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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

JEFFREY WRASE, STAFF DIRECTOR AND CHIEF ECONOMIST
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December 18, 2018

Nicole Hemmenway
Interim CEO
U.S. Pain Foundation
670 Newfield Street, Suite B
Middletown, CT 06457

Dear Ms. Hemmenway:

As Ranking Member of the U.S. Senate Committee on Finance, which has jurisdiction over federal tax matters including those related to charitable organizations, Medicare and Medicaid, I am writing to gather information about reports of financial mismanagement at the U.S. Pain Foundation (“foundation”). The foundation’s admissions and related reporting by the press raise concerns about the foundation’s status as a 501(c)(3) tax exempt organization. Information reported by your organization to the Ranking Member of the Senate Homeland Security and Governmental Affairs Committee (“HSGAC”) also raises questions about your organizations role in a patient assistance programs.

Earlier this month, the foundation disclosed financial irregularities dating back several years that led to the forced resignation of former chief executive Paul Gileno in May.¹ An internal investigation found that Mr. Gileno “misused funds from the U.S. Pain Foundation... [and] repeatedly misled and concealed information from the Board of Directors and staff.”² Mr. Gileno has acknowledged misusing funds;³ however, according to press accounts, he has said that the foundation’s board was aware of the foundation’s accounting and legal problems since early 2017.⁴ Media reports also stated that the foundation had inflated its membership numbers by 600%. The foundation previously said that it had 90,000 members, but now states that it has just 15,000 members.⁵

As a result of the foundation’s actions, the Attorney General and the Department of Consumer Protection for the State of Connecticut have reportedly opened investigations into its activities.⁶

¹ Press Release, “A Statement from the U.S Pain Foundation’s Board of Directors and Interim CEO,” *U.S. Pain Foundation* (Dec. 7, 2018), available at <https://uspainfoundation.org/news/uspainstatement/>

² *Id.*

³ Pat Anson, “Ex-CEO Admits ‘I Took Money From U.S. Pain,’” *Pain News Network* (Dec. 9, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/8/ex-ceo-admits-i-took-money-from-us-pain>.

⁴ Pat Anson, “‘Financial Irregularities’ Found at U.S. Pain Foundation,” *Pain News Network* (Dec. 7, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/7/financial-irregularities-uncovered-at-us-pain-foundation-nbsp>.

⁵ *Supra*, note 4.

⁶ Pat Anson, “U.S. Pain Foundation Under Investigation,” *Pain News Network* (Dec. 12, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/12/us-pain-foundation-under-investigation>.

Mr. Gileno also has reportedly spoken to the U.S. Attorney's Office, the Federal Bureau of Investigation, and the Department of Health & Human Services ("HHS").⁷

These disclosures come on the heels of a report released by U.S. Senator Claire McCaskill, the Ranking Member of HSGAC, revealing that the foundation received \$2.5 million from Insys Therapeutics, Inc. ("Insys") to start a patient assistance program ("PAP").⁸ Insys markets fentanyl and has been the subject of civil and criminal prosecution for abusive marketing practices, some of which were the subject of a 2016 Finance Committee hearing.⁹ The HHS Office of Inspector General and the FDA Office of Criminal Investigations participated in the federal investigation and 2017 arrest of the founder and majority owners of Insys regarding these illegal practices.¹⁰ The purpose of the Insys-funded PAP, called Gain Against Pain, was to subsidize the purchase of medication for people experiencing cancer pain. The PAP would provide up to \$12,000 annually, according to an application form for the program.¹¹ Gain Against Pain appears to have been co-administered by NeedyMeds,¹² a 501(c)(3) organization that consumers utilize to identify and apply for PAPs and other financial help for medicine.¹³ Given the involvement of Insys and questions about the adequacy of the foundation's financial controls, this program deserves additional scrutiny.

Given these concerns, I request that you provide the following information and documents no later than January 22, 2019:

1. Please provide any internal audits or investigations conducted by the foundation its outside counsel, forensic auditors, or other contracted staff or consultants related to the financial irregularities referenced in the December 7, 2018 press release.
2. When and how did the foundation's board of directors first become aware of funds being misused?
3. What is the organization's estimate of the total amount of funds that were misused? What was the source of these funds? What was the intended purpose of the funds? Please describe how the funds were misused.
4. Besides Mr. Gileno, have any other employees, contractors, board members, volunteers or people otherwise associated with the foundation been implicated in the misuse of funds?

⁷ *Supra*, note 3.

⁸ Minority Office of the U.S. Senate Committee on Homeland Security and Government Affairs, "Fueling an Epidemic: Report Two," (Feb. 12, 2018) at 16, *available* at <http://goo.gl/T4qiWh> (link shortened).

⁹ Examining the Opioid Epidemic: Challenges and Opportunities, Before the U.S. Senate Committee on Finance, 114th Cong. 523 (2016) (statement of David A. Hart, Assistant Attorney-In-Charge, Civil Enforcement, Financial Fraud And Consumer Protection, Oregon Department of Justice), *available* at <https://www.finance.senate.gov/hearings/examining-the-opioid-epidemic-challenges-and-opportunities>.

¹⁰ Press Release, "Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering," U.S. Department of Justice (Oct. 26, 2017), *available* at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

¹¹ See attached.

¹² NeedyMeds, "Diagnosis-Based Assistance –Search by Program Name," *available* at <https://web.archive.org/web/20170707062508/http://www.needymeds.org/copay-program/list/G>. An archived screenshot of the NeedyMed's website shows "Gain Against Pain" listed among its programs. An application for the program's subsidies has an address that matches the one listed on NeedyMed's Form 990 for the year 2015.

¹³ NeedyMeds, "Form 990 for the tax year 2015," *available* at http://990s.foundationcenter.org/990_pdf_archive/463/463091990/463091990_201512_990.pdf.

5. The organization stated it is “implementing a more robust system of checks and balances,” which appears to allude to financial controls. Please provide the previous and updated policies referred to in this statement, and an explanation of other steps the organization plans to improve its financial controls.
6. The organization stated that it has contacted legal authorities. Please provide a list of all legal authorities that the organization has contacted. Please list the date of when such contacts were made. Please provide a list of ongoing investigations it is aware are taking place.
7. The foundation’s website and media reports state that the organization has not filed its tax returns for 2016 and 2017. When does the foundation anticipate filing its 2016 and 2017 tax returns? Does the foundation anticipate having to refile any of its previously filed tax returns?
8. Please provide Form 990s for each of the past 10 years, including Schedule B disclosures.
9. The foundation’s membership numbers were reportedly inflated.
 - a. Please describe how and why the foundation’s membership numbers were inflated, and the period during which such inflation occurred.
 - b. Who directed the membership numbers to be inflated, and who else at the foundation—executives, board members, staff, volunteers, sponsors—was aware of it?
 - c. When did members of the board become aware of the membership inflation?
 - d. Please detail any instances in which the foundation misrepresented its membership numbers to donors and/or in its financial reports.
 - e. Please detail any instances in which the foundation misrepresented its membership numbers to state or federal government.
 - f. Please provide any investigation, audit or other review of the foundation’s membership numbers.
10. Please answer the following questions regarding the PAP funded by Insys:
 - a. When did the program begin, and when was it terminated?
 - b. Who at the foundation was involved in Gain Against Pain’s operation?
 - c. Please provide a detailed list and explanation of all donations or payments that Insys and/or other companies made to the foundation in connection to the Gain Against Pain program.
 - d. Please provide a detailed list and explanation of all donations or payments that the foundation, Insys and/or other companies made directly to the Gain Against Pain program.
 - e. Were there any conditions connected to any of the donations from Insys to the foundation or the Gain Against Pain program?

- f. There are conflicting accounts of when the foundation's board of directors was made aware of Gain Against Pain. Please clarify when the foundation's board learned of the program's existence, and when it learned of funding from Insys. Please provide any available supporting documentation.
 - g. Who were the foundation's contacts at Insys? To the best of the foundation's knowledge, who at Insys was involved in the Gain Against Pain's operation? Please provide full names, titles and contact information where available.
 - h. To what extent was Insys involved in the design and operation of the program?
 - i. What was the foundation's relationship with NeedyMeds?
 - j. Who were the foundation's contacts at NeedyMeds? Please provide full names, titles and contact information where available.
 - k. Please describe the types of information, updates and/or data shared between the foundation, NeedyMeds, Insys and any other third-parties involved in Gain Against Pain. Was drug- or brand-specific prescription information shared?
11. Is the foundation involved in or associated with any other PAPs? If so, please provide a list and describe the foundation's involvement.
 12. Please provide a detailed list and explanation of all donations or payments that Insys and/or other companies made in connection to the Gain Against Pain program.
 13. Specifically, the HSGAC report identifies a payment between Insys and the U.S. Pain Foundation related to the Gain Against Pain program—a \$250,000 payment made on April 7, 2017.¹⁴ Please describe the nature and purpose of this payment.
 14. Please provide any documents related to the Gain Against Pain program, including but not limited to contracts, agreements, applications, program manuals (draft or final), memos, reports, emails, text messages, or other written or electronic communication. Such communication should include but not be limited to communication among the foundation's staff, and incoming or outgoing communications to or from Insys, NeedyMeds, and any other entities involved in PAPs associated with the foundation.
 15. Please provide data regarding each of the following:
 - a. The number of applicants, by month, for the Gain Against Pain program.
 - b. The number of applicants accepted, by month, into the Gain Against Pain program.
 - c. The number of patients currently enrolled in the Gain Against Pain program.
 - d. The amount of money expended, by month, for the Gain Against Pain program.
 - e. The amount of money that was expended by patient insurance type, including private insurance, Medicare, Medicaid, TriCare, and uninsured.

¹⁴ *Supra*, note 8, at 22. See footnote 107.

- f. The amount of money that the foundation itself contributed or provided to Gain Against Pain by patient insurance type.
- g. The account balance for the Gain Against Pain program.
- h. Any data that the foundation received or maintains regarding the brands of drugs, or specific prescriptions, that were paid for by the program.

Please direct any questions to Peter Gartrell on my investigative staff. He can be reached at (202) 224-4515. Thank you for your attention to this matter.

Sincerely,



Ron Wyden
Ranking Member