Good morning. Committee Chairman Walden, Subcommittee Chairman Harper, Ranking Members Pallone and DeGette, and distinguished members of the subcommittee, thank you for your invitation to testify before you today, and thank you for your tireless efforts to address our nation’s ongoing opioid epidemic.

I would like to share some background about Miami-Luken with you. The company was originally co-founded by my father, Robert E. Mastandrea, in 1962 as the Miami Valley Wholesale Drug Company, in Dayton, Ohio. Nine years later in 1971, the company acquired the A.G. Luken Drug Company of Richmond, Indiana. It was then that the company Miami-Luken was born. Since then, the company has made additional acquisitions in Ohio and West Virginia, yet has always remained a relatively small regional distributor.

I first started working for the company at the age of fourteen, working in the warehouse. After graduating college, I worked a short time with my father, learning the day to day operations of the business where I was involved in making sales calls, deliveries and various warehouse duties. It was a wonderful place to work and I was proud of my father and what he had achieved. He was born in Italy and came to this country at the age of thirteen. He subsequently graduated from college and began a business career that would lead to the formation of Miami-Luken. Through
my father’s leadership, the company’s culture was more like a family than just a place to work.

I entered medical school in 1979 and after my residency, embarked on my fulltime career as a physician in Dayton. Several years later, I was asked to serve on the Board of Directors of Miami-Luken, which I accepted. Some years later I became the Chairman of the Board and have held that position since that time.

Management of the company remained pretty much the same until 2007 when a new president was appointed by the Board. This individual had extensive managerial experience in both the wholesale drug business and the wholesale grocery business and was more than qualified to lead the company. He was knowledgeable, confident and well-liked by the company’s employees.

It was not until several years later in 2013, after the Board learned that the DEA had issued a number of subpoenas to the company, that we realized the government had concerns with the company’s compliance efforts. In response, we retained the services of a prominent attorney here in Washington D.C. who used to work for the DEA. This attorney worked with management to assist the company in fulfilling its DEA compliance obligations. We also instructed the company’s president to purchase a computer program to better identify suspicious orders from customers, which he did.
When we subsequently learned that management was having difficulties with the computer system they purchased, it was apparent to us that we needed someone more capable in that position. The Board immediately began looking for a replacement and after considering several individuals, hired the company’s current president and CEO, Michael Faul.

In addition to hiring Mr. Faul, the company hired a new Director of Compliance and Security, Benjamin Mink, who worked with Mr. Faul to implement a number of significant changes to the company’s compliance program. These included more frequent and robust customer visits by compliance staff; greater scrutiny of requests from customers to increase purchase quantities; increased facility and transportation security; implementation of compliance training; purchase of the NTIS database; enhancing the controlled substance profile that customers are required to complete during the onboarding process; and a complete overhaul of Miami-Luken’s standard operation procedures regarding DEA compliance. Mr. Mink also worked with the software vendor to re-calibrate the company’s computerized suspicious orders notification system, improve its effectiveness in identifying suspicious orders on a daily basis; and started the process of uploading all relevant data on shared computer drives, providing employees and DEA investigators easier access to information pertaining to individual customers. He also hired additional staff to assist in the company’s compliance efforts and created a new analytical Excel spreadsheet program to assist in conducting due diligence on current and prospective customers. In fact, Mr. Mink last year was recognized by the National
Association of Drug Diversion Investigators for his outstanding work in drug diversion prevention.

As a result of new management’s enhanced compliance efforts, Miami-Luken terminated its relationship with multiple customers, many of whom are still in business purchasing from other sources. Since 2014, we have reduced the sale of Oxycodone by 61 percent, and the sale of Hydrocodone by 50 percent.

It is our understanding that former management took what they believed to be sufficient steps at the time, believing that State Medical Boards and Pharmacy Boards were in a stronger position to monitor the physicians and pharmacists they licensed. Former management also believed that since Miami-Luken regularly provided the DEA with sales data for all its customers, the government would have advised them if they had concerns with sales to specific parties. Unfortunately, we now know that that is not enough, and as you know from the materials we provided this Committee last year, Miami-Luken has taken aggressive actions going back several years to strengthen its compliance efforts and suspicious order monitoring system. And as I sit here now, I can assure you that our company employs a compliance program that is second to none.

In closing, I welcome any questions you have and will answer them to the best of my ability. Thank you again for this opportunity and for all your efforts.