

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

April 24, 2014

Mr. Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Agency
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Rannazzisi:

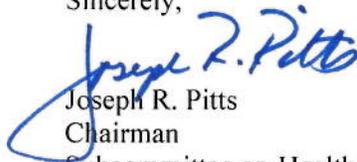
Thank you for appearing before the Subcommittee on Health on Monday, April 7, 2014, to testify at the hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

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

Attachment

Attachment—Additional Questions for the Record

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

The Honorable Michael C. Burgess

1. I am hearing that DEA actions are causing great difficulties for legitimate patients that are not able to access the medications they need to manage chronic pain. According to DEA’s website, “the mission of DEA’s Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate supply for legitimate medical, commercial, and scientific needs.”
 - a. How does DEA ensure that it’s regulatory and enforcement actions are not having the unintended consequences of causing harm to legitimate patients?
 - b. Does DEA meet with chronic pain patient groups and others to ensure that the agency understands the needs and concerns of patients?
2. The federal Controlled Substances Act (CSA) has been federal law since the early 1970’s. Despite decades of DEA enforcement actions, it seems that the drug abuse problem continues unabated, whether the problem is heroin, cocaine, morphine, oxycodone, hydrocodone, etc. Do you not think it is long past due to take a step back and bring together a wide variety of stakeholders to agree upon new solutions to combat drug abuse, as has been proposed by H.R. 4069?
3. How do you response to comments that DEA’s actions to stop prescription drug abuse are merely causing an increase in the heroin abuse problem? Why does the DEA not adopt more holistic approaches to drug abuse so that shutting off one source of abuse does not simply lead to another substance being abused? Do you not think this leads to perceptions that all DEA cares about are the numbers of enforcement actions and not about real solutions to stop drug abuse?
4. Will you explain DEA’s efforts to education physicians about the corresponding responsibility of pharmacists under the CSA? If I understand correctly, the CSA requires a pharmacist, prior to dispensing any controlled substance, to determine if the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a “legitimate medical purpose” by a prescriber acting in the usual course of his or her practice. Simply put, this means that pharmacists are required to perform due diligence on each controlled substance prescription before dispensing the medication—this may mean calling back the physician to obtain and confirm certain information before the prescription can legally be dispensed. Yet, it seems that

some physicians are unaware of this federal requirement—so written guidance and education seems appropriate. Would you agree more agency education can be done?

5. The Drug Quality and Security Act of 2013 provides for the registration with the Food and Drug Administration of “outsourcing facilities.” These entities are engaged in compounding and distribution of sterile medications in interstate commerce. Sterile medications may contain controlled substances. What plans does the DEA have to require registration of these outsourcing facilities? How will these outsourcing facilities be inspected and reviewed? When will the registration and inspections be conducted? What conversations have been held to date with the FDA to coordinate interagency accountability for appropriate oversight of these outsourcing facilities?
6. If questions arise during the inspection process, is there a transparent and formal procedure to provide written agency feedback?
7. Amidst all of the efforts to curb prescription drug abuse, what are you doing to help ensure that legitimate patients can continue to access their prescription pain medications?
8. DEA has no mandated timeline for approval. Do you believe it is medically ethical to deny access to a drug for over a year after FDA has determined that the product is safe and effective?
9. When the FDA approves a product that means the drug has been found to be safe and effective for patients suffering for a particular disease, correct?
10. Will 503b OFs be required to be distributors or manufacturers at DEA?

The Honorable Gus Bilirakis

1. FDA has developed a comprehensive inspection program for each sector it regulates—such as drugs, devices, food, cosmetics. In so doing, FDA has established program inspectional manuals, field guidelines, and industry guidelines.
 - a. Does DEA have similar public materials to address the inspection process and compliance issues for DEA registrants within the legitimate manufacturing, distribution and dispensing of controlled substances? If not, why not?
 - b. How does DEA ensure that its policies across the nation—from region to region and from inspector to inspector—are consistent?
 - c. Is there a DEA internal quality assurance program?
 - d. Has DEA had its inspection process audited by a third party or OIG?