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May 8, 2014

The Honorable Joseph R. Pitts
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

RE: ***Response to Additional Questions for the Record***

Dear Mr. Chairman:

Thank you for the opportunity to testify before the Subcommittee on Health on April 7, 2014. At your request, I am submitting my responses to the additional questions for the record.

Thank you for your leadership in addressing the important issues of prescription drug abuse and patient access to controlled medications. If I can be of assistance to you, Ranking Member Pallone, or the Subcommittee in addressing these issues, I would be pleased to do so.

Sincerely,

D. Linden Barber

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Additional Questions for the Record

Questions from The Honorable Joseph R. Pitts

1. We have been hearing from pharmacies that their wholesalers are cutting them off for ordering above the "normal" amount. Will you describe your expectations of wholesalers and what guidance has been provided to wholesalers in the last year to help them conduct due diligence on their customers?

Response: DEA held a distributor conference on October 22, 2013. At that conference, DEA gave a presentation stating that the distributor initiative was started to educate the supply chain on "their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of controlled substances, and discussing national trends involving the abuse of prescription controlled substances." The presentation also contained slides entitled "Know Your Customers." These slides suggest that ordering a quantity of controlled substances that "far exceeds" the "average purchases" of an "average type registrant" is a "red flag." The slides may be obtained at http://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

My expectations of a wholesaler are that they comply with the regulations that DEA has promulgated. DEA's regulations require a distributor to know that a customer is registered with DEA prior to distributing controlled substances to that customer. The regulations also require a distributor to design and operate a system to detect suspicious orders and to inform DEA of suspicious orders upon discovery. The concepts of "due diligence" and "know your customer" are not addressed in the regulation or in any formal policy statement of the Agency of which I am aware. However, the requirement to detect suspicious orders implies that a wholesaler must have some knowledge about the customer to determine whether an order is suspicious. What constitutes a suspicious order will vary depending on a wide variety of factors such as the total number of prescriptions filled by a pharmacy, the location, the hours of operation, and the proximity of the pharmacy to prescribers. However, to my knowledge, DEA has not provided guidance to wholesalers on whether the use of such factors is appropriate, and if so, how to use those factors in determining whether an order is suspicious. Without clear guidance, distributors are left in a position to determine whether a particular pharmacy's orders "far exceed" the "average purchases" of an "average type registrant." This ambiguity may be one of the reasons why some wholesalers limit or cut off legitimate pharmacies who order a quantity of controlled substances that is above "normal."

2. Does DEA conduct an investigation on pharmacy registrants when wholesalers have reported suspicious orders for a particular pharmacy? Can other wholesalers continue to serve that pharmacy?

Response: I do not know if the DEA conducts investigations on a pharmacy when a distributor reports the pharmacy's orders as suspicious. DEA employees have stated that reporting suspicious orders are important to the Agency because it helps DEA identify potential diverters. DEA has stated that each distributor must decide whether to do business with a particular customer. There is no regulation or formal policy that indicates a distributor must cease

distributing controlled substances to a pharmacy simply because the distributor has informed the DEA of a suspicious order placed by the pharmacy. DEA has stated that a suspicious order does not necessarily make a customer suspicious. Along those same lines, the fact that one distributor has reported a suspicious order placed by pharmacy or refused to continue doing business with a pharmacy does not preclude other distributors from distributing controlled substances to that pharmacy. However, wholesalers do so at their own risk as history indicates that DEA will use the fact that a wholesaler has cut off a customer as evidence that the new wholesaler should have been wary of taking on that customer.

3. Does DEA conduct due diligence on an initial application for DEA registration (pharmacy, wholesaler, physician, etc.)? What does that involve?

Response: DEA does not generally investigate a pharmacy or physician applicant prior to issuing a registration. However, there are exceptions. If the application reveals a history that requires investigation, the Agency will conduct an investigation. According to DEA personnel, some DEA offices have started conducting inspections on pharmacy applicants in the past 3-4 years. Distributor and wholesaler applicants are inspected. The inspections include review of physical security systems and may include review of operating procedures and policies, discussion of DEA's regulations, and other requirements germane to compliance with the CSA and DEA's regulations.

4. Despite efforts by industry and the government, the prescription drug abuse epidemic continues to increase and it is clear we need to do something different than the track we are on now. Do you have any suggestions as to how industry, DEA, and Congress could better address this epidemic?

Response: Education, compliance, enforcement, treatment, and collaboration all play a role in reducing prescription drug abuse. However, these efforts must be properly focused. Fighting prescription drug abuse requires a different strategy than fighting trafficking of illicit drugs. Trafficking of illicit drugs can be addressed by reducing or eliminating supply. With the most widely abused prescription drugs, supply is already limited by DEA through the quota process in which the Agency establishes the amount of narcotics necessary to meet the legitimate medical, scientific, industrial, and export needs of the United States. Although I was once a proponent of supply reduction through enforcement actions on the supply chain as a means to prevent prescription drug abuse, the continued rise in prescription drug abuse during the decade of enforcement action against suppliers has led me to conclude this strategy has limited effectiveness. The reason the strategy is of limited effect is because conduct leading to diversion and abuse occurs at or after the delivery of the controlled substance to the patient or ultimate user, not at the supply chain level. In some cases, patients receive controlled substances for a legitimate medical purpose but misuse the drugs or sell them to others who abuse the drugs. Prescribers and pharmacists who interact with these individuals are best situated to identify these individuals. Education of prescribers and pharmacists is the best way to address this issue. Additionally, community education on how to identify and intervene with friends or family members who abuse controlled substances is helpful. Treatment for those who abuse controlled substance is also a necessary component of addressing this cause of prescription drug abuse.

In other circumstances, prescribers and pharmacists are deceived by individuals who have no legitimate medical need for controlled substances, but feign conditions that lead to the prescribing and dispensing of controlled substances. Here, education of prescribers and pharmacists is essential. Also, collaboration among regulators, healthcare professionals, and law enforcement to establish best practices for prescribers and pharmacists would be helpful. Compliance with prescribing and dispensing guideline and protocols for detecting individuals who misuse or sell their medications will be effective at addressing this cause of diversion.

Finally, in some circumstances, a prescriber and/or pharmacist is a witting participant in delivering controlled substances for other than a legitimate medical purpose. Enforcement is most effective when aimed at these individuals. Collaboration between DEA and the supply chain to develop protocols and systems to identify ordering patterns of those pharmacies and dispensing physicians who are engaged in illicit conduct will allow suppliers to identify for DEA those prescribers and pharmacies who require investigation and action by DEA. The effectiveness of collaboration hinges on compliance by members of the supply chain. When suppliers fail to comply, enforcement is appropriate. However, it is critical to recognize that enforcement against the supply chain does not address the underlying root and intervening direct cause of diversion and abuse.

An effective strategy to address the problem of prescription drug abuse requires identifying the root cause or causes of the problem. Legislation or oversight by Congress can be a catalyst for bringing stakeholders together to identify the root causes and develop realistic strategies aimed at addressing the root causes of prescription drug abuse. Regulations, policies, enforcement strategies, and industry initiatives could then be focused on the main causes of prescription drug abuse.

5. Does DEA use an escalation of enforcement approach?

Response: Some field offices use an escalation of enforcement approach in some circumstances. However, there is no consistency in this matter. In many instances where escalation of enforcement is not used, the likelihood of diversion is increased. An early admonition or warning by DEA is likely to change the conduct of a registrant in many cases. An admonition or oral warning can be given without the evidence necessary to initiate a suspension or pursue a civil penalty. When the Agency fails to use an escalation of enforcement, the Agency may require substantial time to investigate and initiate a more serious action. However, the opportunity to abate conduct early is missed when the Agency does not use an escalation of enforcement approach.

6. Just because a registrant has stopped its bad conduct does not mean they will not start again. How can DEA address those situations?

Response: DEA has the ability to immediately suspend the registration of a registrant whose conduct poses an imminent danger to public health and safety. There are several notable examples of DEA initiating an administrative action to address past conduct and then learning the registrant was again engage in conduct that threatened the public health. In those cases, even

though an administrative hearing was in progress, the Agency issued an immediate suspension to address the imminent danger to public health and safety.

7. The bill I introduced with Mr. Pallone, H.R. 4299, the "Improving Regulatory Transparency of New Medical Therapies Act" requires the DEA to schedule new molecular entities within in a timely manner. Based on your experience working at the DEA, is this approach a safe and effective way to get patients medications faster?

Response: Based on my review of the DEA's scheduling actions over the past decade, DEA has accepted FDA's scheduling recommendation 100% of the time when scheduling a new molecular entity. Based on that history, requiring DEA to schedule a new molecular entity in a timely manner is highly unlikely to have adverse consequences to public health and safety. In fact, public health is likely to be enhanced by the timely availability of new medicines which have been found by FDA to be safe and effective. Since DEA has authority to initiate action to transfer a substance from one schedule to another, requiring the Agency to schedule a new molecular entity in a relatively short period of time will not impede the Agency's ability to later reschedule that substance if evidence warrants rescheduling. Additionally, scheduling a new molecular entity could be done under an interim final rule that would allow the Agency to examine the pattern, scope, significance and duration of abuse of the substance while the approved drug is on the market. DEA could then make that evidence part of the record and issue a final rule scheduling the substance. Expeditious scheduling of new molecular entities is a safe, effective, and sensible approach that allows patients in need to benefit from the new medicines that have been found by FDA to be safe and effective.