Statement from
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Subcommittee on Health

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Good afternoon Chairman Pitts, Ranking Member Pallone, and Members of the Energy and Commerce Subcommittee on Health. My name is Linden Barber, Partner in the law firm of Quarles & Brady and the former Associate Chief Counsel for Diversion Litigation at the Drug Enforcement Administration. Thank you for the opportunity to appear before the Subcommittee to discuss the important issue of preventing the diversion of pharmaceutical controlled substances into illicit channels while ensuring access to these helpful medications for patients with legitimate medical needs. The Ensuring Patient Access and Effective Drug Enforcement Act of 2014 (H.R. 4069) introduced by Representatives Blackburn and Marino is a piece of legislation that will enhance the prevention of diversion of controlled substances while mitigating the unintended consequence of restricting the supply of these helpful medications to patients with legitimate medical needs.

My interest in this issue stems from nearly twelve years of service at the Drug Enforcement Administration during a period of escalating prescription drug abuse. Since leaving the DEA for private practice in late 2011, I have advised many registrants within the pharmaceutical supply chain about DEA compliance issues and have found that members of

industry are keenly interested in working with the DEA to solve the enormous problem of prescription drug abuse.

My interest in this issue is also personal. Like many Americans, I know and love people who have suffered the harms of prescription drug abuse. I also know and love people whose lives and health are better because of the availability of controlled medications.

It is vitally important that steps taken to ensure patient access to controlled medications do not undermine the ability of the DEA to protect the public health from the devastating ills caused by the abuse and misuse of controlled substances. The Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is an Act that addresses both issues by providing clarity in the law and by encouraging collaboration between regulators, law enforcement, health care providers, and the pharmaceutical supply chain.

By providing definitions for two key terms in the Controlled Substances Act, Congress will bring clarity to the regulatory environment. I will focus my comments on defining the term "imminent danger." By defining "imminent danger," Congress can provide clarity that is beneficial to DEA and to the registrants the Agency regulates. How does defining "imminent danger" benefit DEA? The Controlled Substances Act permits DEA to immediately suspend the registration of a registrant whose conduct

poses an imminent danger to public health or safety. Unlike other federal statutes, such as the Mine Safety Act, the Controlled Substances Act does not define imminent danger. In the absence of clarity from Congress, the Agency will determine what constitutes an imminent danger on a case-by-case basis. And when a registrant challenges DEA's use of its immediate suspension power, it is ultimately courts that will determine what constitutes an imminent danger. History is instructive, and there is a long history of judicial challenges to the Agency's use of immediate suspensions. Forty years ago, a registrant successfully challenged an immediate suspension because the conduct that DEA alleged created the danger was not imminent, but was more than seven months old.

More recently, a legal challenge to the Agency's immediate suspension power thwarted the Agency's ability to address illicit Internet pharmacy schemes. In 2005, three pharmacies in Colorado successfully challenged the immediate suspension orders issued by DEA. In early 2006, the U.S. District Court for the District of Columbia ruled that the manner in which DEA processed immediate suspensions deprived the registrants of Due Process. Although the ruling in that case was based on the extraordinary length of time that the registrants had to wait for a hearing, the pharmacy registrants also claimed that the conduct that DEA alleged

created a danger had ceased more than a month before DEA issued the suspensions. Having dissolved the suspensions on Due Process grounds, the court did not need to address the troubling allegation that the conduct at issue ceased well before issuance of the immediate suspension orders.

Because of the court's ruling, the DEA and the Department of Justice imposed a hiatus on issuing immediate suspension orders until the immediate suspension process could be restructured to address the Due Process issue that led to the adverse decision from the court. Several months after that decision, I became the Associate Chief Counsel for Diversion Litigation at DEA and was charged with revamping the immediate suspension process. For more than six months, in the height of the illegal Internet pharmacy schemes that fueled prescription drug abuse, the Agency was effectively stripped of its power to issue immediate suspension orders. Although we fixed the immediate suspension process and, I am proud to say, issued a record number of immediate suspensions in 2007 and 2008, the Agency did not issue immediate suspension orders for more than six months in 2006, during which time millions of dosage units of controlled substances were distributed through illicit Internet pharmacy schemes that could have been dismantled by immediate suspension orders. As a practitioner in this area of the law and an

observer of the courts, I am very concerned that in the absence of legislative clarity about the meaning of "imminent danger," courts will intervene and curtail the Agency's powers in a way that will prevent the Agency from being able to effectively address true imminent dangers. Based on more recent challenges to DEA's suspension authority and some troubling and pointed questions about the imminent danger standard raised by the DC Circuit Court of Appeals in 2012, it is, in my opinion, likely that courts will step in to ensure the fair application of the imminent danger requirement in the absence of a clear legal standard that is consistently applied by DEA. Indeed, many of my colleagues believe that the 2012 case would have resulted in a narrowing of DEA's authority if the Agency had not settled its dispute with the registrant. As a supporter of DEA's mission, I urge this Committee to take legislative action that clarifies the meaning of imminent danger.

The definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is a common sense standard and is similar to the standard that that Agency used for issuing immediate suspensions employed in the immediate aftermath of the adverse court decision in 2006 previously discussed. Using such a standard the DEA issued a record number of immediate suspensions in 2007 and 2008.

Based on that history, I am confident that the definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 will not inhibit DEA's ability to take swift action to address conduct that poses an imminent danger to the public.

However, the Agency appears to have moved away from using a consistent standard when making a finding that a registrant's conduct poses an imminent danger. In doing so, the Agency invites judicial intervention which could severely limit its powers. The definition of imminent danger in the bill is consistent the plain and ordinary meaning of the term, the definition of that term in other federal statutes, and the case law that has developed around that term. The clarity of this bill, and the Agency's consistent application of the standard articulated in this bill, will substantially strengthen the Agency's position in the face of legal challenges to its suspension powers.

Clarity in the law also benefits DEA registrants. Clarity fosters compliance and collaboration with DEA. Conversely, the current lack of clarity fosters confusion and fear. A pharmacist that decides he or she will no longer fill prescriptions issued by a physician because of concerns about their legitimacy is unlikely to communicate that decision to DEA if the pharmacist is concerned that the Agency will use that information to

immediately suspend the pharmacy's DEA registration because the pharmacy previously filled prescriptions issued by the physician. The DEA has issued immediate suspensions in such contexts. While the Agency surely has a right to address past conduct through normal administrative channels, issuing an immediate suspension for conduct that has stopped is not only contrary to the plain meaning of imminent, it is counter-productive and discourages communication with the Agency.

Many times I have heard my former colleagues at DEA say that enforcement alone will not solve the problem of prescription drug abuse. That is why it so important to provide clarity about the meaning of "imminent danger." The definition found in the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is precisely the clarity that will encourage registrants to communicate with DEA, turning registrants into a force multiplier that will help DEA identify those registrants who truly require the swift response of an immediate suspension.

Fostering communication and collaboration between registrants and DEA would be further enhanced by the corrective action plan section of the Ensuring Patient Access and Effective Drug Enforcement Act of 2014. A registrant who knows that the Agency will consider corrective action before deciding to revoke or suspend the registrant's registration is more likely to

communicate with DEA. Addressing the problem of prescription drug abuse requires registrants throughout the supply chain to bring concerns about other registrants to DEA's attention. A distributor who grows concerned about a pharmacy's dispensing practices after several months of supplying the pharmacy needs the assurance that DEA will consider any corrective action taken by that distributor in order to encourage the distributor to communicate its concerns to DEA.

As a supporter of DEA's power to issue immediate suspensions, it is important to note the interplay, or lack thereof, between the corrective action plan provision in the bill and the Agency's power to issue immediate suspensions. Foundational to this discussion is the identification of the two types of suspensions in Controlled Substances Act. There is a post-adjudication sanction that includes suspension or revocation, and there is the pre-adjudication suspension (i.e., an immediate suspension) based on a finding of imminent danger. The corrective action plan section of the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is placed within a subsection of the statute that indicates its application is limited to the context of post-adjudication revocations or suspensions. In other words, DEA would not have to provide a registrant whose conduct poses an imminent danger to the public health an opportunity to submit a

corrective plan prior to issuing an immediate suspension order. This is clear not only from the subsection in which the corrective action plan language is located, but also from standard statutory interpretation. Requiring DEA to give a registrant who poses an imminent danger to public health an opportunity to submit a corrective action plan would eviscerate the clear intent of the statute that empowers DEA to issue immediate suspensions to abate an imminent danger.

Finally, legislative clarity will foster a regulatory environment that will promote access to controlled medications for patients in need. When registrants are uncertain about the regulatory environment, many will take actions to reduce the perceived risk of regulatory action. A pharmacist may refuse to fill prescriptions for narcotics intended to treat chronic pain, not because the pharmacist believes the prescriptions are illegitimate, but simply because dispensing a high volume of narcotics brings scrutiny from suppliers and from the DEA. Similarly, members of the supply chain may refuse to service a pharmacy that dispenses a large volume of narcotics. No one intends for cancer patients, wounded veterans, and those suffering with intractable pain from chronic conditions to have difficulty obtaining pain medication. But this has been an unintended consequence brought about by a chain of actions and reactions that are produced by a lack of clarity in

the law. While some of accounts of the lack of access to drugs may be overstated, the mounting anecdotal evidence that individuals with legitimate medical needs are being refused controlled medications is disturbing. In the absence of clarity in the law, this trend is likely to continue because registrants will continue to take action to limit supply to avoid the perceived threat of administrative action.

It has been nearly a decade since the team of dedicated investigators and lawyers I worked with at DEA used the Agency's administrative power to cripple dozens of illicit Internet pharmacy schemes. Convinced that we would be more effective by expanding our actions to pursue the supply chain, I developed the legal framework to pursue actions against distributors that supplied those Internet pharmacies. We initiated a record number of administrative actions; the Government collected record-setting civil penalties in conjunction with those actions. But prescription drug abuse continued to rise. Action by DEA alone was not and is not enough to address the problem. Now, as then, DEA's actions are fueled by a desire to protect the public. Now, as then, the overwhelming majority of registrants are working diligently to prevent the diversion of controlled substances while ensuring that legitimate patients have access to needed

medications. But how can we channel these efforts to achieve maximum effectiveness?

Prescription drug abuse is a complex problem that no single legislative or regulatory action will fix. Likewise, access to medications for legitimate patients will not be guaranteed by any single piece of legislation. But the clarity provided by the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 is consistent with the findings Congress made when it enacted the Controlled Substances Act -- controlled substance are beneficial in meeting the medical needs of many Americans, but the abuse and misuse of those substances are detrimental to the public health. The clarity in this bill will create a regulatory environment in which DEA and those registrants who are committed to compliance can make meaningful strides to reduce prescription drug abuse while improving access to medication for patients in need. Clarity will foster compliance. Clarity will enhance communication. Clarity will create collaboration and collaboration will address root problems, not just symptoms.

Thank you for inviting me to appear before you. I trust that these insights gleaned from more than a decade of zealously representing DEA and more than two years of assisting registrants with DEA compliance will be of help to you.