No. 20-7831

ORIGINAL

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SUPREME COURT, U.S.

IN THE

SUPREME COURT OF THE UNITED STATES

Lena Lasher — PETITIONER
(Your Name)

vs.

United States of America — RESPONDENT(S)

ON PETITION FOR A WRIT OF CERTIORARI TO

United States Court of Appeals for the Second Circuit
(NAME OF COURT THAT LAST RULED ON MERITS OF YOUR CASE)

PETITION FOR WRIT OF CERTIORARI

Lena Lasher
(Your Name)

16 Patton St
(Address)

High Bridge NJ 08829
(City, State, Zip Code)

908-447-4484
(Phone Number)

QUESTIONS PRESENTED

I. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the District Court's violation of **EX POST FACTO Clause law**?

II. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the District Court's violation of:

A. The **CONTROLLED SUBSTANCES ACT (CSA)** and

B. The legal definition of the word "**DRUG**" which is found in The Food, Drug, and Cosmetics Act and referred to in the Controlled Substances Act.

III. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the **Flaw in the defective indictment and lack of physical evidence?**

LIST OF PARTIES

[√] All parties appear in the caption of the case on the cover page.

[ ] All parties **do not** appear in the caption of the case on the cover page. A list of all parties to the proceeding in the court whose judgment is the subject of this petition is as follows:

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IN THE

SUPREME COURT OF THE UNITED STATES

PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully prays that a writ of certiorari issue to review the judgment below.

OPINIONS BELOW

[√] For cases from **federal courts**:

The opinion of the United States court of appeals appears at Appendix A to the petition and is

[ ] reported at _____; or,
[ ] has been designated for publication but is not yet reported; or,
[√] is unpublished.

The opinion of the United States district court appears at Appendix _____ to the petition and is

[ ] reported at _____; or,
[ ] has been designated for publication but is not yet reported; or,
[ ] is unpublished.

[ ] For cases from **state courts**:

The opinion of the highest state court to review the merits appears at Appendix _____ to the petition and is

[ ] reported at _____; or,
[ ] has been designated for publication but is not yet reported; or,
[ ] is unpublished.

The opinion of the _____ court appears at Appendix _____ to the petition and is

[ ] reported at _____; or,
[ ] has been designated for publication but is not yet reported; or,
[ ] is unpublished.

JURISDICTION

[√] For cases from **federal courts**:

The date on which the United States Court of Appeals decided my case was 1|15|2020.

[ ] No petition for rehearing was timely filed in my case.

[√] A timely petition for rehearing was denied by the United States Court of Appeals on the following date: 6|15|2020, and a copy of the order denying rehearing appears at Appendix B.

[√] An extension of time to file the petition for a writ of certiorari was granted to and including 4|12|2021 (date) on 2|11|2021 (date) in Application No. USC A 2 06.18-2693

The jurisdiction of this Court is invoked under 28 U. S. C. § 1254(1).

[ ] For cases from **state courts**:

The date on which the highest state court decided my case was _____. A copy of that decision appears at Appendix _____.

[ ] A timely petition for rehearing was thereafter denied on the following date: _____, and a copy of the order denying rehearing appears at Appendix _____.

[ ] An extension of time to file the petition for a writ of certiorari was granted to and including _____ (date) on _____ (date) in Application No. ___A_____.

The jurisdiction of this Court is invoked under 28 U. S. C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

EX POST FACTO Clause law

"Both federal and state governments are prohibited from enacting *ex post facto* laws, and the Court applies the same analysis whether the law in question is a federal or a state enactment. When these prohibitions were adopted as part of the original Constitution, many persons understood the term *ex post facto* laws to "embrace all retrospective laws, or laws governing or controlling past transactions, whether . . . of a civil or a criminal nature." But in the early case of *Calder v. Bull*, the Supreme Court decided that the phrase, as used in the Constitution, was a term of art that applied only to penal and criminal statutes. But, although it is inapplicable to retroactive legislation of any other kind, the constitutional prohibition may not be evaded by giving a civil form to a measure that is essentially criminal. Every law that makes criminal an act that was innocent when done, or that inflicts a greater punishment than the law annexed to the crime when committed, is an *ex post facto* law within the prohibition of the Constitution. A prosecution under a temporary statute that was extended before the date originally set for its expiration does not offend this provision even though it is instituted subsequent to the extension of the statute's duration for a violation committed prior thereto. Because this provision does not apply to crimes committed outside the jurisdiction of the United States against the laws of a foreign country, it is immaterial in extradition proceedings whether the foreign law is *ex post facto* or not."

Title V Section 5

5 U.S. Code § 553. Rule making

(b) General notice of proposed rule making shall be published in the Federal Register... The notice shall include—
(1) a statement of the time, place, and nature of public rule making proceedings;
(2) reference to the legal authority under which the rule is proposed; and
(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved...
(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When **rules** are **required by statute to be made on the record** after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.
(d) The required publication or service of a substantive rule shall be made **not less than 30 days before its effective date**

Controlled Substances Act (CSA) 811(a), (b), and (c) (See Exh J):

Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e), the Attorney General may by rule—
(1) add to such a schedule or transfer between such schedules any drug or other substance if he—
(A) finds that such drug or other substance has a potential for abuse, and
(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or
(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.
Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rule making procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances
The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:
(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S. Code § 812 - Schedules of controlled substances

(a) Establishment
There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.[1]

(b) Placement on schedules; findings required Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows: ...

The law continues, laying out the findings required for each schedule, V, then IV, and we present the required findings for III, which is where **Judge Buchwald ILLEGALLY** placed **Fioricet**, absent of any findings for it, which **she then renamed "Butalbital" to conceal her act.**

(3) Schedule III.—
(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.
(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

The CSA clearly states,

(b) UNLESS specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

In this case, **FIORICET is exempted from scheduling as per the exempted prescription products list (See Exh F)**

In the SUPREME COURT of the UNITED STATES

Appeal No. 18-2693(L), 19-1343 (CON), 19-3914(CON)

LENA LASHER, Appellee

v.

UNITED STATES OF AMERICA, Defendant-Appellant

Petition for a Writ of Certiorari so that Plaintiff may bring this case back to the District Court for a Certificate of Appealability

STATEMENT OF THE CASE

Plaintiff Lena Lasher submits this motion for Certificate of Appealability, which was unconstitutional denied by the District Court on 8/20/18 (See Exh A), to prevent manifest injustice, as a result of ineffectiveness of counsels (Roger Stavis, Esq.. and Louis Freeman, Esq.), error of law, judicial violation of the **EX POST FACTO Clause law** and **Controlled Substances Act,** jury verdict unsupported by facts, trial Court's lacks of jurisdiction as well as abusive of its discretion, and prosecutorial misconduct, including fraud, perjuries, and the suppression/withheld of exculpatory evidence, including but not limited to video recordings, a Brady Violation. Most importantly, the Plaintiff was, and still is, a **victim of IDENTITY THEFT** and a **victim of a HATE CRIME, anti-ASIAN Racism.**

In the District Court's recent 8/20/18 memorandum and order, stating that the Plaintiff dispensed OPIOIDS (and barbiturates) via the internet (8/20/18 Memorandum and Order page 2 and 4). However, there was **no evidence** the Plaintiff dispensed OPIOIDS or controlled substances barbiturates via the internet of "her pharmacies" (page 5), **because she didn't**. Also, the pharmacies were not "hers".

This is an appeal by the Plaintiff in a case involving her alleged dispensing a drug, butalbital, a scheduled III controlled substance. **However**, "butalbital", the drug the Plaintiff was indicted, charged, and convicted of dispensing, **NEVER existed in the pharmacies**, and proof of same was withheld from the jury **because it was never stocked in the pharmacy she was in**, as per the pharmacy paper trail. It is easy to tell if Butalbital is being worked with, because it ships as a **powder, not as tablet** which the prosecution claimed,

and is only used in compounding pharmacies, not typical retail pharmacies. Because **fatal defects are jurisdictional,** they can be raised at any time—at trial, on appeal, or post-conviction—and can **never be waived.**

"An **indictment** or a count thereof is **defective** within the meaning of paragraph (a) of subdivision one of section Section 210.20 Motion to dismiss indictment Criminal Procedure (CPL) when:...

2. The allegations demonstrate that the court does not have jurisdiction of the offense charged; or

3. The statute defining the offense charged is unconstitutional or otherwise invalid."

It is also a well-established principle of statutory interpretation that to determine the meaning of a term, one must first ask whether the term has a plain and unambiguous meaning DaSilva v. Attorney General United States, 948 F.3d 629 (3rd Cir. 2020) citing Dobrek v. Phelan, 419 F.3d 259, 263 (3rd Cir. 2005). If the statutory language is unambiguous, the inquiry ends because courts must presume that Congress 'says in a statute what it means and means in a statute what it says there." Da Silva, at 635. In determining whether language is unambiguous, we "read the statute in its ordinary and natural sense." Id.

BACKGROUND

1. The Plaintiff was arrested on November 29, 2012, indicted under the Controlled Substances Act as part of an alleged "narcotics conspiracy", but the indictment used was **defective** and **intentionally misleading**. The most obvious defect is that **Tramadol**, one of the two drugs named in this alleged conspiracy, was **not a controlled substance at the time of dispensing**, clearly a judicial violation of the **EX POST FACTO Clause law.** Tramadol became a Controlled Substance under federal law on August 18th, 2014, **21 months AFTER the Plaintiff's indictment/ARREST** (See Exh E)

2. The indictment also named the drug Butalbital; but this was a deception committed by the prosecutors against the Grand Jury, the district court, and the Plaintiff because the drug in question that was dispensed was Fioricet, not Butalbital. There was never any Butalbital dispensed by any of the pharmacies in question. During the pretrial phase this fact was well established and all sides acknowledged that the drug in question was indeed Fioricet, a **NON controlled drug** (08212014 Buchwald Memorandum and Order).

A. butalbital is not synonymous with Fioricet, a **medication** with three different components.

B. butalbital is **not** Fioricet *See, e.g.*, State v. LePage, __ N.C. App. __, 693 S.E.2d 157 (2010) (indictments identifying the controlled substance as defective).

Butalbital is clearly not the same drug nor an analog, nor has the same strength, indication, or even in the same drug category or classification as Fioricet. They are 2 different drugs for 2 different treatments and **neither are** in the **pain med** category. Fioricet and Butalbital are **not** interchangeable drug names. Fioricet is indicated for tension headache while butalbital is indicated for insomnia. Fioricet as a fixed combination drug is manufactured such that it has no potential for abuse, containing **Butalbital** 50mg, **Acetaminophen** 325mg, and **caffeine** 40mg. Butalbital is not the same drug as Fioricet because in its raw state, Butalbital has a potential for abuse. When incorporated in Fioricet that potential for abuse is eliminated. Long before a patient could be addictive to Fioricet, he would be hospitalized for liver toxicity from the **acetaminophen** (over the counter generic "**Tylenol**") in the same way he would if he abused **over the counter Tylenol** because **Tylenol**'s active ingredient is **acetaminophen**.

One might ask, how does the inclusion of Acetaminophen eliminate the potential for abuse? Taking too much Acetaminophen, be it in Tylenol or Fioricet, will hospitalize someone for liver damage. This will happen long before any potential for abuse manifests itself. They will not abuse or even become addicted to Fioricet, the potential for abuse in Butalbital will not be a factor at all in Fioricet. Fioricet is a fixed-combination drug formulated to eliminate a potential for abuse. The Attorney General has **not** made any findings that show Fioricet has a potential for abuse because it has none. **This is the key to it all!**

To reiterate, because of this lack of a potential for abuse, Fioricet does not meet the criteria for a controlled substance under federal law as set forth under the Controlled Substances Act Subchapters 881 (a), 811 (b), 811 (c), 812 (b) (3) (A), or 812 (b) (3) (C). In particular, it does not meet the criteria that specifies that the findings that cause a drug to be a controlled substance under federal law must "be made on the record after opportunity for a hearing pursuant to the rule making procedures prescribed by subchapter II of Chapter 5 of Title 5."

In summation, the references to Butalbital in the indictment and at trial is false and misleading. It was **NEVER** in the possession of the pharmacies, never stocked by the pharmacies, and never distributed to the pharmacies by a distributor or manufacturer. Instead **NON controlled** drugs were intentionally referred to by the **wrong drug name** and represented to the jury as controlled substances or "highly addictive pain meds". This bait-and-switch of a drug's name for the name of one of its components causes the indictment to be a

defective indictment. The changing of the drugs name was **intentional, deceptive**, and indicative of judicial bias.

Further, the suppressed video recordings showed the Plaintiff never handled nor dispensed "butalbital tablet"; the Plaintiff was not working nor present at the pharmacies where the alleged crimes supposedly took place on the days of the alleged criminal activity. The suppressed video recording will confirm that "butalbital tablet" was not stocked at the pharmacies, and the conviction of the plaintiff was ultimately for a**NON-controlled drug, Fioricet**. "Butalbital tablet" does **not** exist and is not manufactured by manufacturer.

C. Fioricet is not, and never has been, placed on a list of controlled medications by the Attorney General, the only person with the authority to do so, in the nearly 50 years since the Controlled Substances Act was passed.

D. Fioricet is NOT a controlled medication and therefore does not require a valid prescription. DC District Court U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016), Court of Appeals 8th Circuit US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016, Court of appeals 3rd Circuit US v. Elias Karkalas,US District court of Minnesota 13-273 (SRN/JJK) 12/22/15,

E. It is a well-established principle of statutory interpretation that to determine the meaning of a term, one must first ask whether the term has a plain and unambiguous meaning DaSilva v. Attorney General United States, 948 F.3d 629 (3rd Cir. 2020) citing Dobrek v. Phelan, 419 F.3d 259, 263 (3rd Cir. 2005). If the statutory language is unambiguous, the inquiry ends because courts must presume that Congress 'says in a statute what it means and means in a statute what it says there." Da Silva, at 635. In determining whether language is unambiguous, we "read the statute in its ordinary and natural sense." Id.

The actual language of the Controlled Substances Act, which the **court was apparently not made aware of by the prosecutor, supports the Plaintiff's position.**

See ***§ 811. Authority and criteria for classification of substances.....***

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary [of Health and Human Services] a scientific and 9

medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

Judges do not asses drugs BY LAW, and it is not a judicial act to ignore the fact that it is the **Attorney General's job**, and no one else, to assess drugs for scheduling. To reiterate, the ***courts have <u>no jurisdiction</u> over the FDA and HHS, and may not "interpret" the meaning of the plain language of the CSA (Controlled Substances Act), which governs the controlled scheduling of a medication; only Congress can modify the law.***

Further, there was no evidence of any wrong doing of the Plaintiff at her trial, especially in light of the fact that the Government called Fioricet by the wrong name to make her appear guilty. Instead people confessed their own alleged crimes but blamed the Plaintiff for their actions as if the laws regulating pharmacy make it clear we, as pharmacists, are responsible for our own professional conduct.

The legal definition of "**Drug**", as provided in 21 US Code Section 321 (g) (1). The relevant portions are as follows:

> The term "**drug**" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the10

structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).
A component of a drug may be another drug, but in such cases it is **just a component** and **not the drug.**

The **Controlled Substance Act is clear that it regulates drugs as drugs, not drugs based on components.**

The law treats drugs as drugs, not as their components, because the properties of each drug are not the same as that of its components, including their potentials for abuse.

A drug that is made up of multiple components, some of which may be drugs on their own in their raw state, may be considered a **"fixed-combination drug"** as described under Title 21 Chapter I Subchapter Part 300 Subpart B 300.50. The relevant section is as follows:

"(a) Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. Special cases of this general rule are where a component is added:
(1) To enhance the safety or effectiveness of the principle active components; and
(2) To minimize the potential for abuse of the principal active component."

Fioricet is a fixed-combination drug. The definition for Fixed-Combination Drug also allows for a drug to be made up of other drugs, but it does not make the new drug subordinate in name nor law nor anything else to its components. A drug may be, and just is in the case of a Fixed-Combination Drug, a combination of multiple drugs, but that does not eliminate the distinction under the law, and in reality, between the drug and its components. **To declare that Fioricet is Butalbital because it contains Butalbital requires legislative acts, not judicial acts.** Similarly, **to declare that Fioricet is caffeine or acetaminophen (Generic "TYLENOL") because it contains both caffeine and acetaminophen also requires legislative acts, not judicial acts.**

Faulty Syllogism – Please see Exh D "butalbital" - **NON scheduled**

Dr. House: Words have set meanings for a reason. If you see an animal like Bill and you try to play fetch, Bill's going to eat you, because Bill's a bear.

Little Girl: Bill has fur, four legs, and a collar. He's a dog.

Dr. House: You see, that's what's called a **faulty syllogism**; just because you call Bill a dog doesn't mean that he is . . . a dog. ("Merry Little Christmas", House, M.D.)

F. To complete this deception of the Jury, the Prosecutors did not present as evidence any of the prescriptions or medicines received. If the drugs dispensed or the prescriptions were presented as evidence, they would clearly 11

not be Butalbital, but Fioricet. There are brand names and generic names for the drug, but it would never name just one component because that would create confusion. The confusion it would create is three-fold: 1) Butalbital is a controlled substance, Fioricet isn't; 2) Butalbital ships as a powder and is used in manufacturing or in compounding pharmacies, not retail pharmacies, Fioricet at the time only shipped as tablets; and 3) Butalbital, when it was prescribed, was for insomnia, Fioricet is for tension headaches. Fioricet is an old and reliable medicine, and it is common knowledge in the health care professions that it is not a federally controlled substance.

3. AUSA Richenthal presented to the Jury another completely made up standard that has no place in law and held the Plaintiff to this made up standard at trial and at sentencing; AUSA Richenthal **ILLEGALLY** called regular prescription drugs, drugs that we have shown above were not controlled substances and had no known potential for abuse, into a "made-up" category that NO drug has ever been placed in, a category he called "highly addictive pain meds", sometimes calling it "addictive pain meds". These phrases were made up by the executive officials AUSA Richenthal and Greenberg without any facts to back up the invention of these phrases nor any references to scientific, medical, pharmaceutical or pharmacological literature (T.1768). This was done to prejudice and profile the Plaintiff; in fact, NONE of the drugs the Plaintiff dispensed via the "fulfillment" pharmacy were classified as "pain meds" (T.1768), or a controlled substance at the time of dispensing. The use of the word "addictive" itself is problematic. As the American Society of Regional Anesthesia and Pain Medicine provides great resources on the topic. No drugs, not even actual opioid pain meds, are called "addictive"; they have a potential for abuse. The abuse of such drugs may lead to addiction. Addiction is considered a behavior with a wide range of causes and contributing factors. Abuse of medicines with potentials for abuse may lead to addictive behaviors and even addiction. It is this concept of potentials for abuse, and the range of those potentials that are a guiding force behind the Controlled Substances Act: it was never meant to be a playground for overzealous and immature prosecutors to create ways to lock up and shame conscientious professionals.

Let's be honest: There is NO evidence in any of the government's discovery materials that any "butalbital" was dispensed, and the Plaintiff did NOT dispense any butalbital and no pharmacy she ever worked in stocked any butalbital.

To reiterate, the law, the **Controlled Substances Act, does not regulate drugs based on their components**; The definition of **Drug** and of **Fixed Combination Drug** in the law, and the law itself prevents this. The law empowers only the **Attorney General** to make drugs a controlled substance and requires it to be done **on the record**.

4. On September 2, 2016, the Appellate Court wrongfully affirmed Plaintiff's conviction of May 15, 2015 in violation of 18 U.S.C. 371 (Count I); introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 333(a)(2) (Count II); conspiracy to commit mail and wire fraud in violation of 18 U.S.C. 1349 (Count III); and mail and wire fraud in violation of 18 U.S.C. 1341 and 1343 (Counts IV and V). She was sentenced to 36 months' imprisonment, for:

a. dispensing "butalbital" (See Exh D) which **NEVER existed in the pharmacies**,

b. the dispensing of tramadol which was **NOT a controlled substances at the time of dispensing** but the only **misbranding** alleged about Tramadol **is only applicable to controlled substances (Valid Prescription standard)**,

c. the dispensing of "highly addictive pain meds" which is a term that **does not exist in law** nor in the health care industries and used only to deceive the jury by **creating standards that do not exist under the law**, which both the District and Appellate Court failed to mention ONE name of the "highly addictive pain meds" that was dispensed, because there were NONE.

Further, the Plaintiff was ordered forfeiture of $2.5 million when there were no "victim" nor basis for the forfeiture.

Plaintiff now moves for a certificate of appealability to appeal the District Court's unconstitutional denial of her habeas corpus by submitting the attached writ, to affirm her actual innocence. In addition to her actual innocence, the Plaintiff will point out the following:

1. The conviction came about through a deliberate deceit of the jury by presenting a made up legal standards that does not exist under the law and by presenting perjured testimonies to the jury that everyone knew it was perjured testimonies, except for the jury. Without these deceptions, they have no actual physical evidence that would have even associated the Plaintiff with any crime.

2. Judicial's usurpation of Legislative power by the invention of laws to avoid proper application of

the governing pharmacy laws as they exist. The executive officials created a jurisdiction when none exists by treating drugs that are not Federally controlled as controlled substances, and applying the food drug cosmetics act onto the Plaintiff as if it were the "controlled substances act".

INTRODUCTION

The Court denied the Plaintiff's 2255 Motion by FALSELY "holding:

(1) Fioricet is a controlled substance under the Controlled Substances Act despite being subject to certain specific and limited regulatory exemptions;
(2) the indictment adequately alleged that the prescriptions were issued outside a bonafide physician-patient relationship; and
(3) the indictment adequately alleged specific intent."

However:

(1) The Plaintiff was not indicted with the dispensing of Fioricet; she was indicted of dispensing the drug "butalbital".

But if we were to entertain the Court as if the indictment was for the dispensing of the controlled substance "Fioricet", the Court is simply wrong; the Court is wrong when she:

(a). Claimed Fioricet is a controlled substance, a violation of the Controlled Substances Act; the Attorney General has made no findings that Fioricet has a potential for abuse and has **not** made it a controlled substance.

(b). Called Fioricet by the name of one of its components (butalbital); the Court **misnamed/ changed** the drug to **confuse and deceive** the jury and any reading the transcripts, a **violation** of the **Controlled Substances Act,** and thus make the **Indictment defective.** State v. LePage, __ N.C. App. __, 693 S.E.2d 157 (2010) (indictments identifying the controlled substance as defective)

The Prosecutors presented testimony known to be false multiple times during the trial. Multiple **DEA agents testified to receiving the drug "butalbital" even though the drug they were prescribed and received was Fioricet.** As described above, early in the pre-trial phase it was established that the pharmacies never stocked nor dispensed butalbital. It is a very uncommon drug, its use is primarily if not exclusively in manufacturing. **The drug dispensed was Fioricet. To call Fioricet by a different name** or **rename Fioricet by the name of one of its components and then treat Fioricet as if it were a controlled substanceis a lie, intentional deceptive**, and **misrepresenting the material fact of the matter. It also defies the definitions within the law for both Drug and Fixed-Combination Drug.** These agents committed perjury.

(b). Called the drug "highly addictive pain meds" when **such a phrase does not exist** under the law nor in the health care professions in order to avoid the term "controlled substances". Further, Fioricet is not a "highly addictive pain meds"; it is **not even a pain med.**

The **prosecutors made up the phrase "highly addictive pain meds"**, and **used it many times to prejudice and profile the Plaintiff**; the **phrase has absolutely no basis in law nor in the health care fields, nor in pharmacology nor in fields that deal specifically with addiction**. Commonwealth v. Horne 88 Mass. App. Ct. 1109 (2015) Cert granted.

It is important to note that while the District Court acknowledges that Fioricet is "subject(ed) to certain specific and limited regulatory exemptions", she doesn't mention what those are. The brief discussion below about the introduction of Fioricet Capsules gives an indication of what it means especially with regard to these criminal proceedings, where after the new form of the drug had a few months on the market and no pattern of abuse appeared, it meant the manufacturing process for the Fixed Combination Drug that eliminates the potential for abuse was intact and no different than the original form of the drug in tablets, and so that new form was also "no longer regulated as a CIII product"

The aforementioned and below are made extensively in this writ and other motions, but simple put Fioricet is **not on the Controlled Substances List**, the Attorney General has not made any findings nor published any on the recorded which are required for a drug to be made a controlled substance, it has **no potential for abuse**, prescriptions for it are not required to be written on Controlled Substance prescription pads which are regulated differently than regular prescriptions, none of the storage or shipping or recording keeping in any pharmacy for Fioricet is regulated by the Controlled Substances Act. The Judge and the Prosecutors simply ignored most of the law and skipped forward to the scheduling criteria which is **only used once the Attorney General decides to schedule a drug which only after the findings made about the drug show that it is required**. The **law is** easy to read and exceptionally **clear** about all this. The law also provides definitions to make it all that much more clear. This clarity was and still is ignored by the judge, but it is spelled out throughout this writ.

(2)The trial Court incorrectly claimed the Plaintiff violated the **bonafide legal standards for prescriptions**.

The bonafide legal standards for prescriptions **do not apply to this case**, to "normal regular

prescriptions". Pharmacist are not required to ascertain anything regarding the doctor- patient relationship when the prescription is not for a controlled substances (See Exh H); **the doctor's signature on the prescription is their own legal OATH that the prescription is legitimate**. What is clear from the trial transcripts that the two standards were conflated into a " bonafide face to face" standard and presented to the jury as such even though **no such thing exists in the health care professions nor in the law**. The fact remains that the Judge is applying a standard applicable **only to controlled substances, when no controlled substances were dispensed** via the fulfillment pharmacy. It is important to note that no doctor testified at the trial claimed to have written for any controlled substances at all, so whether or not they have a face to face relationship with the patient or deceived the Plaintiff is totally moot; the Plaintiff did nothing wrong.

(3) With regard to the judge's statement about "indictment adequately alleged specific intent", this statement is not supported, because it can't be without exposing the flaws in the indictment. The indictment talks about misbranding drugs introduced into interstate commerce, but pharmacists dispense prescriptions. No prescription was alleged to be misbranded by any one. No evidence of such was provided by anyone. The indictment intentionally conflates an allegation that the Plaintiff did this or that she directed "others" to commit these alleged crimes, but does not name anyone else. Again, no evidence was ever presented to support these allegations other than testimony that can shown to be false. There is nothing of intent in the indictment, there is nothing specific in the indictment.

(4). As discussed, the only misbranding alleged about Tramadol was the implication that the doctors did not have a face to face relationship with their patients.

Tramadol is a **pain reliever just as acetaminophen** (generic for **Tylenol**) **is**; tramadol is **not** a "pain killer" or even a "pain med" which is a phrase commonly used to describe Opioids, and the distinction is a real one as anyone suffering from severe pain and needs a pain med can attest to. "Pain med" is a category of medicine, and those are Schedule II drugs, none of which were dispensed through the fulfillment pharmacy, as no controlled substances on any schedule were dispensed through the fulfillment pharmacy. A**pain reliever is not the same as a pain med**, and the typical potentials for abuse differ similarly for the two.

Tramadol became a controlled substance on August 18th, 2014, **21 months after the Plaintiff's arrest**; when it did, it became a Schedule IV Controlled Substance, a **low potential for abuse as per the**

Controlled Substances Act. Misbranding standard was not applicable to Tramadol in the time covered in the indictment. That fact doesn't really matter to the judge though, she created her own jurisdiction, requiring a "valid" prescription standard which is only found in the Controlled Substances Act for Tramadol just as she did for Fioricet even though the charges did not cite the Controlled Substances Act and even though neither drug is a Controlled Substance. **Neither the Judge nor the prosecutors have explained how they are holding the Plaintiff responsible for the prescription standard for controlled substances for prescriptions dispensed for Tramadol twenty-one (21) months before it became a controlled substance** (Schedule IV - a low potential for abuse as per the law). How they got away with it is clear, **through fake standards placing Tramadol 21 months before the Attorney General did, in violation of the Controlled Substances Act.** "The scope of the indictment goes to the existence of the trial court's subject-matter jurisdiction". Stirone,361 U.S. at 213;Ex parte Bain,121 U.S. At 12-13

Legislation lays down laws or rules. Administration carries those laws into effect. The judicial function is "to carry out the purposes of the statute, not to AMEND it." Miller v. US 79 LEd 977 294 US 435 (1935)."It is not within the power of the Court to "amend the governing pharmacy laws" on the ground that the administrative power conferred on the" State Board of Pharmacy for all pharmacists to abide by. Lambert Run Coal v. Baltimore & Ohio R. Co. 66 LEd 671, 258 US 377 (1922). Judge Buchwald's rulings are indefensible under both the Controlled Substances Act (CSA) and the Food Drug and Cosmetics Act (FDC Act); there is not even a colorable argument supporting Judge Buchwald's unlawful exercise of jurisdiction. The claims of misbranding were supported by no physical evidence, and were presented to the jury in intentionally confusing ways meant to create a conviction out of nothing.

The **judge and the prosecutors** want to have it both ways. They want to pretend they are not using the Controlled Substances Act against the Plaintiff but they also want to use the standards for valid prescriptions only found in the Controlled Substances Act and only applicable to Controlled Substances. What they are doing is **holding the Plaintiff to the Controlled Substances Act's valid prescriptions standards for drugs that are not controlled substances; they did this by confusing the jury and conflating the valid prescriptions standards and the bonafide standards**. The only applicable standards for any of the drugs dispensed through the fulfillment pharmacies is the bonafide standards, and this standards does not require the pharmacists to

access or have any knowledge regarding the doctor-patient relationship. Quite simply: if a face to face relationship between a doctor and a patient is required for a prescription, then that prescription can only be for a controlled substances per the Controlled Substances Act. But very importantly, if the Plaintiff violated this requirement, it would not be in violation of the FDC Act but the Plaintiff did not violate this requirement because NONE of the drugs dispensed via the fulfillment pharmacies were controlled substances. By hiding behind the weasel-words of saying they did not charge the Plaintiff under the Controlled Substances Act they are continuing their deception because that is the standard they applied, and they presented it in an intentionally confusing way to the Jury. They may have not charged the Plaintiff under the Controlled Substances Act in the superceding indictment, the original charges did cite alleged violations of the Controlled Substances Act, even though the drugs named were not controlled substances, Fioricet nor Tramadol.

ARGUMENTS

ARGUMENT I. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the District Court's violation of **EX POST FACTO Clause law**?

The **Plaintiff's conviction came about through a deliberate deceit of the jury by presenting a made up legal standards that does not exist under the law and by presenting perjured testimonies to the jury that everyone knew was perjured testimonies except for the jury.**

If Fioricet is a controlled substance, as the District Court **FALSELY** states (8/20/18 Memorandum and Order page 12) **all the Trial Judge and the Government would have to do and all they should do is point to the Federal Register to show where and when the Attorney General made it a controlled substance. The Judge does not make** an argument as to why Fioricet is, in her view, a controlled substance nor does she make an argument as how or when it became one. She just makes an unsupported and unsubstantiated statement that it is. As shown below, the prosecutors cherry-picked a few lines from section 812 of the Controlled Substances Act that show criteria for scheduling **IF** a drug is found to require scheduling, but they ignore the **requirements** specified within section 812 itself as well as section 811 that specify what findings are required for a drug to be made a controlled substance and the fact that those **findings must be made on the record.** They also ignored the definition of the "**Drug**" and "**Fixed-Combination Drug**" which **prevent the misnaming of Fioricet** that was engaged in in the indictments and during the trial and

the sentencing, and that also prevent the kind of confusion between Fioricet and any of its components. **The deception of the jury over the drugs name that the prosecutors engaged in is a clear violation of the Controlled Substances Act.**

A. EX POST FACTO Clause law

The trial Court falsely states that Fioricet is a controlled substances in denying the Plaintiff her 2255 Motion (Page 1). This is a judicial violation of the **EX POST FACTO Clause law**, an usurpation of administrative power the trial Court does not have. Fioricet is **not** a federally controlled substance, only the Attorney General has the power to make drugs controlled substances, judges do not have the power nor expertise to assess or schedule drugs, a **drug is an entity under the law** not an assemblage of components for a judge to dissect and assess as if it were one of its components, and the **law itself is clear** on all of this both **in the way "drug" and "fixed-combination drug"** is **defined under the law and in** how the **Controlled Substances Act** is written. Further evidence of just how wrong this trial court is on this matter can be found in West Virginia Board of Pharmacy News from September 2014, where they state on page one: **"Fioricet is not federally scheduled"** (W V Vol 34, No. 1, see exhibit B); in other words, the state of West Virginia, (See Exhibit B), stated Fioricet is **NOT a federally controlled substance**. It also stated that there is confusion about the matter. The confusion seems to be that people just do not bother to read the law. For a Drug to be made a controlled substance, there must be a reason such as potential for abuse, the findings for the potential must be ascertained through a process and it must all be done on the record, and it is all done and only done by the **Attorney General**. Drugs are not assessed by judges nor prosecutors, whether that assessment is done by looking at the components or anything else, because they do not have the expertise. If anything this trial has proved it is that they do not have the expertise. Drugs, under the law and in the health care community, are entities unto themselves, as further discussed below. No one regulates a drug simply because of its components, but only if the drug itself requires it. This is ascertained through findings made by the Attorney General, and it is all done on the record as required by the Controlled Substances Act itself. The confusion West Virginia speaks of is a polite way of saying that prosecutors and judges are treating a non-controlled substance as if it were a controlled substance, and innocent people are suffering from their obscene lust to fill prisons with the innocent.

Furthermore:

1. In a case before the 8th Circuit, US Attorney Richard G. Callahan stated **ON THE RECORD** that **Fioricet is a non-controlled medication/drug.** US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016.

2. In a case before the 3rd Circuit, Assistant District Attorney Andrew Demarest, the attorney representing the Commonwealth of Pennsylvania and the State Board of Medicine, in his official capacity, stated **ON THE RECORD** that Fioricet was not a controlled substance. Mot. Hrg..Tr. At 71-72. United States of America vs. Elias Karkalas,US District court of Minnesota 13-273 (SRN/JJK) 12/22/15.

3. The state of West Virginia, (See Exhibit B), stated Fioricet is NOT a federally controlled substance. It also stated that there is confusion about the matter. The confusion seems to be that people just do not bother to read the law. For a Drug to be made a controlled substance, there must be a reason such as potential for abuse, the findings for the potential must be ascertained through a process and it **must all be done on the record**, and it is **all done and only done by the Attorney General**. Drugs are not assessed by judges nor prosecutors, whether that assessment is done by looking at the components or anything else, because they do not have the expertise. If anything this trial has proved it is that they do not have the expertise. **Drugs, under the law** and in the health care community, are **entities unto themselves**, as further discussed below. **No one regulates a drug simply because of its components**, but only if the drug itself requires it. This is ascertained through findings made by the Attorney General, and it is all done on the record as required by the Controlled Substances Act itself. The confusion West Virginia speaks of is a polite way of saying that prosecutors and judges are treating a non-controlled DRUG as if it were a controlled substance, and innocent people are suffering from their obscene lust to fill prisons with the innocent.

4. U.S v TITILAYO AKINTOMIDE AKINYOYENU, Criminal Action No. 15-42 (JEB). "Judge Boasberg of the District of Columbia District Court dismissed an indictment charging the defendant with dispensing Fioricet without an appropriate prescription in U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016), holding that "the Controlled Substances Act authorizes individuals to dispense Fioricet without a prescription." The district court sharply criticized the prosecutor in that case (Appellee Linda Marks) noting that her "plug-and-play legal analysis is not a winning formula," as that court agreed with Defendant that the Controlled Substances Act does indeed authorize distribution of **Fioricet as a NON-controlled medication**."

The simple fact of the matter is that if Fioricet was a controlled substance, Fioricet would belisted on20

the Controlled Substances List (See Exh C) and the announcement scheduling it would be found in the Federal Register. However, **Fioricet is NOT listed on the Controlled Substances List** (See Exh C)

Fioricet was only available in tablet form, and it was not a controlled substance, that it is on the exempted prescription product list actually does not matter, and this seems to have caused "confusion" if we allow the imprisonment of innocent people to be characterized as confusion as opposed to vindictiveness. But, because one of Fioricet's components is a controlled substance, when a capsule form of Fioricet was introduced by manufactures, that form and only that form was made a controlled substance when it first came on to the market. This was done on the record and is easily found, and it only lasted for a brief period of time. Fioricet capsules were regulated as a schedule III controlled substances from July 29, 2013, and once it was realized to be as safe and free of potential for abuse as the original Fioricet TABLET, it was no longer regulated as a CIII product on September 16, 2013. To date, Fioricet is not listed as a controlled substance on the Controlled substance list of July 12, 2018 nor is it regulated as a controlled substances Schedule III. This new form of Fioricet came on the market around 7 months after the Plaintiff's arrest, for charges that alleged violations of the Controlled Substances Act for dispensing Fioricet, which was **deceptively misnamed butalbital** in the indictment, and for dispensing Tramadol but that drug's inclusion in any of this was never explained but it remains true that it was treated as a controlled substance by the judge and the prosecutors not only in these criminal proceedings but also for all the original so-called co-conspirators in the original alleged narcotics conspiracy. The whole thing has been one gigantic usurpation of administrative and legislative power from day one.

The Plaintiff dispensed Fioricet TABLET (See D), but it was **never** regulated as a controlled substance Schedule III. If it were, the judge and Prosecutors could cite something similar to the above reference to the brief amount of time when the Fioricet CAPSULE was first introduced on the market on July 29, 2013, where: that new formula of Fioricet was initially a controlled substance CIII product, but on September 16, 2013 received exempted prescription drug status and is no longer regulated as a CIII product. This event shows the flaws in the prosecution's and the judges arguments over the entire course of these criminal proceedings: it is not on the Controlled Substances list because it is not regulated as one, because it has no potential for abuse. If it did, it would be on the controlled substances list, and when those findings were made BY THE ATTORNEY

GENERAL, it would be found in the Federal Register. When Fioricet capsules was first introduced, the precaution was taken; but once it was established that Fioricet capsules had no potential for abuse, just like Fioricet tablets, it was NO LONGER REGULATED AS A CONTROLLED SUBSTANCE SCHEDULE III.

The only thing backing up the prosecutor's and the judge's argument is an authoritarian 'because I said so' type of argument. If they were so confident about their argument, they would not have lied about the name of the drug dispensed both throughout the trial and at sentencing. Instead of calling it Fioricet, they called it by the name of one of its components, "butalbital", because they want the jury to hear the name of a controlled substance, not the name of a fixed-combination drug whose formula is designed to eliminate the potential for abuse: Fioricet. Their lies point to the truth: they wanted to confuse the jury and anyone reading the transcripts.

The judge and the Prosecution do not understand the requirement in the law that a drug has to have and establishes a potential for abuse in order to be a controlled substance; they don't understand the difference between a drug, as defined by law (Fioricet) and a component (butalbital).

The law is actually very easy to understand. Fioricet is not a controlled substance, and this is spelled out very clearly below where large portions, where nothing relevant is left out, of sections 811 and 812 of the controlled substances act are quoted, along with important definitions that clarify the matter.

There is no dispute that Butalbital, a drug the Plaintiff was indicted with, NEVER existed in the pharmacies and that Tramadol (See Exh E), the other drug named in the indictment, was not a controlled substance at the time of dispensing.

5. The official DEA list of "Controlled Substances By CSA Schedule" dated 9/9/2014 lists Butalbital as CIII with "other names" only given as **Fiorinal** and Butalbital with aspirin". There is **no listing** of **FIORICET**.

6. The Attorney General may, by regulation, **exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter** [Subchapter I - Control and Enforcement] if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

> (A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

The exempt prescription products list, "butalbital, acetaminophen and caffeine" (generic for Fioricet), met the requirement of the aforementioned and therefore placed in the exempt list and is exempt from scheduling (See Exh F)

7. Per NABLEX, as of today, 2.26.2021, **Fioricet remains a NON – controlled drug**.

> The **North American Pharmacist Licensure Examination (NAPLEX)** is administered by the National Association of Boards of Pharmacy (NABP) to assess a pharmacy school graduate's competency and knowledge so that he or she may be licensed to practice. The http://www.pharmacyexam.com web site is an on line **NAPLEX review site** which **gives the following "official" information to pharmacy students**: http://www.pharmacyexam.com/index.cfm/blog/48/fiorinal-is-a-schedule-iii-controlled-drug-but-fioricet-is-not-.cfm **"Fiorinal is a Schedule III controlled drug but Fioricet is not.** **Fioricet contains: 325 mg of acetaminophen (APAP), 50 mg of butalbital, and 40 mg of caffeine. Exceptions from the scheduling have been made if the drug meets the requirements of section 811(g) (3) (A) of the Controlled Substances Act. The exemption requires that one of the active ingredients be a non-narcotic controlled substance and one of the others be a non-scheduled compound. The potential for abuse is decreased if a sufficient amount of a non-controlled substance (e.g., aspirin or acetaminophen) is added. The ratio required for exemption is 70 mg of acetaminophen to 15 mg of butalbital. In contrast, the ratio of aspirin to butalbital is 188 mg to 15 mg.The acetaminophen to butalbital ratio is approximately 97 mg to 15 mg in **Fioricet**, thus **it is exempt from scheduling**. In Fiorinal the aspirin to butalbital ratio is approximately 97 mg to 15 mg, which is less than the 188mg:15mg ratio, so it is classified as a Schedule III substance."

Citation: Section 811(g)(3)(A) Controlled Substances Act

8. Neither the Judge nor the prosecutors have explained how they are holding the Plaintiff responsible for the prescription standard for controlled substances for prescriptions dispensed for **Tramadol 21 months before it became a controlled substance**. How they got away with it is clear, through fake standards placing Tramadol 21 months **before the Attorney General did, in violation of the Controlled Substances Act.** "The scope of the indictment goes to the existence of the trial court's subject-matter jurisdiction". Stirone,361 U.S. at 213;Ex parte Bain,121 U.S. At 12-13

The Plaintiff's case has been one gigantic **judicial violation** of the **EX POST FACTO Clause law** and usurpation of administrative and legislative power from day one.

ARGUMENT II. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the District Court's **VIOLATION** of

A. The **CONTROLLED SUBSTANCES ACT (CSA)** and

B. The legal definition of the word "**DRUG**" which is found in the Food, Drug, and Cosmetics Act and referred to in the Controlled Substances Act?

If a drug is suspected of having a potential for abuse, the Attorney General must make findings to confirm if it does or doesn't. If the Attorney General, after the process is completed, finds the drug should be a controlled substance, the Attorney General will determine what schedule it belongs in, and publish the date it will become a controlled substance so the health care community has fair warning. This fair warning allows doctors and pharmacists to make adjustments needed, especially with regard to alerting their patients and to consider alternatives, if such are desired, to avoid any pitfalls that may be involved for the patients with regard to the newly-established and discovered potential for abuse. This is all spelled out very clearly in sections 811 and 812 of the Controlled Substances Act, that requires that this process occurs on the record and must be in accordance with Title V Section 5, allowing for public notice and fair warning. Also, the definitions under law for the terms "Drug", which is found in the Food, Drug, and Cosmetics Act and referred to in the Controlled Substances Act, both show that a **drug is not judged by its components** but as its own entity, because a drug does not have the same properties that its components have, especially with regard to potential for abuse. By ignoring the definition of the legal terms "**Drug**", the District Court is trying to side-step their errors by calling Fioricet by one of its component name "Butalbital".

1. The **Attorney General has not made Fioricet a controlled substance** and it is not on the controlled substances list; no citation of such an act was ever provided by the judge nor the prosecutors. In order for a DRUG to be made a controlled substance, a very specific and on-the-record process must be initiated by the Attorney General. US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016, US v. Elias Karkalas 13-273 (SRN/JJK) 12/22/15, DC District Court U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016)

Judge Buchwald simply **made "Fioricet" a controlled substance** for the purposes of this prosecution by usurping both legislative and administrative powers. Tramadol went through this process, twice: once by Judge Buchwald usurping administrative power, and once legitimately but very long after the Plaintiff was arrested for violating the controlled substances act for dispensing it via the fulfillment pharmacy. These are simple facts, and in **violation of** 21 U.S. Code § 812 - Schedules of controlled substances **(b) Placement on schedules; findings required**

Fioricet is a drug, and it "may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug." The findings required have nothing to do with just naming

the drug's components, the law is also clear about that. The findings required are set forth the Controlled Substances Act 811(a), (b) and (c):

The first thing worth noticing is that Federal Judges do not decide if a drug is a controlled substance, the **Attorney General does**, after a clearly delineated process that begins in writing from Secretary to the Attorney General. The second thing worth noting is that the first factor (1) under (c) is the potential for abuse, and these factors are to be considered for drugs proposed to be controlled. These factors are part of the recommendation that will include a recommendation as to which schedule the drug is proposed to be placed under.

It is also a **well-established principle of statutory interpretation that to determine the meaning of a term, one must first ask whether the term has a plain and unambiguous meaning** DaSilva v. Attorney General United States, 948 F.3d 629 (3rd Cir. 2020) citing Dobrek v. Phelan, 419 F.3d 259, 263 (3rd Cir. 2005). If the statutory language is unambiguous, the inquiry ends because courts must presume that Congress 'says in a statute what it means and means in a statute what it says there." Da Silva, at 635. In determining whether language is unambiguous, we "read the statute in its ordinary and natural sense." Id. The **Controlled Substance Act is clear that it**

A. **Regulates drugs as drugs, NOT drugs based on components;**

B. Gives the Attorney General and nobody else the ability to make a drug a controlled substance;

C. Requires the Attorney General to make controlled substances on the record

To reiterate, the law is clear that this is all done in writing for the drug being proposed for control and scheduling-- the **drug**, not component-- as per the definitions cited above. Ignoring this and taking the power of scheduling for herself, Judge Buchwald usurps administrative power and violates the Controlled substances Act.

Due to the fact the pharmacies never carried butalbital, whereas at trial the Government switch butalbital, a powder, for Fioricet, a tablet, therefore causing a defective indictment whereby confirming the judicial Court lacked of subject matter jurisdiction over this case. The Indictment must be dismissed as defective since it charges a crime based on the **dispensing of an entirely**

2. Judge Buchwald does not only rename the drug, "butalbital", a component of Fioricet, in order to create jurisdiction over it in her court room, and then usurps Administrative power in placing it in the same category25

as drugs controlled by 812. She also addresses the drug head-on, using the name "butalbital", and in so doing she usurps more power to create jurisdiction for herself under the Controlled Substances Act.

At the June 2014 during oral arguments for the Motion to Dismiss the original indictment, Judge Buchwald also stated that "Fioricet remains a controlled substance despite being an exempted prescription product." MEMORANDUM AND ORDER 08/21/14 Id. Pg. 7-8. In her 8/20/18 Memorandum and Order (Pg. 12) she held that Fioricet was "exempt for administrative purposes only and that Fioricet was nonetheless properly classified as a controlled substance for the purposes of the criminal provisions of the controlled Substances Act. However, this argument failed in that the Plaintiff cannot be prosecuted, as was stated in U.S v **TITILAYO AKINTOMIDE AKINYOYENU**, Criminal Action No. 15-42 (JEB), because the exemption from § 829 constitutes an **authorization to distribute Fioricet without a prescription**.

Most importantly, the law itself shows Judge Buchwald is wrong. It is also clear from reading the law that one can not just read the law to figure out if a drug is a controlled substance or not. **The Legislature writes laws and they did not take the authority of making drugs controlled substances for themselves. Nor do they give it to Judges. They give that authority to the Attorney General** The Attorney General decides if drugs are controlled substances based on very specific findings, and then schedules drugs if the findings made in writing require it. The law is clear that it is no one's job to figure out in a court room if a drug is a controlled substance. A drug is made a controlled substance, or it is not, by the Attorney General. **Fioricet has not been made a controlled substance by the Attorney General.** US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016, US v. Elias Karkalas 13-273 (SRN/JJK) 12/22/15, U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016) **It can not remain something it has never been. So, just as her statements above regarding one of Fioricet's components are wrong, indicative of usurping powers she does not have, and her statement directly addressing Fioricet is also wrong, indicative of usurping powers she does not have, and violations of the Controlled substances Act.**

To reiterate, In renaming Fioricet, Judge Buchwald had to **ignore** the definitions provided in the Controlled Substances Act in 21 U.S. Code § 802 (12), where "Drug" is defined. In a case that involved the controlled substances act, directly in the original charges and covertly by holding the Plaintiff to:

A. The face-to-face doctor-patient standard that is only applicable to controlled substances, none of 26

which were dispensed via the fulfillment pharmacy,

B. An inapplicable standard, requiring a face-to-face requirement where only a bona fide relationship is required, Judge Buchwald ignored the definition "Drug" and thus violated the Controlled Substances Act.

3. The willful ignorance of the law engaged in by the prosecutors and Judge Buchwald, did not have to lead to this miscarriage of justice, if they wanted to follow the law and properly apply the law, because the Administration provides a resource. **The Controlled Substance List created and maintained by the Attorney General of the United States does exactly what its name says it does: IT PROVIDES THE LIST OF CONTROLLED SUBSTANCES. It also indicates alternative names for drugs on it when such names exist.** The list is maintained and published in accordance with the **Controlled Substances Act and Title V section 5 specifically cited in the Controlled Substances Act, as cited above. To find the list of controlled substances promulgated by the Attorney General, one has to simply look to the Federal Register, and to find the list of controlled substances promulgated by the Attorney General that was in effect at the time of the Plaintiff's arrest or at the time the alleged acts were committed, one simply has to look at the Federal Register from the appropriate dates. That is where the scheduling and descheduling of drugs is announced, and fair warning to health care professionals is given, as required by law both in 811 of the Controlled Substances Act and in "the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5" which 811 refers directly to. It shows Judge Buchwald and the Prosecutors violating the Controlled Substances Act.**

4. **Fioricet is not on the list** of the **Controlled Substance List, because the Attorney General has not made it a controlled substance.** Even in the case of drugs listed in the Controlled Substances Act itself, they are made controlled substances and scheduled by the Attorney General and listed on the Controlled Substances List provided by the Attorney General. Fioricet, nor any other brand name or generic name used to identify the drug, is NOT found on the Controlled Substances Act. Butalbital is on the list, and Fioricet is not and it is not listed as an alternative name for it. **Fioricet is not a controlled substance**. US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016, US v. Elias Karkalas 13-273 (SRN/JJK) 12/22/15, U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016)

5. The **Valid Prescription standard** is found in the Controlled Substances Act and is only 27

applicable to Controlled Substances. The Prosecutor is lying, because he did describe the face to face standard to the jury, called it a "bonafide face to face" standard, and even though they dispute the fact that Fioricet is not a controlled substance they were uncertain enough about to use the wrong name for the drug, ignoring the definition of

Drug within the law, and they even applied the standard to Tramadol which nobody disputes was **not a controlled substance at the time of the Indictment.**

There's only one person in the country who decides if a drug is a controlled substance: the Attorney General. Ignoring the law requiring the findings to be on the record, and ignoring Title V section 5, is the only way this conversation can happen.

By using the wrong name for the drug dispensed, the District Court uses the wrong name out of a contempt for the definitions of the word Drug and the phrase Fixed-Combination Drug, as discussed above in violation of the Controlled Substances Act.

6. In fact, the Online Pharmacy Safety Act (S2002) introduced legislation which would have required valid face to face prescriptions for NON controlled substance prescriptions ordered online did **NOT pass** (see Exh H).

The Government also claimed these unnamed and unspecified prescriptions were not valid because there was "no bonafide face-to-face" relationship between a doctor and his patient; but there are two glaring problems with this. Firstly, a "bonafide" relationship is the standard for all prescriptions a doctor writes for a patient, and there a wide range of ways a doctor and patient can have a bonafide relationship. But, a "face-to-face" relationship is only required for Controlled Substances. In order to confuse the jury, the government made up this compound phrase. Secondly, to hold a pharmacist responsible for this without any physical evidence or any specific prescriptions named requires a number of leaps in logic. The Government's claim in this regard is an attempt to shift blame away from the doctors, if there is any genuine blame, shifting the supposed blame to the Plaintiff. There is no formal assessment for a pharmacist to determine whether there is a bonafide relationship between a doctor and his patient, that relationship is between them; there is no established criteria under federal law for a pharmacist to know if the doctor consulted their patients. The signatures on the prescriptions are the doctor's promise to the rest of the health care community and the patients, that the

prescriptions are valid and that their job was done properly. A relationship could in fact exist and be denied at trial, as the doctors testifying at the criminal trial against the Plaintiff in this civil action were only testifying to avoid their own jail time for other crimes. On top of this, the Plaintiff, before filling these fulfillment pharmacy prescriptions, actually required doctors to fill out and submit forms stating that they did phone consult directly with the patients. Evidence of this requirement that went above and beyond the requirements under the law was withheld by the District Court because it was physical evidence that would directly contradict testimony of one of the prosecution's witnesses. (See Exh K)

None of this changes the fact that the Prosecution's and the district court's applying of the face-to-face requirement to non-Controlled Substances is a deception, deceiving the jury that the Controlled Substances Act's requirements for valid prescriptions was meant to be applied to NON – Controlled Substances.

7. **The District Court also presented to the Jury another completely made up standard that has no place in law and held the Plaintiff to this made up standard at trial and at sentencing. This is a wholesale usurpation of Legislative power. The District Court placed regular prescription drugs, drugs that we have shown above were not controlled substances and had no known potential for abuse, into a "made-up" category that NO drug has ever been placed in, a category she called "highly addictive pain meds" sometimes calling it "addictive pain meds". These phrases were made up by the executive officials AUSA Richenthal and Greenberg, who were indulged in this, without any facts to back up the invention of this phrase nor any references to scientific, medical, pharmaceutical or pharmacological literature (T.1768). This was done to prejudice and profile the Plaintiff; in fact, NONE of the drugs the Plaintiff dispensed via the "fulfillment" pharmacy were classified as "pain meds" (T.1768), or a controlled substance at the time of dispensing.** The use of the word "addictive" itself is problematic. As the American Society of Regional Anesthesia and Pain Medicine provides great resources on the topic. No drugs, not even actual opioid pain meds, are called "addictive": they have a potential for abuse. The abuse of such drugs may lead to addiction. Addiction is considered a behavior with a wide range of causes and contributing factors. Abuse of medicines with potentials for abuse may lead to addictive behaviors and even addiction. It is this concept of potentials for abuse, and the range of those potentials that are a guiding force behind the Controlled

Substances Act: it was never meant to be a playground for overzealous and immature prosecutors to create ways to lock up and shame conscientious professionals.

The Legislature created the Controlled Substances Act to regulate drugs that have the potential for abuse. There is no category called "highly addictive pain meds" and the legislature did not create a law governing them. Judge Buchwald usurped Legislative Power by using that made up term that has no basis in law, and presented it to the Jury as if meant something under the law. By usurping legislative power in this way, Judge Buchwald doesn't have to usurp Administrative power to place drugs in her made up category, because its highly likely that, in the law she wrote in her head, district Judges in the Southern District of NY are the parties responsible for placing drugs on this made-up list, upon recommendation from Prosecutors more interested in padding their resume than justice.

8. Even though the "narcotics conspiracy" charges were dropped, and the superseding indictment didn't claim violation of the CSA, instead claiming violations of the Food Drug and Cosmetics Act, **the standard cited only exists in the Controlled Substances Act and only exists for Controlled Substance prescriptions** These entire criminal proceedings have been an exploration of how many ways misguided prosecutors and judges can misapply the Controlled Substances Act to drugs that are not controlled substances. That much has been consistent throughout these proceedings as she used faulty reason after faulty reason to justify her usurpation of powers and her refusal to dismiss either of the flawed documents. Of course if a jury is told something is a crime, such as eating a salad with a salad fork, they would return a guilty verdict against all who know one fork from another. But this is not a misconstruing of etiquette, it is abuse of judicial power and fraud on the court and violation of the Controlled Substances Act.

9. The Attorney General has not placed Fioricet on the Controlled Substances List. The formula of Fioricet distinguishes it from its components in two significant ways: it eliminates the potential for abuse by way of the inclusion of Acetaminophen, and the synergistic effect of the three components make it a safe effective medicine for tension headaches. Butalbital alone was used for insomnia, but it is not used anymore except as a component of other manufactured drugs or in compounded drugs. Acetaminophen alone is a pain reliever, the same class of drug that Tramadol is (and the Judge is saying the prescriptions dispensed by the fulfillment pharmacy for Tramadol in 2012 were controlled substance prescriptions even though they were not). These

are not "pain meds", as the Judge called it these drugs out of her absolute ignorance, which is a term used for Schedule II drugs meant for extreme pain. Caffeine when used alone needs no explanation. One might ask, how does the inclusion of Acetaminophen eliminate the potential for abuse? Taking too much Acetaminophen, be it in Tylenol or Fioricet, will hospitalize someone for liver damage. This will happen long before any potential for abuse manifests itself. They will not abuse or even become addicted to Fioricet, the potential for abuse in Butalbital will not be a factor at all in Fioricet. Fioricet is a fixed-combination drug formulated to eliminate a potential for abuse. The Attorney General has not made any findings that show Fioricet has a potential for abuse because it has none. This is the key to it all. Judges do not asses drugs BY LAW, and it is not a judicial act to ignore the fact that it is the Attorney General's job, and no one else, to assess drugs for scheduling.

10. The District Court ignored the requirements under Title V (record keeping) with regard to scheduling of drugs, ignored the legal definition of "drug", and conflated bona fide doctor-patient relationships and face-to-face doctor-patient relationships, in order to make it impossible to defend against accusations backed up with no physical evidence. This is all backed up in the Plaintiff's Writ of Certiorari.

In order to prosecute this in a federal court, the Prosecution ignored the existing laws, invent new ones on the spot and misinterpreted existing laws.

11. To **ILLEGALLY** make Fioricet a controlled substance and to make Tramadol a controlled substance in 2012, **Judge Buchwald must metaphorically hit the Attorney General in the head with her gavel and take over his job, and then repeal Title V Section 5 and portions of the Controlled Substances Act to get around the issues of fair notice and the requirement for things to be on the record.**

ARGUMENT III. Did the Appellate Court denied the Plaintiff her constitutional right by denying her Appeal 18-2693 (L) without addressing the

A. Flaw in the defective indictment and lack of physical evidence

1. The Prosecution referred the drug "Fioricet" by the name of one of its components, Butalbital, both during the trial and in the indictment, is intentional deceptive. This deception persists from the time of the Plaintiff's arrest through to today, but the fact that the Plaintiff never dispensed Butalbital and the drug in question is Fioricet has never been in dispute. The Prosecution's and the District Court's insistence on this bait and switch of drug names is in violation of the way the term "drug" is defined under federal law: 21 US Code Section 321 (g) (1).

This confusion is exactly what the Prosecution and its witnesses insisted on creating, and this confusion was intentionally indulged by the district Court in order to assist the prosecution gain a conviction. This deception was committed against the Grand Jury that indicted the Plaintiff, against the Plaintiff, against the District who willingly went along with it, against the Jury, and against the entire health care community who are just as susceptible to this wrongful prosecution as the Plaintiff was. To reiterate, the Federal Prosecutors and the DEA along with Federal Judges ignored the process of assess a drug's potential for abuse, and all the other steps involved in placing a drug on the Controlled Substance List, and just freely prosecute professionals based on a drug's components and not the drug's actual known potential for abuse.

At trial, due to the fact the pharmacies never carried butalbital, the executive officials (AUSA Richenthal and Greenberg, DEA Agents Popowich, Germano, and Murphy) and the trial Judge deceived the jury by calling Fioricet, the name of the drug that was dispensed, by the name of one of its components, Butalbital. On its own Butalbital is a drug that is a controlled substance which required a valid prescription. But Butalbital is not Fioricet. Fioricet is a fixed-combination drug as described above.

Fioricet is a **NON controlled substance under federal law**, which does not require a valid prescription, because it does not have a potential for abuse. The combination is formulated such that the patient cannot abuse the drug: doing so would hospitalize them for liver damage due to the addition of a demonstrably non-controlled substance that is available over the counter without any prescription: Acetaminophen. This is no different than if a patient tried to abuse Tylenol, because the active ingredient in Tylenol is Acetaminophen. Because of this lack of a potential for abuse, Fioricet does not meet the criteria for a controlled substance under federal law as set forth under the Controlled Substances Act Sections 881 (a), 811 (b), 811 (c), 812 (b) (3) (A), or 812 (b) (3) (C). In particular, it does not meet the criteria that specifies that the findings that cause a drug to be a controlled substance under federal law must "be made on the record after opportunity for a hearing pursuant to the rule making procedures prescribed by subchapter II of Chapter 5 of Title 5."

This bait-and-switch of a drug's name for the name of one of its components causes the indictment to be a defective indictment. The changing of the drugs name was intentional and indicative of judicial bias. The administration officials, both prosecutors and agents, committed perjury and fraud on the Court and usurped legislative authority by trying to make Fioricet a controlled substance by calling it Butalbital, and the

District Court invented its own laws to create a jurisdiction for itself over Fioricet by blindly accepting this renaming of the drug. If Fioricet was called by its proper name, it would be obvious to the casual observer that the District Court lacked of subject matter jurisdiction over this case.

To reiterate, DEA agents Popowich, Germano, and Murphy falsely testified, stating: 1) that they ordered and received butalbital, and 2) that they had invoices for butalbital. However, no such invoices nor the medicines they ordered were presented to the jury as physical evidence to back up their claims, because if they had presented it everyone would plainly see they received Fioricet which is not a controlled substance. There was no physical evidence of any prescription, receipts, nor invoices of "butalbital" nor controlled substance marking on any of it, because there were none as there are none for Fioricet.

Butalbital ships from the manufacturers as a POWDER. It is a controlled substance that has to be compounded; the Plaintiff could not compound butalbital into a tablet because the pharmacy was not equipped to compound anything into a tablet, nor extract anything out of a tablet. In fact, the pharmacies dispensed Fioricet, which ships from the manufacturers as a tablet, is a NON controlled substance which does not require a valid prescription, the pharmacies never dispensed Butalbital, not on the dates that the indictments claim the crimes were committed and not ever. The pharmacies never received Butalbital from any manufacturer, they had no use for it. The Plaintiff was not working nor present at the pharmacies where the alleged crimes supposedly took place on the days of the alleged criminal activity.

Butalbital is clearly not the same drug nor an analog, nor has the same strength, indication, or even in the same drug category or classification as Fioricet. They are 2 different drugs for 2 different treatments and neither are in the pain med category. Fioricet and Butalbital are not interchangeable drug names. Fioricet is indicated for tension headache while butalbital is indicated for insomnia. Fioricet as a fixed combination drug is manufactured such that it has no potential for abuse, containing Butalbital 50mg, Acetaminophen 325mg, and caffeine 40mg. Butalbital is not the same drug as Fioricet because in its raw state, Butalbital has a potential for abuse. When incorporated in Fioricet that potential for abuse is eliminated. Long before a patient could be addictive to Fioricet, he would be hospitalized for liver toxicity from the acetaminophen in the same way he would if he abused over the counter Tylenol because Tylenol's active ingredient is acetaminophen.

In summation, the references to Butalbital in the indictment and at trial is false and misleading. It was NEVER in the possession of the pharmacies, never stocked by the pharmacies, and never distributed to the pharmacies by a distributor or manufacturer.

2. Shockingly, there was no physical evidence, prescription, invoice, inventory and bill of laden of Butalbital or a name of a "highly addictive pain meds" introduced at trial, because there were NONE. There were no controlled substances dispensed by the Plaintiff or anyone in the pharmacies via the "fulfillment pharmacies", as the District Court claimed in denying the Plaintiff's bail pending appeal. A motion requesting her to name ONE controlled substance or "highly addictive pain meds" that the Plaintiff dispensed, the District Court has not respond to this motion because there were NONE and the phrase they invented for this trial has no legal, scientific, pharmacological, medical or chemical meaning. To further parse the phrase they made up: pain meds are in fact a recognized class of medicines Butalbital is **not a pain med. Neither is Fioricet or Tramadol**. Opioids and Narcotics are, but the Plaintiff was not for any alleged misdeeds with any pain meds.

Further, the Government deceitfully substituted and represented to the jury NON controlling substances as controlled substances or "highly addictive pain meds," tointentionally misled the jury.

3. Under the Controlled Substances Act, the Controlled Substances Act required valid prescriptions(face to face) for dispensing of controlled medications. However, the Online Pharmacy Safety Act (S2002) introduced legislation which would have required valid face to face prescriptions for**NON controlled substance prescriptions** ordered online **did NOT pass**. To reiterate, the **valid prescription standard do NOT apply to NON controlled drugs** per the governing pharmacy law

None of this changes the fact that the Prosecution's and the district court's applying of the face-to-face requirement to non-Controlled Substances is a deception, deceiving the jury that the Controlled Substances Act's requirements for valid prescriptions was meant to be applied to NON – Controlled Substances.

For Pharmacists, the difference between the Controlled Substances Act requirement for a Face-to-face Doctor-patient relationship for and only for federally controlled substances (none of which were dispensed by the fulfillment pharmacy), and the Bona Fide relationship for all other prescriptions, is that a pharmacist is required to confirm from the Doctor that a face to face relationship exists for controlled substance prescriptions and only for controlled substance prescriptions, but for Bona Fide relationships, the pharmacist is only

required to see the doctor's signature on the prescription; the signatures on the prescriptions are the doctor's promise to the rest of the health care community and the patients, that the prescriptions are valid and that their job was done properly. This is the only aspect of the two different standard that mattered at trial, because the person on trial was a pharmacist. But that difference was not explained to the Jury, nor was the distinction between controlled substances versus regular prescriptions made to them.

However, the only standard that was described to the Jury was face-to-face, but the Prosecutors called it "bona fide face-to-face" relationship which is a term they made up for this trial, does not exist in law or in the medical professions, conflates two distinctly different standards that serve two different purposes for two different kinds of drugs, makes no sense in light of the two standards that do exist and is understood clearly by the medical community, is an example of the Prosecutors usurping legislative power by creating their own legal standard that defines the legality of a medical professional's behavior,

At trial and as described above, the prosecutors intentionally mixed the bonafide prescription standard with the valid prescription standard, to confuse the jury.

A. Government's expert witness **Catizone under cross**

confirmed that the Plaintiff did not violate any law.

The Government's expert witness was experienced at misleading the jury. Catizone's purpose was to convict the Plaintiff with opinions; he made the rules as he goes with NO back-up for the law. However, opinion is not the law, rule and regulations. **Under cross examination Catizone changed his testimony:**

"A face to face is NOT required for NON controlled substances" (Catizone: T. 1074):

Freeman: Okay. The Federal law, as you testified -- now I'm talking about 21 U.S.C. 353-- does not say that a face-to-face is required under federal law for "NON controlled" substances, correct?

Catizone: Yes, sir.

Freeman: Let me ask it this way. The state law, all 50 state laws, do not specifically state in their statutes that a face-to-face is required?

Catizone: Correct.

Under cross exam, Catizone, again, was caught in lies in that he contradicted himself, over and over, again (T.1074, 1077-1078) (Catizone: T. 1077-1078)

Catizone under cross confirmed that the Plaintiff did not violate any law.

If not for the creation of standards not found in the law but presented to the jury as if they were of the law, the Plaintiff would not be convicted. As evidenced above (and below), the Plaintiff's constitutional rights were denied.

The Controlled Substances Act (CSA), the Controlled Substances List, and the Scheduling Actions (See Exh I) showed that Fioricet is not a controlled substances and is not on any of their list, because Fioricet has no addictive attributes. Butalbital and Fioricet are two different drugs; they are not analog of each other - one has the potential of being abused (Butalbital) and the other not (Fioricet).

Thus, the Plaintiff's motions have arguable basis both in law and in fact due to the Governmentviolating the governing pharmacy law by switching the substances, Fioricet for Butalbital.

To reiterate, the District Court ILLEGALLY placed NON – controlled substances into a controlled substances class. She further made up her own rule via making up her own phrase "highly addictive pain medications" (there is no such phrase in pharmacy law; the phrase "addictive pain meds" does NOT exist in any classification of drugs), to INVENT a federal jurisdiction, to prejudice and profile the Plaintiff.

REASONS FOR GRANTING THE WRIT

I. Not only that the decision of the Appellate Court is erroneous, but the national importance of having the Supreme Court decide the issue to resolve the existence of multiple conflicts between the decision of which review is sought and a decision of the second appellate court on the same issue.

In this case, **the decision of the court that decided my case is in conflict with the decisions of the:**

A. **US Supreme Court** Stirone,361 U.S. at 213;Ex parte Bain,121 U.S. At 12-13

B. **Supreme Court of Pennsylvania.** Commonwealth of PA v. HERMAN, J-124-2016 May 25, 2017.

C. **Supreme Court of Massachusetts**. Commonwealth v. Horne 88 Mass. App. Ct. 1109 (2015) Cert granted

D. **Court of Appeals of North Carolina** State v. LePage, __ N.C. App. __, 693 S.E.2d 157 (2010) (indictments identifying the controlled substance as defective)

E. **Court of Appeals 8th Circuit** US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016.

F. Court of appeals 3rd Circuit US v. Elias Karkalas,US District court of Minnesota 13-273 (SRN/JJK) 12/22/15.

G. **DC District Court** U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016)

There were **no evidence at trial that the pharmacies ever carried "Butalbital." Fioricet and Tramadol were both NOT controlled drugs at the time of dispensing**, but the misbranding criteria described at trial for them was a standard only for controlled substances. **Neither the Judge nor the prosecutors have explained how they are holding the Plaintiff responsible for the prescription standard for controlled substances for prescriptions dispensed for Tramadol 21 months before it became a controlled substance** (Schedule IV - a low potential for abuse as per the law). How they got away with it is clear, **through fake standards placing Tramadol 21 months before the Attorney General did,** in **violation of the Controlled Substances Act.** "The scope of the indictment goes to the existence of the trial court's subject-matter jurisdiction". Stirone,361 U.S. at 213;Ex parte Bain,121 U.S. At 12-13

No controlled substances nor any "addicted pain medications" were dispensed by the Plaintiff via the "fulfillment pharmacies", as the District Court claimed. The **prosecutors made up the phrase "highly addictive pain meds"**, and **used it many times only to deceive the jury, to prejudice and profile the Plaintiff**; the **phrase has absolutely no basis in law nor in the health care fields, nor in pharmacology nor in fields that deal specifically with addiction.** Also, **both the District and Appellate Court failed to mention ONE name of the "highly addictive pain meds" that was dispensed, because there were NONE** Commonwealth v. Horne 88 Mass. App. Ct. 1109 (2015) Cert granted Further, this **lack of evidence shows the District Court had no Jurisdiction** in the Plaintiff's case.

The nature of this case, involving Fioricet and Tramadol, has national importance because it affects health care professionals across the whole country. In this case, the original charges alleged violations of the Controlled Substances Act involving Tramadol **twenty-one months before it became a federally controlled substance.** Prosecutors also have brought charges against many health care professionals alleging violations of the Controlled Substances Act over Fioricet in a wide variety of ways (See US v. Elias Karkalas). In this case, The Prosecution, which the **District Judge agreed to, altered significant sections of the law in order to manufacture jurisdiction via the Controlled Substances Act over these drugs.** When the superseding indictment dropped the charges alleging violations of the Controlled Substances Act, **and replaced them with charges alleging violations of the Food Drug and Cosmetics Act, it appears to be only a ruse.** The only alleged **misbranding of Tramadol** described at trial was that the prescriptions were not the result of a face

to face doctor patient relationship, but that **is ONLY REQUIRED for controlled substances which Tramadol was not at the time of dispensing. For Fioricet, the Prosecution and the District Judge use a more deceptive tactic, the alleged need for a face to face doctor patient relationship which would be a violation of the Controlled Substances Act, if Fioricet were a controlled substance. But this kind of misbranding allegations against the Plaintiff is false:**

A. Fioricet is not a controlled substance, because it does not meet the criteria required under the Controlled Substances Act. US v. Mark Greaves 4:16-cr-00250-RWS 6/17/2016, US v. Elias Karkalas 13-273 (SRN/JJK) 12/22/15, DC District Court U.S. v. Akinyoyenu, 199 F. Supp. 3D 106, 109 (D.D.C.2016), COMMONWEALTH OF PENNSYLVANIA v. JOEY WAYNE HERMAN, J-124-2016 Decided: May 25, 2017

The Prosecution and the District Judge agreed to call Fioricet by the name of one of its components: Butalbital, which as a drug on its own is a controlled substance; this is violation of the definition of the word "Drug" as it is defined under the law in the Food Drug and Cosmetics Act and referred to directly in the Controlled Substances Act, which is also the **definition used in the Controlled Substances Act**. This made it appear as if face to face doctor patient relationship was required and it also made any one reading only the Trial transcripts and not the pretrial transcripts where the name-change was decided upon by the judge.

It is also a **well-established principle of statutory interpretation that to determine the meaning of a term, one must first ask whether the term has a plain and unambiguous meaning** DaSilva v. Attorney General United States, 948 F.3d 629 (3rd Cir. 2020) citing Dobrek v. Phelan, 419 F.3d 259, 263 (3rd Cir. 2005). If the statutory language is unambiguous, the inquiry ends because courts must presume that Congress 'says in a statute what it means and means in a statute what it says there." Da Silva, at 635. In determining whether language is unambiguous, we "read the statute in its ordinary and natural sense." Id. The **Controlled Substance Act is clear that it**

1. Regulates drugs as drugs, NOT drugs based on components;

2. Gives the Attorney General and nobody else the ability to make a drug a controlled substance;

3. Requires the Attorney General to make controlled substances on the record

Due to the fact the pharmacies never carried butalbital, whereas at trial the Government switch butalbital, a powder, for Fioricet, a tablet, therefore causing a defective indictment whereby confirming the judicial Court lacked of subject matter jurisdiction over this case. The Indictment must be dismissed as defective since it charges a crime based on the **dispensing of an entirely different substance** (Fioricet) that is not a powder, in addition to **not constituting "butalbital,"** is **also not controlled.** State v. LePage, N.C. App. 693 S.E.2d 157 (2010) (indictments identifying the controlled substance as defective)

Thus, if the jury knew the drug "butalbital" **NEVER existed in the pharmacies**, the Plaintiff would **NOT be convicted.**

Crimes must be defined under law and that law must be made clear to the jury, otherwise any alleged misdeed will sound criminal and thus be declared guilty. But that was the Judge's intention. She wrote of the bona fide relationship standard, as described above, but at trial when it mattered, her intention was clear: to hold the Plaintiff to the Controlled Substances Act standard, regardless of applicability and in spite of the fact that the charges did not cite it. In any event, it can not be said that the jury found the Plaintiff guilty of misbranding Tramadol, because no appropriate evidence for misbranding Tramadol at the time of dispensing was presented to the Jury.

CONCLUSION

The Prosecution's case intentionally deceived the jury in many ways, by misrepresenting both the law and material facts to the jury, of two drugs named:

1. Tramadol was **not a controlled substance under the Controlled Substances Act nor in the Controlled Substances List, at the time of the alleged crimes**, but that was the standard applied at trial, and

2. butalbital in the indictment was **NEVER possessed, stocked nor dispensed** by the pharmacies. The **NON controlled drug, "Fioricet"**, was **ILLEGALLY** and in **violation** of the **Controlled Substances Act was** called "butalbital" and represented to the jury as controlled substances. The prosecution even misled the jury about who owned the pharmacies.

To reiterate, the prosecution illegally treated Tramadol and Fioricet as controlled substances and holding the Plaintiff to legal standards that are not applicable, and for making up fake legal standards such as

"highly addictive pain meds" in order to avoid the actual legal standards and to deceive the jury. The law, the Controlled Substances Act:

1) Is very clear in giving the Attorney General and nobody else the ability to make a drug a controlled substance;

2) Requires the Attorney General to make controlled substances on the record

This Court has consistently held that deliberate deception of the jurors by the presentation of known false evidence is incompatible with "rudimentary demands of justice." Pyle v. Kansas, 317 US 213, 87 L Ed 214, Napue v. Illinois, 360 US 264, 3 L Ed 2d 1217 and Brady v. Maryland, 373 United States 83, 10 L Ed 2d 215.

The Plaintiff has a right to due process and a fair trial.

For the foregoing reasons, the Plaintiff prays the Honorable Supreme Court will grant this **writ of certiorari**, or any other remedy that this Court finds necessary, as duly deserved. The evidence is pertinent for the correction of the criminal judgment per the legal brief and factual basis within the body of the 18 U.S.C. 2255 Motion.

The Plaintiff, Lena Lasher, sincerely believes that she can justifiably rely on the US Supreme Court case Haines v. Kerner 404 U.S. 519 (1972), which clearly states that "all Pro-Se litigants must be afforded the opportunity to present their evidence and that the Court should look to the substance of the" appeal "rather than the form."

Respectfully submitted, April 12, 2021

lenalasher

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CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Lena Lasher

Date: 4/12/2021