Questions for the Record from Senator Charles E. Grassley
To President of National Association of Boards of Pharmacy, Dr. Carmen Catizone
U.S. Senate Committee on the Judiciary
"Oversight on the Ensuring Patient Access and Drug Enforcement Act."
Submitted on _____, 2017.

1. Opioid distributors have said that they lacked communication from DEA in trying to figure out their responsibilities to help prevent opioids getting into the hands of bad actors. The NABP has said that this is a false narrative.

    a. Are there communication problems between DEA and the drug distribution industry that limit the effectiveness of self-enforcement?
    NABP convened a number of meetings involving the drug distribution industry (industry) and DEA to discuss the opioid crisis. At every meeting the DEA was engaged, forthright, and willing to address concerns presented by the industry. Several of the issues raised by the industry were openly discussed with agreement reached between the DEA and industry to pursue definitive actions and cooperative outcomes. The primary factors limiting the effectiveness of self-enforcement is an unwillingness of some wholesale distributors to self-enforce and comply with existing state and federal laws and regulations. The concept of self-enforcement is meaningless to those wholesale distributors who are not interested in enforcement of any degree and whose only concerns are diversion and greed.

    b. If not, why is this a false narrative?
    One of the primary concerns raised by the industry that served as the foundational reason for their contention of poor communications with the DEA was the absence of a specific definition of what constituted a suspicious order. Repeatedly, the industry voiced frustration with the lack of clarity in the existing definition and contended that the DEA possessed information about the ordering of controlled substances from wholesale distributors (ARCOS) that it refused to share with the industry. Access to these data, the industry maintains, would allow a view of the total amount of drugs shipped to individual pharmacies or clinics thus making the identification and management of suspicious orders more apparent and manageable.

    The DEA repeatedly communicated to the industry the definition of suspicious orders found in the provisions of federal law and availability of ARCOS data. In defining suspicious orders, the DEA referred the industry to the language of the Controlled Substances Act and Regulations (CSA) and provided additional clarity from "red flag" guidance documents. In response, the industry rejected that explanation and guidance and instead asked for "black and white" threshold parameters or specific "numbers" above which would constitute a suspicious order. The DEA responded, repeatedly again, and explained that specific threshold parameters were not able to be provided and doing so would only

confuse or confound the identification of suspicious orders. In regard to ARCOS data, in the cases that I served as an expert witness for the US Attorney's Office or DEA, ARCOS data from other wholesale distributors was not necessary to identify suspicious orders. The amount of controlled substances shipped by the egregious wholesale distributors involved in the criminal cases was such that the amounts far exceeded what a reasonable wholesale distributor would have provided to the pharmacies or clinics in question.

2. Does the NABP believe that distributors are *not* interested in self-enforcement? Why?
   NABP believes that the wholesale distributors who participate in the Verified-Accredited Wholesale Distributors® (VAWD®) accreditation program are very interested in self-enforcement. Unfortunately, there are a fair number of wholesale distributors that NABP has encountered directly through inspections and actions taken by the state boards of pharmacy that are not interested in self-enforcement or enforcement by any regulatory agency, state or federal. The motivating factor appears to be greed.

   a. Have there been specific examples where distributors have proven either disinterest or refusal to self-enforce? If so, what are some examples?
      NABP has directly witnessed, through inspections conducted as part of the VAWD program, wholesale distributors who are falsifying transaction documents, purchasing and distributing expired or adulterated drugs, purchasing and distributing unapproved drugs, and purchasing drugs under the provisions of government discount programs and distributing those same drugs at retail prices in direct violation of state and federal laws.

3. You have also said that the Corrective Action Plan (CAP) addition to the law through the Ensuring Patient Access and Effective Drug Enforcement Act prevents the ability for DEA to revoke or suspend registration.

   a. Can DEA issue an Immediate Suspension Order (ISO) – and thereby revoke or suspend registration – when there is an immediate threat?
      Yes.

   b. How does NABP reconcile ISOs and CAPs?
      In the letters submitted to Senators Grassley and Leahy on September 4, 2014 and presented again in testimony before the Committee on December 12, NABP noted, "The ability to act decisively when an imminent danger to the public health or safety exists is critical to protecting the public." Any requirement that impedes the implementation of this important enforcement tool, such as a CAP, undermines the ability of the DEA to act expediently and decisively.

4. Part of what DEA monitors is “suspicious order” from pharmacists and other providers.

    a. How do your companies identify suspicious orders?
    NABP and state boards of pharmacy define suspicious orders in accordance with the provisions of the CSA and applicable state laws and regulations.

    b. How does that data get reported to DEA?
    This question may not be directly applicable to NABP and the state boards of pharmacy. The state boards of pharmacy work cooperatively with the DEA and share suspicious orders as part of an investigation or disciplinary action against a wholesale distributor.

    c. Do you work with the distributors in identifying suspicious orders?
    NABP has been asked by states to work with wholesale distributors and the DEA to develop uniform reporting requirements of suspicious orders to the state boards of pharmacy. NABP will begin this work in the first quarter of 2018.