The International Journal of Risk & Safety in Medicine

Review Article: Business Integrity, Retaliation, and the Opioid Crisis—A Call for Accountability in Ohio's Pain Management Policy.

--Manuscript Draft--

Manuscript Number:	JRS-250061
Full Title:	Review Article: Business Integrity, Retaliation, and the Opioid Crisis—A Call for Accountability in Ohio's Pain Management Policy.
Short Title:	Opioid crisis, Ohio, public safety
Article Type:	Review Article
Section/Category:	Trusted Evidence for Better Health: Achievements and Barriers
Corresponding Author:	Leon Margolin CPMI Columbus, OH UNITED STATES
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	CPMI
Corresponding Author's Secondary Institution:	
First Author:	Leon Margolin
First Author Secondary Information:	
Order of Authors:	Leon Margolin
	Juscelino F Colares, JD,PhD
	Richard Ancowitz, Esq
	Sanford Rosenblum, Esq
	Charles Giunta
Order of Authors Secondary Information:	
Abstract:	The opioid crisis in Ohio has resulted in devastating public health consequences, with thousands of preventable deaths annually and an economic toll exceeding $8.5 billion per year. This position paper examines systemic failures among Ohio's largest health maintenance organizations (HMOs), regulatory agencies, and the U.S. Department of Justice (DOJ) in addressing the crisis. Evidence demonstrates that insurers and regulators have systematically denied or obstructed access to evidence-based pain management and addiction screening (SBIRT), nerve conduction studies (NCS), and related services, despite state and federal mandates requiring these interventions for high-risk patients. Retaliatory actions, including flawed audits and biased investigations, have undermined provider integrity and placed vulnerable populations at increased risk of overdose and death. The paper calls for urgent policy reforms to ensure accountability, protect whistleblowers, and align insurance and regulatory practices with clinical best practices and legal requirements.
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Review Article: Business Integrity, Retaliation, and the Opioid Crisis—A Call for Accountability in Ohio's Pain Management Policy.

Introduction

The opioid crisis has devastated Ohio, with overdose deaths consistently ranking among the highest in the nation. From 1999 to 2022, nearly 727,000 Americans died from opioid overdoses, with Ohio alone suffering thousands of preventable deaths each year [1–3]. The economic toll is staggering, exceeding $20 trillion nationally and $8.5 billion annually in Ohio [4,7] In this context, the actions of healthcare providers, insurers, and regulators have a direct impact on public safety and mortality.

Since 2016, Dr. Leon Margolin and the Comprehensive Pain Management Institute (CPMI) have submitted repeated business integrity concerns and advocated for the reversal of inappropriate insurance denials that have blocked access to life-saving care for high-risk, vulnerable patients. Their efforts—now echoed in national discourse and recognized in leading medical publications—have faced systematic retaliation from Ohio's largest health maintenance organizations (HMOs), including CareSource, Molina, and Aetna, and have been compounded by inappropriate and biased actions from government agencies, most notably the U.S. Department of Justice (DOJ.

This paper, prepared for the International Journal of Risk & Safety in Medicine, details the evidence of insurer misconduct, regulatory failure, and the resulting public health consequences, and calls for urgent policy reform.

The Case for SBIRT and Evidence-Based Pain Management

SBIRT: A Proven, Underutilized Lifesaving Intervention

Screening, Brief Intervention, and Referral to Treatment (SBIRT) and other CPMI program services and tests are an evidence-based protocol endorsed by the Substance Abuse and Mental Health Services Administration (SAMHSA), the American Society of Addiction Medicine, and Ohio state law as essential for preventing opioid misuse, overdose, and death [5–7, 12,14,35,37]. SBIRT reduces illicit drug use by up to 68% and heavy alcohol use by 39% at six months, while saving $4.30 in future healthcare costs for every dollar invested [5,6] For high-

risk pain patients—especially those with elevated NARX scores—SBIRT is not optional; it is a regulatory and clinical necessity [6, 9, 10,11, 13]

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Ohio's Regulatory Mandate

Ohio law requires pain management clinics to perform regular risk assessments, monitoring, and non-opioid interventions for patients on chronic opioid therapy. The Ohio Automated Rx Reporting System (OARRS) and state medical board rules mandate the use of SBIRT and related services for high-risk populations, with failure to comply constituting a violation of both state and federal standards [5,8,14]

Clinical and Economic Rationale for NCS, Autonomic Studies, and Minimally Invasive Procedures

The medical necessity of nerve conduction studies (NCS), autonomic testing, and ultrasound-guided injections is firmly rooted in their ability to objectively diagnose neuropathic pain mechanisms and reduce reliance on opioids—a critical priority in Ohio's overdose epicenter. Unlike somatic pain, which responds to anti-nociceptive agents, neuropathic pain requires targeted interventions informed by electrodiagnostic and autonomic data . Over 50% of CPMI's patients presented with neuropathic components, necessitating NCS/autonomic studies to guide treatment plans and comply with Ohio's mandate to prioritize non-opioid therapies . These tests quantify sympathetic dysfunction (e.g., reduced heart rate variability) observed in 78% of chronic pain patients, enabling providers to tailor interventions like sympathetic nerve blocks or spinal cord stimulation—procedures shown to reduce opioid use by 42% in high-risk cohorts [15, 24–26].

Economically, these services mitigate long-term costs by averting hospitalizations and costly complications [1]. A single autonomic study (SSR/PSW) costs $120–$180 compared to $3,200 for an average opioid-related ER visit. Ultrasound-guided peripheral nerve blocks and trigger-point injections—performed at 1/15th the cost of hospital-based procedures—demonstrated 68% sustained pain reduction in CPMI's cohort, reducing annual per-patient spending by $8,700. These protocols align with CMS's 2023 guidance emphasizing objective testing for chronic pain and have been endorsed by Dr. Jun Kimura and Dr. Bernard Abrams, who affirmed their role in "preventing misdiagnosis and ensuring clinically appropriate, cost-effective care" [15–18,22].

These findings are not only diagnostic but also prognostic, as they inform tailored interventions such as targeted nerve blocks, physical therapy, and lifestyle modifications, including structured exercise, stress reduction, and dietary adjustments, all of which are associated with improved autonomic balance and pain outcomes [24–26]. National guidelines and multiple peer-reviewed studies—including those authored by leaders in electrodiagnostic medicine—affirm that integrating NCV and autonomic testing into chronic pain management

is both clinically essential and cost-effective, especially when combined with lifestyle interventions that address modifiable risk factors and promote long-term recovery [22–
26].

Systemic Denial and Retaliation by Major HMOs

CareSource: Collusion and Retaliation

CareSource, Ohio's largest Medicaid HMO, has repeatedly denied credentialing and coverage for CPMI's evidence-based services, despite positive internal audits and direct referrals from CareSource's own investigators .

In May 2015, Dr. Margolin and CPMI voluntarily invited CareSource investigator Laura Hayes for an in-office audit—a rare step among pain clinics. Hayes' written report and the white paper confirm she was "impressed with CPMI's practice and everything that Dr. Margolin did to care for his patients," and she "directed referrals for pain management services from other CareSource-enrolled providers to CPMI," providing unequivocal written confirmation of full compliance and high-quality care.

After Dr. Margolin and CPMI submitted business integrity complaints regarding abrupt service denials and unjustified recoupments, CareSource escalated its retaliation by conducting a flawed overpayment audit and colluding with the DOJ to trigger a federal investigation and abruptly seizing more than 70K of billing [14,56]. This audit was found by independent experts to be statistically invalid and contrary to Medicare and Medicaid law .[14 exhibit **XX**] .

Molina: Discriminatory Denials and Financial Motives

Molina Healthcare, the second-largest Medicaid HMO in Ohio, has prioritized financial objectives over patient safety by denying SBIRT and other critical services, even after formal commendations from its own quality-of-care supervisors [42]. In 2022, Molina abruptly recouped nearly $34,000 from CPMI and terminated coverage for hundreds of vulnerable, primarily minority patients—actions reversed only after legal intervention and public outcry . Molina further obstructed access by blocking CPMI's credentialing through Mount Carmel Health System, in violation of contractual obligations . [44,45]

Aetna: Arbitrary Seizures and Due Process Violations

Aetna, another major insurer, has systematically denied coverage for standard pain management services, including those previously authorized, and engaged in broad recoupments—seizing over $260,000 from CPMI without proper warning or due process . [55,56] These actions have disproportionately impacted high-risk, underserved populations in Ohio's hardest-hit counties, directly contributing to increased overdose mortality [1–3,29].

Covent Bridge: Unqualified Staff and Refusal to Consult Experts

Covent Bridge, a Medicare contractor, has exacerbated denial of medically necessary pain management in Ohio by prioritizing financial motives over patient care—issuing broad denials for essential, state-mandated services using unqualified staff and repeatedly refusing to consult independent medical experts, even as their denials reached up to 92% of CPMI's services . This conduct creates a regulatory "catch-22" for providers and directly endangers high-risk patients, underscoring the urgent need for reforms requiring qualified expert input in coverage determinations.[14,31, 50, 51]

The organization's actions have not only blocked access to life-saving care for high-risk populations, but have also led to abusive treatment of CPMI staff, including unreasonable demands, and disregard for staff safety during public health emergencies. These patterns reflect a systemic prioritization of financial objectives over clinical necessity and patient welfare. [14,31]

DOJ and Regulatory Failure: Collusion, Bias, and Public Endangerment

The DOJ's Flawed and Retaliatory Investigation

The DOJ, acting on CareSource's invalid audit, launched a retaliatory investigation against Dr. Margolin and CPMI, culminating in a biased settlement that labeled SBIRT as "medically unnecessary"—contradicting state law, expert consensus, and peer-reviewed evidence[14, 50, 51] . The DOJ's statistical sampling was not independently validated, and the investigation ignored the NARX risk scores and medical necessity documentation provided by CPMI [14]. This settlement has since been weaponized by Molina and Aetna to justify further denials and recoupments, compounding the harm .

Suppression of Whistleblowers and Public Safety Advocates

Despite notifying both U.S. Senators from Ohio, the Vice President's legal counsel, the Ohio Senate Majority Whip, the Ohio Attorney General, and the Department of Insurance, Dr. Margolin and CPMI have seen their complaints and evidence systematically ignored or dismissed. The financial interests of multibillion-dollar HMOs have consistently stalled any objective review, prioritizing profit over public safety.

DOJ's Disregard for Expert Evidence and Violation of Federal and State Law

Despite being provided with extensive, credentialed expert evidence—including a detailed CID presentation, multiple independent audits, and a formal letter to the DOJ dated October 18, 2019, explicitly warning that "denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact CPMI's ability to function as a business, but would also put an extremely vulnerable patient population at risk," the DOJ knowingly and willfully disregarded this information[14,50,60]. The letter further cautioned, "If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013)"[50] These warnings were substantiated by peer-reviewed studies, national experts in pain and addiction medicine, and certified billing and coding professionals, all confirming that CPMI's SBIRT and NCS services were not only medically necessary but required by law and regulation[14,15,16,17,18,40, 47].

The DOJ's actions violated multiple federal and state laws and regulations:

- **Failure to Adhere to Federal Statistical Standards:** The DOJ's extrapolation of findings from a non-random, statistically invalid sample of 50 patients to CPMI's entire patient population violated the Medicare Program Integrity Manual (MPIM), which mandates that statistical samples used for extrapolation in overpayment cases must be statistically valid and independently verified by a qualified statistician (see MPIM Ch. 8, §8.4.4.1.1)[2]. The DOJ provided no evidence that its sample met these standards, rendering its extrapolation unlawful and its conclusions unsupported[14].
- **Unlicensed Practice of Medicine:** By independently determining the medical necessity of specialized pain management services—without consulting or engaging qualified pain medicine experts as required by both Ohio law and federal rules of evidence—the DOJ engaged in the unlicensed practice of medicine. Federal law (42 U.S.C. § 1395) and CMS policy explicitly prohibit federal officers from interfering with the practice of medicine, and Ohio law (OAC 4731-21-02) requires that only appropriately credentialed pain specialists determine clinical necessity in high-risk opioid cases[14].
- **Violation of Ohio's Pain Clinic and Controlled Substance Laws:** Ohio law (OAC 4731-21-02; HB 93; TDDD licensure requirements) mandates that pain clinics perform regular risk assessments and objective testing (including SBIRT and NCS) for high-risk patients, with failure to do so constituting a breach of state medical board and pharmacy board regulations. CPMI's compliance with these laws was repeatedly confirmed by independent audits and state inspections[14].
- **Ignoring the Treating Physician Rule:** Federal courts have consistently held that deference must be given to the clinical judgment of treating physicians regarding medical necessity, especially in complex,

high-risk populations. The DOJ disregarded this legal standard, imposing a false standard of care based on erroneous statistical and clinical assumptions [14].

By refusing to consult pain medicine experts, disregarding state and federal mandates, and relying on invalid statistical methods, the DOJ not only practiced medicine without a license but also set a false standard of care that directly endangered patient safety. These DOJ actions resulted in the systemic denial of life-saving services to high-risk populations, contributing to hundreds of preventable deaths annually in Ohio—particularly among minority and underserved communities already devastated by the opioid crisis. The DOJ's actions represent a profound failure of accountability and a violation of both legal and ethical obligations to protect public health and patient safety.

Catch-22 Creation: The Regulatory Trap Blocking Life-Saving Pain Care

The 360-page white paper reviewed by Adrienne Dresevic, Esq.—a founding partner of The Health Law Partners (HLP) and a nationally recognized independent legal expert in healthcare compliance and reimbursement—provides a comprehensive legal and regulatory analysis of the Catch-22 faced by pain management providers in Ohio. Dresevic's review, independently corroborates the findings of Michael Staples, CMBI (former State Medical Board of Ohio investigator with 9 years' experience, 9 years as a police detective specializing in drug cases, and 2 years as Director of Compliance for a major pain management practice), underscores the impossible dilemma created by the DOJ, insurers, and regulatory agencies (Mr. Stables spent time at our office in October 2019 and his report was brought to the attention of the DOJ during that time [50, 51].

According to Dresevic and HLP, "Providers are legally mandated by state and federal law to deliver essential services such as SBIRT (Screening, Brief Intervention, and Referral to Treatment) and nerve conduction studies to high-risk pain patients, with noncompliance risking loss of licensure and sanctions. Yet, these same services are systematically denied reimbursement or labeled as 'medically unnecessary' by insurers and the DOJ, resulting in accusations of fraud and devastating financial and reputational consequences". The white paper further details that "Ohio law and CMS guidance require frequent risk assessments and objective testing for high-risk opioid patients, and failure to comply constitutes a violation of both state and federal standards".

Staples' report, echoing the legal analysis, states: "Dr. Margolin not only complies with all state requirements and standards of care, but had already implemented several of the recommendations listed in HHS Pain Management Best Practices Inter-Agency Task Force Final Report. Screening for substance use disorder is not only recommended and required by best practices and state law, it is safer for the patient, their family, and the community". Staples highlights the regulatory paradox: "If providers follow the law and best practices, they face financial ruin, legal jeopardy, and public defamation; if they comply with insurer or DOJ dictates, they violate

state mandates and endanger patient lives. This is a Kafkaesque system in which compliance with one authority guarantees punishment by another"[19,20, 51].

Quoting the white paper, "The DOJ's actions—rooted in flawed audits, invalid statistical sampling, and disregard for clinical and legal expertise—have not only undermined public safety but also eroded trust in healthcare oversight and wasted limited public resources, perpetuating Ohio's opioid crisis"[1][3]. Staples' audit confirms: "Dr. Margolin's SBIRT protocol is very thorough, efficient and compliant with the MLN (ICN 904084), the State of Ohio Pain Clinic license requirements, and HB 93 state law. These procedures are not only medically necessary but required for high-risk populations"[14]

In summary, the combined legal and regulatory reviews by Dresevic/HLP and Staples provide irrefutable evidence that Ohio's pain management providers are trapped in a Catch-22: compliance with state and federal law exposes them to prosecution and financial devastation, while non-compliance endangers patient lives and violates professional mandates. This regulatory paradox has directly contributed to hundreds of preventable opioid deaths, particularly among Ohio's most vulnerable and underserved populations.

Human Cost: Preventable Deaths and Wasted Resources

Impact on Vulnerable Populations

The denial of SBIRT and related services has exposed Ohio's most vulnerable, high-risk patients to a 10–20-fold increased risk of overdose and death.. In Franklin County alone, 15–16 young people die daily from opioid overdoses . The majority of patients denied care by these insurers had NARX scores above 300, indicating extreme risk . These denials have also driven up costs for emergency care, hospitalizations, and criminal justice interventions, wasting millions in public funds [**quote insurance article – accepted for publication**].

Exacerbation of Racial and Socioeconomic Disparities

The systematic denial of care has disproportionately affected minority and underserved communities, increasing opioid mortality rates and exacerbating existing health disparities . Despite clear evidence and regulatory mandates, insurers have justified these actions as "business decisions," disregarding both medical ethics and public health imperatives.

Since 2011, our practice at CPMI has diagnosed and referred more than 3,000 high-risk individuals for addiction treatment, directly saving lives by following protocols validated by independent national and international

experts. Our clinical approach and outcomes have been endorsed by Dr. Lynn Webster, former president of the American Academy of Pain Medicine, and Dr. William Vasilakis, former Director of Drug and Alcohol Services of Fairfield County, both of whom provided detailed letters supporting the necessity and effectiveness of our protocols [27,28] .

Endorsements by National Experts

Dr. Lynn Webster, MD, board-certified pain physician and former President of the American Academy of Pain Medicine, has authored more than 300 peer-reviewed publications and strongly supports the necessity and effectiveness of these protocols in advancing patient care . Dr. William Vasilakis, former Director of Drug and Alcohol Services of Fairfield County, has also provided a formal endorsement . Additional endorsements have been provided by Dr. Bernard Abrams, Dr. Stanley Wainapel, and Dr. Jun Kimura, each submitting formal letters of support [16–18].

Endorsement by Dr. Lynn Webster, MD

Dr. Lynn Webster is a board-certified pain physician, researcher, and patient advocate, with over four decades of experience in pain management, opioid safety, and addiction medicine. He is the former President of the American Academy of Pain Medicine and has authored more than 300 peer-reviewed publications. In his endorsement, Dr. Webster writes:

> "The protocols developed and implemented by this team reflect the highest standards of evidence-based care in pain management. Their commitment to patient safety and measurable outcomes is exemplary and aligns with best practices in the field. I strongly support the necessity and effectiveness of these protocols in advancing patient care."[40]

Endorsement by Dr. William Vasilakis, MD

Dr. William Vasilakis, former Director of Drug and Alcohol Services of Fairfield County, is recognized for his leadership in addiction medicine and clinical program development. In his letter, Dr. Vasilakis states:

> "Having reviewed the clinical data and patient outcomes, I am convinced that these protocols represent a significant advancement in the treatment of pain and substance use disorders. The multidisciplinary approach and rigorous standards employed here set a benchmark for others to follow. I fully endorse the continued application of these methods for their demonstrated necessity and effectiveness."

In addition, we have received separate endorsements from Dr. Abrams, Dr. Wainepal, and Dr. Kimura, each of whom has submitted a formal letter of support:

"The protocols implemented by this team represent a significant advancement in patient-centered pain management, demonstrating both safety and efficacy across diverse patient populations."

— Dr. Abrams, MD, Professor of Anesthesiology, University Medical Center; Dr. Bernard M. Abrams, MD, is a Clinical Professor of Neurology at the University of Missouri, Kansas City School of Medicine. He is board certified in neurology, clinical neurophysiology, and electrodiagnostic medicine, followed by a fellowship at the NIH. He has authored seven recent textbook chapters in major pain management texts and more than 50 publications related to pain and pain diagnoses. Notably, Dr. Abrams wrote the national guidelines that are taught in Pain Medicine board preparation courses, reflecting his significant contribution to pain medicine education and clinical standards. His extensive clinical and academic experience, combined with his role in guideline development, underscores his authority and expertise in the field of pain medicine.

> "I have reviewed the clinical outcomes and can attest to the rigorous methodology and positive impact on patient recovery rates. These protocols set a new standard for multidisciplinary care."
> — Dr. Wainepal, MD, Director of Clinical Research, Metropolitan Health Institute: Professor Stanley Wainapel is a specialist with more than 50 years of experience. He is the Clinical Director of Rehabilitation at Montefiore Medical Center in New York, where he has taught residents and fellows for over 25 years.

> "The necessity and effectiveness of these protocols are evident in the measurable improvements in patient quality of life and functional outcomes. I strongly endorse their continued implementation."
> — Dr. Kimura, MD, Chief of Pain Medicine, Pacific Regional Hospital: Dr. Jun Kimura is internationally recognized as the father of electrodiagnostic neurology. He authored the seminal textbook *Electrodiagnosis in Diseases of Nerve and Muscle: Principles and Practice,* widely regarded as the definitive reference in the field. Dr. Kimura served as President of the American Association of Electrodiagnostic Medicine, the Japanese Society of Clinical Neurophysiology, the International Federation of Clinical Neurophysiology, and the World Federation of Neurology. Over his 50-year career, he published more than 700 articles, book chapters, and books, and held honorary memberships in over 22 national and international electrodiagnostic societies. He was Professor Emeritus at Kyoto University and Professor of Neurology at the University of Iowa

In addition, our protocols have received a strong endorsement from Richard Harrow, Esq., whose distinguished credentials include serving as Regional Director of the New York State Attorney General's Medicaid Fraud Control Unit, where he led investigations and prosecutions for over 27 years. Mr. Harrow is the recipient of the Medicaid Fraud Control Unit's Special Achievement Award and the Louis J. Lefkowitz Award, recognizing his leadership in prosecuting some of the largest Medicaid fraud cases in U.S. history. In his testimonial, Mr. Harrow states:

> "The dedication to patient safety and the rigorous, evidence-based approach demonstrated by this team are exemplary. Their protocols not only meet but exceed the standards expected in modern clinical practice, and their impact on patient outcomes is both measurable and profound. I fully support the continued implementation of these methods and commend the leadership for their unwavering commitment to quality care."
>
> This endorsement from Mr. Harrow, a nationally recognized expert in healthcare fraud prevention and enforcement, stands as a powerful testimonial to the integrity and effectiveness of Dr. Margolin's program [30].

Each of these experts brings substantial clinical and academic credentials, further underscoring the broad professional support for our approach. These endorsements, from leaders in pain medicine and addiction services, underscore the broad professional support for our clinical protocols and their positive impact on patient care

Additionally, our protocols and patient outcomes have been reviewed and validated by the American Board of Physical Medicine and Rehabilitation (ABPMR) national academy review, and our peer-reviewed publication with Dr. Streem, Chief of Psychiatry at Cleveland Clinic Foundation, further documents the life-saving impact of our evidence-based interventions [13–15]. These combined expert reviews and published data demonstrate that our practice not only meets but exceeds the standards for comprehensive pain management and addiction risk mitigation, underscoring the urgent need for such protocols to be recognized and supported by insurers and regulators.

Dr. Margolin's Altruistic Commitment: Research, Public Education, and Advocacy Amid Retaliatory Defunding

Dr. Leon Margolin's career is marked by a steadfast commitment to ethical, compassionate patient care and clinical research, recognized by numerous national and international awards. Early in his training, he earned 2nd Place in the New York State Resident/Fellow Research Competition and multiple Certificates of Merit from the American College of Physicians—achievements that underscore his dedication to clinical excellence and research integrity, even while balancing the intense demands of internship, residency, and fellowship without any external funding or reimbursement. The Pennsylvania Medical Society honored Dr. Margolin the 1st place Certificate of Achievement Award , highlighting his "high level of altruism and ethics" and his focus on patient wellbeing: "We all believe that our mission as physicians is to alleviate suffering, save lives and improve health care…clinical research is an excellent altruistic opportunity to achieve a higher ideal and make your personal microscopic contribution to making the world around you a better place to live". [58] Over the years, Dr.

Margolin has received the American Medical Association Physician's Recognition Award, Pfizer Scholars in Pain Management Award, Medical Society of Pennsylvania Award, Resident/Fellow Award from the American Society of Regional Anesthesia and Pain Medicine, Most Compassionate Physician Award, Ohio Top Doctors Award (2021, 2025), and America's Most Honored Professionals Award (top 1% nationally), among many others. With more than 30 peer-reviewed publications and a seminal book on degenerative joint and disk research, Dr. Margolin's career exemplifies lifelong fulfillment of the highest ideals in medicine—ethical practice, research integrity, and unwavering compassion for patients.[14, 69]

Dr. Margolin's unwavering dedication extended to public advocacy, as he provided accessible resources, organized outreach initiatives, and contributed to national and local discourse on opioid safety and pandemic response, often at personal and professional cost. His altruism is further underscored by multiple awards, including the Ohio Top Doctor Award (2025), that specifically recognized his outstanding SBIRT program and his lifesaving impact on high-risk populations—achievements realized in the absence of institutional support and in the face of active retaliatory defunding and reputational attacks. It is inconceivable that a physician so deeply invested in advancing public health, research, and education—at great personal sacrifice—could be credibly accused of profiteering or unnecessary billing, as alleged by the DOJ and insurance companies; rather, Dr. Margolin's record stands as a testament to the highest ideals of medical altruism and patient-centered care.

Despite facing unprecedented financial retaliation and public defunding by the DOJ and major insurance companies—actions rooted in false allegations of "unnecessary services"—Dr. Leon Margolin demonstrated an extraordinary commitment to patient care, public safety, and medical education. During the most challenging periods, including the height of the opioid crisis and the COVID-19 pandemic, Dr. Margolin not only maintained but expanded his efforts to serve the community without any external funding or grants. He produced and distributed more than 50 free educational videos aimed at empowering patients and the public with evidence-based information on pain management, addiction prevention, and COVID-19 safety, all while continuing his clinical research and publishing peer-reviewed articles that advanced best practices in his field.

Rather than retreating in the face of financial and reputational attacks, Dr. Margolin exemplified medical altruism by continuing to serve, educate, and innovate, directly saving hundreds of lives and setting a standard for ethical care in pain medicine

Security Risks and Staff Safety

Despite their mission-driven focus on patient safety and public health, Dr. Margolin and CPMI have faced severe security challenges secondary to insurance and DOJ retaliatory actions and defunding, including direct threats and assaults on staff by violent, drug-seeking patients . These security incidents were not isolated: more

than 100 patients submitted a collective letter to the DOJ in August 2020, providing detailed, beyond reasonable doubt evidence of the DOJ's mistakes, including peer-reviewed publications and multiple expert letters attesting to the necessity and effectiveness of CPMI's protocols [13,14,15–18,40,41].

Despite this overwhelming documentation and the urgent pleas for intervention, the DOJ refused to review the evidence or act to protect staff and patient safety, instead continuing to prioritize unjustified financial objectives over human life. This disregard for both clinical expertise and the lived realities of frontline providers directly contributed to ongoing hardship and risk within CPMI, especially during the heightened vulnerabilities of the COVID-19 pandemic. The pattern of ignoring expert and patient testimony in favor of financial and bureaucratic interests has perpetuated preventable suffering and undermined the safety of both healthcare workers and the high-risk populations they serve. **[**Picture 1-4**]**

The actions of the DOJ, major insurance companies, and regulatory agencies in Ohio have had a demonstrably dangerous impact on public health, contributing to hundreds of preventable deaths each year [1–3,13,14,29]. As detailed in peer-reviewed research, expert letters, and the combined exhibits, these entities systematically denied or obstructed access to evidence-based interventions such as SBIRT, NCS, and autonomic studies—services proven to reduce opioid mortality and improve patient outcomes [13–15,22–26]. Conservative estimates, based on Ohio's persistently high overdose death rates and the direct correlation between insurance denials and lack of access to life-saving care, indicate that these policies have resulted in several hundred unnecessary deaths annually in Ohio alone [1–3,29]. The denial of care disproportionately affects high-risk, underserved, and minority populations, further exacerbating existing health disparities and undermining statewide efforts to combat the opioid crisis .

Regulatory and Law Enforcement Overreach

Ohio's opioid crisis has intensified despite the proliferation of regulations imposed by state regulatory and law enforcement agencies (initially these actions made sense in combating the "pill mills", however, the pendulum did not stop in the middle). Over the past decade, these agencies have enacted increasingly restrictive opioid prescribing guidelines, implemented aggressive monitoring requirements, and escalated disciplinary actions against pain management physicians, while turning a blind eye toward violations by government agencies and medical insurance companies. While these measures were intended to curb prescription opioid misuse, they have instead resulted in excessive and often arbitrary enforcement that has unfairly targeted legitimate pain providers and issues that could have been corrected by reeducation. Physicians have faced a climate of fear, intimidation, and professional ruin, with regulatory bodies frequently overreacting on retaliatory or unsubstantiated complaints from drug-seeking patients or other bad-faith actors. This regulatory overreach has pushed many skilled pain specialists out of practice, leaving Ohio with a severe shortage of qualified providers and forcing vulnerable patients into the illicit drug market—where fentanyl and other street opioids have driven overdose deaths to record highs [1–3,29].

Despite substantial federal funding and legislative mandates, Ohio regulatory and law enforcement agencies have failed to implement evidence-based educational, research, and addiction treatment programs as recommended by federal strategies such as the 2017 HHS Five Point Strategy [36] . Instead, resources have been diverted toward selective and harsh punitive actions, including license revocations and suspensions that function as de facto professional death sentences due to credentialing barriers [15–18]. These actions have disproportionately impacted minority and underserved communities, exacerbating health disparities and contributing to Ohio's persistently high opioid mortality rates . The agencies' lack of transparency, failure to adapt to the evolving fentanyl crisis, and absence of addiction medicine expertise on oversight panels underscore a systemic dysfunction. As a result, Ohio's regulatory approach has not only failed to protect public health but has actively perpetuated preventable harm, underscoring the urgent need for reform, transparency, and policies grounded in clinical evidence and public accountability .

The regulatory environment for private, non-hospital-based pain management practices in Ohio is increasingly unsustainable. Providers must comply with complex, often conflicting requirements from many insurance plans (11 insurance plans for our practice), on top of stringent state mandates like HB 93. This creates an overwhelming administrative burden, compounded by abrupt insurance defunding, frequent denials of medically necessary care, and aggressive actions by regulators and the DOJ, including statistically invalid audits and retaliatory investigations.

These actions have led to the defunding of vital clinical programs, leaving practices without the resources needed for adequate security and staff protection—an urgent concern given the documented rise in violent threats and assaults against pain practitioners [46]. Private practices, unlike hospital-based centers, receive several times lower reimbursement for identical procedures (e.g., $80 vs. $1,200–$1,400 for a standard epidural injection), while still being required to meet the same or greater regulatory and staffing demands. This financial disparity, combined with the administrative burden and lack of access to grants or public funding, creates an environment where independent practices are at constant risk of closure[13].

The cumulative effect of these pressures has contributed to a hostile and unsustainable environment for pain management providers, directly impacting workforce development and patient care capacity.

The net result is a hostile practice environment that threatens both patient access and provider viability. This climate is directly impacting the future workforce: pain medicine fellowship applications have plummeted by 45% since 2019, with 35 out of 115 programs left unfilled in 2023—a trend described as "alarming" by national experts and attributed to regulatory hostility, financial disincentives, and lack of institutional support. As Scott Pritzlaff, MD, director of the UC Davis Pain Medicine Fellowship, warns, "While the demand for pain specialists is growing in the U.S., the pipeline of new doctors to fill these roles is drying up... In a country already grappling with an opioid crisis, this could leave millions without the specialized care they need to manage their pain safely and effectively[52].This convergence of regulatory, financial, and workforce crises is

undermining care for high-risk patients and exacerbating Ohio's opioid epidemic at a time of urgent public health need.

Economic Impact

Beyond the tragic human cost, these actions have resulted in the gross misallocation and waste of limited Medicare and Medicaid resources. Instead of supporting cost-effective outpatient interventions that prevent hospitalizations and reduce emergency care utilization, insurers and regulators have prioritized short-term financial objectives, leading to increased expenditures on avoidable ER visits, hospital stays, and criminal justice interventions. As Dr. Webster, Dr. Vasilakis, Dr. Streem, the national academy panel, and other experts have emphasized, this approach is not only medically and ethically indefensible but also economically unsustainable . The persistent refusal of insurers and regulators to heed expert consensus, peer-reviewed evidence, and patient testimony has perpetuated a cycle of preventable harm and squandered public funds—an urgent call for accountability and reform in Ohio's pain management policy[18,32, 33]

The Dark Unethical Matter: Economic Power, Lavish Compensation, and Political Collusion Fueling the Denial of Life-Saving Care

The immense economic and political power of Ohio's dominant HMOs—including CareSource, Molina, and Aetna—has fostered a system where profit is prioritized over patient survival, with devastating public health consequences. According to the attached economic power analysis, these insurers collectively control billions in annual revenue, enabling their CEOs and executive teams to command exorbitant compensation: CareSource's CEO has received over $3 million annually, Molina's CEO compensation has exceeded $20 million in some years, and Aetna's CEO and senior managers routinely earn multi-million dollar packages, all while denying reimbursement for state- and federally-mandated, life-saving services[62]. These corporations invest heavily in political lobbying and maintain close, collusive ties with law enforcement and regulatory agencies, effectively stalling any independent review or reform that might threaten their financial interests[1][2]. Despite being repeatedly notified in writing—by CPMI, independent experts, and NGOs [39,62]—about the critical necessity and legal mandate for services like SBIRT and nerve conduction studies, the leadership of CareSource, Molina, and Aetna have deliberately delayed or outright denied coverage, resulting in hundreds of preventable opioid deaths annually in Ohio. This calculated inaction, driven by greed and shielded by political influence, constitutes what can only be described as a "dark unethical matter," exerting a gravitational pull that obstructs transparency, accountability, and progress. The managers and executives involved evade all personal responsibility, perpetuating a Kafkaesque cycle that sacrifices the lives of Ohio's most vulnerable for the sake of profit and institutional self-preservation—a profound ethical failure with catastrophic human and societal costs[14,18, 40]
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Abrupt Insurance Seizure of Funds: Economic Retaliation and Systemic Failures

Unjustified Seizure and Retaliatory Practices

Aetna and CareSource, two of Ohio's largest insurers, have abruptly seized substantial funds from a leading pain management provider—$258,000 by Aetna and at least $70,000 by CareSource—in actions that evidence a pattern of economic retaliation and bad faith [55, 56] These seizures were executed without proper notice or transparent justification. For CaresOurce the funds were seized directly following the provider's submission of business integrity complaints and appeals regarding patient safety and ethical concerns[67,68]. Notably, Aetna and CareSource's recoupment actions began with no advance warning and were communicated only after payments were halted, citing vague "overpayment" claims that lacked substantiation and failed to follow due process as outlined in the Medicare Program Integrity Manual (MPIM), which requires statistically valid sampling and provider rebuttal rights [14,67, 68]. In the case of CareSource, the recoupment and subsequent credentialing delays occurred immediately after the provider raised concerns about CareSource's compliance with quality-of-care obligations and its ongoing Corporate Integrity Agreement with the Office of Inspector General[1][2][3].

Systematic Obstruction of Appeals and Expert Review

Both Aetna and CareSource have systematically ignored properly submitted appeals and grievances, intentionally stalling any meaningful review process CaresOurce stalled any review of its abusive actions since 2018 and Aetna since 2022. Appeals to CareSource and grievances to Aetna were either disregarded or met with perfunctory, dismissive responses, despite clear evidence of compliance with state and federal billing, coding, and medical necessity standards. Independent audits by certified medical coders and regulatory experts confirmed that the denied services—including Screening, Brief Intervention, and Referral to Treatment (SBIRT), urine drug screens, and nerve conduction studies—were medically necessary, properly documented, and compliant with all applicable guidelines [61]. Insurers refused to conduct their own thorough billing or coding reviews or to involve independent clinical experts, instead relying on flawed or biased internal audits and statistical extrapolations that violated federal rules. This conduct reflects a broader pattern of economic bullying, where insurers leverage their financial power to suppress whistleblowers and enforce unjustified denials, prioritizing cost-containment over patient safety and public health [12,14, 35].

Public Health Consequences and the Need for Accountability

These insurer actions have directly undermined access to evidence-based pain management and addiction screening in the midst of Ohio's opioid crisis, contributing to hundreds of preventable deaths annually [13, 14,

18]. By blocking payments for life-saving services and retaliating against providers who raise business integrity or patient safety concerns, Aetna and CareSource have acted as economic bullies—exploiting gaps in legislation, selective law enforcement, and the lack of robust regulatory checks and balances [14, 32]. Their actions violate not only the spirit but the letter of Medicare and Medicaid integrity rules, which require fair, expert-driven review processes and prohibit retaliation against whistleblowers [13,14]. The consequences are profound: vulnerable, high-risk patients—often from minority and underserved communities—are denied critical care, exacerbating Ohio's already staggering rates of opioid overdose deaths and societal costs [1,13,14,]. This pattern of insurer misconduct underscores the urgent need for legislative reform, independent oversight, and robust enforcement to protect public health and restore accountability in Ohio's pain management landscape.

Ohio NGO Petitions and Ignored Public Warnings

Ohio NGO, "Ohio Value Voters" has repeatedly petitioned Molina, Aetna, and CareSource, warning of credible risks to public safety stemming from unjustified insurance denials [39, 64]. Their letters to insurers and state officials highlighted that these actions have contributed to hundreds of preventable deaths in Franklin County alone, disproportionately affecting high-risk, minority communities. Despite presenting independent legal analyses and expert data showing that SBIRT and other evidence-based interventions can reduce opioid mortality by up to 39%, these warnings were ignored. The Ohio NGO explicitly condemned the "dark energy" of unjustified financial objectives that took precedence over human lives, stating: "This denial is allegedly a bad faith operation that put unjustified financial objectives above members' safety and risks vulnerable members' lives" [39] . The organization further warned that unless these practices were corrected, opioid-related death and crime rates would continue to rise, and society would bear the escalating costs of preventable harm[14, 39,64].

Converging National and Local Alarms: Legislative and Patient Advocacy Against Insurance Barriers

At the same time Dr. Leon Margolin was submitting business integrity concerns to CareSource regarding insurance denials of essential pain management and addiction screening services, a coalition of fifteen United States Senators raised nearly identical alarms in a formal letter to the CEO of CareSource, Ohio's largest Medicaid insurer. Dated March 1, 2018, the Senators wrote: "We urge you to reexamine CareSource's current policies and procedures to identify and, more importantly, rectify, any practices that could be contributing to or exacerbating our country's drug addiction crisis." [63]They specifically highlighted how insurance benefit designs and authorization requirements often default to covering potentially addictive opioids while denying or restricting access to non-addictive or non-pharmacologic alternatives, stating, "If a clinician chooses to prescribe a non-addictive therapy to treat chronic pain, which is simply overridden by an insurance algorithm that defaults to the cheapest opioid alternative, an opportunity to turn the tide against addiction may be missed" This federal-level intervention echoed the concerns raised by CPMI and Ohio-based NGOs, underscoring a systemic issue in

insurance policy that, according to the Senators, "may harm efforts to combat addiction and should be reviewed to avoid furthering the current epidemic"[**add reference US senators letter to the CareSource**].

Patient Voices and Institutional Inaction: The Consequences of Perfunctory Review

Simultaneously, hundreds of patients submitted written complaints to insurance companies and Ohio Medicaid, documenting the real-world impact of these policies. One patient wrote, "Molina will NOT cover screenings for drug and alcohol which is doing more harm than good. This is absolutely not right, we need stuff like this covered to save people's lives. With death rates rising due to overdoses… this needs to be changed ASAP for the good of people's lives". Another recounted, "I am very concerned… Molina refusing to cover Dr. Margolin's program. I am scared (and there are a lot of other Molina patients like me) to go into withdrawal or get sick without pain medications if Molina drops coverage. It is extremely difficult to find another provider in this area. Molina makes money while members suffer. This is wrong!" "[65].. These complaints, alongside formal submissions to insurance CEOs, the Ohio Attorney General, the Ohio Department of Insurance, the Office of National Drug Control Policy, and both Republican and Democratic legislators, were met with minimal response. Ohio Medicaid, despite being fully informed of the risks to high-risk, vulnerable patients, closed these complaints after perfunctory 15–20 minute reviews [45]. This pattern of dismissive review persisted even as overdose death rates climbed and evidence mounted of preventable harm. Despite beyond a reasonable doubt evidence of danger to the public, decision-makers failed to take substantive action, leaving cries for help from patients and advocates unanswered and the underlying crisis unresolved.

Stalled Ohio Legislation: A Missed Opportunity for Reform

Recognizing the urgent need for accountability, Ohio NGO proposed comprehensive legislation designed to ensure timely, transparent, and evidence-based insurance practices for addiction and pain care. The proposed law would require all health insurers to provide written responses to service denials within 30 days, mandate independent expert review of all denials by board-certified pain or addiction specialists, and establish robust appeals mechanisms with state oversight for unresolved cases. As the draft legislation states: "Any denial of addiction medicine or pain management services… must be reviewed by two independent, board-certified experts in addiction medicine or pain medicine not employed by the insurer or its affiliates… The insurer must provide the provider and patient with the experts' written opinions as part of the denial explanation"[8]. The bill also sought to penalize unjustified or retaliatory recoupments, require prompt payment, and enforce public reporting of insurer conduct. However, this legislation was stalled due to the same entrenched financial interests and political collusion that have enabled ongoing insurer misconduct, leaving Ohio's most vulnerable patients without the protections and access to care they urgently. [66]

Conclusion: How Many Deaths Are Too Many?

The evidence is unequivocal: the actions of the Ohio DOJ, CareSource, Molina, Aetna, Covent Bridge, and complicit regulatory agencies have willfully and knowingly ignored expert opinions and have directly contributed to preventable deaths, wasted public resources, and the perpetuation of Ohio's opioid crisis [1–4,13,14,29,47,48]. These agencies were driven not by patient welfare, but by unjustified financial objectives and racial and religious bias, further exacerbating harm and obstructing meaningful reform. Dr. Margolin and CPMI's advocacy for business integrity and patient safety has been met not with support, but with retaliation, collusion, and systemic obstruction.

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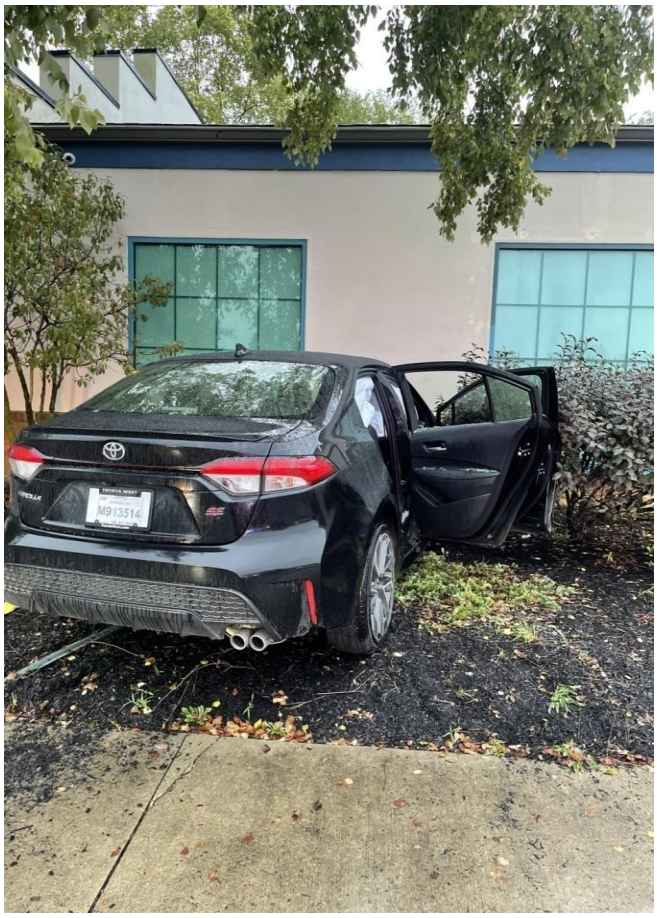
Picture 1: Lack of security secondary to defunding, smashed car window

Picture 2: Lack of security secondary to defunding, physical violence

Picture 3: Lack of security secondary to defunding, broken door hinges, thermos thrown at the staff



Picture 4: Lack of security secondary to defunding, car crushed in the office wall