

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Hearing entitled “Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities.”

The Subcommittee on Health will hold a hearing on Wednesday, February 1, 2023, at 10:00 a.m. (ET) in 2123 Rayburn House Office Building. The hearing is entitled “Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities.”

I. Witnesses

Panel One

- **Mr. Kemp Chester**, Senior Advisor, International Relations and Supply Reduction, Office of National Drug Control Policy (ONDCP)
- **Dr. Neerja Gandotra**, Chief Medical Officer, Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Mr. Jon C. DeLena**, Associate Administrator, Business Operations, Drug Enforcement Administration (DEA)

Panel Two

- **Ms. Kandi Pickard**, President and CEO, National Down Syndrome Society (NDSS)
- **Frederick Isasi, J.D. MPH**, Executive Director, Families USA
- **Ms. Molly Cain**, Parent Advocate
- **Dr. Stephen Loyd, MD**, Chief Medical Officer, Cedar Recovery
- **Dr. Timothy Westlake, MD**, Emergency Medicine Physician

II. Background

Fentanyl and Controlled Substances

In 2022, the Drug Enforcement Administration (DEA) seized enough fentanyl to kill every American.¹ Fentanyl is a synthetic opioid that is up to 50 times stronger than heroin and 100 times stronger than morphine, and most recent cases of fentanyl-related overdoses are linked to illicitly manufactured fentanyl and fentanyl related substances

¹ U.S. Drug Enforcement Administration. (20 December 2022). *Drug Enforcement Administration Announces the Seizure of Over 379 million Deadly Doses of Fentanyl in 2022*. <https://www.dea.gov/press-releases/2022/12/20/drug-enforcement-administration-announces-seizure-over-379-million-deadly>

(FRS).² These substances are distributed through illegal drug markets for their heroin-like effect, and it are often added to other drugs because of their strong potency.³ Further, FRS have a related chemical structure to fentanyl but have no accepted medical use in the United States.⁴

This legislative hearing will examine policies related to permanently scheduling FRS, commonly referred to as fentanyl analogues. Currently, FRS are temporarily classified as a Schedule I controlled substance under the Controlled Substances Act, but this emergency scheduling order expires December 31, 2024.⁵

The Energy and Commerce Committee released a report in December of 2018 that examined the role that drug distributors and others played in the opioid crisis. Currently, under the Controlled Substances Act, drug manufacturers and distributors are required to report suspicious orders of opioids to the DEA.⁶ One recommendation of the report was to consider additional requirements to clarify DEA registrants' responsibilities in halting suspicious orders.⁷ This hearing will also consider legislation that requires DEA registrants to report and stop suspicious orders of all controlled substances.

9-8-8

The 9-8-8 Suicide & Crisis Lifeline is a critical program that was created to provide support services to people in suicidal crisis or emotional distress.⁸ In December 2022, Intrado, a contractor for 9-8-8, was taken offline for several hours. 9-8-8 was unable to take calls, though the text service was still available. The Committee will consider legislation to improve cybersecurity protections for 9-8-8.

QALYs

² Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and Opioid-Involved Overdose Deaths — United States, 2017–2018. *MMWR Morb Mortal Wkly Rep* 2020;69:290–297. DOI:

<http://dx.doi.org/10.15585/mmwr.mm6911a4>

³ U.S. Centers for Disease Control and Prevention. (23 February 2022). *Fentanyl Facts*.

<https://www.cdc.gov/stopoverdose/fentanyl/index.html#:~:text=Fentanyl%20is%20a%20synthetic%20opioid,nonfatal%20overdoses%20in%20the%20U.S.&text=There%20are%20two%20types%20of,fentanyl%20and%20illicitly%20manufactured%20fentanyl>.

⁴ U.S. Drug Enforcement Administration. (January 2023). *Fentanyl Related Substances*.

https://www.deadiversion.usdoj.gov/drug_chem_info/frs.pdf

⁵ Consolidated Appropriations Act, 2023. Public Law: 117-328. 2023.

<https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf>

⁶ Controlled Substances Act, 2023. Public Law: 117-215. <https://www.govinfo.gov/content/pkg/COMPS-10355/pdf/COMPS-10355.pdf>

⁷ U.S. House Committee on Energy and Commerce. 19 December 2018. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*.

https://d1dth6e84htgma.cloudfront.net/Opioid_Distribution_Report_Final_REV_57e438426b.pdf?updated_at=2023-01-24T15:21:04.037Z

⁸ U.S. Substance Abuse and Mental Health Services Administration. *988 Suicide & Crisis Lifeline*.

<https://988lifeline.org/>

Quality-Adjusted Life Years (QALYs) are a metric used for determining the cost-effectiveness of a course of treatment that evaluates the merits of covering the costs of a drug or treatment relative to the quantity and so-called “quality” of years that will be gained from such a course of treatment.⁹ While cost management in health care is important, the nature of defining an individual’s quality of life, ultimately wades into ethical dilemmas. For example, one formula for determining QALYs is as follows:

(A number, between 0 and 1, representing the quality of life) x (The number of years a patient is expected to live under a treatment) = Number of QALYs¹⁰

The reliance on such a calculation ultimately raises questions about how to quantify the value of an individual’s life. In many examples of QALY calculations, the coefficient for valuing the quality of an individual's life will be lowered based on the diagnosis of a disability like Down Syndrome or ALS. In doing so, the formula devalues the life of an individual with a disability by claiming that their life is not of the same quality as a person without a disability. The result is that a treatment for an individual with a disability gets stricter scrutiny for cost-effectiveness or more often gets an outright denial of coverage for a treatment.

Using QALYs has been shown to restrict coverage in countries that heavily rely on their usage. For example, in the United Kingdom, the National Institute for Health and Care Excellence’s (NICE) reliance on QALYs has been found to limit access to Alzheimer’s treatments and Cystic Fibrosis drugs, which can slow the progression of the disease or provide an increase in quality of living, all because the life that the individual would live as a result of such a treatment did not meet a standard worth paying for.¹¹

In the United States, the usage of QALYs is inconsistent. In Medicare, QALYs are limited, although not totally prohibited. In other payers like Medicaid, the VA, or private insurance; however, the usage of QALYs is permitted, although payers do use a multitude of other cost-effectiveness calculations.¹² Nonetheless, QALYs have been proposed to be used by the Centers for Medicare and Medicaid Services and the Center for Medicare and Medicaid Innovation.

III. Legislation

H.R. 467, the “Halt All Lethal Trafficking (HALT) of Fentanyl Act”

⁹ National Council on Disabilities. *Quality-Adjusted Life Years and the Devaluation of Life with Disability* (2019). https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹⁰ National Council on Disabilities. *Quality-Adjusted Life Years and the Devaluation of Life with Disability* (2019). https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹¹ National Council on Disabilities. *Quality-Adjusted Life Years and the Devaluation of Life with Disability* (2019). https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

¹² National Council on Disabilities. *Quality-Adjusted Life Years and the Devaluation of Life with Disability* (2019). https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

H.R. 467, the “Halt All Lethal Trafficking (HALT) of Fentanyl Act,” authored by Rep. Morgan Griffith (R-VA) and Rep. Bob Latta (R-OH), would place fentanyl-related substances (FRS) permanently into Schedule I of the Controlled Substances Act. The bill also simplifies the registration processes for certain research with Schedule I substances and exempts an individual FRS from Schedule I when evidence demonstrates it is appropriate.

H.R. 498, the “9-8-8 Lifeline Cybersecurity Responsibility Act”

H.R. 498, the “9-8-8- Lifeline Cybersecurity Responsibility Act,” authored by Rep. Jay Obernolte (R-CA) and Rep. Tony Cardenas (D-CA), would amend the section 520E-3 of the Public Health Service Act to require internal coordination within HHS to protect the 9-8-8 lifeline from cybersecurity incidents. Additionally, the bill requires 9-8-8 network administrator to report potential cybersecurity threats to SAMHSA immediately upon their discovery. The bill also requires the Comptroller General to conduct a study to evaluate cybersecurity risks and vulnerabilities associated with the 9-8-8 lifeline.

H.R. 501, the “Block, Reporting, and Suspend Suspicious Shipments Act”

H.R. 501, the “Block Reporting, and Suspend Suspicious Shipments Act,” authored by Rep. Diana Harshbarger (R-TN) and Rep. Debbie Dingell (D-MI), would require drug manufacturers, distributors, and other DEA registrants to practice due diligence when discovering suspicious orders of controlled substances. Specifically, these DEA registrants are required to report and decline to fill these orders of all controlled substances. Additionally, the bill requires the DEA to go through rulemaking to specify the indicators that give rise to suspicious orders and the likelihood of diversion if an order is filled.

H.R. 485, the “Protecting Health Care For All Patients Act”

H.R. 485, the “Protecting Health Care for All Patient Act,” authored by Rep. Cathy McMorris Rodgers (R-WA), Rep. Jason Smith (R-MO), Rep. Michael Burgess (R-TX), and Rep. Brad Wenstrup (R-OH), would prohibit the usage of Quality-Adjusted Life Years (QALYs) by federal health care payers.

Staff Contacts

If you have questions regarding this hearing, please contact Grace Graham, Seth Gold, Alec Aramanda, or Kristin Flukey of the committee staff at 202-225-3641.