United States House of Representatives
Committee on Transportation and Infrastructure
"The Opioid Epidemic in Appalachia:
Addressing Economic Hurdles to
Economic Development in the Region"

Jonathan P. Novak, Esq.
Former Attorney
Drug Enforcement Administration
Office of Chief Counsel
Diversion and Regulatory Litigation Section

From 2010 through 2015, I had the great honor to serve as an attorney for the Drug Enforcement Administration. My work was focused almost entirely on enforcement actions against doctors, pharmacies, distributors, and manufacturers of opioid controlled substances, all registrants under the Controlled Substances Act. For several years, under amazing leadership and with an eye on protecting the public health and safety, DEA shut down pill mills and practices run by greedy, immoral drug dealers in lab coats, all betraying not only their duties under the CSA, but their ethical obligations to their fellow human beings. I watched as DEA fought hard against the rising tide, and struggled not to drown as the opioid epidemic swelled around us all.

The opioid epidemic was a slow burn fire. Traditionally, many opioids used to treat pain included acetaminophen, a drug which, if taken long-term, can cause severe liver damage. So in the 90s, a pharmaceutical company decided to remove the acetaminophen, and start promoting the use of opioids for long-term pain management.

Their proposal was backed by claims that opioid medicines are <u>rarely addictive</u>. Too late, we now know this to be untrue.

As these drugs were marketed, the very people selling the pills went about changing hearts and minds about the dangers of opioids. Soon, "opioidphobia" was replaced frowny-face pain measurements and a general misunderstanding by many physicians of what, exactly, they were prescribing. Over the course of time, opioid usage was normalized in America, and heralded as a wonder drug. Opioids were digging in everywhere across the country, especially in blue collar and poorer areas, where those seeking a prescription felt validated by the fact that their drugs came from a doctor, and where those seeking a buck found incredible profits in sharing their stash. Unemployment and disability numbers rose, and the number of employable members of the workforce diminished.

As DEA endeavored to help the people of this country, we began broadening our investigations and enforcement actions to look at the role of distributors and manufacturers in

the spread of opioid addiction. Then, for no readily apparent reason, DEA began to slow down, not ramp up its enforcement.

A new section chief arrived, and with him, inexplicable new standards for charging cases were put into place. Soon, attorneys for DEA were being shut down. Draft pleadings would go through farcical rounds of edits and re-edits, almost as if the section chief and his second-in-charge were simply stalling cases rather than charging them. Attorneys began to be singled out and put into the crosshairs of the section chief, who seemed intent on making things difficult for those attorneys who questioned his rationale. New policies were drafted and enacted unilaterally by the section chief, declaring higher standards of proof, unfounded new demands on field investigators, an increased need for the use of expert witnesses, and, more so, an almost palpable fear of utilizing DEA's strongest tool for enforcement: the immediate suspension order, or ISO.

The ISO was a tool for immediately halting the shipments of opioid controlled substances sent by a distributor to a pharmacy. During my time at DEA, it seemed to me that these larger pharmaceutical corporations and industries were not interested in doing the right thing; at least until their profits were hurt and their names were being tied to the opioid epidemic in headlines.

When this new section chief began running my section, discussions turned to an almost palpable fear that, if DEA utilized the ISO and a corporation challenged the ISO, DEA could receive a "bad ruling" against it in a federal court, which could ultimately take away DEA's ability to utilize the ISO at all. This fear appeared to be based, largely, on the fact that DEA began losing some of its best, brightest, most driven, and most talented attorneys. A former section chief was hired into private practice to represent one of the largest opioid distributors in the country. Soonafter, DEA began losing more and more attorneys, recruited over to represent the industry.

When these attorneys left for the industry, they brought with them an intense and brilliant understanding of DEA regulations and case law. I believe this brilliance and understanding, now representing some of the largest DEA registrants in the country, was what DEA began to fear. This was, to my understanding, what caused much of the Slowdown in DEA enforcement actions.

During this Slowdown, I witnessed a staggering drop in morale at DEA, based in part on the feelings of futility and downright absurdity in the face of the ever-increasing death toll related to the opioid epidemic. And more so, morale continued to plummet as employees from all parts of DEA began "switching sides." Not just attorneys, but special agents, group supervisors, and in many cases, management would resign or retire, only to immediately take a job with a pharmaceutical manufacturer or distributor.

I understand the idea behind this revolving door. But for me, there was a downright confusion when the very special agent who referred to the distributors and manufacturers as

"evil" and "the bad guys" happily took a position employed with one of those bad guys just two weeks after his retirement.

It was, to my knowledge, a former DEA attorney who drafted the Ensuring Patient Access and Effective Drug Enforcement Act, which stripped DEA of the ISO. While DEA attorneys feared that a bad decision in federal court might strip DEA of the ISO, Congress effectively legislated the ISO away, ostensibly in the name of ensuring patient access to opioid controlled substances. Without the ISO in its toolbelt, DEA will likely have very little effect enforcing regulations against manufacturers, distributors, and large pharmacy chains who, in my experience, only ever seemed to listen when it hurt their bottom line. "Ensuring patient access" is a misleading description, painting the picture of an altruistic industry only concerned with saving lives and easing pain.

While we may now consider corporations to be people, I laugh at the idea of an altruistic corporation. And by limiting DEA's ability to enforce its regulations and the CSA against these pharmaceutical corporations, we have effectively condoned the continued poisoning of our populace and ushered in the loss of an entire generation to highly addictive and deadly drugs.

According to the CDC, 80% of heroin users in America today got started on opioid painkillers. Overdose deaths in America are at an all-time high, making the heroin epidemic of the 70s and the cocaine epidemic of the 80s look tiny in comparison. We are killing our own people, and DEA is falling down on the job. This is an epidemic that focuses on no race, no gender, no socioeconomic classification - because it affects them all. Everyone has a story of loved one, injured on the job, now living a life of addiction, pain management, and unemployment because their doctor kept increasing their prescribed dosage. Or of a student, injured in a high school football game, prescribed opioids by a well-intentioned physician, and now in jail for possession of heroin, or dead of an accidental overdose.

Significant damage has been done not only to those who are now our addicts, but to our communities, our workforces, our economies. Old methods of treatment are failing in the face of this long term physical and biological addiction. And yet these pills seem easier and easier to find, and harder and harder to avoid.

DEA has been hobbled by legislation intended to defang the agency, and communities are now suffering the consequences of this drug epidemic with a long, arduous road ahead. The influence of the pharmaceutical manufacturers and distributors, the very ones who promoted and profited from the widespread, dangerous use of of opioids, have influenced legislation in order to further limit DEA's ability to enforce its laws. And while this battle between the agency, the industry, and the lobbyists continues, American people keep dying.

We need to focus on changing the laws, restoring DEA's ability to enforce, and looking at funding to educate our population and to help those already addicted to fully recover and become productive members of society again.