To: Governor Chris Christie  
Presidential Commission on Combating Drug Addiction and the Opioid Crisis

From: Gary Mendell, Shatterproof

Date: June 16, 2017

Re: Shatterproof Recommendations for the Presidential Commission

Unlike most other chronic medical illnesses, substance use disorders have always carried a negative connotation. Years of misconstruing addiction heavily fueled our country’s public health crisis, and have left the quality of treatment for substance use disorders decades behind other chronic illnesses.

As a result, the epidemic took the lives of over 33,000 of our sons and daughters in 2015. It is expected that a greater number of lives were lost in 2016, and will continue to be lost in 2017. And without immediate action, the number will be much higher in the coming years. In addition, it is estimated that the opioid epidemic cost our society approximately $78 billion in 2013 in healthcare costs, lost productivity and criminal justice, and is certainly much higher today.

Addiction became personal for me and my family when I lost my son Brian to the disease on October 20, 2011. In the months that followed, it haunted me knowing how many families were being shattered every day by this disease. And even worse, that NIH funding had created a wealth of knowledge that had proven to provide the capability to reduce the number of our loved ones who ever become addicted, and also increase the number of those in addiction to recover. However, most of this research was not being implemented.

Shortly thereafter I founded Shatterproof, the first national organization dedicated to attacking addiction from all perspectives and spare other families from the devastation my family suffered.

Today, we respectfully submit the following evidence-based recommendations, based upon the urgency and resources consistent with the continuing growth of this epidemic.

While ending this epidemic will be difficult, cutting this by two thirds, in just a few short years, and saving countless lives, is possible.

I’d like to begin by emphasizing three points that helped craft these recommendations:

1. We believe our federal government should limit the circumstances in which it regulates our states. However, there is no question that federal involvement can save tens of thousands of lives. In this regard, several of our recommendations are patterned after what our federal government did
years ago to ensure states drop their speed limits to 55 mph; tying highway funding to state compliance.

2. Most of these recommendations do not require a single penny; rather immediate and efficient implementation. For the few that do require funding, the return on investment is far greater than needed to justify their cost.

3. When I use the phrase “Federal Funding”, I am referring to four funding streams; funding related to SAMHSA block grants, funding related to the Comprehensive Addiction and Recovery Act, funding related to the 2nd $500,000 of the 21st Century Cures Act, and other funding channels yet to be determined.

We have divided the following recommendations into two categories: 1) treat and save the lives of ~3 million Americans currently afflicted with an Opioid Use Disorder (OUD); and 2) prevent ~320 million Americans and future generations from developing an OUD.

**Treatment**

*Treat and save the lives of ~3 million Americans currently afflicted with an Opioid Use Disorder*

1. **End the Treatment Gap**

   80% of those addicted to opioids do not receive The most potent weapon to reduce overdose deaths is Medication Assisted Treatment (MAT). Approximately 80 percent of those with an OUD in the United States are not treated due to enormous gaps in 1) providers certified to prescribe medication, 2) professionals who can effectively provide evidenced-based behavioral therapies, and 3) financing to cover the costs. To close these gaps, we recommend the following:

   a. Close the gap of certified prescribers by eliminating the eight hours of training needed to prescribe Buprenorphine. Buprenorphine has a lower risk profile than full agonist opioids. While there are important considerations to be aware of in its use, it is not more complicated to prescribe than many other medications that providers prescribe regularly without required training, such as insulin or warfarin. This can be done quickly, will not cost a single penny, and could be reversed after certain lifesaving benchmarks are achieved.

   b. Close the gap of needed specialists to deliver evidence-based behavioral therapies by mobilizing an Emergency Training Program. The program can be developed by the federal government within 60 days of this letter, and fully implemented by December 31, 2018.

   c. Close the **financing** gap via two tactics:

      i. Federal funding for any American that does not have insurance, for a to-be-determined time period, for those Americans whose insurance does not cover all aspects of MAT (emergency funding through September 2017 and within the federal budget starting October 1, 2017). We note that a large portion of the costs are already covered through existing financing channels. All FDA approved medications for opioid treatment (methadone, buprenorphine and naltrexone) are already covered by Medicare, Medicaid, VA, Indian Health Service and most
private insurers. We also recommend that funding of the federal SAMHSA block grants to states be contingent upon acceptance by state authorities of appropriately prescribed and monitored use of MAT for those with an OUD. As is recommended throughout this letter, using the incentive of federal funding to states is a lever we recommend.

ii. Eliminate all prior authorizations in all insurance plans in the United States for any, and all aspects of MAT.

We believe that these recommendations can be implemented by Presidential Order, emergency legislation/regulation, and/or presidential influence.

There is precedent for this in England. In 2000, England had the highest rates of untreated opioid addiction in Europe (94 percent of known opioid addicted individuals were untreated) and were threatened with the potential for massive increases in AIDS and Hepatitis C. The public health department trained and incentivized primary care physicians to screen and engage addicted individuals into treatment. This was accompanied by a massive public health information campaign that took the stigma away from being addicted, and transferred it to accessing treatment. Within two years, over 65 percent of known opioid addicted individuals were under treatment, rates of new opioid addictions had fallen by 45 percent, and England still has the lowest rates of AIDS and Hepatitis in Europe.

In addition, it goes without saying that full enforcement of the Mental Health Parity and Addiction Equity Act needs to be accomplished. Numerous recent reports indicate there has been significant progress, but these reports also indicate much more needs to be done. Full compliance with this law is essential, and needs to be achieved.

Lastly, the health care bill recently passed by the U.S. House of Representatives and now being considered by the Senate takes several steps backwards on combating the opioid epidemic. We recommended that President Donald Trump not support any bill that reduces insurance benefits in the aggregate for those who need treatment for a substance use disorder or mental illness.

2. Develop the Infrastructure to Ensure All Treatment is Evidenced Based

Well-supported scientific evidence shows that substance use disorders can be effectively treated, with recurrence rates no higher than those for other chronic illnesses such as diabetes, asthma and hypertension. However, treatment for OUD is most often delivered without the use of evidence-based quality measures.

In 2006, the Institute of Medicine published a report, Improving the Quality of Health Care for Mental and Substance-Use Conditions. This report urged HHS, in partnership with the private sector, to direct and financially support an entity to convene government regulators, accrediting organizations, consumer representatives, providers and purchasers, with the purpose of reaching consensus and implementing a common, continuously improving set of M/SU health care quality measures for providers, organizations and systems of care to follow. Participants in this consortium should commit to:
• Requiring the reporting and submission of the quality measures to a repository of performance measures.
• Requiring validation of the measures for accuracy and adherence to specifications.
• Ensuring the analysis and display of measurement results in formats understandable by multiple audiences, including consumers, those reporting the measures, purchasers, and quality oversight organizations.
• Establishing models for benchmarking and quality improvement purposes at sites of care delivery.
• Performing continuing review of the measures’ effectiveness in improving care.

These recommendations have not been implemented, and in this regard, Shatterproof recently began a process to do so (See Exhibit A).

Pursuant to the IOM recommendation 4.3, we suggest that HHS become involved in our initiative to accelerate its implementation.

3. **Rescuing those Experiencing an Overdose**

If administered in time, naloxone can save lives and give people a second chance so they can get into treatment or take other actions to reduce their risk. It is inexpensive and effective to administer, has essentially no side effects on individuals or the public at large, and must be incentivized for much broader availability. It should be accessible in college health centers, ERs, homes, restaurants, prison and jail health clinics, as well as through primary care physicians who provide the greatest proportion of opioids for treatment of pain.

Through Governor Proclamations, state legislation and state regulation, states are gradually expanding access by making naloxone available by pharmacists without doctor prescriptions and providing indemnities to those able to administer this medication in an emergency. However, progress is far too slow. In 2016 Shatterproof documented nine best practices each state should implement (See Exhibit B), and scored each state. The scores indicate much is left to be accomplished.

We recommend three levers to expand access to naloxone:

a. HHS recommends that every first responder in the United States become trained and stocked with naloxone by September 1, 2017. Any state which has not accomplished this by that date will not have access to Federal Funding in 2018.

b. HHS recommends that every state enact legislation and/or regulations that comply with the nine best practices referenced above, with a stipulation that any state which has not accomplished this by February 28, 2018 will not have access to Federal Funding in 2018.

c. The federal government leverage its purchasing power on behalf of states to counter recent dramatic increases in price that threaten local supply in the face of surges in overdose.
The federal government could also consider supporting the FDA in making naloxone an over-the-counter drug to increase accessibility. We have yet to list the advantages and disadvantages of this.

We believe that this all can be implemented by Presidential Order, emergency legislation/regulation, and/or presidential influence by early 2018.

4. **Increase Provider Education**

Seven percent of medical schools mandate courses in substance use disorders. This leaves those who will ultimately prescribe opioids and who will encounter the health effects of opioid and other substance use disorders in their practices utterly unprepared to provide safe and effective care. Meanwhile, the federal government provides literally every medical and nursing school in our country with billions of dollars in low-cost loans for student tuition.

We recommend that medical and nursing students who access these federal loans, can only do so if they attend a school that has at least one approved course in addiction. We believe that this can be implemented by Presidential Order, emergency legislation/regulation, and/or presidential influence by December 31, 2017.

The immediate effect would be that all medical, nursing, dental and likely other related professional schools would adopt existing courses that have been to this date ignored. There are approved, online courses for second year medical and nursing students, and there are well structured residency training programs available through ASAM – these simply have not been used by the schools.

5. **Ensure Treatment as a Condition of Community Release**

One of the populations most at risk for overdose death in this country are the 30 – 40 percent of inmates who will be released from federal/state prisons and community jails and were incarcerated for opioid related crimes. Not only are they at personal risk for overdose and relapse, but they are a significant vector for the spread of opioid misuse in the communities to which they will return.

Treatment as a condition of community release is a well-established practice and has been since the mid-1990s. But with little training of community correction officers, problems with insurance (including Medicaid) among those released, and caseloads of over 500 per corrections officer, efforts in addressing this issue haven’t been effective.

We recommend that in order to ensure treatment as a condition of community release, caseloads be reduced, and training in addiction monitoring and management be increased by a Mobilization and Training Plan developed by the federal government within 60 days of the date of this letter, and fully implemented by December 31, 2018. Additionally, as part of this plan, positive drug tests should not result in automatic return to incarceration, but instead in increased intensity of treatment, monitoring, and supervision. These provisions worked during Portugal’s drug policy overhaul, and could work in the United States.

6. **End the Shame, Isolation and Stigma**
The stigma that is associated with those afflicted with OUD is unjust and needs to end. Societal stigma inhibits resources applied to this disease that are indicated by both its cost in human suffering and its cost to our society. Societal stigma leads to self-stigma, further increasing the human and societal costs of this disease.

We recommend President Trump lead the way in ending the stigma of this disease with his messaging and prioritization of our resources.

**Prevention**

*Prevent our ~320 million Americans and future generations from developing an OUD*

7. **Implementation of CDC Guideline**

On March 15, 2017, the Centers for Disease Control and Prevention issued the *CDC Guideline for Prescribing Opioids for Chronic Pain* (CDC Guideline). We believe the greatest opportunity to stem the opioid epidemic is to impact the over-prescribing and/or misprescribing of opioid medications. The CDC Guideline must be adopted in emergency timeline.

We recommend the federal government develop a robust goal setting and reporting process to drive local prescriber and state accountability. This would include:

- An analysis of new patient prescribing that is outside the CDC Guideline to set a benchmark level for each state, and our nation in the aggregate;
- Stringent goals to reduce inappropriate prescribing;
- Clinical education and interventions targeted to physicians and states with the greatest levels of inappropriate prescribing;
- Annual publishing of results, within 60 days of the end of each year, to drive accountability.

We further recommend tying Federal Funding to achieving these aforementioned goals.

And we also recommend exploring the following additional tactics:

a. Medicare Part D to raise the cap on speech and physical therapy. It is currently at $1,960, discouraging prescriptions for physical therapy.

b. CMS incorporate the CDC Guideline into the Conditions of Participation (CoPs) for the Medicare and Medicaid programs. Such reliance on the CDC Guideline is fully consistent with the purpose of CoPs, which serve as standards to protect the health and safety of beneficiaries and to ensure the quality of their care. CMS can work closely with providers, health systems, state agencies and HHS, and can provide a wealth of guidance as well as technical assistance to State Medicaid programs nationwide. This step would impact all healthcare organizations that participate in CMS.
c. CMS Part D plans put in a prior authorization requirement which would state that prior to the prescribing of any opioid for longer than three days, an Informed Consent Form must be signed by the patient, or CMS would impose a requirement that all Part D plans include a prior authorization requirement which would state all prescribers must take the soon to be issued CDC online course in the CDC Guideline for Prescribing Opioids for Chronic Pain and adopt as a standard of care.

d. The Food and Drug Administration (FDA) incorporate the CDC Guideline into its “Blueprint” for prescriber education on extended-release and long-acting opioid analgesics. Once the CDC Guideline is finalized, the FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program for prescription opioids must be immediately updated to reflect what will be the most up-to-date regulatory science and clinical guidance.

e. HHS begin work through CMS, the Center for Medicaid and Medicare Innovation (CMMI), CDC, the Agency for Healthcare Research and Quality (AHRQ), and its other agencies, to develop and evaluate performance measures for adoption of the Guideline through annual Medicare and Medicaid payment rules, in Accountable Care Organizations (ACOs), as well as in other innovative value-based payment pilots.

f. Academic detailing or other quality improvement protocols be developed and implemented to educate providers on guideline-recommended practices.

g. Mechanisms be developed to reach providers and patients in underserved areas, such as in rural and tribal areas, including telehealth and telemedicine strategies.

We recommend all of these be announced within 30 days of this letter, and we further believe these recommendations can be implemented by Presidential Order, emergency legislation/regulation, and/or presidential influence by April 1, 2018.

8. Effective Use of Prescription Drug Monitoring Programs (PDMPs)

Per the CDC, PDMPs are among the most promising state-level interventions to improve opioid prescribing, inform clinical practice and protect patients at risk. However, in 2015, the patient history was not checked by the prescriber in approximately 80 percent of prescriptions written for opioids. Half of our state pharmacies only upload the information weekly. Interstate sharing is horrendously low.

In March 2017, Shatterproof published Prescription Drug Monitoring Programs: Critical Elements of Effective State Legislation, detailing 12 recommendations (See Exhibit C). Each state has recently been scored, and the scores indicate much is left to be accomplished.

We recommend the following:

a. Reporting of each patient drug overdose becomes the 13th recommendation.
b. Federal government recommends that every state enact legislation and/or regulations that comply with these 13 recommendations, with a stipulation that any state which has not accomplished this by March 2018 will not have access to Federal Funding in 2018.

c. CMS require that all Part D plans include a prior authorization requirement which would state that prescribing physicians must attest that he/she has checked the state PDMP prior to prescribing any drug in Schedule II, III, or IV. This to be announced within 30 days of this letter and accomplished by December 31, 2017.

d. PDMPs incorporate universal use, real time, actively managed and easy to use and access features. Consider the cost/benefit of a national PDMP to replace state PDMPs. This could be accomplished with a national system with certain required features, along with additional features decided by each state.

9. **FDA Labeling of Opioids**

Opioids are one of the only medication classes that lack a suggested maximum dose on its FDA-approved label. Even over-the-counter medications include a suggested upper dose. Another problem with opioid labels is that they are too broad, allowing opioid makers to promote use for conditions where risks outweigh benefits. FDA can promote more cautious prescribing through improved labeling.

We recommend President Trump issue a Presidential Executive Order, or the levers of his influence, to ensure this occurs no later than September 1, 2017.

10. **Mandatory Provider Education**

We recommend an amendment to the Controlled Substance Act whereby all DEA registrants are required to take a course in the proper treatment of pain by December 31, 2017, and then on a rolling basis, as part of their regular on-going renewal. This course, prepared by HHS by October 1, 2017 includes CDC training on *Prescribing Opioids for Pain*. We recommend that providers who intend to prescribe more than a 3-day supply of opioids have a requirement to take this course. Many will not do so, limiting the pool of prescribers allowed to give more than 3-day supply. And those that opt-in should have no issue taking a comprehensive course. Alternatively, this may be able to be accomplished by Presidential Executive Order.

11. **Patient Education**

We recommend an amendment to the Controlled Substance Act whereby every time a prescription is written for greater than three days, the prescriber must have the patient sign a consent form explaining the risks and benefits. Alternatively, this may be able to be accomplished by Presidential Executive Order.

12. **Data, Accountability**

Require payers (e.g., Medicaid, Medicare) and Prescription Drug Monitoring Programs (PDMPs) to provide feedback to providers on prescribing metrics, focusing on providers with high-risk
prescribing histories (e.g., provide letters to inform of high-risk prescribing practices, with references to guidelines and education available). Further recommendations on this will be forthcoming.

Every morning I wake up thinking of the Serenity Prayer. The serenity to accept what I cannot change, and the courage to change the things we can.

Our society must find the serenity to accept the lives that have already been lost. However, working together, Republicans and Democrats, elected leaders and government officials, business leaders and families, we need to the courage to ‘change the things we can’ and save countless others.

We can, and we must.

Sincerely,

Gary Mendell
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Exhibit A
Substance Use Disorder Treatment Task Force

The Issue

It is estimated that approximately 21 million Americans have a Substance Use Disorder (SUD):

- The combination of the misuse of alcohol and drug overdoses took the life of approximately 140,000 Americans in 2015.
- Drug overdoses related to opioids have increased five times in the last 15 years, and drug overdoses now exceed car accidents as the number one cause of injury death.
- The cost to our society in lost productivity, healthcare costs, and criminal justice exceed $400 billion per year.
- And beyond this cost, a recent study showed that the presence of a substance use disorder often doubles the odds for the subsequent development of chronic and expensive medical illnesses, such as arthritis, chronic pain, heart disease, stroke, hypertension, diabetes, and asthma.

Well-supported scientific evidence shows that substance use disorders can be effectively treated, with recurrence rates no higher than those for other chronic illnesses such as diabetes, asthma, and hypertension. However, treatment for SUD is often delivered without the use of evidence-based quality measures:

- Well-supported scientific evidence shows that medications can be effective in treating serious substance use disorders, but they are under-used.
- Well-supported scientific evidence shows that behavioral therapies can be effective in treating substance use disorders, but most of these are often implemented with limited fidelity and are under-used.

What is Different About this Task Force / Mission

There are numerous reports that provide the evidence of what treatment and recovery services should include, and recommendations of what should be done to improve the quality of treatment.

This Task Force is different. It has been formed to ensure implementation of the most up-to-date research findings to boost the quality/quantity of treatment (ultimately, improving patient outcomes). It is taking a business approach to this broad, public crisis with the foundation that “what does not get measured, often does not get done.”

Background Documents


In 2006, the Institute of Medicine published a report titled Improving the Quality of Health Care for Mental and Substance-Use Conditions. This report urged the Department of Health and Human Services, in
partnership with the private sector, to direct and financially support an entity to convene government regulators, accrediting organizations, consumer representatives, providers, and purchasers with the purpose of reaching consensus and implementing a common, continuously improving set of M/SU healthcare quality measures for providers, organizations, and systems of care to follow.

Participants in this consortium should commit to:

1. Requiring the reporting and submission of the quality measures to a repository of performance measures.
2. Requiring validation of the measures for accuracy and adherence to specifications.
3. Ensuring the analysis and display of measurement results in formats understandable by multiple audiences, including consumers, those reporting the measures, purchasers, and quality oversight organizations.
4. Establishing models for benchmarking and quality improvement purposes at sites of care delivery.
5. Performing continuing review of the measures’ effectiveness in improving care.

**Approach**

The approach of this Task Force will be to combine the content and recommendations of the two reports outlined above in the following steps:

1. Bring together a subset of its Task Force and others to gain consensus on a select number of quality measures that have strong evidence in improving patient outcomes and whose success and usage can be measured.

2. Bring together a subset of its Task Force and others to decide upon the prioritization of the levers of implementation described below.

3. Bring together a subset of its Task Force and others, and finalize a tactical plan to ensure implementation of evidence-based treatment.

**Levers of Implementation**

This Task Force views the following channels as levers of implementation:

1. Tie the use of evidence-based quality measures and/or patient outcomes to the state licensing of providers;
2. Payers of treatment provide incentives to providers for the use of evidence-based quality measures and/or patient outcomes;
3. Educate consumers to boost demand for evidence-based treatment quality measures and/or patient outcomes; and/or
4. Improve the education of providers in quality measures to improve provider satisfaction and improved outcomes.

When considering incentivizing providers, the Task Force reviewed estimates of 2014 spending on SUD Treatment ($34 billion) and its distribution of spending by payer:

- 29 percent State and Local
• 21 percent Medicaid
• 18 percent Private Insurance
• 12 percent Other Federal
• 19 percent Various smaller categories

**Process**

1. Quality measures finalized as a National Standard of Care.
3. Levers of Implementation prioritized.
4. Implementation.

Phoenix Marketing Services has been retained to plan, organize, and facilitate the process. Their process will result in a document with Action Items, measurable by outcome and dates, outlining those responsible for getting each action accomplished. Shatterproof will lead the effort to coordinate completion of the Action Items and document measurable results.

**Current Steering Committee**

- **Michael Botticelli**, Executive Director of the Grayken Center for Addiction Medicine at Boston Medical Center, and former Director of Office of National Drug Control Policy.
- **Jay Butler**, President, ASTHO Board of Directors and Director of Public Health, Alaska Department of Health and Social Services.
- **David Calabrese**, SVP and Chief Pharmacy Officer, OptumRX
- **Chris Hocevar**, MBA, President of both Cigna Healthcare’s Select and Pharmacy businesses.
- **Charles Ingoglia**, MSW, Senior Vice President, Public Policy and Practice Improvement at the National Council of Behavioral Health.
- **Thomas McLellan**, PhD, founder and chairman of the Treatment Research Institute, and served as the Deputy Director of the Office of National Drug Control Policy under President Obama.
- **Gary Mendell**, MBA, founder and CEO of Shatterproof, a national non-profit dedicated to reducing the devastation associated with addiction.
- **Penny S. Mills**, MBA, Executive Vice President / CEO, American Society of Addiction Medicine.
- **Daniel Polsky**, PhD, Executive director of the Leonard Davis Institute of Health Economics. LDI is the leading university institute dedicated to improving health and health care through data-driven, policy-focused research. $100 million/year in research grants among 240 Senior Fellows.
- **Martin H. Rosenzweig**, MD, Senior Medical Director, Optum Behavioral
Exhibit B
Naloxone Best Practices

1. Prescription by standing order to laypersons authorized.

2. Prescriptions authorized to 3rd parties.

3. Prescribers have immunity from civil liability for prescribing, dispensing or distributing naloxone to a layperson.

4. Dispensers have civil immunity for prescribing, dispensing or distributing naloxone to a layperson.

5. Laypersons have immunity from civil liability for administering naloxone.

6. The law removes criminal liability for possession of naloxone without a prescription.

7. Pharmacists allowed to distribute naloxone via Standing Order, Protocol Order, Collaborative Practice Agreement or Pharmacist Prescriptive Authority.

8. Persons or organizations not otherwise permitted to dispense prescription medications permitted to possess, store, and dispense naloxone.

9. The law mandates insurance coverage for at least one form of naloxone.
Exhibit C
PDMP Best Practices

1. Dispensers report specified information expeditiously. This will allow health care providers to have the most up-to-date and accurate prescription information, which helps them make better-informed prescribing decisions.

2. Prescribers query PDMP before prescribing drugs in Schedules II, III and IV, obtaining vital, sometimes life-saving, background information before they write a script.

3. Licensed prescribers register with PDMP, ensuring the across-the-board compliance that will make the system most effective.

4. Enable delegation of PDMP data queries, which saves doctors valuable time.

5. Authorize specified recipients of PDMP data, allowing insurers and other stakeholders to become strategic partners in preventing and identifying drug abuse.

6. Proactively analyze and distribute PDMP data, identifying any inappropriate prescribing and misuse patterns early.

7. Require interstate sharing of PDMP data to provide doctors with complete information.

8. Provide de-identified information, so providers can identify patterns and trends that could aid in the effort to end addiction (while protecting patient confidentiality).

9. Take a community-based approach to PDMP data so communities can work together to monitor, treat and prevent substance use disorders.

10. Link PDMP data to pain and addiction treatment, so that interventions can be arranged before lives are lost.

11. Institute confidentiality protections to keep patients’ privacy safe.

12. Track and report evaluation measures so that every PDMP can continue to get better and better.