2019-513504 A
- Title: Opioid + Device Combination Products with Improved Safety and Efficacy Profiles
- Assignee: Valentine, Edmund L.
- Key Features:
 - Integrates biometric authentication (e.g., fingerprint scans) with opioid dispensers.

- Tracks patient compliance via mobile app and centralized data system.
- Relevance:
- Used to prove "diversion" or non-compliance.
- Conceals false rejection rates and fails to distinguish between intentional misuse and technical errors.

3. Medical Record Copy-Paste Detection (Medical Documentation Fraud)

- Patent No.: WO 2015/167852 A1
- Title: Identification and Analysis of Copied and Pasted Passages in Medical Documents
- Assignee: 3M Company
- Key Features:
- Assigns "risk levels" to copied content based on similarity thresholds.
- Relevance:
- Cited in fraud cases to allege fraudulent documentation.
- Undisclosed similarity thresholds and lack of peer review violate FRE 702 .

4. Healthcare Fraud Detection (Palantir System)

- Patent No.: GB 2514239 A
- Title: System for Detecting Health Care Fraud
- Assignee: Palantir Technologies Inc.
- Key Features:
- Graphs relationships between providers, patients, and pharmacies.
- Flags "suspicious" patterns (e.g., outlier prescription volumes).

- Relevance:
- Used to allege conspiracy or fraudulent billing.
- Proprietary graph algorithms prevent scrutiny of bias or false positives, violating *Loomis*.

5. Forensic System for Controlled Substances (Dr. Timothy King's Method)

- Patent No.: US 2020/0143925 A1
- Title: Forensic System and Method for Detecting Fraud, Abuse, and Diversion in the Prescriptive Use of Controlled Substances
- Inventor: Timothy Earl King
- Key Features:
 - Manual scoring system for compliance with clinical standards (e.g., ✓/X ratings).
 - Color-coded timelines of prescription and medical record data.
- Relevance:
 - Used in criminal trials to allege "non-legitimate" prescribing.
 - Subjective scoring criteria and lack of validation studies violate *Daubert*.

Appendix B of Relevant Testimony By Dr. Timothy King

(United States v. Anand; Exhibit 14)

Dr. Timothy King's Testimony Concerning Government Recruitment; Page 700

BY MR. REYNOLDS:

Q. And how long is it that you've been testifying for the Government in cases such as this?

BY Dr. Timothy King:

A. I was approached approximately 15 years ago to assist in reviewing cases with regard to opioid prescribing.

Q. And fair to say you get paid for that; correct?

A. Correct.

Q. And you get paid pretty handsomely; correct?

A. Yes.

Q. And how much are you going to make on this particular case?

A. I'm not sure what you mean, how much am I going to make.

Q. How much are you going to be paid by the Government?

A. Well, I'm getting paid \$6,000 a day for testimony for my time in court.

Dr. Timothy King's Testimony Concerning DEA Publications; Page 728-729

BY Dr. Timothy King:

A. I would say they're a standard of care. The consensus amongst all those publications is such that a doctor would be outside the standard of care if a physical exam of some sort were not performed.

BY MR. REYNOLDS:

Q. Standard of care. That's a term that's used a lot in civil cases, isn't it?

A. I don't participate in civil cases except infrequently, so I would have no opinion on that.

Q. You have no knowledge of it either?

A. No, I have knowledge of it.

Q. You do have knowledge of it?

A. Yes.

Q. And my statement was correct, wasn't it?

A. It is correct, yes.

Q. Does the DEA, the Drug Enforcement Administration, require a physical examination every time a patient comes in to get an opioid?

A. What did you say, the DEA?

Q. DEA, Drug Enforcement Administration.

A. I don't --

Q. That you know, if you know.

A. I'm reviewing in my mind DEA publications. To my mind --you're asking me to go through a lot of publications in my mind, and my memory isn't that good. So I can't answer that as specifically as you might like.

Dr. Timothy King's Testimony Concerning Medical Records; Page 738-739

BY Dr. Timothy King:

A. And for a physician to document that. And, again, in answer to your question, all my information came from what was documented in the medical chart.

BY MR. REYNOLDS:

Q. And you would agree there's limitations to that; correct?

A. I'm not sure what limitations you're referring to. The medical chart is supposed to represent the complete and thorough history of the patient such that an outside observer will be able to garner a complete picture.

Q. But you really can't, can you?

A. Oh, I think you can.

Q. But you don't get to talk to the person?

A. No, but that's not necessarily the same thing.

Q. You don't get to look them in the eye as you're manipulating their shoulder and you see a little wince in their face, do you?

A. Well, that's an attorney speaking. You're --

Q. Well, I am an attorney.

A. I realize that. But although it's important for me and helpful when I can talk to a patient face-to-face, when I'm done with that interaction, I have to document the pertinent diagnostic observations in the chart so it will support ultimately what my diagnosis and treatment plan is. The chart is where the story is expected to be told in its fullness, such that an outside observer or a consultant can understand what the patient's condition is, diagnosis and rationale for treatment.

Dr. Timothy King's Testimony Stating Map Is the Terrain; Page 757

BY Dr. Timothy King:

A. Well, that's an attorney speaking. You're --

BY MR. REYNOLDS:

Q. Well, I am an attorney.

BY Dr. Timothy King:

A. I realize that. But although it's important for me and helpful when I can talk to a patient face-to-face, when I'm done with that interaction, I have to document the pertinent diagnostic observations in the chart so it will support ultimately what my diagnosis and treatment plan is. The chart is where the story is expected to be told in its fullness, such that an outside observer or a consultant can understand what the patient's condition is, diagnosis and rationale for treatment.

Dr. Timothy King's Testimony Stating That Medical Records Were Cherry Picked Based on Government Metrics; Page 758

BY MR. REYNOLDS:

Q. The Government chose them; right?

BY Dr. Timothy King:

A. Correct.

Q. Did you ever ask them for more patients to review?

A. No.

Q. Just took what you had and went with that; correct?

A. They appeared to be fairly consistent in terms of what I was looking for. And I saw no reason or indication that they were unique. So the ones that were chosen appeared to be adequate.

Q. Any concerns that it was the Government who decided what evidence for you to review?

A. I had no concerns, no.

Dr. Timothy King's Testimony On His Making Millions of Dollars From the Government; Page 2222

BY MS. GRASSO:

Q. And you've testified for the Government approximately 38 to 40 times previously; right?

BY Dr. Timothy King:

A. Over the course of many years, correct.

Q. Right. Over -- your relationship in terms of being consultant, if you will, for the Government, has been over the course of 15 years?

A. I have consulted with the Government that would be approximately correct, yes.

Q. And over the course of those 15 years, your total compensation would be into the millions of dollars if we added it all up; is that correct?

A. I have not added it up. I wouldn't want to estimate. But it's a matter of record. Whatever it is, it is.

Dr. Timothy King's Testimony on Creation of Forensic Chronology; Page 2223-2227

BY MS. GRASSO:

Q. And in this case you were provided 14 patient files and reviewed those along with the PDMP data as well; correct?

BY Dr. Timothy King:

A. Correct.

Q. And you've done that obviously before in those roughly 38 to 40 other cases; correct?

A. Correct.

Q. And you developed a system for sort of working on these cases and getting to the point where you are today rendering an opinion; right?

A. That's correct.

Q. And the system includes the forensic chronology; is that right?

A. The forensic chronology is one of the work -- well, it's not a work product. It's what I refer to as my notes. So it's the foundational way I organize and format my review and put it into a bound volume. And that's what we refer to as the forensic chronology.

Q. Okay. And so there's a forensic chronology in this case for each of the 14 patients; correct?

A. Correct.

Q. And the forensic chronology is an overview of the patient medical records and the PDMP data that you receive from the Government; correct?

A. It's my notes, correct.

Q. And you don't create the forensic chronology yourself, do you?

A. No, I do.

Q. Okay.

A. I do it in coordination with my team, but I'm the one who overviews it at the end and then adds probably the last 50 percent or so to it.

Q. Okay. So some of the data that's inputted into that forensic chronology is done by your team; is that right?

A. Some of the data from the medical chart is put into an Excel spreadsheet. That's the portion that they do.

Q. Okay. And that's fairly tedious; correct?

A. Yes.

Q. And because -- for example, for one of the patients that you reviewed, the files are close to 800, maybe 900 pages roughly; correct?

A. Correct.

Q. So somebody has to go through all of those and gather the data; correct?

A. Correct.

Q. And part of your team includes your wife and your daughter; correct?

A. Correct.

Q. And they are paid for their -- they're compensated as well as part of your package of consulting with the Government; correct?

A. They're registered nurses, yes, and they're paid for their time.

Q. Great. And the system that you developed that includes the forensic chronology, that is what you tried to get patented; is that correct?

A. A form of it. The -- a form of it. Not in its entirety.

The actual patent was a little more inclusive than what we're forensic chronology is done by your team; is that right?

A. Some of the data from the medical chart is put into an Excel spreadsheet. That's the portion that they do.

Q. Okay. And that's fairly tedious; correct?

A. Yes.

Q. And because -- for example, for one of the patients that you reviewed, the files are close to 800, maybe 900 pages roughly; correct?

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Q. And they are paid for their -- they're compensated as well as part of your package of consulting with the Government; correct?

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A. They're registered nurses, yes, and they're paid for their time.

Q. Great. And the system that you developed that includes the forensic chronology, that is what you tried to get patented; is that correct?

A. A form of it. The -- a form of it. Not in its entirety.

The actual patent was a little more inclusive than what we're use my exhibit number. And if we could -- I think it's already been shown to the jury if we could publish it to the jury. The first page --

THE COURT: It's not been shown. It's been used for impeachment.

MS. GRASSO: Okay. I'm sorry.

BY MS. GRASSO:

Q. So the -- you would agree with me that's the first page of the patent application; correct?

A. If you represent it as such. It's been many years since I've looked at it.

Q. And it does say in the highlighted portion the applicant is Timothy Earl King; correct?

A. Correct.

Q. And that's you?

A. Correct.

Dr. Timothy King's Testimony Concerning Expert Opinion; Page 2228-2232

BY MS. GRASSO:

Q. And it's a reference to "Too many times practitioners are willing to provide opinions for hire." And that's a practice --

MR. BODAPATI: Objection, Your Honor. Again, counsel is just reading the document into the record.

THE COURT: Finish it and let me ask you -- you ask the question and then we'll go to sidebar.

Q. It indicates that too many times practitioners, that means -- referring to medical practitioners; right?

BY Dr. Timothy King:

A. Correct.

Q. And that they're too willing to provide opinions for hire; correct?

A. That's what it reads.

Q. Right. And that an opinion for hire degrades the efforts to support the justice system in a credible and professional and helpful manner; correct?

A. That's what it says, correct.

Q. Okay. And so part of the reason that this application, the patent application that you submitted, was to sort of you believed your way of providing the forensic chronologies and the method by which you come to an opinion would prevent the opinions for hire and people just -- medical practitioners just testifying for money; correct?

A. Again, counselor, this is a little bit out of context. What we're talking about here -- and I'd have to read the whole thing to be totally accurate on this, but the concern here was that when professional or second opinions from other experts, myself and other people, were put forth, there was a lack -- there's a lack of uniformity. There's a lack of methodology. In the legal system it's referred to as a - - sometimes as a Daubert challenge, to define the methodology. So when I first began this process and was approached many, many years ago on it, it was important to me to define what is the appropriate way to document the medical aspects of a review. And that's what led to the forensic chronology. And it was based on universal precautions, which we've talked about several times. And it was based on definitions put forth by a state government in terms of what defines the practice of medicine. So the forensic chronology, when you refer to it as my approach, really is a compilation of various points put forth in the peer-reviewed literature and by statute with the various states, so that there would be, in my opinion, a uniform approach to evaluating a case with regard to whether controlled

substances were prescribed for a legitimate medical purpose and within the usual course of medical practice.

Q. So, basically, you took the method that you have so that you could -- it would be uniform, and then you would sell it, so that other doctors could testify using your methodology, so to speak; correct?

A. Well, Part A -- I'm sorry. Part A is correct. I wanted to put together a uniformity -- a uniform format that could be used and applied to anyone who wanted to use it. And, indeed, I made it available to anyone who wanted to use it, other colleagues, insurance companies, and various Government agencies. The fact that you say that -- so we could sell it, no, I've never sold it. That was --

Q. Because you abandoned the patent; correct?

A. Well, there never was an intent to sell it. I wanted to formalize the approach and the formatting. I thought that was valuable in and of its own right, as a contribution to the legitimate process of evaluating controlled substance prescribing.

Q. Right. And you said that there's a concern about opinions for hire. That's what that paragraph references; correct?

A. It references the fact that there is not a uniformity in terms of approach to the overprescribing issue. And this was an attempt to look at the peer-reviewed literature, the statutes that were out there, and to try to provide some uniformity, correct.

Q. Okay. But you are here today giving an opinion and you're being paid by the Government; correct?

A. That is correct.

Q. And you've done that 38 to 40 times before.

THE COURT: All right. That's been asked and answered.

MS. GRASSO: Okay. I'll move on.

BY MS. GRASSO:

Q. You also -- if I could turn your attention to the second column in the patent application that's before you. If you could read that paragraph, if you will, to yourself.

A. Okay.

Q. And, again, this is from your application that you would have signed; correct?

A. Right. This is a statement my background --

THE COURT: Wait for the question.

THE WITNESS: Yes, sir.

BY MS. GRASSO:

Q. It says "he aids." The "he" is you; correct?

A. Correct.

Q. And it says that you aid in the criminal prosecution of pill mills and --

MR. BODAPATI: Your Honor, objection to just reading the document into the record.

THE COURT: Go ahead and finish the question. You can go ahead and answer.

BY MS. GRASSO:

Q. It says that you aid in the criminal prosecution of pill mills and overprescribing practitioners; correct?

A. In the sense that I evaluate the data that's presented to me.

Dr. Timothy King's Testimony on Cherry Picking Page 2235-2236

BY MS. GRASSO:

Q. Now, you told us earlier, I believe it was on cross-examination from Mr. Reynolds, that the 14 patients were fairly consistent in terms of what you were

looking for and you saw no reason or indication that they were unique and the ones that were chosen appeared to be adequate. That was your testimony on cross-examination?

BY Dr. Timothy King:

A. I'm sorry, I didn't hear what you said. They appeared to be what?

Q. They appeared to be fairly consistent in terms of what I was looking for and I saw no reason or indication that they were unique, so the ones that were chosen appeared to be adequate.

Q. So -- but, generally speaking, you were satisfied with the 14 patients in terms of what you were looking for and that it was adequate; correct?

A. It was adequate in the sense of there was enough information documented that I could formulate an objective opinion.

Dr. Timothy King's Electronic Health Records Testimony; Page 2246-2249

BY MS. GRASSO:

Q. Okay. I want to ask a few questions if I can to change the subject a little bit to the electronic medical records. I think it's been made very clear that they're pretty much universally accepted and they're almost pretty much required in the practice of medicine these days; correct?

BY Dr. Timothy King:

A. The second part is correct. They're pretty much universally required. Universally accepted, they have not evolved to the state that we would like them to be.

Q. And you use them in your practice; correct?

A. Correct.

Q. And I think you mentioned in cross-examination there are several medical companies that you've consulted with and they all have different standards of reproducing the electronic records indifferent options, if you will; is that right?

A. Well, simply put, they are different products.

Q. And is it fair so say then that the physician who runs the practice can pick the product; correct?

A. Correct.

Q. And the physician who runs the practice, they can work with the software company, if you will, to sort of tailor the medical records software to their practice; right?

A. We like to think that happens. It has not been my experience that that's a reality.

Q. Well, I would assume that a podiatrist has a different type of system than a gynecologist. They might have the same program, but it's formatted differently; right?

A. I would expect that to be. I haven't looked at podiatry or gynecology EMRs.

Q. But just knowing what you know about electronic medical records in your course of practicing medicine, you would know that they would have to have something different because they're different specialties; right?

A. Well, they're different specialties, but the practice of medicine still has a certain uniformity and has certain categories that have to be documented with patient interaction, regardless of what the specialty is.

Q. Okay. And some of those selections -- the selections that are on these electronic medical records are -- they utilize drop-down menus; correct?

A. Very frequently, correct.

Q. Okay. And the drop-down menus limit the choices; correct?

A. Which is one of the problematic issues with EMRs, which is why there's always a section there where the doctor can add additional information by dictation or typing in.

Q. And that would depend on the software as to whether or not a certain person is permitted to add additional information or not; correct?

A. That's fairly uniform throughout all the ones that I've seen, that there's the ability to add ad hoc information that may not be available or clarified with the drop-down options.

Q. Okay. And -- but there are certain programs that prohibit users, if you will, once they're in a particular medical practice, from a particular user from being able to add or subtract things from the medical record; correct?

A. There is a requirement for a doctor to -- we would refer to it as E-sign the entry when the doctor perceives the entry is complete. There's generally -- there's -- as far as I know, there's always the ability to go back and add something. But for purposes of tracking, if something were added, it would be a separate entry and notated in terms of time and date. So there could be a trail, as it were, of any modifications.

Q. Okay. And all of the 14 patients' files that you examined in this case, they were e-filed by a licensed physician; correct?

A. My recollection is they were. I'd have to go back and look specifically to answer that question 100 percent.

Q. But off the top of your head, you can't think of any particular patient where the file was not electronically signed by a licensed physician?

A. Nothing off the top of my head, correct.

Q. And you saw signed photographs of prescriptions in the documents for each of the 14 patient files; correct?

A. Correct.

Dr. Timothy King's Patent Testimony; Page 2272-2291

BY MR. HETZNECKER:

Q. Well, let's talk about your credibility as a witness. You've testified about the social psychological impact on your assessments; correct?

BY Dr. Timothy King:

A. I'm not sure of your question.

Q. Well, psychosocial impact as a potential area of examination for possible risks for a patient for opioid use; correct?

A. The way I would phrase that is that the biopsychosocial approach to chronic pain management is standardized and understood to be required for evaluation of both risk and treatment options.

Q. You're not a psychologist, are you?

A. No, sir.

Q. You're not a psychiatrist, are you?

A. No.

Q. You're not a sociologist, are you?

A. Correct.

Q. And yet in your patent application you presented, through your lawyers -- by the way, I want to be clear about this. The patent application, is it yours or is it your lawyers?

A. Lawyers wrote it, I signed it.

Q. So you adopted everything that was in it?

A. Well, I signed it.

Q. No, no. No, no. You adopted -- just like you did your report in this case -- everything that was in it; correct?

A. Well, to the extent that I signed it and let them proceed with it, I gave them permission to do so.

Q. You gave them permission because you agree when you signed off on it in 2019 -- and specifically the application was October 29th, 2019; correct?

A. Correct.

Q. Pending through May 7th, 2020. That was the publication date of your patent pending; correct?

A. I assume you're representing that correctly.

Q. It's on the front page of it. You've looked at it; correct?

A. Correct.

Q. And you've looked at it overnight since you were asked about it yesterday, have you not?

A. No, I did not study up on it.

Q. You did not study it. So when was the last time you looked at this patent application?

A. When it was presented to me yesterday I guess it was, or today I guess it was.

Q. Prior to that?

A. Years. When I withdrew it, that was the last time I reviewed it.

Q. So when you withdrew it -- when was that? Was that two years ago? Three years ago? When was that?

A. Something on that order.

Q. Let's be clear about this. You signed something, you adopted something that you didn't necessarily agree with. Is that what you're telling this jury?

A. I eventually came to disagree with --

Q. Yes or no. Yes or no. Did you -- are you telling this jury that you signed a federal patent application that you did not agree with certain statements in there? It's a yes or no answer. You can -- they can ask you on redirect if you want to elucidate. Yes or no.

A. Yes.

Q. So there are things in that patent application that are, according to you, inaccurate; correct?

A. Correct.

Q. False; correct?

A. Well, there are some that are inaccurate. I think I've answered that. Q. False; correct?

A. Inaccurate.

Q. Fabrication; correct?

A. Inaccurate.

Q. I want you to answer my question.

THE COURT: Wait. He answered it. He answered your questions. You want a conclusion that you can argue to the jury, the conclusion they can draw. He's answering inaccurate.

MR. HETZNECKER: Very well.

THE COURT: If you want to ask him why do you consider it inaccurate, you can. I suspect you're not going to ask him that. So go ahead and --

MR. HETZNECKER: Well, no, no, no.

BY MR. HETZNECKER:

Q. I'll ask you this: Did you represent in the patent that individuals who did not follow recommendations to exercise that were overweight, to stop smoking, are individual patients that possibly, because of this risk factor, this biosocial risk factor, should not be in receipt of opioids to alleviate their pain?

A. Not in that context, no.

Q. So is it your position that people who do not follow the directions of their doctor when they're asked to exercise and they don't, when they're asked to secede from smoking and they don't, when they're asked to reduce their weight and they don't, are you saying that you didn't represent in the patent that those individuals should or should not receive opioids?

A. I don't recall saying it that way, no.

Q. Well, how do you recall saying it?

A. To the extent that multidisciplinary approaches of treatment options are required for treatment of chronic pain, we always want to start with the safest and the ones that will be associated with the least adverse effects. Each individual is going to be uniquely evaluated and diagnosed and will be given what is appropriate for that individual. Keeping in mind that there's a biopsychosocial set of components that define each of us, so each individual will get what they need. But I said nothing about contingency in terms of who would or would not get opiates based on what they did or didn't do.

Q. But if a prescriber ignored the biosocial factor, as you've described it, then prescribing opioids would be against medical necessity according to your opinion; is that right?

A. You've mixed a lot of terms there, counselor, that don't make sense to me.

Q. Why don't we do -- why don't we make it make sense..Let's go to Page 11. If we can expand that a little bit. This is your patent application. If we go to the front

page, Mr. Reed, just to show Dr. King what this is. Do you see the patent application, the front page?

A. I do.

Q. It says, "United States Patent Application Publication"; correct?

A. Correct.

Q. Underneath it has your name, King; is that right?

A. Correct.

Q. And it says -- has a publication number; is that correct?

A. Correct.

Q. And "Published date: May 7, 2020."

A. Correct.

Q. And then underneath that, "Filed: October 29, 2019."

A. Correct.

Q. So this is the patent application that you've discussed that you say is not accurate; is that correct? That you signed off on as inaccurate; is that correct?

A. It is the one that I have stated is inaccurate, correct.

Q. Can we go to Page 11, Mr. Reed. I want you to look at the highlighted portion towards the bottom of the page. If we could expand that. Now, Mr. Reynolds read to you the first portion of this particular paragraph yesterday. I want you to look down further. Did you represent that in your patent application as an accurate part of your application?

A. Give me a moment. I'm just reading through it.

Q. Sure. Take your time.

A. If we could go to the top of the next page, please?

Q. Yes, yes.

A. Okay. Your question?

Q. My question is, is this the part that's inaccurate or is this accurate?

A. This is accurate.

Q. So let's go to the bottom of the Page 11. The first part of the highlighted portion, Mr. Reed. So in this, what you say is that, "Preadolescent individuals who have undergone any kind of abuse, sexual, emotional, or physical abuse are statistically prone to develop addiction to multiple substances, drugs, alcohol, nicotine"; is that right?

A. And that is correct, yes.

Q. You didn't cite any studies in this patent application, did you?

A. It was not required. That was not part of the context here of the application.

Q. No, it's not required because it's not a peer-reviewed article; is that right?

A. Correct. It is not a peer-reviewed article.

Q. And, in fact, you have no peer-reviewed articles on painmanagement published, do you?

A. That is correct.

Q. You've never submitted one, you've never written one?

A. Correct.

Q. So this is written by the lawyers; correct?

A. Correct.

Q. With your assistance?

A. Correct.

Q. And here you're saying that, likewise, recognizing that divorce, family dysfunction interactions, adult abuse, either on the male or female side, are social factors that would contribute to the proclivity for addiction as a way to cope; is that right?

A. And those are standard and well understood in peer-reviewed risk factors, that is --

Q. So anybody with a divorce, anybody that has what you've described here -- or what your lawyers have written and you've adopted -- described as adult abuse, would be considered a biosocial factor -- risk factor that might lead to the proclivity to abuse opioids; correct?

A. The social part of the biopsychosocial bottle requires that all these things be considered and be considered individually with each patient.

Q. But you're not a doctor --

THE COURT: Let him finish, please.

MR. HETZNECKER: Sure. THE WITNESS: Some of these --

THE COURT: What do you mean, "sure"?

MR. HETZNECKER: Oh, I'm sorry. Absolutely. I was responding to him, not to you. I apologize.

THE COURT: Go ahead.

THE WITNESS: Some of these issues are recognized as part of their daily life but are not a component of something that would lead individually to us having addiction or abuse, but would nevertheless be factors that would need to be considered by a prudent physician who is considering an opioid or a similar type of psychoactive drug.

BY MR. HETZNECKER:

Q. "The prescribing doctor should be expected to consider the biosocial issues of a patient as part of their foundational workup. If it is determined that the prescribing doctor has ignored or not considered the biosocial issues of a patient yet went ahead and prescribed the controlled substance, or they have prescribed the controlled substance despite knowing that the biosocial issues are present, then the prescribing doctor should be scored as one who did not prescribe the medications for a legitimate medical purpose"; is that correct?

A. That's correct.

Q. So biosocial factors such as divorce, family dysfunction, those individuals, if evaluated by the doctor, and still they want to prescribe medication because the person is in pain because of a car accident, because of some other physical matter, according to this, you should not prescribe opioids to alleviate pain to that patient; correct?

A. No, incorrect.

Q. If we go to Page 12. Want you to look at the paragraph that's in highlight. Do you see that?

A. It's --

Q. I'm sorry. Do you see it now?

A. Okay, so give me a chance to review it?

Q. Sure. Take your time.

A. Okay. I have read it.

Q. You've read it. Inaccurate?

A. It's -- within the context here, it is accurate.

Q. So the context is this: "Alternative conservative treatment options might include weight loss, cessation of smoking, improvement of eating habits, aerobic exercise, physical therapy, acupuncture. Appropriate treatment options should be considered

before starting chronic opioid therapy. According to the method herein, one looks to see if the treatment plan has been looked at from a more conservative stance" --

MR. BODAPATI: Your Honor --

THE COURT: Overruled. Go ahead.

BY MR. HETZNECKER: Q. -- "more conservative stance to begin with and then expanded as necessary depending upon how the patient responded and cooperated." That's your adopted statement; correct?

A. Correct.

Q. "Then this becomes an iterative process. If the patient, for instance, has not been cooperating with the treatment plan, for example, has not lost weight, continues to eat unhealthily and nothing has changed in their habits, et cetera, then it is not appropriate for the doctor to prescribe narcotics." Is that your statement in that patent application?

A. To the extent that narcotics may not be appropriate if the patient's not consistent with the recommended schedule. Again, Counselor, I would urge and you would understand this, that it has to be taken in a specific patient context. Not each individual is going to be the same and each one is going to require a separate analysis.

Q. Of course. And in this particular statement in your patent application it doesn't talk about the extreme pain or chronic pain that a patient might be suffering even if they haven't lost weight, even if they didn't stop smoking, even if they are eating unhealthily, according to the prescriber who's making those judgments; is that right?

A. Opiates have not been shown to be effective for chronic pain. Q. My question to you is, it's the judgment of the prescriber, according to your patent application, that decides what's healthy, what's unhealthy, whether a person should stop smoking. And then because of that, if they don't follow the doctor's regimen, they don't get the opioids to alleviate pain.

A. No, sir. You're taking it out of context. The patent was a methodology to examine the whole patient, all the risk factors, the biological, the psychological, and the social picture. And according to the results from that evaluation, then a decision could be made as to whether opiates were appropriate.

Q. You're board certified in pain management, not in psychiatry, not in psychology, not in any other field. Pain management; correct?

A. Pain management includes the multidisciplinary approach of psychiatry. It was in fact --

Q. But you don't --

THE COURT: Just let him finish.

MR. HETZNECKER: Yes, Your Honor.

THE WITNESS: Psychiatry was a major part of our board exams.

BY MR. HETZNECKER:

Q. You are not a psychiatrist and you are not board certified in psychiatry, are you?

A. No, I'm not.

Q. So when you talk about pain management in the context of the individual patient who is describing to you, as the patients have on the witness stand in this case, they're describing to you the pain that they suffer walking in with walkers and other devices to assist them, people assisting them to the door, those patients who are suffering real pain, according to your patent application, you would have to reserve judgment on whether to issue opioids if, in fact, they didn't stop eating unhealthily, didn't stop smoking or didn't stop one of your particular psychosocial biosocial factors; correct?

A. It's not my biopsychosocial factors. Those are the peer-reviewed requirements that are necessary to evaluate a patient for any kind of therapy, including opioids. Secondly, the opioids have not been shown to be effective for treatment of chronic pain but are associated with significant harms. And then, thirdly, with regard to

the biopsychosocial approach, psycho is both the psychology and the psychiatry. So even though you harp on the fact that I'm not a psychiatrist, which is true, nevertheless, that was a large foundational part of our pain management training. And ignoring that, as in the case of Dr. Anand's patients here, has contributed significantly overall to the opioid crisis that --

MR. HETZNECKER: Objection, Judge. Nonresponsive.

THE COURT: He's being responsive. So go ahead

BY MR. HETZNECKER:

Q. Go ahead. Are you done?

A. Yes, sir.

Q. All right. But the patent application was not based on any peer-reviewed articles. You did not submit any peer-reviewed articles in the body of this patent application, did you?

A. Part A is incorrect.

Q. Yes or no?

A. Part B is correct. I did not submit any because they were not required.

Q. Because this --

A. But to the extent that I reviewed very carefully, as I've said many times, to come up with this formatting or the review process that is in here and presented, yes, I'm very proud that I put together a lot of background, reviewed peer-reviewed articles, statutes and generally understood the white papers from our pain management organizations to put together this process of evaluation.

Q. So proud that you wanted to make money on it; correct?

A. No, sir. That was not a part of it and that has not been put forth as a contingency on this.

Q. Well, that's the purpose of the patent. The purpose of the patent -- it is a product. It's a package. You put together a rubric that you've described in detail and you've packaged that and you said, I'm going to submit a patent so that anybody who uses this rubric will owe you a royalty. Isn't that the purpose of the patent, sir?

A. You may think that way --

THE COURT: Hold on a second. Answer the question. Please don't point.

MR. HETZNECKER: I'm sorry.

THE COURT: Answer the question.

THE WITNESS: Yes, no. That is not the purpose. And although you may interpret it as such, the reason I put it together was for the ability to submit something that could be used by any individuals, recognizing that there is a concern regarding how experts in the field of pain management might interpret a record to come to a conclusion. My goal was to present a methodology that could be used across the board based on a wide spectrum of peer review of the statutory requirements. And I made it available to many agencies. And, no, sir, dollars were not a part of that.

BY MR. HETZNECKER:

Q. Any individual doctor or expert or anyone who used the patent, if it had been approved, would owe you a royalty; correct?

A. That was not the intent --

Q. Yes or no?

THE COURT: That's a yes or no.

BY MR. HETZNECKER: Q. Yes or no?

A. So rephrase it, please.

Q. Very easy. Anybody that uses -- if this had been approved, anybody that used the patent would owe you a royalty; correct?

A. No. They would have required my permission.

Q. And if you didn't get the permission, they would owe you a royalty; correct?

A. Well, you keep combining -- you keep taking this back to royalty. I have -- I offered this, even during the application process pending, or I forget exactly how it was phrased, but while this was pending, I allowed other individuals to use it. And, no, sir, there were no royalties required.

Q. You just -- you had other individuals use it before and because the patent was never approved; correct?

A. It was in process.

Q. So let's talk about the way you've described how you prepared the patient charts briefly. I know you have your notes up there, the chronologies; is that correct?

A. Correct.

Q. And the chronologies you prepared; is that correct?

A. Yes, correct.

Q. But 50 percent -- I think you said a few minutes ago, 50 percent of what was prepared was by other people; is that right?

A. From an hours invested standpoint, typically, yes.

Q. Because it would take hours to go through these patient files. They're 6-, 700 pages, are they not?

A. Correct.

Q. And so it would take someone hours and hours to go through these 600 or 700 pages of files to distill all the information down for you to then review from the Excel spreadsheets; correct?

A. I reviewed the original charts as well.

Q. You reviewed the 700 pages on each and every one of these 14 files? You individually looked at every page. Is that your testimony?

A. That is correct.

Q. So when you looked at them, you did not distill any of the information. You had others do that on an Excel sheet. That's what you testified to about an hour ago; correct?

A. Very much like a paralegal might work with an attorney, I have the nurses go through and organize them. Typically what occurs is these files are jumbled. They are not in chronological order. They are confused and there's a lot of organizational detail lacking. So one of the main jobs of the nurses is to put it together from an organizational standpoint, to integrate the PDMP data, the drugs prescribed, such that ultimately we could put together an Excel spreadsheet that told the chronological story, here is how the patient presented, here is how they proceeded, here were the drugs that they got along the way, such that the entire story could be told in a coherent manner. The nurses assisted with the organization, but I also went through each page of the medical charts. And then I invested considerable hours thereafter to analyze and put forth an opinion.

Q. And compared it against the PDMP reports; correct?

A. I'm sorry, the --

Q. I'm sorry. Compared them against the PDMP reports; correct?

A. Well, no. The PDMP drug results were integrated in that. The chronology here integrates the drugs prescribed, as well as what happened clinically with the patient.

Q. And who did that integration of the drug reports?

A. My team did. In terms of the spreadsheet, they integrated it. I secured the data, reviewed the data, and then they did the integration into the spreadsheet.

Q. And then you signed off and adopted it; correct?

A. That is correct.

Q. So if there are any mistakes in the PDMP reports or in the review of the documents by your assistants, you've adopted those mistakes by signing off on the reports; correct?

A. Well, the data I verified as being correct as I received it from the Government. And then we just simply put it into an Excel format. And then I double checked it to make sure that the key parts were there and then I signed off on it. That is correct.

Q. So if there are any -- my question again: If there are any mistakes made, you've adopted those mistakes by signing off on the work that was done by others; correct?

A. In terms of my team, that is correct.

Q. And not only in terms of the team, but in terms of the PDMP reports as well?

A. Well, the PDMP, as I indicated, was presented to me by the Government. So I reviewed that, accepted that as appropriate and complete, and went forward with that assurance.

Q. So if there were mistakes made by whoever entered the information in the PDMP, the drug reports, whether they were the druggist or the people who were submitting those drugs into the reports, those mistakes you adopted as well; correct?

A. I didn't adopt those. Those would be -- if there were issues with regard to the way the PDMP was put together, and that's put together individually by the state, generally through the Department of Pharmacy. If they made mistakes in that, but represented it to me as correct, I would take it at face value and go forth at that point. I did not own any mistakes they may have made in terms of putting it together.

Q. There have been a number of questions posed to you by the Government, as well as my cocounsel on cross-examination regarding the videos. I want to ask you

this again. You viewed the entire videos, both of them, from November 6th and December 4th; correct? A. That is correct.

Q. Start to finish?

A. Yes.

Q. If we can go to the November 6th video, Mr. Reed. This is 601. (Playing the video.)

BY MR. HETZNECKER: Q. So here is a statement by Special Agent McDonald saying that recorders, multiple recorders, were being provided to the confidential human source, Ms. Rodriguez, focusing on Dr. Anand and others unknown. You heard that; right?

A. Correct.

Appendix C Mathematics and Artificial Intelligence Companies That Are Members of the Healthcare Fraud Preventive Partnership (HFPP)

Market Summary > Elevance Health Inc

413.25 USD

+ Follow

+397.92 (2,595.69%) ↑ all time

Oct 30, 12:17 PM EDT • Disclaimer

1D | 5D | 1M | 6M | YTD | 1Y | 5Y | Max



Open	410.62	Mkt cap	95.22B	CDP score	B
High	415.10	P/E ratio	-	52-wk high	567.26
Low	409.42	Div yield	-	52-wk low	397.98

Market Summary > UnitedHealth Group Inc

565.98 USD

+ Follow

+565.84 (404,171.43%) ↑ all time

Oct 30, 12:17 PM EDT • Disclaimer

1D 5D 1M 6M YTD 1Y 5Y Max



Open	561.25	Mkt cap	523.01B	CDP score	B
High	570.31	P/E ratio	36.80	52-wk high	608.63
Low	560.95	Div yield	1.48%	52-wk low	436.38

Market Summary > Cigna Group

314.78 USD

+ Follow

+310.43 (7,136.32%) ↑ all time

Oct 30, 12:19 PM EDT • Disclaimer

1D 5D 1M 6M YTD 1Y 5Y Max



Open	308.00	Mkt cap	88.30B	CDP score	B
High	316.05	P/E ratio	24.75	52-wk high	370.82
Low	308.00	Div yield	1.78%	52-wk low	253.95

Market Summary > Humana Inc

266.29 USD

+ Follow

+258.54 (3,336.00%) ↑ all time

Oct 30, 12:19 PM EDT • Disclaimer

1D 5D 1M 6M YTD 1Y 5Y Max



Open	260.00	Mkt cap	32.25B	CDP score	B-
High	273.28	P/E ratio	18.98	52-wk high	527.18
Low	259.82	Div yield	1.33%	52-wk low	213.31

CERTIFICATE OF SERVICE

Barbara Doyle Marino hereby certifies that on the date set forth below, a copy of the foregoing was filed with the clerk of courts. Notice of this filing will be sent to all parties by email or by regular mail.

Douglas C. Dreier, Esquire

Assistant United States Attorney for District of Columbia

555 4th Street, N.W.

Washington D.C. 20530

Tel: (202) 252-2551/ (202) 725-4614 (office cell)

Email: Douglas.Dreier@usdoj.gov

/s/ *Barbara Marino*

Barbara Doyle Marino

5/21/2025

Date