# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND (Northern Division)

UNITED STATES OF AMERICA, Plaintiff,	
v.  ELIZABETH ALLEN, 139 E. Ostend St. Baltimore, Maryland 21230-4309	Case No.
Defendant.	

# **COMPLAINT**

- 1. The present opioid epidemic is a national public health crisis. Healthcare practitioners who prescribe and distribute controlled substances, including opioid painkillers, with no legitimate medical purpose and outside the usual course of professional practice, fan the flames of this crisis. By abusing their prescription-writing privileges, these practitioners cross the legal divide from lawfully practicing medicine to violating the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (the "CSA").
- 2. Elizabeth J. Allen, PA, contributed to this epidemic. Allen violated the CSA by issuing prescriptions that had no legitimate medical purpose and fell outside the usual course of professional medical practice.

## **JURISDICTION AND VENUE**

- 3. This Court has jurisdiction under 21 U.S.C. §§ 842(c)(1)(A) and 822(a), and 28 U.S.C. §§ 1345 and 1355.
  - 4. Venue is proper in this District under 21 U.S.C. § 843(f)(2) and 28 U.S.C.

§§ 1391(b)(2) and 1395(a), because Allen is located, resides, and did business in this district, and because a substantial part of the events giving rise to the claims here occurred in Maryland.

# **PARTIES**

- 5. Plaintiff is the United States of America.
- 6. Allen is a Maryland resident. At all times relevant to this Complaint, Allen was, and is currently, licensed to practice in Maryland as a physician assistant by the Maryland Board of Physicians. At all times relevant to the Complaint, Allen practiced medicine as a physician assistant at the Centers for Rehabilitation, Pain Management, and Wellness in Pikesville, Maryland.

#### THE CONTROLLED SUBSTANCES ACT

- 7. The CSA and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of controlled substances from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, or dispense, any controlled substances except in a manner authorized by the CSA.
  - 8. The CSA categorizes controlled substances in five schedules.
- 9. Schedule I contains drugs that lack any accepted medical use. 21 U.S.C. § 812(b)(1).
- 10. Schedule II contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence" but still have "a currently accepted medical use in treatment." *Id.* § 812(b)(2). Pertinent to Allen's prescribing, Oxycodone and oxycontin are Schedule II controlled substances.

- 11. Schedule III contains drugs with less abuse potential than those in Schedule II, but where abuse may still lead to "moderate or low physical dependence or high psychological dependence." *Id.* § 812(b)(3). Schedule III drugs also have "a currently accepted medical use in treatment." *Id.*
- 12. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, may still lead to physical or psychological dependence when abused. *Id.* § 812(b)(4). Pertinent to Allen's prescribing, Alprazolam is a schedule IV controlled substance.
- 13. Schedule V contains drugs with lower potential for abuse than Schedule IV and consist of medications containing limited quantities of certain narcotics. *See id.* § 812(b)(5).
- 14. The CSA requires those who dispense controlled substances, including physician assistants, to obtain a registration from the United States Drug Enforcement Administration (the "DEA"). See id. § 822(a)(2). A physician assistant who receives a DEA registration may only dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with" the CSA. *Id.* § 822(b).
- 15. A prescription for a controlled substances may only be dispensed by a practitioner who is: (i) authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed; and (ii) registered with the DEA. 21 U.S.C. § 822(a)(2); 21 C.F.R. § 1306.03(a).
- 16. Unless dispensed directly by a practitioner (other than a pharmacist) to an ultimate user, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner. 21 U.S.C. § 829(a). And no schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner. *Id.* § 829(b).

- 17. A prescription is legally valid under the CSA only if issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. "An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent" of 21 U.S.C. § 829 and "the person issuing it shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*
- 18. "The responsibility for proper prescribing and dispensing of controlled substances is upon the prescribing practitioner." *Id*.

# **FACTUAL ALLEGATIONS**

- 19. Allen first received a physician assistant license from the Maryland Board of Physicians in 1988. Eventually, the DEA provided Allen with a registration under the CSA to prescribe controlled substances (MA1246950). Allen's DEA registration was retired effective August 1, 2020.
- 20. Between 2014 and 2019, Allen wrote hundreds of prescriptions for controlled substances without a legitimate medical purpose and outside the usual course of professional practice.
- 21. During that period, Allen administered toxicology screens to her patients and some tested positive for illicit or unprescribed substances. Despite the presence of illicit or unprescribed substances, Allen continued prescribing those patients controlled substances.
- 22. During that period, Allen wrote the same patient prescriptions for both opioids and benzodiazepines—a dangerous and potentially lethal combination—concurrently.
- 23. During that period, Allen routinely and repeatedly copied notes from one visit to the next, often with no visit-specific information.

- 24. During that period, although the Centers for Disease Control and Prevention cautions prescribers from increasing patients' dosages to more than ninety morphine milligram equivalents ("MME") a day, Allen routinely wrote prescriptions to patients causing their MME levels to be as high as 700 daily MME or higher.
- 25. Just as an example, Allen began seeing patient G.S. in November 2013 for lumbar spondylosis, neck pain, knee pain, hip pain, and osteoarthritis.
- 26. An October 2014 urine drug screen of G.S. was positive for Suboxone, which neither Allen nor any practitioner at the Centers for Rehabilitation, Pain Management, and Wellness prescribed to G.S.
  - 27. In March 2015, G.S. admitted to using his wife's pain medications.
- 28. Despite that G.S. tested positive for an unprescribed controlled substance and admitted using his wife's pain medications, Allen prescribed G.S. a monthly regimen of controlled substances, beginning no later than 2015.
- 29. Most months, Allen prescribed G.S. a combination of the opioids oxycodone and oxycontin, and the benzodiazepine alprazolam. This combination of opioids and benzodiazepines was dangerous and potentially lethal.
- 30. G.S. was last seen at the Centers for Rehabilitation, Pain Management, and Wellness on March 29, 2018. On that day, Allen prescribed G.S. oxycodone, oxycontin, and alprazolam. On April 14, 2018, G.S. died. A post-mortem toxicology screen found oxycodone and alprazolam in G.S.'s system.
- 31. Allen's prescribing of controlled substances to G.S. was without a legitimate medical purpose and outside the usual course of professional practice.
  - 32. Allen's prescribing of controlled substances to G.S. was a substantial contributing

5

factor to G.S.'s death.

# **CAUSES OF ACTION**

#### Count I

# (Unlawful Prescribing of Controlled Substances: 21 U.S.C. §§ 829, 842(a)(1), 842(c)(1)(A)) Civil Penalties

- 33. The United States restates and incorporates the allegations in Paragraphs 1-32 of this Complaint as set forth fully herein.
- 34. Allen issued prescriptions without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a), (b), and (c); 842(a)(1); and 21 C.F.R. § 1306.04, as set forth in paragraphs 20-22, 24, and 28-30 of this Complaint.
- 35. As a result of the foregoing, Allen is liable to the United States for a civil penalty of not more than \$67,627.00 for each violation under 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

#### **Count II**

# (Unlawful Prescribing of Controlled Substances: 21 U.S.C. §§ 829, 842(a)(1), 843(f), 882(a))

## **Injunctive Relief**

- 36. The United States restates and incorporates the allegations in Paragraphs 1-35 of this Complaint as set forth fully herein.
- 37. As a result of the violations set forth above, the United States is entitled to injunctive relief under 21 U.S.C. §§ 843(f) and 882(a).

WHEREFORE, the United States requests that the Court enter judgment in its favor and against Allen, and:

A. On Count I, impose a civil penalty on Allen of not more than \$67,627.00 for each and every violation of 21 U.S.C. §§ 829 and 842(a)(1); and

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B. On Count II, order appropriate injunctive relief under 21 U.S.C. §§ 843(f) and 882(a).

Dated: November 12, 2021

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