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7

8 UNITED STATES DISTRICT COURT
9

10 DISTRICT OF ARIZONA
11

12 David Edward Smith,) Case No. _____
13)
14 Plaintiff,) PETITION FOR REVIEW OF FEDERAL
15 vs.) TORT CLAIMS ACT CLAIMS,
16) AND FOR REVIEW OF
17 UNITED STATES,) CONSTITUTIONAL RIGHTS
18) VIOLATIONS AND
19 Defendant) INTERNATIONAL TREATY
20) VIOLATIONS

21 ~~~~~)
22

23 **PARTIES:**
24

25 Plaintiff, David Edward Smith, a resident of Buckeye, Arizona
26

27 The United States is substituted for the Defendants:
28

1 Mandy K. Cohen, Director, Centers for Disease Control and Prevention

2
3 Anne Milgram, Administrator, Drug Enforcement Administration

4
5 Merrick B. Garland, Attorney General, United States Department of Justice

6
7 **JURISDICTION AND VENUE:**

8
9 1. Plaintiff now brings a request for review of his denied Federal TORT Claims

10
11 Act (FTCA) claims. The District Court has jurisdiction under 28 U.S.C. § 1346(b):

12
13 “Subject to the provisions of chapter 171 of this title, the district courts,
14 together with the United States District Court for the District of the Canal
15 Zone and the District Court of the Virgin Islands, shall have exclusive
16 jurisdiction of civil actions on claims against the United States, for money
17 damages, accruing on and after January 1, 1945, for injury or loss of
18 property, or personal injury or death caused by the negligent or wrongful act
19 or omission of any employee of the Government while acting within the
20 scope of his office or employment, under circumstances where the United
21 States, if a private person, would be liable to the claimant in accordance with
22 the law of the place where the act or omission occurred.”

23
24 2. The District Court has jurisdiction to rule on Plaintiff’s contention that 28

25
26 U.S.C. § 2680(a):
27
28

1 “Any claim based upon an act or omission of an employee of the
2 Government, exercising due care, in the execution of a statute or regulation,
3 whether or not such statute or regulation be valid, or based upon the exercise
4 or performance or the failure to exercise or perform a discretionary function
5 or duty on the part of a federal agency or an employee of the Government,
6 whether or not the discretion involved be abused,”

7
8 does not apply to the publication of the grossly negligent 2016 Centers for Disease
9
10 Control and Prevention (CDC) “Clinical Practice Guidelines for Prescribing
11
12 Opioids for Pain (CDC Guidelines),” because that publication was an ultra vires
13
14 (out of the bounds of the authority of the CDC) act in violation of 42 U.S.C. §
15
16 1395:

17
18 “Prohibition against any Federal interference.
19

20 “Nothing in this sub chapter shall be construed to authorize any Federal
21 officer or employee to exercise any supervision or control over the practice
22 of medicine or the manner in which medical services are provided, or over
23 the selection, tenure, or compensation of any officer or employee of any
24 institution, agency, or person providing health services; or to exercise any
25 supervision or control over the administration or operation of any such
26 institution, agency, or person.” (42 U.S.C. § 1395).
27

28 This publication and the refusal to retract or to rescind this publication is an act

1 which constitutes an EXCEPTION to the Qualified Discretionary Immunity
2
3 defense for which the Director of the CDC is liable for TORTS according to “the
4
5 law of the place” where Plaintiff’s harm occurred. Therefore, the United States is
6
7 substituted as the responsible party pursuant to 28 U.S.C. § 2679 (d)(1):

8
9 “Upon certification by the Attorney General that the defendant employee
10 was acting within the scope of his office or employment at the time of the
11 incident out of which the claim arose, any civil action or proceeding
12 commenced upon such claim in a United States district court shall be
13 deemed an action against the United States under the provisions of this title
14 and all references thereto, and the United States shall be substituted as the
15 party defendant.”

16
17 3. The District Court has jurisdiction to rule on Plaintiff’s contention that the
18
19 Administrator of the Drug Enforcement Administration (DEA) and the Attorney
20
21 General of the United States Department of Justice (DOJ), who have been notified
22
23 of the negligent formulation of the CDC Guidelines yet continue to allow the
24
25 enforcement of misapplied rules and regulations enacted and enforced by the DEA
26
27 and DOJ, including dose caps, medication combination prohibitions, continued
28

1 policing-for-profit with asset forfeiture, and arrests and prosecutions of pain
2
3 doctors without having met the evidentiary standard set forth by the Supreme
4
5 Court of the United States (SCOTUS) in *Ruan vs. United States* (597 U.S. ___,
6
7 June 27, 2022), are abuses of process, all additional Proximate Causes of harms to
8
9 Plaintiff, pursuant to 28 U.S.C. § 2680(h):

10
11 “The provisions of this chapter and section 1346(b) of this title shall not
12 apply to- (h) Any claim arising out of assault, battery, false imprisonment,
13 false arrest, malicious prosecution, abuse of process, libel, slander,
14 misrepresentation, deceit, or interference with contract rights: Provided,
15 That, with regard to acts or omissions of investigative or law enforcement
16 officers of the United States Government, the provisions of this chapter and
17 section 1346(b) of this title shall apply to any claim arising, on or after the
18 date of the enactment of this proviso, out of assault, battery, false
19 imprisonment, false arrest, abuse of process, or malicious prosecution. For
20 the purpose of this subsection, "investigative or law enforcement officer"
21 means any officer of the United States who is empowered by law to execute
22 searches, to seize evidence, or to make arrests for violations of Federal law.”

23
24 4. The District Court has jurisdiction to rule on the Constitutional questions raised
25
26 by Plaintiff under 28 U.S.C. § 1331:
27
28

1 “Federal question. The district courts shall have original jurisdiction of all
2 civil actions arising under the Constitution, laws, or treaties of the United
3 States.”

4
5 5. The District Court has jurisdiction to rule on the questions raised by Plaintiff
6
7 about whether the actions taken by the United States government are in violation of
8
9 international treaties to which the United States is a signatory, pursuant to 28
10 U.S.C. § 1331:
11

12
13 “Federal question. The district courts shall have original jurisdiction of all
14 civil actions arising under the Constitution, laws, or treaties of the United
15 States.”

16
17 6. The District Court is no longer required to defer to federal government agency
18
19 “experts” or their interpretation of any public health law, of any agency rule or
20
21 regulation enacted, now that the “Chevron Deference doctrine” has been
22
23 overturned by the Supreme Court of the United States (SCOTUS) in *Loper Bright*
24
25 *Enterprises v. Raimondo* (603 U.S. 369, *Loper Bright Enterprises v. Raimondo*, 28
26
27 June 2024), and now has jurisdiction to examine evidence presented in the case
28

1 record for the purposes of making a ruling.

2
3 7. Plaintiff continues to suffer bodily and economic harms, and absent judicial

4
5 review and relief, the possibility of additional future harms exists. The District

6
7 Court has jurisdiction to review Plaintiff's FTCA claims under 28 U.S.C. §

8
9 1346(b), in the venue of the 9th Circuit District Court in Phoenix Arizona, for

10
11 harms caused to Plaintiff when he lived in Denton County, Texas, since Plaintiff

12
13 now resides in Maricopa County, Arizona.

14
15 8. The District Court has jurisdiction to rule on the Proximate Causes of action of

16
17 Plaintiff's harms even though the harms occurred more than 6 years following the

18
19 publication of the CDC Guidelines, since in *Corner Post v. Board of Governors of*

20
21 *the Federal Reserve System*, SCOTUS ruled that the six-year statute of limitations

22
23 under 28 U.S.C. § 2401 for challenging federal agency action under the

24
25 Administrative Procedure Act only commences when the plaintiff is injured by the

26
27 challenged action. (603 US 799, *Corner Post, Inc. vs Board of Governors*. 1 July

28

2024). Plaintiff's harm date was July 14, 2022.

FACTUAL ALLEGATIONS:

**9. CLAIM 1: CDC NEGLIGENCE AND UNLAWFUL TORTIOUS
INTERFERENCE WITH THE PRACTICE OF MEDICINE, IN
VIOLATION OF 42 U.S.C. § 1395.**

Plaintiff contends that the CDC was negligent in formulating the 2016 CDC Guidelines and that Mandy K. Cohen, Director of the CDC, has been made aware of the factual errors yet has refused to retract or to rescind the Guidelines. Stephen A. Martin, M.D., Ed.M., in one of the many criticisms of the CDC Guidelines that followed the publication, stated shortly after the publication of the Guidelines in 2016 that they were not serving either the protection of the public health nor (sic) individual patient care:

“Public health interventions are different than clinical interventions. The former are scaled, diffuse and unilateral. The latter are individualized and

1 shared. The CDC recommendations are more focused on public health
2 concerns (such as non-medical use of prescribed drugs) rather than the
3 individual risks and benefits of opioids for actual patients. These guidelines
4 may have, in some form, been helpful in the late 1990s or early 2000s when
5 OxyContin's faulty, criminal formulation made for tragic outcomes for
6 patients and communities alike. [52] In 2016, many regions and prescribers
7 have already taken steps to improve clinical education and prescription
8 monitoring. [53,54]. The added constraints of the CDC recommendations
9 and hyperbole that surrounds them serves neither public health nor
10 individual care well." (Martin, S., M.D, Ed.M.; Potee, R., M.D., DABAM;
11 Lazris, A., M.D. Neat, Plausible, and Generally Wrong: A Response to the
12 CDC Recommendations for Chronic Opioid Use. Medium, 7 Sept 2016,
13 Page 9-10). (Exhibit 1).

14
15 10. Plaintiff contends that the Director of the CDC is liable for TORT claims
16
17 arising from the negligent formulation and publication of the Guidelines, or for the
18
19 ongoing tortious interference with both the practice of medicine and the legally
20
21 protected doctor/patient relationship by refusing to retract or to rescind the
22
23 Guidelines, a publication that is an ultra vires (out of the bounds of the legal
24
25 authority of the CDC) act, a Proximate Cause of harm to Plaintiff. The Director of
26
27 the CDC has been notified about the negligent and incorrect assertions on which
28

1 the CDC Guidelines were based and about the harms and deaths caused to patients,
2
3 including to Plaintiff, yet continues to fail to retract or to rescind the CDC
4
5 Guidelines. The CDC Guidelines became the defacto basis for all of the
6
7 discriminatory federal laws, rules, regulations, and settlement clauses that restrict
8
9 access to opioid pain medications and to other controlled substances on which
10
11 chronic, intractable, cancer, end-of-life, surgical pain, and other groups of severely
12
13 ill, injured, and disabled patients depend to be able to perform the most basic
14
15 activities of daily living and to therefore survive, and to have any quality of life
16
17 whatsoever, and was a Proximate Cause of harm to Plaintiff. The Qualified
18
19 Discretionary Immunity defense does not apply to the ultra vires formulation,
20
21 publication, and continued use of the Guidelines as a basis for public health policy,
22
23 since a private person would be liable under similar circumstances, pursuant to the
24
25 Texas Title 4, Chapter 88, Section 002, and therefore the United States would be
26
27 substituted as the responsible party pursuant to 28 U.S.C. § 2679 (d)(1):
28

1 “Upon certification by the Attorney General that the defendant employee
2 was acting within the scope of his office or employment at the time of the
3 incident out of which the claim arose, any civil action or proceeding
4 commenced upon such claim in a United States district court shall be
5 deemed an action against the United States under the provisions of this title
6 and all references thereto, and the United States shall be substituted as the
7 party defendant.”
8
9

10 **11. CLAIM 2: DEA NEGLIGENCE AND UNLAWFUL TORTIOUS**
11
12 **INTERFERENCE WITH THE PRACTICE OF MEDICINE, IN**
13
14 **VIOLATION OF 42 U.S.C. § 1395.**
15

16 Plaintiff contends that the DEA’s continued ongoing negligent and unlawful
17 enforcement of opioid dose caps, blanket medication combination prohibitions
18 (such as with opioids and benzodiazepines), without regard to individual patient
19 metabolism rates, absorption rates, reactions to, or tolerance of such medications,
20 resulting in forced-tapers, sudden discontinuation, and loss of access to opioids and
21 to other controlled substances, has been a Proximate Cause of harm to Plaintiff and
22 to millions** of patients, for which Anne Milgram, Administrator of the DEA, is
23
24
25
26
27
28

1 liable for TORT claims, pursuant to the exception clause of the FTCA in 28 U.S.C.
2
3 § 2680(h) concerning abuse of process on the part of law enforcement, negating
4
5 the Qualified Discretionary Immunity defense of the FTCA, thereby making the
6
7 United States the responsible party pursuant to 28 U.S.C. § 2679 (d)(1):
8

9 “Upon certification by the Attorney General that the defendant employee
10 was acting within the scope of his office or employment at the time of the
11 incident out of which the claim arose, any civil action or proceeding
12 commenced upon such claim in a United States district court shall be
13 deemed an action against the United States under the provisions of this title
14 and all references thereto, and the United States shall be substituted as the
15 party defendant.”
16

17 **(CDC: "19-to-70 MILLION ADULTS SUFFER CHRONIC PAIN with
18 considerable sub-group variation," (Dahlhamer, J., PhD., et al. Prevalence
19 of Chronic Pain and High-Impact Chronic Pain Among Adults — United
20 States, 2016. Centers for Disease Control and Prevention, Morbidity and
21 Mortality Weekly Report, 14 September 2018, Page 1001-1006. (Exhibit 2).
22

23 **12. CLAIM 3: DEA VIOLATIONS OF THE UNITED NATIONS SINGLE**
24
25 **CONVENTION ON NARCOTIC DRUGS.**
26

27 Plaintiff contends that the DEA’s annual cuts in production and distribution of
28

1 opioid medications and other controlled substances violate the provisions of the
2
3 Preamble of the United Nations Single Convention on Narcotic Drugs, which
4
5 stipulates that:

6
7 “The Parties, Concerned with the health and welfare of mankind,
8 Recognizing that the medical use of narcotic drugs continues to be
9 indispensable for the relief of pain and suffering and that adequate provision
10 must be made to ensure the availability of narcotic drugs for such purposes,
11 (United Nations Single Convention on Narcotic Drugs, Preamble, 30 March
12 1961. Page 1.). (Exhibit 3)

13
14 There are no longer sufficient supplies of controlled substances to meet the needs
15
16 of patients, and pharmacies and hospitals nationwide have inadequate amounts of
17
18 medications on hand to fill prescriptions. Plaintiff suffered additional harms due to
19
20 encountering 7-10 day delays in obtaining his prescription medications in late 2023
21
22 due to pharmacy shortages caused by the DEA production cuts, which occurred
23
24 after the Administrator of the DEA was more than adequately warned that
25
26 additional cuts would cause patient harms and deaths by commenters during the
27
28 periods of the requests for public comments prior to the annual proposed cuts in

1 the production and distribution of controlled substances through the 2024 annual
2
3 for additional cuts, as documented in Section 11, Pages 23-27 of Plaintiff's
4
5 Administrative Complaint (Exhibit 4). Forced-tapers and sudden discontinuation
6
7 of opioid medications are known to pose significant risks to patients, increasing
8
9 their risk of heart problems, strokes, high blood pressure that is unresponsive to
10
11 blood pressure medications, patient suicide, and overdoses from the cartels' black
12
13 market illegal drugs, all caused by uncontrolled, untreated or undertreated complex
14
15 pain syndromes.

16
17 "Untreated and undertreated chronic pain sufferers are 20% more likely to
18 have a heart attack and 30% more likely to have a stroke than the general
19 population. They are also more likely to commit suicide." (Parker, L., M.D.,
20 Killing Them Quietly: Government versus Medicine. The Daily Remedy,
21 Perspectives. Page 4. 6 April 2024. (Exhibit 5).

22
23
24 **13. CLAIM 4: DOJ NEGLIGENCE AND UNLAWFUL TORTIOUS**

25
26 **INTERFERENCE WITH THE PRACTICE OF MEDICINE, IN**

27
28 **VIOLATION OF 42 U.S.C. § 1395, AND IN VIOLATION OF A SUPREME**

1
2 **COURT RULING.**

3
4 Plaintiff contends that Merrick Garland, Attorney General of the DOJ has
5
6 continued to allow the DEA to arrest and to prosecute doctors for the “crime” of
7
8 treating pain without having met the evidentiary standard required to do so as set
9
10 forth by SCOTUS in *Ruan vs. United States* (597 U.S. ___, June 27, 2022), as
11
12 described in Section 5, Pages 11-15, of Plaintiff’s Administrative Complaint
13
14 (Exhibit 6). These prosecutions are a misapplication of the CDC Guidelines,
15
16 which exempted trained pain doctors from the recommendations set forth by the
17
18 CDC, and a misapplication of the same exemption present within the 2017
19
20 Presidential Commission on Combatting Addiction and the Opioid Crisis on pages
21
22 48-49 (Exhibit 7). These abuses of process have created a pervasive and endemic
23
24 climate of fear within the medical profession as a result of these unlawful
25
26 prosecutorial tactics, have reduced the number of pain doctors willing to accept the
27
28 patients of the incarcerated doctors, causing patient abandonment, forced-tapers

1 and sudden discontinuation of opioid therapy, loss of access to opioid pain
2
3 medications and other controlled substances, and have been a Proximate Cause of
4
5 harm to Plaintiff and to millions of patients. Plaintiff contends that the Attorney
6
7 General of the DOJ is liable for TORT claims for harm caused to Plaintiff by the
8
9 abuses of process on the part of law enforcement pursuant to 28 U.S.C. § 2680(h),
10
11 one of the exceptions which negate the Qualified Discretionary Immunity defense
12
13 of the FTCA, thereby making the United States the responsible party pursuant to
14
15 28 U.S.C. § 2679 (d)(1):

16
17 “Upon certification by the Attorney General that the defendant employee
18 was acting within the scope of his office or employment at the time of the
19 incident out of which the claim arose, any civil action or proceeding
20 commenced upon such claim in a United States district court shall be
21 deemed an action against the United States under the provisions of this title
22 and all references thereto, and the United States shall be substituted as the
23 party defendant.”
24

25
26 **14. CLAIM 5: CDC, DEA, DOJ, AND CONGRESSIONAL ACTS IN**
27
28 **VIOLATION OF THE 5th AND 14th AMENDMENTS OF THE**

1 **CONSTITUTION OF THE UNITED STATES.**

2
3 Plaintiff contends that the conditions that exist currently in the United States are
4
5 tantamount to a STATE-SANCTIONED PAIN PATIENT TORTURE AND
6
7 MASS EXTERMINATION PROGRAM. Plaintiff contends that the government's
8
9 efforts to protect the public health by restricting access to prescription opioids and
10
11 other controlled substance medications for chronic, intractable, cancer, end-of-life,
12
13 surgical pain, and other classes of patients in order to attempt to reduce the number
14
15 deaths caused by illicit fentanyl analog poisonings, abused by a different cohort of
16
17 patients, do not reasonably meet the Rational Basis Test of the Due Process clause
18
19 requirements of the 5th and 14th Amendments to the Constitution of the United
20
21 States.

22
23
24 **15. CLAIM 6: UNITED STATES VIOLATION OF THE NUREMBERG**
25
26 **CODE.**

27
28 Plaintiff contends that the United States is in violation of the Nuremberg Code, an

1 international treaty to which it is a signatory, because the government is
2
3 experimenting upon the pain patient population without their knowledge or consent
4
5 to try to formulate non-opioid pain treatments for the complex pain syndromes of
6
7 chronic, intractable, cancer, end-of-life, and surgical pain patients, denying these
8
9 patients the only known medical treatment that relieves their suffering while
10
11 having no alternative available, as described in Section 13, Pages 29-33 of
12
13 Plaintiff's Administrative Complaint (Exhibit 8).

14
15
16 **EXHAUSTION OF ADMINISTRATIVE REMEDIES:**

17
18 16. Plaintiff now brings for review his denied Federal TORT Claims Act claims
19
20 against the United States. Plaintiff filed claims for harms caused to him by the
21
22 negligent, unlawful, and tortious interference with the practice of medicine, as well
23
24 as for Constitutional violations, as described in the documents in the first 13
25
26 Sections of Plaintiff's Administrative Complaint (Exhibit 9), and in Plaintiff's
27
28 Personal Harm Story (Exhibit 10), naming Mandy K. Cohen, Director, Centers for

1 Disease Control and Prevention (CDC), Anne Milgram, Director, Drug
2
3 Enforcement Administration (DEA), and Merrick B. Garland, Attorney General,
4
5 U.S. Department of Justice (DOJ) as the responsible parties. Plaintiff's claims and
6
7 Administrative Complaints were delivered to the Defendants by registered mail,
8
9 certified return receipt requested, through the United States Postal Service,
10
11 pursuant to 28 U.S.C. §2675(a). Plaintiff's claim against the Director of the CDC
12
13 was DENIED on August 15, 2024 (Exhibit 11). Plaintiff's claims against the
14
15 Directors of the DEA and DOJ (Attorney General), received in those offices on
16
17 May 30, 2024, via certified return receipt mail (Exhibit 12), after six months of
18
19 inaction, the automatic invocation of Constructive Denials has resulted under the
20
21 Federal TORT Claims Act rules, as of November 30, 2024. The deadline for filing
22
23 Plaintiff's District Court case is February 15, 2025. Plaintiff has exhausted the
24
25 Administrative Remedies pursuant to 28 U.S.C. § 2675:

26
27 "Disposition by federal agency as prerequisite; evidence - (a) An action shall
28 not be instituted upon a claim against the United States for money damages

1 for injury or loss of property or personal injury or death caused by the
2 negligent or wrongful act or omission of any employee of the Government
3 while acting within the scope of his office or employment, unless the
4 claimant shall have first presented the claim to the appropriate Federal
5 agency and his claim shall have been finally denied by the agency in writing
6 and sent by certified or registered mail. The failure of an agency to make
7 final disposition of a claim within six months after it is filed shall, at the
8 option of the claimant any time thereafter, be deemed a final denial of the
9 claim for purposes of this section.”

10
11
12 **DAMAGES, PRAYERS FOR REVIEWS CONCERNING THE**
13
14 **CONSTITUTIONAL AND INTERNATIONAL TREATY VIOLATIONS:**
15

16 17. Plaintiff, after having been subjected to bodily harm, economic harm, and
17
18 harms caused by the international crimes of “torture, cruel, inhuman and degrading
19
20 treatment or punishment,” as described by the United Nations General Assembly
21
22 and by international treaties as described in Section 12, Pages 27-29, and Section
23
24 13, Pages 29-33, of Plaintiff’s Administrative Complaint (Exhibit 13), from the
25
26 sudden discontinuation and loss of access to the controlled substance prescriptions
27
28 used to manage his condition and symptoms, which are the only known medical

1 treatment that can alleviate his symptoms and that allow him to perform the most
2
3 basic activities of daily living and to therefore survive his extreme conditions,
4
5 surgical interventions, and disabilities, and, after suffering additional bodily harms
6
7 and torture caused by shortages of medications at Arizona pharmacies causing 7-10
8
9 day delays in obtaining his controlled substance prescriptions after his access to
10
11 short-acting opioid medications was reinstated, demanded \$7,364.00 for moving
12
13 costs, and \$992,636.00 for bodily injuries, economic injuries, and pain and
14
15 suffering caused by this infliction of torture, totaling \$1,000,000, a reasonable
16
17 settlement demand during the Administrative Complaint process.

18
19 Additionally, given that:

- 20
21 1. The injuries sustained by Plaintiff are of a peculiar nature, so that
22
23 compensation in money cannot atone for them;
24
- 25 2. The nature of the harms is not easily quantifiable or cannot be fully
26
27 remedied through financial compensation;
28

1 3. Without reversal of the laws, rules, and regulations enacted since the
2
3 publication of the 2016 CDC Guidelines, Plaintiff will continue to be at risk
4
5 of immediate irreparable injury, since increasing restrictions to access of
6
7 controlled substance medications to treat severely injured, sick, and disabled
8
9 patients, like Plaintiff, continue to escalate everywhere in the United States;
10

11 4. Legal remedies such as monetary damages alone are inadequate to
12
13 address the harms caused to Plaintiff, and to ensure that additional harms
14
15 will not occur;
16

17 5. The threat of actual and substantial harms in the future have a real,
18
19 affirmative prospect of occurring, unless the alleged CDC data
20
21 misrepresentations concerning the alleged role of “prescription opioid
22
23 medications” in the current “opioid crisis” and other misrepresentations are
24
25 corrected, and unless clauses of all federal laws, rules, regulations, and
26
27 settlement clauses that restrict access to controlled substance medications are
28

1 NULLIFIED;

2
3 6. The continued allegedly negligent, unlawful, and tortious interference
4
5 the practice of medicine by the CDC, DEA, and DOJ, as well as by Acts of
6
7 Congress codifying the misapplied CDC Guidelines, would directly threaten
8
9 to cause Plaintiff (and millions of other patients) irreparable harms and
10
11 would violate Plaintiff's 5th and 14th Amendment rights to Life and to
12
13 Liberty without having met the Rational Basis test of the Due Process
14
15 Clause of the 5th and 14th Amendments of the Constitution of the United
16
17 States;

18
19 Plaintiff therefore also prays that the Court will accept his demands for a review of
20
21 the Constitutional questions posed about the violation of patients' rights under the
22
23 5th and 14th Amendments of the Constitution of the United States, and a review of
24
25 the international treaty violations by federal statute and agency rules and
26
27 regulations, so as to stop the STATE-SANCTIONED STRUCTURES WHICH
28

1 TORTURE PAIN PATIENTS AND RESULTS IN NEEDLESS DEATH.

2
3
4 18. Plaintiff prays that the Court will accept his demand that the Court provide a
5
6 review of the Constitutional violations to the rights of patients under the 5th and
7
8 14th Amendments, thereby nullifying all clauses of any federal laws, rules, or
9
10 regulations that restrict access to controlled substances for proper, appropriate
11
12 medical use by patients within a legally protected doctor/patient relationship, so
13
14 that the rights of Plaintiff and of all patients whose Liberty and whose Lives
15
16 depend upon access to these medications can be fully restored. Plaintiff contends
17
18 that unless and until these laws, rules, and regulations are corrected, the United
19
20 States will remain in violation of the 5th and 14th Amendments since the
21
22 restriction of access to prescription opioid medications and other controlled
23
24 substances from the class of patients who depend on those medications to be able
25
26 to perform the most basic activities of daily living and to have any quality of life
27
28 whatsoever does not satisfy the Rational Basis Test of the Due Process Clause of

1 the 5th and 14th Amendments. Plaintiff prays that the Court will deem all clauses
2
3 of the Controlled Substances Act, NO PAIN Act, SUPPORT Act, and CARA Act,
4
5 the rules and regulations enacted by various federal agencies which restrict access
6
7 to opioid pain medications and to other controlled substances on which severely ill,
8
9 injured, and disabled patients depend, to be UNCONSTITUTIONAL.

10
11
12 19. Plaintiff prays that this ruling will include the clause in the CARA act, as
13
14 documented in Section 10, Pages 22-23, of Plaintiff's Administrative Complaint
15
16 (Exhibit 14), so that no patient should be dismissed from pain management care or
17
18 be denied their proper and appropriate opioid pain medications after a false
19
20 positive reading from a rapid result immunoassay test unless the test results are
21
22 first confirmed by a gas chromatography-mass spectrometry test. The rapid result
23
24 tests are known to have a high incidence of false-positive readings and are not
25
26 reliable enough to use as a basis for dismissing a patient from care or for denying
27
28 prescriptions. The dismissal of patients from care for allegedly violating the terms

1 of a pain management contract on the basis of a failed rapid result urine screen
2
3 with known high rates of incidence of false-positive readings does not satisfy the
4
5 Rational Basis test of the due process clause of the 5th and 14th Amendment.
6
7 Plaintiff prays that the Court will accept his demand that the Court recognize the
8
9 undeclared Public Health Emergency that has been caused by the alleged and
10
11 probable negligent, unlawful, and tortious actions of these federal agencies and by
12
13 the avalanche of laws, rules, and regulations that followed the publication of the
14
15 2016 CDC Guidelines for Prescribing Opioids for Pain by Congress and other
16
17 bodies and agencies that failed to perform any due diligence to confirm whether
18
19 the CDC assertions were true, which have caused harms to Plaintiff and to millions
20
21 of chronic, intractable, cancer, surgical pain, and other classes of patients, and
22
23 which have caused the deaths of an untold number of these patients, possibly
24
25 multiples of tens of thousands or more.
26
27
28

20. Plaintiff prays that the Court will accept his demand that the Court ORDER

1 the complete retraction of the CDC Clinical Practice Guidelines for Prescribing
2
3 Opioids for Pain, since that document was based on data about deaths caused by
4
5 “prescription opioid medications” that was factually incorrect. The Guidelines are
6
7 not only NOT having the intended effect of lowering rates of illicit drug use and
8
9 addiction, or of lowering the rates of deaths from the use of illicit drugs, but are
10
11 also causing harms and death to patients in the undeclared Public Health
12
13 Emergency caused by the CDC Guidelines, which became the defacto basis for the
14
15 creation of laws, rules, and regulations concerning the prescription of controlled
16
17 substances, and which was an ultra vires (out of the bounds of the authority of the
18
19 CDC) publication in violation of 42 U.S.C. § 1395 which should never have been
20
21 published.

22
23
24 21. Plaintiff prays that the Court will accept his demand that the Court ORDER
25
26 the Department of Health and Human Services and CDC to create a website
27
28 modeled after the Vaccine Adverse Event Reporting System (VAERS) website,

1 where patients and families of patients who did not survive the loss of access to
2
3 controlled substances as a result of the actions of these agencies can report the
4
5 nature and extent of their harms and deaths, beginning several years prior to 2016
6
7 since the Veterans' Administration began restricting access to controlled
8
9 substances prior to the publication of the 2016 CDC Guidelines, so that the number
10
11 of patient harms and deaths can finally be approximated and known, and so that the
12
13 heretofore undeclared Public Health Emergency created by the agency actions and
14
15 by the Acts of Congress can be quantified and documented. The Department of
16
17 Health and Human Services, the CDC, and the VA, should examine the Medicare
18
19 and VA beneficiary data and the Social Security Disability and Death Reports in
20
21 order to determine the number of patients who were formerly prescribed controlled
22
23 substances who have now been placed on disability or who have perished in the
24
25 several years prior to and after the publication of the 2016 CDC Guidelines for
26
27 Prescribing Opioids for Pain and the avalanche of regulatory events that followed,
28

1 and to report this number to the Court, to the media and to scientific publication
2
3 journals.

4
5
6 22. Plaintiff prays that the Court will accept his demand that the Court provide a
7
8 ruling on the international treaty violations of both the United Nations Single
9
10 Narcotics Treaty (since there is no longer a sufficient supply of numerous opioid
11
12 pain medications and other controlled substances to ensure an adequate provision
13
14 for the relief of pain and suffering) and the Nuremberg Code (since the government
15
16 has been experimenting on the pain patient population without their knowledge or
17
18 consent, as described in Section 13, Pages 29-33, of Plaintiff's Administrative
19
20 Complaint). (Exhibit 15).

21
22
23 23. Plaintiff prays that the Court will accept his demand that the Court will
24
25 ORDER the Attorney General, the DOJ, and the DEA, to cease and desist the
26
27 practice of unjust arrests and prosecutions of doctors without having met the
28

1 evidentiary standards set forth by SCOTUS in *Ruan vs United States*, (597 U.S.
2
3 ____, June 27, 2022), as documented in Section 5, Pages 11-15, of Plaintiff's
4
5 Administrative Complaint (Exhibit 16).

6
7
8 24. Plaintiff prays that the Court ORDER the DEA to stop the continued DEA
9
10 practice of the forfeiture of assets prior to obtaining a conviction of any doctor,
11
12 as documented in Section 8, Pages 20-21, of Plaintiff's Administrative Complaint
13
14 (Exhibit 17), because without a conviction, the DEA cannot be certain that any
15
16 assets were "derived from, traceable to, or intended to be used for illicit drug
17
18 trafficking" as defined by the agency Mission Statement.

19
20
21 25. Plaintiff prays that the Court will accept his demand that the Court ORDER
22
23 the CDC to immediately fund and staff the "Opioid Rapid Response Program," and
24
25 create "Rescue Clinics" in every state, or by telemedicine, where long-term opioid
26
27 therapy patients and patients using medication assisted treatment/medication for
28

1 opioid use disorder (MAT/MOUD) can obtain immediate prescriptions after
2
3 having lost access to their medications, especially through actions of the DEA,
4
5 since that previously funded program is neither staffed nor available to assist
6
7 patients who lose access to their medications, as documented in Section 9, Page 21,
8
9 of Plaintiff's Administrative Complaint (Exhibit 18). The Court may
10
11 require an investigation into the whereabouts of the funding that was provided for
12
13 this program, which was never implemented.

14
15
16 26. Plaintiff prays that the Court will accept his demand that the Court ORDER
17
18 the protection of patient data protected by the Health Insurance Portability and
19
20 Accountability Act (HIPAA) from the unbridled access to confidential patient data
21
22 which is now freely accessible to the DEA and to other law enforcement agencies
23
24 without obtaining a warrant. Otherwise, law enforcement access to this data
25
26 should be restricted. Medical practitioner and pharmacy access to this data should
27
28 be restricted only to the patients with whom a doctor/patient relationship with a

1 prescriber or with a pharmacy has been established. Medicare officials, and the
2
3 insurance companies who administer Medicare benefits, should likewise be
4
5 restricted from accessing/sharing this confidential patient data for law enforcement
6
7 purposes, without first obtaining a warrant. Plaintiff believes that access to this
8
9 confidential patient data was granted by various Acts of Congress such as the
10
11 Controlled Substances Act, the NO PAIN, CARA, and SUPPORT Acts, as part of
12
13 the government efforts to reduce the number of deaths reported that were
14
15 incorrectly attributed to “prescription opioid medications.” Plaintiff has asked the
16
17 Court to deem those efforts as UNCONSTITUTIONAL, and that such a ruling
18
19 would make the unbridled access to confidential patient data as part of those efforts
20
21 to be no longer appropriate or necessary.

22
23
24 27. Plaintiff prays that the Court will accept his demand that the Court ORDER
25
26 the DOJ to enforce the request of several members of Congress who asked the
27
28 Attorney General in January 2024 to stop funding and using A.I. predictive

1 policing software programs after allegations arose that the DEA was targeting
2
3 minority-owned medical practices and pharmacies, documented in Section 7, Pages
4
5 16-20 of Plaintiff's Administrative Complaint (Exhibit 19). The Attorney
6
7 General has failed to put a stop to the A.I. datamining software in use at the
8
9 Department of HHS, the DEA, and throughout law enforcement, which is
10
11 continuing to lead to unfair, unjust prosecutions, without the proper investigative
12
13 standard through which law enforcement officials are required to have due cause
14
15 and to obtain a warrant before having access to confidential patient data, including
16
17 the names of their doctors. Plaintiff believes that access to this confidential patient
18
19 data was granted by various Acts of Congress, such as the Controlled Substances
20
21 Act, the NO PAIN, CARA, and SUPPORT Acts, as part of the government efforts
22
23 to reduce the number of deaths reported that were incorrectly attributed to
24
25 "prescription opioid medications." Plaintiff has asked the Court to deem those
26
27 efforts as UNCONSTITUTIONAL, and that such a ruling would make the
28

1 unbridled access to confidential patient data as part of those efforts to be no longer
2
3 appropriate or allowed.
4

5
6 **LEGAL BASIS:**
7

8 **Background:**
9

10 28. Plaintiff is a scoliosis patient who has undergone two radical surgeries,
11
12 including Harrington rod implantation with torsion hooks to counter vertebral and
13
14 rib cage rotation, with fusion of the entire thoracic spine at the spinous processes in
15
16 1979, and lumbar pedicle screw and stabilizer fixation in 2009, which have left
17
18 him with 18-level spinal fusion, all bolted into the back of his pelvis. Plaintiff was
19
20 diagnosed with arachnoiditis, present in a 2019 MRI, and cauda equina syndrome,
21
22 which was the reason he underwent the 2009 surgery, so as to stay ambulatory
23
24 instead of possibly becoming confined to a wheelchair. Plaintiff was declared to
25
26 be permanently and totally disabled by the Social Security Administration on
27
28 March 11, 2009 (Exhibit 20). Plaintiff has been treated with pain medications

1 since the 2009 surgery, and is considered to have chronic, intractable, daily pain,
2
3 relieved with no other known medical treatment except full-agonist opioid
4
5 medications. At the time Plaintiff was suddenly discontinued from his prescription
6
7 medications, his morphine milligram equivalent (MME) dose was 90 MME, with
8
9 occasional increases to 105 MME as a result of increased situational pain caused
10
11 by either cold, damp weather conditions or increased activity, such as the sudden
12
13 move to Texas after losing his condo lease in California when the owners decided
14
15 to sell, and he had only 60 days to vacate. This MME dose was already within the
16
17 standards recommended by the CDC Guidelines, and there was therefore no
18
19 medical indication for the sudden discontinuation of his medication regimen,
20
21 especially given his extensive and radical surgical treatments for scoliosis and his
22
23 documented medical conditions.

24
25 29. Plaintiff is a 5th-generation Texan but had been a resident of California since
26
27 September 14, 2000. Plaintiff had returned to Texas to assist his mother from
28

1 2012 to 2015. Plaintiff transferred his care and prescriptions to Southwest Pain
2
3 Clinic at Presbyterian Hospital in Dallas, Texas, with no problem during that time
4
5 frame. Plaintiff returned to California in 2015, at which time he was able to
6
7 resume the use of THCA tincture and other cannabis products for the treatment of
8
9 his condition, as recommended by physicians there, and Plaintiff then voluntarily
10
11 reduced his dose of the long-acting opioid which had been prescribed since 2009
12
13 by half due to severe gastrointestinal complaints. This brought Plaintiff's usual
14
15 daily opioid dosage to 90 MME, a therapeutic dose on which he was stable for 8
16
17 years, after having voluntarily lowering it from 150 MME that he was prescribed
18
19 for the first 6 years following stabilization after his radical lumbar surgery in 2009.
20
21 Plaintiff's mother sold her home in Texas and joined him in Palm Springs, CA on
22
23 October 1, 2016. Plaintiff and his 83-year-old mother then suddenly moved from
24
25 California back to their home state of Texas on April 28, 2022, after losing the
26
27 condo lease in Palm Springs, because his mother was in need of immediate
28

1 medical care, had a large network of physicians there with whom she was familiar,
2
3 and because they could not find any suitable, available housing within their budget
4
5 in the desert southwest, where Plaintiff prefers to live due to the climate and its
6
7 help in maintaining a lower pain burden. Plaintiff was prescribed two months of
8
9 his usual pain medication regimen for his travel and relocation, with an increase of
10
11 one additional Percocet tablet daily to account for the drastic increase in activity
12
13 during the move. Plaintiff arrived in Texas on May 1, 2022. Plaintiff attempted to
14
15 become re-established as a patient at Southwest Pain at Presbyterian Hospital
16
17 where he had been a patient from 2012-2015 when he had gone to Texas to help
18
19 his mother with some surgeries and some financial difficulties. Plaintiff learned
20
21 that Southwest Pain no longer existed. Plaintiff attempted to locate a pain
22
23 management practice where he could get his pain medication regimen prescribed,
24
25 which was comprised of 5 mg methadone tablet twice daily as his long-acting
26
27 opioid, and 10/325 oxycodone/acetaminophen two to three times daily as his short-

1 acting, breakthrough pain medication. The first doctor that Plaintiff visited told
2
3 him that “he would have a very difficult time here” (in Texas,) but did not
4
5 elaborate. The doctor told Plaintiff to “get someone else to prescribe his
6
7 medications.”
8
9

10 30. Plaintiff sought treatment at a total of five pain management clinics but was
11
12 told that the use of oral opioids for the treatment of daily, intractable pain was no
13
14 longer permitted by the Texas Medical Board, due to the publication of the 2016
15
16 CDC Clinical Practice Guidelines for Prescribing Opioids for Pain, and the
17
18 avalanche of laws, rules, and regulations that followed. Plaintiff ran out of
19
20 medication at the end of June 2022, after having failed to locate a prescriber, and
21
22 was then denied the prescription of his pain medication regimen on July 14, 2022
23
24 by his selected pain management provider, where he had been referred by his
25
26 primary care doctor, and suffered classic opioid withdrawal, high blood pressure,
27
28 uncontrolled pain, new pain which he never experienced before, insomnia, nerve

1 tingling, difficulty ambulating, headaches, and even facial pain due to the hardware
2
3 that had been placed into his upper and lower jaws during a 1999 facial
4
5 reconstruction surgery to correct the bony deformations in his face. After Plaintiff
6
7 learned that Arizona had passed an intractable pain law in 2022 protecting patients
8
9 and doctors, Plaintiff moved states again to Arizona to attempt to get proper,
10
11 appropriate pain management care restored. Plaintiff was immediately reinstated
12
13 onto his short-acting opioid medication but is still without the long-acting opioid
14
15 medication dose prescribed since 2015, even after having voluntarily reduced that
16
17 dose (initiated in 2009) by half, due to gastrointestinal side effects. Plaintiff lost
18
19 the ability to continue his part-time employment as a rideshare driver due to
20
21 increased pain and decreased functionality from this interruption in his pain
22
23 management care, and due to his inability to cope with that work and his mother's
24
25 declining health. Plaintiff had to file bankruptcy as a result of the loss of this
26
27 income, and that case is pending. Plaintiff's blood pressure is still elevated
28

1 (hypertension stage 1, down from hypertension Stage 2 earlier in 2024) (Exhibit
2
3 21), and remains under monitoring in order to determine whether treatment with
4
5 medications will be necessary.
6
7

8 **31. CLAIM 1: CDC NEGLIGENCE AND TORTIOUS INTERFERENCE**
9
10 **WITH THE PRACTICE OF MEDICINE IN VIOLATION OF 42 U.S.C. §**
11 **1395.**
12
13

14 The CDC published the 2016 Guidelines for Prescribing Opioids for Pain as
15
16 recommendation guidelines only, because the CDC was fully aware that it could
17
18 not create rules or regulations concerning the medical use of opioids, since federal
19
20 law prohibits federal agencies from interfering with the practice of medicine (42
21
22 U.S.C. § 1395). However, this publication then became the basis of an avalanche
23
24 of federal and state laws, rules, regulations, and settlement clauses, that in essence
25
26 made the 2016 CDC Clinical Practice Guidelines for Prescribing Opioids for Pain
27
28 a defacto creation of rules and regulations by a federal agency, in violation of 42

1 U.S.C. § 1395. Authors of the CDC Guidelines have admitted that the Guidelines
2
3 were “widely misapplied,” and should never have been the basis for the creation of
4
5 hard dose caps, prescribing rules, or other rules (Dowell, Deborah, M.D., M.P.H.,
6
7 Haegerich, Tamara, Ph.D., and Chou, Roger, M.D. No Shortcuts to Safer Opioid
8
9 Prescribing. New England Journal of Medicine, Vol. 380, No. 24. Page 2. April
10
11 24, 2019.) (Exhibit 22), but the Director of the CDC has refused to retract or to
12
13 rescind the Guidelines following these events, except for minor revisions published
14
15 in 2022. Plaintiff contends that since the Director of the CDC has been made fully
16
17 aware of the harms and deaths caused to patients since the Guidelines were
18
19 misapplied, and since the CDC knows that the Guidelines became a defacto basis
20
21 for the enactment of laws, rules, and regulations, whether intended or unintended,
22
23 yet continues to refuse to retract or to rescind the Guidelines completely, while
24
25 knowing that the resulting federal and state laws, rules, and regulations continue to
26
27 cause patient harms and deaths, that this equates to an ultra vires (out of the bounds
28

1 of the authority of the CDC) and equates to continued tortious interference with the
2
3 practice of medicine, which is unlawful pursuant to 42 U.S.C. § 1395:
4

5 “From Title 42-THE PUBLIC HEALTH AND WELFARE CHAPTER 7-
6 SOCIAL SECURITY SUBCHAPTER XVIII-HEALTH INSURANCE FOR
7 AGED AND DISABLED
8

9 §1395. Prohibition against any Federal interference
10

11 Nothing in this sub chapter shall be construed to authorize any Federal
12 officer or employee to exercise any supervision or control over the practice
13 of medicine or the manner in which medical services are provided, or over
14 the selection, tenure, or compensation of any officer or employee of any
15 institution, agency, or person providing health services; or to exercise any
16 supervision or control over the administration or operation of any such
17 institution, agency, or person.” (Aug. 14, 1935, ch. 531, title XVIII, §1801,
18 as added Pub. L. 89–97, title I, §102(a), 79 Stat. 291.). (Exhibit 23).
19
20

21 32. The CDC has continued to assert that “prescription opioid medications” have
22
23 been the cause of the “overdose and death crisis” even though the CDC’s own data
24
25 do not support this assertion.
26

27 ” Yet a third major false meme in public policy is also contradicted by
28 published demographic data accumulated by the US Centers for Disease

1 Control and Prevention (CDC) and the National Bureau of Statistics. This is
2 the false idea that prescription drugs are responsible for the majority (or
3 even a reliably large portion) of all accidental drug overdose deaths. A
4 major study of drug-related mortality published in the prestigious journal
5 Science in 2018, conclusively refutes this notion.” Lawhern, R., PhD. An
6 Indictment of US Public Health Policy on Pain Management. Clinical
7 Medicine and Health Research Journal (CMHRJ) Volume 04, Issue 06,
8 November-December, 2024, Page No. 1031-1036. (Exhibit 24).

9
10 After the CDC was captured by an anti-opioid group of addiction specialists,
11
12 Physicians for Responsible Opioid Prescribing (PROP), led by Andrew Kolodny, a
13
14 psychiatrist who specializes in addiction medicine, and others who have NOT
15
16 treated pain, the unscientific opinion that “all opioid medications are bad and
17
18 should never be used” has been inserted into the public narrative. Experts have
19
20 written extensively about this error in judgement and about the harm caused to
21
22 patients and have described alleged conflicts of interest that existed among the
23
24 PROP doctors and this “Core Expert Group” contracted with the CDC to formulate
25
26 the Guidelines.
27
28

1 “As other doctors and patient advocacy groups review the guidelines, they’re
2 speaking out against the document that they argue has little scientific
3 grounding. The process of writing the guidelines, they say, was tainted by
4 decisions made behind closed doors in consultation with anti-opioid activists
5 and a paid consultant for a law firm, which stands to make substantial gains
6 from pending suits.” (McCoy, S., Dysfunction, Lobbying, and Conflict of
7 Interest in the Debate Over Opioids. InsideSources.com. Page 2. 15 Oct
8 2015.). (Exhibit 25).

9
10 There was a Congressional Investigation of those alleged conflicts of interest,
11
12 which ended when Representative Jason Chaffetz of Utah retired from Congress,
13
14 described in Section 4, Pages 10-11, of Plaintiff’s Administrative Complaint
15
16 (Exhibit 26). Those records are not subject to the Freedom of Information Act and
17
18 cannot be obtained, so the results of the investigation are unknown. The history of
19
20 the influence of the PROP addiction psychiatrists over the CDC and of their
21
22 conflicts of interest were documented by Chad Kollas, M.D., a board certified in
23
24 internal medicine and provides palliative and supportive care physician in Orlando,
25
26 FL, in his article entitled “PROP’s Disproportionate Influence on U.S. Opioid
27
28 Policy: The Harms of Intended Consequences,” published on PalliMed, a Hospice

1 and Palliative Medicine Blog, 3 May 2021. (Exhibit 27). Proven conflicts of
2
3 interest are pervasive. “PROP members have failed on repeated occasions to
4
5 disclose these business relationships, but when questions were raised about them,
6
7 they filed revised conflict of interest statements — without providing details on
8
9 who they worked for or the amount they were paid.” (Kolodny Returns as PROP
10
11 President. Anson, P., Editor. Pain News Network. Page 3. 22 June 2022.).
12
13 (Exhibit 28).

14
15
16 33. These specialists who are focused on addiction, harm-reduction, and
17
18 decreasing overdose deaths have perpetrated the false narrative that “prescription
19
20 opioid medications” make every patient equally “at-risk for addiction and
21
22 overdose,” which is factually incorrect.

23
24 “Unlike Brat et al, we now know that “dependence” is not a voluntary
25 misuse of opioid pain relievers. It is a purely physiological response [7] to
26 prolonged opioid use at doses strong enough to build tolerance. Doctors also
27 know that dependence is much more frequent in patients under a doctor’s
28 care than are either addiction or overdose. According to the American

1 Medical Association, [8] “an estimated 3% to 19% of people who take
2 prescription pain medications develop an addiction to them.” The work of
3 Brat strongly contradicts that estimate and is confirmed by work of Dr. Nora
4 Volkow, [9] Director of the US National Institute on Drug Abuse.
5 Addiction is a very rare and unpredictable outcome of prescribing. If opioid
6 dependency occurs even as few as five times more often than opioid
7 addiction among post-surgical patients, then the estimated number of post-
8 surgical patients in Brat’s large records review who may actually be in
9 danger of addiction caused by clinical treatment is on the order of one
10 patient in a thousand or substantially less. Some researchers would put the
11 estimate at one in 100,000.” (Lawhern, R., PhD. United States Centers for
12 Disease Control and Prevention, Veterans Administration, and Law
13 Enforcement Versus The “Opioid Crisis” – Incompetence or Bad Faith? The
14 European Society of Medicine, Medical Research Archives, Volume 12
15 Issue 12, Page 2. 31 December 2024). (Exhibit 29).

16
17 In the usual course of events for the vast majority of cases, patients undergo
18
19 surgery every day, are prescribed opioid pain medications for surgeries as they
20
21 have been for many decades, use them during the recovery period, and then move
22
23 on with their lives with no issues whatsoever related to the use of pain medications.
24
25 Plaintiff is a perfect example of that, having been through numerous surgeries
26
27 during his lifetime, including great toenail bed resection on each foot at age 13,
28

1 Harrington rod and torsion hook implantation with 13-level spinal fusion at the
2
3 spinous processes at age 16, rhinoplasty at age 28 to correct a broken nose
4
5 sustained at age 14, a cyst removal from under the right earlobe at age 32,
6
7 orthognathic surgery to correct facial bony deformations of the maxilla and
8
9 mandible and bilateral TMJ joint dysfunction at age 36, and cholecystectomy at
10
11 age 41, recovering successfully from each of these procedures and having no
12
13 continued dependence on opioid pain medications following each surgery.

14
15 Plaintiff only became dependent upon (not “addicted” to) opioid pain medications
16
17 following the second radical back surgery which left him permanently and totally
18
19 disabled, with confirmed arachnoiditis (caused either by spinal cord crush injuries
20
21 due to his dessicated lumbar discs, or by the diagnostic CT Myelogram performed
22
23 during the workup for the 2009 lumbar surgery during which he suffered a
24
25 puncture of the dural membrane, or, by a combination of these two factors), cauda
26
27 equina syndrome, bilateral neuropathy of the lower extremities, sensory
28

1 disturbance in the lower extremities, and complete loss of motion from his hip
2
3 joints through the lowest cervical vertebrae, upper extremities and shoulder joints,
4
5 causing daily intractable pain relieved by no medical treatment other than a
6
7 therapeutic dose of full-agonist opioids.

8
9
10 34. Several of the addiction psychiatrists who were either on the “Core Expert
11
12 Group” panel or who have otherwise influenced the formulation of the 2016 CDC
13
14 Guidelines have lucrative careers as paid expert witnesses in trials involving opioid
15
16 manufacturers, distributors, and other proceedings. Andrew Kolodny, M.D.,
17
18 President of Physicians for Responsible Opioid Prescribing is providing courses to
19
20 teach other addiction specialists to diagnose “substance use disorder” using the
21
22 Diagnostic and Statistical manual in a way that was never intended, in legitimate
23
24 chronic and intractable pain patients who take their medications exactly as
25
26 prescribed and who display no indicators that would qualify them for this
27
28 diagnosis. Dr. Kolodny published an article about this subject and claimed that:

1 “Over the past 30 years, health and social problems related to opioid use
2 disorder (OUD) have intensified in the United States, with high rates of
3 neonatal opioid withdrawal syndrome, children entering foster care,
4 injection-related infectious diseases, homelessness, illicit opioid use, and
5 opioid-poisoning deaths being reported. Yet as this public health catastrophe
6 unfolded, the National Survey on Drug Use and Health (NSDUH), one of
7 the main tools used by the federal government for substance-use
8 surveillance, consistently reported low rates of OUD.

9
10 “In reflecting on the discrepancy between these low estimates and the
11 worsening opioid crisis, close observers pointed to the NSDUH’s
12 limitations, such as the omission of people who are unstably housed or
13 incarcerated. But a report published in July 2024 by authors affiliated with
14 the Department of Health and Human Services (HHS) shows that one of the
15 main problems with the NSDUH was far more elusive.¹ The survey wasn’t
16 identifying millions of cases of OUD because it had explicitly excluded a
17 large group of Americans with OUD: people who take opioids as prescribed.
18 Essentially, earlier versions of the survey seem to have relied on the
19 incorrect assumption that OUD can occur in patients taking prescribed
20 opioids only if they misused their medications. Patients taking opioids as
21 prescribed were therefore asked to skip the OUD-assessment questions.

22
23 “In 2021, HHS changed the NSDUH’s methods. Now, all patients who
24 report use of prescribed opioids in the previous year receive an assessment
25 for OUD based on Diagnostic and Statistical Manual of Mental Disorders,
26 fifth edition (DSM-5), criteria. As recommended by DSM-5, the NSDUH
27 didn’t include the tolerance and withdrawal criteria in its assessment of
28 patients who took opioids as prescribed.

1 “The results of this methodologic change are startling. According to
2 NSDUH annual reports, in 2019, HHS estimated that 1.6 million people in
3 the United States had OUD; in 2022, this estimate jumped to 6.1 million
4 people. Also accounting for people receiving OUD treatment who don’t
5 report active OUD symptoms, HHS now estimates that there are 9.4 million
6 people with OUD in the United States.² The enormous increase in estimated
7 prevalence was driven primarily by the number of people who have been
8 prescribed opioids for pain and take them as prescribed.

9
10 “According to the new data, most Americans with OUD are people who
11 have been prescribed opioids for pain. Moreover, 62% of the estimated 4.8
12 million people with OUD involving prescribed opioids don’t misuse their
13 medications.¹ This finding turns on its head the conventional wisdom that
14 OUD develops primarily in a subset of patients who have misused their
15 opioids. The three most common DSM-5 criteria for OUD reported by
16 people who took opioids as prescribed were unsuccessful efforts to cut down
17 or control use, opioid craving, and spending a great deal of time obtaining or
18 using opioids or recovering from opioid use.

19
20 “To be sure, assessing whether people using opioids for pain have OUD is
21 challenging. Some people receiving long-term opioid therapy who were
22 identified by the NSDUH as having OUD may have met the criteria for mild
23 OUD because of difficulty tapering off opioids. In addition, some patients
24 probably reported spending substantial time obtaining opioids because many
25 prescribers have become more reluctant to treat patients with opioids for
26 long periods.

1 “The discovery of millions of previously undetected cases of OUD should
2 prompt an urgent investigation to improve understanding of the overlooked
3 population. According to the NSDUH, more than one third of people with
4 OUD who had been prescribed opioids — including people who misused
5 and people who didn’t misuse their medications — met the DSM-5 criteria
6 for moderate or severe OUD,¹ which suggests they are at high risk for
7 overdose, transition to illicit opioids, and other serious health and
8 psychosocial problems associated with opioid use. State and federal health
9 authorities should ensure that patients prescribed opioids can easily obtain
10 access to OUD treatment.” (Screened Out — How a Survey Change Sheds
11 Light on Iatrogenic Opioid Use Disorder. Kolodny, A., M.D., and Bohler,
12 R., Ph.D., M.P.H., N Engl J Med VOL. 391 NO. 23. Page 1-2. 26
13 November 2024.). (Exhibit 30).

14
15 35. Chuck Dinerstein, M.D., M.B.A., offered these critiques about Dr. Kolodny’s
16
17 new assessment of the dramatic increase of the numbers of substance use disorder:

18
19 “Just when you thought the opioid crisis may have peaked, Dr. Andrew
20 Kolodny, arguably the world’s foremost anti-opioid zealot, has found a
21 shiny new way to inflate the numbers. In the HHS’s redefining of opioid use
22 disorder (OUD) to include patients responsibly taking their prescribed meds,
23 he’s managed to conjure millions of “new” cases out of thin air. But don’t
24 worry, it’s all in the name of “progress.” That’s because nothing says
25 compassionate care like labeling chronic pain patients as addicts and patting
26 yourself on the back for the chaos you helped create.”

1 “But is it truly a craving when opioids are the only medication that provides
2 a quality of life? Is it the patient unsuccessful when in consultation with their
3 physician they increase the dosage or create different medication usages [2]
4 to meet their clinical needs?”

5
6 “If a patient is indeed functioning well, then where is the disorder?
7 Certainly, a functional assessment is more valid than a DSM checklist. And
8 if an individual is unable to taper off opioids, one of the hallmarks of OUD,
9 then how is switching to buprenorphine, an opioid with a different, albeit
10 “safer” profile, an improved outcome?” (Dinerstein, C, M.D., M.B.A. Dr.
11 Kolodny’s New Math: Turning Chronic Pain Patients into OUD Statistics.
12 American Council on Science and Health. Page 1, 4-5. 16 December
13 2024.). (Exhibit 31).

14
15 36. Plaintiff found that the authors of the 2013 DSM-5 Revisions do not agree
16
17 with Dr. Kolodny’s assessment either. The assertion that a stable pain patient
18
19 taking a prescription medication for a medical condition has "substance use
20
21 disorder" because they cannot successfully taper without withdrawal symptoms is
22
23 erroneous, because they would not be expected to taper in the first place from a
24
25 therapeutic dose of medication.

26
27 “According to the authors of the 2013 DSM revisions, "The ‘abuse category’
28 has been eliminated from the proposed structure because of the lack of data

1 to support an intermediate state between drug use and drug addiction. The
2 symptoms created for DSM-III-R remain the same, except for the
3 elimination of the ‘legal difficulties’ symptom and the addition of ‘drug
4 craving.’ Tolerance and withdrawal symptoms are not counted towards the
5 diagnosis when the patient is involved in an appropriate medical treatment
6 program for a problem such as pain, depression or anxiety. Patients enrolled
7 in such programs can qualify for a substance use disorder only if they have
8 other symptoms of aberrant behavior demonstrating compulsive drug-
9 seeking." (O'Brien, C. Addiction and dependence in DSM-V. Addiction
10 (Abingdon, England), 106(5), 866–867, (2011). Page 3.). (Exhibit 32).

11
12 Furthermore, what are doctors doing trying to diagnose patients with “opioid use
13
14 disorder” using only a checklist in a diagnostic manual in the first place?

15
16 “Addiction is a chronic condition that is difficult to diagnose and treat.
17 While the signs can be clear, diagnosis first relies on the person with an
18 addiction or people close to them acknowledging and wanting to address the
19 problem.” (Felman, A. How does a doctor diagnose addiction?: The
20 Diagnostic Process. Medical News Today. Page 1. 2 November 2018.).
21 (Exhibit 33).

22
23 The addiction psychiatrists are not making these recommendations from a
24
25 position of being concerned for patient health, but rather, because they have
26
27 conflicts of interest and are being PAID to do so. Dr. Kolodny testified that he had
28

1 made between \$300,000 and \$500,000 in expert witness fees during anti-opioid
2
3 litigation. (Sammon, J. J&J's lawyers note opioids researcher being paid hundreds
4
5 of thousands for testimony in Oklahoma trial. Legal Newslne. June 2019).
6
7 (Exhibit 34).
8
9

10 37. Severely sick, injured, disabled patients with pain syndromes that are so severe
11
12 as to require therapeutic doses of opioid pain medications in order that they can be
13
14 able to perform the most basic activities of daily living and to therefore survive,
15
16 and to have any quality of life whatsoever, who do not exhibit any compulsive
17
18 behaviors, do not fit the criteria to be diagnosed with substance use disorder.
19

20 “It is unfortunately clear that many clinicians know little about opioid use
21 disorder. They do not understand it is a disease, and many believe opioid
22 dependence is the same as opioid use disorder. Lack of a clear
23 understanding results in clinicians confusing a patient with chronic non-use
24 disorder with the one misusing their prescribed opioid. Lack of training and
25 educational deficits often interfere with the appropriate prescription of
26 opioid analgesic agents.” (Preuss, C., Kalava, A., King, K. Prescription of
27 Controlled Substances: Benefits and Risks. Continuing Education Series,
28

1 National Institute of Health. National Library of Medicine. Page 2. Last
2 updated 29 April 2023.). (Exhibit 35).

3
4 38. Plaintiff's allegations of tortious and unlawful interference with the practice of
5
6 medicine by the Director of the CDC means that the legal question has arisen about
7
8 whether the formulation of the CDC Guidelines was predicated by negligence, and
9
10 Plaintiff offers the following evidence:

11
12 1. Plaintiff contends that the CDC knew or should have known that the basis
13
14 of its rationale for attempting to protect public health was flawed, and knew
15
16 or should have known that "prescription opioid medications" were not a
17
18 causal factor in the parabolic rise of opioid deaths beginning in 2010. One
19
20 of the authors of the CDC Guidelines wrote in the Journal of the American
21
22 Medical Association in 2017, about 2016 drug overdose data:

23
24 "Provisional data from the US Centers for Disease Control and
25 Prevention (CDC) indicate drug overdose deaths increased again from
26 2015 to 2016 by more than 20% (from 52,898 deaths in the year
27 ending in January 2016 to 64,070 deaths in the year ending in January
28 2017). Increases are greatest for over-doses related to the category

1 including illicitly manufactured fentanyl (i.e., synthetic opioids
2 excluding methadone), which more than doubled, accounting for more
3 than 20,000 overdose deaths in 2016 vs less than 10,000 deaths in
4 2015. This difference is enough to account for nearly all the increase
5 in drug overdose deaths from 2015 to 2016.” (Dowell, D., M.D.,
6 Noonan, R., PhD., Houry, D., M.D., M.P.H. Underlying Factors in
7 Drug Overdose Deaths. JAMA. 2017; 318(23):2295-2296.).
8 (Exhibit 36).

9
10 There would seem to be no rational basis for any author or for the Director
11
12 of the CDC to claim that this information about illicit fentanyl analog
13
14 compounds being the driver of the parabolic increase in the number of
15
16 overdose deaths beginning in the years just prior to and during the
17
18 formulation and publication of the CDC Guidelines was unknown, when
19
20 those authors published this data in 2017 about the overdose deaths that
21
22 occurred in 2016. Clearly the authors of the CDC Guidelines absolutely
23
24 knew that “prescription opioid medications” were not a causal factor in the
25
26 parabolic increase in the number of overdose deaths as reported.

27
28 Additional evidence that the CDC was aware of fentanyl analog compound

1 poisonings being the cause of the parabolic increase in the number of deaths,
2
3 due to coding errors built into the ICD-9 and 10 coding systems was
4
5 presented in Section 2, Pages 7-8, of Plaintiff's Administrative Complaint
6
7 (Exhibit 37). The 2016 CDC Guidelines were based upon data
8
9 misrepresented by the Department of Health and Human Services (HHS)
10
11 and the CDC in a negligent manner, specifically because the data concerning
12
13 overdoses and deaths from illicit fentanyl analog poisonings were
14
15 categorized as having been caused by "prescription opioid medications." As
16
17 a result, the CDC recommendations for enacting lower opioid prescribing
18
19 rules were enacted by Congress, state legislatures, state medical boards, and
20
21 federal agency rules and regulations, based on the false narrative that
22
23 "prescription opioid medications" were the cause of the overdoses and
24
25 deaths, which was not factual.

26
27 "In a 2018 report titled, Quantifying the Epidemic of Prescription
28 Opioid Overdose Deaths, four senior analysts of the Centers for

1 Disease Control and Prevention (CDC), including the head of the
2 Epidemiology and Surveillance Branch, acknowledged for the first
3 time that the number of prescription opioid overdose deaths reported
4 by the CDC in 2016 was erroneous. The error, they said, was caused
5 by miscoding deaths involving illicitly manufactured fentanyl (IMF)
6 as deaths involving prescribed fentanyl.” (Peppin, J. F., & Coleman,
7 J. J. (2021). CDC's Efforts to Quantify Prescription Opioid Overdose
8 Deaths Fall Short. *Pain and therapy*, 10(1), 25–38. Page 1.). (Exhibit
9 38).

10
11 However, no correction formally occurred to the public record of the CDC’s
12
13 awareness that the narrative about the alleged role of “prescription opioid
14
15 medications” in the wave of overdose deaths until the 2023 Congressional
16
17 Testimony by Christopher M. Jones, PHARMD, DRPH, MPH, CAPT, of the
18
19 US Public Health Service, was provided one week following the
20
21 appointment of Mandy K. Cohen as Director of the CDC. (Responding to
22
23 America’s Overdose Crisis: An Examination of Legislation to Build Upon
24
25 the Support Act. CDC Congressional Testimony, House Energy and
26
27 Commerce Committee, Subcommittee on Health. 21 June 2023.). (Exhibit
28

1 39).

2
3 2. Plaintiff contends that the CDC should have known that the unscientific
4
5 MME chart used as the basis for recommending maximum doses of opioid
6
7 medications, even to opioid naïve patients, was flawed since that MME chart
8
9 in no way accounts for CYP 450 genetic pleomorphism or individual
10
11 differences in the way different patients metabolize or absorb opioids, or to
12
13 respond to different medication formulations. Evidence that the CDC should
14
15 have known about the unscientific nature of the MME chart because that
16
17 information was known in the medical literature since 2010 and was publicly
18
19 available is documented in Section 2, Pages 7-8, of Plaintiff's
20
21 Administrative Complaint (Exhibit 40).

22
23 3. Congress, state legislatures, state medical boards all failed to perform any
24
25 due diligence to confirm that the CDC assertions about the alleged role of
26
27 prescription medications in the overdose and death crisis and other false
28

1 narratives were true, and then numerous laws, rules, regulations, and
2
3 settlement clauses were enacted, based upon these false narratives
4
5 perpetrated by the CDC. The three false narratives most widely published
6
7 by the CDC are that:

- 8
9 1. Overprescribing by physicians allegedly caused the “opioid crisis;”
- 10
11 2. That prescription drugs are responsible for some reliably large
12 portion of accidental overdose deaths,” and;
- 13
14 3. That every patient prescribed an opioid by a physician is equally
15 “at-risk for addiction and overdose.”

16
17 Patient advocate and subject matter expert Richard A. Lawhern, PhD.,
18
19 summarized three major studies that refute these three assertions in a peer
20
21 reviewed journal article in Clinical Medicine and Health Research Journal
22
23 (CMHRJ) Volume 04, Issue 06, November-December, 2024, Page No.
24
25 1031-1036, entitled “An Indictment of US Public Health Policy on Pain
26
27 Management.” (Exhibit 41)

1 Additionally, Chad Kollas, M.D, “presented evidence that providing
2
3 outpatient palliative care longitudinally over four years offered lasting
4
5 treatment-related reductions in pain intensity, preservation of performance
6
7 status, and reduction in overall overdose risk,” in a four-year clinical study
8
9 performed in the outpatient palliative medicine clinic of a regional cancer
10
11 center in Orlando, Florida (United States). The subjects were a cohort group
12
13 who received palliative care during the time period between July 2018 and
14
15 October 2022. (Kollas, C., M.D., Ruiz, K., Laughlin, A. “Effectiveness of
16
17 Long-Term Opioid Therapy for Chronic Pain in an Outpatient Palliative
18
19 Medicine Clinic,” Journal of Palliative Medicine, Vol 27, No 1,
20
21 5 Jan 2024.). (Exhibit 42). This long-term peer reviewed clinical
22
23 study refutes the government’s claims that long-term use of opioids for pain
24
25 is “ineffective.” That false narrative has been used to force-taper and to
26
27 discontinue patients from therapeutic doses of opioid pain medications and
28

1 other controlled substances, causing medical complications, patient collapse,
2
3 and death.

4
5 4. The CDC purportedly published the 2016 Clinical Practice Guidelines for
6
7 Prescribing Opioids for Pain as recommendation guidelines only, because
8
9 the CDC was fully aware that it could not create rules or regulations
10
11 concerning the medical use of opioids (or other controlled substances), since
12
13 federal law prohibits federal agencies from interfering with the practice of
14
15 medicine (42 U.S.C. § 1395). However, since neither Congress nor any
16
17 other entity performed any due diligence in order to confirm whether the
18
19 assertions made by the CDC were true, this publication then became the
20
21 basis of an avalanche of federal and state laws, rules, regulations, and
22
23 clauses, that in essence, made the 2016 CDC Guidelines for
24
25 Prescribing Opioids for Pain a defacto creation of rules and regulations by a
26
27 federal agency, in violation of 42 U.S.C. § 1395. Authors of the CDC
28

1 Guidelines openly admitted that the agency has committed tortious
2
3 interference with the practice of medicine with the publication of these
4
5 Guidelines and are quoted in the New England Journal of Medicine as
6
7 saying that they have been working to inject the recommendations of the
8
9 Guidelines into medical education programs.

10
11 “The CDC offers several tools to assist, including a pocket guide on
12 tapering, a mobile app and online training with motivational
13 interviewing components, and information about nonopioid treatments
14 for pain. We are also working to identify ways to integrate
15 recommendations into medical education and to support best practices
16 among the next generation of medical professionals.” (Dowell, D.,
17 Haegerich, T., & Chou, R. (2019). No shortcuts to safer opioid
18 prescribing. New England Journal of Medicine, 380(24), 2285-2287.
19 Page 2.). (Exhibit 43).

20
21 Now medical schools are teaching doctors that opioid pain medications
22
23 should not be used, and we now have doctors openly advertising the fact that
24
25 they do not prescribe opioids under any circumstances, which can never be
26
27 allowed to remain in place as a medical dictate. There is a class of patients
28

1 like Plaintiff, whose injuries, illnesses, and disabilities will never allow them
2
3 freedom from pain, a reasonable quality of life, or the ability to function well
4
5 enough to perform the absolute minimum of activities of daily living to
6
7 sustain life without a therapeutic dose of opioid pain medications and other
8
9 controlled substances. This is also contributing to widespread patient
10
11 abandonment, failure to perform the proper duty of care, and the new trend
12
13 of “opioid-free surgeries” which delay recovery, since uncontrolled pain
14
15 increases stress on the body and harms the ability to recover.
16
17

18 Plaintiff contends that the preceding list of four items is more than sufficient
19
20 evidence to demonstrate negligence in the formulation and publication of the
21
22 2016 CDC Guidelines for Prescribing Opioids for Pain.
23
24

25 **39. CLAIM 1, LEGAL BASIS FOR: CDC LIABILITY FOR NEGLIGENCE**
26
27 **AND TORTIOUS INTERFERENCE WITH THE PRACTICE OF**
28

1 **MEDICINE IN VIOLATION OF 42 U.S.C. § 1395.**

2
3 Texas law permits TORT suit of a government official for committing an ultra
4
5 vires act.

6
7 “However, “[t]o fall within this ultra vires exception, a suit must not
8 complain of a government officer’s exercise of discretion, but rather must
9 allege, and ultimately prove, that the officer acted without legal authority or
10 failed to perform a purely ministerial act.” Id. We held that “as a technical
11 matter, the governmental entities themselves—as opposed to their officers in
12 their official capacity—remain immune from suit” on such claims. Id. at
13 372–73. This rule “derives from the premise that the ‘acts of officials which
14 are not lawfully authorized are not acts of the State.’” Id. at 373 (quoting
15 Cobb v. Harrington, 190 S.W.2d 709, 712 (Tex. 1945)). We concluded that
16 suits complaining of ultra vires action may not be brought against a
17 governmental unit possessed of sovereign immunity, but must be brought
18 against the allegedly responsible government actor in his official capacity.”
19 (*TEXAS DEPARTMENT OF INSURANCE v. RECONVEYANCE SERVICES,*
20 *INC.*; from Travis County; 3rd district (03-06-00313-CV, 240 SW3d 418,
21 08-31-07). (Exhibit 44).

22
23 Plaintiff contends that the publication of and continued refusal to retract or to
24
25 rescind the 2016 CDC Guidelines are ultra vires acts in violation of 42 U.S.C. §
26
27 1395, since the CDC is specifically prohibited from interfering with the practice of
28

1 medicine.

2
3 “Henceforth, government officials performing discretionary functions
4 generally are shielded from liability for civil damages insofar as their
5 conduct does not violate "clearly established" statutory or constitutional
6 rights of which a reasonable person would have known.” (*Harlow v.*
7 *Fitzgerald*, 457 U.S. 800, 1982. Page 4.). (Exhibit 45).

8
9 Plaintiff contends that the evidence shows that this burden has been met, given that
10
11 the CDC Guidelines are a defacto basis for laws, rules, and regulations that
12
13 unlawfully interfere with the practice of medicine in violation of 42 U.S.C. § 1395,
14
15 while purporting to be an attempt to formulate public policy as a harm-reduction
16
17 effort, when that effort is not even focused on the correct cohort of people who are
18
19 dying from illicit fentanyl analog poisoning, and that the Director of the CDC has
20
21 been made fully aware that the CDC Guidelines became a defacto basis for the
22
23 avalanche of laws, rules, and regulations causing patient harms and deaths yet has
24
25 refused to retract or to rescind the Guidelines.

26
27 40. The Court must now determine whether Plaintiff’s harms (caused by the ultra
28

1 vires act of the publication and the refusal to retract and to rescind the 2016 CDC
2
3 Guidelines) “caused by the negligent or wrongful act or omission of any employee
4
5 of the Government while acting within the scope of his office or employment,
6
7 under circumstances where the United States, if a private person, would be liable to
8
9 the claimant in accordance with the law of the place where the act or omission
10
11 occurred.” 28 U.S.C. § 1346(b) (emphasis added)” (*Johnson v. Sawyer*, 47 F.3d
12
13 716, 5th Cir. 1995). (Exhibit 46).

14
15
16 41. We look to Texas Title 4, Chapter 88, Section 002, (Exhibit 47), which states
17
18 that:

19
20 “Sec. 88.002. APPLICATION.

21
22 (a) A health insurance carrier, health maintenance organization, or other
23 managed care entity for a health care plan has the duty to exercise ordinary
24 care when making health care treatment decisions and is liable for damages
25 for harm to an insured or enrollee proximately caused by its failure to
26 exercise such ordinary care.

27 (b) A health insurance carrier, health maintenance organization, or other
28 managed care entity for a health care plan is also liable for damages for

1 harm to an insured or enrollee proximately caused by the health care
2 treatment decisions made by its:

- 3
4 (1) employees;
5 (2) agents;
6 (3) ostensible agents; or
7 (4) representatives who are acting on its behalf and over whom it has
8 the right to exercise influence or control or has actually exercised
9 influence or control which result in the failure to exercise ordinary
10 care.”

11
12 “*Johnson v. Sawyer*, 47 F.3d 716, 727-29 (5th Cir. 1995) explains that “the
13
14 violation of a federal statute or regulation does not give rise to FTCA liability
15
16 unless the relationship between the [government actor] and the [plaintiff] is such
17
18 that the former, if a private person or entity, would owe a duty to the latter in a
19
20 nonfederal context.” (Dinnell, A. Using the “Private Individual Under Like
21
22 Circumstances” to Your Advantage: The Analogous Private Liability Requirement
23
24 Under the Federal Tort Claims Act. Federal TORT Claims Act II, Vol. 59 No.1,
25
26 [Jan 2011]. Page 11.). (Exhibit 48).

1 42. Plaintiff contends that the ultra vires role of the CDC in making treatment
2
3 recommendations in violation of 42 U.S.C. § 1395 that have “actually exercised
4
5 influence or control which result(ed) in the failure to exercise ordinary care”
6
7 (Texas Title 4, Chapter 88, Section 002(b)(4)), (Exhibit 49) in his treatment,
8
9 causing him loss of access to therapeutic doses of the FDA-approved medications
10
11 and to the only known medical treatment that relieve his symptoms that allow him
12
13 to perform the most basic activities of daily living and to therefore survive or to
14
15 have any quality of life whatsoever, causing him increased risk of uncontrolled
16
17 blood pressure, heart attack, stroke, and suicide in the future, is analogous to the
18
19 role of the Health Maintenance Organization, it’s “employees, agents, ostensible
20
21 agents, and representatives” and its “insured enrollees” that have “actually
22
23 exercised influence or control which result(ed) in the failure to exercise ordinary
24
25 care” in this context of comparing the government employee or agency to a private
26
27 individual or group.
28

1 43. Plaintiff contends that this shows that a “private person, would be liable to the
2
3 claimant in accordance with the law of the place where the act or omission
4
5 occurred,” pursuant to 28 U.S.C. § 1346(b), negating the Qualified Discretionary
6
7 Immunity defense. Therefore, the Director of the CDC is liable under the FTCA,
8
9 and the United States is therefore substituted as the responsible party pursuant to
10
11 28 U.S.C. § 2679 (d)(1):

12
13 “Upon certification by the Attorney General that the defendant employee
14 was acting within the scope of his office or employment at the time of the
15 incident out of which the claim arose, any civil action or proceeding
16 commenced upon such claim in a United States district court shall be
17 deemed an action against the United States under the provisions of this title
18 and all references thereto, and the United States shall be substituted as the
19 party defendant.”

20
21 44. There are no general caps on non-economic damages in most personal injury
22
23 cases in Texas, except for medical malpractice claims, which are capped at
24
25 \$250,000 per defendant. Other than for medical malpractice, there are no statutory
26
27 caps. Texas statutes have not enacted a cap for non-economic damages for
28

1 damages in personal injury claims, although punitive damages are not allowed.

2
3 (Civil Practice and Remedies Code, Title 2. Trial, Judgment, and Appeal, Subtitle
4
5 C. Judgments, Chapter 41. Damages). (Exhibit 50).
6
7

8 **45. CLAIM 2: DEA NEGLIGENCE AND TORTIOUS INTERFERENCE**
9
10 **WITH THE PRACTICE OF MEDICINE IN VIOLATION OF 42 U.S.C. §**
11 **1395.**
12

13
14 Both the 2016 CDC Guidelines for Prescribing Opioids for Pain and the 2017
15
16 President’s Commission on Combating Drug Addiction and the Opioid Crisis
17
18 (Exhibit 51) specifically excluded board-certified, trained pain doctors from the
19
20 prescribing recommendations, which were directed toward primary care physicians
21
22 treating new, opioid naïve patients. Every federal and state law, federal agency
23
24 rule and regulation, state medical board rule, and opioid settlement clause, have
25
26 failed to comply with these edicts, and pain doctors have been relentlessly targeted
27
28 and prosecuted unjustly by the DEA and DOJ. DoctorsofCourage.org maintains a

1 listing of doctors incarcerated for the “crime” of treating pain on their website.

2
3 The abuses of the DEA prosecution of doctors have been known since The Libby
4
5 Report was published in 2005 (Treating Doctors as Drug Dealers; The DEA’s War
6
7 on Prescription Pain Killers, Libby, R., The CATO Institute, Policy Analysis No.
8
9 545, 6 June 2005.). (Exhibit 52).

10
11
12 46. The Administrator of the DEA, Anne Milgram, has been made aware of the
13
14 factual errors committed by the CDC in the formulation of the 2016 CDC
15
16 Guidelines, and of the DEA abuses of continuing to prosecute doctors without
17
18 having met the evidentiary standard required as set forth by SCOTUS in *Ruan vs.*
19
20 *United States*, (597 U.S. __, June 27, 2022), as documented in Section 5, Pages 11-
21
22 15, of Plaintiff’s Administrative Complaint (Exhibit 53). However, the DEA
23
24 continues to commit tortious acts of interference with the practice of medicine in
25
26 violation of 42 U.S.C. § 1395 by allowing DEA enforcement of dose caps for
27
28 various categories of controlled substances, and medication combination

1 prohibitions, while ignoring the fact that these substances, including prescriptions
2
3 of a higher dose than the CDC Guidelines recommended for newly injured, opioid
4
5 naïve patients, have legitimate medical uses for chronic, intractable, cancer, end-
6
7 of-life, and surgical pain patients, as well as for anxiety patients (benzodiazepines),
8
9 and ADHD and fatigue patients (stimulants). The DEA has continued with annual
10
11 cuts to the production and distribution of various classes of controlled substances
12
13 through 2024, even after having been more than adequately notified with
14
15 comments posted to the annual requests for comments about the proposed quota
16
17 changes that these cuts would cause additional harms and deaths to patients, as
18
19 documented in Section 11, Pages 23-27, of Plaintiff's Administrative Complaint
20
21 (Exhibit 54). The DEA has continued with annual cuts in the production and
22
23 distribution of various categories of controlled substances such that sufficient
24
25 quantities of opioid medications and other controlled substances are no longer
26
27 available in pharmacies for patients to be able to fill prescriptions (in violation of
28

1 the United Nations Single Convention on Narcotic Drugs). The DEA continues to
2
3 perpetuate the pervasive and endemic climate of fear within the medical
4
5 community, wherein doctors are afraid to treat patients with the proper duty of
6
7 care, while doing no harm, since they might be arrested unjustly or lose their
8
9 medical licenses. Widespread patient abandonment has resulted, causing an untold
10
11 number of cases of torture and of deaths from medical complications such as the
12
13 known increased risks of cardiovascular disease, uncontrolled blood pressure, heart
14
15 attack, and stroke, and by suicide after patients have lost access to prescription
16
17 opioid medications and other controlled substances.

18
19 “The DEA acts like cutting people off their treatment, or, not treating them
20 at all with any effective medication is some kind of solution. It is not.
21 Untreated and undertreated chronic pain sufferers are 20% more likely to
22 have a heart attack and 30% more likely to have a stroke than the general
23 population. They are also more likely to commit suicide. Ten percent of all
24 suicides are linked to severe chronic pain. From my estimates we now have
25 at least 6,156,000 people with severe life-limiting chronic pain that cannot
26 find treatment. What is also not pointed out by the federal authorities, is how
27 many of those patients suffering from untreated chronic pain in a world
28 where it is no longer safe for doctors to treat them, will go to the streets,

1 finding fentanyl-laced fake pills rather than their expected medication. The
2 evidence is clear. In their misguided attempts to stop prescription opiate
3 overdose, which accounts for less than five hundred deaths per year, the US
4 federal government is killing tens of thousands. They may be killing them
5 quietly and indirectly, but those patients are dead just the same.” (Parker, L.
6 Joseph, M.D. Killing Them Quietly: Government versus Medicine. The
7 Daily Remedy, Perspectives. April 6, 2024. Page 7). (Exhibit 55).

8
9
10 **47. CLAIM 2, LEGAL BASIS FOR: DEA LIABILITY FOR NEGLIGENCE**
11
12 **AND TORTIOUS INTERFERENCE WITH THE PRACTICE OF**
13
14 **MEDICINE IN VIOLATION OF 42 U.S.C. § 1395, AND FOR IGNORING A**
15
16 **SUPREME COURT DECISION.**

17
18 The FTCA allows claims against law enforcement officers for injury as a result of
19
20 the abuse of process through the “law enforcement proviso.” For the purposes of
21
22 this exception, a "law enforcement officer" is defined as “any officer of the United
23
24 States who is empowered by law to execute searches, seize evidence, or make
25
26 arrests for violations of federal law.” The FTCA permits claims against law
27
28 enforcement officers that involve assault, battery, false imprisonment, false arrest,

1 malicious prosecution, or abuse of process. The text of the Proviso is linked to the

2
3 Intentional Torts Exception at 28 U.S.C. § 2680(h):

4
5 “Provided, That, with regard to acts or omissions of investigative or law
6 enforcement officers of the United States Government, the provisions of
7 [The FTCA] shall apply to any claim arising, on or after the date of the
8 enactment of this proviso, out of assault, battery, false imprisonment, false
9 arrest, abuse of process, or malicious prosecution,” (28 U.S.C. § 2680(h).

10
11 Should the Court agree that the Administrator of the DEA has negligently and
12
13 unlawfully interfered with the practice of medicine, and with Plaintiff’s contention
14
15 that liability for TORTs exists for the abuses of process described, including the
16
17 enforcement of opioid dose caps, controlled substance medication combination
18
19 prohibitions in violation of 42 U.S.C. § 1395, cuts in production and distribution of
20
21 controlled substances such that there is not a sufficient quantity of these
22
23 medications to fill all legal prescriptions, and for ignoring a SCOTUS Decision
24
25 concerning the evidentiary standard needed to arrest and prosecute doctors
26
27 prescribing controlled substances, Plaintiff requests that the Court find that the
28

1 Qualified Discretionary Immunity defense does not apply, and the Administrator of
2
3 the DEA is liable for TORT claims pursuant to 28 U.S.C. § 2680(h). The United
4
5 States would then be substituted as the responsible party pursuant to 28 U.S.C. §
6
7 2679 (d)(1):

8
9 “Upon certification by the Attorney General that the defendant
10 employee was acting within the scope of his office or employment at the
11 time of the incident out of which the claim arose, any civil action or
12 proceeding commenced upon such claim in a United States district court
13 shall be deemed an action against the United States under the provisions of
14 this title and all references thereto, and the United States shall be substituted
15 as the party defendant.”
16
17

18 **48. CLAIM 3, LEGAL BASIS FOR: UNITED STATES VIOLATIONS OF**
19
20 **THE UNITED NATIONS SINGLE CONVENTION ON NARCOTIC**
21
22 **DRUGS.**
23

24 The DEA has continued with annual cuts to the production and distribution of
25
26 various classes of controlled substances through 2024, even after having been more
27
28 than adequately notified with comments posted to the annual requests for

1 comments about the proposed quota changes that these cuts would cause additional
2
3 harms and deaths to patients, as documented in Section 11, Pages 23-27, of
4
5 Plaintiff's Administrative Complaint (Exhibit 56). DEA cuts to the production and
6
7 distribution of opioid pain medication and other controlled substances have caused
8
9 Plaintiff to face delays in obtaining prescription medications, since there are no
10
11 longer sufficient supplies of controlled substances to meet the needs of patients,
12
13 and since pharmacies nationwide have inadequate medications on hand to fill
14
15 prescriptions. Plaintiff contends that unless and until these laws, rules, and
16
17 regulations are corrected that the United States will remain in violation of United
18
19 Nations Single Convention on Narcotic Drugs, which stipulates that:

20
21 "ensuring the availability of controlled narcotic drugs and psychotropic
22 substances for medical and scientific purposes and ensuring the availability
23 of precursor chemicals for legitimate industrial use" (United Nations Single
24 Convention on Narcotic Drugs, March 30, 1961. Page 1). (Exhibit 57).
25
26

27 **49. CLAIM 4: DOJ TORTIOUS INTERFERENCE WITH THE PRACTICE**
28

1 **OF MEDICINE IN VIOLATION OF 42 U.S.C. § 1395, WHILE IGNORING**
2
3 **A SUPREME COURT DECISION.**
4

5 The Attorney General of the United States DOJ has allowed the DEA to continue
6
7 to arrest and to prosecute pain doctors, without having met the evidentiary standard
8
9 required to do so as set forth by The Supreme Court of the United States
10
11 (SCOTUS) in *Ruan vs. United States*, (597 U.S. ___, June 27, 2022),
12
13 and to continue using “paid expert witness testimony” to convince
14
15 juries of guilt when there is none. This was described and documented in Section
16
17 5, Pages 11-15, of Plaintiff’s Administrative Complaint (Exhibit 58). The
18
19 prosecutions of doctors for the “crime” of treating pain have created a pervasive
20
21 and endemic climate of fear among medical professionals and has resulted in a
22
23 group of thousands of physicians having been prosecuted unfairly and/or
24
25 incarcerated, and a class of patients who have become “pain refugees,” unable to
26
27 get their pain and conditions treated. Doctors of Courage maintains a listing of
28

1 incarcerated physicians at their website and regularly publishes stories about
2
3 doctors unjustly prosecuted by the DEA/DOJ. As of January 2025, conditions are
4
5 so bad that even surgical patients are being tortured in hospitals post-operatively,
6
7 being denied proper, appropriate opioid pain relief. Some surgical patients do not
8
9 survive this torture. The hundreds of anecdotal reports provided to Plaintiff during
10
11 2024 in his networking with other harmed patients include:

- 12
13 1. An open-heart surgery patient only provided Tylenol post-operatively
14 whose blood pressure from uncontrolled pain was so high that his heart
15 sutures burst, causing his death;
- 16 2. A 4-year-old girl given only Tylenol after a liver transplant who was left
17 crying and screaming in the hospital bed with her mother posting videos on
18 social media asking for help;
- 19 3. A 6-year-old boy not given pain medication following a laparoscopic
20 appendectomy who was screaming so loud that the nurses moved him from
21 recovery to a private room so as to not scare the other recovering patients,
22 after which he was finally provided IV pain medication so as to calm him
23 down, but no prescription to take home upon his same-day discharge;
- 24 4. A woman whose chemotherapy allowed her to survive cancer, but which
25 had the unintended consequence of causing paraneoplastic syndrome and
26 uncontrolled vomiting, relieved only by high dose opioid therapy, which she
27 can no longer get in the current medical climate and regulatory environment,
28 so the uncontrolled vomiting will surely kill her;

1 5. The case of Brittany Hightower, the Texas sickle-cell patient in crisis
2 who posted TikTok videos from her emergency room where she was treated
3 like a criminal seeking drugs, was discharged forcefully from the hospital
4 without being treated, and who died within a few months.

5
6 50. This unscientific agenda to force-taper all patients under treatment with full-
7
8 agonist opioid medications and to restrict access to these medications for new
9
10 patients, which has caused an unknown number of patient deaths as a result of
11
12 medical complications or by suicide, has created an undeclared Public Health
13
14 Emergency that continues to be undeclared and ignored by the CDC, the
15
16 Department of Health and Human Services (HHS), the DEA, the DOJ, Congress,
17
18 and the Veterans Administration (VA).

19
20
21 51. Merrick B. Garland, Attorney General of The United States Department of
22
23 Justice (DOJ) has been fully briefed about the factual errors made by the CDC in
24
25 the formulation of the CDC Guidelines, of the DEA's unlawful enforcement of
26
27 dose caps, medication combination prohibitions, and of the failure of the DEA to
28

1 abide by the SCOTUS Decision in *Ruan vs United States*, (597 U.S. ___, June 27,
2
3 2022), yet continues to allow these abuses of process to continue. This tortious
4
5 interference with the practice of medicine committed by the Attorney General in
6
7 violation of 42 U.S.C. § 1395, and in violation of the SCOTUS Decision in *Ruan*
8
9 *vs United States*, (597 U.S. ___, June 27, 2022), whether done through negligence
10
11 or deliberate malfeasance, is also contributing to the harms, torture, and deaths of
12
13 patients nationwide, including the harms caused to Plaintiff.

14
15
16 **52. CLAIM 4, LEGAL BASIS FOR: DOJ LIABILITY FOR NEGLIGENCE**
17
18 **AND TORTIOUS INTERFERENCE WITH THE PRACTICE OF**
19
20 **MEDICINE IN VIOLATION OF 42 U.S.C. § 1395, AND FOR IGNORING A**
21
22 **SUPREME COURT DECISION.**

23
24 The FTCA allows claims against law enforcement officers for abuse of process
25
26 through the “law enforcement proviso.” For the purposes of this exception, a "law
27
28 enforcement officer" is defined as “any officer of the United States who is

1 empowered by law to execute searches, seize evidence, or make arrests for
2
3 violations of federal law.” The FTCA permits claims against law enforcement
4
5 officers that involve assault, battery, false imprisonment, false arrest, malicious
6
7 prosecution, or abuse of process. The text of the Proviso is linked to the
8
9 Intentional Torts Exception at 28 U.S.C. § 2680(h):

10
11 “Provided, That, with regard to acts or omissions of investigative or law
12 enforcement officers of the United States Government, the provisions of
13 [The FTCA] shall apply to any claim arising, on or after the date of the
14 enactment of this proviso, out of assault, battery, false imprisonment, false
15 arrest, abuse of process, or malicious prosecution,” (28 U.S.C. § 2680(h).
16
17

18 53. Should the Court agree that the Attorney General of the United States and DOJ
19
20 have negligently and unlawfully interfered with the practice of medicine in
21
22 violation of U.S.C. § 1395, Plaintiff contends that liability for TORTs exists for the
23
24 abuses of process described, for allowing the DEA to continue to prosecute doctors
25
26 while ignoring a SCOTUS Decision concerning the evidentiary standard needed to
27
28 arrest and to prosecute doctors prescribing controlled substances, a Proximate

1 Cause of harm to Plaintiff. These abuses of process on the part of law enforcement
2
3 negate the Qualified Discretionary Immunity defense, and the Attorney General of
4
5 the United States DOJ is liable for TORTS under the FTCA pursuant to U.S.C. §
6
7 2680(h). The United States is then substituted as the responsible party pursuant to
8
9 28 U.S.C. § 2679 (d)(1):

10
11 “Upon certification by the Attorney General that the defendant employee
12 was acting within the scope of his office or employment at the time of the
13 incident out of which the claim arose, any civil action or proceeding
14 commenced upon such claim in a United States district court shall be
15 deemed an action against the United States under the provisions of this title
16 and all references thereto, and the United States shall be substituted as the
17 party defendant.”
18
19

20 **54. CLAIM 5, LEGAL BASIS FOR: CDC, DEA, DOJ, RULES AND**
21
22 **CONGRESSIONAL ACTS IN VIOLATION OF THE 5th AND 14th**
23
24 **AMENDMENTS OF THE CONSTITUTION OF THE UNITED STATES.**
25

26 An undeclared Public Health Emergency has been created by the negligent,
27
28 unscientific, and factually incorrect policy decisions and implementations by the

1 US government concerning the harm-reduction efforts to attempt to reduce the
2
3 number of deaths caused by overdose. The death wave since at least 2010 and
4
5 possibly longer ago has been the result of people taking illicit fentanyl analog
6
7 compounds, polysubstance drug abuse, and alcohol abuse, not “prescription opioid
8
9 medications” as reported by the US Centers for Disease Control and Prevention
10
11 through 2023.

12
13 In a 2018 report entitled, “Quantifying the Epidemic of Prescription Opioid
14 Overdose Deaths,” four senior analysts of the Centers for Disease Control
15 and Prevention (CDC), including the head of the Epidemiology and
16 Surveillance Branch, acknowledged for the first time that the number of
17 prescription opioid overdose deaths reported by the CDC in 2016 was
18 erroneous,” (Peppin, J. F., & Coleman, J. J. (2021). CDC's Efforts to
19 Quantify Prescription Opioid Overdose Deaths Fall Short. Pain and therapy,
20 10(1), 25–38. Page 1.). (Exhibit 59).

21
22 However, this misdirection was not formally corrected until the presentation of
23
24 Congressional Testimony by Christopher M. Jones, PHARMD, DRPH, MPH,
25
26 CAPT, of the US Public Health Service, who reported:
27
28

1 “Among the nearly 110,000 Americans that are predicted to have died from
2 a drug overdose in the 12-month period ending in December 2022, over 75%
3 involved at least one opioid, with 75,217 (68.6%) involving synthetic
4 opioids, primarily illicitly manufactured fentanyl or fentanyl analogs.
5 Driving the historic increases in overdose deaths, particularly since 2013, is
6 the continued proliferation of a highly potent and unpredictable illicit drug
7 market saturated with synthetic opioids, especially illicitly manufactured
8 fentanyl.” (Jones, C., PHARMD, DRPH, MPH, CAPT of the US Public
9 Health Service. Responding to America’s Overdose Crisis: An Examination
10 of Legislation to Build Upon the Support Act. CDC Congressional
11 Testimony, House Energy and Commerce Committee, Subcommittee on
12 Health. Page 1. 21 June 2023.). (Exhibit 60).

13
14
15 55. The CDC, DEA, DOJ, Department of Health and Human Services (HHS), and
16
17 the US House Subcommittee on Health have been fully briefed about the
18
19 misrepresentation of data and about the harms and deaths caused to chronic,
20
21 intractable, cancer, end-of-life, and surgical pain patients as a result of the
22
23 government focusing on the wrong cohort of patients. Instead of reducing the
24
25 number of deaths, these efforts are causing widespread harms of torture and death
26
27 to the most sick, most injured, most disabled, and most vulnerable among us,
28

1 including to injured U.S. Military Veterans. The recently published report about
2
3 Veterans' suicide indicated that the most frequently reported risk factor for suicide
4
5 during the data period 2020-2022 was pain. (Plaintiff contends that this report fails
6
7 to indicate that these suicides resulted from untreated/undertreated pain, because of
8
9 the restrictions to access of opioid pain medications and other controlled
10
11 substances that have been enacted based on the negligent and incorrect CDC
12
13 Guidelines).

14
15 “Among Recent Veteran VHA Users whose suicide deaths occurred in
16 2020-2022 and were reported to VHA Suicide Prevention teams, VA
17 Behavioral Health Autopsy Program⁹ data indicated that the most frequently
18 identified risk factors were pain (53.8%), sleep problems (51.4%), increased
19 health problems (42.5%), recent declines in physical ability (34.3%),
20 relationship problems (33.1%), hopelessness (30.4%), impulsivity (27.1%)
21 and unsecured firearms in the home (27.1%).”
22 (2024 National Veteran Suicide Prevention ANNUAL REPORT, Part 2 of 2:
23 Report Findings, Page 6. US Department of Veterans Affairs, Office of
24 Suicide Prevention. Page 6. December 2024.). (Exhibit 61).

25
26
27 56. Plaintiff contends that the conflagration of events that began with the
28

1 collaboration between the CDC, members of an anti-opioid physicians' group of
2
3 addiction psychiatrists called Physicians for Responsible Prescribing of Opioids
4
5 (PROP), and DEA agents prior to the publication of the 2016 Clinical Practice
6
7 Guidelines for Prescribing Opioids for Pain, have created a multitude of complex,
8
9 difficult legal questions regarding the government's interests in protecting public
10
11 health, alleged probable tortious interference with the doctor/patient relationship,
12
13 unlawful interference with the practice of medicine, the erosion of the duty of care
14
15 and the responsibility for harms caused to patients, whether intentional or
16
17 unintentional, and TORT responsibility for harms to patients and to doctors caused
18
19 by negligent and intentional law enforcement actions. A former CDC employee
20
21 has written an entire book about the subject, detailing the inside story about the
22
23 problems with the CDC's formulation of the CDC Guidelines, which he contends
24
25 has created the opposite of the intended effect and has increased the number of
26
27 opioid deaths rather than decreased them:
28

1 “This book recounts in four parts the untold story of how the nationwide
2 implementation of a seemingly simple, rational, plausible intervention by the
3 CDC had the paradoxical effect of turbocharging the opioid epidemic. The
4 first part is an in-person tour of the current narcotic landscape through my
5 own painful experiences with opioids. The second draws on my 28 years of
6 disease-control work at CDC to give a narrative insight into the unique
7 institutional psychology that shaped the agency’s approach to opioids as if
8 they were an infectious pathogen whose transmission needed to be
9 interrupted. The third describes how CDC began its attempt in 2016 to
10 control the opioid epidemic, applying that transmission-interruption strategy,
11 and how six years of loud signs of devastating failure were ignored, during
12 which the period the opioid explosion became self-sustaining. In the fourth
13 part, I describe the opioid control struggles of a Native American hospital
14 where I was a physician, struggles both successful and unsuccessful,
15 struggles that seem a microcosm of the national dilemma around opioids and
16 its possible solutions. And in an afterward, I bring these disparate stories
17 into convergence to summarize what data and experience suggest about how
18 we may be able to emerge from the cruel, lethal paradoxes of our self-
19 inflicted opioid war. Which is really a war upon ourselves.” (LeBaron, C.
20 Greed to do Good: The Untold Story of CDC’s Disastrous War On Opioids:
21 A CDC Physician’s Personal Account. Amplify Publishing Group. 2024.).
22 (Exhibit 62).

23
24
25 57. These legal questions are further complicated by the misapplication of CDC
26
27 Guidelines now admitted to by that agency, (see: Dowell, Deborah, M.D., M.P.H.,
28

1 Haegerich, Tamara, Ph.D., and Chou, Roger, M.D. No Shortcuts to Safer Opioid
2 Prescribing. New England Journal of Medicine, Vol. 380, No. 24. Page 2. 24
3 April 2019.). (Exhibit 63). The restriction of access to FDA-approved controlled
4
5 substance medications, arbitrary, capricious and malicious prosecution of pain
6
7 doctors, asset seizure and policing-for-profit actions that have created a pervasive
8
9 and endemic climate of fear in the medical community, and artificial intelligence
10
11 datamining, as described in Section 5, Pages 11-15, (Exhibit 64), Section 6, Pages
12
13 15-16, (Exhibit 65), Section 7, Pages 16-20, (Exhibit 66) and Section 8, Pages 20-
14
15 21, (Exhibit 67) of Plaintiff's Administrative Complaint, have all been the
16
17 Proximate Causes of immeasurable harms to Plaintiff, and to millions of chronic,
18
19 intractable, cancer, end-of-life, surgical pain, and to other classes of patients. No
20
21 effort was made to protect the class of patients who are dependent upon (not
22
23 "addicted to") opioid pain medications and other controlled substances in order to
24
25 be able to perform the most basic activities of daily living so that they may survive
26
27
28

1 their severe illness, injuries, disabling pain conditions, and other types of
2
3 conditions, and in order that they be able to have any quality of life whatsoever.
4

5 The Federal Court of Appeals issued a 2018 ruling in the case of a Veteran that
6
7 says pain is a disabling condition, qualifying the individual for disability payments,
8
9 which should therefore also mean that the group of patients who depend upon
10
11 opioid pain medications and other controlled substances to manage their disabling
12
13 pain are qualified for protected status as a group under the Americans with
14
15 Disabilities Act and any other public law that protects equal access: “pain alone,
16
17 without an accompanying diagnosis of a present disease, can qualify as a
18
19 disability.” (*Saunders v. Wilkie*, 886 F.3d 1356, Fed. Cir. 2018). (Exhibit 68).
20

21 The use of opioid pain medications and other controlled substances for this class of
22
23 patients with disabling pain constitute legitimate medical use, and the laws, rules
24
25 and regulations enacted since the publication of the CDC Guidelines have almost
26
27 eliminated this legitimate medical use of FDA-approved controlled substances,
28

1 causing untold suffering, torture, and death to patients, in violation of their
2
3 Constitutional rights. The American Medical Association (AMA) is calling for
4
5 “the nation’s policymakers to change course and focus on increasing access to
6
7 evidence-based care for patients with pain, including non-opioid and non-
8
9 pharmacologic interventions when appropriate and opioid therapy when clinically
10
11 indicated. The AMA further encourages medical boards to adopt updated, 2024
12
13 guidelines from the Federation of State Medical Boards as well as state
14
15 legislatures, payers and pharmacy chains to remove arbitrary policies based on
16
17 outdated 2016 guidelines from the CDC.” (AMA 2024 Advocacy, Epidemic
18
19 Report Opioid Prescriptions. Page 1). (Exhibit 69).

20
21
22 58. The avalanche of laws, rules, and regulations based upon disinformation that
23
24 followed the publication of the 2016 CDC Guidelines, including The Controlled
25
26 Substances Act, the Non-Opioids Prevent Addiction in the Nation (NO PAIN),
27
28 Comprehensive Addiction and Recovery Act (CARA), and Substance Use–

1 Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients
2
3 and Communities (SUPPORT) Acts, the rules and regulations enacted by the DEA
4
5 and DOJ, whether through negligence or deliberate malfeasance, have led to the
6
7 implementation of an agenda comprised of actions such as forced tapers and
8
9 sudden discontinuation of therapeutic opioid medications or other loss of access of
10
11 controlled substance prescriptions for patients who have a legitimate medical need
12
13 for these controlled substances. As a result, many thousands of patients have
14
15 suffered medical complications, and many thousands of others have died either
16
17 from medical complications or by suicide after a forced-taper, sudden
18
19 discontinuation, or other loss of access to controlled substance medications.
20
21 (Numerous studies have demonstrated the risk of suicide following forced-tapers
22
23 and sudden discontinuations, including Comparative Effectiveness of Opioid
24
25 Tapering or Abrupt Discontinuation vs No Dosage Change for Opioid Overdose or
26
27 Suicide for Patients Receiving Stable Long-term Opioid Therapy. Larochelle MR,
28

1 Lodi S, Yan S, Clothier BA, Goldsmith ES, Bohnert ASB., JAMA Network Open,
2
3 Vol 5 Issue 8. 12 Aug 2022.). (Exhibit 70).
4

5
6 59. This agenda was initiated without regard to patient outcomes, including to the
7
8 harms caused to Plaintiff, regardless of consequences. Patient outcomes were
9
10 never tracked, and egregiously, oversight has not been instituted by any
11
12 government agency under which these rules and regulations were enacted. These
13
14 acts of negligent, tortious interference have created an undeclared Public Health
15
16 Emergency, and as of the date of this filing, the number of patients harmed or
17
18 killed by these policies remains unknown. The University of Alabama, under the
19
20 direction of Dr. Stefan Kertesz, is currently conducting a study of suicides
21
22 following a forced-taper or other loss of access to prescribed controlled substances,
23
24 but no figures have yet been published. (Kertesz, Stefan, M.D. Why We Need to
25
26 Study Suicides After Opioid Tapering. Pain News Network, 8 Dec 2023.).
27
28 (Exhibit 71). However, this study is not attempting to gather data about deaths

1 caused by medical complications such as uncontrolled blood pressure, increased
2
3 risk of heart attack and stroke, following denial of or loss of access to proper,
4
5 appropriate opioid pain relief, so the data from Dr. Kertesz's suicide study will not
6
7 completely represent the entire scope of the harms or number of deaths caused.
8
9

10 60. Plaintiff contends that laws, rules, and regulations that deprive patients of
11
12 proper, appropriate opioid and other controlled substance medications on which
13
14 they depend, purportedly enacted in order to protect the public health, are not
15
16 reasonable, since the peer-reviewed evidence shows that patients prescribed an
17
18 opioid medication and followed by a physician have far less than a 1% likelihood
19
20 of ever having a substance use disorder condition:
21

22 “The findings of this systematic review suggest that proper management of a
23 type of strong painkiller (opioids) in well-selected patients with no history of
24 substance addiction or abuse can lead to long-term pain relief for some
25 patients with a very small (though not zero) risk of developing addiction,
26 abuse, or other serious side effects.” (Noble M, Treadwell JR, Tregear SJ,
27 Coates VH, Wiffen PJ, Akafomo C, Schoelles KM, Chou R. Long-term
28 opioid management for chronic noncancer pain. Cochrane Database of

1 Systematic Reviews 2010, Issue 1. Art. No.: CD006605. DOI:
2 10.1002/14651858.CD006605.pub2. Page 2. Accessed 23 January 2025.).
3 (Exhibit 72).

4
5 And, because the vast majority of deaths since at least 2010 and possibly longer
6
7 have not been caused by “prescription opioid medications” as asserted by the CDC,
8
9 but rather by illicit fentanyl analog compound poisonings, after illicit drugs were
10
11 consumed by a completely different cohort of people and not by chronic,
12
13 intractable, cancer, end-of-life, surgical pain, and other classes of patients.

14
15
16 61. Plaintiff alleges that the publication of the 2016 CDC Clinical Practice
17
18 Guidelines for Prescribing Opioids for Pain, which were based upon (a)
19
20 manipulated, misrepresented, or misinterpreted data, (b) unscientific assertions,
21
22 and (c) factually incorrect conclusions, which became the defacto basis of laws,
23
24 rules, and regulations that led to restrictions of access to opioid pain medications
25
26 and to other controlled substances which were applied to all patients, purportedly
27
28 enacted as a public health measure to prevent the “risks of addiction and

1 overdose,” including to the group of severely ill, injured, surgical, and disabled
2
3 patients who are not the cohort of people affected by these risks or these deaths
4
5 caused by the use of illicit fentanyl analog compound poisonings, polypharmacy,
6
7 and alcohol abuse. This publication was a Proximate Cause of bodily and
8
9 economic harms to Plaintiff violating Plaintiff’s 5th and 14th Amendment rights to
10
11 Liberty, and could in the future be a Proximate Cause of the violation of Plaintiff’s
12
13 5th and 14th Amendment right to Life, if the public record is not corrected.
14
15

16 62. The unscientific agenda to force-taper all opioid patients was implemented,
17
18 Including the denial of the initiation of proper, appropriate opioid pain relief for all
19
20 new injury and surgery patients, cancer, chronic, intractable, and end-of-life
21
22 patients, without regard to their specific conditions, the severity of their illnesses,
23
24 injuries, or disabilities, and without regard to the fact that long-term opioid therapy
25
26 with full-agonist opioid medications is the only known medical treatment indicated
27
28 to relieve their suffering, to allow them to function, if even at a rudimentary level,

1 and to allow them a minimal quality of life. This agenda, purported to be enacted
2
3 to protect the public health and to stop overdose deaths in a different cohort of
4
5 people who are using illicit fentanyl analog compounds and abusing other illicit
6
7 drugs or alcohol, which has resulted in the group of severely ill, injured, and
8
9 disabled patients, including Plaintiff, to be deprived of the Liberty to have their
10
11 pain and conditions treated with the only known therapeutic medical treatment
12
13 available, and for many to be deprived of Life, does not meet the Rational Basis
14
15 test of the Due Process clause, a clear violation of the 5th and 14th Amendments of
16
17 the Constitution of the United States.

18
19
20 63. The unscientific agenda to reduce opioid prescribing is based on false
21
22 narratives and abstract concerns about patients being “at-risk” for “addiction,” for
23
24 being points of the diversion of medication (with no evidence that medications
25
26 were being diverted by any individual patient), and for “overdose,” even though
27
28 these patients, like Plaintiff, have adhered to their pain management contracts for

1 many years, and in some cases for decades, without incident, represents a clear
2
3 violation of the 5th and 14th Amendments of the Constitution of the United States,
4
5 since this agenda does not meet the Rational Basis test of the Due Process clause
6
7 prior to the deprivation of Liberty or of Life.
8
9

10 64. Congress, following its failure to perform any due diligence to confirm the
11
12 accuracy of the CDC assertions about prescription opioid medications, codified the
13
14 use of “Summary Statistics” and the use of the Bell Curve in order to datamine all
15
16 of the Medicare Beneficiary data to find “outliers” who receive prescription opioid
17
18 medications “in excess of the norm,” without defining the term “norm,” other than
19
20 by using the unscientific morphine milligram equivalent (MME) chart and the use
21
22 of the Bell Curve. Human beings and their responses to opioid pain medication
23
24 therapy cannot be measured in this way because too many variables exist.

25
26 Variables that were not considered include CYP 450 genetic pleomorphism and
27
28 variability in the way some humans metabolize opioid medications, different

1 responses to different medications which are dependent upon the type of injury or
2
3 illness, upon individual response to different medications and formulations, as
4
5 discussed previously in Section 2, Page 7, of Plaintiff's Administrative Complaint.
6
7 (Exhibit 73). Therefore, Sections of multiple Acts of Congress are also 5th and
8
9 14th Amendment violations since they are depriving patients of Liberty and of
10
11 Life, without satisfying the Rational Basis test of the Due Process clause of the 5th
12
13 and 14th Amendments of the Constitution of the United States.

14
15
16 65. Federal Laws including the Controlled Substances Act, the NO PAIN Act, the
17
18 CARA Act, and the SUPPORT Act, which were enacted or amended based upon
19
20 the problematic recommendations of the 2016 CDC Guidelines, include
21
22 unconstitutional regulations which have been the Proximate Causes of harms of
23
24 bodily and economic injury to Plaintiff in violation of the 5th and 14th
25
26 Amendments to the Constitution of the United States. These laws unreasonably
27
28 deprived Plaintiff of the Liberty to continue having his condition treated by the

1 only known medical treatment that relieves his pain and allows him to perform the
2
3 most basic activities of daily living, and of the Liberty to obtain treatment with a
4
5 controlled substance or medication combination, without Due Process afforded by
6
7 the 5th and 14th Amendments to the Constitution of the United States. Absent
8
9 judicial review and relief, Plaintiff remains at risk for being deprived of Life
10
11 without Due Process afforded by the Constitution of the United States in the future,
12
13 since the known health risks of cardiovascular problems like uncontrolled high
14
15 blood pressure unresponsive to blood pressure medications, heart attack, stroke,
16
17 and suicide, threaten to shorten his life. Plaintiff contends that it is not reasonable
18
19 to deprive patients of proper, appropriate opioid or other controlled substance
20
21 treatment on which they depend to protect the public health, since dependence is
22
23 NOT “addiction,” and since the peer reviewed evidence shows that patients
24
25 prescribed an opioid medication and followed by a physician have far less than a
26
27 1% likelihood of ever having a substance use disorder condition. Richard A.
28

1 Lawhern, PhD., pain patient advocate and subject matter expert, reviewed the
2
3 landmark study by Brat, et al. (Brat, G. A., Agniel D., Beam A., Yorkgitis B.,
4
5 Bicket, M., Homer, M., et al. Postsurgical Prescriptions for Opioid Naive Patients
6
7 and Association with Overdose and Misuse: Retrospective Cohort Study. BMJ
8
9 January 17, 2018, (Exhibit 74), finding that:

10
11 “Brat and his colleagues provided the largest multi-year study ever
12 published on opioid abuse in opioid-naive patients treated with opioid pain
13 relievers following surgery. When their error in defining opioid
14 “dependence” as opioid “abuse” is accounted for, the net rate of real opioid
15 abuse or overdose in this large population is significantly below one-half of
16 one percent. And in view of the poor training of most doctors who diagnose
17 abuse, the likely net rate of abuse is almost certainly below 0.2 to 0.3
18 percent.” (Lawhern, R., PhD. The Real Cause of the Opioid Crisis Isn’t
19 What You Think. MedPage Today’s KevinMD.com, Conditions. Page 4.
20 13 November 2024.). (Exhibit 75).

21
22
23 66. Plaintiff contends that it is not reasonable to deprive patients of proper,
24
25 appropriate opioid or other controlled substance treatment on which they depend in
26
27 order to protect the public health, because the vast majority of deaths since at least
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2010 and possibly longer have not been caused by “prescription opioid medications” as asserted by the government, but rather by illicit fentanyl analog compound poisonings. Plaintiff contends that the government’s efforts to protect the public health by restricting access to prescription opioids and to other controlled substance medications for chronic, intractable, cancer, end-of-life, and surgical pain patients and other classes of patients in order to attempt to reduce the number deaths caused by illicit fentanyl analog compound poisonings, abused by a different cohort of patients than chronic, intractable, end-of-life, and surgical pain patients, causing patient abandonment, forced-tapers and sudden discontinuation of therapeutic opioid medications and other controlled substances, torture, and death to an untold number of these critically ill, injured, and disabled patients, do not reasonably meet the Rational Basis Test of the Due Process clause requirements of the 5th and 14th Amendments to the Constitution of the United States.

67. Plaintiff contends that the unbridled access to confidential patient data which

1 is now freely accessible to the DEA and to other law enforcement agencies without
2
3 obtaining a warrant, through the Prescription Drug Management Programs
4
5 (PDMP) operated by each state, is a breach of the confidentiality of data that is
6
7 protected by the Health Insurance Portability and Accountability Act (HIPAA).
8
9 Plaintiff contends that the unbridled access to confidential patient records which is
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11 a violation of HIPAA is unlawful, and that law enforcement access to this data
12
13 should only be available with a warrant, shown for good cause. Otherwise, law
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15 enforcement access to this data should be restricted. Medical practitioner and
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17 pharmacy access to this data should be restricted only to the patients with whom a
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19 doctor/patient relationship with a prescriber or with a pharmacy has been
20
21 established. Medicare officials, and the insurance companies who administer
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23 Medicare benefits, should likewise be restricted from accessing/sharing this
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25 confidential patient data for law enforcement purposes, without first obtaining a
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27 warrant. Plaintiff contends that any law, rule, or regulation enacted by Congress or
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1 any federal agency that authorized this unbridled access to confidential patient data
2
3 is another violation of Plaintiff's 5th and 14th Amendment rights that does not pass
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5 the Rational Basis test of the Due Process clause of the 5th and 14th Amendments.
6
7 A complete review of the laws, rules, and regulations will be required in order to
8
9 confirm where this authorization originated.
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11

12 **68. CLAIM 6, LEGAL BASIS FOR: UNITED STATES VIOLATIONS OF**
13
14 **THE NUREMBERG CODE.**
15

16 Plaintiff contends that the VA and HHS have been unlawfully experimenting on
17
18 the pain patient population, to attempt to find alternative non-opioid therapies for
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20 the treatment of pain for chronic, intractable, cancer, end-of-life, and surgical pain
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22 patients, without their knowledge or consent, even though it is already well-
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24 established that full-agonist opioid therapy is the only known therapeutic treatment
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26 for these patients, in violation of international treaties such as the Nuremberg
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28 Code. Evidence of this experimentation was obtained by publications on the

1 National Institute of Health website and is the subject of Section 13, Page 29, of
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3 Plaintiff's Administrative Complaint (Exhibit 76). Plaintiff contends that this is a
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5 Proximate Cause of harm to him, since therapeutic doses of opioid medications and
6
7 other controlled substances have been restricted without there being an alternative
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9 treatment for the control of patients' symptoms, or to allow the patients to perform
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11 the most basic activities of daily living. Plaintiff prays that the Court will agree
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13 that the United States government actions of experimenting upon the pain patient
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15 population to try to find "non-opioid" alternatives for the treatment of chronic and
16
17 intractable pain are in violation of international treaties to which the United States
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19 is a signatory, and that a ruling can be issued, pursuant to 28 U.S.C. § 1331,

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21 "Federal question. The district courts shall have original jurisdiction of all
22 civil actions arising under the Constitution, laws, or treaties of the United
23 States."
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Dated this _____ day of February, 2025.

David Edward Smith
Pro Se Litigant