UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	CASE NO.: 1:17-MD-02804
	)	JUDGE DAN A. POLSTER
	)	MAGISTRATE JUDGE DAVID A. RUIZ
	)	**STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA**

STATEMENT OF INTEREST

Pursuant to 28 U.S.C. § 517, the United States respectfully submits this Statement of Interest to attend to its interests in connection with these actions.

INTRODUCTION

These consolidated actions seek damages from manufacturers and wholesale distributors of prescription opioids. The Complaints in each of these cases allege, generally, that defendants used false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids, which has resulted in a national epidemic of opioid overdose deaths and addictions. The plaintiffs in these actions include numerous cities, municipalities, and medical institutions that have borne the costs of the prescription opioid crisis. Plaintiffs seek to recover the costs associated with providing treatment and public safety measures relating to the opioid epidemic.

The United States submits this Statement of Interest to inform the Court of some of the substantial costs that the federal government has borne as a result of the opioid epidemic. In light of its substantial costs and significant interest in addressing the opioid epidemic, including significant public health and regulatory interests not discussed in this Statement, the United States

respectfully asks that the Court afford it a period of thirty days to evaluate whether to participate in these proceedings at this stage.

THE UNITED STATES' INTERESTS

On October 26, 2017, the President of the United States directed the Secretary of the Department of Health and Human Services to declare the opioid crisis a national public health emergency under federal law. *See* President's Commission on Combating Drug Addiction and the Opioid Crisis, *Chairman's Letter* at 5 (Nov. 2017). As the President has acknowledged, "the leading cause of unintentional deaths in the United States is now drug overdose deaths." *Id.* More than 175 Americans are dying every day from drug overdose. *Id.* Sadly, the opioid epidemic "actually lowered American life expectancy in 2015 and 2016 for the first time in decades." *See Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), available at: https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force ("PIL Task Force Announcement").

The federal government has deployed extensive efforts to combat the opioid epidemic. For example, in July, 2017, Attorney General Jeff Sessions announced charges against more than 120 defendants for crimes related to prescribing or distributing opioids and other dangerous narcotics. *See* PIL Task Force Announcement. Subsequently, the Department of Justice seized AlphaBay, the largest criminal marketplace on the Internet (which hosted some 220,000 drug listings). *Id.* In October, 2017, the DEA established six new enforcement teams focused on combatting the flow of heroin and illicit fentanyl into the U.S., based in communities facing some of the most significant challenges with these drugs. *Id.* The federal government is also continuing to assist state and local efforts to combat the crisis. For example, on September 22, 2017, the Attorney General announced that nearly $20 million in federal grants would be awarded to help law

enforcement and public health agencies address prescription drug and opioid abuse. *See* Attorney General Jeff Sessions, Remarks by Attorney General Sessions to Law Enforcement About the Opioid Epidemic (Sept. 22, 2017). Continuing these many efforts, on February 27, 2018, Attorney General Sessions announced the appointment of an experienced federal prosecutor, Mary Daly, to serve as Director of Opioid Enforcement and Prevention Efforts. *See* Attorney General Sessions, Remarks (Feb. 27, 2018), available at: https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-prescription-interdiction-and. The Attorney General also announced the creation of the Prescription Interdiction and Litigation Task Force to fight the prescription opioid epidemic. *See* PIL Task Force Announcement. Among its responsibilities, the PIL Task Force is "directed . . . to examine existing state and local government lawsuits against opioid manufacturers to determine what assistance, if any, federal law can provide in those lawsuits." *Id.*

It is unsurprising that the federal government has borne substantial costs from the opioid epidemic. In 2013, the total economic burden associated with opioid overdose, abuse, and dependence was estimated to be $78.5 billion. *See* President's Commission on Combating Drug Addiction and the Opioid Crisis, *Health, Financial, and Social Consequences* at 31 (Nov. 2017). "Approximately 25% of the economic burden was borne by public sector (Medicaid, Medicare, and veterans' programs) and other government sources for substance abuse treatment." *Id.* In November 2017, the Council of Economic Advisors found that previous estimates of economic costs associated with the opioid crisis were "greatly understate[d]." *See* Council of Economic Advisors, Exec. Office of the President, *The Underestimated Costs of the Opioid Crisis* (Nov. 2017). The Council estimated that in 2015, the economic cost of the opioid crisis was $504 billion, or 2.8 percent of the GDP that year. *Id.*

The economic burden from the opioid epidemic includes considerable costs associated with the medical treatment of opioid users. "Opioid users have higher numbers of [Emergency Department] visits, more inpatient hospital stays, along with almost double the inpatient costs compared to their non-opioid using counterparts." President's Commission on Combating Drug Addiction and the Opioid Crisis, *Health, Financial, and Social Consequences* at 30 (Nov. 2017). The United States' various agencies provide treatment to, or provide payments for medical services on behalf of, patients who have used prescription opioids. And the costs of such treatment is significant. For example, the Department of Defense's cost of care related to opioid use, abuse, and dependence was $82 million in Calendar Year 2017.

FEDERAL RECOVERY STATUTES

Multiple federal statutes afford the United States the right to recover funds when the United States has paid for or provided treatment. Those statutes include, *inter alia*, (1) the Medicare Secondary Payer Act, 42 U.S.C. § 1395y, (2) the Federal Medical Care Recovery Act ("MCRA"), 42 U.S.C. §§ 2651-2653, and (3) the Veterans Benefits Act, 38 U.S.C. § 1729.

I. THE MEDICARE SECONDARY PAYER ACT

"Medicare is a federal entitlement program that provides health insurance benefits to qualified elderly and disabled individuals." *Taransky v. Secretary of U.S. Dep't of Health and Human Serv.*, 760 F.3d 307, 310 (3d Cir. 2014). Initially, "Medicare served as the primary payer of health costs for eligible individuals, but in 1980 Congress enacted the Medicare Secondary Payer Act to counteract escalating healthcare costs." *Bio-Med. Applications of Tennessee, Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund*, 656 F.3d 277, 281 (6th Cir. 2011). "To this end, when both Medicare and a private plan would cover a Medicare beneficiary's expenses, the Act makes Medicare the 'secondary' payer and the private plan the 'primary' payer. The primary

payer is responsible for paying for the patient's medical treatment; however, if Medicare expects that the primary payer will not pay promptly, then Medicare can make a 'conditional payment' on its behalf and later seek reimbursement." *Id.* (citing 42 U.S.C. § 1395y(b)).

Under the Medicare Secondary Payer Act, Medicare payments are secondary and reimbursable "if it is demonstrated that [a] primary plan has or had a responsibility to make payment with respect to such item or service." 42 U.S.C. § 1395y(b)(2)(B)(ii). A primary plan and any entity that receives payment from a primary plan, including a Medicare beneficiary that obtains a judgment against or settles with a primary plan, is responsible for reimbursing Medicare for conditional payments.

The Medicare Secondary Payer Act affords the United States a cause of action against a "primary plan" (or any entity that has received payment from a primary plan) to recover Medicare payments for items or services where the primary plan is responsible for that payment. This cause of action lies "against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan." 42 U.S.C. § 1395y(b)(2)(B)(iii).[1]

II. THE FEDERAL MEDICAL CARE RECOVERY ACT

The Federal Medical Care Recovery Act ("MCRA"), 42 U.S.C. §§ 2651-2653, "provides that when the United States furnishes medical care to a person who is injured under circumstances

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[1] Under the cooperative federalism model of Medicaid, State Medicaid agencies are responsible for identifying third parties with primary liability for payment, and pursuing recovery from those primary payers. 42 U.S.C. § 1396a(a)(25)(A), (B). The federal government then shares in the recovery from a liable third party.

creating tort liability on a third party, the government may recover the value of medical services from the third party." *Heusle v. National Mut. Ins. Co.*, 628 F.2d 833, 836 (3d Cir. 1980). "The operation of this statute in the context of a routine negligence case is relatively straightforward; the government simply stands in the position of a favored subrogee to the claim of an injured party against the tortfeasor." *Id.* at 837. The MCRA "confers an independent right of action on the federal government, one that is not subject to a state's statute of limitations, a state's rules of interspousal immunity, or other procedural restrictions . . . ." *Id.* (internal citations omitted).

III. THE VETERANS BENEFITS ACT

"Federal law pertaining to veterans benefits places the United States on an equal footing with private hospitals in its attempts to recover from third parties the cost of medical services provided veterans for non-service-related injuries." *United States v. Maryland*, 914 F.2d 551, 553 (4th Cir. 1990); *see also United States v. State of Ohio*, 957 F.2d 231, 232 (6th Cir. 1992). Section 1729 of Title 38, United States Code, is a no-fault statute and applies to health care plans, workers compensation plans, and no-fault insurance plans. 38 U.S.C. § 1729; *see also United States v. Blue Cross/Blue Shield of Alabama*, 999 F.2d 1542, 1544 n.2 (11th Cir. 1993) ("38 U.S.C. § 1729 provides that when a veteran is furnished medical services by the United States for a non-service-connected condition, the United States can recover the cost of such service under a health-plan contract if the veteran would be eligible to recover the cost had the services not been provided by the United States."). "[S]ection 1729 proscribes any . . . discriminat[ion] in practice against VA facilities" relative to facilities not operated by the VA, and forbids the "law of any State" and the "provision[s] of any contract or other agreement" from "operat[ing] to prevent recovery or collection by the United States." *United States v. Capital Blue Cross*, 992 F.2d 1270, 1272 (3d Cir. 1993); 38 U.S.C. § 1729(f). The United States may enforce its right to recovery under 38

U.S.C. § 1729 by electing subrogation, intervention, or by pursuing a separate action against the third-party payor in federal court, *see Maryland*, 914 F.2d 551, and "[t]his collection activity assists with the funding of VA medical care for veterans." *Grant v. United States*, No. 11-cv-00360, 2012 WL 5289309, at *2 (E.D. Cal. Oct. 23, 2012).

OTHER LEGAL CONSIDERATIONS FOR THE UNITED STATES

In addition to the interests described above, the United States must consider its other law enforcement and legal activities in conjunction with any decision to engage with the multidistrict litigation. The broad scope of the United States' activities is reflected in the Department's many actions over the past year to help end the opioid crisis, as well as the ongoing responsibilities Attorney General Sessions has assigned to the PIL Task Force, including the coordination of:

- Criminal and civil remedies available under federal law to hold opioid manufacturers accountable for unlawful practices.

- Use of criminal and civil tools to crack down on pain-management clinics, drug testing facilities, and physicians that prescribe opioids.

- Criminal and civil tools available under the Controlled Substances Act against doctors, pharmacies, and others that break the law.

- Holding distributors such as pharmacies, pain management clinics, drug testing facilities, and individual physicians accountable for unlawful actions.

- Criminal and civil actions to ensure that distributors and pharmacies are obeying Drug Enforcement Administration rules designed to prevent diversion and improper prescribing.

- Interdiction of criminal marketplaces used for the distribution of opioids.

See PIL Task Force Announcement. Specific provisions of law under which the United States may accordingly act include, but are not limited to, anti-fraud statutes, 18 U.S.C. §§ 1341-1347, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, the Controlled Substances Act, 21 U.S.C.

§ 811, et seq., and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. The United States does not believe that it would be proper to consolidate a possible action under one of these statutes with the actions in this multidistrict litigation.

CONCLUSION

The United States respectfully requests that this Court consider its interests as set forth above, and afford the United States a period of thirty days to evaluate whether to participate in these proceedings at this stage.

Respectfully submitted,

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