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Submitted Electronically via Federal Rulemaking Portal

Administrator Anne Milgram **Drug Enforcement Administration** Attn: DEA Federal Register Representative/DPW 8701 Morrissette Drive Springfield, VA 22152

> Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (RIN 1117-AB40; Docket No. DEA-407)

Dear Administrator Milgram:

On behalf of Americans United for Life ("AUL"), I am writing in support of the Proposed Rule, "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation," 88 Fed. Reg. 12875, regarding its regulation of controlled substances prescribed to enable suicide. AUL is the oldest and most active pro-life nonprofit advocacy organization in the country. Founded in 1971, before the Supreme Court's decision in Roe v. Wade, AUL has dedicated over fifty years to advocating for comprehensive legal protections for human life from conception until natural death. AUL attorneys are legal experts on constitutional law and bioethics, and regularly testify before state legislatures and Congress on abortion and end-of-life issues.² Courts have cited AUL briefs, such as the Supreme Court in Washington v. Glucksberg, holding there is no federal due process right to assisted suicide, and the Massachusetts Supreme Judicial Court in Kligler v. Attorney General, ruling there is no fundamental right to assisted suicide under the state constitution.4

The Proposed Rule is a lawful exercise of the DEA's power to regulate physician-assisted suicide drugs, properly protects patients from assisted suicide

¹ 410 U.S. 113 (1973).

² See, e.g., Revoking Your Rights: The Ongoing Crisis in Abortion Care Access Before the H. Comm. on the Judiciary, 117th Cong. (2022) (testimony of Catherine Glenn Foster, President & CEO, Americans United for Life).

³ 521 U.S. 702, 774 n.13 (1997) (citing Brief Amicus Curiae on behalf of Members of the New York and Washington State Legislatures 15, n.8).

⁴ 491 Mass. 38, 40 n.3 (2022) (citing Brief Amicus Curiae of Christian Medical & Dental Associations).

drug diversion, and is consistent with Congress' public policy stance of preventing suicide. AUL urges DEA to retain the Proposed Rule and defend patients from assisted suicide drug diversion.

I. The Proposed Rule Regulates Telemedical Assisted Suicides, Which Use Schedule II Drugs and Narcotics.

Under the Proposed Rule, "[a] telemedicine prescription may only be for a . . . schedule III, IV, or V non-narcotic controlled substance," unless certain criteria are met, such as when "[t]he prescribing practitioner has received a qualifying telemedicine referral . . . for that patient from a referring practitioner who has conducted a medical evaluation" 5 Since assisted suicide drugs include Schedule II substances and often use narcotics, the Proposed Rule restricts the use of telemedical prescriptions for these drugs.

According to official Oregon data, doctors have experimented with a variety of drugs over the past decade to assist suicides. These drugs include:

- Pentobarbital
- Secobarbital
- Phenobarbital ("dispensed as a combination of phenobarbital, chloral hydrate, and morphine sulfate")
- DDMP (diazepam, digoxin, morphine sulfate, and propranolol)
- DDMA (diazepam, digoxin, morphine sulfate, and amitriptyline)
- DDMAPh (diazepam, digoxin, morphine sulfate, amitriptyline, and phenobarbital)⁶

As of 2022 Oregon patients that ingested assisted suicide drugs, more than 70% of these patients used DDMAPh, while 28% of patients ingested DDMA.⁷ Notably, pentobarbital, secobarbital, and morphine sulfate are Schedule II substances, and morphine sulfate is, of course, a narcotic.⁸ Accordingly, assisted suicide drugs are ineligible for telemedical prescriptions under the Proposed Rule, unless there is a qualifying telemedicine referral.

⁵ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875, 12889 (proposed Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306).

 $^{^6}$ Or. Pub. Health Div., Oregon Death with Dignity Act: 2022 Data Summary 10, 15 (Mar. 8, 2023). 7 Id. at 9.

⁸ Diversion Control Division, Conversion Factors for Controlled Substances, U.S. DRUG ENF'T ADMIN. (Apr. 2021), https://www.deadiversion.usdoj.gov/quotas/conv_factor/index.html.

II. Congress Delegated Authority to DEA to Establish Safeguards Against Assisted Suicide Drug Diversion.

Eleven jurisdictions have decriminalized physician-assisted suicide. Of these jurisdictions, only Vermont currently permits the use of telemedicine for assisted suicides, 10 but other states have considered allowing telemedical assisted suicides. Nevertheless, Congress has delegated the authority to DEA to restrict telemedical suicide assistance. Congress explicitly authorizes controlled drug prescriptions being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety. As the U.S. Department of Health and Human Services recognizes, [d]rug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber. Opioids, such as morphine, particularly have a high potential for diversion and abuse. DEA promulgated the Proposed Rule in accordance with this delegated authority to prevent drug diversion.

As a note, Gonzales v. Oregon is inapplicable to the Proposed Rule. ¹⁶ In Gonzales, the Supreme Court held unlawful the U.S. Attorney General's guidance that interpreted the Controlled Substances Act ("CSA"), and "declar[ed] that using controlled substances to assist suicide is not a legitimate medical practice and that dispensing or prescribing them for this purpose is unlawful under the CSA." ¹⁷ Gonzales dealt with a ban on assisted suicide drugs and the Attorney General's interpretation of "legitimate medical practice" as applied to assisted suicide drugs. In contrast, the Proposed Rule does not ban assisted suicide drugs. Rather, it regulates the telemedical use of these lethal drugs. Notably, the Proposed Rule does not even

 $^{^9}$ Ten jurisdictions have decriminalized physician-assisted suicide through legislation. Cal. Health & Safety Code §§ 443 to 443.9 (2016); Colo. Rev. Stat. §§ 25-48-101 to 25-48-123 (2016); D.C. Code §§ 7-661.01 to 7-661.16 (2017); Haw. Rev. Stat. §§ 327L-1 to 327L-25 (2019); Me. Stat. tit. 22 § 2140 (2019); N.J. Stat. §§ 26:16-1 to 26:16-20 (2019); N.M. Stat. Ann. §§ 24-7C-1 to 24-7C-8 (2021); Or. Rev. Stat. §§ 127.800 to 127.897 (2017); Vt. Stat. Ann. tit. 18 §§ 5281 to 5293 (2013); Wash. Rev. Code §§ 70.245.010 to 70.245.903 (2009). One state, Montana, has decriminalized the practice through judicial activism. 354 Mont. 234, 239, 251 (Mont. 2009) (declining to recognize a patient's right to assisted suicide, but nevertheless holding physicians may raise a statutory "consent" defense against homicide charges in assisted suicide cases).

¹⁰ VT. STAT. ANN. tit. 18 § 5283.

 $^{^{11}}$ See, e.g., H.B. 1281, 68th Leg., Reg. Sess. (Wash. 2023) (authorizing assisted suicide drugs to be sent by mail or courier); S.B. 5179, 68th Leg., Reg. Sess. (Wash. 2023) (same). 12 21 U.S.C. 802(54)(G).

 $^{^{13}}$ Drug Diversion: What Is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?, U.S. DEP'T OF HEALTH & HUM. SERVS. 1, 1 (Feb. 2016), https://www.hhs.gov/guidance/sites/default/files/hhsguidance-documents/DrugDiversionFS022316.pdf.

¹⁵ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12881 (citing 21 U.S.C. 802(54)(G)). ¹⁶ 546 U.S. 243 (2006).

¹⁷ Id. at 249, 275.

foreclose the use of telemedicine, so long as there is a qualifying telemedicine referral. Accordingly, *Gonzales* presented different legal issues, and is distinguishable from the DEA's regulation of telemedical suicide assistance.

As DEA recognizes, there is an "ongoing opioid epidemic at the time of publishing, . . . [and] allowing for the prescription of any schedule II substances or the general prescription of narcotic controlled substances as a result of telemedicine encounters would pose too great a risk to the public health and safety." ¹⁹ Assisted suicide prescriptions use Schedule II drugs, many of which are narcotics. These drugs are at lethal dosages, which presents risks of abuse and diversion in and of itself.

Moreover, not all patients ultimately ingest the dispensed lethal medications. In 2021 in Washington, for example, pharmacies dispensed assisted suicide drugs to 400 individuals, but the state only has reports of 291 patients dying from ingesting these lethal drugs, or 72.8% of the dispensed medications. ²⁰ 772 Californian patients received prescriptions for assisted suicide drugs, but only 448 patients, or 58.0%, died following ingestion of the drugs. ²¹ Oregon, which has the most complete statistical data, shows a 66% patient ingestion ratio to prescriptions over the history of its statute. ²² Although some statutes require drug disposal of unused lethal medication, there often is no oversight to ensure proper drug disposal. ²³

Additionally, there are grave risks of drug diversion within assisted suicide since the drugs are experimental and statutory "safeguards" insufficiently protect patients from coercion and abuse. Regulating the use of telemedical suicide assistance is a lawful exercise of the power Congress delegated to DEA, because DEA is establishing controls to prevent drug diversion.

A. Suicide Doctors Use Experimental Drugs Directly on Patients Without FDA Approval or Clinical Trials.

There is no standardized drug or dosage for ending a patient's life through assisted suicide. "Of course, there is no federally approved drug for which the primary indication is the cessation of mental or physical suffering by the termination of life." Federally, the Food and Drug Act regulates pharmaceuticals and requires "that both 'safety' and 'efficacy' of a drug for its intended purpose (its 'indication') be demonstrated in order to approve the drug for distribution and marketing to the

¹⁸ Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12889.

¹⁹ *Id*. at 12881.

²⁰ WASH. DISEASE CONTROL & HEALTH STATS., 2021 DEATH WITH DIGNITY ACT REPORT 1 (July 15, 2022).

²¹ CAL. DEP'T OF PUB. HEALTH, CALIFORNIA END OF LIFE OPTION ACT: 2021 DATA REPORT 4 (July 2022).

²² OR. PUB. HEALTH DIV., *supra* note 6, at 6.

²³ See, e.g., CAL. HEALTH & SAFETY CODE § 443.20; WASH. REV. CODE § 70.245.140.

²⁴ Steven H. Aden, You Can Go Your Own Way: Exploring the Relationship Between Personal and Political Autonomy in Gonzales v. Oregon, 15 TEMP. POL. & CIV. RTS. L. REV. 323, 339 (2006).

public."²⁵ Lethal medication could never meet the safety or efficacy requirements for treating mental or physical ailments.

Since states that have legalized suicide assistance cannot provide guidelines for assisted suicide drug composition or dosages, suicide doctors have experimented with the dosage and composition of these lethal drugs. Around 2016, suicide doctors turned away from using short-acting barbiturates due to price gouging and supply issues. 26 Consequently, suicide doctors began mixing experimental drug compounds at lethal dosages to assist suicides.²⁷ As the U.S. Food and Drug Administration ("FDA") notes on its website, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients." 28 As The Atlantic reported in 2019, "[n]o medical association oversees aid in dying, and no government committee helps fund the research. In states where the practice is legal, state governments provide guidance about which patients qualify, but say nothing about which drugs to prescribe."29 As a result, assisted suicide proponents have experimented their lethal drugs on end-oflife patients with "no government-approved clinical drug trial, and no Institutional Review Board oversight when they prescribed the concoction to patients."30 Accordingly, assisted suicide uses experimental drugs without patient safeguards, which presents risks of drug diversion.

B. Assisted Suicide Statutory "Safeguards" Have High Risks of Drug Diversion.

At both the medication request and time of ingestion stages, there are grave competency and informed consent concerns for assisted suicide patients. Scholarship shows "[a] high proportion of patients who request physician-assisted suicide are suffering from depression or present depressive symptoms." [A]round 25–50% of patients who have made requests for assisted suicide showed signs of depression and 2–10% of patients who have received physician-assisted suicide were depressed." 32

²⁵ *Id*. at 340.

²⁶ Sean Riley, Navigating the New Era of Assisted Suicide and Execution Drugs, 4 J. L. & BIOSCIS. 424, 429–430 (2017).

²⁷ See Robert Wood et al., Attending Physicians Packet, END OF LIFE WASH. 1, 7 (Apr. 11, 2022), https://endoflifewa.org/wp-content/uploads/2022/04/EOLWA-AP-Packet_4.11.22.pdf (describing suicide doctors' experiments with different lethal drug compounds).

²⁸ Compounding Laws and Policies, U.S. FOOD & DRUG ADMIN (Sept. 10, 2020), https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

²⁹ Jennie Dear, *The Doctors Who Invented a New Way to Help People Die*, THE ATL. (Jan. 22, 2019), https://www.theatlantic.com/health/archive/2019/01/medical-aid-in-dying-medications/580591/. ³⁰ *Id*.

³¹ Jonathan Y. Tsou, Depression and Suicide Are Natural Kinds: Implications for Physician-Assisted Suicide, 36 INT'L J. L. & PSYCHIATRY 461, 461 (2013).

³² Id. at 466; see also Linda Ganzini et al., Prevalence of Depression and Anxiety in Patients Requesting Physicians' Aid in Dying: Cross Sectional Survey, 337 BMJ 1682 (2008) (finding 25% of surveyed Oregon patients who had requested lethal medication had clinical depression and the "[statute] may not adequately protect all mentally ill patients").

These patients' "desire for hastened death is significantly associated with a diagnosis of major depression." Their psychiatric disability also may impair decision-making, "such as the decision to end one's life." ³⁴

Even with the high rates of depression in patients considering assisted suicide, counseling referrals are uncommon.³⁵ In Oregon in 2022, for example, assisted suicide physicians prescribed lethal drugs to 431 patients yet only referred three of these patients for counseling—approximately 0.7% of patients.³⁶ Even during counseling, psychiatrists have limited ability in diagnosing depression. One study shows that "[o]nly 6% of psychiatrists were very confident that in a single evaluation they could adequately assess whether a psychiatric disorder was impairing the judgment of a patient requesting assisted suicide."³⁷

Patients may engage in "doctor shopping," where a patient will seek a different physician if a first physician refuses or denies prescribing lethal drugs to the patient.³⁸ More concerning is that, as of 2022, Oregon data shows that the median duration of an assisted suicide patient-physician relationship was only five weeks.³⁹ Doctor shopping raises serious concerns about a physician's ability to diagnose depression in new patients.

All assisted suicide statutes require two witnesses to attest to a patient's capacity at the time of the medication request. All jurisdictions but Vermont require that "one of the two witnesses must be unrelated to the patient and must not receive any benefits upon his or her death." In those jurisdictions, "no requirements are in place for the second witness to be disinterested in any way—the two witnesses could be an heir and his cousin or an heir and his best friend." In this case, there are no requirements for witnesses to attest to the patient's capacity at the medication request, nor are there safeguards against an heir or coercive family caregiver from being present when the patient requests medication.

Doctors also have difficulty in accurately dating terminal illness life expectancy. In the assisted suicide context, terminal illness "means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months." 42 As the National Council on

 $^{^{33}}$ *Id*.

 $^{^{34}}$ *Id*.

³⁵ Catherine Glenn Foster, The Fatal Flaws of Assisted Suicide, 44 HUM, LIFE REV. 51, 54 (2018).

³⁶ OR. PUB. HEALTH DIV., *supra* note 6, at 9.

³⁷ Linda Ganzini et al., *Attitudes of Oregon Psychiatrists Toward Physician-Assisted Suicide*, 153 AM. J. PSYCHIATRY 1469 (1996).

 $^{^{38}}$ Nat'l Council on Disability, The Danger of Assisted Suicide Laws, Bioethics and Disability Series 27 (2019).

³⁹ OR. PUB. HEALTH DIV., supra note 6, at 14.

⁴⁰ Foster, *supra* note 35, at 53; *see* VT. STAT. ANN. tit. 18 § 5283(a)(4).

 $^{^{41}}$ *Id*.

⁴² OR. REV. STAT. § 127.800(12).

Disability notes, "[a]ssisted suicide laws assume that doctors can estimate whether or not a patient diagnosed as terminally ill will die within 6 months. Actually, it is common for medical prognoses of a short life expectancy to be wrong." Likewise, "[t]here is no requirement that the doctors consider the likely impact of medical treatment, counseling, and other supports on survival." 44

Unfortunately, assisted suicide doctors do not provide oversight during the actual ingestion process. "[O]nce the prescription is written, there are no further protections. At no point does the law require [a physician or other healthcare provider] to be at the bedside. Nothing needs to be done to ensure that the patient is competent or to prevent coercion." ⁴⁵ In California in 2021, a physician or health care worker only was present 43.0% of the time when the patient ingested the drugs. ⁴⁶ In Oregon in 2022, excluding unknown data, the prescribing physician only was present when the patient ingested the lethal medication 24.4% of the time while a non-prescribing healthcare worker was present in 16.7% of cases. ⁴⁷ Without a medical professional present, there is no medical oversight over the ingestion process or lethal outcome. This is concerning as there are no requirements that a disinterested person, or even anyone at all, witness the patient's death or that the patient is the one ultimately taking these drugs. ⁴⁸ In sum, assisted suicide "safeguards" inadequately protect patients against coercion and drug diversion. DEA should regulate the use of telemedical assisted suicides to prevent additional risks of drug diversion.

III. The Proposed Rule Furthers Congress' Public Policy Stance of Suicide Prevention.

The United States has a robust public policy of suicide prevention.⁴⁹ The Centers for Disease Control and Prevention ("CDC") recognizes that "[s]uicide is a serious public health problem . . . [and] is a leading cause of death in the United States." ⁵⁰ "Suicide and suicide attempts cause serious emotional, physical, and economic impacts" in suicide survivors, loved ones, and the community. ⁵¹ According to the CDC, "[t]he financial toll of suicide on society is also costly. In 2019, suicide

⁴³ NAT'L COUNCIL ON DISABILITY, *supra* note 38, at 21.

⁴⁴ *Id*. at 22.

⁴⁵ WESLEY J. SMITH, CULTURE OF DEATH: THE AGE OF "DO HARM" MEDICINE 130 (2d ed. 2016).

⁴⁶ CAL. DEP'T OF PUB. HEALTH, CALIFORNIA END OF LIFE OPTION ACT: 2021 DATA REPORT 8 (July 2022).

⁴⁷ OR. PUB. HEALTH DIV., *supra* note 6, at 14.

⁴⁸ Marilyn Golden & Tyler Zoanni, *Killing Us Softly: The Dangers of Legalizing Assisted Suicide*, 3 DISABILITY & HEALTH J. 16, 20 (2010); Foster, *supra* note 35, at 53.

⁴⁹ Suicide Prevention, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 13, 2022), https://www.cdc.gov/suicide/index.html.

Facts About Suicide, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 24, 2022), https://www.cdc.gov/suicide/facts/index.html.
51 Id.

and nonfatal self-harm cost the nation nearly \$490 billion in medical costs, work loss costs, value of statistical life, and quality of life costs."⁵²

Assisted suicide exacerbates suicide rates. According to recent scholarship published by the Anscombe Bioethics Centre, when a jurisdiction introduces assisted suicide, the "[r]ates of non-assisted suicide also increase, in some cases significantly."⁵³ The research examined assisted suicide scholarship and found "[t]here is no evidence that legalisation of EAS [euthanasia or assisted suicide] would have a beneficial effect on suicide prevention."⁵⁴ In fact, legalization of assisted suicide undermines suicide prevention policies:

There is robust evidence, taken from different jurisdictions and using a variety of statistical methods, that the total number of self-initiated deaths rises significantly where EAS is legally available, and strong evidence that this has a greater impact on older women. There is some evidence, less robust but by some measures statistically significant, that deaths by non-assisted suicide also increase. There is no evidence of a reduction in non-assisted suicide.⁵⁵

Similarly, "[c]ontrolling for various socioeconomic factors, unobservable state and year effects, and state-specific linear trends," research has demonstrated that assisted suicide legalization in U.S. jurisdictions is "associated with a 6.3%...increase in total suicides (including assisted suicides)." However, in individuals over 65 years old, this increase was 14.5%. Consequently, expanding assisted suicide subverts suicide prevention policies.

The Proposed Rule is consistent with Congress' decision to limit the harmful effects of suicide assistance. The Supreme Court has recognized there is no constitutional right to suicide assistance. Similarly, nothing in federal law creates a right to suicide assistance or otherwise decriminalizes the practice. Rather, Congress has sought to decrease the harmful effects of assisted suicide. In the Assisted Suicide Funding Restriction Act, Congress broadly prohibits the federal funding of suicide assistance, recognizing the Act's purpose is "to continue current

⁵³ David Albert Jones, Suicide Prevention: Does Legalising Assisted Suicide Make Things Better or Worse?, Anscombe Bioethics Ctr. 1, 2 (2022), https://bioethics.org.uk/media/mhrka5f3/suicide-prevention-does-legalising-assisted-suicide-make-things-better-or-worse-prof-david-albert-jones.pdf. ⁵⁴ Id. at 9.

⁵² Id.

⁵⁵ *Id*

⁵⁶ David Albert Jones & David Paton, How Does Legalization of Physician Assisted Suicide Affect Rates of Suicide, 108 S. MED. J. 599, 599, 601 (2015).

⁵⁸ Washington, 521 U.S. at 706, 710–719 (holding nothing in "our Nation's history, legal traditions, and practices" give rise to a due process right to assisted suicide); *Vacco v. Quill*, 521 U.S. 793, 797, 801–808 (finding New York's assisted suicide ban was different in causation and intent from refusal of life-sustaining medical treatment and, thus, did not violate the Equal Protection Clause).

Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide . . . of any individual."⁵⁹ In turn, Congress has restricted the federal funding of suicide assistance in health care programs, certain grant programs, advocacy programs, funds appropriated to the District of Columbia, and a catch-all prohibition that "no funds appropriated by the Congress shall be used to provide, procure, furnish, or fund any item, good, benefit, activity, or service, furnished or performed for the purpose of causing, or assisting in causing, the suicide . . . of any individual."⁶⁰

Similarly, Congress robustly defends the conscientious objections of medical professionals who oppose assisting a suicide. Section 1553 of the Affordable Care Act prohibits discrimination against "an individual or institutional health care entity . . . on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."⁶¹ The provision broadly applies to "[t]he Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act . . . or any health plan created under this Act"⁶² Accordingly, Congress has explicitly limited assisted suicide and promoted suicide prevention. The Proposed Rule establishes common-sense telemedicine safeguards to prevent assisted suicide drug diversion, which is consistent with the federal policy stance of suicide prevention.

IV. Conclusion.

Congress has delegated the authority to DEA to regulate telemedical assisted suicides, which present grave risks of drug diversion. Restricting the use of telemedicine within assisted suicides is consistent with Congress' public policy of suicide prevention. AUL urges DEA to retain the Proposed Rule and protect vulnerable patients from assisted suicide drug diversion.

Sincerely,

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⁵⁹ 42 U.S.C. § 14401(b).

⁶⁰ Id. §§ 14402 to 14405, 14407.

⁶¹ Id. § 18113(a).

 $^{^{62}}$ *Id*.