



Dossier



The
Violation
of a
Nation

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Executive Summary



The Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG) is a national non-profit organization that promotes both a common-sense, compassionate and research-based approach to palliative care along with the responsible prescribing of opioid medication to those experiencing chronic pain and illnesses, including: serious injuries, intractable pain, and those who suffer from painful chronic diseases.

CIAAG's mission is to work collaboratively with legislators in crafting the policy changes and legislation enacted to combat opioid abuse (including heroin and illegally-obtained fentanyl) in a way that does not restrict patients' access to their medication. Restricting access is not just a problem for the individual; it negatively impacts the nation's public and economic health, resulting in previously functioning members of society being forced into unemployment and disability in response to the relentless, inhumane and debilitating pain they experience.

Intractable pain and forced isolation often leads to depression and other mental health crises as well. Unfortunately, some patients have turned to the street to find unsafe alternatives (including dangerous counterfeit pills) in a desperate effort to relieve their untreated pain, while others have succumbed to suicide as a final escape.

CIAAG offers lawmakers and other decision-makers fact-based research on prescription opioid use from qualified physicians, as well as policy white papers, testimonials and other resources to aid in crafting sensible policies around opiate use.

CIAAG is a 503-C Non-Profit Organization, therefore any and all donations are 100% tax deductible.

Bios

Lauren Deluca, CPCU



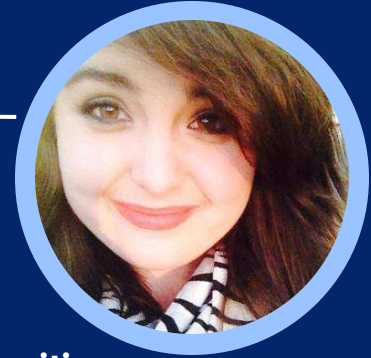
Lauren Deluca, Founding President, graduated from Nichols College with a Bachelor's in Finance. She earned several professional designations including, Charter Property Casualty Underwriter with a concentration on Commercial Insurance, Associates in Personal Insurance and Associate in General Insurance. She spent her career working as a Commercial Insurance Account Executive & Risk Manager specializing in Large & Middle Market accounts.

After a life altering medical emergency she Founded Chronic Illness Advocacy & Awareness Group to raise awareness to the medical industry abuse being imposed upon the chronically ill due to health policy and legislative changes taking place.

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Position:
President & Founder

Jayne Flanders



Jayne Flanders, Vice President & Director of Communications, graduated from Germanna Community College in 2015 with an Associate's degree in Psychology. Jayne has been Interviewed by the "Circa News" in Washington D.C., where she discussed her struggle living with multiple co-morbidities since birth, her experience with the health care system and how it has impacted the treatment of her 12 illnesses as well as her work as Co-Founder of CIAAG and our work to ensure proper legal protections are put in place to protect the chronically ill, disabled and those suffering from chronic and intractable pain. Jayne is the Director of Communications, she manages and designs content as well as oversees the media team for CIAAG's social media and grassroots advocacy efforts.

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Position:
Vice President & Co-Founder

Shasta Rayne Harner



Shasta Rayne Harner, Director & Senior Policy Analyst, graduated from Sonoma State University with a Bachelor's in Political Science. She worked for many years as a Certified Medical Assistant and Project Coordinator for a large medical group. In her career she focusing on the delivery of patient care to medical practice administration. Shasta, lives with a rare, disabling auto-immune disease called, Dermatomyositis.

After the onset of her disease, Shasta gained insight into the experience of being a chronically ill patient in today's medical/political climate. As a result of this experience combined with her work history, personal interests, disability and educational background, she was inspired to advocate for others who also have disabling conditions.

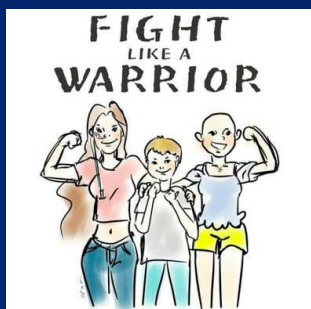
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Director

Contributors-

A huge thank you to Andrew Auell and Peggy O'connor for their contributions to this report.

Our Coalition Partners



April 1, 2019

United States House and Senate
1600 Pennsylvania Avenue NW
Washington, DC 20510

RE: Implementing a Crisis

Dear Honorable Members of the House and Senate:

Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG) is a national non-profit representing the 100 million American citizens who suffer from chronic pain from chronic illnesses, diseases and/or incurable conditions. As you know, America is facing an unprecedented overdose crisis, which has drastically increased in the past five years despite efforts to reduce prescribing. Prescribing of opioid medication is at a [25 year low](#) (1), yet overdoses are at an all-time high. The statistics highlight the indisputable fact that the problem of opioid misuse is *not* fueled by legally prescribed opioid medication, but is instead the result of the illicit fentanyl, carfentanil and heroin flooding our streets.

How did it come to this? In the following pages, we outline startling findings from our unique, new research regarding the issuance of the controversial “Centers of Disease Control and Prevention’s Opioid Guidelines.” These guidelines are at the epicenter of the justification of both bad federal and state policy denying patient access to opioid medication (no matter how necessary and justified.) To date, there has been no official Centers for Disease Control (CDC) or government response to the public outcry regarding the negative and even tragic impact these draconian guidelines have had on healthcare services and patient quality of life. The official talking point, that the guidelines were merely issued in part due to the “opioid crisis,” is naïve at best and perhaps willfully deceptive.

Our findings indicate that the CDC guidelines are actually ***part of a massive population-based study – a clinical trial if you will*** - that has been implemented into the national healthcare delivery system without the consent or knowledge of the American citizens impacted. In review of the CDC guidelines’ execution, our organization has discovered what appear to be serious conflicts of interest, potential financial incentives between parties intimately involved in the study, and violations of patient privacy, as well as of the constitutional, legal, ethical and moral rights of the citizenry.

The background information

On March 23, 2010, the Affordable Care Act (ACA) was adopted into Federal Law. [Section 4305](#) (2), Title IV: Prevention of Chronic Disease and Improving Health. Doing so established a 15 person council within the Department of Health and Human Services (DHS), to be known as the “[National Prevention, Health Promotion and Public Health Council](#).”(3)

The ACA of 2010 also created a [Center for Medicare and Medicaid Innovation](#) (4), with the specific purpose of identifying interventions to address the triple aim of: improving the overall health of the population, enhancing the patient experience of care, and reducing the per capita cost of patient care (Institute of Healthcare Improvement).

Upon review of a series of documents issued by Health & Human Services, we discovered that a number of concerning federal government reports and events released/occurring in 2010-2011 likely lead to the exacerbation of the opioid crisis and the ensuing crisis of untreated pain and suicide that we see today. It was during these years that the government created a framework to undermine the serious nature of chronic medical conditions in favor of the promotion of “healthy” or “wellness” based living. This may have caused the costs to health insurers and the government to decrease, but the costs of adopting such a framework would be high for sufferers of chronic illness often caused by complex genetic, biochemical, anatomical, etc. factors, and not “curable” with simple lifestyle changes, etc.:

- [Healthy People 2010](#) (5) established leading “health indicators” to reflect federal public health concerns in the US. The initiative focused on disease prevention, with little regard for the needs of chronically ill populations, recommending one-size-fits-all approaches to health and “healthy life indicators,” like “vigorous exercise.”
- The Arthritis Foundation sought assistance from the Institute of Medicine (IOM) to identify **population-based public health actions** that could, allegedly, help reduce disability and improve functioning and quality of life among individuals who are at “high risk” of developing a chronic illness, and those with one or more chronic illnesses.
- The IOM issued the ‘[Living Well with Chronic Illness](#)’(6) report, which outlined a number of issues relevant to those living with chronic illness, as well as the role of the healthcare delivery system in addressing them. There were 9 diseases chosen for the purposes of the soon-to-come population-based study: arthritis, cancer survivorship, chronic pain, dementia, depression, type 2 diabetes, posttraumatic disabling conditions, schizophrenia, vision, and hearing loss.
- IOM’s ‘[Living Well with Chronic Illness](#)’ also set the parameters for the soon-to-come population study, one of which dictated the study focus on African Americans, Hispanic Americans, Asian Americans, American Indians and women with chronic pain. It is noteworthy that the targeted groups for the study included all major U.S. populations *with the exception of white males*.
- The development of the "Health in All Policies" (HIAP) approach, supported by "Health Impact Assessments." The CDC defines the HIAP approach as “one way to achieve the National Prevention Strategy and Healthy People goals and enhance the potential for state, territorial, and local health departments to improve health outcomes.” The National Prevention Council consists of the secretary of every agency in the nation, which permits the HIAP approach to be implemented

into all facets of society. HIAP allows secretary heads to communicate with other stakeholders regarding any regulatory and legal changes that must take place in achieving Healthy People, etc. study goals. Of note: HIAP analysis work is currently underway at the University of California, Los Angeles and the San Francisco Dept. of Health.

- Other discriminatory parameters/acknowledgements outlined in the IOM report included, but were not limited to:
 - *"The direct costs associated with chronic illness have many adverse societal consequences, including that they undermine the public and private health insurance programs."*
 - *"The committee was advised by the sponsors of this study not to focus on the common high-mortality disease but rather consider disease that have the potential to cause or that actually cause functional limitations and/or disabilities."*

Since 2010-2011, the Institute of Medicine published an additional report recommending leading health indicators for [Healthy People 2020](#) (2011) (7). And HHS has subsequently recommended the HIAP as a planning resource for implementing [Healthy People 2020](#) (7).

In order to determine if the program and community goals of the 2010-2011 government initiatives were being met, a comprehensive surveillance system was required, one that included *incentives* for individuals and organizations to participate in surveillance activities. The state Prescription Drug Monitoring Programs (PDMPs) that have since been built in all 50 states have helped accomplish this goal, but as the government itself has acknowledged, there are still "many barriers continue to prevent optimal integration and use of the data." (CIAAG points out that these include those "pesky" HIPAA laws, rules surrounding use of and access to the PDMPs, and human clinical trial rules, regulations and ethical considerations).

The below agencies have been charged with the responsibility to track the state level policies that pertain to chronic illness:

- National Council for State Legislatures
- National Governors Association
- National Academy of State Health Policy

All in the name of cutting costs?

The Institute of Medicine (IOM's) "Living Well with Chronic Illness" report set goals for federal health agencies and others to *create and promulgate guidelines* to catalogue and evaluate the effectiveness of clinical healthcare services for persons with chronic illness. They also defined how the guidelines should be disseminated to various public health agencies and healthcare organizations/providers, in order to implement them.

Since its inception, the stated goals of “Living Well with Chronic Illness” have been to identify social and economic determinants of health, as well as the indicators that lead to chronic illness, and to develop and implement policies to encourage a healthy lifestyle and prevent the development of often painful, incurable conditions in future generations.

Prior to the issuance of the Affordable Care Act (ACA) in 2010, healthcare policy was devised to improve the health outcome of individuals based on individualized medical needs, regimen and treatment. In contrast, the goal of public health has been to improve the health status of the *population* through steps such as public health promotional activities and disease prevention measures. Sections of the ACA and subsequent actions from HHS and related agencies have created research guidelines and policies, however, that attempt to combine individual health needs and societal needs into one single silo.

“Living Well with Chronic Illness” was released around the time of the ACA’s adoption, when the government began considering healthcare outcomes (even those relevant to individual health) in the context of how they would impact *society*, rather than considering the health outcome/benefit to the individual. Further, as the U.S. health system under the Affordable Care Act transformed from a from fee-for-service model to that of an [accountable care organization](#),⁽⁸⁾ what was best for individual patients was not always what was best for keeping costs down.

The government understood that the less a population got sick, the less the costs to a government-funded healthcare program like the ACA. But what was to happen to patients with chronic illness? If they could “get better” by implementing the lifestyle changes recommended in the government’s reports, costs could be cut dramatically. Nevermind the fact that the nature of “chronic” illness/pain is that it does not “get better,” but must instead be medically managed for the comfort and health goals of the individual patient.

At the same time the government was considering how to cut healthcare costs with the rollout of the ACA, the CDC released a Public Health Action Plan (2011) on mental health promotion and chronic disease prevention, which contained 8 strategies to integrate mental health and public health programs to address chronic disease. The committee recommended combining what it considered “related” illnesses as “public health” (or as we have seen, individual health) challenges to overcome, in order to “avoid the trap of pitting one disease against another in competing for resources and attention. It [the CDC plan] conceptualizes the commonalities across diseases with the intent of developing strategies that benefit all affected by the vast array of chronic diseases.”

HHS too has recommended combining “related” illnesses (such as substance abuse and chronic illness, or anxiety and chronic pain), and it appears it has *in-fact strategized* to combine the public health response to the “opioid crisis” with the goals outlined in “Living Well with Chronic Illness.” Along with the CDC, HHS has conflated the two into a single public health campaign addressing (and erroneously connecting) both substance use disorder and chronic pain/use of prescribed pain prescriptions as a similar “challenge” to overcome. Finally, a number of subsequent documents released from

Institute of Medicine and CDC have also made explicit recommendations for changes in healthcare policy delivery that involve the integration of mental and physical health.

Unfortunately, we've seen the result of these misguided definitions/policies. Chronic pain patients who use opioid pain medications responsibly have been lumped in with those who misuse opioids (prescription and/or illicit). Some ill-informed politicians and members of the media have even deemed the use of opioids for pain and illness a lesser form of substance use disorder. In the media and at the legislative level, both in states and federally, the response to the opioid crisis is taking precedence over any response to the untreated pain crisis that's now occurring, with many policymakers stating that once the opioid abuse crisis is "reigned in," those needing opioids for pain will finally be the subject of their attention via more funding for research, for better pain treatments, etc. Patients in pain are also being told, increasingly, that their pain is all in their "minds." Stress reduction techniques, mental health services and the rest are being offered for serious pain and illness, while appropriate pain medication is being withheld. Unfortunately, without effective, alternative pain medication, patients in pain are killing themselves.

Perhaps not surprisingly, The committee members anticipated public resistance to the proposed messaging/study, specifically noting how Americans value personal choice, freedom and privacy: "For this reason, it is critical to integrate healthcare policy with public health policy and *reframe* them both to be consistent with other societal values."

Below is a list of additional reports/actions the federal government issued/took to assist with the implementation of Healthy People and other related chronic illness healthcare cost-cutting initiatives it rolled out around the time of the ACA

- The [Public Health Action Plan to Integrate Mental Health Promotion and Mental Illness Prevention with Chronic Disease Prevention](#) (CDC, 2011c) (9), which stated healthcare providers should "stress the importance of mental health in...preventing or reducing disability and death from chronic disease." The plan suggested the federal government "define the impact of coping, depression, and other emotional responses to [chronic physical illnesses such as] arthritis." It also emphasized "surveillance" as a way for various agencies to measure progress towards meeting Healthy People initiative goals.

- The "[National Action Plan to Improve Health Literacy](#)" (2010) (10), which further worked to coordinate care between various "professionals, policymakers, communities, individuals, and families" to track the success of the Healthy People initiative.

- The Institute of Medicine (IOM's) 2011 "[Public Health: Revitalizing Law and Policy to Meet the New Challenges](#)"(11). This document described these policies and made detailed recommendations about the need to review and *revise* various public health policies and *laws* in order to improve population health.- The ACA of 2010 required the Secretary of Health & Human Services to contract with IOM, which subsequently issued "[Relieving Pain in America](#)"(12) (June 2011).

- HHS appointed the [Interagency Pain Research Coordinating Committee](#) (13) (IPRCC) to coordinate all pain research efforts with HHS and across the other Federal Agencies.

- October 2012: Assistance Secretary of HHS asked IPRCC to oversee the creation of the comprehensive population health level strategy (a population Study which was requested by the Arthritis Foundation and, in the opinion of CIAAG, constitutes a [pragmatic clinical trial](#), which by law requires the informed consent of those being study but which was performed on its “subjects” without their knowledge or consent.) (14)
A population-wide, non-consensual clinical trial is born

After initiating the aforementioned non-consensual arthritis study, the IPRCC and National Institutes of Health partnered to establish a framework for developing a National Pain Strategy in consultation with the chair and vice chair of IOM committee. IPRCC selected an expert working group to address 6 key areas that would comprise the National Pain Strategy:

1. Population Research
2. Prevention & Care
3. Disparities
4. Service Delivery & Payment
5. Professional Education & Training
6. Public Education & Communication

The first objective of the National Pain Strategy was to confirm the [# of high impact chronic pain](#) sufferers (defined as those experiencing chronic pain that frequently limited life or work activities) (15) and the categories of the conditions the study would be tracking as part of its “population research.” The second objective defined the collaborators to be used, including:

- The Patient-Centered Outcomes Research Institute, or [PCORI](#) (16), an NGO that was created as part of a modification to the *Social Security Act* by Clauses in the ACA.
- Stanford University
- Other Federal Agencies:
 - Centers of Disease Control
 - Agency for Healthcare Research & Quality
 - Centers for Medicare & Medicaid Services
 - Food & Drug Administration
 - Office of the National Coordinator
 - National Institute of Health
 - Public & Private Health Insurers
 - Professional Organizations

Through a systematic review of the various agencies and organizations involved, our research team identified a number of stakeholders participating in the creation, implementation and dissemination of information for the National Pain Strategy’s unethical and likely illegal population-based study of chronic pain patients.

- The CDC contracted with the government **affairs/technical assistance** and implementation firm Abt Associates, allegedly to help roll out their guidelines to

support safe prescribing and reduce the adverse consequences of opioid use. See [CDC developed a prescribing guidelines](#)⁽¹⁷⁾, March 15, 2016. In reality, the guidelines were used to reduce or eliminate chronic pain patient access to needed opioid pain medication.

- Abt synthesized, researched and assembled evidence tables and provided editorial support for the guideline’s draft clinical recommendations on opioid “ceilings” for pain patients. Abt “conducted rapid literature reviews on the harms associated with the use of opioids for chronic and acute pain; the harms of combining opioids with alcohol, other prescription drugs and illicit drugs; the effectiveness of non-opioid treatments for pain; patient and provider values and preferences specific to opioids; the cost-effectiveness of opioid therapy for chronic pain; and the impact of prescription drug monitoring programs on prescribing behavior and patient outcomes.” Abt and the CDC’s rapid and reckless introduction of poorly researched guidelines directly led to the untreated pain epidemic and pain patient suicides we are seeing today.
 - The CDC hired Abt Associates to develop a coordinated care plan (CCP) for “safe” opioid prescribing. **This plan included dosing thresholds.** This plan was communicated to the medical community nationally.
- March 16, 2016 HHS’ Agency for Healthcare Research and Quality (**AHRQ**) issued grant # R18HS0237850 / AHRQ for: “Improving Opioid Care” to fund a project called the Six Building Blocks, or “six key work areas you [physicians] need to redesign to improve your clinic’s management of patients who are on long-term opioid therapy.” *It is noteworthy that this HHS grant was provided just 1 day after the CDC guidelines were issued publicly.*
 - Additional funding for the Six Building Blocks project was awarded by the Washington State Department of Health Subcontract HED23124 of Cooperative U17CE002737, funded by the Centers of Disease Control (See appendix A). It’s interesting to note that this grant publication states: “*This project is solely the responsibility of the authors and does not represent the views of the **AHRQ**, CDC, or WA DOH*”, particularly since the Six Building Blocks that were funded via this grant were in the sole control of these agencies and are now being used to implement changes into the public health system. It is also important to note that the private insurer Kaiser Permanente was involved in the Six Building Blocks grant study (and that Kaiser, in their materials and in visits with their doctors, is notorious for promoting a “mental” health approach to physical chronic health issues.)
 - The **AHRQ** gave funds to ABT Associates to evaluate and implement the [Six Building Blocks](#)⁽¹⁸⁾. The Six Building Blocks program would go on to provide healthcare providers and programs in the U.S. with the structure needed to implement a new delivery care model that aligns with the goals outlined in “Living Well with Chronic Illness.” **This model inappropriately and outrageously encourages self-management for those living with serious chronic pain and illness.** It is important to note that the outcome of everything

described in this briefing is that those living with chronic illness and pain now being **involuntarily pushed** into these **cost-cutting** (for insurance companies, the ACA) “self-management” programs, which including mental “coping skills” and cognitive behavioral health interventions to address complex physical maladies. Self management also includes techniques such as “meditation” in lieu of the science-based, clinically appropriate healthcare services and medications formerly provided by to those with chronic illness/pain by their primary care doctors and/or specialists. The result is nothing short of widespread **human rights abuses**.

- Of note: The **AHRQ**’s website, which previously stored 20 years of medical best practices, was defunded and shut down on July 16, 2018. The site noted that “summaries of guidelines” were going to be issued in lieu of the previous database that permitted clinicians to view guidelines with supporting clinical research.
 - The removal of clinical research/best practices in treating medical conditions allows the AHRQ and other stakeholders charged with developing the chronic illness guidelines the ability to publish their harmful “self-management” recommendations without supporting data and/or necessary clinical trials for safety and efficiency.
- **Well Being Trust** is a national foundation that describes itself as “dedicated to advancing the mental, social and spiritual health of the nation.” This organization has been charged with overseeing a portion of the Six Building Blocks study and directing government officials to implement changes to the public health policy/laws to align with the goals identified in the study. CIAAG recommends Congress research further what parties are funding and directing the activities of this organization.
- **Trust for America’s Health** “makes the prevention of illness of illness and injury a national priority.” The organization promotes “cost control” of healthcare in the states, especially as it relates to treating chronic illness and “prevention.” Well Being Trust and Kaiser Permanent are funders. CIAAG recommends Congress research this organization as well.
- **Robert Wood Foundation and Providence St. Joseph Health** co-funded “[Pain in the Nation](#)”⁽¹⁹⁾ and the National “[Resilience Strategy](#)”⁽²⁰⁾ The Resilience Strategy website asks “How do we care for people in pain?” and recommends improving “substance use disorder treatment services” and increasing “medication assisted treatment” for this population, which is *not* appropriate for those with chronic pain at all, but is to be used for those in recovery from substance use disorder. The “strategy” again conflates people in need of pain medication with those with substance use disorder.
- **Brandies Opioid Collaborative** The Opioid Policy Research Collaborative (OPRC), based in the [Institute for Behavioral Health](#) ⁽²¹⁾ (IBH) of the [Schneider Institutes for Health Policy](#)⁽²²⁾ at [Brandeis University Heller School for Social Policy and Management](#)⁽²³⁾, is advancing scholarship on interventions to address

the opioid addiction epidemic. They are serving as a primary resource for state and federal health officials, policymakers and private organizations and play prominent roles in **four key areas**:

- **Providing research:** OPRC generates research to evaluate local, state and national interventions and policies that have been implemented in response to the opioid crisis.
- **Offering policy “solutions”:** OPRC develops guidance and recommendations for a wide range of stakeholders, including federal, state and local government agencies, health care systems, and industry.
- **Serving as a “convener and collaborator”:** OPRC brings together researchers, clinicians and policymakers from diverse disciplines to develop coordinated strategies for responding to the opioid addiction epidemic. The collaborative creates opportunities for university faculty to collaborate with other top researchers in the fields of public health, health services research, epidemiology, addiction treatment, medical education and drug policy.
- **Public relations/propaganda:** OPRC shares findings from innovative research and policy initiatives across academic, medical, nonprofit and government fields. OPRC works closely with media outlets to highlight key accomplishments for an even wider audience.

Violation of a Nation:

We as a nation face many complex issues every day. The needs of all citizens must be weighed and balanced carefully for the benefit of society and for the safety, health and prosperity of the country. Chronic illness accounts for 70% of all deaths worldwide (2008), with over 48 million Americans reporting a disability related to chronic illness (CDC, 2009) and more than 1 in 4 having 2 or more chronic conditions.

The medical care costs for these individuals represent 75% of the \$2 trillion dollars the United States spends annually on healthcare (Kaiser Family Foundation, 2010). By 2030, the economic burden of non-communicable chronic disease is estimated to be \$47 trillion (Bloom et al., 2011).

It is estimated that the financial costs associated with chronic disease will account for 69% of all global deaths by 2030, and 80% of those deaths will occur in low-income and middle-income countries.

The anticipated increase in costs are being driven by the aging of our nation as the first baby boomers reach retirement age of 65 in 2011. Of these, 37 million, or 6 out of 10, will be managing one or more chronic diseases by 2030.

In addition, cancer rates are expected to increase in all non-white racial and ethnic groups between 2000 and 2030, with a projected increase of 31% in whites and 99% in non-white racial and ethnic groups.

Under the Affordable Care Act (ACA), Health & Human Services (HHS) was granted expanded authority to address the impact chronic illness and disease has on society and the economy.

In an attempt to better understand the mechanisms of chronic illness and disease, HHS deployed a number of measures into the public and private healthcare system through its newly granted powers via the ACA. In particular, the agency launched a population-based study to be deployed through the existing and transforming national healthcare delivery system.

In 2010, the Institute of Medicine was contracted by the Arthritis Foundation, which appointed a committee for the early development of what would soon become the population-wide study. Interestingly, the committee recommended the study focuses on illnesses that result in disability and limited function rather than on those with a high morbidity.

While the study may have been well intended, the execution of it has introduced numerous ethical, moral and legal issues that must be addressed by our elected officials immediately:

1. **Informed Consent:** Respect for persons requires that subjects, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them.

2. **Comprehension:** The manner and context in which information is conveyed is as important as the information itself.
3. **Voluntariness:** An agreement to participate in a research study constitutes valid consent *only* if voluntarily given. Investigators are responsible for ascertaining that the subject has comprehended this information.

The population-based study that has been implemented into the American healthcare system violates all three basic mechanisms of a valid clinical trial.

Furthermore, in order for a pragmatic clinical trial of this nature to take place via the healthcare system, certain concerning and likely illegal elements had to be present, including but not limited to:

1. A lack of informed consent, comprehension and voluntariness among study “participants.”
2. A lack of proper protocols established for each of the trials taking place
3. No published identification of the control group being studied
4. Barriers to individual citizen’s ability to access their needed healthcare services. This was unfortunately manipulated by the study investigators/other stakeholders (such as policy makers) for the sake of the study (e.g. “Can we cut costs and not treat those with chronic illness?” “Will they accept meditation as a treatment if denied medication?”)
5. Federal and state laws being actively changed by the government, without consideration of the implications to patients, healthcare providers, and other populations, to help enable to execution of the study trial upon the public.
6. *Mandating* the adoption of lifestyle and treatment changes for those with chronic illness/disease, including but not limited to:
 - a. Physical activity
 - b. Diet
 - c. Tobacco use
 - d. Screenings and vaccinations
2. Investigators actively changing the study variables to measure the outcome by working directly with state and national legislative bodies and other stakeholders to promote “best practices.” However, these “best practices” are in-fact untested and a part of the new population-based study. Yet, rather than changing public policy to redirect the study (when negative outcomes are found), CIAAG is seeing that the variables are simply being changed to comply with the underlying population study and desired social outcomes (e.g. If meditation does not help fix your chronic, complex medical condition, try pain acceptance or tai-chi, etc..).

Further, upon review of the Health & Human Services own report, “*lifestyle behavior changes cannot generally substitute for effective medical management of chronic illness but often supports ‘Living Well.’*”

Throughout the preliminary report “Living Well with Chronic Illness,” the committee acknowledged that the implementation of the study into the healthcare system would be based upon the *theory* that chronic illness patients would benefit from the study’s

proposed alternative therapies (tai-chi, mindfulness, meditation, cognitive behavioral therapy, acupuncture, massage therapy, pain acceptance, and self management). Ultimately, the committee reasoned, the results would help guide public health policy and legislative changes to combat the economic costs of chronic illness on society. It was noted by the committee that these changes **may not be beneficial to the individual patient** but are preferable for society and were “intended to direct or influence the actions, behaviors or decisions of others.”

It's clear the study was launched to “transform” America's healthcare system from a focus on the individual's personal health status to that of societal health and the will (and cost concerns) of our legislative, executive and judicial branches of government.

The committee noted: “Americans value their health, many also value their ability to make individual choices about healthcare, health behavior and quality of life.” This statement is very telling that stakeholders knew the American public would not accept the government dictating what they should and should not do with their personal behavior, including the effective medical treatments they could pursue for their underlying conditions.

Given their awareness that the American public would resist being experimented on in an inhumane manner with often painful health implications, its clear stakeholders implemented the study **without disclosure to the public**. What's more, federal Agencies and other stakeholders are being used *to this day* to **disseminate the study guidelines** throughout the nation via medical conferences, state regulations and law enforcement, the internet and patient advocacy groups.

The Kaiser Family Foundation, the Robert Wood Johnson Foundation, the National Association for State Health Policy, the Commonwealth Fund and parties who stand to gain financially from the expansion of the addiction treatment industry are those the federal government is relying on for information and advice on current and needed federal and state laws and policies as they relate to chronic illness. In addition, the Well Being Trust and Trust for America's Health are being used to inform local, state and national policy as they relate to chronic illness. All of this activity has taken place without public input or transparency, placing the power of the entire healthcare system, along with the handling of the country's “opioid crisis,” in the hands of a small group of privately appointed stakeholders. These same invested stakeholders appear to have undue influence over health policy, including access to medicine, addiction treatment services and the laws that govern medicinal supply chains, thereby **creating a de facto monopoly** with a concerning **concentration of power** with no effective checks, balances or independent review.

Numerous laws have already been enacted to permit this study to even take place. It appears consumer and patient privacy is still at risk as the laws warp and bend to accommodate the “needs” of researchers. Most recently, the federal docket has proposed changes to [HIPAA](#) (24) that would allow for increased healthcare information sharing in order to permit the gathering of Americans' private Electronic Medical Records and Electronic Health Records by investigators and other stakeholders, including data mining

organizations that assign “opioid risk scores” to humans (based on unknown algorithms), such as Appriss Health.

The Food & Drug Administration (FDA) has also issued a “[Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects](#).”⁽²⁵⁾ This proposal was not allowed the customary and often required 180-day public comment period; rather it was passed and issued for immediate release in February 2019. The chronic pain patient population-wide study/clinical trial was implemented under the assumption of “minimal risk to human subjects.” Rather than having to get approval for this waiver prior to a study’s implementation, the FDA can now close this legal loophole and proceed without violating the law, post fact (regardless of violations to “human subjects.”)

A chilling conclusion

The previously noted reports issued by HHS and their associated committee provides the parameters for the study, the agencies to be used, and the goals of each agency. A careful review of the Institute of Medicine: “[Living Well with Chronic Illness](#)”⁽⁶⁾ and “[Relieving Pain in America](#)”⁽¹²⁾ along with the “[National Pain Strategy](#)”⁽²⁶⁾, reveals that they are directly related documents that relate to one another.

The issuance of the CDC Opioid Guidelines in March 2016 were in fact satisfying the requirements outlined in the Institute of Medicine’s Report: “[Living Well with Chronic Illness](#)”⁽⁶⁾, which as we outlined earlier in this report, called for various “guidelines” to be devised and implemented into society using the healthcare delivery system.

The CDC’s opioid guidelines have long been contested by the patient and medical community as far-reaching and inappropriate since their issuance. They have caused widespread pain and suffering for patients. To this date, there has largely been no action or recognition of how the CDC opioid guidelines have impacted patient care. There has been no attempt by the CDC to make any corrective statements to curb the misapplication of these guidelines (despite the agency admitting they have been misapplied to chronic pain patients). This misapplication has lead to widespread patient abandonment, forced tapering from stable medical regimes, medical neglect, bodily injury, suicides and psychological harms taking place despite demands to stop the suffering from distinguished organizations ranging from the [American Medical Association](#)⁽²⁷⁾ to [Human Rights Watch](#)⁽²⁸⁾. Countless citizens have delivered phone calls and emails to the CDC begging them, on their own behalf and that of their loved ones, to publicly decry the guidelines so that doctors will restore access to medication for chronically ill patients.

It is apparent the ACA’s population-based study is at the root of the CDC Guidelines. As such, there it is the responsibility of the Secretary of Health and Human Services, who is overseeing the study, to instruct the Centers of Disease Control to issue the requested “corrective statement” making clear the intent and legal application of the 2016 CDC Guidelines. In addition, granted within these authorities is the power of the study’s investigators to devise revised guidelines based upon the current outcome of their study. Given the overwhelming outcry from the constituents living with chronic illness and

pain, it is irresponsible at this juncture for Health & Human Services to fail to correct course.

In addition, there must be public transparency in formulating any forthcoming healthcare system changes or planned changes, to ensure these changes are intended to benefit patient care and support the quality of life of the individual healthcare consumer.

Patient access to opioid analgesics is a necessity for post operative, acute and emergency care as well as the long-term treatment of incurable illness and disease. The United States has a history of being a humanitarian country and as such we have a duty to our citizens and to the world to maintain the proper line between drug diversion and medicinal/scientific use. The implementation of an illegal population-based study with painful and even deadly direct effects on patient populations has not only revealed, but by its very nature worsened a failure in the healthcare system and caused a betrayal of the trust between the governed and the government, as well as trust in the sanctity of the doctor-patient relationship.

Given the dramatic increase in suicides since the issuance of the CDC opioid guidelines, as well as patient decline in physical condition and quality of life, we at Chronic Illness Advocacy & Awareness Group specifically request a Congressional investigation of the population-wide study, the organizations engaged by HHS and related agencies. We are also available to discuss meaningful national legislation to, moving forward, protect the rights of those with chronic pain and illness.

Sincerely,

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