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RPTR RULL
EDTR SECKMAN

EXAMINING PUBLIC HEALTH LEGISLATION
TO HELP PATIENTS AND LOCAL COMMUNITIES
TUESDAY, JANUARY 27, 2015
House of Representatives,
Subcommittee on Health,
Committee on Energy and Commerce,
Washington, D.C.

The subcommittee met, pursuant to call, at 11:16 a.m., in Room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Whitfield, Shimkus, Blackburn, Griffith, Bilirakis, Long, Bucshon, Collins, Upton (ex officio), Green, Capps, Butterfield, Sarbanes, Matsui, Schrader, Kennedy, Cardenas, and Pallone (ex officio).

Staff Present: Brenda Destro, Professional Staff Member, Health; Andy Duberstein, Deputy Press Secretary; Carly McWilliams,

Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Chris Sarley, Policy Coordinator, Environment & Economy; Macey Sevcik, Press Assistant; Adrianna Simonelli, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Ziky Ababiya, Minority Policy Analyst; Jeff Carroll, Minority Staff Director; Eric Flamm, Minority FDA Detailee; Hannah Green, Minority Policy Analyst; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; and Ashley Jones, Minority Director, Outreach and Member Services.

Mr. Pitts. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today the subcommittee will consider some unfinished business from the last Congress in the form of six bills.

The Veteran Emergency Medical Technician Support Act, sponsored by Representative Adam Kinzinger, would assist States in streamlining their certification requirements for those veterans with emergency medical technician training who want to work in the civilian workforce.

The National All Schedules Prescription Electronic Reporting Reauthorization Act, or NASPERR, sponsored by Representative Ed Whitfield, would reauthorize the NASPERR program to support State prescription drug monitoring programs.

The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, sponsored by Representative Burgess and Ranking Member Green, would reauthorize certain trauma care programs through fiscal year 2019.

The Access to Life-Saving Trauma Care for All Americans Act, to be sponsored by Representative Burgess, Ranking Member Green, would reauthorize trauma care -- centered care grants.

H.R. 471, introduced by Representative Marino, Blackburn, Welch, and Chu, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015, would improve law enforcement efforts regarding prescription drug diversion and abuse.

And the Improving Regulatory Transparency for New Medical

Therapies Act, which I introduced, along with Ranking Member Pallone, last Congress and will be reintroducing shortly, seeks to improve the transparency and consistency of the Drug Enforcement Agency's scheduling of new FDA-approved drugs under the Controlled Substances Act.

[The information follows:]

***** INSERT 1-1 *****

Mr. Pitts. I look forward to hearing the testimony of all of our witnesses today.

I yield the remainder of my time to Representative Whitfield.

[The prepared statement of Mr. Pitts follows:]

***** COMMITTEE INSERT *****

Mr. Whitfield. Well, Chairman Pitts, thank you very much for having this hearing today on the important topic of public health and for including NASPERR reauthorization draft as part of that discussion.

I am delighted that Mr. John Eadie is with us today, and we look forward to his testimony. He has 35 years or so of experience with the drug monitoring issues.

And I look forward to your testimony.

I might add that we have reached a point, unfortunately, in America today where more people are dying from drug overdoses than they -- from prescription drug overdose than they are from automobile accidents.

And I would just say that, back in 2001, the Appropriations Committee, without any authorization from the authorizing committee, started a drug monitoring program, which turned out to be a very good program. In 2005, this committee came back, through Congressman Pallone and Mr. Pitts and myself and others, and we authorized NASPERR, a National All Prescription Drug Monitoring Program for the entire country. We had great difficulty obtaining funding for it because the appropriators always funneled the money through the drug monitoring program at the Department of Justice. NASPERR was at HHS. And so, ever since 2005, we have had sort of two different programs. Unfortunately, the one at HHS was not getting any funding basically.

Today, most States do have drug monitoring programs, but we still have these separate programs -- one at DOJ and one at HHS. And so, hopefully, we tried to explore about a year ago a way to sort of combine these programs to just make it more efficient and more helpful to the American people. And I don't think we have totally resolved that yet, but I do think it is important we reauthorize this program.

And I look forward to maybe having some discussions with you, Mr. Eadie, and others that have an interest. And is there a way that we can still try to get these programs together?

And, with that, I yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Whitfield follows:]

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Mr. Pitts. Now, recognize the ranking member of the subcommittee, Mr. Green, 5 minutes for opening statements.

Mr. Green. Thank you, Mr. Chairman.

And good morning to our witnesses for you all being here today.

This hearing is called to examine six proposals which will strengthen public health, each which is the product of bipartisan efforts.

I thank the chairman for having this hearing. It is not only an opportunity to further these important pieces of legislation. But it also serves as a reminder of the great work this committee can accomplish when we work together to advance our healthcare system.

The Veteran Emergency Medical Technician Support Act, as led by Representatives Kinzinger and Capps, the legislation will save lives -- will help States utilize the skills of our Nation's veterans and address emergency medical technician shortages by streamlining the certification and licensure requirements of returning veterans who have completed military EMT training.

The Improving Regulatory Transparency for New Medical Therapies Act -- that is the last time I will say that -- provides a solution to current delays experienced by patients in need.

The amount of time the DEA has asked before acting on FDA recommendations has lengthened in recent years, delaying the availability of new therapies. Led by Chairman Pitts and Ranking

Member Pallone, this legislation will improve patient access by bringing clarity and transparency to the process of scheduling new FDA-approved therapy.

Representatives Marino, Welch, Blackburn and Chu introduced the Ensuring Patient Access and Effective Drug Enforcement Act. This legislation would promote patient access to medically necessary controlled substances and, with the DEA's authority, to suspend a DEA registrant acting in a manner that puts public health and safety at risk.

The National All Schedules Prescription Electronic Reporting or NASPERR Reauthorization Act, by our Ranking Member Pallone and Representative Whitfield, will reauthorize the improved prescription drug monitoring programs -- are essential to part of our Nation's effort to combat the epidemic of prescription drug and opioid overdose. The reauthorization of NASPERR will help States implement and improve their PDMS, which improve clinical decisionmaking and reduce diversion.

The final two bills that are being considered today are the Trauma Systems and Regionalization of Emergency Care Authorization Act and the Access to Life-Saving Trauma Care for All Americans Act. My good friend and fellow Texan, Dr. Mike Burgess -- I wish Mike was here to hear me brag about him -- and I have led these legislative efforts. I thank him and his staff for their continued dedication and hard work. Both bills will reauthorize important programs that are designed to ensure that availability

and effectiveness of effective use of trauma care. Trauma is the leading cause of death under age 44. Federal investments in trauma centers and systems will save lives, improve patient outcomes, and provide downstream cost savings to the healthcare system.

Again, I want to thank Dr. Burgess for his partnership on this issue and the chairman for bringing these legislative proposals before the committee today. I thank my colleagues on both sides of the aisle for their thoughtful and worthy proposals and their commitment to improving access and delivery of health care.

I look forward to working on a bipartisan manner on many issues before our subcommittee, including our solutions with the expiration of the Health Centers Fund in September. Unless we take action, community health centers will reduce an immediate 60 to 70 percent funding cut. Health centers alone are bipartisan. And letting the fund expire without a solution in place will severely limit patient access to the cost effective primary and preventive care that is provided to millions of Americans.

With that, Mr. Chairman, I would like to yield the remainder of my time to my colleague from California, Lois Capps.

[The prepared statement of Mr. Green follows:]

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Mrs. Capps. I thank the ranking member for yielding.

And, Mr. Chairman, thank you for holding this important hearing today.

I am pleased to, again, be working with Representative Kinzinger to introduce the Veteran Emergency Medical Technician Support Act, as we did in the past two Congresses, to see it up for discussion today.

While our military men and women receive some of the best technical training in emergency medicine anywhere, when they return home, they are often required to start back at square one to receive the same certification for civilian jobs. At the same time, military medics with civilian credentials often must let these civilians certificates lapse while they are defending our country. Either way, this keeps our veterans out of the civilian workforce and withholds valuable medical personnel from our communities.

Vets EMT is a small but straightforward bipartisan bill to help States streamline their certification processes to take military medic training into account for civilian licensure. I look forward to testimony today about the training these men and women have already received, the need for this bill, and the impact it could have as written or if expanded.

I, also, must again plug my Emergency Medic Transition Act, a more comprehensive bill to help develop appropriate fast-track military-to-community programs which also deserves a hearing. I

am hopeful we can continue to work together in a bipartisan way to move these important pieces of legislation out of the committee so that we can help these talented professionals join our healthcare workforce and improve the care in our communities.

And I am out of time.

I will yield back and thank my colleague for yielding to me.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Mrs. Capps follows:]

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Mr. Pitts. I now recognize the chairman of the full committee, Mr. Upton, for 5 minutes for opening statement.

The Chairman. Well, thank you, Mr. Chairman.

In the last Congress, this committee established an impressive record of success with 51 bipartisan bills signed into law, many of which are now helping improve public health.

Families in local communities expect us to work together to solve problems, and we look forward to using our prior success as a springboard to further boost the public health that this new -- in this new Congress. Today, we are going to examine a half a dozen bills that collectively will help our Nation's veterans; address the prescription drug abuse crisis; secure access to trauma systems; and, yes, improve the Controlled Substances Act.

First, we are going to hear testimony on our bill authored by Mr. Kinzinger, the Veteran Emergency Medical Technician Support Act, passed by the full House in February of 2013, which would help military medics in those States with a shortage of emergency medical technicians.

We will also discussed the National All Schedules Prescription Electronic Reporting Reauthorization Act led by Mr. Whitfield to help address the prescription drug crisis here.

We are also going to hear testimony on two trauma bills, led by Dr. Burgess and Ranking Member Green. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, which was

passed to the full House in June of last year, would help support State and rural development trauma systems.

The second bill will reauthorize language from the Public Health Service Act to fund trauma care centers.

And, finally, the subcommittee will hear about two bills related to the Controlled Substances Act: Improving Regulatory Transparency for New Medical Therapies Act, led by Chairman Pitts and Ranking Member Pallone, which would amend the CSA to improve and streamline the DEA's process for scheduling new drugs approved by the FDA; ensuring Patient Access and Effective Drug Enforcement Act, led by Vice Chair Blackburn and Reps Marino, Welch and Chu, would help prevent prescription drug abuse, establish clear and consistent enforcement standards, and ensure that patients have access to medications by promoting collaboration among government agencies, patients, industries, stakeholders.

Thank you all for being here, and I yield to Mr. Whitfield.

[The prepared statement of The Chairman follows:]

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Mr. Whitfield. Thank you very much.

I would like to ask unanimous consent to set in the record a statement from the National Council for Prescription Drug Programs and a white paper on recommendations for improving prescription drug monitoring programs.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

***** INSERT 1-2 *****

Mr. Whitfield. Thank you.

Mr. Pitts. All right. The gentlemen yields back.

I would like to ask unanimous consent -- since the ranking member, Mr. Pallone, is not here -- to yield his time to Representative Kennedy.

Without objection, Mr. Kennedy is recognized for 5 minutes for opening statement.

Mr. Kennedy. Thank you, Mr. Chairman. I will take about 30 seconds, I hope. But thank you for yielding and recognizing me.

I want to thank the witnesses for their testimony today and Mr. Whitfield and Mr. Pallone for their work on the NASPERR reauthorization.

This is an issue that is of particular importance for me back in my home district. At the end of 2014, there were about 209 heroin overdoses in Taunton, Massachusetts, alone. In less than 20 days into 2015, there have already been 10 suspected overdoses.

We can often trace the origin of those overdoses back to opioid addiction and prescription drug abuse. Tufts Health Care Institute's Program on Opioid Risk Management released a report in 2011 with some alarming findings. They estimated that the societal cost of opioid abuse in the U.S. are substantial, with total societal costs being \$55.7 billion and healthcare costs about \$25 billion. The annual cost per patient diagnosed with opiate abuse dependence and misuse are considerably higher than those with patients without such diagnoses.

I was a prosecutor for several years before running for Congress. I saw the effects of opioid addiction every single day in the courtroom through property crimes, breaking and entering, larcenies, and other such crimes that would end up -- this addiction would drive people to such lengths to break the law to try to continue to feed an addiction.

Prescription drug abuse programs and prescription monitoring programs are an absolutely critical part to trying to come up with a comprehensive plan to combat this epidemic. And I applaud Mr. Pallone and Mr. Whitfield for their efforts on this.

And I would like to yield 1 minute of my time back to Mr. Butterfield.

[The prepared statement of Mr. Kennedy follows:]

***** COMMITTEE INSERT *****

Mr. Butterfield. Thank you very much, Mr. Kennedy, for yielding.

And thank you, Mr. Chairman, and the ranking member for the opportunity to sit in Mr. Pallone's seat for just a few minutes and to claim some of his time this morning.

But, Frank, I will be moving on in just a minute. I have got one or two other places to go.

But, Mr. Chairman, I appreciate the opportunity to discuss a number of bipartisan bills that many of us have worked on in the past. In particular, I was a supporter of the Trauma Systems and Regionalization of Emergency Care, the reauthorization act, and the Regulatory Transparency for New Medical Therapies Act that we handled in the 113th Congress. Finding innovative ways to improve access to care in rural communities, particularly ones like mine in eastern North Carolina, can mean the difference between life and death. The ACA went a long way. It went a long way toward improving rural health care and created or reauthorized the four programs included in the Trauma Systems Act. We must reauthorize this program and put our money where our mouths are by fully funding these programs.

Furthermore, the New Medical Therapies Act would improve access to care by accelerating the process to help patients access important medicines.

I thank you, Mr. Kennedy.

I yield back to you, sir.

[The prepared statement of Mr. Butterfield follows:]

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Mr. Kennedy. Thank you, Mr. Butterfield.

I think I yield my time, which was Mr. Pallone's time, back to Mr. Pallone.

Mr. Pitts. Mr. Pallone, you have 2 minutes left.

Mr. Pallone. All right. Thank you, Mr. Chairman.

I just wanted to say briefly that I think that these six public health bills are important. They all aim to address important public health issues within our communities. I am not going to go into all the details about them.

The first two, the Improving Regulatory Transparency Act, speeds up Drug Enforcement Administration decisions on scheduling of new FDA-approved drugs with regard to controlled substance.

And the second one, Ensuring Patient Access and Effective Drug Enforcement, adds two definitions to controlled substances. The goal of that bill is to help drug distributors, pharmacies, and others work with DEA to achieve the difficult balance between keeping controlled substance prescription drugs away from drug abusers but not from patients who need them.

The next bill, the veterans bill, authorizes a demonstration grant programs for States to streamline certification and licensure requirements for returning veterans to become emergency medical technicians. We had some great good hearings with this.

And I want to thank Congresswoman Capps for her work on this issue.

And then we have the two bills reauthorizing a number of

trauma programs, which are very important, because traumatic injury is the leading cause of death for children and adults under the age of 45. And it is critical that States are equipped to deliver these medical services.

And the last one the subcommittee will review is the NASPERR bill, which I coauthored with my colleague from Kentucky, Mr. Whitfield. And this legislation helps States establish and maintain prescription drug monitoring programs in order to combat drug abuses, which is an epidemic in the United States. So it is critical that we continue to support a program like this through Federal funding.

Many of these bills passed our committee in the House last Congress with broad bipartisan support, as you know, Mr. Chairman. And I look forward to working with my colleagues to do the same this year. Thanks.

Mr. Pitts. The chair thanks the gentlemen.

[The prepared statement of Mr. Pallone follows:]

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Mr. Pitts. That concludes the opening statement of the Members. As usual, all Members' written statements -- opening statements will be made a part of the record.

I would like to thank the witnesses for the efforts they made to be a part of the hearing today, especially in light of the hazardous travel conditions due to wintry weather. Since we announced a 1-hour delay in the start of our hearing today, one of our witnesses, Mr. John Eadie, has informed that he may need to leave early because of travel constraints. But thank you for all the effort that you made to get here.

I want my colleagues to be aware of this so they can form their questions with this in mind. So thank you.

On our panel today, we have five witnesses: Mr. Ben Chlapek, deputy director of Central Jackson County Fire in Blue Springs, Missouri; Mr. John Eadie, director of Prescription Drug Monitoring Program Center of Excellence at Brandeis University; Dr. Blaine Enderson from the Department of Surgery at the University of Tennessee Medical Center; Dr. Nathan Fountain, professor of neurology and director of the F.E. Dreifuss Comprehensive Epilepsy Program here on behalf of the Epilepsy Foundation; and Mr. Linden Barber, partner and director of DEA Compliance Operations at Quarles & Brady.

Thank you for coming today. Your written testimony will be made a part of the record. You will be each given 5 minutes to summarize your testimony.

And, Mr. Chlapek, we will begin you. You are recognized for 5 minutes for your summary.

STATEMENTS OF BEN D. CHLAPEK, DEPUTY CHIEF, CENTRAL JACKSON COUNTY FIRE, BLUE SPRINGS, MISSOURI; JOHN L. EADIE, DIRECTOR, PRESCRIPTION DRUG MONITORING PROGRAM CENTER OF EXCELLENCE, BRANDEIS UNIVERSITY; BLAINE L. ENDERSON, M.D., DEPARTMENT OF SURGERY, UNIVERSITY OF TENNESSEE MEDICAL CENTER; NATHAN B. FOUNTAIN, M.D., PROFESSOR OF NEUROLOGY, DIRECTOR OF F.E. DREIFUSS COMPREHENSIVE EPILEPSY PROGRAM, ON BEHALF OF EPILEPSY FOUNDATION; AND D. LINDEN BARBER, PARTNER AND DIRECTOR, DEA COMPLIANCE OPERATIONS, QUARLES & BRADY

STATEMENT OF BEN D. CHLAPEK

Mr. Chlapek. Thank you, Chairman Pitts, Vice Chairman Guthrie, and Mr. Green, and members of the subcommittee. My name is Ben Chlapek, and I am here to discuss the issue of military medics veterans who are honorable transitioning into the civilian EMS field. I am representing the National Association of Emergency Medical Technicians that represents roughly 40,000-plus EMTs, paramedics, and first responders of all delivery models, fire-based, hospital-based, privates, third services, industrial, and military medics.

I currently serve on the Board of Directors and as the chair of the Military Relations Committee; recently retired as the deputy chief of Central Jackson County Fire; and have been a

registered paramedic -- nationally registered for over 30 years. Also, recently retired from the United States Army as Lieutenant Colonel and have 36 years of service in the Army, starting in 1975, with one small break.

Bottom line up front is we have an obstacle course when a military medic transitions from the military and tries to get a civilian EMS license. Currently, the Army and Air Force graduate their medics at the Joint Training Facility in San Antonio with a National Registry EMT card. The Navy does not. They almost meet the criteria, but the medics split off at one point and get their specialty training or specialized training.

We have a lot of people who are helping us with this. And when they have to repeat it, it is a waste of their skills. They are doing the same thing over and over. In addition, a lot of military medics gain advanced skills, such as suturing and doing other forms of advanced medicine that civilian medics don't.

One of the biggest concerns -- and it is voiced by Sergeant Major Harold Montgomery, the senior medical enlisted advisor of Special Operations Command at MacDill Air Force Base in Tampa, Florida, his biggest concern is that we lose the knowledge and advances we have gained in Iraq and Afghanistan and Kosovo and don't use those, don't learn from them, and they will be lost. These military medics that are transitioning have that ability. For example, many law enforcement agencies across the country now carry combat tourniquets and hemostatic agents, which have saved

some lives. It has been documented by the first responders, the officers being able to use these skills.

There is a shortage in rural America of paramedics. And when these medics get out, even as EMTs, they need to advance to paramedic. We have gone the gap analysis. We know what needs to be done. And House Bill 235 is a great, big jump in getting that achieved.

It won't solve all the issues. But we have done the gap analysis. There are many States now passing legislation -- over 30 at this point -- to help veterans and streamline the process to become civilian medics because the State licensing procedures differ. They aren't the same.

Another thing we have done is written an interstate compact, and that is being presented to the States now.

We need a common registry. The Senate bill would help make a solid jump to get this achieved. This is near and dear to my heart. I have deployed with fire department medics, with private medics who have gone back and tried to integrate back into their services. Some have. Some haven't. The National Registry of EMTs has gone a long way toward helping. The National Association of EMTs has led this charge. I had 40 medics and EMTs on one tour and worked very hard for them to keep their certification.

I suffered a traumatic brain injury in 2008 in Afghanistan. It was moderate, and I still receive therapy today at the Kansas City VA, who does a great job. This -- this initiative is near

and dear to my heart, and I thank you for letting me speak today.
God bless.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Chlapek follows:]

***** INSERT 1-3 *****

Mr. Pitts. Mr. Eadie, you are recognized for 5 minutes for your summary.

STATEMENT OF JOHN L. EADIE

Mr. Eadie. Thank you, Chairman Pitts, Ranking Member Green, and Representative Whitfield for providing this opportunity to testify regarding proposed legislation to help fund State prescription drug monitoring programs, PDMPs, through the National All Schedule Prescription Electronic Reporting Act, i.e. NASPERR.

I am John Eadie. I have worked on public health for 45 years and specifically on PDMPs for 30 years. I currently serve as director of the Prescription Drug Monitoring Program Center of Excellence at Brandeis University, where we identify what makes PDMPs effective and help them reach their full potential. For example, through a partnership with Pew Charitable Trust and support from BJA, we have published a white paper on PDMP best practices.

PDMPs are operating in 49 States and Guam with another authorized for the District of Columbia. They are essential ingredients in the Nation's effort to reverse the epidemic of prescription opioid overdoses and deaths and rising heroin abuse. The health and safety of families across America depend on PDMPs being as effective as possible.

The Center of Excellence reviews PDMP's performance and has

found that they improve clinical decisionmaking and patient care by prescribers and pharmacies; identify and reduce doctor shopping; impact on controlled substances availability and prescribing; help improve health outcomes; reduce drug and medical costs related to inappropriate prescribing; reduce diversion into illegal use; and assist drug investigations; monitor compliance in drug abstinence; assist in substance abuse treatment and medical examiner practices; assist in drug abuse prevention and surveillance efforts.

Some States have recently issued broad mandates on prescribers to obtain and review PDMP data prior to issuing the first scheduled controlled substance to each patient and periodically thereafter, for example, every 3 months. Kentucky, Tennessee, and New York report rapid increases in prescribers registering for PDMP use, increases in requests for PDMP data -- over a 300 percent increase in Tennessee, over 500 percent in Kentucky, and over 10,000 percent in New York -- decreases in the prescribing of some commonly abused controlled substances and decreases in doctor shopping.

Florida, in 2011, implemented its PDMP and other initiatives. The Florida Medical Examiner has just reported for 2013 that there was an 8.3 percent decrease in one year in the number of deaths in which one or more controlled substance prescription was identified as the primary cause, while oxycodone deaths declined by 27.3 percent.

Further developments are needed. One example, after proactively analyzing their data, PDMPs should proactively send out unsolicited reports to prescribers, pharmacists, healthcare professional licensing boards, and law enforcement. This is one of the most effective best practices. But more than two-thirds of PDMPs still need to fully implement that.

A second example. Medicaid/Medicare, workers compensation, and other third-party payers need to protect their enrolled patients' health and safety and do so by helping prescribers and pharmacists avoid issuing and dispensing prescriptions that will cause harm to their patients. But this can only be done by PDMPs providing secure patient data access to third-party payers. And this is not a common practice today.

In order to reduce the opioid epidemic, PDMPs need to adopt the most effective practices, and this requires money. But the cost is miniscule compared to the price in lives and dollars if PDMPs do not rise to their full potential.

The reauthorization of NASPERR, with proposed changes, will assist States by adding important funds that complement other initiatives. States need NASPERR to encourage the technological development of PDMPs' interoperability with electronic health records and health information exchanges.

This development will allow PDMP data to reach prescribers and pharmacists in their normal workflow, increase clinicians' ability to properly treat their patients and avoid prescribing or

dispensing to doctor shoppers or persons counterfeiting or forging prescriptions. Importantly, NASPERR can help States sustain critical PDMP operations.

I thank the bill sponsors for their efforts to improve NASPERR and encourage the Subcommittee on Health to approve it.

Mr. Pitts. The chair thanks the gentlemen.

[The prepared statement of Mr. Eadie follows:]

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Mr. Pitts. Dr. Enderson, you are recognized for 5 minutes for summary.

STATEMENT OF BLAINE L. ENDERSON, M.D.

Dr. Enderson. Chairman Pitts, Ranking Member Green, and members of the committee, thank you for holding this hearing on examining public health legislation to help patients in local communities and for inviting the Trauma Center Association of American, TCAA, to speak.

TCAA is a nonprofit 501(c)(6) association representing trauma centers and systems across the country and is committed to ensuring access to lifesaving trauma services.

TCAA, along with our advocacy partners -- the American Trauma Society, the American Association for the Surgery of Trauma, the American College of Surgeons, the American College of Emergency Physicians, the American Burn Association, the American Association of Neurological Surgeons, the College of Neurological Surgeons, the Emergency Nurses Association, the Society of Trauma Nurses, the American Academy of Orthopedic Surgeons, and the Eastern Association for the Surgery of Trauma -- are on the forefront of providing trauma and emergency care to millions of Americans. And it is out of that commitment that we submit these comments for your consideration.

As organizations that care deeply about access to trauma and

emergency care, we would like to thank you for passing the Trauma Systems and Regionalization of Emergency Care Reauthorization Act, H.R. 4080, last session and express our strong support for the passage of this vital legislation again this session.

We would also like to thank Dr. Burgess and Representative Green for their continued leadership and recognize the importance of these systems of care in saving lives.

Trauma is a major public health issue, as we have heard. In the United States, approximately 35 million are treated every year for traumatic injury. It is the leading cause of death under age 44. And at an annual cost of \$67.3 billion, trauma is the third most expensive medical condition.

The value proposition for trauma care is well documented. The care provided by trauma centers, including specialist physicians, nurses, and their entire trauma team, has a dramatic and cost-effective impact on a patient's subsequent quality of life. In fact, trauma care is more cost effective than many other interventions, including dialysis for kidney failure.

Victims of traumatic injury treated at a level 1 trauma center are 25 percent more likely to survive than those treated at a general hospital. Unfortunately, 45 million Americans lack access to major trauma centers. And if they are taken to nontrauma centers, the risk of death increases to 30 percent within 48 hours.

The Trauma Systems and Regionalization of Emergency Care

Reauthorization Act would reauthorize two important grant mechanisms: The Trauma Care Systems Planning Grants Program and the Regionalization of Emergency Care Pilots Program, each authorized at \$12 million per year.

The Trauma Care Systems Planning Grant supports State and rural development of trauma systems. The Regionalization of Emergency Care Pilots Program funds pilot programs to design, implement, and evaluate innovative models of regionalized emergency care.

Unfortunately, in 2015, we still lack effective regionalized care systems for infectious diseases, like Ebola, or even for cardiac or stroke patients. The vast majority of hospitals addressing patients with these conditions also serve as our Nation's regional trauma centers. These hospitals must have the tools and capabilities to care for all of these patients with emergent, time-sensitive, and life-threatening conditions, whether it is trauma, stroke, or Ebola. The funding to support these hospitals must follow and support their willingness to provide care to the sickest Americans in the greatest hour of need.

In addition to the Trauma Care Systems Planning Grant and Regionalization of Emergency Care Pilots, there are two other programs contained in the Public Health Service Act, said to expire this year, which need to be addressed by Congress. The Access to Life-Saving Trauma Care For All Americans Act would reauthorize these vital programs to prevent more closures and

improve access to trauma care.

The Trauma Care Center Grants are authorized at \$100 million in a year -- per year in an effort to prevent more trauma center closures by supporting their core missions, curtailing losses from uncompensated care, and providing emergency award to centers at risk of closing. Also, the Trauma Service Availability Grants, authorized at \$100 million per year, are channelled through the States to address shortfalls in trauma service and improve access to and the availability of trauma care in underserved areas.

In addition, the Interagency Program for Trauma Research is in need of reauthorization. This program is designed to facilitate collaboration across the National Institutes of Health on trauma research.

All the programs are designed to ensure the availability and effective use of trauma care to save lives, cost, and improve patient outcomes. Trauma can happen to anyone any time and anywhere, as demonstrated by the Boston Marathon bombing and other recent casualties. And yet trauma care is not available for millions of Americans, especially in rural areas.

We would encourage the Congress to reauthorize these vital programs to maintain trauma services for Americans in the United States. And if there are any questions, please feel free to contact the Trauma Center Association of America. Thank you.

Mr. Pitts. The chair thanks the gentlemen.

[The prepared statement of Dr. Enderson follows:]

***** INSERT 1-5 *****

Mr. Pitts. Dr. Fountain, you are recognized for 5 minutes for your summary.

STATEMENT OF NATHAN B. FOUNTAIN, M.D.

Dr. Fountain. Thank you, Chairman Pitts and Ranking Member Green, for allowing me to testify on behalf of the more than 2.8 millions Americans living with epilepsy and, of course, their families.

As chair of the Epilepsy Foundation's Professional Advisory Board, I am here to support a legislative initiative that I know is important to the committee. The reintroduction of and passage of last year's Improving Regulatory Transparency for New Medical Therapies Act. The Epilepsy Foundation is extremely grateful for the committee's leadership for what we believe is an important problem that has a reasonable and workable legislative solution.

The most important thing I can tell you today is that the delay caused by the lack of a timeline for the Drug Enforcement Agency in making FDA-approved drugs available to patients threatens the lives and health of Americans. The magnitude of the problem is astounding by every reasonable measure.

The timeline for DEA approval has increased significantly, when comparing the era of the late 1990s. So if you look at the period from 1997 to 1999, compared to late 2000 -- so 2009 through 2013 -- the average time between FDA approval and then DEA final

scheduling of a controlled substance has increased substantially. If we look at the late 1990s, it was 49.3 days. And it increased, then, in the most recent era, to 237 days. So many days -- it is probably more appropriate to look at it in months. So from 49 days to almost 8 months.

There is a particular anti-epileptic drug called Fycompa that was approved by the FDA in 2012, but the final scheduling by the DEA occurred almost 400 days later. Now, we have to talk in terms of years instead of months or days.

The delay in drug approval by the DEA, as addressed by this legislation, is particularly important to people with epilepsy because epilepsy is common; it causes serious problems, including death; and previously approved epilepsy drugs that are scheduled by the DEA are not subject to abuse by any major we can identify. So it appears that there is a delay of potentially lifesaving treatments without a compelling reason.

And, of course, this applies equally to people with other conditions that might very well die while waiting for new drugs to be approved. So you can imagine how this would apply to someone with cancer or heart disease that is advancing while waiting for a drug to be approved.

But, today, I will specifically address this issue as a representative of the Epilepsy Foundation, which is the leading national voluntary health organization that speaks on behalf of the 2.8 million Americans with epilepsy. I serve as chair of our

medical advisors, but I am also a practicing neurologist at the University of Virginia and director of a large epilepsy program, where I have firsthand experience with the problems caused by the delays in drug approval. I would like to share information about epilepsy so that you can better understand why our organization is steadfast in support of this bill.

Epilepsy is any condition of the brain that causes seizures. So you can imagine it has diverse causes; acquired things like head trauma or stroke, or you can be born with a genetic predisposition and otherwise be perfectly normal. Approximately 1 in 26 people will develop epilepsy. That is a lot of people; 1 in 26 people develop epilepsy at some point in their lives. The onset is greatest in childhood and in older adults. That is why epilepsy is the fourth most common neurological condition -- after migraine, stroke and Alzheimer's disease, then comes epilepsy. So that might beg the question, "What is a seizure," for your own curiosity.

A seizure is an electrical storm of the brain. The storm can be confined to just one small area of the brain and cause something as isolated as just staring and responsiveness or jerking of one arm, or it can involve the whole brain.

The type of seizure most people are familiar with is a generalized tonic-clonic or grand mal seizure, during which the whole brain is involved. The person becomes stiff, straightens out, falls to the ground, is unconscious and jerks all over for a

few minutes. Afterwards, their brain is entirely exhausted and so is the person. They are unresponsive, but then they recover to normal over the course of typically about an hour.

You can understand that this can cause injury from falling, choking, crashing a car, drowning. Even milder seizures that consist only of staring and confusion can cause serious problems. During confusion, people may put their hand into boiling water, thinking they are stirring it with their arm, for instance; pick up an iron by the hot face and not realize it; or be chopping vegetables and not realize it becomes part of them that they are cutting.

In addition to the direct injury that seizures can cause, it can also result in the tragic circumstance of sudden, unexpected death in epilepsy or SUDEP, S-U-D-E-P, sudden unexpected death in epilepsy, which is the most common cause of epilepsy-related death.

SUDEP occurs when someone with epilepsy dies for no obvious reason. That is, there may be evidence of a typical seizure, a seizure like they have had a hundred or a thousand times before, for instance, but there is no evidence of choking; there is no evidence of trauma or prolonged seizure.

In my last testimony to this committee, I related a story of Matthew, a delightful, young engineering college student, who was very much like my own son, who is a college student. Matthew died from SUDEP during the time that Fycompa was waiting to be

scheduled by the DEA. It had been approved by the FDA, had already been suggested, had been scheduled, and DEA was waiting its approval. 2,800 Americans die from SUDEP each year. For people like Matthew, waiting a year to get an effective drug to treat their seizures, is not acceptable since the drug could be lifesaving.

It is troubling, as a patient advocacy organization as well, that we can't offer a clear explanation of why the delay occurs at the DEA, since the DEA review has never made a change to the drug schedule recommended by the FDA. They have always followed FDA recommendations. Nor can we offer an explanation of why there is no timeline for DEA approval. After all, the FDA drug review process is largely transparent with predictable timelines. And our committee wonders why the DEA approval process doesn't have a similar timeline or transparency requirement.

The current delays discouraging innovation in epilepsy therapy development, the unpredictable delay at the DEA means companies cannot accurately predict the amount of time they will have left on their drug patent or exclusivity. This bill proposes a simple solution to the problem and will ensure that drugs will not sit idly waiting to be scheduled while patients wait for potentially lifesaving drugs.

We urge all members to consider full support of this legislation. Predictable and timely access to new therapies would be a phenomenal accomplishment for epilepsy patients and all

Americans suffering from conditions like epilepsy. I thank the committee for its time and attention today.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Dr. Fountain follows:]

***** INSERT 1-6 *****

Mr. Pitts. Now recognizes Mr. Barber, 5 minutes for opening statement.

STATEMENT OF D. LINDEN BARBER

Mr. Barber. Good morning, Mr. Chairman, Ranking Member Green, members of the subcommittee.

For the last 3 and a half years as the director of the DEA compliance and litigation practice at Quarles & Brady, I have dealt with registrants on a daily basis. But, prior to that, I was the associate chief counsel at DEA. I worked at the agency for 12 years. And there I was the associate chief counsel in charge of the litigation section that took administrative actions against registrants.

Over these last 15 years, we have seen a chain of well-intentioned actions and reactions by DEA and by the industry that have unintentional consequences, consequences that undermine the ability of DEA and industry to address the issue of prescription drug abuse while ensuring that there is adequate supply of controlled substances to meet the legitimate medical needs of the United States.

These unintended consequences are produced, in large part, by a lack of clarity in the law and the uncertainty produced in the regulatory environment. Ensuring Patient Access and Effective Drug Enforcement Act of 2015 provides much needed clarity in the

Controlled Substances Act. Consider the unintended consequences that have occurred as a result of the lack of clarity.

Communication between DEA and members of industry is thwarted. And communication is the cornerstone of a regulatory environment that promotes compliance and collaboration, particularly in an area like prescription drug abuse, an area that changes frequently and is difficult for DEA and industry to detect those who are attempting to obtain controlled substances for an illicit purpose.

This breakdown has led to a lack of access to controlled substances for certain patients. It has altered the ordering patterns of pharmacies, making it more difficult for DEA and members of the supply chain to detect suspicious orders. And there is growing evidence to suggest that these actions and reactions are contributing to the rise in heroin use.

When patients with chronic pain are forced to go from pharmacy to pharmacy in search of a pharmacist who will dispense a controlled substance that the patient has taken for years to control legitimate pain, we have a problem. When a pharmacist fears that filling such a prescription will result in being second-guessed by DEA and having their DEA registration suspended, we have a problem. When wholesale distributors decide to limit the supply of narcotics to pharmacies simply to avoid the risk of regulatory action, we have a problem. And certainly, if the lack of supply of controlled substances leads some people to use heroin, as some of the recent evidence suggests, we have a

problem. That is why clarity in the law is so important.

H.R. 471 provides clarity in a way that will allow DEA and industry to address these unintended consequences. While addressing these unintended consequences is essential, it is also important to preserve DEA's ability to issue immediate suspensions to address imminent danger to public health and safety. The lack of clarity and an inconsistent approach to immediate suspensions over the last 40 years has led to judicial challenges of DEA's authority.

In 2006, when I was the associate chief counsel at DEA, the agency stopped issuing immediate suspensions because of a Federal court ruling that found that the DEA had -- its process for immediate suspensions was unconstitutional. During an 8-month period while the Internet pharmacies were out of control, fueling prescription drug abuse, the agency issued no immediate suspensions. That is Exhibit A for why clarity in the law and protecting DEA's authority is so important.

Clarity also promotes access to controlled medications for patients. Without clarity, registrants often act to reduce perceived regulatory risk. A pharmacist refuses to fill legitimate prescriptions for narcotics simply because dispensing a high volume of narcotics brings scrutiny from DEA and from the wholesale distributor. No one wants cancer patients, wounded veterans, those in chronic pain to go without medication, but restricting access is an unintended consequence of a regulatory

environment that lacks clarity.

The Ensuring Patient Access and Effective Drug Enforcement Act of 2015 holds the promise of fulfilling its name. By defining key terms in the CSA, the regulatory and enforcement environment will be clarified. Communication between DEA and registrants will be enhanced. Registrants will be less likely to restrict access to legitimate patients out of a fear that they may be second-guessed by DEA. Registrants will also be encouraged to assist DEA in detecting controlled substance diversion. And DEA's authority to issue immediate suspensions will be protected from judicial curtailment because there will be a clear, legal standard.

I thank the chairman and the committee.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Barber follows:]

***** INSERT 1-7 *****

Mr. Pitts. I will begin questioning and recognize myself 5 minutes for that purpose.

Dr. Fountain, in your testimony, you mention that the DEA has no set timeline or transparency requirements when making scheduling determinations. How does this impact patients, particularly those who have not benefited from currently available therapies?

Dr. Fountain. About one-third of people with epilepsy will continue to have seizures, despite available treatments. For those third of patients, every new therapy is vitally important. Because the incidence of SUDEP, sudden unexplained death in epilepsy, seems to be related to the number of seizures, logically. So for those patients who are most severely affected, they are in most need of new therapies. And those new -- the sooner those new therapies are available, the sooner that their seizures can be reduced in frequency; the less likely they are going to die as well as suffer those other consequences.

So, of course, the epilepsy community, the Epilepsy Foundation wants to have safe and effective drugs. That is paramount. But if the FDA has already determined them to be safe and effective, then, for our community, it is difficult to understand why it would be delayed at the FDA -- I mean, at the DEA while waiting to be scheduled. So it can impact patients very directly.

Mr. Pitts. Now, give me the length of time, the longest time

patients have had to wait on DEA after FDA has conducted its own detailed abuse liability analysis and approved a new therapy.

Dr. Fountain. I think, based on the analysis that has been done in the published literature, the drug I mentioned before, Fycompa, I think, is the longest time. And it was 400 days. So 400 days after FDA approval was when the drug was finally made available, scheduled, and finally scheduled by the DEA. So approximately 400 days, more than a year.

Mr. Pitts. Do you know of any widespread abuse or criminal diversion of epilepsy treatments?

Dr. Fountain. I am not aware of a single case report. So I have done my own literature search of the medical literature. And I am not aware of even a single case report of abuse of what we would consider standard epilepsy drugs. It is true in epilepsy, we sometimes, in special circumstances, use other drugs that might be subject to control, the so-called benzodiazepines, that have a different role. But for normal epilepsy drugs, the ones that have been approved in the recent many decades, I am not aware of any actual abuse.

Mr. Pitts. Mr. Chlapek, both the GAO and the IOM have addressed the need of the EMS system in the U.S. Two of the areas of need, personnel and training, were highlighted. Since those reports were issued, there have been several events that have reinforced the need for a highly trained effective responsive EMS system -- terrorist attacks, natural disasters, pandemics. Do you

see this bill as another way of improving preparedness?

Mr. Chlapek. Chairman Pitts, absolutely.

This bill will help take a trained and -- a trained group of medics and transition them so they take care of the shortfall. They are more able to help in disasters. They are more able to help with protection of a license or certification in incidents like Boston or Katrina and can go from State to State.

Mr. Pitts. Now, if you were making recommendations to the States to streamline the process for veterans to become EMTs, what would you focus on?

Mr. Chlapek. Approving education programs, the training centers and education facilities to offer something similar to Lansing Community College in Michigan, that sits down with the veteran and looks at their electronic military training record and gives them credit -- transcripts credit -- for that at no cost and then fills the gap and gets them out within a few weeks or a weekend.

Mr. Pitts. Okay.

Mr. Eadie, you have mentioned that there is a white paper that describes best practices PDMPs need to adopt.

Mr. Eadie. Yes, sir. It is available on our -- the Web site of the -- at PDMPexcellence.org. And it is the -- that is the Web site for the PDMP Center of Excellence at Brandeis University. Yes.

Mr. Pitts. Could you highlight a few of the practices you

think are important to improve PDMPs.

Mr. Eadie. Absolutely. I would first comment that there are 35 best practices listed, so it comes -- deals with everything from the way data is collected from pharmacies right through how the data is used.

In terms of the data use, the recent advent of the mandated use of the systems by prescribers has certainly proven to be very effective in the States that have already initiated that, and I mentioned the examples of that in my earlier comments.

The major one that has yet to be fully implemented is the use of unsolicited reporting or proactive reporting called both -- proactively States analyze the data that is in their system and then share it with those people who need to see it based upon what the analysis shows. To date, only about a third of States are covering that -- doing that adequately. And so there is a great deal of room there.

There are other things, like, the -- the excellent effort that is underway to allow data to be shared through electronic health records and health information exchanges that is a technological fix, so to speak, that will allow the prescribers and pharmacists to get data faster and right within their normal workflow so they can review it more readily.

Mr. Pitts. Thank you. My time has expired.

The chair recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

And I am going to focus my questions on the two trauma related bills that Dr. Burgess and I have introduced. And Dr. Burgess is actually chairing another subcommittee of our full Energy & Commerce Committee downstairs.

Both bills will reauthorize a number of important programs aimed at strengthening trauma systems, developing regionalized systems of care, and improving availability of high-level trauma services.

Dr. Enderson, it is disappointing fact that 44 million Americans currently lack access to the major trauma centers within the golden hour of the injury, the time period when the chances of survival are greatest. Can you elaborate on the issue of access and why timely and appropriate care within the first hour of injury is so critical?

Dr. Enderson. Traumatic injury is a surgical disease. Basically the injuries that kill patients when they are injured are -- frequently, they are bleeding to death and they need access to surgical care within that time to stop the dying process while they are bleeding.

The access problems occur commonly in the United States in rural areas, but we also have access problems in some of our major cities where there is a maldistribution of level 1 trauma centers. So someone who is injured on one side of the city has problems getting transported to that trauma center in the length of time

before they bleed to death. And if they are taken to a hospital that is not part of the system, that delays the care until they reach that definitive surgical care.

Mr. Green. Thank you.

I represent Houston, Texas. And I first became involved in this issue when hurricane Allison -- or Tropical Storm Allison flooded our two level 1 trauma centers in our Medical Center and the area was under water. While tropical storms and hurricanes are not typically the greatest threat to trauma centers' operations, cost pressures, providers shortages have caused many trauma centers to close and many more are struggling to maintain operations.

As you mentioned in your testimony, from 1990 to 2005, 30 percent of our trauma centers closed their doors. Can you discuss why access to trauma care is threatened by losses associated with the high cost of treating severely injured patients, a problem compounded by uncompensated care and the growing shortage of trauma-related physicians?

Dr. Enderson. The cost does keep going up. The demands on providers are increasing. And if we close down trauma centers, that just puts a further strain on the system. In many areas, such as our area, we are the only trauma center in our area. And we don't have any backup. And the fewer trauma centers you have, they are more likely to get overloaded with all of the patients so that, when they are needed for critical events, they can't provide

care for their patients.

So it is nice to have some redundancy in that system, but that redundancy has to make sense. It has to be in places where they can work with the higher level trauma centers where they can take care of their patients and provide the care that is needed in that region and for those injured patients.

Mr. Green. And I want to point out that some of these programs have not received funding for several years.

Dr. Enderson. They have not. They have been authorized, but they have not had appropriations.

Mr. Green. Dr. Enderson, what can you talk about the value of investing in trauma centers and trauma care programs like these?

Dr. Enderson. We have heard that trauma is the leading cause of death in patients under the age of 44. If you have young patients who are injured and you treat them and get them back to normal life, they can return to a long working life for society.

As an example, we recently had a young man. He was at work. He got ill. He was driving home, and he had a bad wreck. He had terrible injuries. He had a ruptured thoracic aorta. He had extremity fractures. He had a head injury. And yet, by getting brought quickly to our trauma center, we were able to treat those injuries over a period of time, and in 6 months, he was back working and back with his family.

Mr. Green. Well -- and, Mr. Chairman, I realize a lot of us

have been to both Iraq and Afghanistan. And that was the same goal that we had for our military, to make sure that there was a -- within that hour period, they could reach a trauma center, whether it be in Kabul, Kandahar in Afghanistan, or in Baghdad, or Balad in Iraq.

Mr. Enderson, can you talk about the value of investing in trauma systems and trauma care programs like these?

Dr. Enderson. I think the value is simply what you pointed out. So, in the military, they have a great regionalized system where they provide lifesaving care at the scene. They quickly transport to a place for more definitive care. And then they transfer them back to the United States for rehabilitation.

What we need is a system that involves all levels of trauma care so that we can take our young people and return them to a normal life.

RPTR BAKER

EDTR SECKMAN

[12:14 p.m.]

Mr. Green. Thank you, Mr. Chairman, again.

I will yield back my time, except I want to thank Dr. Burgess for his partnership and leadership.

And I also thank the Trauma Coalition, who has worked hard on the of reauthorization of these programs.

And I yield back.

Mr. Guthrie. [Presiding.] Thank you.

The gentleman yields back, and I will recognize myself for 5 minutes for questioning

Mr. Eadie, I am from Kentucky, and we have been very active in this area. According to the Department of Health and Human Services, as of July 2013, 47 States had operational prescription drug monitoring plans or PDMPs. However, they are significantly underutilized by providers. A number of factors contribute to this underutilization, including the cumbersome nature of accessing current systems and privacy concerns. Would you elaborate on some of the factors that may lead to underutilization of PDMPs?

Mr. Eadie. Certainly, I am happy to do that, and I want to acknowledge Kentucky's leadership for the country on many issues, including this one.

In many cases, the cumbersome nature of this process as you describe it is correct. Doctors have to take the time to do it. Recent developments in Kentucky and other States has been actually to allow the physicians to delegate the responsibility to a subordinate person in the practice, with the prescriber keeping responsibility. That is also a practical thing that can be done, and we encourage every State to look at that. And in fact, those States that have mandated use have found it essential because of the increased workload of having to pull up the data.

Mr. Guthrie. I want to ask you, on the mandate, do you think that is the right approach, to mandate the use? Kentucky and I think New York -- I know my State has and also the State of New York.

Mr. Eadie. Yes.

Mr. Guthrie. Will you elaborate on mandating?

Mr. Eadie. Yes. What those mandates -- there are multiple types of mandates out there, some, like the State of Nevada, which mandates the prescribers use the system but only when they have a reason to believe that the patient in front of them is not there for legitimate medical purposes. Such States have not significantly increased their use of the data by prescribers with that kind of a mandate. But Kentucky, New York, and Tennessee have pioneered a new one in which basically every patient is required, with a few logical exceptions, before the first prescription is issued and then periodically thereafter. And, in

the case of Kentucky, it is at least every 3 months, they have to check before issuing an additional prescription beyond 3 months. What that does is it allows a prescriber in each case to check.

We know from work that we did with the State of Massachusetts that in that State, when these unsolicited reports I talked about were sent out and they sent to prescribers and then we, with them, did a survey, found that only 8 percent of the prescribers acknowledged after receiving those reports that they had known about the multiple doctor episodes or doctor shopping that was going on by their patients. Putting it the other way, more than 90 percent of the prescribers did not know what was going on and, therefore, would not have asked for the data had it not been sent to them. Or, in the case of a mandate, they have to look, which is why they are effective.

And we have seen in Kentucky and, frankly, in all three of those States, that medical opposition at first to being required to use the system has modified itself after implementation.

Mr. Guthrie. I am going to try to get another question in from another panelist.

Mr. Eadie. Please.

Mr. Guthrie. That was very helpful. I appreciate what you were saying.

Mr. Chlapek, when you were talking about the situation, you said there were a lot of people helping and involved and working in this, and so I have two questions really I will ask you because

we have a minute and a half. Who were the stakeholders that should be addressing this and giving us information for policy questions? And you also said H.R. 235 will address issues, but there is still a lot of other issues to be addressed. You talk about State licensing, and I understand how that, you know, with each State having its own and us reluctant to get into that because that is a States issue would be a problem. What other issues besides the State licensing do you think maybe other legislation would help? So who are the stakeholders, and what other issues need to be addressed?

Mr. Chlapek. Vice Chairman Guthrie, other issues are standardization of training at the Joint Services Medical Training Facility in San Antonio. If we could get all of those folks with a National Registry EMT card, that would really help as they try to transition out.

Other issues, H.R. 235 mainly helps with providing some funds for educational facilities to develop their transition program, especially in the rural or shortage areas. Other issues are standardization of State licenses. If there was a National Registry, that would really help us. Many States accept the registry now, but all don't.

Mr. Guthrie. I used to be a State legislator. It probably would be easy for States to adopt rules if it came out with a standard uniform service. As you said, if the uniform services would have a standard training program with a standard card or

standard criteria, then it would be easy for States to -- so maybe that is where to start.

But my time is actually expired. I appreciate you doing so.

I would like to recognize Mr. Schrader from Oregon for 5 minutes of questioning.

Mr. Schrader. Thank you, Mr. Chairman.

I appreciate the opportunity. First question for Mr. Eadie. I am curious, as you have heard testified by Mr. Whitfield that we currently have a program, a registry, if you will, that is operated out of the DOJ unit and wondered what the advantages of or need for the unit out of HHS would be and why that is critical for making this program work effectively?

Mr. Eadie. I appreciate your question. It is my experience that both law enforcement and the public health professions have to be involved in addressing these issues. Neither one can address it. I mean, a fundamental thing is that prescriptions are issued by healthcare professionals. And the entire system of delivery of opioids, for example, are through the health care system. So a public health involvement and regulatory involvement involving health care is essential. At the same time, as long as we have had these types of drugs available for medical use, which is so important, they have also had the risk of making people addicted. And when that happens, people move into all sorts of illegal and criminal behavior patterns, including forgeries, counterfeitings, organized rings of drug shoppers, et cetera, and

pill mills. Those are outside the realm that can be dealt with and addressed effectively by traditional public health entities.

And I give you simply the examples. Public health, if you look at seatbelts, that is a triumph basically of both public health and law enforcement working together. The simple thing of people being quarantined in a public health emergency and an epidemic, public health orders it; law enforcement enforces it. And I could go on.

But my point is that both aspects are essential, and we cannot hope to solve this epidemic if we don't keep both parts working together.

Mr. Schrader. Very good. Thank you.

Mr. Barber, I was wondering if you could elaborate a little bit on the lack of clarity in the DEA guidelines, particularly as it affects distributors, and talk about why the definition of "imminent danger" is so important, and modifying the corrective action is important also?

Mr. Barber. Yes, sir. The statute currently does not have a definition for "imminent danger," unlike other Federal statutes designed to protect public health and safety, such as the Mines Safety Act. When an attorney, when an agent for DEA is faced with making a decision about whether or not, prior to a hearing, to issue an immediate suspension, which brings due process rights to bear, the question is, what constitutes an imminent danger? In my written testimony, I cite an example where DEA has issued a

suspension for conduct that they knew had ceased for months. So it is those types of scenarios that create a lack of clarity about what the standard is that will lead to an immediate suspension, and that is why courts have at times intervened.

And going back to the year after DEA was created in 1974, all the way to as recently as 2013, courts have questioned and in many cases overturned suspensions issued by the agency because of that lack of clarity. As far as the corrective action plan, that is an important piece of the legislation in that it provides an assurance to a registrant who has taken corrective action that that will be taken into account, thereby enhancing collaboration and communication with the agency. There are times where registrants get it wrong, and the agency needs to take action. But if the registrant has taken corrective action, it is appropriate for the agency to consider that.

Mr. Schrader. Very good. Thank you.

Mr. Enderson, could you talk very briefly about what the benefits are with regard to regionalization. What does that translate into? What does that really mean?

Dr. Enderson. What regionalization really means is that all of the parts of a system work together, and it may be under one head. So you have a Level 1 trauma center. You may have other trauma centers. You have other hospitals, but there is a system set up to ensure that the right patient gets to the right place at the right time, and they all work together. In the past, we have

talked about exclusive trauma systems where you just have one center. Now we talk about inclusive trauma centers. You want everyone involved so that they know what their role is in making sure that the patient gets to the right place.

Mr. Schrader. So they can get the immediate care they need no matter what.

Dr. Enderson. The immediate care. So there is not delays. If they are closer to another hospital, there is not a delay there. There are ways set up to automatically get the patient to where they need to be.

Mr. Schrader. Thank you.

I yield back.

Mr. Guthrie. The gentleman yields back.

Recognizes Mr. Griffith of Virginia for 5 minutes of questioning.

Mr. Griffith. Thank you, Mr. Chairman.

Dr. Fountain, if you could talk a little bit about where you think we ought to go in regard to the DEA and how we can better improve that process. I know the bills that we have here today, but are there other things that we can be doing as a committee to assist in making sure that we get some action on those things that have already been approved by the DEA or maybe even some research into things that we know might help epileptic patients that we are not able to do studies on yet?

Dr. Fountain. I guess there are two other DEA-related issues

that are important to the epilepsy community and to Americans in general. One of them peculiar to epilepsy drugs is that although they are scheduled by the FDA, they are scheduled at a low level. And for administrative reasons, they have been scheduled because the FDA, when it makes a recommendation to the DEA, follows eight specific criteria, and if these eight specific criteria boxes are checked off, then it requires DEA to schedule it. But those boxes -- while they are perfectly reasonable, for instance, if the drug is approved in a class in which that class of drugs is already regulated, then the DEA is forced to schedule it. Well, for epilepsy drugs, because of historical reasons, they are in those classes, so they end up getting scheduled by the DEA. But from a medical perspective, it sort of somewhere between unbelievable and comical because they aren't the kind of drugs that you would typically regulate like that. So the physicians who are not epilepsy physicians always ask the question, Well, why is that a regulated drug?

So specifically for our community and maybe for other drugs regulated by the DEA, especially given the burden that the DEA has of dealing with these specific and important issues that we have been addressing, it might be reasonable to revisit for epilepsy drugs but perhaps other drugs, speaking for myself, that don't necessarily need to be regulated by the DEA.

Mr. Griffith. And there may be some drugs that do need to be regulated by the DEA, but maybe we need to take a look at how they

are regulated. Currently I am working on some language with the epilepsy folks in regard to figuring out a way that we can use the cannabinoid oil from the marijuana plant. Of course, it is hard to figure out how much cannabinoid oil and how much THC you need to make it work for the children who apparently -- at least anecdotally, it appears that is a treatment plan for some patients. But we haven't had a lot of studies done over the years by the DEA. Would you agree?

Dr. Fountain. That is right. So the other issue relevant to the epilepsy community and to those with severe medical conditions is regulation of cannabis derivatives and cannabidiol, which is one derivative of marijuana that doesn't cause a high, doesn't cause euphoria or anything like that, seems to have some effectiveness in treating seizures and a few other medical conditions and is not the part of the plant or the compound that typically is associated with drug abuse. THC is, and so, consequently, for the epilepsy community, we would like to find a way to have cannabidiol oil available, first of all, to be studied and have research to know it is safe and effective; but then, beyond that, to make it available to people with the most severe epilepsies in certain circumstances.

Mr. Griffith. And we definitely want to go in that direction but also make sure -- because clearly that is a drug that can be abused -- and we want to make sure that we don't overlook that when we go down that path.

Mr. Barber, I know you sometimes get on the hot seat in here because we are trying to get things accomplished and get new treatments out there at the same time you are trying to make sure we don't have a lot of abuse of drugs. When last we were here and discussing these items, I had a situation where a small town pharmacy couldn't do what they can do. You mentioned that in your opening statement, and I appreciate that. You felt like we needed to try to make a better system so that we didn't have those problems where small town pharmacies with one supplier might have these issues. Do you have any suggestions that you can think of that we can do to be of assistance in that? Is there legislation that we need to pass that we haven't thought of yet or aren't moving on?

Mr. Barber. I believe the Ensuring Patient Access and Effective Drug Enforcement Act of 2015 is a great step in the right direction. I do think that there are certainly oversight roles that committees such as this can play. For example, DEA's regulation calls on distributors to detect and report suspicious orders to DEA. Those are, according to the regulations, orders of unusual size, unusual frequency, or those that deviate substantially from a normal ordering pattern. What is unusual depends on the context of the ordering pharmacy. What deviates substantially is somewhat amorphous, and so if there is greater clarity around regulatory obligations like that, it will help pharmacies who now find themselves oftentimes not having

sufficient drug supply to meet the needs of their patients.

Mr. Griffith. If I can take just a minute, Mr. Chairman, and just say I understand what he is saying. If I am translating it correctly, what that means is if you have a pharmacy that serves a lot of older people who are more likely to have pain needs, a senior population, than a pharmacy that serves a younger, you can't have a one-size-fits-all for the pharmacy that is in a community that is younger and a pharmacy that is in a community that is substantially older and is going to have more pain issues. Is that a fair translation?

Mr. Barber. That is a fair translation. Context always matters, both in the law enforcement and healthcare arena.

Mr. Griffith. I appreciate it, and I appreciate the panel being here today.

Thank you, Mr. Chairman. I yield back.

Mr. Guthrie. Thank you. The gentleman's time is expired.

The chair recognizes Mr. Sarbanes from Maryland for 5 minutes for questioning.

Mr. Sarbanes. Thank you, Mr. Chairman. I won't take 5 minutes.

Most of you have come from great distances to share your expertise with us, and it is deeply appreciated by the committee.

Mr. Chlapek, is that how I pronounce it?

Mr. Chlapek. It is Chlapek, sir.

Mr. Sarbanes. Chlapek, sorry. I gather you were here to

testify primarily with respect to the helping veterans with emergency medical training proposal --

Mr. Chlapek. Yes, sir.

Mr. Sarbanes. Which I think is a terrific opportunity to showcase how we can streamline bringing providers of all kinds, frankly, more quickly into the healthcare workforce. I have been working for many years on this idea of looking in nontraditional places for people that can help meet some of the shortages we have, whether that is physicians or nurses or, in this case, EMTs. In looking at military medics, who obviously come with a vast amount of experience, for that resource makes a tremendous amount of sense, and seeing if there is ways that we can streamline the process for actually getting them deployed here in the homeland to help respond to these emergencies makes a lot of sense.

So this demonstration project that Adam Kinzinger and Congresswoman Capps have proposed I think could make a tremendous amount of difference.

I was just curious whether you have had the opportunity -- I imagine you have -- to work with some EMT professionals who are former military medics and what your observation has been as to the kind of expertise and experience that they bring to the job?

Mr. Chlapek. It depends, sir. You have the Special Forces or SEAL or PJ medic that is deployed forward that does a whole lot of different things -- puts chest tubes in, uses conscious sedation, and some other adjuncts. These folks can come out and

go -- they should be able to challenge the paramedic test right away. And I will get phone calls that ask, What can I do, from these medics, and so I try to link them up with an educational institution that will let them do a weekend refresher and then challenge the test through their institution.

Mr. Sarbanes. Excellent. Excellent. Well, that is a good perspective, and I think what they can bring to a team, to an EMT team on the ground, given their experience and perspective, is incredibly valuable. In other words, it is not just another source of finding people for this job. It is finding people that are particularly qualified in certain respects for the job, and that is why I support this bill in particular. Thank you very much for your testimony. Appreciate it.

And all of you.

Mr. Guthrie. The gentleman yields back.

The next recognized is Mr. Long from Missouri for 5 minutes for questions.

Mr. Long. Thank you, Mr. Chairman.

Mr. Chlapek, number one, it is nice to have a fellow Missourian here, so welcome. Can you kind of walk us through the traditional State credentialing or licensing process for EMTs?

Mr. Chlapek. Yes, sir. The military EMTs or the civilian EMTs, Mr. Long?

Mr. Long. Well, the traditional -- just the civilian is what I am getting at.

Mr. Chlapek. Civilian EMTs, normally for the basic course, go through a one-semester or roughly 6-month time period with two clinical shifts and then take the test. The State of Missouri, for example, as well as about 40 other States, have adopted the National Registry exam because it takes a lot of pressure off of them. It is standardized. It is vetted, and they will take that exam and then receive a license. For paramedics, they go anywhere from two to three semesters and do an excess of 600 to 700 clinical hours, both in a hospital and in an ambulance. And then, once they do a certain number of skills, they are allowed to move on.

Mr. Long. Okay. Can you kind of juxtapose that with the military training? For someone with previous training, such as a military medic in Missouri, would they be qualified as EMT basic or EMT intermediate or EMT paramedic?

Mr. Chlapek. The military medics, for the most part, that go through the program at San Antonio at the Joint Training Facility qualify; if they are in the Army or the Air Force, they will have a National Registry card. They present that to most States, and they are handed a State license to work within that State.

The Special Forces medics come in, and they are expected -- they have done everything to qualify to test for a paramedic level card. Sometimes they do, and sometimes they don't. It depends. A Navy SEAL medic retired after 22 years and went to LA County Fire, and he wound up going through their whole

paramedic course again. But it was one of the few things he could do that really satisfied him after the job he had been doing.

Mr. Long. I know there are EMT shortages, and would you characterize that problem -- is it a problem of recruitment or a problem of retention or both?

Mr. Chlapek. Both, along with pay. EMS is severely underfunded, especially in rural areas, and some of these folks either volunteer or work for about \$15,000 a year. If they are paramedic level, they can make 50 to 60 or a little more. There is a huge difference, and it is underfunded.

Mr. Long. I was going to ask how you think that State healthcare systems could keep qualified EMTs working in the field, but I think you kind of answered that.

Mr. Chlapek. Yes, sir.

Mr. Long. With that, Mr. Chairman, I yield back.

Mr. Chlapek. Thank you.

Mr. Guthrie. The gentleman yields back.

The next recognized is Mr. Bucshon of Indiana for 5 minutes of questions.

Mr. Bucshon. Thank you, Mr. Chairman.

Prior to coming to Congress, I was a cardiovascular and thoracic surgeon for 15 years, so I am pretty familiar with the subject matter, especially as it relates to trauma and really all the medical issues, including EMT and how you deal with pharmacies and what the process is. And I just would like to say at the top

that this is a huge problem. My law enforcement in my community, in Evansville, Indiana, recently told me that prescription drug issues have overtaken methamphetamine as a community health problem in our county. And that I think is probably widespread across the country.

Mr. Eadie, your comments about combining law enforcement and medical are very critical. I can tell you, as a practicing physician, one of the issues is time and the information in an expedient manner. Most physicians, as you know, 99.9 percent don't want to prescribe narcotics to people that are doctor shopping, but available information quickly is so critical if we can provide that.

As a surgeon, of course, I provided acute medical care and acute pain management, which is a completely different area than our primary care physicians or neurologists and others have to deal with, so maybe you can expand further on how you think -- I mean, getting the information from medical records, for example, the two major hospital systems in Evansville have two EMR systems that don't communicate with each other. And some of the medical practices have EMR systems that don't communicate with either hospital. How do we make progress in that area, because I know that there is a lot of smart IT professionals that can probably fix this problem overnight. Right? But it is about proprietary information. It is about economics. It is about profit for different systems, and I totally understand that. But how do we

get past that and get the physicians the information immediately so that they, on the prescribing side, we don't overprescribe?

Mr. Eadie. I thank you for your question, and I want to also acknowledge that I would be happy to put you in contact with the people in Indiana who are experimenting with this. There is a trial underway in Indiana. You are one of the 16 States where there is an effort being made to translate PDMP data directly into the existing systems of electronic health records and health information exchanges. The details of that, they would have to provide to you, but it is important work. And that is why we support the NASPERR. It is one of the major reasons we support NASPERR, is that -- and feel it is so important -- is that we have seen the value and importance of doing exactly what you are talking about. And these 16 States have started, but that is not nearly enough, and they have got a long way to go. They are just experimenting. NASPERR funding has, in its refocused form, in the redrafted legislation would really encourage this. It would provide funding to support States to do the necessary work. And it is going to take time. The complications of proprietary systems, multiple systems in each State, it is going to take a while to overcome those barriers and hurdles that have been put in place by multiple systems, but it is doable.

And there is a real national effort underway, and in fact, the Substance Abuse and Mental Health Services, or SAMHSA, is the one that is spearheading this effort with the office from the

White House on technological developments for health care. There is a lot of work that has been done, and I would be very happy to put you in touch with them to learn about that.

Mr. Bucshon. That would be great.

And, of course, the medical systems need to be able to communicate with pharmacies and, honestly, with law enforcement also in some way. So it is a complicated problem. But my wife is an anesthesiologist -- still practicing -- so she tells me every day the number of patients that come to the hospital for other procedures that are on, have been taking narcotics or, honestly, benzodiazepines for many, many years. This is really an epidemic problem. It is across socioeconomic class. It is something I have been working on since I have been in Congress in the State, on the methamphetamine issue, trying to solve that. But now the prescription drug issue is, it has been and is surpassing that.

So I can tell you firsthand, you know, the significance. And I appreciate all your testimony and everyone working towards solutions to solve the problem.

And on the EMT side, quickly, Mr. Chairman, the last Congress, we were able to get legislation passed on commercial driver's license for veterans who had driving experience in the military, making that a streamlined process so that they could get a commercial driver's license to drive a semi, for example, across the country because of their military experience. So I do think there is a good chance that this legislation will move forward and

become law, and I hope it does.

So I yield back.

Mr. Guthrie. The gentleman yields back.

And I ask unanimous consent to enter into the record a report, "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction."

Without objection, so ordered.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Guthrie. The chair now recognized Mr. Collins of New York for 5 minutes of questions.

Mr. Collins. Thank you, Mr. Chairman. This has been a great hearing.

I think, first of all, Mr. Chlapek, we all agree: Anything we can do help our vets coming back, we want to do. And while this may not be a lot of money per year -- a couple hundred thousand per year I understand is what has been requested -- do you know how many States have this issue? I mean, one of the requirements is the State claim a shortage of EMTs, and there is a need. Do you happen to know, is this 2 or 3 States or 10 or 15? How great is the need for what we are proposing here?

Mr. Chlapek. Nearly every State that has a rural area has a shortage in those areas. They are currently served by volunteers, but as more and more folks go back into the city for work and both members of the household work and requirements keep increasing for the mobile healthcare providers, the folks on the street, EMS professionals, they can't keep people at all. And veterans are coming out. They know how to be on time for work. They know how to follow orders, and they just need help with the license.

Illinois is a prime example. And Carle out in Champaign-Urbana, has a conference every year on rural health care. EMS is the big thing.

Mr. Collins. I know this has bipartisan support, and we won't know until we get this approved and appropriated just how

many folks are going to apply for it, but certainly a worthy objective. And thank you for bringing that up.

My other question really is for Dr. Enderson on the trauma piece. First of all, I am just curious, do we know, since this one is a reauthorization, in the last couple of years, how many hospitals have applied? And what is the average amount of money they are getting? And have we seen a report that tracks how this money has allowed us to either get new trauma centers or keep trauma centers open? In other words, what are the metrics coming back at us?

Dr. Enderson. Well, sir, unfortunately, these have been authorized over the past several years, but there have been no appropriations for that.

Mr. Collins. I am glad you brought that up as well. As an authorizing committee but not the appropriators, that is information I didn't know as a new Member, and I am glad to know that so we can move forward. Certainly the access to trauma, as we talked about, that golden hour is critical. I represent the Western New York area, and Erie County Medical Center has one of the best Level 1 trauma centers in the country. And it is quite expensive to set that up, and I know it is always the issue with the county government and others, tight budget times deciding where this money goes; but it is a lifesaver quite literally, whether it is the ski resorts that are 60 miles away and the incidents there, which tend to be head trauma and the like, that

access has saved many lives in western New York, and I know we are blessed to have that. I know it is very much of a cost burden, but we have decided as a community it is worth that money.

Would you see that in something like I am explaining -- they are existing; they are there; the community is behind them -- would they qualify for one of these grants, or is this really more focused on, assuming it is appropriated, those areas that don't have one now?

Dr. Enderson. Both. So part of it applies to trauma centers that exist, especially trauma centers that are having significant difficulties and are in danger of closing, we are trying to prevent that, but we are also trying to help States look at the models of trauma care that they have and make sure that they are allocating the resources the way that make sense. So, in a regionalized system, these, as you pointed out, are very expensive resources. You don't want every hospital duplicating those resources. You have to understand how it works best in a system, know how it works, and how that system can work together to take care of their patients.

Mr. Collins. Yeah. I mean, the good news for our area is we did designate the Erie County Medical Center as the Level 1 trauma center. The other hospitals recognize that. It is also the, regional am, and in many cases, that 1 hour works with our mercy flight, the helicopters coming in. I suspect we are probably an example of best practices, both in the type of facility and also

the way the other hospitals recognize that that is our designated trauma center.

Dr. Enderson. Absolutely.

Mr. Collins. So, again, very important issue. Thank you for your testimony.

Mr. Chairman, I yield back my remaining 5 seconds.

Mr. Guthrie. The gentleman yields back.

The gentlelady from Tennessee is recognized for 5 minutes for questions.

Mrs. Blackburn. Thank you, Mr. Chairman.

I want to thank you all for being here, especially Dr. Enderson, my fellow Tennessean, and we are delighted to have him here and with us today.

Mr. Chairman, I have got some things to submit for the record. First of all, the statement of the National Association of Chain Drug Stores on today's hearing.

[The information follows:]

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Mrs. Blackburn. And, secondly, letters of support for the Ensuring Patient Access and Effective Drug Enforcement Act of 2015, which is the work product of Ms. Chu, Mr. Welch, Mr. Marino, and I. These are from the American Pharmacists Association, the Healthcare Distribution Management Association, the National Association of Chain Drug Stores, and the National Community Pharmacists Association.

Mr. Guthrie. Seeing no objection, so ordered.

[The information follows:]

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Mrs. Blackburn. Thank you, Mr. Chairman.

Very quickly as we wrap up, I did have a couple of questions on H.R. 471, which is the Ensuring Patient Access and Effective Drug Enforcement Act.

Mr. Barber, you mentioned in your remarks to one of the questions that context matters, and I appreciate hearing that. So I wanted to go back to your testimony. You said that little has changed in the past year in regard to the issue of dealing with DEA and guidance. And I want to know, has there been any improvement in the guidance the DEA is giving to distributors and pharmacists on this issue?

Mr. Barber. It hasn't changed, so I would say there has been no improvement or any decrement. It is unchanged.

Mrs. Blackburn. Well, I was hoping there was a sliver of a right step in the right direction, but I guess not, and it shows why we need to go ahead and get this bill passed.

I wanted to also ask you, we hear some discussion about whether or not to define "imminent danger," and I would like for you briefly to touch on why giving definition to "imminent danger" would benefit the DEA?

Mr. Barber. Well, as a former counsel who appeared in Federal courts, assisted U.S. Attorney's Office in defending the suspension power of the agency, having a clear legal standard is always best. There are Federal statutes that were passed around the same time as the CSA that contain a definition of "imminent

danger," and rather than having it undefined and having courts second-guess the agency's important power, to me it seems like if Congress gave a clear standard in the law, then the agency could enforce it and courts would not be left to second-guess DEA.

Mrs. Blackburn. Okay. So you would say the harm comes in having no definition of "imminent danger"?

Mr. Barber. I believe that is the harm. It is a harm both to the agency and to the regulated community, who doesn't know where the lines are, and we have those unintended consequences I mentioned in my testimony.

Mrs. Blackburn. Thank you.

And, Mr. Chairman, just for the record, we are speaking in reference to the Controlled Substance Act.

Well, I know you all are ready to step away from the desk. And we are appreciative that you are here.

And, Mr. Chairman, in the interest of time and ending the hearing, I will yield back my time.

Mr. Guthrie. Thank you. The gentlelady yields back her time.

All Members have been recognized. I remind Members that they have 10 business days to submit questions for the record, and I ask that the witnesses respond to the questions promptly. Members should submit their questions by the close of business on Tuesday, February 10.

Without objection -- the subcommittee -- we have one more.

We have a unanimous consent request for "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices for the record."

Without objection, so ordered.

[The information follows:]

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Mr. Guthrie. Without objection, the subcommittee is adjourned.

[Whereupon, at 12:52 p.m., the subcommittee was adjourned.]