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The Honorable Gregg Harper
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Congressman Harper:

It was my pleasure to appear before the Subcommittee on Oversight and Investigations on July 24, 2018, to testify at the hearing entitled, "Examining Advertising and Marketing Practices within the Substance Use Treatment Industry." I am writing to respond to the letter dated September 26, 2018, with additional questions posed by yourself and The Honorable Gus Bilirakus.

Responses to Congressman Harper's questions:

1. Question: *Throughout the Committee's investigation, we've seen facilities suggest that out of state treatment may have higher success rates than staying local. Is there any evidence that would suggest that is accurate? If so, please explain.*

   Response: I am aware of no published studies which demonstrate that if all else is equal, attending treatment out of the state where the patient lives is associated with superior treatment outcome. There are numerous predictors of positive response to treatment. As I communicated in my testimony, provision of high-quality, evidence-based treatment, making pharmacotherapies available when indicated, is of critical importance. Combining pharmacotherapies with psychosocial treatments, and using behavioral interventions, can maximize response. Matching patient needs to treatment setting and intensity, over time, is also important (e.g., using the ASAM Criteria). Recovery environment can also support recovery or hinder recovery. For example, the person's housing and community situation can interfere with, or facilitate, the recovering person's ability to maintain sobriety and engage in ongoing treatment. The more social supports the person has who reinforce recovery, the better chance they have at developing a strong recovery. I am concerned when patients specifically seek out distant programs for what some call "geographic cures" in order to separate from potential triggers in the community where they and their family live; they are also leaving any positive community supports they may have. When they return to their home community, if not well-linked to into ongoing treatment, and prepared to face such triggers, they all too often fall back into a pattern of substance use. For these reasons I believe that it is ideal for treatment to be 1) well-matched in type, setting and intensity to the patient's needs over time, and 2) long-term in nature (including, ultimately, ongoing outpatient) – where work is done to address potential and actual relapse, while living in the community where the individual will continue to reside and work. To the extent that some communities may unfortunately not have readily accessible treatment programs that are well-

suited to the person's needs, it may be necessary to widen the geographic scope of the search for the best treatment program for that individual at that point in his or her recovery journey.

2. Question: *Is there anything else that you'd like to add, clarify, or correct for the record?*

   Response: I would like to express my appreciation for the U.S. House and Senate's work on passing critically needed legislation to address the opioid crisis, and in particular, including language that will lead to the creation of a reimbursement structure allowing Medicare beneficiaries to access, for the first time, the comprehensive and evidence-based treatment available in opioid treatment programs. Considering the aging population of people with opioid use disorder, the impact of this recent positive development will be tremendous, and undoubtedly will save many lives.

Responses to Congressman Bilirakis's question:

- Question: *What entity is responsible for auditing your facilities? Since opening your doors, how many times have you been audited, and is your experience unique or common in the industry?*

  Response: Both of the programs where I work, at Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center are federally certified opioid treatment programs (OTPs). As such they are subject to intensive scrutiny, including numerous audits. I will provide a brief outline here:

  a. **Initial**: OTP's operate under CFR 42 CFR, Part 8. Upon opening, OTP's are inspected by SAMHSA, the DEA, and the accreditation body the program chooses (most often The Joint Commission or CARF). The state also inspects the program prior to opening - typically licensure, behavioral health agency, opioid treatment authority, and controlled substances oversite agency. The county/city (sometimes referred to as the "local jurisdictional entity") may also inspect the facility prior to opening.
  b. **Ongoing**: Our programs are audited/surveyed by multiple entities, including the following:
     - Accreditation body: in our case, it is The Joint Commission, which conducts 2 surveys every 3 years: one for the OTP component (lasting 2 full days at each treatment site), and one for our non-OTP component (lasting about ½ day).
     - U.S. DEA: Approximately 1 day, focusing on medication (methadone, buprenorphine) security and accountability (unpredictable frequency, but average frequency every 2-3 years).
     - State of Maryland: Various oversight and licensing entities (licensing, quality oversight entities, controlled substance, with average frequency of about 3 times per year.
     - Maryland SOTA: Each state, including Maryland, has a State Opioid Treatment Authority ("the state SOTA") which oversees, and at times may visit, opioid treatment programs.
     - Local jurisdictional entity – in our case, Behavioral Health Systems Baltimore: Routine (once every 4 months) and random.
     - Payors: Public (e.g., Medicaid) or private (unpredictable but infrequent on-site visits).
     - CMS: This may be unique to hospital-based programs. (very rarely, and typically on-site visit would be "for cause").
     - SAMHSA: (infrequent as well, given that the accreditation body is responsible for creating standards consistent with SAMHSA guidelines, and conducting regular surveys based on those standards).

  This experience is not unique for OTP's, although the exact frequency of visits, and the extent to which local jurisdictions audit programs, may vary among states and cities. The degree of such

oversight for opioid treatment programs is much higher than among non-OTP substance use disorder treatment providers. It has been said that OTP oversight is greater than for any other medical treatment setting.

Thank you for providing me with the opportunity to respond to your questions. I would be very pleased to host a visit should you and any colleagues like to see the programs, meet my colleagues, staff and patients, and discuss how we can best support your efforts to improve the nation's treatment system.

Sincerely yours,

Kenneth B. Stoller, M.D.