Ohio Value Voters

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01/19/25

Office of Professional Responsibility/Civil Division

950 Pennsylvania Avenue, NW

Washington, DC 20530

My name is Charles Giunta. I am writing this letter as the executive director of the Ohio Voters Organization (32,000 members strong in Ohio) and an Ohio citizen. I want to express my respect for the DOJ's mission to uphold the rule of law, to keep our country safe, to ensure public safety, to uphold civil rights, and to ensure fair and impartial administration of justice for all Americans. We are driven strictly by public safety and benefit when we raise concerns in this letter.

I am deeply concerned about the deepening opioid crisis in Ohio and nationwide. We would like to draw your attention to One of the modifiable factors in the opioid crisis: access to quality screening and brief intervention services (SBIRT) and quality pain management programs. I strongly believe that reviewing the issues raised in this letter can help save hundreds of lives in Ohio and nationwide. According to the Swank report "TAKING MEASURE OF OHIO'S OPIOID CRISIS" only 20-40% percent of the potential patients have access to these services in Ohio. In addition, there is a serious concern about insurance coverage of these services in Ohio (please see the reference below).

The Ohio Voters organization saves lives and promotes safety from drugs and crime. This is an urgent issue for us.

From 1999 to 2022, nearly 727,000 people in the U.S. died from opioid overdoses (CDC). The opioid epidemic's economic toll has been staggering, with costs reaching $631 billion between 2014 and 2018 alone and nearly $1.5 trillion annually by 2020. Cumulatively, the total cost of the opioid crisis since 1999 is estimated to exceed $20 trillion (David Trone, US Congress ZJoint Economic Committee (JEC), 09/28/22). The annual cost is about 8.5 billion in Ohio alone (Swank Report, 2017). COVID-19 national state of emergency has ended. However, the US is still in the state of a national opioid crisis emergency under section 319 of the Public Health Service Act, 42 U.5.C. 5 247d (https://aspr.hhs.gov/legal/PHE/Pages/Opioid-31Mar2023.aspx).

According to the Centers for Disease Control and Prevention (CDC), between 2015-2020, Ohio had consistently been one of the top-5 states for drug overdose mortality rates. (CDC 2022). In 2015, Ohio tied with Kentucky for the third highest drug overdose mortality rate in the United States, with 29.9 deaths per 100,000 people (3,310 total deaths). (CDC 2022). In 2016, Ohio had the second-highest drug

overdose mortality rate, with 39.1 deaths per 100,000 people (4,329 total deaths). (CDC 2022). In 2017, Ohio had the second-highest drug overdose mortality rate in the nation, with 46.3 deaths per 100,000 people (5,111 total deaths). (CDC 2022).

Additional research conducted in 2017 focusing on opioid mortality found Ohio to have the second-highest opioid mortality rate in the US, representing more than 2.6 times the death rate compared to the US average (39.2 per 100,000 people in OH vs. 14.6 per 100,000 people in the US.

Background of the SBIRT Services:

Screening, Brief Intervention, and Referral to Treatment ("SBIRT") services are evidence-based, early interventions that physicians use to address the risk of substance abuse, overdose, and death with patients receiving treatment with opioids or other dangerous drugs. SBIRT consists of three primary components:

(1) screenings to assess a patient's risk for substance abuse and to determine the appropriate level of treatment;

(2) brief interventions by engaging the patient in a short conversation to increase their awareness of risky substance use behaviors and to provide feedback, motivation, and advice; and

(3) referral for additional treatment or services when necessary

There is a very strong evidence for the SBIRT (for example):

SAMSHA study shows strong evidence for SBIRT:

A large-scale study funded by SAMHSA found significant decreases in substance use after SBIRT implementation: 75.8% reduction in illicit drug use: Aldridge A, Linford R, Bray J. Substance use outcomes of patients served by a large US implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT). Addiction. 2017 Feb;112 Suppl 2:43-53. doi: 10.1111/add.13651. PMID: 28074561.

A SAMHSA-funded study of over one million people screened for drug and alcohol use disorders over five years demonstrated SBIRT's effectiveness in various medical and community settings:

https://pgdf.org/large-cohort-samhsa-study-shows-effectiveness-of-sbirt/

Notably, a large study of SBIRT outcomes found that SBIRT, at the six-month follow-up point, lowered illicit drug use by 68% and lowered heavy alcohol use by 39%. (Agerwala, SM, et al.2012).

According to the Pew Institute, peer-reviewed research indicates that SBIRT may be effective in reducing drug misuse in a variety of medical and community settings. A 2017 study of 11 programs serving over 1 million total people found an 80% reduction in self-reported illicit substance use, including opioid use, following the intervention. For example, Washington state's SBIRT program found that 84% of those who had been assessed using the process reported a reduction in days of drug use six months later. The program also saw an increase—from 55% to 71%—in the number of people reporting abstinence from illicit drugs: https://www.pewtrusts.org/en/research-and-analysis/articles/2021/01/25/primary-care-providers-can-help-steer-people-to-opioid-addiction-treatment

Evidence for the SBIRT cost saving:

People who received SBIRT from their physician experienced 20% fewer ED visits, 33% fewer nonfatal injuries, 37% fewer hospitalizations, 46% fewer arrests, and 50% fewer motor vehicle crashes

Economic analyses showed that screening and brief counseling of non-dependent, risky alcohol users allowed for a cost savings of $4.30 in future healthcare costs for every dollar invested in the intervention

SBIRT ranks among the top five preventative services based on benefit and cost-effectiveness, providing a net savings of $254 per person screened: https://oasas.ny.gov/system/files/documents/2019/08/OASAS-1%20NY_SBIRT_Flyer.pdf

SBIRT is mandatory for pain management patients on opioid medications in Ohio:

Moreover, SBIRT protocols are often mandatory for the compliant operation of a pain management clinic, especially clinics providing medical management to populations with a significant portion of high-risk patients in high-risk areas like Ohio. By way of example, Ohio law sets stringent requirements for pain management clinics and physicians that prescribe controlled substances as part of their pain management services. (OAC § 4731-29-01; please see the white paper below for additional sources).

We are deeply concerned by the unreasonable DOJ position, which is dangerous to the public

We came across the attached DOJ press release regarding Dr. Margolin/ CPMI (the top-rated SBIRT programs in the state of Ohio) The DOJ press release below is very aggressive and deters other providers, hospitals, and insurance companies from performing or covering SBIRT (which is the purpose of this release). The DOJ created a very dangerous situation and likely contributed to the opioid mortality in Ohio (see the article link below):

"alcohol and/or substance assessments ...were not necessary because the patients had no history of drug or alcohol abuse" (see the release attached). The DOJ labeled SBIRT **as "medically unnecessary"** and a **"waste of the taxpayer money."**
https://drive.google.com/file/d/1VNUScjtFm1GXOKNLq7poiYd5dcy5wToY/view?usp=sharing

It seems like the DOJ holds that if a patient does not have a history of alcohol or drug abuse, there is no need to screen that patient for illicit drugs or alcohol when the patient is on an opioid medication program (no urine screen, no PMD, no psychological assessment, pill counts, etc.) and no need to make any interventions. This position apparently is unreasonable; it contradicts expert opinions and evidence-based data, and is dangerous to the public.

The purpose of the DOJ press release is to deter other providers, hospitals, and insurance companies from performing or covering SBIRT (which is the purpose of this release). The DOJ created a dangerous situation and contributed to the opioid mortality in Ohio (see the article link below):

https://drive.google.com/file/d/1BpEG_DUaqIAM3g9DixSCjzg30txCZVxK/view?usp=sharing

The DOJ position contradicts expert opinion and evidence-based data:

Unlike the standard practice for meetings with government agents or contractors to discuss billing concerns, the government failed to engage a certified coder and/or a medical professional of Dr. Margolin's specialty to review Dr. Margolin's record of claims from January 1, 2013, to September 19, 2019, the time period for claims included in the Settlement Agreement, in this care DOJ failed to do so and was willfully blind to the plethora of evidence presented to them.

We got three volumes (see the links below) of additional supporting evidence from a host of sources and peer-reviewed data; however, the only way to reverse this is by making regulators within the justice system review the issue and the evidence on the grounds of public safety. Such review may expose additional issues like collusion with insurance plans, unjustified financial objectives, and willful DOJ blindness towards expert opinions sent to them:
https://cpmiohio.com/wp-content/uploads/2024/03/White-Paper-SBIRT.x25291.pdf

https://cpmiohio.com/wp-content/uploads/2024/11/Addendum-to-the-White-Paper-FINAL.x25291.pdf

We are deeply concerned that the DOJ made a mistake that created a public hazard for thousands of Ohioans.

Despite clear evidence of effectiveness, SBIRT is grossly underutilized nationwide, particularly in Ohio (National Survey by SAMSHA).

The 2021 National Survey on Drug Use and Health (NSDUH) Releases alarmed the public with the extremely low access to the SBIRT for the high-risk population. The evidence of underutilization is particularly concerning, given that 94% of people with a diagnosable SUD did not receive treatment in 2021, underscoring the critical need for more widespread and effective implementation of SBIRT. Low reimbursement and/or lack of coverage by insurance were named as one of the main barriers to treatment:

https://www.chess.health/blog/how-to-improve-sbirt-to-address-substance-use-disorder/

Since SBIRT is underutilized by most providers and Dr. Margolin utilized it properly, it is possible that Dr. Margolin may have appeared as a frequency outlier; however, the frequency can be an indicator of medical necessity as per the Medicare medical integrity manual. This emphasizes the need for an expert statistician and an independent expert involvement. In fact, the DOJ added insult to injury by further limiting access to the SBIRT.
Driven by financial objectives and bias, the DOJ attacked, defunded, and disparaged one of the top SBIRT programs, which is a heavily underutilized service in the underserved area in the epicenter of the opioid crisis, further increasing soaring opioid crisis mortality and costs.

Dr. Margolin/CPMI background:

Dr. Margolin and CPMI have a reputation for being among the state's top pain management/SBIRT programs. They have made several presentations and publications at the state and international levels (without outside grants). CPMI enjoys a high professional ranking. Since 2011, Dr. Margolin has diagnosed and referred more than 3000 patients to Addiction Medicine using SBIRT. He received several accolades, including the Ohio Top Doctor Award in 2021 and 2025 (specifically for the outstanding SBIRT pain management program that saved hundreds of lives).

Dr. Margolin created more than 50 free educational videos for the public. Despite being unjustly defunded by the DOJ, Dr. Margolin spent his money on public education and research. He risked his health by not closing the doors and switching to telemedicine only during COVID to provide the best care for vulnerable, high-risk patients. Dr. Margolin and CPMI frequently contribute to the Wounded Warriors Project, the Gary Sinise Foundation, and other worthy causes. As the DOJ falsely claimed, this is not a profile of a physician who would "waste taxpayer money" on questionable services.

Former President of the American Academy of Pain Medicine, Lynn Webster MD endorses Dr. Margolin's practice and services (his letter is enclosed)

Dr. Margolin's program and protocol were endorsed by the former president of the American Academy of Pain Medicine, Lynn Webster and many other experts (chrome extension://efaidnbmnnnibpcajpcglclefindmkaj/https://cpmiohio.com/wp-content/uploads/2024/11/Leon-Margolin-letter-of-support-116-Nov-2024.x36240.pdf).

Former Director of Drug and Alcohol Services of Fairfield County, Ohio, points to the danger to the public

Dr. William Vasilakis, former Director of Drug and Alcohol Services of Fairfield County, a board-certified clinical psychologist with certification in addiction medicine and over 30 years of practice in OH, fully endorsed Dr. Margolin/CPMI services. Dr. Vasilakis cared for hundreds of Dr. Margolin/CPMI patients over eight years, including all the patients reviewed by the DOJ.

Dr. Vasilkis pointed out that the DOJ's position is inaccurate, contradicts the accepted guidelines, and is dangerous to the public (his letter is enclosed).

In 2025, Dr. Margolin received the Ohio Top Doctor Award for the same service (SBIRT) that the DOJ attacked (see enclosed)

In 2025, Dr. Margolin received the Ohio Top Doctor award for the second time after the settlement agreement (the first time in 2021), this time specifically for the SBIRT (the code falsely labeled as unnecessary by the DOJ). Despite being defunded and publicly disparaged by the DOJ's false determination, Dr. Margolin continued to screen high-risk patients for drugs and alcohol as per evidence-based publications, the National Academy (ABPMR), Dr. Lynn Webster's endorsement, and state and federal regulations.

Based on conservative estimates, Dr. Margolin and his team have screened and referred to addiction medicine more than 3000 patients since 2011, saving a few hundred lives.

The DOJ's position and conduct are unreasonable; it is Kafkaesque and dangerous to the public.

The DOJ position has devastating effects on pain specialists in Ohio, essentially handcuffing them from appropriately practicing pain management. Ohio law explicitly requires frequent monitoring of opioid patients (See, e.g., OAC 4731-11-14(F)-(G)), which creates a catch-22 with the DOJ position. We have evidence of approximately 200+ patient complaints submitted by Ohio patients to Medicaid insurers regarding the lack of access to vital pain management services. (*See* patient complaints example at RESOURCES | Comprehensive Pain Management Institute, LLC and the letter sent to the DOJ (as described in the white paper).

The DOJ policy has far-reaching implications, including a negative impact on opioid-related death and crime rates. While these are nationwide issues, Ohio is a key focal point of the opioid epidemic, with one

of the highest death rates for years in the U.S. due to drug overdose. (https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm). The year the DOJ published the above-cited press release regarding its settlement with CPMI, Ohio experienced a 22% increase in drug-related overdoses. (https://ohiocapitaljournal.com/2021/07/15/new-data-fatal-overdoses-leapt-22-in-ohio-last-year/). Ohio-based pain medicine practices have also experienced increased criminal activity from drug-seeking patients, including property destruction, attempted break-ins, and assaults on staff. Many drug-seeking patients are lashing out due to a lack of access to appropriate pain management services.

So long as the DOJ continues to falsely label the SBIRT and other life-saving services as medically unnecessary, the opioid-related death and crime rate will continue to rise, and our society will continue to face negative implications from the opioid epidemic. For example, every branch of the U.S. military has announced record-low recruitment this year due, in part, to the opioid epidemic. (*See* https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078*)*.

Reviewing this case can help create checks and balances and regulations that save many lives.
I am convinced that an objective review of our concerns will result in the creation of proper checks and balances and reasonable regulations to prevent the denial and false labeling of life-saving services as "unnecessary" (e.g., enforcement of the requirement of an independent statistician and an expert). This can save hundreds of lives in Ohio and thousands nationwide.

The DOJ inappropriately extrapolated an invalid patient Sample

The DOJ's investigation wrongfully relied on inappropriate statistical sampling. In part, the DOJ's investigation consisted of a review of 50 CPMI patients' records. The DOJ never provided evidence that this 50-patient sample met applicable statistical sampling requirements. Federal law prohibits extrapolating overpayments from a statistical sample unless it is statistically valid. *See* 42 (U.S.C.A. § 1395ddd(f)(3), Exhibit UU in the white paper).

As specified in the MPIM (which sets standard requirements for statistical samples), a statistical sample must be reviewed and verified by a statistician to ensure it meets the minimum requirements for a statistical sample. The DOJ never indicated that such a review had occurred. As the DOJ provided no evidence that its 50-patient sample was reviewed and verified to meet applicable standards by a statistician, the DOJ's 50-patient sample was invalid. While the DOJ also appears to rely on the CareSource audit, the CareSource audit sample was also determined to be erroneous by an expert statistician. Consequently, the DOJ was prohibited from extrapolating any determinations based upon either the statistical sample, the CareSource audit sample, or its own 50-patient sample to CPMI's entire patient population (see the white paper for additional details).

The DOJ findings violate both federal regulations, which require providers to be given the opportunity to rebut, and federal law, which requires providers to be able to challenge the statistical validity of a sample.

Federal case law supports that statistical sampling does not deprive a provider of its right to challenge the sample or its due process rights incident to a payer's recoupment of an overpayment (Chaves County Home Health Service, Inc. v. Sullivan, 931 F.2d 914,(D.C. Cir. 1991). However, under Chavez and federal regulation, a provider must have the opportunity to rebut the statistical validity of the sample.

The DOJ's failure to provide evidence that its sample was representative and statistically significant was willful blindness to the expert opinions and evidence-based data provided to them, violating CPMI's due process rights under federal law.

DOJ's presentation contradicts legal and ethical guidelines and Medicare AANEM's informed consent policy.

DOJ's disregard of the written informed consent signed by the patients violates patients' autonomy and conflicts with all ethical and legal mandates from HHS, AANEM, and other professional associations and that imposed by Ohio's Medical Practice Act (RC Ch. 4731). AANEM's policy is set forth in its "Guidelines for Ethical Behavior Relating to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine." In these clinical guidelines, AANEM states that physicians "MUST obtain valid verbal or written consent from the patient." Section 1.3. More importantly, the physician "MUST disclose information that the average person would need to know to make an appropriate medical decision."

The SBIRT DOJ determination is arbitrary and is based on unjustified financial objectives

In the summer of 2019, after receiving and ignoring beyond reasonable doubt evidence regarding proper use of NCS and other services (in the form of PowerPoint presentation and expert letters), the DOJ attacked a new service that was not discussed before (and not part of the CID). I am concerned that the DOJ staff involved either had no understanding of the life-saving benefits of the SBIRT or willfully ignored them. The DOJ labeled the SBIRT service as "unnecessary" purely because of the SBIRT frequency that helped the DOJ to archive the predetermined unjustified financial objectives of 650K recoupment.

I am concerned that the DOJ intentionally avoided engaging an independent expert and ignored all expert data provided to the DOJ by Dr. Margolin since the DOJ knew very well that all the CPMI/Dr. Margolin's services were medically necessary, compliant, and billed according to the CMS guidelines. In particular, the DOJ was aware that CMS' guidance does not specify any limitations as to how often HCPCS Codes G0396 or G0397 may be used to bill for SBIRT services (see exhibit H, the white paper).

650K recoupment was a predetermined number, which is not based on evidence of statistical extrapolation

Driven by unjustified financial objectives and racial and religious bias, the DOJ set 650 K is an arbitrary number not supported by any evidence or statistical extrapolations. I have information and evidence that the DOJ systematically resisted the review of the evidence-based data and expert opinions and avoided engaging in retaining an independent medical expert and a statistician despite credible written warnings about serious danger to the public and an increase in opioid deaths. This seriously violates state and federal laws, regulations, and the DOJ code of ethics. Proper regulations must be set to avoid such abuse of power in the future.

DOJ set a new false and dangerous medical standard of care

Through the two press releases aired by local TV and publicized by the media, the DOJ created a new false and dangerous standard of care regarding the SBIRT and other services described above. Since no medical expert or physician was consulted by the DOJ, the DOJ is guilty of practicing medicine without a license and liable for the loss of life and substantial economic damages to the public.

DOJ intentionally and willfully ignored the NARX core, which was validated at the state and national levels.

A patient's risk level is determined by their NARX score (*i.e.*, an analytic score of 000-999 based on the patient's accidental overdose risk). The higher the NARX score, the higher the patient's risk of substance abuse. The majority of CPMI patients have a high to extremely high-risk NARX score, meaning they are at extreme risk and must be closely monitored during treatment.

NarxCare scores range from 000 to 999, with higher scores indicating riskier drug use patterns (above 300, the risk is much higher).

Dr. Margolin and Dr. Stream, the Chief of Psychiatry/Medical Director of the Alcohol and Drug Recovery Center at the Cleveland Clinic Foundation, published a peer-reviewed article demonstrating the medical necessity of frequent SBIRT services to treat chronic pain patients (exhibit H in the white paper) The article reviewed the same fifty (50) high-risk CPMI chronic pain patients that were reviewed by the DOJ, seventy-four (74%) percent of which had high-extremely high NARX scores ranging from 100-350+. Patients within these ranges of high-risk NARX scores are 10-12 times more likely to overdose on opioids than the average patient. As noted in the article, high-risk patients need more frequent SBIRT services due to the heightened risk of over-prescription, overdose, and/or diversion (please review the white paper for more details).

The medical necessity of frequent SBIRT services for treating chronic pain patients is further supported by the Ohio Automated RX Reporting System User Support Manual (the "OARRS Manual"). The OARRS Manual states that NARX scores should be utilized in the daily workflow to trigger a discussion with the patient regarding any concerns about their prescription drug use. Dr. Margolin's utilization of SBIRT services complied with the OARRS Manual. The OARRS Manual includes specific treatment recommendations for certain ranges of NARX scores. In fact, the OARRS Manual specifies that physicians should conduct regular consultations and assessments (i.e., SBIRT services) for patients with NARX scores as low as 10. High-risk NARX patients would certainly require more frequent SBIRT services.

(See Ohio Bd of Pharmacy, Ohio Automated RX Reporting System PDMP Aware User Support Manual, p. 60 (available at https://www.ohiopmp.gov/Documents/OARRS%20User%20Manual.pdf), attached as Exhibit M in the white paper).

Dr. Margolin documented the NARX score for each and every patient/ record provided to the DOJ (in the patient record and as part of the PMD OARRS report. In addition, Dr. Margolin addressed the NARX score and warned the DOJ about the risk to the public in his letter to the DOJ in October of 2019.

Therefore, the DOJ's refusal to review and address the NARX score is evidence of willful blindness and criminal neglect that stemmed from unjustified financial objectives and led to hundreds of opioid deaths in Ohio.

DOJ caused not only an increase in opioid mortality but also the waste of taxpayer money and limited Medicare Medicaid resources.

The DOJ limited patient access to certain life-saving addiction screening (SBIRT) and pain management care throughout Ohio, including traditionally underserved, mostly minority communities (like the one served by CPMI), and an increase in opioid-related mortality and death rates.

This has led to a severe limitation of patient access to certain live-saving addiction screening and pain management care throughout Ohio, including traditionally underserved, mostly minority communities

(like the one served by CPMI), and an increase in opioid-related mortality and death rates (please find the original patient complaints in the white paper enclosed).

This could have caused hundreds of deaths that could have been prevented, an increase in crime, family violence, drug-related human trafficking in the area, and a substantial medical expense related to the cost of the hospital stay, ICU, ER, detox program, medical cost of the crime and drug-related motor vehicle accidents based on the state and federal statistics (please find the evidence for the SBIRT cost effectiveness enclosed). The Swank report mentioned above-estimated opioid epidemic cost of about 8.5 billion dollars in Ohio alone and about 650 billion nationwide.

In summary, the unjustified financial objectives presented as a saving limited Medicare and Medicaid resources have resulted in a huge loss of life and overuse of the limited Medicare and Medicaid resources that DOJ is supposed to save.

Concern for retaliation for submitting public safety concerns:

The OIG press release below was not visible on the search engines in the first 2-3 years after the settlement. We are concerned whether the second DOJ press release (via OIG) was made 2-3 years after the settlement concerning the patient letters, peer-reviewed publications, and Ohio value Voters petion sent to the DOJ.
https://oig.hhs.gov/fraud/enforcement/columbus-pain-clinic-and-owner-agree-to-pay-650000-to-resolve-allegations-of-unnecessary-procedures/

The DOJ made a false determination on the nerve conduction studies (possibly based on the retaliatory bad faith data provided by CareSource).
DOJ claimed that they took this position relying on the CareSource data (which was retaliatory in nature and supported by any objective evidence; please see the white paper enclosed).

To our amazement, after being confronted by multiple experts and elected officials, CareSource has canceled the inappropriate retaliatory "overpayment" claims and reversed labeling these services as unnecessary when confronted in June 2023. However, the DOJ and other payers' erroneous decisions have not been reversed. In fact, several payers used biased data to deny payments for life-saving services, as discussed below.

There is a serious concern about whether CareSource used the DOJ as a "hit by proxy" method to silence Dr. Margolin's concerns and to retaliate for Dr. Margolin's business integrity complaints, as discussed in the white paper (see the link above).

The DOJ was willfully blind to the strong expert support for Dr. Margolin's use of the nerve conduction studies presented to them.

Dr. Margolin's use of the nerve conduction studies was endorsed by ABPMR Prof. Kimura (who wrote the textbook and co-authored the guidelines) and Prof. Wainepal. The neurodiagnostic tests were done without the needle when the patients consented in writing against the needle test, were on anticoagulation, or had anxiety issues (see Dr. Vasilakis's endorsement below):
https://cpmiohio.com/wp-content/uploads/2021/12/ABPMR-PIP-NCV-EMG-Autonomic-Studies_approval.x25291.pdf
https://cpmiohio.com/wp-content/uploads/2021/11/Prof-Kimura-endorsement_author_of_Kimura_textbook.x25291.pdf

https://cpmiohio.com/wp-content/uploads/2022/02/Prof-Wainepal_expect_letter.x25291.pdf
https://cpmiohio.com/wp-content/uploads/2020/12/Dr-Vasilakis-PhD-chart-review.x25291.pdf
https://cpmiohio.com/wp-content/uploads/2020/12/Self-Audit-report-Mike-Staples.x25291.pdf

Concern for the DOJ willful blindness toward expert opinions and evidence-based data regarding risk to the public

The white paper and its addendum document the expert opinions, the PowerPoint presentation, and the first part of the ABPMR (the national academy review presented to the DOJ). In addition, Dr. Margolin wrote a letter to the DOJ in October presenting expert opinions and peer-reviewed data and emphasizing the danger to the public (please see the addendum to the white paper link above).

In August 2020, a group of patients sent a letter to Mr. DeVillers (see the white paper) that included the publication with Dr. David Sreem, Director of the Drug and Alcohol services at the CCF, who supported Dr. Margolin's position and raised concerns about the risk to the public that resulted from the DOJ position.

Despite the overwhelming evidence, the DOJ did not engage a single expert or a statistician as required by the guidelines.

Serious concerns about the DOJ's undue influence over Dr. Margolin's counsel

As described in the white paper, Dr. Margolin's counsel (Michael Crites and Eric Plinke) suddenly abruptly resigned during the crucial phase of settlement negotiations without referring him to another lawyer. They connected the abrupt resignation to the DOJ's dissatisfaction with the convincing evidence and expert opinions Dr. Margolin presented to the DOJ, especially the letter Dr. Margolin emailed to Christopher Wilson in October 2019 (see addendum to the white paper IID). The letter clearly showed strong expert and evidence-based support for Dr. Margolin's services and billing. It especially emphasized the public safety concern (SBIRT false labeling as not medically necessary by the DOJ).

This is extremely concerning since public records indicate that Michael Crites was a former senior associate of Andrew Malik (the person in charge of Dr. Margolin's investigation). Mr. Crites hired Mr. Malik for his current position and maintained close social connections with Mr. Malik.

The second counsel that Dr. Margolin had to hire, Nick Oberheiden, was mostly interested in his personal financial objectives. Despite overwhelming evidence from the experts, peer-reviewed data, and government rules and regulations, Mr. Oberheiden has not raised any objections during negations with the government, passively agreed with the government to avoid discussing expert opinions, did not request independent experts, statisticians, etc. as required by the Medicare integrity manual and federal rules and regulations (see the white paper). In fact, Mr. Oberheiden had no comment or no objection to the DOJ presentation (even when DOJ willfully relied on the retaliatory CareSource data or attacked Dr. Margolin on the sharp increase of the screening code use, ignoring the fact that this code was new and just introduced). Mr. Oberheiden failed to request a reasonable 30-day extension to review the national academy (ABPMR) review of the SBIRT code the DOJ attacked and Dr. Margolin's charts in question. Mr. Oberheiden actually threatened to abandon Dr. Margolin if Dr. Margolin would raise additional questions and objections. We find this very concerning. As evident from his excessive legal fees and prior precedents, Mr. Oberheiden seemed driven purely by unjustified financial objectives.

In summary, it is abundantly clear that Dr. Margolin and CPMI did not have adequate ethical counsel regarding the settlement issue.

Concern for the DOJ cruelly ignoring the credible evidence regarding the distress of Dr. Margolinand COMI patients and staff

As documented in the letter that Dr. Margolin emailed to Christopher Wilson on October 18, 2019 (see addendum to the white paper IID): "Our practice has already run into a 6 figure cost for this protracted investigation, productivity loss and significant time investment in the review and production of more than 35,000 documents that have already taken a toll on our ability to operate, manage records and treat our patients (as you know, we are a small independent practice). Many of our patients are opioid-dependent; if their medications are not timely reviewed, this can cause patient morbidity incident to abruptly stopping treatment." DOJ was aware that about 6 weeks after this credible warning, Dr. Margolin was attacked and injured by a drug-seeking patient, and 2 other female staff members were assaulted (see addendum to white paper IVB). The practice needed funds to continue providing patient care and improving staff security (the case went to the city of Columbus courts, case 2020 CR B 001416).
Nevertheless, the DOJ refused to wait a reasonable time until Dr. Margolin and his practice recovered. A few months of the technical extension was a formality to effectively leverage unjustified payments during the COVID crisis.

Later, the DOJ cruelly ignored the patient and staff letters presented to the DOJ during COVID-19. Around August 2020, Dr. Margolin's patients sent an email letter to Mr. DeViller (see the white paper enclosed) reporting multiple safety and other concerns. The letter included the link to the national academy reviews of the SBIRT, publication with Dr. Streem (director of drug and alcohol services at CCF), and expert opinions that raised a serious public safety concern. The DOJ willfully and deliberately the beyond reasonable doubt evidence presented to them and the danger to the public, leading to hundreds of preventable opioid deaths in the state and a substantial economic cost.

Concerns of systemic issues in the DOJ and lack of proper accountability

The issues described in this letter show a systemic problem in the DOJ system, review of this issue can help to correct these issues in Ohio and nationwide.

Accountability concerns: The DOJ faces serious challenges in ensuring accountability when its employees engage in misconduct and loss of public trust: Strengthening Public Trust in the U.S. Department of Justice: https://oig.justice.gov/tmpc/challenge-2 ;

CTmirror, by Creg Dillon," recent polling shows that two-thirds of the Americans lost confidence in the Department of Justice": Most Americans have a negative perception of the DOJ: https://ctmirror.org/2023/11/02/us-department-of-justice-public-perception/

An objective review of this issue should result in regulations and changes that will restore proper accountability and public trust.

Failure to act on the evidence-based data "Swank program "TAKING MEASURE OF OHIO'S OPIOID CRISIS":

Swank report estimated in 2017 that there were likely 92,000 to 170,000 Ohioans abusing or dependent upon opioids in 2015, resulting in annual costs associated with treatment, criminal justice, and lost productivity of $2.8 billion to $5.0 billion. Additionally, they estimated that the lifetime lost productivity of those who died from an opioid overdose in 2015 would be $3.8 billion, for an annual total cost of opioid addiction, abuse, and overdose deaths ranging from $6.6 billion to $8.8 billion. To put this into perspective, Ohio spent $8.2 billion of General Revenue Funds and Lottery Profits money on K-12 public education in 2015. Thus, the opioid crisis was likely as costly as the state's spending on K-12 education.

Swank report estimated that in the best-case scenario, Ohio likely only can treat 20 percent to 40 percent of the population abusing or dependent upon opioids. Swank's report concluded by offering two policy recommendations based on the report analysis. In the near term, the state should prioritize expanding access to treatment (i.e. SBIRT) in underserved areas. Specifically, they recommended that the state focus on improving educational investments as a way of deterring drug abuse and overdose.

Fully aware of the report and the increase in opioid deaths since 2017, the DOJ wilfully increased opioid mortality and healthcare and other opioid costs because of the unjustified financial objectives (as described above).

Noncompliance with the 2023 DEA MATE ACT

The DEA MATE data also recently confirmed the shortage of physicians: "Comprehensive pain education is needed in the United States for many reasons. One of the more prominent reasons is that more than 50 million people are experiencing chronic pain—and only 6240 active pain medicine/management physicians are available to help them. In addition, there is an ongoing opioid overdose crisis that can be mitigated in part by education for healthcare professionals (HCPs) managing people with pain, regardless of specialty. There is a lack of pain management education in medical training curricula, so comprehensive pain education is highly needed."

Even after the DEA MATE Act upgraded the SBIRT to a mandatory requirement, the DOJ has stalled the review of the Ohio Value Voters petition submitted to it in May 2023 until today.

Noncompliance with the 2017 HHS Five Point Strategy

The U.S. Department of Health and Human Services (HHS) developed a comprehensive Five-Point Strategy to combat the opioid crisis in the United States based on "the best science and evidence. This strategy focuses on addressing the complex issues surrounding opioid abuse, misuse, and overdose through a multifaceted approach.

https://health.maryland.gov/pophealth/Documents/Local%20Health%20Department%20Billing%20Manual/PDF%20Manual/Section%20IV/Opioid%20Five%20Point%20Strategy%20-%2020180917-508%20Compliant.pdf

Here's a description of the key points:

1. Better Addiction Prevention, Treatment, and Recovery Services. This point aims to improve access to prevention, treatment, and recovery support services.

2. Better Data: HHS focuses on enhancing data collection, analysis, and dissemination to inform interventions and policy decisions.

3. Better Pain Management

The strategy aims to advance pain management practices to enable access to high-quality, evidence-based pain care. Supporting the development of non-pharmacologic, non-opioid, and/or non-addictive pain therapeutics. Promoting evidence-based best practices to improve pain control and decrease inappropriate opioid use

5. Better Research

HHS supports cutting-edge research to advance understanding of pain, overdose, and addiction. Developing new treatments and identifying effective public health interventions

The DOJ failed to implement these points of the HHS strategy (especially point 3 above, "to advance pain management practices," for example) by falsely labeling SBIRT "unnecessary." This deterred other providers and patients from participating in SBIRT (addiction, screening and prevention) and defunded one of the top SBIRT programs in the state of Ohio. The DOJ unjustly defunded one of the top SBIRT clinical research programs in the state.

Failure to adjust the strategy to the Fentanyl crisis

The unjustified DOJ attack on the screening for drugs and alcohol is especially devastating when the streets of Ohio are flooded with Fentanyl and other high-risk opioids. The DOJ policy is responsible for pushing high-risk, vulnerable patients to the Ohio streets and increasing opioid mortality and societal and economic damage.

Documented concerns of racial bias and anti-Semitism

Racism in healthcare in Ohio is a significant issue, with evidence showing systemic discrimination against minorities. This discrimination leads to a significant shortage of physicians, poor access to care for minority populations, and an increase in opioid mortality. Ohio ranks poorly in health outcomes due to racial bias, among other factors.

We cannot help but conclude that the Kafkaesque approach taken by the DOJ towards a minority-run practice that treats most minority patients in violation of multiple laws, regulations, and ethical norms and willful disregard of the expert opinions and peer-reviewed data stemmed from racial and religious bias.

Concerns about the DOJ competency

The opioid crisis, opioid medication management, and addiction medicine issues seem to be the highest priority on the Ohio legal agenda. We are shocked and dismayed not to find any proper medicolegal background related to this issue among the DOJ officials who made decisions in this case and set the false medical standard that likely caused the loss of hundreds of lives in Ohio.

An objective review of this issue will help to restore public trust in the DOJ and the justice system

Public trust in the U.S. Department of Justice (DOJ) has significantly declined recently, raising concerns about the department's legitimacy and effectiveness. As of January 2025, several key issues contribute to this erosion of public confidence:

Widespread loss of trust: Recent polling shows that approximately two-thirds of Americans have lost confidence in the DOJ, with only 33% believing it is doing a good or excellent job **(see David Levi et al.,** Losing Faith: Why Public Trust in the Judiciary Matters; https://judicature.duke.edu/articles/losing-faith-why-public-trust-in-the-judiciary-matters/) and Strengthening Public Trust in the U.S. Department of Justice: https://oig.justice.gov/tmpc/challenge-2): CTmirror, by Creg Dillon" recent polling shows that two-thirds of the Americans lost confidence in the Department of Justice": Most Americans have a negative perception of the DOJ: https://ctmirror.org/2023/11/02/us-department-of-justice-public-perception/

The 'sDOJ's handling of this issue clearly violated the core values described in its mission statement, which include Independence and Impartiality: Earning public trust by adhering to facts and law without prejudice; honesty and Integrity: Maintaining high ethical standards as public servants; respect: Valuing diversity and treating all individuals with dignity and compassion; and excellence: Striving to provide the highest levels of service to the American people.

Addressing this issue can help to restore public trust in the DOJ and the justice system.

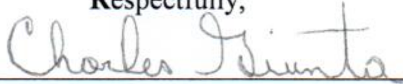
Summary

Driven by unjustified financial objectives and racial and religious bias, the DOJ willfully and knowingly ignored federal and state laws and regulations and deterred providers and patients by falsely labeling SBIRT, NCS, and other services as "medically unnecessary," deterring other providers and patients from participating in the SBIRT and defunding one of the top SBIRT programs in the state of Ohio. This caused hundreds of potentially preventable opioid deaths because of the lack of screening and soaring healthcare costs (wasting of limited Medicare and Medicaid resources) based on expert reviews and peer-reviewed publications.

Correcting this issue can save lives and healthcare costs, generate regulations that prevent such violations in the future, and restore the public's trust in the DOJ and the justice system.

4200-5200 individuals (most young people) die in Ohio every year because of the opioid crisis, more than 100,000 nationwide. How many deaths are too many?

Respectfully,



Charles Giunta

Executive Director, Ohio Value Voters