Pain Strategy Proposal

The Violation of a Nation
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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.
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 the 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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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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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 autoimmune 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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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 Congress & Senate
1600 Pennsylvania Avenue NW
Washington, DC 20510

RE: Implementing a Crisis

Dear Honorable Members of Congress & Senate:

Chronic Illness Advocacy & Awareness Group, Inc., is a national non-profit representing the 100 million American citizens whom suffer from chronic pain from either chronic illness, disease and/or incurable conditions. As you know America is facing an unprecedented overdose crisis which has drastically increased in the past 5 years despite efforts to reduce prescribing. Prescribing of opioid medication is at a 25 year low (1) but overdoses are at an all time high which highlights the fact that our country’s issue is not fueled by legally prescribed opioid medication, but is instead the result of illicit carfentanil and heroin flooding our streets causing an overdose crisis.

In the following pages we outlined our research findings regarding the issuance of the controversial “Centers of Disease Control and Prevention’s, Opioid Guidelines.” To date there has largely been no answers to the public outcry regarding the impact these guidelines have on healthcare services and patient quality of life. The public narrative surrounding these guidelines were that they were merely issued in part due to the “opioid crisis.” Our findings are that these guidelines are actually a part of a population based study that has been implemented into the healthcare delivery system without the American citizens consent, or even knowledge this study was taking place. In review of its execution our Organization has serious concerns of conflict of interest, potential financial incentives between parties of the study, privacy, constitutional, legal, ethical and moral violations that have, and continue to take place.

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

The PPACA of 2010 also created the new Center for Medicare and Medicaid Innovation (4), which is specifically seeking to identify interventions to address the triple aim of public health of improving health of the population, enhancing the patient experience of care and reducing the per capita cost of care (Institute of Healthcare Improvement).
Upon review of a series of reports issued by Health & Human Services there were a number of events that took place in 2010, all of which lead to the exacerbation of opioid crisis and the ensuing crisis of untreated pain and suicides we see today.

- **Healthy People 2010** (5) established leading health indicators to reflect major public health concerns in the USA.

- In "2010 Arthritis Foundation sought assistance from Institute of Medicines (IOM) to identify the population-based public health actions that can 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 illness"

- In response, the Institute of Medicine (IMO) issued the ‘Living Well with Chronic Illness’(6) report in 2011. This report outlines a number of issues related to those living with chronic illness as well as the healthcare delivery system. There were 9 diseases chosen for the purposes of the population-based study.

- The 9 Diseases selected are arthritis, cancer survivorship, chronic pain, dementia, depression, type 2 diabetes, posttraumatic disabling conditions, schizophrenia, vision and hearing loss.

- The report further goes on to set the parameters for the study, one of which dictates the study is to focus on African Americans, Hispanic Americans, Asian Americans, American Indians and differentiating women’s pain. It is noteworthy that the targeted groups for the study includes all populations with the exception of white males.

- Other parameters outlined in the report include, but are not 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."
  
  - Supported "Health in All Policies" Approach supported by the "Health Impact Assessments" which seeks to assess the health implications of health and non-public health.

    **HIAP work is under way at:**
    
    University of California
    Los Angeles
    San Francisco Dept of Health

- The Institute of Medicine published an additional report recommending leading health indicators for **Healthy People 2020** (2011) (7)
HHS subsequently recommended the HIAP as a planning resource for implementing Healthy People 2020 (7).

In order to determine if the program and community goals are being met, a comprehensive surveillance system is required that includes incentives for individuals and organizations to participate in surveillance activities. There are "many barriers continue to prevent optimal integration and use of the data" (including HIPAA, state Prescription Drug Monitoring Programs, Human Clinical Trial Rules, Regulations and Ethical considerations).

The Living Well with Chronic Illness report further sets goals for the federal health and related agencies to create and promulgate guidelines for general, community and clinical preventive services evaluate the effectiveness of these services for persons with chronic illness and specifically catalog and disseminate these guidelines to the public health agencies and the health care organizations to implement them.

The goal of Living Well with Chronic Illness is to identify social and economic determinants of health as well as other indicators that lead to chronic illness. And, for policies to be implemented to encourage a healthy lifestyle to prevent the development of these painful, incurable conditions in future generations.

Prior to the issuance of the ACA in 2010, healthcare was devised to improve the health outcome of individuals based on individualized medical regimen and treatment. In contrast, the goal of public health is to improve the health status of the population through public health promotional activities and disease prevention measures. The ACA and subsequent actions from HHS and related agencies are an attempt to combine individual health and society health into a single silo. Thereby, a focus is now being placed upon the outcome of healthcare in the context of how it will impact society rather than a focus on the individuals’ outcome. It further goes to provide a guide for broader concepts related to the transformation of the health systems from fee for service to accountable care organization(s).

The below agencies are charged with the responsible 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

At the same time this was occuring, the CDC released a Public Health Action Plan (2011) on mental health promotion and chronic disease prevention which contains 8 strategies to integrate mental health and public health programs that address chronic disease.
The committee recommended to combine related illnesses to “avoids the trap of pitting one disease against another in competing for resources and attention. it conceptualizes the commonalities across diseases with the intent of developing strategies that benefit all affected by the vast array of chronic diseases."

As such, socially we have seen this trending in the Media and with our Legislative bodies as the response to the opioid crisis is taking precedence over the untreated pain crisis with Legislative response advising once the opioid crisis is “reigned in” that people with pain’s issue will be addressed via research and better pain treatments.

However, in recommending the combination of related illnesses, it appears that HHS has in-fact strategized to combine the public health response to the “opioid crisis” with the goals outlined “Living Well with Chronic Illness” into a singular public health campaign.

There have been a number of subsequential documents released from Institute of Medicine and CDC providing recommendations for changes in healthcare policy delivery integrating mental and physical health.

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. This permits the Secretary heads to communicate with other stakeholders regarding the regulatory and legal changes that must take place. This also allows full implementation of the HIAP approach.

The committee members noted they anticipated public resistance to the proposed agenda specifically noting how American’s value personal choice, freedoms and privacy concerns. “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.”

Additional Reports Issued to assist with the implementation process:

Public Health Action Plan to Integrate Mental Health Promotion and Mental Illness Prevention with Chronic Disease Prevention (CDC, 2011c) (9)

"National Action Plan to Improve Health Literacy” (2010) (10)

Institute of Medicine (2011) issued the "Public Health: Revitalizing Law and Policy to Meet the New Challenges”(11) This document describes these policies and makes detailed recommendations about the need to review and revise various public health policies and laws in order to improve population health.

- The PPACA of 2010 required the Secretary of Health & Human Services to contract with Institute of Medicines who subsequently issued “Relieving Pain in America”(12) (June 2011).
- HHS appointed the Interagency Pain Research Coordinating Committee (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. *(Population Study which was requested by Arthritis Foundation & IMO and is a pragmatic clinical trial)*

- The IPRCC and National Institute of Health then established a framework for developing a National Pain Strategy in consult with the Chair and Vice Chair on the Institute of Medicine’s Committee.

- IPRCC selected a expert working group to address each of the 6 key areas in the National Pain Strategy:
  1. Population Research
  2. Prevention & Care
  3. Disparities
  4. Service Delivery & Payment
  5. Professional Education & Training
  6. Public Education & Communication

- Objective 1: of the National Pain Strategy: Confirm the # of high impact chronic pain and the categories of conditions they are tracking.

- Objected 2: Collaborators to be used:
  - PCORI NGO created as part of a modification to the Social Security Act by Clauses in the Patient Protection & Affordable Care Act
  - 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

A systematic review of the various agencies and organizations our research team identified a number of stakeholders involved in the creation, implementation and dissemination of information for the population based study to take place.
Centers of Disease Control contracted with Abt Associates to support safe prescribing and reduce the adverse consequences of opioid use, CDC developed a prescribing guidelines. (17) March 15, 2016.

- Abt synthesized research, assembled evidence tables and provided editorial support for draft clinical recommendations. We 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.
- CDC hired Abt Associates to develop a coordinated care plan (CCP) for safe opioid prescribing. This included limit dosing thresholds.

March 16, 2016 Grant # R18HS0237850 / AHRQ for: “Improving Opioid Care” It is noteworthy this grant was provided just 1 day after CDC Guidelines were issued publically. Additional funding awarded by the Washington State Department of Health Subcontract HED23124 of Cooperative U17CE002737, funded by the Centers of Disease Control. (Appendix A)

The 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.” However, the 6 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.

Agency for Healthcare Research and Quality (AHRQ) funded ABT Associates to Evaluate and Implement the 6 Building Blocks (18) which is the structure of multiple programs in the United States which are concerned with implementing a new delivery care model; which aligns with the goals outlined “Living Well with Chronic Illness” encouraging self-management goals and clinic goals for those living with chronic illness.

- It is important to note that those living with chronic illness pain are now being involuntarily pushed into “self-management” programs including coping skills, cognitive behavioral health interventions and meditation in lieu of previously healthcare services provided by their Primary Care and/or Specialists.

Agency for Health Research and Quality’s website previously stored 20 years of medical best practices were 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 the supporting research.

- The removal of clinical research of best practices permits AHRQ and the other stakeholders of population study whom were charged with developing the chronic illness guidelines the ability to publish their recommendations without the supporting data and/or necessary clinical trials for safety and efficiency.
- **Well Being Trust** is a national foundation dedicated to advancing the mental, social and spiritual health of the nation. This organization has been charged with overseeing a portion of the study and directing Officials to necessary changes to the public health policy/laws to align with the goals they’ve identify.

- **Trust for America’s** “makes the prevention of illness of illness and injury a national priority.”

- **Robert Wood Foundation and Providence St. Joseph Health** co-funded “Pain in the Nation”(19) and the National “Resilience Strategy”(20)

- **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 Cutting-Edge Research:** OPRC generates research to objectively evaluate local, state and national interventions and policies that have been implemented in response to the opioid crisis.
  - **Offering Innovative Policy Initiatives:** OPRC develops evidence-based 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.
  - **Communicating Activities, Outcomes and Accomplishments:** 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 nation. 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 Americans have 2 or more chronic conditions.

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

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 ACA, Health & Human Services was granted additional 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, Health & Human Services deployed a number of measures into public and private healthcare system with newly granted powers via the ACA. In particular, they launched a population based study to be deployed through the healthcare delivery system.

The Institute of Medicine was contracted by the Arthritis Foundation in 2010 whom appointed a committee for the development of the study. The committee recommended the study to focus on illnesses that result in disability and limited function rather than those with a high morbidity.

While the study is well intended the execution of it has numerous ethical, moral and legal considerations 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 happened 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 the research constitutes a valid consent only if voluntarily given. Investigators are responsible for ascertaining that the subject has comprehended the information.
The population based study that was implemented into the American healthcare system violates all three basic mechanisms of a valid clinical trial. In order for a pragmatic clinical trial of this nature to take place via the healthcare system there must be certain elements present including but not limited to:

1. Informed Consent, Comprehension and Voluntariness
2. Proper Protocols for each of the trials taking place
3. Identify the Control Group to be studied
4. Individual citizens access to their healthcare services should not be manipulated by the Investigators or other stakeholders, such as policy makers and other officials.
5. The Federal and State laws are being actively changed to help enable to execution of the trial upon the public.
6. The study calls for adoption of lifestyle and treatment changes for those with chronic illness/disease including but not limited to:
   a. Physical Activity
   b. Diet
   c. Tobacco
   d. Screening & Vaccination
7. The investigators are actively changing the variables to measure the outcome by working directly with the Legislative bodies and other stakeholders to promote “best practices” However, these said “best practices” are in-fact untested and a part of the population based study. Yet, rather than the study outcomes changing public policy to redirect the study (when negative outcomes are found), the variables are simply being changed to comply with the underlying population study and desired social outcomes.

Further, upon review of the Health & Human Services own reports, “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 acknowledges that the implementation of the study into the healthcare system is based upon the theory that chronic illness patients will benefit the proposed alternatives therapies (tai-chi, mindfulness, meditation, cognitive behavioral therapy, acupuncture, massage therapy, pain acceptance, and self management). Ultimately, the results will help guide public health policy and legislative changes to combat the economic costs of chronic illness on society. It was noted that these changes may not be beneficial to the individual patient but are preferable for society and “is intended to direct or influence the actions, behaviors or decisions of others.”

Therefore, this study was launched to “transform” America’s healthcare system from focusing on the individuals personal health status and shifting focus to the societal health and the will of our legislative, executive and judicial branches of the 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 the stakeholders knew the American public would not accept the Government dictating what they should and should not do with their personal behavior, including the medical treatments they would pursue for their underlying conditions.

Given this known resistance of the American public, the study has been implemented without disclosure to the public. In addition, Federal Agencies and other stakeholders are being used to disseminate the information 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 and the Commonwealth Fund are providing the information about the current federal and state laws 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 it relates to chronic illness. All this activity has taken place without public input, transparency, and places the power of the entire healthcare system along with the handling of the country’s “opioid crisis” to a small group of privately appointed stakeholders. These same stakeholders appear to have undue influence over health policy including access to medicine, 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.

We can see numerous laws have been enacted to permit this study to even take place. Most recently, the Federal docket has proposed changes to HIPAA to allow for more information sharing to permit the gathering of our private Electronic Medical Records and Electronic Health Records to the Investigators and other stakeholders including data mining organizations such as Appriss Health.

The FDA has also issued a “Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects.” This was not provided the customary and legally required 180 day public comment period and rather it was issued for immediate release in February 2019.

The population wide study/clinical trial was implemented under the assumption of “minimal risk to human subjects.” Rather than having this waiver processed prior to the studies implementation, the FDA is seeking to close this legal loophole so they may proceed without violating the law post fact.

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” and “Relieving Pain in America” along with the “National Pain Strategy” are directly related documents that interplay with 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) that calls for various “guidelines” to be devised and implemented into society using the healthcare delivery system.

The CDC Opioid Guidelines have long been contested by the patient and medical community as far reaching and inappropriate since their issuance. To this date there has largely been no action or recognition of how the CDC Opioid Guidelines have impacted patient care. There has not been any response from the Centers of Disease Control to make any corrective statements to curb the misapplication of these guidelines that have lead to widespread patient abandonment, forced tapering from stable medical regimes, medical neglect, bodily injury, suicides and psychological harms taking place despite demands from distinguished organizations such as the American Medical Association (27), the Human Rights Watch (28) and countless citizens phone calls and emails.

It is apparent the PPACA’s population based study is at the root of the CDC Guidelines. As such, there is explicit ability of the Secretary of Health and Human Services overseeing the population based study to instruct the Centers of Disease Control to issue the requested “corrective statement” of the intend and legal application of the 2016 CDC Guidelines. In addition, granted within these authorities is the power of the Investigators to devise revised guidelines based upon the outcome of the study. Given the overwhelming outcry from the constituents living with chronic illness pain, it is irresponsible at this juncture for Health & Human Services to fail to correct course.

In addition, there must be public transparency to the forthcoming healthcare system changes planned to ensure these changes are intended to benefit patient care and support 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 the population based study has created a systematic failure in the healthcare system and caused a betrayal of the trust of the doctor patient relationship.

Further, 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.

Sincerely,

Lauren Deluca, CPCU, API, AINS
President
Chronic Illness Advocacy & Awareness Group, Inc.
Sources


