

UNITED STATES SENATE COMMITTEE ON THE JUDICIARY

HEARING ON
“TACKLING THE OPIOID CRISIS: A WHOLE-OF-GOVERNMENT APPROACH.”

DECEMBER 17, 2019

QUESTIONS FOR THE RECORD FROM

SENATOR DIANNE FEINSTEIN

Questions for Ronna B. Hauser, PharmD, Vice President, Policy & Government Affairs Operations, National Community Pharmacists Association (NCPA)

1. Communication with the Drug Enforcement Administration DEA

Communication between the Drug Enforcement Administration (DEA) and opioid manufacturers and distributors can play a critical role in identifying, reporting, and preventing suspicious orders of opioids. This point has been underscored in several reports issued by the GAO, and most recently, by the Department of Justice’s Inspector General.

a) In your view, has the communication between your members and the DEA improved in recent years?

Yes, NCPA has witnessed improved collaboration between our members with both the DEA and supply chain partners including manufacturers, wholesalers, technology vendors and others to tackle the opioid crisis. NCPA and our members continue to work with agency partners, including the DEA, to facilitate open dialogue about the challenges facing pharmacies when purchasing, dispensing, and disposing of controlled substances.

b) What additional steps can be taken to increase communication among all of the players in the supply chain?

NCPA highlights the DEA can provide clarity to pharmacies by releasing an updated version of the DEA’s Pharmacist’s Manual, which has not been updated

since 2010.¹ Updating the Pharmacist’s Manual is important because there have been several changes to the law since 2010 regarding the purchasing, dispensing, and disposing of pharmaceutical product.

NCPA also supports enhancing integration and data-sharing, recommending increased interoperability of robust electronic databases, such as prescription drug monitoring programs. Interoperability with certified electronic health record technology applications will improve prescriber access to a patient’s prescription opioid history at the point of prescribing.

Lastly, NCPA supports enhanced ARCOS transparency and as Congress and the DEA continue to strengthen usage of ARCOS data, NCPA is supportive of measures that would require supply chain entities, including pharmacies, to report the sale of controlled substances to such database.

NCPA supports your bill, S.3070, the *Preventing Pill Mills Through Data Sharing Act* and thanks you and your office for communicating with us and our members when drafting the legislation.

¹ DEA, Pharmacist’s Manual, *available at* https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

Questions for the Record from Senator Charles E. Grassley
U.S. Senate Committee on the Judiciary
“Tackling the Opioid Crisis: A Whole-of-Government Approach”
Submitted on January 7, 2020

Dr. Ronna Hauser

1. Transparency among manufacturers, distributors, and the DEA is critical to limit drug diversion. I’ve supported measures to require monthly updates on the sale and delivery of controlled substances, and also penalize the inaction or criminal behavior of manufacturers, distributors, and pharmacies.
 - a. Can you explain why consistent reporting of sales and delivery of opioids are important to limit drug diversion?
 - b. How can the relationship between each of your groups and the DEA improve in this area to prevent drug diversion?

- a) *According to the DEA, ARCOS, is “an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level – hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions.” As Congress and the DEA continue to strengthen usage of ARCOS data, NCPA is supportive of measures that would require supply chain entities, including pharmacies, to report the sale of controlled substances to such database, subject to important exclusions that ensure patient access to needed medications. NCPA supports S.3070, the Preventing Pill Mills Through Data Sharing Act and thanks you for co-sponsoring this important bill.*
- b) *NCPA has witnessed improved collaboration between our members with both the DEA and supply chain partners including manufacturers, wholesalers, technology vendors and others to tackle the opioid crisis. NCPA and our members continue to work with agency partners, including the DEA, to facilitate open dialogue about the challenges facing pharmacies when purchasing, dispensing, and disposing of controlled substances. NCPA highlights the DEA can provide clarity to pharmacies by releasing an updated version of the DEA’s Pharmacist’s Manual, which has not been updated since 2010.¹ Updating the Pharmacist’s Manual is important because there have been several changes to the law since 2010 regarding the purchasing, dispensing, and disposing of pharmaceutical product.*

¹ DEA, Pharmacist’s Manual, available at https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

**Questions for Dr. Ronna B. Hauser, Pharm.D.
From Senator Mazie K. Hirono**

1. I was glad to hear you say in your opening statement that community pharmacies want an expanded role in combatting the opioid epidemic. But I want to make sure that community pharmacies are ready for that increased responsibility.

Last summer, *The Washington Post* published an analysis of data from the DEA's ARCOS database in which it found that certain community pharmacies were responsible for dispensing an inordinate amount of prescription opioids. For example:

- Shearer Drug in Clinton County, Kentucky dispersed over 6.7 million pills between 2006 and 2012. That's 96 pills for each person in the county.
- Hardin County District Pharmacy in Hardin County, Illinois dispersed almost 2.8 million pills during that same time, or 90 pills per person.

The list goes on. I find it hard to believe that people at these pharmacies did not recognize that something nefarious was going on.

What are community pharmacies doing right now to make sure we don't see such massive quantities of addictive drugs being dispersed?

While NCPA cannot speak to a specific pharmacist's decision-making, NCPA highlights that the Oath of a Pharmacist includes both alleviating suffering and practicing at the highest ethical standards. As an organization we are cooperative and believe we are on the front lines responding to this crisis. We have been partners and we want to continue to work with you to fight this epidemic.

Community pharmacists often practice in underserved communities or in pharmacy "deserts" and NCPA acknowledges there may be legitimate reasons why certain pharmacies have increased orders of controlled substances. Locations that contract with hospices or that are near cancer treatment centers may also be a factor. Because PBMs mandate the use of PBM owned pharmacies or mail order for chronic meds, some pharmacies may have a higher percentage of controlled substances dispensed in relation to their overall prescriptions dispensed.

Community pharmacists are a valuable tool to fight the epidemic. NCPA members participate in numerous initiatives to appropriately dispense and dispose of controlled substances and to identify possible overutilization.

Examples include:

- Evaluating prescriptions to attempt to detect forgeries or alterations.
- Adopting electronic prescribing, which has helped eliminate forgery efforts.
- Taking part in Dispose My Meds™, which has more than 2,100 participating sites across the country.

- Utilizing Allied Against Opioid Abuse's Pharmacist Toolkit, which aids pharmacists in conversations with patients and caregivers regarding opioid prescriptions.
- Advocating for greater pharmacist access to naloxone, which has resulted in increased access across the country, and in turn, saved lives.

These initiatives are having a positive impact witnessed by the decrease in prescriptions for opioids. Advancing the pharmacist's role in Medication-Assisted Treatment for opioid use disorder can also help improve access and outcomes, while reducing the risk of relapse. Lastly, NCPA supports enhanced ARCOS transparency and as Congress and the DEA continue to strengthen usage of ARCOS data, NCPA is supportive of measures that would require supply chain entities, including pharmacies, to report the sale of controlled substances to such database.