CHRONIC ILLNESS ADVOCACY & AWARENESS GROUP

A CRISIS EXPLOITED

Executive Director & Founding President

Lauren Deluca, Founding President, graduated from Nichols College with a Bachelor's Degree 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.

Vice President

Shasta Rayne Harner, Director & Vice President, graduated from Sonoma State University with a Bachelor's Degree in Political Science. She worked for many years as a Certified Medical Assistant and Project Coordinator for a large medical group. During the course of her career, she focused on the delivery of patient care to medical practice administration. Shasta lives with a rare, disabling auto-immune disease; 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 live with disabling diseases and conditions.

Chronic Illness Advocacy & Awareness Group (CIAAG) would like to thank you for your leadership in addressing the heroin/illicit opioid addiction crisis in America — a very serious issue impacting approximately 2.1 million citizens.(1) While we greatly appreciate your attention to this problem, as an organization representing the 100 million U.S. patients living with daily chronic pain (caused by often disabling medical conditions and illnesses, including the recently discovered, long-term neurological/musculoskeletal impacts of COVID-19), we *must* bring to your attention the suffering this underserved and stigmatized population has been — and is *continuing* to experience due to a misguided federal response to the addiction crisis.

At least 100 million U.S. adults — more than the number affected by heart disease, diabetes, and cancer combined, suffer from daily chronic pain.(2) As a result, the federal government has developed a number of strategies in an effort to resolve this public health crisis, while concurrently addressing the harms of illicit drug abuse. Unfortunately, in doing so, these two vastly different public health issues have been erroneously combined into a single silo — and are being inappropriately managed as such.

Chronic Illness Advocacy & Awareness Group's (CIAAG) goal is to work with the community, legislators and other stakeholders to educate them on the patient experience and on how public health policy changes are impacting the individual health of the consumer. As such, we are reaching out to your office to discuss the negative impact a number of recent and proposed federal healthcare changes will have on those suffering with chronic painful diseases and syndromes, intractable pain from accidents and abuse, terminal cancer pain, and those requiring palliative care – along with any other moderate to severe pain experienced by the millions of individual patients we represent. In this document, we outline the potential conflicts of interest of a a small group of special interests that have a seemingly undue influence over government policy making / decisions —many with a vested financial interest in controlling and barring access to appropriate full mu agonist opioid analgesics for individuals with painful illnesses and conditions.

The Centers for Disease Control and Prevention (CDC) recently opened Docket # CDC-2020-0029-0001 "Management of Acute and Chronic Pain: Request for Comment, (3) requesting public comments regarding patient experiences with the management of acute and chronic pain conditions. This federal register entry asked concerned parties to list factors that have influenced patient decision-making (in the treatment of their pain), as well as the accessibility of patient care options (opioid pain medications, physical therapy, alternative therapies, etc.).

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For several years, various agencies have utilized the federal register to request public feedback surrounding opioid pain medication. CIAAG has anecdotally observed that the majority of this feedback has originated from patients suffering from lost access to previously stable pain care (i.e. to effective opioid pain medication regimens). These patients generally express deep concerns (and grief) around uncontrolled pain, which causes: the loss of their jobs/careers; limited interactions with children and family members (unable to play with them, hold them, etc.); missed social opportunities; heightened depression and anxiety, even suicide and, generally, a marked decrease in quality of life resulting from having been forcibly tapered or outright denied previously-prescribed pain medication due to structural changes in the healthcare system.

However, despite this observation, it seemed patient comments were not being taken into account, as when subsequent reports would be issued the reports would not reflect much, if any, of the feedback that was received. Rather, they read very much as expected, with recommendations for multimodal care, buprenorphine first and stigmatizing/demonizing the use of mu agonist opioids such as hydrocodone, fentanyl and morphine as outlined in the National Pain Strategy's goals.

Our organization has observed over the past 3 years that the various federal agency committee recommendations continuously fixate on predetermined goals outlined in the National Pain Strategy such as the "multimodal" or "biopsychosocial" care model (at the expense of patient outcomes). Thus irresponsibly instructing doctors to use these models as forms of medical treatment in lieu of medication management for those with painful conditions. Such so-called "treatments" include the encouragement of meditation, tai chi, acupuncture, psychological counseling and other unproven and often ineffective "self management" techniques. This is not an acceptable form of medical treatment in the year 2020. There is a major focus on self management and acceptance of pain. This is essentially telling the patient to accept not receiving any treatment for their condition and equates to patient abandonment and abuse.

A Random Review of the Data

In order to ascertain if our historical observations regarding lack of pain patient input were correct we opted perform a review of the federal register request for comment (Docket # CDC-2020-0029-0001 "Management of Acute and Chronic Pain.") We randomly sampled and reviewed 1,450 of the 5,385 public comments received (representing a 27% sampling of the total) to identify the number of comments coming from organizations standing to benefit

financially from changes in the marketplace availability of opioid medications, along with the primary concerns outlined (by source of comment):

Total Comments	# of Comments from Organizations w/ Financial Interests	Primary Concern Category
100	0	**comments removed from register**
40	4	**HHS Task Force recommendations**
318	0	**pro kratom for pain mgmt.**
35	11	**anti opioid pain med. position**
62	27	**pro multidisciplinary ("multimodal") treatment**
52	0	**pro medical marijuana & holistic medicine (supplements, etc.)**
843	0	**pro access to opioids pain medications**
1450	**42**	

Our research revealed a total of 843 comments (58%) in support of access to traditional opioid analgesics such as morphine, hydrocodone and fentanyl. None of these comments originated from organizations with financial interests in making these recommendations (e.g. Big Pharma, etc.). As we've witnessed in the past, the comments submitted speak largely of patient abandonment, stigma, forced tapers, loss of quality of life and suicides.

In addition, 40 individuals commented in support of the HHS Inter-Agency Task Force Report on Pain Management Best Practices (4) – four of these individuals work with entities that have a vested interest in having the recommendations in the report implemented. Additionally, the HHS Task Force report recommends multimodal therapies including "acceptance and commitment therapy" which "focuses on creating psychological flexibility through acceptance of psychological and physical experiences rather than by challenging them" and meditation that "teaches patients to self-regulate their pain and pain-related comorbidities by developing nonjudgmental awareness and acceptance of present-moment sensations, emotions, and

thoughts." It also promotes "emotional awareness" and presents as fact that this "therapy" can work based on the principle that "pain is exacerbated or maintained by unresolved emotional experiences." Finally, it recommends hypnotherapy, yoga and "spirituality" to treat serious and severe pain from neurological, musculoskeletal and physiological conditions, included by not limited to, complex regional pain syndrome, autoimmune disorders, gastrointestinal disorders and other painful illnesses and/or conditions.

*Please see CIAAG's Fact Sheet which outlines 10 Highlights on the HHS Inter-Agency Task Force Report (See Exhibit 1) which breaks down ten other "recommendations" being made by the task force which create financial opportunities for businesses while simultaneously creating harms to patients physical and mental well-being.

It is notable that the majority of the 35 comments made in opposition of the use of opioids in the treatment of chronic pain came from individuals who abused illicit drugs and did not indicate they had any history of having an acute or chronic pain condition. These individuals' comments came from their own experiences from illicit use which should not be a part of the decision making process regarding the *medical use* of this substance, which is the purpose of the docket. Further, in reviewing the 35 comments, a total of 11 (or 31%) were submitted by entities that had a financial interest in having full mu agonist opioid analgesics removed from the market.

Of the 62 comments in favor of implementing multidisciplinary care, 27 (or 43%) originated from those parties with a financial investment/interest in this area.

Frozen out of the process

On July 22, 2020, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BCS, NCIPC), at the Centers for Disease Control and Prevention (5) hosted a virtual meeting. Unfortunately, despite our organization pre-registering for this event, we did not receive the dial in instructions and were effectively locked out of this meeting. We have remitted a formal inquiry to members of Congress who are looking into this issue at this time. At this meeting, the committee presented their analysis of the comments received on the Federal Docket; listing their initial observations. (6)

Our organization analyzed a portion of the comments. It appears that the figures being presented by the NCIPC fail to express the serious concerns made by the patients. Of the comments made by patients, the committee failed to categorize what type of feedback was expressed within the 4,085 patient comments that were received. Instead, they rely on basic

talking points that support the goal of their workgroup; to clarify the CDC Opioid Prescribing Guidelines and to create new Acute Pain Guidelines, indicating patients had expressed their "experiences with multimodal care."

In addition, on July 22, 2020, there was a new item added to the Federal Register, Management of Acute and Chronic Pain: Opportunity for Stakeholder Engagement (7). This docket seeks to further the discussions surrounding the management of pain and the CDC's ongoing work to update or expand the CDC Guideline for Prescribing Opioids for Chronic Pain.

In addition, they will be hosting a 100 person stakeholder phone call to discuss this docket as well as a prior docket addressing, "Agency Forms Undergoing Paperwork Reduction Act Review."(8)

Under this docket, the Office of Management and Budget is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected;
- Minimize the burden of collection of information on those who are to respond, including, though the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- Assess information collection costs.

A review of these recent activities under the related federal dockets show there may be an objective at the CDC to eliminate the collection of public comments related to opioid analgesics. Our organization finds this deeply concerning given the vast amount of public feedback expressing the negative impact the public health recommendations made by the CDC are having on patients' lives and well-being. Rather than the CDC taking action on the feedback they are receiving, they appear to be opting to cut off the public discussion. This creates a situation where a federal agency is able to conduct its work unopposed and without any regard for the implications of their actions.

In addition, a review of the activities taking place at various federal agencies, including the recent CDC Federal Docket on Acute Pain, there is a clear coordination of activities taking place under the direction of Health & Human Services to implement the National Pain Strategy.(9)

Please note, CIAAG Founder, Lauren Deluca, a Massachusetts resident, had to contact Congressman James McGovern on two occasions in 2018 because our organization's comments were being removed from the federal register. 100 comments were seemingly removed from the federal register in this latest Docket # CDC-2020-0029-0001 "Management of Acute and Chronic Pain" request for comment. As this has occurred multiple times one has to question why comments are being removed from the federal register. Is it being done to suppress opposing feedback? If so, by whom? We need oversight to ensure public feedback is taken into account in the rulemaking process as permitted by law.

Who's got a seat at the table?

On July 24, 2020 the Congressional Integrative Health & Wellness Caucus hosted a webinar, The Pain-demic: Fallout from COVID-19 Solutions for Our Worsening Opioid Crisis and the Rising Impact of HealthCare Disparities (10) They state the purpose of this webinar is to teach about how:

*"COVID-19 has exacerbated the raging opioid crisis **driven by** the nation's more than 50 million chronic pain sufferers, magnifying existing healthcare disparities and heightening barriers to essential, cost effective, non-opioid, non-drug pain treatments."*

The featured speaker is Ms. Vanila Singh, M.D., the Chairperson of the HHS Inter-Agency Task Force on Pain Management where she presents the findings of the report and promotes the recommendations as "Best Practices." However, it should be noted, there are a number of federal documents reflecting that the recommendations within the Task Force report are not in fact "Best Practices" and rather are being marketed as such without any supporting studies. In fact, "Best Practices" have yet to be developed and are actively being studied through the use of patient Electronic Health Records without patient knowledge or consent.

It is notable, the language used by the Caucus and presenters is highly stigmatizing as they can be heard directly blaming the nation's opioid epidemic on individuals suffering from painful illnesses, diseases and incurable conditions. This is clear misrepresentation of the facts. It has been proven in studies that only 0.27% of individuals (11) suffer from the disease of addiction as a result of legitimate medical use of a prescription opioid.

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An individual who has been appointed to such a position of authority has a great responsibility to use their platform carefully as to not harm the individuals they represent. It is clear from this webinar and other business activities that Ms. Vanilla Singh, M.D., has not taken this responsibility seriously and is using her platform to spread misinformation and further stigmatize a vulnerable patient population.

Vanila Singh, M.D.'s other business interests include, advisor role for Lucid Lane. (12) This organization's focus is on promoting Cognitive Behavioral Health approaches to management of pain, "relapse and recovery" coaching and other mental health services. In addition, she is an advisor for the "Alliance to Advance Integrative Pain Management" (13) which is an advocacy organization promoting comprehensive complementary integrative pain management.

On July 9, 2020 Vanila M. Singh, MD, MACM Elected to Virpax (R) Pharmaceuticals' Board of Directors. Virpax Pharmaceuticals is "*developing branded prescription products and providing more efficient drug treatments using its proprietary cutting-edge delivery technologies designed to satisfy unmet global market needs. Virpax's pipeline consist of non-addictive products being studied to manage musculoskeletal pain, post-operative pain and moderate to severe chronic pain. While Virpax is a market leader in the development of non-addictive pain management products, Virpax is also using its patented delivery technologies to develop therapies to manage PTSD*."(14)

Vanilla Singh, M.D., was appointed as a Board Member of BioDelivery Sciences International, BDSI, Inc., retro-dated to August 6, 2018. (15). However, this would pre-date her participation in the HHS Inter-Agency Task Force which started their activities on May 30, 2018. (16) This leads to the question about the failure to disclose this business interest on the Financial Disclosures (17) for participation on the HHS Inter-Agency Task Force as required by Federal Advisory Committee Act requirements, as this was not announced publicly or voted on by the board until July 23, 2020.

Given Vanila Singh, M.D.'s position as chairperson on the HHS Inter-Agency Task Force, she has access/influence over confidential governmental strategies and goals which provides unfair advantage in business pursuits and investing. It also lends concern regarding the validity of the recommendations that were included in the Inter-Agency Task Force report and if there were personal motivations and/or business dealings behind the recommendations agreed upon.

In reviewing the various agencies and committees working to address the healthcare costs associated with pain, we see a common thread of bias and financial conflicts of interest among individuals and organizations with influence over public policy decisions, regulatory and legislative processes. In particular, we have seen the same organizations and private citizens influencing policy making decisions made by a number of federal agencies, including, but not limited to:

- Agency for Healthcare Research & Quality (AHRQ)
- National Academies of Sciences previously the Institute of Medicine
- Centers for Disease Control & Prevention
- Food & Drug Administration
- Health & Human Services
- Department of Defense
- Veteran Administration
- Inter-Agency Pain Research Coordinating Committee (IPRCC)
- Centers for Medicare & Medicaid
- Patient Centered Outcomes Research Institute (PCORI)
- National Prevention, Health Promotion & Public Health Council
- Center for Medicare and Medicaid Innovation
- National Council for State Legislatures
- National Governors Association
- National Academy of State Health Policy

These organizations, including Advocacy Organizations, Pharmaceutical Companies and Academia, that have financial conflicts of interest while maintaining undue influence over public policy include, but are not limited to:

- BioDelivery Sciences International, Inc.
- Pacira BioSciences, Inc.
- Quintiles/IQVIA
- Physicians for Responsible Opioid Prescribing
- Shatterproof
- Stanford University
- University of Washington
- US Pain Foundation

BioDelivery Sciences International (BDSI)

November 3, 2014, BioDelivery Sciences International (BDSI) entered into an exclusive agreement with Evonik Corporation for the commercialization of a new long acting formulation for buprenorphine which was marketed as providing up to "30 days of continuous pain therapy with a single injection."(18) BDSI was to develop the product for the indication of opioid dependence (notably using the term dependence in their materials rather than addiction, misuse or abuse which makes it clear, the product was intended for dependence - not addiction treatment - as far back as 2014). Further, BDSI obtained the rights to develop a future product

for the treatment of chronic pain and secured options to license the intellectual property for these products from Evonik.

"Not only would a single monthly injection provide an opportunity to substantially improve adherence to buprenorphine treatment, which is a formidable problem for many patients, it could also help to eliminate the problem of diversion. We also believe this will be an outstanding companion product to Bunavail and, if approved, provides another product for our existing sales team."

This statement itself is stigmatizing. First, BDSI indicates their product can solve the issue of adherence to buprenorphine treatment; however, fail to clarify the adherence issue is with individuals prescribed this medication for the purposes of treatment of their substance use disorder and not for those being treated for chronic pain and illness.

Additionally, on November 3, 2014 (the same day), BDSI announced it had launched its new pain medication, Bunavail, in the U.S. along with its commercialization partner Quintiles.

The most notable statement on the announcement made by BDSI. Their original announcement was removed from the web:

In March 2014, BDSI entered into an agreement with Quintiles to support the launch and subsequent commercialization of BUNAVAIL in the U.S. BUNAVAIL is supported by an experienced, sixty person field sales team as well as a team of Medical Science Liaisons (MSLs). Separately, BDSI has entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL. Ashfield Market Access is actively in the process of executing a payer strategy aimed at maximizing patient access to BUNAVAIL. At launch, it is anticipated that BUNAVAIL will be available to approximately 165 - 175 million covered commercial lives.(19)

Question to consider:

If the estimated number of individuals suffering with opioid use disorder is approximately 2.5 million, how did BDSI come to conclude they have a potential "sales base" of 165 to 175 million people?

Additionally, BDSI runs an awareness campaign called "This is Pain." (20) In the campaign, they highlight the 2019 HHS Inter-Agency Task Force Report on Pain Management (they refer to it as a "government sponsored task force") which recommends that each patient has a specific treatment plan that considers using a range of therapies to treat pain. The website proceeds to describe restorative, complementary, behavioral and alternative therapies to the reader. This

campaign is their public awareness campaign to help shape the public perception of pain and to influence the future market potential for their product to meet this demand.

Pacira BioSciences & IQVIA (formlerly Quintiles & IMS Health)

IQVIA bills itself as a "The Human Data Science Company."(21) It contracts with pharmaceutical and biotech companies looking to outsource their clinical trials processes. Consumer advocacy groups like Patient Privacy Rights were created in the 1990s in response to the disturbing amount of private consumer healthcare data that IQVIA (then IMS Health) had begun scooping up without patient knowledge or consent. IQVIA is now the world's greatest aggregator and broker of consumer health data yet few have ever heard of the company—it operates largely behind the scenes. (Note: There are billions of dollars to be made in the selling of patient medical data and patients on prescribed opioids represent a convenient "excuse" for companies to subvert HIPAA laws by claiming they "need" to track and monitor patient prescriptions, behaviors, lifestyle choices and more.)

In 2011, IQVIA entered into an agreement with Pacira Pharmaceuticals (now Pacira BioSciences, Inc), Quintiles Commercial US, Inc. (Quintiles), and Integrated Commercial Services, Inc. (ICS), to support the launch of Pacira's injectable anesthetic product, Exparel. Exparel is given "at the time of surgery to control pain"; in Pacira's view, the product should "reduce or eliminate the use of opioids for acute postsurgical pain" and is being marketed as a replacement for post-surgical pain management therapies such as traditional opioid analgesics.

According to Pacira's 2011 press release announcing the joint venture, Quintiles was to "provide a U.S. sales force exclusively dedicated to EXPAREL that will consist of approximately 70 people and will support sales efforts through December 31, 2012, or beyond if extended in accordance with the terms of the agreement. Under the terms of the agreement with ICS, ICS will serve as the exclusive third party logistics provider to Pacira to support the U.S. commercialization of EXPAREL for the next three years."(22)

In a Press Release dated February 28, 2019, Pacira BioSciences, CEO David Stack stated:

"*Our significant partnership with Johnson & Johnson continues to drive uptake with Exparel being integrated across its world class educational platforms and comprehensive offering of orthopedic procedural solutions. Altogether this strong growth trajectory provides us with a solid operating foundation to support the strategic expansion of our commercial and clinical offering within the non-opioid pain management and regenerative health space. This substantial momentum has continued into 2019 and we plan to build on our success by executing on multiple opportunities, including expanding the role of Experal as a catalyst for shifting in patient procedures to the ambulatory setting and building out our differentiated non-opioid portfolio with innovative products that address the need for improving patients journeys' along the neural pain*

pathway. We believe this strategy provides the greatest opportunities to build value in both the near and long term." - (See Exhibit 2)

It is notable that Pacira BioSciences CEO, David Stack, was the President and General Manager of Innovex, Inc.

Innovex, Inc. was a commercial solutions company offering a full range of marketing, sales and clinical development capabilities to pharmaceutical and biotechnology customers, and was sold to Quintiles in November 1997 for $897 million.

Additionally, Pacira BioSciences, Inc., tapped Coyne PR (23) to "change the conversation around opioid use following surgery." Through an analysis conducted by IQVIA, Coyne PR developed the report called the, "United States for Non-Dependence".(24) Together, Pacira and Coyne PR created the "Plan Against Pain: Choices Matter Campaign".(25)

The campaign legitimized the idea that surgery had become an unintentional gateway to opioid use and dependence. Leveraging Gabby Reece (former professional volleyball player and recent knee surgery patient) as a spokesperson, along with Dr. Scott Sigman, a board-certified orthopedic surgeon, Coyne fielded a national survey, introduced a dedicated website (www.planagainstpain.com) and launched a national media relations campaign.

Pacira and Coyne PR set out to find real people with real stories to humanize the surgical gateway storyline and show how opioid addiction can happen to anyone. The result was a deeply moving 40-minute documentary titled GATEWAY, which provides a look into how the overprescribing of opioids – especially after surgery – can lead to downstream consequences like addiction and dependence. This documentary is currently on a nationwide screening and film festival tour.

The United States for Non-Dependence report was based on a survey (26) about opioid dependence and addiction following opioid treatment for surgical pain. The data from the survey was independently analyzed by Quintiles who later merged (27) with IMS Health to become IQVIA.

A second report, "Exposing a Silent Gateway to Persistent Opioid; Use a Choices Matter Status Report." (28) was published. IQVIA conducted the research that this report is based on. The funding (29) for both of these reports was provided by Pacira BioSciences, Inc. By producing the data for Pacira that is being used to promote their product (Exparel) while advocating for legislative changes that will benefit their organization, such as the NOPAIN Act (30), IQVIA is creating an opportunity for Pacira's products to meet the market demand.

Behind the scenes: Moneyed interests provide self-serving data to government

In March 2018, it was discovered that IQVIA had miscalculated the amount of pharmaceutical fentanyl that had been distributed and sold by over 20%. As a result of this error,(31) the FDA identified additional quality control issues which in turn raised serious questions about the reliability of IQVIA's database which is also used by the DEA to set opioid production quotas. Since this time, there have been shortages of pharmaceutical grade fentanyl in the hospital setting which has created another opportunity for Pacira to market their product (Exparel).

The Choices Matter Campaign partnered (32) with Gary Mendell, Founding President of the anti-opioid addiction group Shatterproof who recently started promoting non-opioid, multimodal pain management as seen on his website; the "Plan Against Pain Campaign."(33)
By legislating the HHS InterAgency Task Force recommendations, that non-opioid options are to be utilized first, this not only opens the market but creates a market demand for other non-opioid options like Exparel or other Buprenorphine based products. Given the financial benefit Pacira Pharmaceuticals could gain if this legislation were to pass and with their seemingly undue influence on the factors driving this legislation, it is our duty to ask our representatives to take a closer look at this organization and their activities as it relates to the proposed legislation, The NOPAIN Act.

Additionally, on July 28, 2020 (34), the United States Department of Justice alleged:

"The United States contends that Pacira sales representatives or marketing executives typically initiated Grants, which were conditioned upon acceptance of EXPAREL onto the institution's formulary. The United States contends that certain Pacira executives coached Grant recipients and other employees on how to avoid internal scrutiny of the Grant payments. The United States contends that Pacira approved and funded the Grants despite receiving little or no documented description of the proposed research, and Pacira also did not document a reasonable commercial need or a fair market value assessment for the Grants. The United States contends further that after awarding the Grants, Pacira personnel conducted little or no follow-up on the proposed research, which certain Grant recipients did not carry out according to the original proposal, and sometimes did not perform at all. The United States contends that the Grant payments caused sales of EXPAREL at the recipient institutions to increase during the time period of December 1, 2012, through April 30, 2015. The conduct, actions, and claims described in this paragraph are collectively referred to in this Agreement as the "Covered Conduct."

Our organization has reviewed the Board of Directors (35) for Pacira BioSciences and found high powered individuals sitting on the board. Former New Jersey Governor, Chris Christie (36) is one of these individuals. (37) Chris Christie was also the Chairman (38) of the President's Commission on Combating Drug Addiction and the Opioid Crisis.

In considering legislation, we always need to examine the motives of the individuals involved and ask our representatives to do the same. When these types of decisions are based on research, the research should be reliable and performed with transparency and oversight; not by an entity that has a potential conflict of interest and ability to self enrich.

Reckitt Benckiser Pharmaceuticals Inc and Indivior PLC

Another organization with undue influence over healthcare policy in the field of pain management is Reckitt Benckiser and Indivior PLC**.** Indivior is a global pharmaceutical company that develops medication assisted therapy for the treatment of the disease of addiction. Their product has been promoted as being a safer, less addictive form of opioids to treat opioid use disorder and most recently, off-label for the treatment of pain.

However, upon review of a series of court documents issued by the Department of Justice, Indivior as well as their CEO, Shaun Thaxter have been found guilty for a number of civil actions related to the marketing of Suboxone.

According to one indictment,(39) Indivior obtained billions of dollars in revenue from Suboxone prescriptions by deceiving healthcare providers and healthcare benefit programs into believing suboxone film was safer, less divertible and less abusable than other opiate addiction treatment drugs. Indivior is also alleged to have sought to boost profits by using a quote, “Here to Help”; a program that connected opioid addicted patients to doctors that the company knew were prescribing at high rates in a clinically unwarranted manner.

It should be noted that Indivior’s recent endeavor included expanding the marketing of their product for treating pain and in doing so, used the same proven fraudulent statements about their product being safer and less divertible as a reason for patients to be switched to Suboxone and/or other buprenorphine based products. The indictment alleges; “rather than marketing it’s opioid addiction drug responsibly, Indivior promoted it with a disregard for the truth about it’s safety despite known risks of diversion and abuse.” The indictment also alleges; “to further its scheme, Indivior announced a ‘discontinuance’ of it’s tablet form of suboxone based on supposed ‘concerns regarding pediatric exposure’, when in fact, Indivior executives knew the primary reason for the discontinuance was to delay Food and Drug Administration's approval of the generic tablet form of the drug.”

Indivior’s scheme was highly successful, converting thousands of opioid addicted patients over to suboxone film and as a result, caused Medicaid programs to expand and maintain coverage at a substantial cost to the government. Until early 2019, when suboxone film became subject to generic competition, Indivior retained 85% (40) of all spending on MAT in the USA.

The indictment alleges a wide ranging, truly shameful scheme to prioritize profits over the health and the wellbeing of the patients.

On July 11, 2019, Reckitt Benckiser group agreed to pay $1.4 billion (41) to resolve its potential criminal and civil liability related to the federal investigation of the marketing of the opioid addiction treatment drug suboxone. It should be noted that this is the largest opioid settlement to date in the United States. Despite this, we still see a massive push from the federal government, advocacy organizations and harm reduction organizations for patients to be put on buprenorphine based opiate medications whether they suffer from the disease of addiction or pain.

It should be noted that in addition to these prior offenses, recent legislative changes are presenting new opportunities for organizations like Indivior to repeat these same types of abuses at a much larger and more damaging level (as seen in the below example):

- In Sept 2012, with generics getting closer to approval, Reckitt Benckiser announced its intention to take the tablet versions of its drug off the market on the grounds that the pills posed a safety risk for children who might inadvertently eat them. On the same day, it filed a "Citizen's Petition" with the Food and Drug Administration, calling on the agency to postpone approval of generics in the interest of public safety. The company based its child-safety claims on a single study it had paid for itself. According to the plaintiffs, they used the findings to sow fear among medical professionals to only prescribe the Suboxone Film."
- As a result of this, they were awarded an Orphan Patent extension successfully blocking competition from generics.
- NAFTA 2.0 Signed into Law January 29, 2020 (42) which permits pharmaceutical organizations to obtain extensions on their patents if they can "repurpose" their drug. By repurposing Suboxone for the treatment of pain, they will be able to extend their patent once again and not only will they be able to maintain their market share and continue to lock out competition from generic drugs, they will be able to expand it as they open their product to be used as the primary treatment for those suffering from chronic pain as was recommended by the Pain Management Task Force Report on "Best Practices."

Shatterproof nonprofit leaves pain patients to pick up the pieces

Shatterproof is a national nonprofit focused on reversing the impact of drug addiction. It was founded by Gary Mendell in 2012. In October 2017, Shatterproof announced their partnership with the Choices Matter Campaign. (43) The Choices Matter Campaign was funded by Pacira Pharmaceuticals who used IQVIA to perform the data and survey analysis. The analysis and subsequent report concluded that over-prescribing* was the driving force of chronic opioid use after surgery and therefore, long-term opioid abuse.

This same report is being used by Shatterproof, Voices for Non-Opioid Choices, U.S. Pain Foundation and others (44) to promote legislation that will restrict the access to opioid analgesics in the postoperative setting.

This opens a number of business opportunities for those engaged in creating alternative treatments, such as Exparel, Buprenorphine, multimodal care and complementary health strategies. These businesses can recommend their products or services to replace medication management thereby creating a financial profit from both the opioid epidemic and the epidemic of untreated pain facing those living with chronic illnesses, disease and incurable conditions.

**It should be noted that the term over-prescribing has no definitive meaning and is liken to a marketing slogan which has taken off and been used to justify the business goals of various entities who stand to profit off this narrative. Including but not limited to Pharmaceutical companies, Advocacy Organizations, Research Professionals, Insurance Companies and Professional Societies.*

These organizations have a vested interest in the types of medications and treatments patients are receiving. We can see through their activities; there is a collaborative effort to influence the public narrative surrounding opioid prescriptions and to push integrative care over medication management regardless of the patient's actual needs.

On June 16, 2017, (50) Gary Mendell submitted Shatterproof's Recommendations for the Presidential Commission (51) to Governor Chris Christie. Shatterproof's recommendations would later be incorporated into the final draft of the official report.

Additionally, Shatterproof has run a number of successful national campaigns that have subsequently been adopted by major insurance companies across the nation and implemented into healthcare plans. Unfortunately, rather than seeing Shatterproof making strides in the arena of addiction by expanding access to medication assisted therapy, improving insurance coverage for inpatient or out-patient care for addiction services, or helping to better fund addiction centers, Shatterproof's business interests have switched into pain management, (in particular the denial of opioid analgesics) and the expansion of the multimodal, biopsychosocial and buprenorphine first models of care.

A review of the composition of the board of directors for various organizations reveals there are some cross-overs of related but separate organizations, including but not limited to:

Shatterproof Opioid Overdose Advisory Board:

Notable members on Shatterproof's Opioid Advisory Board include, but not limited to, Andrew Kolodny, M.D., who has a reputation for being against the use of opioid analgesic medications. He is a public figure that is often quoted in the media using extreme, inflammatory language that misleads the public regarding the use/misuse of opioid medications which leads to stigma for those suffering with chronic pain.

Andrew Kolodny, M.D., has a number of financial interests related to the subject matter of the opioid crisis. He is Co-Founder of Physicians for Responsible Opioid Prescribing as well as the Co-Director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management. He previously held roles as the Medical Director of Phoenix House; an addiction center which he ultimately resigned (45) due to public outcry.

Additionally, in 2019, he received $500,000 in fees (46) for his testimony in the Oklahoma trials against Purdue Pharmaceuticals.

Other activities he is engaged in include, but are not limited to:

- National Judicial Opioid Task Force
- Pennsylvania Department of Aging
- October 2016 Massachusetts Hospital Association
- The National Governors Association
- The National Association of Attorneys General
- Office of Massachusetts Attorney General
- Office of Kentucky Attorney General New York State InterAgency Task Force

Other individuals of interest include John L. Eadie, Director of the Prescription Drug Monitoring Program (PDMP) Center of Excellence at Brandeis University (same location as Andrew Kolodny, M.D.). John Eadie holds several other influential positions including that of Public Health, Prescription Drug Monitoring Programs (PDMP) and Project Coordinator for the National Emerging Threats Initiative of the National HIDTA Assistance Center.

He co-founded and served as the President for both the Alliance of States with Prescription Monitoring Programs and the National Association of State Controlled Substances Authorities. Since leaving New York state service in 2001, he has served as a consultant on PDMP's, and served as the administrative reviewer for the Massachusetts PDMP.

He was a signatory (47) on the "Prescription Drug Monitoring Programs: Critical Elements of Effective State Legislation" document. Published by Shatterproof in March 2016, this document urges states to optimize the effectiveness of PDMPs by adopting Shatterproof's Critical Elements of Effective State Legislation (48). This document was also endorsed by Andrew Kolodny, M.D., Gary Franklin, M.D., M.P.H., and promotes *"the usage of PDMP as a tool to prevent drug misuse"* and also states, *"the data collected can also be used more broadly to analyze prescribing patterns and trends in use and ultimately inform patient centered public health initiatives."*

Yvonne Greenstreet (49) is a Non-Executive Director at Indivior as well as serving on the Board of Directors for Pacira Pharmaceuticals.

Physicians for Responsible Opioid Prescribing

Physicians for Responsible Opioid Prescribing (PROP) is a private nonprofit organization focused on the reduction of opioid prescribing co-founded by Andrew Kolodny, M.D..

Despite their name, PROP promotes dangerous theories surrounding the use of opiate medications for medical purposes. The members on their board of directors have a very clear history of bias against the use of opioids even in the most dire of circumstances.

In 2012, PROP approached the Food & Drug Administration seeking dose caps on opioid medications and were met with opposition from the American Society of Anesthesiology. (See Exhibit 3) Despite lack of evidence to support their request for dose limits, PROP continued to lobby to have limits applied to opioid medications. Eventually finding success when co-founder Michael Von Korff, ScD was appointed to the National Pain Strategy Population Research Work Group. In addition, a number of individuals on their Board of Directors were appointed to the work groups that would create the 2016 Guideline for Prescribing Opioids for Chronic Pain.

President Jane Ballantyne, M.D., and Vice-President Gary Franklin, M.D., were members of the Core Expert Group, while board member David Tauben, M.D., served on the CDC's peer review panel. David Juurlink, M.D., and Andrew Kolodny, M.D., participated in the "Stakeholder Review Group" that provided input to the Centers for Disease Control & Prevention for the creation of the Guideline for Prescribing Opioids for Chronic Pain.

On November 17, 2015, Washington Legal Foundation sent a letter (52) to Tom Frieden, M.D., M.P.H., and Debra Houry, M.D., M.P.H., at the CDC outlining a number of concerns with regards to "flawed procedures" employed by the CDC in regards to the issuance of the Guideline for Prescribing Opioids for Chronic Pain. Washington Legal Foundation cites the secretive manner in which the CDC had been operating and repeated violations of the Federal Advisory Committee Act (FACA) in connection with the establishment and utilization of the Core Expert Group (CEG) and requested withdrawal of the guideline.

We recommend your office to review the below media articles regarding PROP and their board members' involvement in the creation of the 2016 Guideline for Prescribing Opioids for Chronic Pain.

CDC Opioids Not Preferred Treatment for Chronic Pain (53)
What is the CDC Trying to Hide? (54)

CDC Maintains Secrecy Over Opioid Guidelines (55)
PROP Linked to New Opioid Study (56)

Note: Please review the entire reference articles including enclosed hyperlinks. Some of these hyperlinks are no longer active however they contain very important information that we feel is vital for your office to review in their entirety.

We want to also bring to your office's attention some notable media pieces regarding a number of the members of the Board of Directors for PROP as well as their previous business dealings. Their historical profiles reflect an attitude of indifference at best, or even targeted disdain towards patients who require opioid pain medications to manage their illnesses, diseases and conditions.

Further, we can see these individuals and their related partners and business associates project an inaccurate image of patients who need opioid analgesics despite their responsibility to be unbiased, objective participants while participating on these various committees and in their employment roles. They often cite patients as the reason for drug addiction in America while using false statistics from small, remote studies to mislead their intended audience. Their public messaging is stigmatizing and discriminatory towards individuals with painful conditions and other disabilities.

We at Chronic Illness Advocacy & Awareness Group understand the federal government's desire to combine mental and physical health into a single silo to improve the health and well being of the American public. We also see this admirable goal has been derailed by special interest groups looking to profit off the structural changes while simultaneously securing financial opportunities as a result of the desires of our legislative bodies.

It is for this reason we bring our findings forward to your office. It is imperative for the health and safety of the American public that the studies being performed are done in a safe manner that respects the autonomy and civil rights of the citizenry. In addition, the individuals appointed to work on various federal committees must be free from bias and financial conflict of interest.

According to the Comprehensive Addiction Recovery Act (CARA) (57) the federal committees appointed to do the work associated with pain management and other healthcare structural changes were required to have representation from individuals on all sides of this issue, including but not limited to, harm reduction, pain advocacy and integrative medicine. Unfortunately, the composition of the federal committees have lacked any real representation for individuals who medically require opioid pain medication for management of long term illnesses, rare diseases, palliative care, cancer and other incurable long term painful conditions.

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Those appointed to the committee whom the public has been informed are representing their interests have been found engaging and assisting in the implementation of the National Pain Strategy. This is against the better interests and needs of the individuals they are incorporated to assist and represent. They were appointed to said committees to represent the public's needs; not the needs of the federal government, their personal organizations or future business dealings.

Please see a brief summary PROP's Board of Directors and their other business dealings:

Andrew Kolodny, M.D., is among the most vocal of the Board of Directors and is often cited in the media as an expert on opioids. However, rather than using his platform to promote unbiased public health messaging, he has been found to weaponize his messaging against some of the most vulnerable citizens in the country. He uses common talking points that equate people with painful diseases to "addicts" that have no self awareness, that need third parties like himself to come in to tell them they are "addicted".

Additionally, the recent CDC Federal Docket ID #: CDC-2020-0029-Management of Acute & Chronic Pain, PROP provided feedback asking for the many patients expressing negative impact from lost access to opioid pain medications to be disregarded as signs of patient addiction. Below is an excerpt from their statement to the CDC: (See Exhibit 4)

- *For many pain patients who are **physiologically dependent on opioids, the shift away from the excessive use of high opioid** doses unique to the United States has been difficult. The 2016 guideline envisioned dose reduction or discontinuation achieved gradually through shared decision making with patients. For a variety of reasons, this goal proved difficult to achieve. Some patients using opioids long-term now have difficulty finding clinicians willing to continue them on a risky treatment lacking evidence of effectiveness. Many of these patients are **fearful of losing access to opioids and believe they are being unfairly penalized for opioid misuse**, as evidenced by anecdotes submitted to this docket. We believe that the problems these patients have experienced can be avoided without returning to the ineffective and unsafe opioid prescribing practices that resulted in hundreds of thousands of needless deaths and millions becoming addicted to medically prescribed opioids.*

When faced with real-life, quantifiable, feedback from patients impacted by dose reductions and difficulty accessing appropriate pain care, PROP requests the CDC to dismiss the patient feedback as merely anecdotal.

Rather than giving thoughtful consideration to the feedback provided by the patients, their caregivers and the organizations representing them, PROP uses degrading language,

gaslighting the patient experience altogether while negating it to "patients believing they are being unfairly treated."

There are many valid, serious concerns taking place within the healthcare changes; the NIH studies - including the HEAL Initiative (58) - as well as the committee work being undertaken. We have witnessed a complete failure of a number of nonprofit advocacy organizations to have any sort of transparency to the communities they serve. It should be noted, nonprofits have a duty to serve the community they were incorporated to help. By having organizations work to simply implement pre-determined governmental strategy; these nonprofits have abandoned this duty to their members, sponsors and donors, thereby violating their duty under their directors and officers in management of the nonprofits activities, which are meant to serve the public good.

Michael Von Korff, ScD is an epidemiologist and Senior Investigator at Kaiser Permanente's Washington Health Research Institute as well as the co-founder (59) of Physicians for Responsible Opioid Prescribing.

In 2010, Michael Von Korff, ScD, (60) published a study (61) which led federal officials to call (62) for reduced opioid prescribing for chronic pain.

Michael Von Korff ScD, and other Board Members of PROP including David Tauben, M.D., and Gary Franklin, M.D., M.P.H., were responsible for the development and testing of opioid-prescribing metrics by the Washington State Bree Collaborative (63) opioid work group where they wrote the academic paper "Surveillance of Opioid Prescribing as a Public Health Intervention: Washington State Bree Collaborative Opioid Metrics." (64) This paper addresses what they perceive as the risks associated with prescription opioid medications and presented guidelines that recommend lowering the dose with a shorter duration of use and discusses avoidance of concurrent sedatives. These reports have been used in an effort to influence public health officials to adopt policies to reduce opioid prescribing and to implement the recommendations they created in their related work as solutions to the same perceived issues they have identified.

Additionally, Michael VonKorff ScD, was the principal investigator (65) of the PCORI study, "Evaluating a Program to Lower Prescription Opioid Doses for Patients with Chronic Pain". (66) This study outlines the results of a study using the Electronic Health Records of patients receiving opioid medications who were put through dose reductions. This research report validates/supports the findings in the CIAAG Dossier: Violation of a Nation,(67) which outlined how the federal government implemented a number of legal changes in the past ten years that would permit pragmatic clinical trials using the private medical care system. It also shows how the implementation of a guideline was necessary to get physicians to comply in regards to a guideline that would be perceived as "ineffective, disruptive and the cause of net-harm".(68)

Michael Von Korff, ScD., worked on the "Team Based Opioid Management" (69) project which is funded by the Agency for Healthcare Research and Quality. The centerpiece of this project, "Primary Care Clinic Re-Design for Prescription Opioid Management" is the "Six Building Blocks" (70) which highlights the core components of team-based opioid prescribing that have been implemented in primary care settings across the country. The aim of this project is to provide a public website with resources and tools (71) that were created to share opioid prescribing practices that this entity endorses. The Six Building Blocks program promotes the idea that debunked doctor shopping and overprescribing are common occurrences, further stigmatizing the patient population.

In 2015 and 2016, Michael Von Korff, ScD., (72) worked with the National Institutes of Health to develop a comprehensive research agenda based on studying people with chronic pain. He served as Chair of the National Pain Strategy Population Research Work Group, which developed methods for defining and identifying "high-impact chronic pain"—an effort that has since been applied in the U.S. National Health Interview Survey. This new approach is utilized to inform health care systems and policymakers in regards to people with chronic pain.

It is important to note that one of the primary objectives of the National Pain Strategy was to identify the number of individuals suffering with high-impact chronic pain and reduce the number of individuals who transition from acute pain to chronic/high-impact chronic pain.

Finally, the 2016 Guidelines for Prescribing Opioids for Chronic Pain were adapted from (73) the Washington State Interagency Guidelines and Michael Von Korff's study, "De facto long-term opioid therapy for noncancer pain". (74)

Additionally, the Public Relations firm Abt Associates (75) was hired to aid with the implementation and guideline plans for the Six Building Blocks. The Six Building Blocks provides a structured, systems-based approach for managing patients on long-term opioid therapy. Abt Associates partnered with Michael Parchman of the MacColl Center at Kaiser Permanente Washington Health Research Institute and Laura-Mae Baldwin and Brooke Ike of the University of Washington to develop the Six Building Blocks. Abt Associates has since expanded (76) the Opioid Quality Improvement Collaborative as of March 2018 to further disseminate the CDC Guidelines across the country. Utilizing CDC funding, Abt Associates will disseminate and implement the Six Building Blocks into 120 additional primary care practices from Massachusetts to Oregon with the goal of aligning current practice standards with the opioid prescribing guideline recommendations.

Jane Ballantye, M.D., President of PROP and Board Certified Anesthesiologist at University of Washington Medical Center. Additionally she has worked as a paid consultant for the law firm

Motley Rice and is in the position to make "billions of dollars in contingency fees from opioid litigation." (77)

Dr Ballentyne often promotes ideas that those with chronic pain need to "accept it" while learning how to manage it without medical interventions and equates our medical conditions to mental health illnesses. Additionally, she publishes op-eds in prestigious outlets enabling her rhetoric to be seen by the public as seen in an op-ed she wrote with Anna Lembke, M.D., and Roger Chou, M.D., titled "Rethinking Opioid Dose Tapering, Prescription Opioid Dependence, and Indications for Buprenorphine. (78) Her messaging indicates that she feels it is medically necessary for "every patient receiving long-term opioid therapy" to go through rigorous re-evaluations to determine if they should be forcibly tapered from their medication regimen.

David Tauben, M.D., FACP, Chief of Pain Medicine, University of Washington Medical Center who has been credited with creating the 90 morphine milligram equivalent (MME) limits. He describes the process and discusses in the following interview how he came to the conclusion regarding the 90 MME dose threshold. (See Exhibit 5) As you can see from this document, David Tauben based his recommendation of the 90 MME dose cap on an arbitrary figure without using any sort of scientific methodologies. Since that time, this figure has been codified into law and used as a threshold for patients across the nation as an "evidence based" maximum limit of medication they should be using. However, in reality, the figure is based solely upon one individual's arbitrary opinion they stated during an interview one day.

Adriane Fugh-Berman, M.D., is a board member of PROP as well as the Director and Principal Investigator for PharmedOut (79) which is a Georgetown University Medical Center project. The project consists of a website that provides free continuing medical education (CME) programs for physicians. This program (80) is funded (81) by the Attorney General Consumer and Prescriber Grant Program.

Adriane Fugh-Berman is an outspoken activist that is against the use of opioid medications. For example, Dr. Fugh-Berman has previously stated that "*there is no evidence that supports the effectiveness of daily opioid use for chronic pain and that long-term opioids are the wrong treatment for chronic pain"* despite there being thousands of studies stating the contrary.

In consideration of her stance about opioids, it is concerning that she holds a position as principal investigator of the CME program at Georgetown University Medical Center. As such, she is in a position to extend her bias into the course material that she is providing for physicians who are obtaining CME credits to maintain their license.

Anna Lembke, MD, (82) is a psychiatrist employed at Stanford University. She is also a Board Member of Physicians for Responsible Opioid Prescribing. Anna Lembke, M.D., is well known

for her book, "Drug Dealer MD (83): How Doctors Were Duped, Patients Got Hooked and Why It's So Hard to Stop".

The following passage from the book reinforces the overprescribing narrative and shows her bias: *"But as prescription painkillers became more available, patients became less willing to endure pain. Suddenly, Lembke says, "doctors began to feel that pain was something they had to eliminate at all cost."*

She is often cited giving speeches or writing op-eds against the use of opioid analgesics even for the management of serious illness and disease. She often uses her platform to stigmatize the disabled community and promote the idea that they are "useless eaters" that use their disability to engage in laziness and take from the Social Security Disability System.
It is deeply concerning that an individual who holds open disdain and discriminatory bias against an entire population of people would have influence over the healthcare said community receives.

Additionally, it is important to note the National Pain Strategy (84) states that academia and higher educational institutions will be needed to help with the implementation of the National Pain Strategy goals. Stanford University was named as one of these Institutions that would be provided the opportunity to work on these projects designated for the purposes of studying pain, addiction and other related to healthcare disparities.

As such, Dr. Lembke has dedicated a large focus of her work to tapering protocols.(85) The BRAVO Protocol:(86) A Biopsychosocial Approach to Opioid Tapers was featured by the Lines for Life (87) organization. The Lines for Life organization formed in Oregon to "help communities in Oregon prevent substance abuse".

In the Video (88), "Compassionate Doctor Meets Drug Seeking Patient", Anna Lembke M.D., can be seen reinforcing the commonly held misconceptions about painful disease patients who take opioid medication thus reinforcing the negative stigma that is existent in society today. She promotes the idea that patients should be tapered (See Exhibit 6) even if they

don't agree to it. She promotes buprenorphine for patients that are unable to taper even if they do not meet the diagnostic criteria for addiction. She also has stated in an article, "Why Doctors Prescribe Opioids to Known Abusers," (89) that patients are aware of the narratives of illness and victimhood and that they use these to get the prescriptions they want which shows bias towards those who are disabled and live with painful diseases/conditions.

Gary Franklin, M.D., M.P.H., (90) is a research professor at the University of Washington Department of Environmental & Occupational Health Sciences and in the Department of Medicine. He served as the Medical Director of the Washington State Department of Labor & Industries where he develops and administers Workers' Compensation health care policy and conducts outcomes research (91).

He is the Director of the Occupational Epidemiology and Health Outcomes Program at the University of Washington where Workers' Compensation data is examined for research purposes with the goal of reducing disability related to occupational injuries and illnesses. As such, he has conducted several studies (92) related to opioid prescribing practices and disability rates. One study (93) concluded, *"exposure to high-risk opioid prescribing within 90 days of injury was significantly and substantially associated with long-term temporary and permanent disability"*.

His research has been translated back into state healthcare policy (94) in an effort to re-educate providers about "best practices" they are developing regarding the use of opioids for chronic pain based on financial outcomes/expenditures rather than personal health outcomes.

Additional business relationships include the Steve Rummler HOPE Network (95), a 501(c)(3), (96) which provides funding to PROP (97) as well as the FedUp! Coalition.(98) The FedUp! Coalition is another advocacy organization working to have access to opioids restricted as a result of drug addiction. As noted on the IRS 2017 filing, the FedUP! Coalition and FedUp! Rally are listed as two separate entities.

Both of these organizations are staunch anti-opioid advocates that have made statements in the past that they have little regard for the physical damage their messaging has on populations that require opioid medications as they believe that our pain is "addiction in disguise" despite having valid medical diagnosis for serious diseases and ailments.

For example, the FedUp! Coalition has been promoting the repeal of The Ensuring Patient Access and Effective Drug Enforcement Act of 2016.(99)

Additionally, Harold Tu, M.D., DMD, FACS, is a director (100) on the board of the Steve Rummler HOPE Network. He was also appointed (101) as a member of the HHS Pain Management Inter-Agency Task Force and is the father in law (102) of PROP's Andrew Kolodny, M.D..

Andrew Kolodny, M.D., is also on the executive committee and advocacy committee (103) for the FedUp! Coalition.

Chris Johnson, M.D., (104) is another individual who sits on both the Board of Directors of Rummler HOPE (105) (2017 990 IRS form) and for Physicians for Responsible Opioid Prescribing.

As seen here, there is a large amount of crossover taking place among these organizations Board of Directors and various Advisory Committees. This effectively allows these individuals to project a larger amount of support for their ideals of what is considered “best practices” and to lobby to have their discriminatory personal beliefs codified into healthcare policy for personal financial interests.

In a time when our nation is focused on systematic discrimination we must not permit bad actors to get involved in the serious work being done to address the dual crisis of addiction and pain in America. Further, it is imperative we ensure the individuals involved in this work are unbiased, without financial motives and have the interest of the population they represent in mind when approaching this work at all times.

It is clear at this juncture we need oversight and a Congressional investigation into what is taking place with the recommendations being made regarding opioid pain medication and pain management in America.

The claim (106) that PROP is a 501c3 non-profit organization is puzzling because PROP is not a registered charity with the Internal Revenue Service. Instead it uses the Steve Rummler HOPE Network as its "fiscal sponsor" -- an IRS designation that allows PROP to piggyback onto another organization’s 501c3 status. Because it is not a charity, PROP has never filed a federal or state tax return and is not required to disclose anything about its revenue, donations or spending.

We recommend Congress do research into Physicians for Responsible Opioid Prescribing, Pacira Pharmaceuticals, American Chronic Pain Association, BioDelivery Sciences International, Indivior, Steve Rummler HOPE Foundation, FedUp! Rally, FedUp! Coalition, Shatterproof and US Pain Foundation as well as their Board of Directors influence and activities surrounding the CDC Guidelines, the National Pain Strategy, Inter-Agency Pain Research Coordinating Committee and Federal Pain Research Strategy activities. It is notable that members of the Board of Directors of these organizations were intimately involved in the activities at these committees as well as the implementation strategy work done at Abt Associates to produce the National Pain Strategy and subsequent changes in pain care.

US Pain Foundation & Integrative Health Policy Consortium

On July 22, 2020, it was announced that the HHS Pain Management Inter-Agency Task Force Report was added to the 2021 Appropriations Bill. (107) In doing so, this will permit Congress

to allocate funds to the recommendations made by the Task Force in the report. One such recommendation is a National Pain Awareness Campaign. It should be noted that the Legislative Policy Director, Cindy Steinberg, from the U.S. Pain Foundation was on the HHS Inter-Agency Task Force and therefore, would have direct influence over what the "national campaign on pain" would look like in the United States as a result.

Since their participation on the committee, their organization held a Virtual Advocacy Day to promote the report to congress and subsequently announced that it was added to the 2021 Appropriations Bill on July 22, 2020. The U.S. Pain Foundation has long been the only voice in Washington, D.C. representing pain patient rights, effectively having a monopoly on this subject matter as it relates to the patient side of the opioid issue for a number of years. However, it has been seen in their recent work, they now support the government strategy of "multimodal care," as recommended in the HHS Inter-Agency Task Force report they participated in. In addition, they have shown to have financial difficulties in recent years, including extreme financial mismanagement resulting in, "A former board member (108) of the U.S. Pain Foundation raising questions about how former CEO Paul Gileno was able to misappropriate over $2 million in funds from the Connecticut-based non-profit."

Given the history of this organization and their recent participation on the HHS Inter-Agency Task Force, they have direct influence over what type of advocacy campaign the United States "should have." In order to ensure the integrity of the committee work and recommendations made in the HHS Inter-Agency Task Force report, we feel the individuals who participated on the committee should be barred from applying for any grant monies that result from the recommendations they helped create; in this case, the National Advocacy Campaign. However, this same idea would apply to all members on the committee and any monies allocated by Congress in the 2021 Appropriations Bill to fund the recommendations of the report.

On July 24, 2020, the Integrative Health Policy Consortium (109) hosted the first in a series of Congressional briefings to the Congressional Integrative Health and Wellness Caucus with Co-Charis Congresswoman Judy Chu (D-CA) and Congresswoman Jackie Walorski (R-IN) where they presented "Pain-Demic: Fallout from COVID-19 Solutions for Our Worsening Opioid Crisis and the Rising Impact on Healthcare Disparities."

A Key-Note Speaker was Vanila Singh, M.D., Chair of the HHS Inter-Agency Task Force. They presented the idea the COVID is leading to an exacerbation of the opioid crisis.
"COVID-19 has exacerbated the raging opioid crisis driven by the nation's more than 50 million chronic pain sufferers, magnifying existing healthcare disparities and heightening barriers to essential, cost effective, non-opioid, non-drug pain treatments." (110)
It is clear in looking at the language used in this presentation that the goal is to promote the idea that the opioid epidemic is a result of prescribing opiate analgesics for medical purposes despite the fact that this has been scientifically proven untrue. (111)

In addition, the presentation outlines a number of their goals which include "Building a Pain Program" (112) that would provide the "benefits" of:

- Mitigating Opioid Prescribing
- Aligning with Best Practices

This language shows that their organization is working with the Congressional Caucus to help implement strategies into the community that would address recommendations within the HHS Inter-agency Task Force report.

Vanila Singh, M.D., was a chairperson on a HHS Inter-Agency Task Force and is highly aware of the importance of using proper language to avoid the stigmatization of patients.
During this presentation, in which she is a speaker, they are directly blaming patients by saying, "the raging opioid crisis is being driven by the 50 million pain sufferers." This shows a clear intent to weaponize their platform and the narrative against individuals suffering from painful illnesses, diseases and painful conditions. In addition, they indicate this will mitigate opioid prescribing. It has been presented publicly through HHS, CDC, FDA and other agencies that the goal should be individualized patient care, not the mitigation of opioid prescribing.

The work being done by the most prominent advocacy organizations in the nation that have influence over public health policy as it relates to pain management have been publicly presented (for the past decade) as working to protect patient rights. However, reviewing the work taking place, the goals for these organizations are aligning with government policy that was outlined over a decade ago, as outlined in the report "Violation of a Nation" (113) to reduce the amount of available opioids in the nation and create a cultural shift towards integrative treatments including non-opiate medications, non-pharmacological treatments and self management.

This creates a serious question about the motivations of the recommendations being made by the individuals sitting on various federal and state committees, pharmaceutical companies, data analytic companies and advocacy organizations. There is a clear alignment taking place with these groups. Advocacy organizations in particular provide a public service and therefore, have a duty to serve the needs of the population they are incorporated to assist. These goals should be aligned with the needs of the population, not with those outlined in governmental strategies; especially when this information is being misrepresented and hidden from the public.

In reviewing the activities of the most prominent organizations involved in pain advocacy, their goals are precisely aligning with that of governmental strategy, despite the needs of the populations they are meant to represent.

The American Pain Society presented the National Pain Strategy and Prescribing Guidelines: Balancing Pain Care and Risks in 2016. (114) There was a clear coordinated effort to recruit pain organizations to help support and implement the National Pain Strategy into society in order for it to be successful.

It was presented as though this would be beneficial to both those suffering from addiction along with those suffering from chronic pain. However, the ultimate goal of the program was to reduce the available supply of opiate pain medications in society, to create a cultural shift towards pain acceptance and self management, to promote research and the development of new strategies to replace opioid analgesics.

However, after 4 years, it has been more than proven that these strategies have failed. In addition, these strategies have attracted a number of individuals with special interests and the sole purpose of trying to profiteer off of the crisis which must be addressed by our legislative officials before we create any future guidelines or regulatory/rule changes.

Voices for Non-Opioid Choices

Voices for Non-Opioid Choices (VNOC) (115) launched on May 16, 2019 (116) is a 501(c)(3) nonprofit, that describes themselves as a nonpartisan coalition dedicated to preventing opioid addiction *before it starts* by increasing patient access to non-opioid therapies and approaches to managing acute pain by focusing on the post surgical experience.

VNOC supports (117) the Department of Health and Human Services Pain Management Best Practices Task Force report and is using it as a marketing tool to promote the increased utilization of non-opioid pain management approaches. As a part of this strategy, they are promoting payment and coverage incentives for non-opioid treatments in the outpatient setting in surgery centers and hospitals. As such, VNOC urged (118) the Office of Management and Budget to include separate reimbursement for non-opioid acute pain management approaches in the forthcoming 2020 Outpatient Prospective Payment System rule.

It is notable that VNOC Executive Director, Chris Fox, was a lobbyist for the lobbying firm Venn Strategies (See Exhibit 7) who also lists Pacira Pharmaceuticals as another one of their clients. Pacira hired Chris Fox of Venn Strategies to be their lobbyist. Chris Fox then becomes the Executive Director of VNOC with the goal in mind that Pacira is promoting opioid sparing strategies in the hospital outpatient setting, Chris Fox has publicly stated that in no way is VNOC attempting to take away the ability of pain patients access to opioid analgesics however, everything that we see coming out of Pacira/Choices Matter speaks to the contrary. It is like he is talking out of both sides of his mouth. He drives the anti-opioid, overprescribing, chronic opioid user narrative then states the goal is not to take our meds. To realize that he was

working at Venn Strategies and was hired to lobby and represent Pacira then became the Executive Director of VNOC, leads us to believe that Pacira created VNOC specifically to promote their product while demonizing opioids.

Additionally, they lobbied and successfully obtained signatures of 53 members of Congress for a letter (119) to the Department of Health and Human Services to urge the utilization of non-opioid approaches to pain management. They obtained (120) Medicare Advantage (MA) guidance allowing plans to provide access to alternative pain management approaches, including, but not limited to, peer support services, chiropractic services, acupuncture, psychological services, and therapeutic massage.

Further, VNOC joined (121) the National Academy of Medicine Action Collaborative on Countering the U.S. Opioid Epidemic to promote the need for policy changes to increase access to and utilization of non-opioid approaches to pain management.

In September 2019, VNOC sent a letter (122) to CMS and DHHS regarding Proposed Changes to the Hospital Outpatient PPS Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates again promoting the incentivization of non-opioid medications for the management of acute pain; erroneously correlating prescribing with illicit use and addiction.

Finally, as a part of their work, VNOC is lobbying for the NO PAIN Act, (123) which is a bipartisan piece of legislation being promoted to increase patient and provider access to non-opioid approaches to acute pain management, particularly in the surgical setting. This would be accomplished by "incentivizing" the use of non-opioid pain management approaches and creating a system that discourages the use of opioids in the postoperative setting.

It is interesting to note, the press release that went out from Representative Sewell and Representative McKinley in support of the NO PAIN Act, cited information taken from Pacira Pharmaceuticals Plan Against Pain. (124) As mentioned previously, the report titled, "The United States for Non Dependence," focused on the relationship between opioid prescriptions for surgical procedures and later issues of dependency and abuse; however, was based on information that was funded and procured by Pacira themselves. Which leads us to question the validity of the data itself. Dr Josh Bloom of the American Council on Science and Health also addressed the issues with this legislation in his article, "Rep. Sewell's NOPAIN Bill Is Really NO-BRAIN". (125)

G. Caleb Alexander (126) is a pharmacoepidemiologist at John Hopkins Bloomberg School of Public Health. In addition, he is the Chair of the US Food and Drug Administration's Peripheral and Central Nervous Systems Advisory Committee, has served as a paid advisor to IQVIA, serves on the advisory board of MesaRX Innovations, is a member of Optum RX's National

Pharmacy & Therapeutic Committee and holds equity in (and is the Founder of) Monument Analytics, a health care consultancy whose clients include the life science industry as well as the plaintiffs in opioid litigation as outlined in his Conflict of Interest Statement on the enclosed (127) study.

Additionally, he is the Founding Co-Director of the Johns Hopkins Center for Drug Safety and Effectiveness. (128) Under this program, the principal investigators are able to utilize a plethora of data access points such as Medicare Claims or QuintilesIMS Data, for the purposes of conducting research.

He also is the Co-Founder of "Monument Analytics" (129) which is a healthcare consulting firm that works with federal clients including Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE), FDA and CDC giving them direct influence over healthcare policy at a number of federal agencies.

In 2015, Caleb Alexander was one of the lead authors of the report, "The Prescription Opioid Epidemic: An Evidence Based Approach" (130). The published report included 3 public health recommendations:

1. Repeal existing permissive and lax prescription laws and rules.
2. Require oversight of pain treatment.
3. Provide physician training in pain management and opioid prescribing and establish a residency in pain medicine for medical school graduates

At the invitation of the Johns Hopkins Bloomberg School of Public Health and the Clinton Foundation, a diverse group of experts were convened to chart a path forward to address these issues. After a town hall meeting at the School, featuring an inspiring call to action from President Bill Clinton, the group — including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers and patient representatives — spent the next day and a half:

- Reviewing what is known about prescription opioid misuse, abuse, addiction and overdose;
- Identifying strategies for reversing the alarming trends in injuries, addiction, and deaths from these drugs; and
- Making recommendations for action.

Following this meeting, the group released a consensus statement with three guiding principles for translating the meeting discussion into action items. These items were presented at the

meeting and it was discussed that the identified action items should be scaled up and widely disseminated on a “rush” basis due to the emergency situation presented by the opioid crisis.

Additional business dealings include his annual speaking (131) engagement with the FedUp! Rally where he publicly promotes the idea that prescribing is the root cause of drug addiction and misframes statistical data and other research as a means to fear monger.

He has also been engaged in lobbying with a number of key decision makers including the Black Caucus, the National Governors Association, National Academies of Science, Engineering and Medicine as a means to influence public health policy and promote his principles and ideals to be adopted by lawmakers when shaping healthcare policy change.

His work focused on the opioid epidemic has been funded by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation, the Centers for Disease Control and Prevention, the Robert Wood Johnson Foundation and the National Institute of Health.

Other notable research papers and studies he has contributed to include, but not limited to,

- “The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction” (132) which states that overprescribing is the cause of the opioid crisis and was co-authored by Kreiner, Alexander, Kolodny, Eadie, Clark, et al..
- “Prescription Drug Monitoring Programs: Critical Elements of Effective State Legislation” (133) which was co-authored with Clark, Eadie, Franklin, Kolodny, Mendell, et al.
- “Opioid addiction caused by overprescribing, not recreation abuse, is the key driver of painkiller and heroin overdose crisis” (134) which was published by Brandeis University.

Conclusion

We recognize the effort put forth to manage the needs of the public health and safety of the varying individuals and communities in the American public as it is no small challenge. The Affordable Care Act of 2010 put forth bold goals to try to manage these challenges in a way that would be equitable to all citizens. Unfortunately, to date, this has not happened. Rather, we have seen thousands of patients suffering from chronic pain, illness and other diseases exploited and harmed, while organizations and individuals pursue business opportunities and double dealings to self enrich. However, we are confident that by open communication and collaboration with our lawmakers, progress can be made to help both those suffering from substance use disorder and those who suffer from long term chronic pain.

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Our organization is asking our lawmakers to hold an oversight hearing on the NIH Pain Studies taking place and the committee work connected to it at the various agencies and organizations, including but not limited to: HHS, FDA, CDC, IPRCC, AHRQ, VA, DoD, Stanford University, Oregon HERC, PCORI, Michigan Open, US Pain Foundation, American Chronic Pain Association, Indivior, FedUp Rally FedUp Coalition, Steve Rummler Hope Foundation, Shatterproof, PCORI, Voices for Non-Opioid Choices, BioDelivery Sciences International, Pacira BioSciences, National Center for Integrative & Integrative Health, Kaiser Permanente, Robert J. Woods Foundation, Brandeis University, Physicians for Responsible Opioid Prescribing, Alliance for Balanced Pain Management.

In addition, moving forward we ask that individuals appointed to committees are balanced and include individuals who have the patients best interest in mind and are free of conflicts of interest. Specifically, legitimate pain patients and pain management doctors with pain patient best interests in mind.

We ask for Congressional oversight committees to be developed to oversee the work being done by these agencies and their committees to ensure the public health and safety

Our organization is available for further discussion on meaningful public health policy changes.

I thank you for your time.

Regards,

Lauren Deluca
Executive Director
Chronic Illness Advocacy & Awareness Group

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