ETHICAL GUIDANCE IN PUBLIC-PRIVATE PARTNERSHIPS

Gaps, Inconsistencies, and Recommendations

November 2021

Chronic Illness Advocacy & Awareness Group

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EXECUTIVE DIRECTOR

Lauren Deluca is the Founding President and Executive Director of the Chronic Illness Advocacy & Awareness Group (CIAAG), a national nonprofit organization that advocates for systemic changes in the nation's approach to managing the healthcare needs for people with painful illnesses/conditions who are being denied access to pain medications and left in a state of inhumane suffering. She is passionate about her work and together with her team drives activities to advance awareness around this issue and influence a positive change in society.

Having launched her career in commercial insurance, Lauren worked her way up the ranks in risk mitigation for large and middle market accounts in a wide variety of industries. She is proficient in General Liability, Clinical Trials, Data/Privacy Liability, Fidelity, Workers Compensation, Directors & Officers, Educators Legal, Foreign Liability and Enterprise Risk Management. She founded CIAAG as a result of her experience being denied appropriate medical services which led to the disabling condition she lives with today, including intractable pain syndrome.

In facing her own fight, Lauren discovered a real lack of mobilization and even willingness on the part of industry groups to stand up for people with chronic illness, many citing due to fears of government reprimand via the withholding grants or even being falsely accused of fueling the opioid crisis. She knew the time had come to take matters into her own hands, and founded the CIAAG.

Today, Lauren has built of a thriving community of people and given thousands a platform upon which to research, advocate and work together to help build a better healthcare system that works for all of us.

As the spokesperson at CIAAG she is responsible for business partnerships, the strategic mission and participates in media appearances and events.

Since founding CIAAG, she has spoken numerous times at the United Nations Office of Drugs & Crime and has been featured in Fox News, USA Today, Politico, Times Union, Prevention Magazine, Telegram & Gazette, Hampshire Gazette, MetroWest Daily News, Lowell Sun, Sentinel & Enterprise, Milford News, Boston Business Journal, Boston University News, BATV's Foundations of Change, FATV's Barbara & You, The Jordan Levy Show, Worcester Speaks Out, and Narcotica, Matt Connorton Speaks Out.

EXECUTIVE SUMMARY

The Chronic Illness Advocacy & Awareness Group, dba CIAAG, is a multi-stakeholder collaborative comprised of non-profit organizations and independent groups representing people living with pain, patient and caregiver advocates, purchasers of healthcare, policy experts, and 27 non-governmental organizations representing the full spectrum of healthcare providers and consumers. These diverse experts are united in a shared interest to advance access to a compassionate, patient-centered model of individualized pain care focused on maximizing quality of life and function while preserving patient civil liberties.

It is with this unique perspective that CIAAG respectfully offers the following analysis and recommendations regarding the use of public-private partnerships to explore solutions to the nation's most complex issues; including that of pain management and opioid medications. We are incredibly grateful for the efforts of the Administration to address healthcare disparities within our nation's systems.

An integral part of creating successful public-private partnerships is ensuring proper systems are in place to address issues related to bias, conflicts of interest, and other acts of corruption; including, but not limited to: the production of fraudulent studies and/or data and stock market abuses.

The entities selected to partner with our federal and state authorities are in a uniquely powerful position to substantially influence the design of Medicare benefits, payment structures, and access to evidence-based modalities for the treatment of pain, including opioid pain management treatments. The work conducted by these public-private partnerships will impact payment design and healthcare delivery far beyond the Medicare program and the practice of pain management.

In 2010, the National Institutes of Health (NIH) contracted with the Institute of Medicine (IOM) to undertake a study and make recommendations "to increase the recognition of pain as a significant public health problem in the United States."

The resulting 2011 IOM Report, *Relieving Pain in America: A Blueprint from Transforming Care*, called for a "cultural transformation in pain prevention, care, education, and research and recommended the development of a comprehensive population health strategy" to address these issues.

In response to the report, the Assistant Secretary for Health, Department of Health and Human Services (HHS) asked the Interagency Pain Research Coordinating Committee (IPRCC) to oversee the creation of the National Pain Strategy (NPS).

The National Pain Strategy identified 6 key areas of the healthcare delivery system to be transformed and provided guidance on the necessary steps that would achieve the goals as outlined in the report.

One such complementary strategy was the issuance and subsequent implementation of the nation's "Opioid Prescribing Guidelines" issued by the Centers for Disease Control and Prevention in 2016; published within one week of the National Pain Strategy.

This set the stage for the implementation of the recommendations made in the National Pain Strategy which resulted in the subsequent mass-forced discontinuation and tapering of opioid medications that took place in the United States from 2016 and is still ongoing to this day.

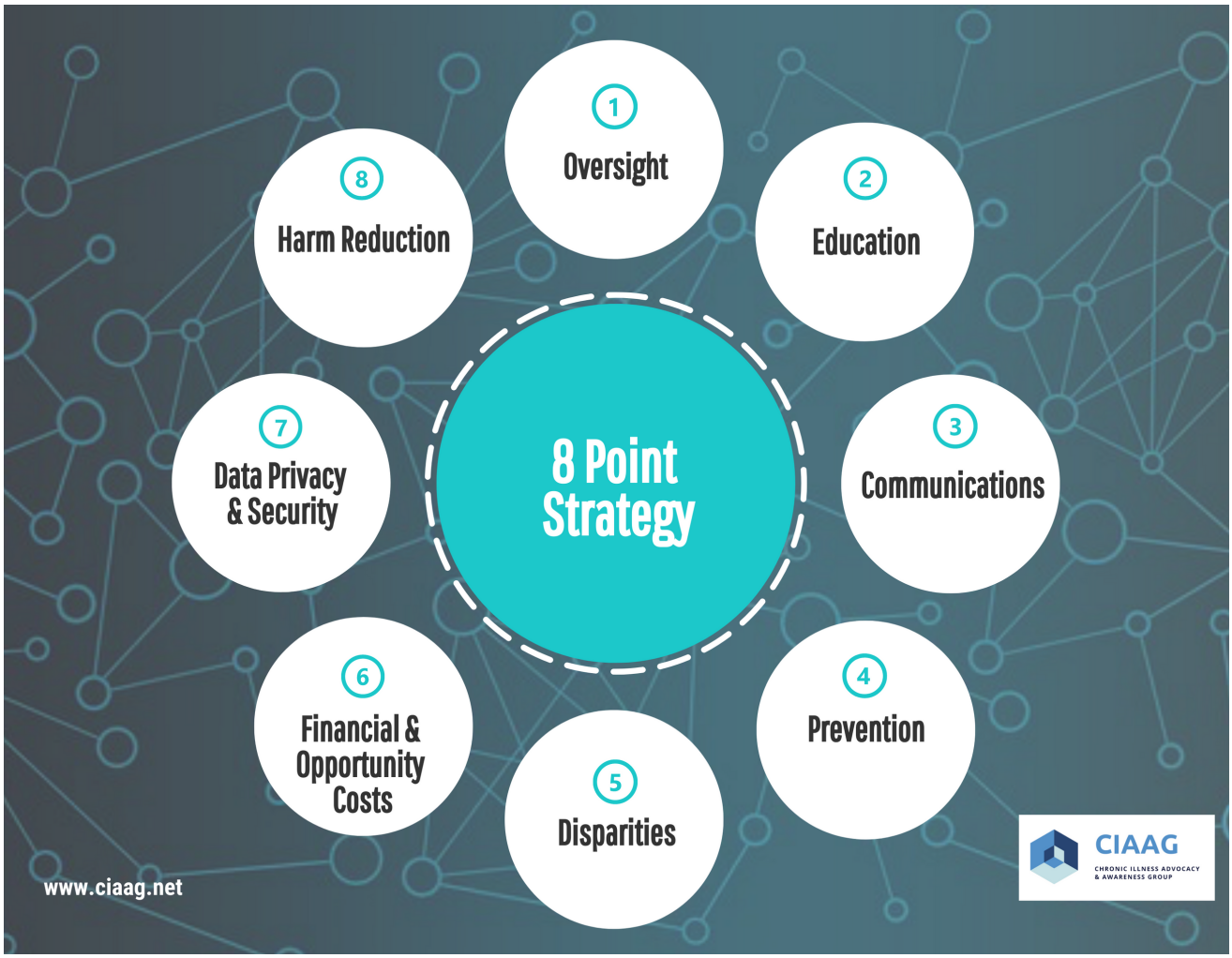
Since the implementation of the National Pain Strategy, there has been an increase in patient suffering and suicides due to untreated pain. Additionally, the rates of overdoses have steadily increased each year since 2010 with stark increases noted in the past 5 years.

Despite goals to reduce rates of overdoses, disability claims, and suicides, we have seen the opposite. Adverse effects in all of these areas have increased. Despite this fact, there has been little to no change in neither the nation's strategic response to the drug overdose crisis nor the crisis of untreated pain.

THE 8-POINT STRATEGY

CIAAG performed a historical and statistical analysis resulting in the development of an 8-Point Strategy that addresses the systemic issues created as a result of the nation's use of public-private partnerships in healthcare.

1. Oversight
2. Education
3. Communications
4. Prevention
5. Disparities
6. Financial & Opportunity Costs
7. Data Privacy & Security
8. Harm Reduction



OVERSIGHT

Issue: Data related to the projects undertaken and work conducted by public-private partnerships are not easily accessible for public inspection.

Recommendation: Create a centralized website for all activities related to public-private partnerships.

- Names of federal and state agency partners.
- Names of the public-private partners and the agencies they are contracted with.
- Contractual parameters to include deliverables and timelines.
- The yearly contract value.
- Dates for all meetings related to the public-private partnership's activities (including prior and future dates).
- Copies of all meeting notes and discussions (including attendee names).
- Annual reports and other written documents related to the public-private partnership's activities.

Issue: There is a lack of oversight and accountability for the conduct of organizations and their employees who are engaged in public-private partnership work. Issues with existing public-private partnerships include, but are not limited to:

- Lack of public transparency
- Personal/financial conflicts of interest
- Acts of collusion
- Stock market abuses (insider trading)
- Lack of oversight (with some individuals/entities overseeing themselves)
- Lack of accountability
- Lack of reporting for public inspection

Recommendation: Develop a Public-Private Partnership Oversight Committee.

- Report concerns of corruption and/or abuse (including RICO and insider trading).
- Create and enforce a public-private partners code of conduct.
- Review and revise the Federal Advisory Committee Act (or similar national guidance documents) to ensure individuals with financial/personal conflicts of interest are not permitted to partake in public-private partnership contracts/project work.
- Review the progress of the public-private partnership to determine if goals are being met.
- Review the applications for the public-private partnership contracts ensuring there are no financial/personal conflicts of interest.
- Cancel contracts with public-private partnerships found in violation of the committee's code of conduct.
- Create and remit a report to Congress documenting the progress of all public-private partnerships annually.

Issue: Federal and/or state task force composition is imbalanced and includes individuals with financial and/or personal conflicts of interest. Organizations partnered under the public-private partnerships have failed to uphold their responsibility to represent the public interest on the Federal and/or State Opioid Task Forces and Committees.

Recommendation:

- Create a public-private partnership commitment statement for all organizations and their representatives to abide by. Acknowledgment of a code of conduct, morality clause, etc.
- Review and revise the Federal Advisory Committee Act to address the unique conflicts of interest presented by public-private partnerships. For example; are there any policies and procedures that can be implemented to ensure the integrity of the individuals participating on these committees? Are there any rules that we need to implement in order to prevent individuals with potential biases and/or conflicts of interest from participating on these committees and/or task forces? Certain professionals may possess an inherent bias due to the nature of their work. Should these professionals be afforded the opportunity to engage in public-private partnerships? (For example; researchers who stand to financially benefit/profit from grant monies allocated by said committees. In this scenario, they should be required to opt-out of receiving potential grants in order to participate in the committees).
- Review the composition of Opioid Task Forces/Committees and remove/replace individuals that are found to have conflicts of interest.

Issue: Lack of balanced stakeholder representation on the federal and state task forces/committees.

Recommendation: Ensure federal task forces and/or committees include:

- (1-2) Individuals with painful illnesses/conditions
- (1-2) Palliative care advocates
- (1) Privacy rights advocate
- (1) Subject matter expert on ethics

All committees must include (1-2) individuals who promote access to opioid medications as a human right. Individuals for these committee seats would be chosen from a patient portal of pre-screened individuals who qualify to participate on these panels. Qualification will be incumbent upon:

- The participants' lived-experience as patients.
- The participants' professional background.
- A signed commitment statement agreeing to adhere to a code of conduct.
- The participants will undergo a formal review process confirming they are free from potential conflicts of interest.
- The patient portal should be managed by an oversight committee.

*This is not an all-encompassing list and further qualifications should be created by the appropriate federal committee/agency.

Issue: Increased instances of scientific fraud with individuals/entities manipulating research outcomes to satisfy a predetermined goal while actively seeking to discredit individual research/entities that conflict with the desired personal and/or financial goals of the committee.

Recommendation: Develop an oversight committee within the FDA to regulate the clinical trials conducted under the public-private-partnership agreements.

- Review and revise the peer to peer review process to reduce bias.
- Review potential conflicts of interest of the principal investigators/grantees.
- Develop policies and procedures to accept and investigate complaints regarding the behavior/activities undertaken by the public-private partners.

EDUCATION

Issue: New education taught at colleges and universities are focused on opioid-sparing strategies. Current guidelines are still under development; however, are actively being taught to students and providers (via CME) as "best practices" and/or "evidence-based."

Recommendation: Require medical schools and continuing medical education courses (CME's) to include classes on the initiation, management, and proper discontinuation of opioid-based medications.

- Examine the differences between illicit versus medicinal use of opioid medications.
- Provide education regarding the differences between palliative care and hospice care.
- Expand education on the proper use of palliative care and opioid pain management.
- Demonstrate the negative impacts and outcomes of untreated/undertreated pain.
- Focus on patient quality of life, functionality, and activities of daily living.
- Provide education on improving provider/patient communication emphasizing utilization of active listening skills.
- Recognizing the difference between biomedical and biopsychosocial needs.
- The importance of addressing biomedical care as the primary focus with the biopsychosocial model as a secondary/complementary approach.

Issue: Organizations partnering with federal and/or state governments to address the harms of illicit drug abuse have historically conflated the issues of addiction and chronic pain. These organizations often cite and promote known propaganda; stating opioid prescriptions are the "root cause" of the nation's drug crisis and that "overprescribing" is a common, ongoing practice.

*Studies show only 1/10th of 1% of prescribers were found guilty of opioid prescribing outside of the scope of practice. (2009)

Recommendation: Create and implement a public health campaign highlighting the differences between illicit drug misuse versus medicinal use of pain medications.

- Submit organizational commitment agreement statements to collaborate on a Safe Use Campaign.
- Adopt de-stigmatizing language for both communities.
- Appoint a committee to review and analyze the current strategies meant to address the harms of illicit drug abuse and its impact on medicinal/scientific access to opioid analgesics.

Issue: The adoption/implementation of the biopsychosocial model of care has negatively impacted patient care and quality of life. The biopsychosocial model of care assumes a patient's symptoms are psychogenic in nature before considering a potential biomedical cause. Disregarding a patient's symptoms in this manner may leave the individual under/untreated. Under/untreated biomedical needs may lead to an exacerbation of a worsening physical and/or mental health crisis. The adoption of the biopsychosocial model of care has resulted in an increased incidence of suicide and at-risk behaviors such as self-medicating with illicit substances and alcohol.

Recommendation: The biomedical model of care should be the primary model utilized when examining and diagnosing a patient. It is imperative for medical providers to rule out any biomedical causes for the patient's symptoms/concerns prior to exploring any biopsychosocial factors.
The biomedical and biopsychosocial needs of the patient can and should be duly considered and attended to in order for the patient to receive adequate and appropriate individualized care with the biomedical needs addressed primarily and the biopsychosocial secondarily.

Issue: The development of treatment guidelines for every major illness, rare disease/condition, as well as surgical procedure are in direct conflict with the concept of individualized patient care. This is creating a difficult situation for those attempting to access individualized care. The population health model is now taking precedence over individualized treatment.

Recommendation: Re-evaluate the guideline development process. The current aggregate of data is not reflective of true patient need and therefore, is providing misleading data that is then used in the guideline creation process. Data used in the creation of guidelines needs to reflect the real-world patient experience in order to create appropriate and effective "best practices". This utilization of misleading data has resulted in ineffective treatments now being promoted as best practices; this is leading to poor outcomes in overall patient health and well being.

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CIAAG proposes that committees/task forces review the prescribing data of individuals prior to the implementation of opioid-sparing policies to determine the true ranges of opioid prescribing based on illness type and other relevant data points. This data can then be analyzed to identify patterns among patients/prescribers based on illness type during a time when prescribing practices were not unduly influenced by third parties. The resulting data can be used to create a prescribing baseline range that can then be explored/studied.

Issue: Lack of guidance and/or formal procedures to deal with patients that fail drug screens.

Recommendation: Develop parameters on how to manage patients who fail urine drug screens.

- Provide an opportunity for the patient to retest using hair follicle testing technology (reimbursable by insurance if negative).
- If it is determined that the patient must be tapered; provide medication assisted therapy to manage symptoms during the discontinuation of the medication.
- Prohibit immediate/rapid discontinuation/tapering..
- Preserve patient safety and continuity of care by providing a rapid referral and/or connection to services to ensure the patient does not endure/is not subjected to a rapid discontinuation.
- Create potentially stricter monitoring guidelines for the patient to earn back medications. Implement weekly drug screens and/or prescription pick ups; more or less often as dictated by patient circumstances and provider discretion.

COMMUNICATIONS

Issue: Federal Law HR5736 - Smith-Mundt Modernization Act of 2012 amended the Forgeign Relations Authorization Act of 1986-1987 which permitted propaganda to be published regarding American social and political issues.

Recommendation: Reinstate the provisions of the Foreign Relations Authorization Act of 1986-1987 to prohibit funds from the Department of the State or the Board from being used to influence public opinion or propagandizing in the United States. This will extend beyond propaganda related to healthcare issues and pain management and will help combat current propaganda's negative influence on American policy and public communications campaigns.

Issue: The lack of diverse representation of views in the media. Despite acknowledgement of the "undesirable chilling effect" of sensationalized media cases regarding inappropriate physician prescribing practices, the media continues to publicize and senationalize these infrequent events.

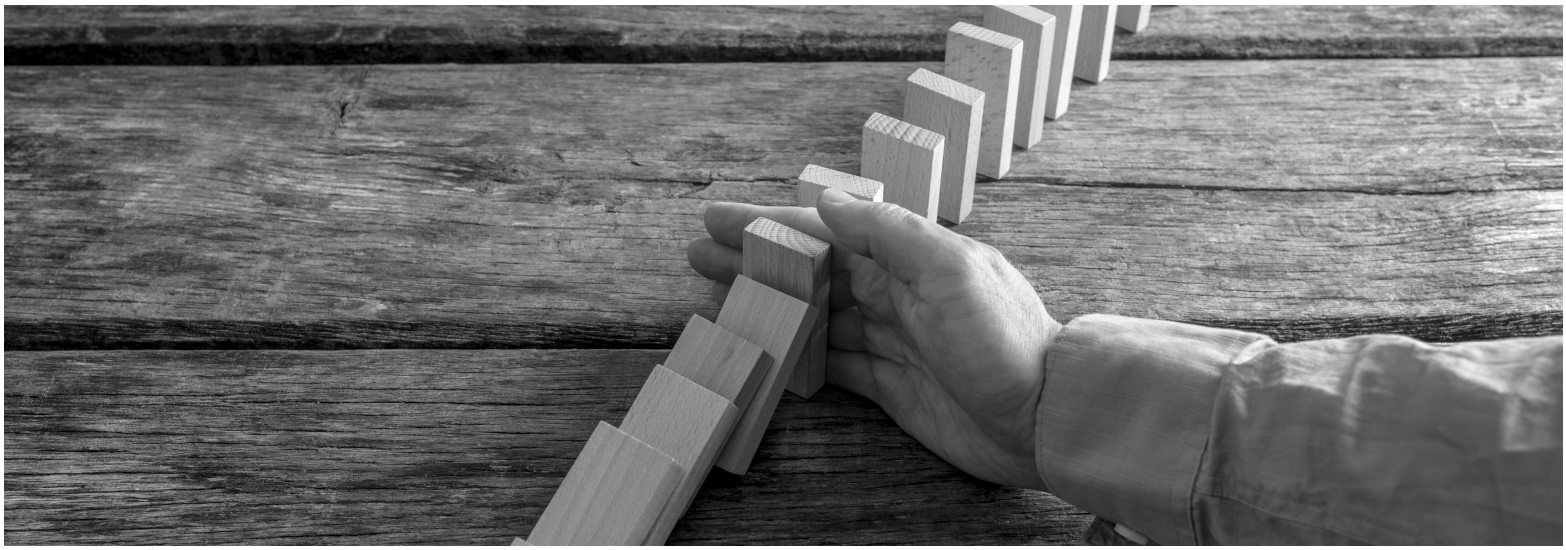
Recommendation: Create and implement strategies to address the gaps and inconsistencies with prior guidance issued in the "PAINS Project, Policy Brief: Balance, Uniformity and Fairness for Law Enforcement Investigations and Prosecution of the Diversion of Prescription Pain Medications While Preserving Appropriate Medical Practice." February 2009.

- Law Enforcement should not use SWAT tactics to arrest physicians. They are (generally) not violent offenders, nor are they armed. This tactic sensationalizes the event and sends the wrong message to the public.
- Law Enforcement should not arrest doctors at the physician's office, nor during operating hours. This creates fear among patients and victimizes individuals who may be on site.
- Law Enforcement who remove patient medical records - MUST provide copies IMMEDIATELY to the patients when seized.
- Must establish a patient emergency help line to ensure/protect continuity of care. Help patients establish care with new providers as a result of their displacement for emergency care until a new primary provider is found.

Issue: Lack of support for the medicinal use of opioids. Public health campaigns, politicians and media outlets focus on the negatives of opioid medications and contribute to the rising stigma against individuals who require these medications to manage their illness/conditions.

Recommendation: Creation of an opioid analgesic *Safe Use Campaign* for medical and scientific purposes.

- Allocate 25% of the state and federal agency budgets for addressing the harms of opioid use towards the creation and implementation of a *Safe Use Campaign*.
- Balance the media representation of illicit drug abuse with the issue of necessary access to opioids for medicinal and scientific purposes. Highlight the harms of untreated pain and the importance of proper, individualized treatment.



PREVENTION

Issue: Lack of public access to impact studies on the forced tapering that took place in the United States since the issuance and implementation of the CDC Opioid Prescribing Guidelines of 2016.

Recommendation: Current data results should be provided on a centralized database (free to the public). Funding should be allocated to support further studies on the impact of forced tapers; including but not limited to:

- Social implications.
- Impact on the disability rate.
- Impact on the suicide rate.
- Implications for mental health.
- Impact on biomedical conditions.
- Impact on the medical error rate.

Issue: Lack of data acknowledging that favorable outcomes related to the use of opioids in the treatment of pain exist. Additionally, previous research findings establishing these positive outcomes have been disregarded and/or claimed to be illegitimate.

Recommendation: Appoint a committee to perform a systematic review of all studies regarding the effectiveness of opioid analgesics and send a summary report to Congress. The resultant data should be used to create and implement a public health *Safe Use Campaign*. Fund additional studies to fill any potential research gaps and inconsistencies.

Issue: Lack of available data on whether or not opioids provide additional palliative and/or inflammatory benefits for individuals with intractable pain, chronic illnesses, and/or conditions.

Recommendation: Allocate funding to support studies to determine what, (if any), benefits opioid analgesics provide for patients with intractable pain, chronic illness, and/or incurable conditions.

Issue: There is a lack of public access to the studies that were conducted during the past 5 years. It is imperative the public be able to review the types of projects taking place as well as any results.

Recommendations: Studies must be published on a centralized website and made readily available for public review of the outcomes of various projects funded by Congress, including but not limited to:

- Centers of Disease Control & Prevention (CDC)
- Centers of Medicare & Medicaid (CMS)
- Agency Healthcare Research & Quality (AHRQ)
- Food & Drug Administration (FDA)
- Health & Human Services (HHS)
- Veterans Association (VA)
- Department of Defense (DoD)
- Health Resources & Services Association (HRSA)
- National Academy of Medicine (NAM)
- Public Private Partnership Contracted projects
- National Institute of Health & all related sub-agencies (NIH)
- Drug Enforcement Agency (DEA)
- Inter-Agency Pain Research Coordinating Committee (IPRCC)
- Patient Centered Outcomes Research Institute (PCORI)
- Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION)
- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)
- Public-Private-Partnerships including, but not limited to, Advocacy Organizations, Colleges & Universities
- National Pain Strategy
- Federal Pain Strategy
- HEAL Initiative
- NAM Opioid Collaborative

Issue: Citizens may not always proactively seek medical care which may lead the individual to develop a variety of health conditions, including chronic pain and/or disabilities. This leads to increased disability rates which negatively impacts economic activity and ultimately increases the cost of social measures for the citizenry.

Recommendation: Allocate funding to support a public health campaign focused on the importance of preventive health measures. By focusing on the repercussions of a failure to do so, there is a higher probability patients will become personally invested in their preventative health measures. This campaign should highlight the damaging impacts chronic pain and illness can have on an individual and how preventive care can result in healthier outcomes. A campaign of this type will raise awareness for individuals with chronic pain as well as others who suffer from the variety of chronic illnesses and conditions that exist. In addition, this will also simultaneously encourage individuals to proactively seek preventive care and adopt a healthy lifestyle.

Issue: There have been increases in the overdose rates since 2010 with stark increases in 2016-2021; largely attributed to the rise of illicit fentanyl.

Recommendation: Allocate funding for a public health campaign highlighting the dangers of illicit fentanyl. The United States's inappropriate focus on medicinal opioids has allowed the illicit market to expand exponentially. Educate the public regarding the dangers of illicit drugs. Inform citizens that the pills found on the street are not diverted prescriptions but are actually illicit substances processed with a pill press in order to resemble a legitimate, pharmaceutical grade medication.

Issue: The rise of illicit fentanyl has contributed to the increased risk of overdose.

Recommendation: Allocate funding to the states to produce and supply test kits to individuals who use illicit drugs. This will allow these individuals to "test" their supply before using; it will reduce the rate of unintentional overdoses while helping to identify the true representation of the illicit drug supply.

DISPARITIES

Recent public health changes have exacerbated disparities in a number of uniquely vulnerable populations, including but not limited to: people living with disabilities, women, children, victims of sexual/physical assault, racial minorities, and physicians.

Issue: Patients' pain continues to be dismissed and inappropriately equated to that of a mental health issue. This issue is magnified for women and individuals of various ethnicities. Examples:

- A teenager's abdominal pain was dismissed as drug-seeking after a pelvic procedure when in fact she had a perforated intestine that was leaking into her abdomen for 4 days before her mother brought her to another hospital for assessment.
- Debilitating pain from endometriosis is often dismissed as "bad periods".
- Patients are often accused of exaggerating their pain and/or being hysterical when advocating for themselves.
- Patients are accused of catastrophizing their pain.
- Patients are accused of being too emotional.
- Parents have difficulty advocating for their children to receive pain care due to these same biases.
- Some hospitals and surgical centers are now promoting themselves as "opioid-free centers" which impedes the individualized care model and adds to the stigma against individuals who necessitate the use of opiate medications.

Recommendation: Provide proper representation and oversight for each of these communities' unique needs on all federal committees and task forces dedicated to addressing healthcare disparities with a focus on individualized care models.

Issue: There is a public campaign/initiative to promote equitable preventative care and pain management for the black/brown community; however, the pain management modalities currently offered are largely untested. Oftentimes, these patients' electronic medical records are used to perform clinical testing behind the scenes. The use of pragmatic clinical trials, in which these vulnerable communities of patients will be the subjects without their knowledge or informed consent, violates their personal autonomy as well as their civil liberties.

Recommendation: Reinstate full informed consent for human clinical trials. Patients who are offered untested modalities as treatment must be made aware that they are indeed untested and not currently accepted/proven best practice. Patients must be afforded the option for medication anagement; not soley offered nonpharmacological/self management techniques as a stand alone treatment option (as determined by their provider).

Issue: Untested modalities are being promoted as “best practices”, pushed into the private medical system and administered to patients as treatment without patient knowledge and/or consent.

Recommendation: Restore informed consent for human clinical trials (which was rescinded by the FDA in 2017). Recruit patients with full informed consent for clinical trials (as was always done until recently). Develop regulatory guidance and rules regarding the use of pragmatic clinical trials specifying the limits of their use, respect for patient privacy, etc. Develop regulations that prohibit legislatures from passing laws that effectively create a live clinical trial using the private citizenry (i.e., restricting quantity/dosages of medications, requiring step therapy, implementing excessive regulations that make accessing pharmaceutical treatments effectively illegal, etc).

Issue: Victims of sexual and/or physical assault are being penalized due to the implementation of risk scores. Additionally, a number of an individual's personal life circumstances/characteristics are now being factored into the metrics used to create the risk scores. Many of these personal circumstances/characteristics which are protected by the Americans with Disabilities Act and the Civil Rights Act are being used to create the risk scores which are then used to determine an individual's ability to access basic care and some public services.

Recommendation: Require transparency of the proprietary data used to develop patient risk scores. Permit patients to review the data in their files to ensure accuracy. Create the ability for patients to contest and remove inaccurate information from their risk profiles. Remove any/all penalties for patients who have experienced physical/sexual and/or emotional assault. The inclusion of this metric in a patient's risk score re-victimizes the individual and penalizes them for being a victim in the first place. The usage of this metric will result in disincentivizing a victim's self-report of harm as they will fear retribution in the form of negative consequences in their ability to access quality healthcare and other general services (as the use of risk scores become more widely used in society as a measure to access/obtain certain services and/or goods).

Issue: People living with painful illnesses/conditions and/or disabilities are being denied access and/or experiencing forced discontinuation of opioid medications while being offered only non-pharmacologic and non-opioid options despite a lack of evidence of their efficacy.

Recommendation: Allocate funding for a *Safe Use Campaign* that will ensure access remains in place for individuals who use opioids for the treatment of pain and/or disease. Additional action items to be addressed, include but are not limited to:

- Statement issued from the Federal and State Agencies indicating their support for the *Safe Use Campaign* and to discourage inappropriate use of step-therapy and/or the denial of access to opioid analgesics.
- Create a national pathway for "legacy patients" to continue to receive access to opioid medications without undue obstacles and ensure continuity of care when changing physicians.
- Prohibit propaganda that promotes alternative/complementary therapies as "evidence-based" when said modalities are, in actuality, still being studied for their efficacy.

Issue: Physicians and other providers are unable to provide individualized patient care due to the increased use of algorithms in the electronic medical record. These algorithms are to guide physician decision-making in an effort to implement a population-based approach to patient care. The current strategy has created competing goals between individualized care and the population health model, with individualized care now considered as a secondary concern.

Recommendation: Review and revise the strategic approach to managing these competitive goals. We cannot have a thriving population while sacrificing individual rights and health.

Issue: Access to opioids for pediatric patients is being discouraged.

Recommendation: Address disparities in the pain care delivery system for pediatric patients with an emphasis on pain control. Failure to do so may lead to mental health difficulties and impede the healing process, resulting in an exacerbation of the child's condition. These types of negative outcomes can lead to disability; therefore, impacting the individual's ability to contribute to society and maintain gainful employment later in life .

Issue: Opioid sparing and opioid free surgeries are increasingly used and recommended despite evidence of their efficiency. The few studies that have been conducted are largely flawed due to inherent bias. For Example: If the treating physician documents the patient is suffering unmanaged pain and the provider does not intervene, they expose themselves to legal liability for medical negligence. Therefore, participating physicians may opt to omit any negative outcomes from the patient's file/medical record. This resultant data is then selected by a principal investigator to use in a clinical trial to falsely claim the opioid-sparing approach is successful when in reality, the patient suffered tremendously. Additionally, patients are not provided the opportunity to decline participation in these experimental procedures. Oftentimes they are not aware they have been placed into a pragmatic clinical trial. This violates the Belmont Agreement on Human Rights.

Recommendation: Disallow the use of financial incentives for opioid sparing and/or opioid free surgeries. Blue Cross Blue Shield offers up to 35% incentive to withhold opioid pain medications for postoperative patients. Reinstate informed consent for human clinical trials and rescind the FDA Waiver on Human Clinical Trials issued by the FDA in 2017. Provide patients an opt-in/opt-out option to participate in opioid-sparing medical procedures and/or surgeries.

Issue: Pharmacists are denying to fill/refill valid patient prescriptions.

Recommendations: Review and revise the National Stewardship Program for Pharmacists, addressing their responsibility in preventing illicit prescriptions and ensure the continuity of care for patients. Emphasize the legal liability, exposure, and dangers of denying a patient their medications and/or putting a patient into a forced withdrawal/discontinuation. Create formal procedures for the denial of prescriptions; only if the writing physician's license is suspended by the Medical Board and/or under investigation by the DEA.

Issue: Hospitals and pharmacies are unable to meet acute/chronic pain needs of the citizenry due to reduced inventory. The DEA has reduced opioid manufacturing quotas by over 50% in the last 5 years.

Recommendation: Review and revise the DEA guidance regarding their role in the management of the medicinal and scientific supply of opioid analgesics. The DEA recently issued a statement acknowledging the fact that illicit drugs are the driving force of overdoses in the nation. As such, they should be required to take this into account when creating the pharmaceutical grade opiate production quotas for the nation. Through the use of the PDMP, pharmacies, and other available data resources, they can accurately predict the quantity needed to meet chronic pain needs along with an additional supply for post-operative and acute pain needs. A collaborative alliance must be created between the DEA and Medical Societies to ensure the mutual goals of reducing illicit drug diversion while preserving the adequacy of the medical and scientific supply chain.

Issue: Patients who already receive opioid pain medications and/or other scheduled substances are being required to obtain prior authorizations from insurance carriers before filling additional prescriptions/quantities of opioid medications prescribed as a result of medical procedures, surgeries, and childbirth.

Recommendation: Require providers to have a post-operative pain management discussion with the patient. If additional opioid pain medications are to be provided, the physician must submit a prior authorization to the insurance provider prior to performing the procedure and/or as soon as practical.

FINANCIAL AND OPPORTUNITY COSTS

Issue: New education taught at colleges and universities are focused on opioid-sparing strategies. Current guidelines are still under development; however, are actively being taught to students and providers (via CME) as "best practices" and/or "evidence-based."

Recommendation: Require medical schools and continuing medical education courses (CME's) to include classes on the initiation, management, and proper discontinuation of opioid-based medications.

- Examine the differences between illicit versus medicinal use of opioid medications.
- Provide education regarding the differences between palliative care and hospice care.
- Expand education on the proper use of palliative care and opioid pain management.
- Demonstrate the negative impacts and outcomes of untreated/undertreated pain.
- Focus on patient quality of life, functionality, and activities of daily living.
- Provide education on improving provider/patient communication emphasizing utilization of active listening skills.
- Recognizing the difference between biomedical and biopsychosocial needs.
- The importance of addressing biomedical care as the primary focus with the biopsychosocial model as a secondary/complementary approach.

Issue: The increased rates of overdose, disability, and suicide, negatively impacts the economy, increases societal expenses, and reduces economic activity.

Recommendations: Allocate funding under the public-private partnership initiative for a dual campaign that highlights the importance of recognizing the differences of medicinal opioid use versus illicit drug abuse. Align all federal and state initiatives, task forces, and committees to support the goals of the dual campaign. The continual conflation of these issues is contributing to bad public health policy while creating undesirable outcomes for people with painful illnesses/conditions and substance use disorder.

DATA PRIVACY AND SECURITY

Issue: The increased reliance on technology in healthcare is lacking appropriate oversight in regards to data security/privacy.

Recommendations: Congress to allocate funding for the creation of a Data Security/Privacy Agency that will address how to bring data privacy and digital rights under a single silo. Address the coordination/implementation of this agency and combine these public services as such.

- The task force should also examine the social, ethical, and economic impacts of high-risk data processing, such as that being untaken in the healthcare setting. There are concerns regarding the new biopsychosocial model of care and how it will create a healthcare system with systematic discrimination built into the algorithms. This scenario creates difficulty for underserved populations; (black/brown, immigrants, disabled, women, and elderly) from accessing necessary services.
- Prepare an analysis report regarding the findings of the task force and their recommendations to ensure protection of consumers' privacy and civil rights as related to data collection being performed by various federal agencies and private business enterprises.

Issue: Risk scores and algorithms utilize private patient data including race, gender, and other personal identifiers currently protected by law under the Civil Rights Act. The entities that create the risk scores/algorithms are claiming proprietary rights in order to keep the metrics used to calculate these scores hidden from Congressional scrutiny.

Recommendation: Compel a Congressional Hearing to review the use of proprietary algorithms with a goal to require transparency with both Congress and the general public. Allow the public the ability to review the metrics in their personal files and ability to contest inaccurate information. Establish a process that documents when the individual's request to review their record was received and the resultant outcome of the inquiry (whether or not the record was amended or the request was rejected).

HARM REDUCTION

Issue: The COVID-19 Pandemic exposed a number of gaps and inconsistencies in the healthcare delivery system which resulted in the inability for some individuals to access necessary medical services.

Recommendation: Create and implement emergency/disaster management plans for these vulnerable communities.

Issue: Funding has been primarily granted for research projects that are focused on delegitimizing the use of opioid analgesic medications and/or replacing opioid analgesic medications in healthcare. This results in an imbalance of available research studies; therefore, negatively impacting informed decisions regarding their use.

Recommendation: Allocate funding for research studies that explore the safety and efficacy of opioid analgesic medications. Also, explore any possible additional usages this medication may have for individuals with painful diseases and conditions (i.e. does this class of medication have any anti-inflammatory, social, and behavioral health benefits?)

Issue: State Medical Boards, insurance carriers, and the DEA are sending "benchmarking letters" to doctors thus creating an environment where physicians are fearful of providing opioid medications to their patients.

Recommendation: Review current agency practices and develop guidance for interagency collaboration on investigations and other processes with a focus on ensuring the practice of medicine is not undermined by these regulatory bodies. Current practices are exacerbating patient stigma and interfering with patients' ability to access evidence-based treatments. The DEA, Medical Boards, and National Association of Insurance Commissioners should work together to review current practices and procedures. They should also be required to report the impact of current practices and appoint an independent committee to create recommendations for addressing other various identified issues.

Issue: The Drug Enforcement Agency's use of SWAT tactics to arrest physicians suspected of inappropriately prescribing scheduled medications, (including opioid analgesics) oftentimes includes taking possession of patient files for evidence. These tactics have been highly publicized and sensationalized by the media which has lead to an exacerbation of fear amongst providers who prescribe scheduled medications.

When patient medical records are seized and taken as evidence, the patient is left at risk of experiencing a disruption to their continuity of care. When this occurs, the patient is often left without a provider which puts them at risk of experiencing discontinuation syndrome and suffering further medical consequences as a result. Sparse access to providers willing to assume the care of patients with chronic pain is compounded by the patient's inability to access their medical records in a timely manner. The consequences of this scenario can be catastrophic for the patient's physical and mental health.

Recommendation: There is no justification for the Drug Enforcement Agency to use SWAT tactics during the arrest of medical providers suspected of inappropriate prescribing. These individuals are often not considered armed or dangerous. The Drug Enforcement Agency must cease all use of SWAT tactics during the arrests of medical providers (unless warranted by other factors such as likelihood of weapons on the premises). The use of these tactics is known to create a negative impact on provider perception and results in fear of prescribing. Caution has been previously advised in the *"Policy Brief on Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigation and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice"* (February 2009).

Additionally, the Drug Enforcement Agency should work with State Medical Boards to create a program to manage displaced patients as a result of DEA investigations. These patients are dramatically impacted by these arrests and programs must be in place to ensure that patient continuity of care is preserved and that any subsequent transition of medical services occurs in a timely manner.

Issue: There have been reported shortages of both intravenous and oral opioid based medications across the nation for the management of acute and chronic pain. Despite these shortages, the Drug Enforcement Agency has proposed an additional reduction in the manufacturing of opioid based pain medications for the year 2022. This comes in addition to the previous cuts in the supply chain of over 50% in the past 5 years. This has created an inability for pharmacies to meet patient demand for both acute and chronic pain prescriptions. Additionally, due to the arrival of the COVID-19 pandemic, hospitals have been unable to keep up with the high demand for intravenous fentanyl that is used during the intubation of patients suffering from the virus. These shortages have caused providers to start rationing and switching formulations to meet the demand in the hospital setting. As a result, there is now less medication available for those patients needing to fill prescriptions for the management of acute and/or chronic pain (in some cases, patients are not able to obtain any medication).

Recommendation: The Drug Enforcement Agency must work collaboratively with Health and Human Services, the Food & Drug Administration, and other relevant agencies to better estimate the manufacturing quotas for the nation's opioid analgesic supply chain. Use of state databases, pharmacy reports, and other verifiable and accessible data analytics can provide for a better estimation of the quantity needed to meet the demand for the management of chronic and acute pain, post-surgical pain, and other various in-patient needs. Allocations should be included to allow for unexpected market demand for opioid analgesics; such as a terrorist attack, pandemic(s), and/or other natural disasters.

Issue: There is a lack of consistency in the reporting of potential overdoses. Data is not being accurately reported, tracked, or cross referenced against existing available data sources (i.e., the coroner's office not checking the decedent's name in the Prescription Drug Monitoring Program database) to determine if the cause of death was related to an illicit substance, a valid prescription, a possible suicide, or unintentional overdose.

Recommendation: Create national practice guidance for law enforcement regarding the gathering of data at a crime scene; such as, identifying the presence of a prescription bottle versus evidence of intravenous use. Require a mandatory review of the states Prescription Drug Monitoring Program database to determine if the individual had a valid prescription.. (If they did not have a current, valid prescription, the death should be recorded as related to illicit use). The recording of additional details and the cross-referencing of existing data will help to create a more detailed and accurate representation of the true cause of death. Proper identification of the cause of death is vital to helping shape the public health response.

Issue: Individuals denied proper pain management and/or involuntarily discontinued from their opioid medication management regime are at an increased risk of suicide.

Recommendation: Implement protecting access to opioid medications as a harm reduction measure. Protecting access will reduce patient use of illicit substances and suicide rates. Implementing harm reduction measures help prevent cruel and unusual suffering.

Issue: The Food & Drug Administration issued a Waiver of Informed Consent for Human Clinical Trials in 2017. This helped pave the way for the increased use of pragmatic clinical trials where the patient has not granted consent to participate. The waiver states it is only applicable under two conditions:

(1) when there is minimal risk to the patient
(2) the federal government has declared a national emergency

The federal government has declared an emergency as it relates to opioid analgesics as well as the COVID-19 pandemic. Therefore, the federal government has permitted human clinical trials to take place, without requiring patient knowledge or consent.

Recommendation: Reinstate informed consent for human clinical trials that was originally waived in 2017 by the Food & Drug Administration. The pragmatic clinical trials taking place are not of minimal risk to the patients. Declaring a national emergency does not justify the violation of a citizen's constitutional, civil and human rights.

Issue: Increased use of propaganda is resulting in the creation and implementation of public health policy changes that increase disparities, including increase in overdoses, suicides, medical errors and the disability rate (FY 2016-2021).

Recommendation: Prohibit the use of propaganda by federal agencies and any federally funded programs and/or partners, media publications, and/or educational courses/events.

Issue: Increased incidence of patient abandonment and/or forced discontinuation from previously managed opioid analgesic therapies. Oftentimes, patients have no recourse in these situations and are at the will of the provider. This creates duress in patients due to their inability to self-advocate and contributes to feelings of helplessness, which may lead to engaging in at-risk behaviors and/or self-harm.

Recommendation: Allocate funding to the development of state programs to support patients on opioid-based medications who are in need of a provider. It is of vital importance that these patients have continuity of care. States should create programs for these patients to provide assistance when losing access to a provider. These providers will be required to continue the patient's previous prescriptions. The provider would help re-establish care for the patients, review their records, establish a care plan, communicate with the patient and assess whether or not any changes in medications are needed. Many patients do quite well on opioid analgesics yet are having an increasingly difficult time finding a provider willing to prescribe this class of medication for them (due to fear of reprimand from the Drug Enforcement Agency, Medical Board, or other state agency). We must provide a pathway for patients who benefit from opioid analgesics to continue to safely receive them while establishing an environment that their providers feel safe prescribing in.

Issue: Patients who are abruptly discontinued from opioid analgesics are at increased risk of engaging in high-risk activities; such as, illicit substance use, self harm, and suicide.

Recommendation: Establish policies that guide ethical and medically safe pathways when discontinuing opioid analgesics from a patient's medical regimen. Current standards recommend 10% reduction in dose every 4 weeks; the patient has the ability to slow and/or stop the taper at any time. An ethical and safe taper may take years to accomplish and should always be done with respect to the patient's biomedical and psychological needs. Providers should be strictly prohibited from abruptly discontinuing a patient from any controlled substances. The provider should be required to follow best-practices during a taper or be held legally liable to the patient for any resultant damages.

Issue: There has been a dramatic increase in overdoses resulting from the increased presence of fentanyl analogs in the illicit drug supply.

Recommendation: Allocate funding for a national awareness campaign on the dangers of illicit fentanyl use. This campaign should clarify the difference between medical grade fentanyl and illicit fentanyl (*Example Campaign Slogan: "This isn't your parent's fentanyl"*). Failure to clarify this important fact has led to an uninformed population that is unaware of the true dangers regarding the use of illicit drugs, especially those pressed into a pill form. The pressing of illicit fentanyl to appear like a prescription medication often leads the user to have a false sense of security that they are consuming a pharmaceutical grade, regimented dose. A national awareness campaign would help address this issue. Additionally, funding should be allocated to the states to provide drug test kits for substance users. This simple measure will help reduce accidental poisonings among drug users.

Issue: Lack of available space for individuals suffering from substance use disorder in need of medically managed detoxification services.

Recommendation: Allocate funding to the development of in and out-patient hospitals for individuals with substance use disorder in need of medically managed detoxification services, behavioral management support, medication assisted therapies, and other social services.

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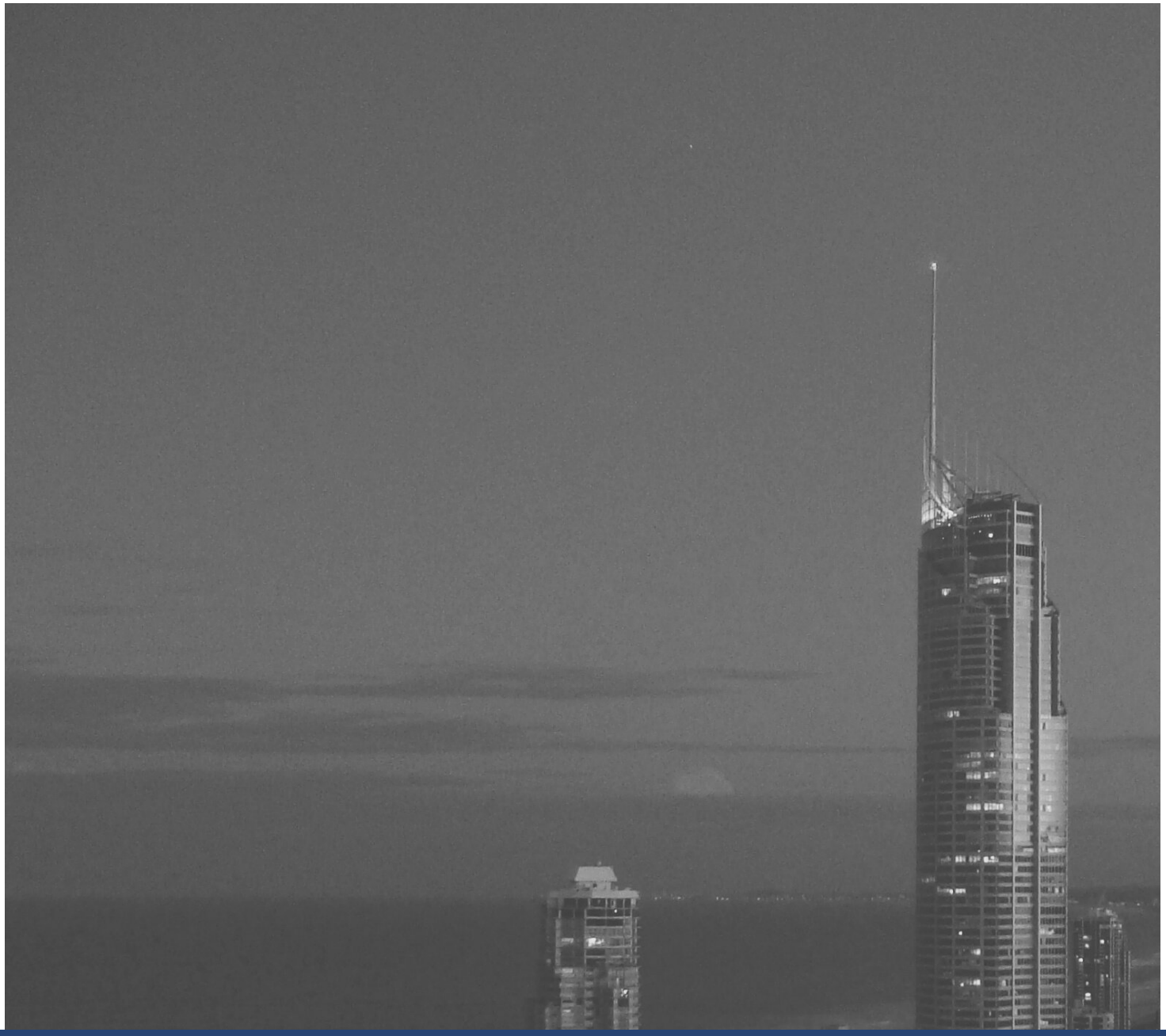

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