

May 21, 2015

The Honorable Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
Ranking Member  
Subcommittee on Oversight and Investigations  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Murphy and Ranking Member DeGette:

I am contacting you to thank you for conducting the series of hearings on the epidemic of prescription drug and heroin addiction the country is facing. I know you have heard in prior hearings from public health professionals, local community leaders and, today, from the states about steps being taken to stem the tide of the CDC-declared and much under reported epidemic exploding in our country. Through this letter, I am adding my voice as a citizen and impacted family member to these deliberations. It is my sincere hope that this letter will become part of the subcommittee's report on this serious public health crisis.

My name is Don Flattery and I live in the Mt. Vernon area of Fairfax County, Virginia. I am a recently retired federal manager, I am a member of the Virginia Governor's Task Force on Prescription Drug and Heroin Abuse, and I am an active participant in the development of a strategic plan for community action on opioid and heroin use in Fairfax County. But I am not writing today in any of those roles. I am addressing the subcommittee in this letter solely as a grieving parent, someone who has lost his 26 year old and only son to an opioid overdose less than nine months ago.

It is critically important to me and to my wife that we do our part to ensure that discussions about this scourge are personalized. You have already heard the appalling statistics about the explosion of opioid prescriptions, addiction rates and overdose deaths. I am intimately familiar with them and will not repeat them here. But those discussions are often far too clinical. As you, federal officials, state officials and public health practitioners deliberate and consider solutions, it is far too easy to become detached. As you proceed, I implore you to recall the personal impacts – we are not just speaking about shocking, obtuse statistics – we are speaking about my son, your daughter and our neighbors. They are real people, with real lives, suffering from a disease and their losses are the face of the epidemic we must stop.

## **PERSONAL IMPACT**

Allow me to share my son's story. On the Friday of last Labor Day weekend, my family suffered the loss of our son Kevin to an opioid drug overdose. He had been battling and was being treated for issues related to panic attacks, stress, depression and starting in 2013, after self medicating with the opioid prescription drug Oxycontin, was being treated for dependence and then addiction. He had returned home to Northern Virginia in the fall of 2013 to his family, seeking treatment and our support.

He was working hard, with our help, to beat what I consider to be not a crime, not a moral failing, but a serious illness – a disease this subcommittee has been informed affects brain chemistry and nerve function. We hoped and believed he was on a good path. Like many struggling with opioid addiction, he tried a variety of treatment options including in-patient, intensive out-patient, medically assisted therapy and abstinence only step programs. Days before he was to start a program that we felt had great promise for success, the medically assisted treatment drug, Vivitrol, he used again, and did not recover.

My son attended parochial schools, was an altar server in our church, played golf at a local country club, participated in youth sports including travel ice hockey and later varsity high school ice hockey. He was a good student and was a 2006 graduate of a local all-male Jesuit prep school in Washington, DC. He was also a 2010 graduate of the University of Virginia where he enjoyed student and fraternity life.

He was intelligent, creative and expressive and made films/videos in the UVa film community. He had talent and was chosen by his university as their student representative to the Toronto International Film festival and after graduation, worked in LA and NY in film and video production.

He came from a loving two-parent home and led the quintessential middle class life, enjoying all of life's and God's blessings. He did not surrender his adolescence, abandon friends, personal interests or turn his back on his school work. He was pursuing his career passion as a working adult when he developed his addiction. Kevin had a lot to live for.

The short bio description I just gave you is an example of how the scourge of the opioid addiction epidemic before us today has no stereotypical victim. It is affecting people of all walks of life, all income levels and all backgrounds. This epidemic and my son's addiction do not respect income, social status or intelligence. That's what epidemics do.

## **SOLUTIONS**

Since my son's death, I have retired from federal service to dedicate myself to advocacy for those suffering from addiction and for those who have lost loved ones to this avoidable and treatable disease. In the nine months since his passing, I have learned a great deal about the disease of addiction, this current epidemic, its underlying causes and painfully for me and my wife, some evidence-based treatment opportunities that offer hope, but now, only for others.

From the perspective of an impacted parent, as a citizen and as an advocate, I would like to share my view of what is needed to stem the tide of the epidemic before us. I attended your May 1<sup>st</sup> hearing at which the co-chair, with notable exasperation, challenged the seven federal

agency witnesses to identify the single thing they would recommend to solve this problem. While most strategies I hear discussed focus on preventing addiction from taking place, keeping the afflicted alive and expanding access to the most effective treatment possible, I will start by offering my singular focus -- my answer to the co-chair's fundamental question.

**We must ensure more cautious prescribing of opioid drugs in this country.** You have seen the statistics regarding the absolute exponential explosion of prescriptions and the coincident fourfold increase in overdose deaths in the last two decades. The nexus between the two is immutable. Until we can "bend the curve" of the number of prescribed opioid pain relievers, we will continue to swim in place and all the federal, state and community resources we can bring to bear for education, prevention, and treatment will be for naught.

This subcommittee can and should hold the Food and Drug Administration accountable for their role in the change in the culture of opioid prescribing in the US. In the face of what the Centers for Disease Control have declared as the most significant prescription drug and heroin epidemic the nation has ever experienced, the FDA continues to inexplicably approve new, more potent opioid drugs, at unnecessarily high dosage rates, and in less than transparent manner.

There are two dozen opioid drugs on the market and I understand there are four more in process of approval. Despite protestations from some advocacy groups that there are over 100 million (or nearly one out of every three) Americans suffering from chronic long-term pain that require the use of opioid pain relievers, an examination of the treatment of pain in many western European nations will yield a number of effective alternatives to OPRs. Moreover, several leading medical experts believe that continued use of OPRs for the treatment of chronic pain actually worsen the underlying pain conditions. We must ask ourselves, how many opioid drugs do Americans need. You have heard the statistic that the US with 5% of the world's population consumes over 80% of all prescribed opioids. If this does not change, the high rates of opioid and heroin overdose deaths will become a uniquely American problem. In reality, it already has.

I implore the oversight subcommittee to challenge a number of policy and process changes implemented by the FDA in recent years that have significantly contributed to the 259 million opioid prescriptions written in the country last year that are driving addiction caused by both non-medical use and medically prescribed overuse.

Some of the processes that should be re-examined include "enriched enrollment" which allows expedited safety reviews of proposed new opioid drugs by excluding patients from clinical trials who might have low tolerance. This practice clearly underestimates risk of use. Such a process was used for the reintroduction of the highly addictive and still abusable (via injection) opioid, Opana, which has now been implicated in the explosion of HIV and Hepatitis C infections in the midwest. The enriched enrollment process has been used to approve every new opioid since 2006 and it must stop.

A second questionable practice of the FDA is the abuse of the review process conducted by their own drug advisory panels. Without re-litigating the questionable Zohydro approval process, the complete dismissal of advisory panel recommendations, particularly those with overwhelming positions must be corrected.

I believe the pressure on the FDA to expedite requests for new drug approval is overriding more compelling public safety interests. If any drugs deserve more thorough and considered review, it is a newly proposed Schedule II opioid narcotic and the process should take as long as necessary to ensure risks are fully examined before approval. Expedited review processes should not apply given the number of such drugs already available in the marketplace. Moreover, the FDA is ignoring their own review policy on when to convene an advisory panel, resulting in decisions without expert review. This is a practice ripe for the subcommittee to review.

Finally, the composition of advisory panels, with some permanent members and some industry-associated temporary members, must be reexamined. The role of advisory panels should be transparent and have no element of potential conflict of interest.

As citizens, we rely on the FDA as our last line of defense for assessing products before widespread availability in the marketplace. Public health considerations are undermined by the FDA's current practices. As a follow up to your May 1<sup>st</sup> hearing on the federal response to this crisis, please ask the FDA to justify, in writing, the policies and practices I have delineated.

I would also like to bring to the attention of the subcommittee my strongly held conviction about the use of medically assisted treatment borne out of my son's treatment experience. My son was confronted at some AA and NA meetings (he attended many different meetings given the wide variety of meetings, people and discussions) where he faced judgment and pressure about his use of buprenorphine. He was made to feel that he was not in recovery, not serious about his sobriety and substituting one addiction for another - all utterly false but damaging to him nonetheless. Under no circumstances should anyone with an already impaired sense of self esteem be faced with such judgment and stigma when they are trying to find a supportive environment.

Further, when my son applied to attend a well known abstinence-only residential treatment facility, he was told he would have to taper off his buprenorphine (done in one week's time). He was conflicted - we were conflicted - we didn't know better. While there, he was faced with a step program focus including lectures about discipline, self control and appealing to a higher power to cure his disease. Few, if any, other diseases are treated in this way.

Sixty-four days after leaving the abstinence-only residential facility and being "released to the wild" without his MAT support, my son succumbed to an overdose. It is a well documented fact among those practicing addiction medicine that the afflicted detoxed or removed from their MAT support are at their highest risk for a fatal overdose even with a dose that previously would barely make them high. When working with local parents seeking information from me about treatment, I strongly encourage them to avoid such abstinence-only facilities. By ignoring today's emerging consensus, abstinence-only adherents are unnecessarily contributing to the rate of opiate overdose deaths. This must change.

Earlier this year, an extensive expose by Jason Cherkis entitled "Dying to Be Free" published in the Huffington Post documented the significant damage caused by the imposition of a one-size-fits-all abstinence-only approach, useful in the past for treating alcohol addiction but with horrific success rates in addressing opioid addiction. Within weeks of the release of this article, ONDCP director Michael Botticelli changed federal policy to deny Drug Free

Community grants to states whose drug courts shamefully force their participants to taper of MAT medications. That is a powerful statement of support coming from our federal government and much welcome.

The American Society of Addiction Medicine, the National Association of State Alcohol and Drug Abuse Directors, ONDCP and SAMHSA all have embraced the use of MAT tied to individual therapeutic assessment and individual and group support mechanisms as the most effective form of treatment for opioid addiction. It is time for the standard of care for treatment of opioid addiction to be changed to reflect this consensus. This issue, with lives in the balance, is worthy of further subcommittee investigation. As a minimum, I hope the subcommittee fully endorses MAT treatment when its hearings are completed and findings produced.

## **CONCLUSION**

Mr. Chairman and members of the subcommittee thank you again for addressing this vastly under addressed public health crisis. While many solutions must and will be addressed at the community and state levels, this subcommittee can ensure federal entities do their part to appropriately protect our loved ones and the public health. We deserve no less.

Sincerely,



Don Flattery