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EXAMINING PUBLIC HEALTH LEGISLATION TO HELP PATIENTS AND LOCAL COMMUNITIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

JANUARY 27, 2015

Serial No. 114–5

Printed for the use of the Committee on Energy and Commerce

energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

95–851 PDF WASHINGTON : 2015

For sale by the Superintendent of Documents, U.S. Government Publishing Office
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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, DC.

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.

Members 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 and the Economy; Macey Sevcik, Press Assistant; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Ziky Ababiya, Democratic Policy Analyst; Jeff Carroll, Democratic Staff Director; Eric Flamm, Democratic FDA Detailee; Hannah Green, Democratic Policy Analyst; Tiffany Guarascio, Democratic Deputy Staff Director and Chief Health Advisor; and Meredith Jones, Democratic Director, Outreach and Member Services.

Mr. PITTS. The subcommittee will come to order. The Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

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 NASPER, sponsored by Representative Ed

Whitfield, would reauthorize the NASPER 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 appears at the conclusion of the hearing.]

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

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

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 Rep. Adam Kinzinger, would assist States in streamlining their certification requirements for those veterans with emergency medical technician (EMT) training who want to work in the civilian workforce.

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

• The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, sponsored by Rep. Burgess and Ranking Member Green, would reauthorize certain trauma care programs through FY2019.

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

• H.R. 471, introduced by Reps. 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 (DEA) scheduling of new FDA-approved drugs under the Controlled Substances Act (CSA).

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

Mr. PITTS. I yield the remainder of my time to Representative Whitfield.

Mr. WHITFIELD. Well, Chairman Pitts, thank you very much for having this hearing today on the important topic of public health and for including the NASPER 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 NASPER, 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. NASPER 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.

Now, recognize the ranking member of the subcommittee, Mr. Green, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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 NASPER 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 NASPER 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.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Good morning and thank you all for being here. This hearing was called to examine six proposals that will strengthen public health, each of which is the product of bipartisan effort.

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 health care system.

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

The Improving Regulatory Transparency for New Medical Therapies Act provides a solution to current delays experienced by patients in need. The amount of time the DEA has taken 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 a new FDA-approved therapy.

Representatives Marino, Welch, Blackburn, and Chu introduced the Ensuring Patient Access and Effective Drug Enforcement Act. This legislation will promote patient access to medically necessary controlled substances and protects 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 NASPER Reauthorization Act, led by Ranking Member Pallone and Representative Whitfield, will reauthorize and improve prescription drug monitoring programs. PDMPs are an essential part of our Nation's effort to combat the epidemic of prescription drug abuse and opioid overdose. The reauthorization of NASPER will help States implement and improve their PDMPs, which improve clinical decisionmaking and reduce diversion.

The final two bills being considered today are the Trauma Systems and Regionalization of Emergency Care Reauthorization Act and the Access to Life-Saving Trauma Care for All Americans Act. My good friend and fellow Texan Dr. Mike Burgess 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 the availability and 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 health care system. Thank you again to Dr. Burgess for your partnership on this issue and to Mr. Chairman for bringing these legislative proposals before the committee today.

I thank all of my colleagues from both sides of the aisle for putting forward these thoughtful and worthy proposals, and for their commitment to improving access and delivery of health care.

I look forward to continuing to work in a bipartisan manner on the many issues before our subcommittee, including on a solution to the expiration of the Health Centers Fund in September. Unless we take action, community health centers will experience an immediate 60-70 percent funding cut.

Health centers have a long history of bipartisan support, and letting the fund expire without a solution in place will severely limit patient access to the cost-effective primary and preventive care they provide to millions of Americans.

Thank you, and I yield the remainder of my time to the Congresswoman from California, Lois Capps.

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

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.

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

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. 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.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

In the 113th Congress, the Energy and Commerce Committee established an impressive Record of Success with 51 bipartisan bills signed into law, many of which are now helping improve public health. Families and 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 this new Congress. Today we will examine a half dozen bills that collectively will help our Nation's veterans, address the prescription drug abuse crisis, secure access to trauma systems, and improve the Controlled Substances Act.

First, we will hear testimony on a bill authored by Mr. Kinzinger. The Veteran Emergency Medical Technician Support Act, passed by the full House in February 2013, would help military medics and those States with a shortage of Emergency Medical Technicians.

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

We will hear testimony on two trauma bills led by Dr. Burgess and Ranking Member Green. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act was passed through the full House in June 2014 and would help support State and rural development of trauma systems. The second bill will reauthorize language from the Public Health Service Act to fund trauma care centers.

Finally, the subcommittee will hear about two bills related to the Controlled Substances Act. The Improving Regulatory Transparency for New Medical Therapies Act, led by Chairman Pitts and full committee Ranking Member Pallone, would amend the CSA to improve and streamline the Drug Enforcement Agency's process for scheduling new drugs approved by the Food and Drug Administration.

The Ensuring Patient Access and Effective Drug Enforcement Act, led by Vice Chairman Blackburn and Reps. Marino, Welch, and Chu would help prevent prescription drug abuse, establish clear and consistent enforcement standards, and ensure patients have access to medications by promoting collaboration among Government agencies, patients, and industry stakeholders.

I thank the witnesses for attending today's hearing, and I look forward to their testimony and recommendations as we begin to build upon our strong record of bipartisan success.

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

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 appears at the conclusion of the hearing.]

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 an opening statement.

OPENING STATEMENT OF HON. JOSEPH P. KENNEDY, III, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF MASSACHUSETTS

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 NASPER 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 dependance 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.

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 reau-

thorize 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.

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 NASPER 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.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Chairman Pitts, for holding this hearing on the six public health bills before us today. All of the bills aim to address important public health issues within our communities.

The Improving Regulatory Transparency for New Medical Therapies Act would speed up Drug Enforcement Administration (DEA) decisions on scheduling of new FDA-approved drugs containing controlled substances, so that they could get to patients more quickly. It also would speed up the DEA registration process allowing the manufacture and distribution of controlled substances for use only in clinical trials. The bill aims to ensure that there are not unnecessary delays of medicines getting to patients in need. I want to thank Chairman Pitts for working with me on this bill last Congress and committing to move forward early this Congress.

The Ensuring Patient Access and Effective Drug Enforcement Act would add two definitions to the Controlled Substances Act to better focus DEA's enforcement activities. It also would require DEA to provide registrants an opportunity to submit an action plan to correct any violations for which DEA is considering revoking or suspending their controlled substance registration. The goal of the 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. I thank Representatives Blackburn, Marino, Welch, and Chu for introducing this legislation.

The next bill, the Veterans Emergency Medical Technician Support Act, authorizes a demonstration grant program for states to streamline the certification and licensure requirements for returning veterans to become emergency medical technicians. Returning vets have important skills and experiences that make them highly qualified for jobs in health care and particularly in emergency medicine. This bill passed both the committee and the House last Congress, and I want to thank Congresswoman Capps for her work on this issue.

We are also considering two bills reauthorizing a number of trauma programs. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, which passed the House last year, is aimed at planning and implementing trauma care systems in the States and establishing pilot projects for innovative models of regionalized trauma care. The second bill, the Access to Life-Saving Trauma Care for All Americans Act, reauthorizes two additional trauma programs that expire this year that aim to increase the availability of trauma services, as well as an interagency program for basic and clinical research on trauma. 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. I would again like to thank Mr. Green and Mr. Burgess, who are both leaders on trauma care, for their work on these bills.

Finally, the subcommittee will review the National All Schedules Prescription Electronic Reporting Reauthorization Act, which I coauthored with my colleague from Kentucky, Mr. Whitfield, during the last Congress. This legislation helps States establish and maintain prescription drug monitoring programs in order to combat prescription drug abuse, an epidemic in the United States. It is critical that we continue support for this program through Federal funding.

Many of these bills passed our committee and the House last Congress with broad bipartisan support. I look forward to working with my colleagues to do the same this year.

Mr. PITTS. The Chair thanks the gentlemen.

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 CHLAPEK, PUBLIC SAFETY TRAINING COORDINATOR, MID–AMERICA REGIONAL COUNCIL, ON BEHALF OF THE NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS; JOHN L. EADIE, DIRECTOR, PRESCRIPTION DRUG MONITORING PROGRAM CENTER OF EXCELLENCE, BRANDEIS UNIVERSITY; BLAINE ENDERSON, M.D., CHAIRMAN, TRAUMA CENTER ASSOCIATION OF AMERICA; NATHAN B. FOUNTAIN, M.D., CHAIR, PROFESSIONAL ADVISORY BOARD, EPILEPSY FOUNDATION OF AMERICA; AND D. LINDEN BARBER, PARTNER AND DIRECTOR, DEA COMPLIANCE OPERATIONS, QUARLES & BRADY, LLP

STATEMENT OF BEN 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:]

Statement of LTC (Ret.) Ben Chlapek

Public Safety Training Coordinator, Mid-America Regional Council

Kansas City, MO and representing

The National Association of Emergency Medical Technicians (NAEMT)

on the topic of

Veteran Emergency Medical Training Transition to Civilian Service

before

Health Subcommittee,
Committee on House Energy and Commerce
U.S. House of Representatives

January 27, 2015

Introduction

Chairman Pitts, Vice Chairman Guthrie, Mr. Green and members of the Subcommittee, thank you for giving me this opportunity again to discuss the certification/licensure issue plaguing honorably discharged transitioning military medics to civilian emergency medical services. I am Ben Chlapek, Public Safety Training Coordinator for the Mid-America Regional Council in Kansas City, MO and here representing the National Association of Emergency Medical Technicians (NAEMT), of which I currently serve as a member of the Board of Directors and the Chair of the Military Relations Committee. Formed in 1975, the National Association of Emergency Medical Technicians (NAEMT) is the nation's only organization solely dedicated to representing the professional interests of all EMS practitioners, including paramedics, emergency medical technicians, emergency medical responders and other professionals working in prehospital emergency medicine. NAEMT's 40,000+ members work in all sectors of EMS, including government service agencies, fire departments, hospital-based ambulance services, private companies, industrial and special operations settings, and in the military.

I recently retired as the Deputy Chief of Central Jackson County Fire Protection District, Blue Springs, Missouri. As a former Lieutenant Colonel in the United States Army for 36 years of service, I served tours in Afghanistan, Kosovo, Central America, and multiple other countries. I also served as faculty at Louisiana State University and hold undergraduate degrees in Chemistry and Fire Science, a Master's Degree in Public Administration and a second Master's Degree in Homeland Defense and Security from the Naval Postgraduate School (pending acceptance of thesis). I serve on numerous national, state, and local committees including the Missouri Governor's Advisory Council for EMS.

Background

The smooth transition of our veterans into civilian life underscores the importance of these hearings and the responsibilities of the subcommittee in developing policies that honor the training of our military medics to seamlessly transition our veterans into the workforce to provide valuable medical personnel for our communities. Military veterans receive some of the best medical training and experience available when serving our country. Their sacrifices, commitment to duty, and ability to get the job done in austere environments make them exceptionally well suited for working as EMTs and paramedics in our communities upon their honorable separation from the armed services. Transitioning military medics are highly sought after by civilian EMS agencies throughout our nation. These agencies seek the medical, leadership, and even the soft skills these veterans provide.

Currently, experienced military medics are often required to entirely repeat their medical training again at the most basic level to receive certification to be hired for a civilian EMS job. Depending on the state, the returning veteran has to obtain or renew his or her EMS license and the requirements can vary significantly. Furthermore, the requirements that exist at certified EMS education facilities that allow candidates to test for the EMS licenses have vast differences.

A Navy Independent Duty Corpsman, a Navy SEAL medic, an Army Special Forces medic (18D), and an Air Force Special Operations Pararescue medic receive extensive medical training and are trained to operate in austere environments. They learn skills and perform procedures in

the field that are many times reserved for physicians and specialists in operating rooms or trauma rooms. External fixation of multiple fractures, shunts to restore circulation to a mangled limb, and insertion of chest tubes to expand a collapsed lung are just a few of the procedures they learn and perform in the most severe conditions. Depending on current leadership framework in the respective school houses, these Special Operations medics may or may not hold a paramedic license with a licensing entity. When they get out of the service and try to enter the EMS profession, they are required to go through a year-long paramedic class and several hundred clinical hours; upon completion they must test to get a license to work. In reality, all they may need is a two-day Advanced Cardiac Life Support class, a module on geriatric medicine, a refresher on obstetrics, and a chance to challenge the written and practical tests. In a matter of weeks or a month at the most, they should be able to work as paramedics for any service in the world. However, that is rarely the case.

Currently, it appears that Army medics and Air Force medics graduate from their military training eligible to test for EMT licenses or registry cards from the National Registry of Emergency Medical Technicians; Navy Corpsmen do not. By the time they leave the service, many do not have current licenses so they are not eligible to go to work at civilian EMS agencies. Making matters worse, many have licenses that have been expired long enough that they cannot even challenge a state test or take a refresher to challenge the test; they have to take a complete provider course to work as an Emergency Medical Technician. This requires a semester of classroom work, a weekend of clinical work, and waiting for a test date to take the licensing test. It can take half of a year to get an Emergency Medical Technician license waiting for test dates and results. Basic combat medics, Navy Corpsmen, and Air Force medics have all

of the training they need to challenge the test and should be allowed to do so. If they are rusty or need a review in a specific area, a weekend refresher is plenty to prepare them for the test.

Some states and training entities have made adjustments and are starting to streamline the education process for service members. Veterans in positions of authority like Greg Natsch, the former Director of the Missouri Bureau of EMS, met with veterans on a case by case basis. If the veterans can document the training experience they had in the military, at their mobilization stations, or on a forward operating base, he adjusted their requirements to allow them to streamline the licensing and testing process. Finding an EMS education facility to streamline this process can be a challenge. A bill with bipartisan support and sponsors was introduced in the Missouri House in a previous session to streamline EMS licensure for honorably discharged veterans. Tennessee, Alabama, Arkansas, Texas, Missouri, Michigan, Louisiana, and a growing number of states have training entities and educational institutions that take veterans and their training records through individualized processes to streamline the process for the veterans and get them into the workforce. This helps veterans get licensed and get to work as soon as possible while alleviating Paramedic shortages in some portions of the country. Almost all suburban fire departments require that applicants are Emergency Medical Technicians or Paramedics. Paramedics are not as plentiful and streamlining the process would help staff open Paramedic positions; the Kansas City Missouri Fire Department currently has multiple and recurring Paramedic openings and is struggling to find candidates with Paramedic licenses who want to work in their extremely busy environment. Streamlining the licensing process for veterans will help them be employed more quickly.

The National Registry of Emergency Medical Technicians and an increasing number of states have established policies and passed legislation to allow veterans a grace period and renewed certification upon returning. We appreciate the assistance and hard work by you that assists us in obtaining this much needed help for our veterans who are returning to civilian EMS jobs.

Gentlemen like Navy Captain (Dr.) Frank Butler, retired, Army Lieutenant Colonel (Dr.) Robert Mabry, Army Colonel (Dr.) Todd Fredricks, Army Colonel (Dr.) Patricia Hastings, and other Special Operations and Emergency Medicine physicians have taken EMS education and training to a new level in educating special operations medical personnel, Emergency Medical Technicians, Paramedics, Physician Assistants, and others allied health personnel. Their guidance and tutelage in the military and the civilian sectors have helped medics keep soldiers alive on the battlefield and civilians alive in our communities. They continue to work tirelessly to make sure the front line medics are the best in the world and work to keep them educated, licensed, and employed. Lessons from the battlefield and adjuncts such as QuikClot zeolite granules, Combat Gauze, and the Combat Action Tourniquet have helped us transition efficacy in trauma care into our communities to increase civilian levels of care and survivability. The military experience is too rich and too costly to throw away and deny in our civilian communities. Congressional assistance in streamlining the licensing process to get these experienced combat medics and corpsmen into the civilian EMS community will help our communities and the level of care provided to our citizens.

Conclusion

Due to the committee's focus and work to pass H.R. 235 in the 113th Congress, we have seen

some national, DoD and state recognition of this issue. The implementation of transition programs across the nation have been slow to emerge due to funding support, causing military medics to defer their pursuit of a career in emergency medical services based on convenient access to programs.

The subcommittee continues to have the potential to help veterans transition quickly to the civilian profession upon their completion of military duty, essentially reducing unemployment among veterans and instilling positive morale and hope for their futures. I wholeheartedly support any process and legislation that helps military medics transition into the civilian world and use their skills and expertise to make our communities safer and better. I firmly believe your continued attention to this issue is the right direction and an excellent investment to help our military veterans, our civilian emergency response agencies, patients and this great country.

Thank you for your time and attention. I sincerely appreciate the opportunity to come before you again to present a perspective from the emergency medical response community on this important subject. God bless.

I would welcome any feedback or questions.

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., NASPER.

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 Sates 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 1 year in the number of deaths in which 1 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 NASPER, with proposed changes, will assist States by adding important funds that complement other initiatives. States need NASPER 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, NASPER can help States sustain critical PDMP operations.

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

Mr. PITTS. The Chair thanks the gentlemen.

[The prepared statement of Mr. Eadie follows:]

Committee on Energy and Commerce
United States House of Representatives

Subcommittee on Health
January 27, 2015

Testimony by John L. Eadie

Thank you, Chairman Pitts, Ranking Member Green, and Representative Whitfield for providing this opportunity to testify regarding proposed legislation to help fund States' Prescription Drug Monitoring Programs (PDMPs) through the **National All Schedules Prescription Electronic Reporting Act, (**NASPER).

I am John L. Eadie. I have worked in public health for 45 years and, specifically on PDMPs for 30 years. I currently serve as Director of the Prescription 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 Trusts and support from BJA, we published a White Paper on PDMP Best Practices.[1]

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

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1. Clark, T., Eadie, J., Knue, P., Kreiner, P., Strickler, G. Prescription drug monitoring programs: an assessment of the evidence for best practices. PDMP Center of Excellence. 2012. http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

The Center of Excellence reviews PDMPs' performance and has found that they:[2]

- Improve clinical decision-making and patient care by prescribers and pharmacies.
- Identify and reduce "doctor shopping."
- Impact on controlled substance 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 and drug abstinence.
- Assisting 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 Schedule II, II or IV prescription to each patient and periodically thereafter, e.g. every three months. Kentucky, Tennessee, and New York, report:

- Rapid increases in prescribers registering for PDMP use.
- Increases in requests for PDMP data (over 300% TN, over 500% in KY and over 10,000% in NY)[3].
- Decreases in the prescribing of some commonly abused controlled substances.
- Decreases in multiple provider episodes (i.e. doctor shopping).

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[2] PDMP Center of Excellence at Brandeis University. Briefing on PDMP Effectiveness: Updated September 2014. http://www.pdmpexcellence.org/sites/all/pdfs/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf

[3] PDMP Center of Excellence at Brandeis University. COE Briefing: Mandating PDMP participation by medical providers: current status and experience in selected states. Revision 2, October 2014 http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf

Florida, in 2011, implemented its PDMP and other initiatives. The Florida Medical Examiner 2013 annual report shows an 8.3% decrease in one year in the number of deaths in which one or more controlled substance prescriptions was identified as the primary cause of death, while oxycodone deaths declined by 27.3%.

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 it.

A second example: Medicaid, Medicare, workers compensation, and other third party payers need to protect enrolled patients' health and safety, by helping avoid prescribers and pharmacists from issuing and dispensing prescriptions that patients will harm patients. But this can only be done by PDMPs providing secure data access to third party payers.[4]

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 NASPER, with proposed changes will assist states by adding important funds that compliment other initiatives. States need NASPER 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

[4] PDMP Center of Excellence at Brandeis University. PDMPs and Third Party Payers Meeting December 2012: Report of Proceedings. April 2014 http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_PDMP_3rd_pty_payer_mtg_rpt.pdf

and avoid prescribing or dispensing to doctor shoppers or persons counterfeiting or forging prescriptions. Importantly, NASPER can help states sustain critical PDMP operations.

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

SUMMARY OF TESTIMONY on January 27, 2015

By John L Eadie

States need federal financial assistance for their Prescription Drug Monitoring Programs (PDMPs) to operate effectively in interdicting the opioid overdose epidemic. The **National All Schedules Prescription Electronic Reporting Act, (**NASPER), can provide such assistance.

PDMPs provide information to improve clinical care by prescribers and pharmacies, reduce "doctor shopping," impact controlled substances prescribing, improve health outcomes, reduce medical costs and diversion of medications into illegal use and assist in substance abuse prevention and treatment.

States that mandate prescribers review PDMP data before all first prescriptions and periodically thereafter report rapid increases in prescribers requesting PDMP data from over 300% to over 10,000%. They also report decreased prescribing of abused controlled substances and in doctor shopping.

Florida reports significant declines in overdose deaths involving prescription opioids, particularly oxycodone, since implementing its PDMP.

PDMPs should upgrade their programs by proactive analyses of data and distribution of unsolicited reports to prescribers, pharmacists, healthcare professional licensing boards and law enforcement. To protect patients, PDMPs should also provide data to all third party healthcare payers.

Reauthorization of NASPER will assist states by adding funds that compliment other initiatives, particularly to develop interoperability with electronic health records and health information exchanges.

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

STATEMENT OF BLAINE ENDERSON

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 innovate 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 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:]

TRAUMA CENTER
Association of America
ADVOCACY • FINANCE • OPERATIONS

TESTIMONY BEFORE THE

HOUSE COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

"Examining Public Health Legislation to Help Patients and Local Communities"

Blaine Enderson, MD, FACS, MBA

Chairman, Trauma Center Association of America (TCAA)

January 27, 2015

2322 Rayburn House Office Building

Washington, DC

For further information, contact:

Jennifer Ward, RN, BSN

TCAA President

(575) 525-9511

Statement

Chairman Upton, Ranking Member Pallone, Chairman Pitts, Ranking Member Green, and members of the Committee, thank you for holding this hearing on examining public health legislation to help patients and local communities, and for inviting the Trauma Center Association of America (TCAA) to speak. TCAA is a non-profit, 501(c)(6) association representing trauma centers and systems across the country and is committed to ensuring access to life-saving trauma services.

TCAA, along with our advocacy partners, the American Trauma Society (ATS); the America Association for the Surgery of Trauma (AAST); the American College of Surgeons (ACS); the American College of Emergency Physicians (ACEP); American Burn Association (ABA); the American Association of Neurological Surgeons (AANS); College of Neurological Surgeons (CNS); Emergency Nurses Association (ENA); Society of Trauma Nurses (STN); American Academy of Orthopaedic Surgeons (AAOS) and the Eastern Association for the Surgery of Trauma (EAST) 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 in recognizing the importance of these systems of care in saving lives.

Trauma Care Saves Lives

Trauma is a major public health issue. In the United States, approximately 35 million people are treated every year for traumatic injuries[i] -- constituting one hospitalization every 15 minutes. Traumatic injury is the leading cause of death under age 44[ii]. At an annual cost of $67.3 billion, trauma is the third most expensive medical condition (behind only heart disease ($90.9billion) and cancer ($71.4billion).[iii]

The "value" proposition for trauma care is well documented. The care provided by trauma centers, including specialist physicians, nurses and their entire trauma teams, has a dramatic and cost-effective impact on patients' subsequent quality of life. In fact, trauma care is more cost effective than many other interventions, including dialysis for kidney failure.[iv] Victims of traumatic injury treated at a Level I trauma center are 25% more likely to survive than those treated at a general hospital. Unfortunately, 45 million Americans lack access to major trauma centers within the "golden hour" post injury when chances of survival are greatest. For those severely injured in motor vehicle crashes[v], initial triage to a non-trauma center increases the risk of death within the first 48 hours by at least 30%.[vi] Compared against the two higher cost medical conditions, significantly more adult patients are treated for trauma (26.4 million) than are treated for heart disease (22.5 million) or cancer (15.3 million) at a substantially lower cost per patient[vii].

The Trauma Systems and Regionalization of Emergency Care Reauthorization Act

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 Grants support state and rural development of trauma systems. The Regionalization of Emergency Care Pilots Program funds pilot projects to design, implement, and evaluate innovative models of regionalized emergency care. *The Trauma Systems and Regionalization of Emergency Care Reauthorization Act* would also direct states to update their model trauma care plan with the input of updated stakeholders one year after enactment.

Unfortunately, in 2015, we still lack effective regionalized care systems for infectious disease like Ebola or even for cardiac or stroke patients. The vast majority of hospitals addressing patients with these significant events also serve as our nation's regional trauma centers. These hospitals must have the tools and capabilities to care for all their patients with emergent, time sensitive and life-threatening conditions -- whether Ebola, trauma or stroke. The funding to

support these hospitals must follow and support their willingness to provide care to the sickest Americans in their greatest hour of need.

On June 25, 2014, the House passed *The Trauma Systems Regionalization of Emergency Care Reauthorization Act* (H.R. 4080). However, the Senate was not able to pass H.R. 4080 before the end of the 113th Congress. Thus, it is up to the 114th Congress to take up these important programs. On behalf of the trauma and emergency care community, thank you again for your leadership and we urge your continued efforts to reauthorize these vital programs.

The Access to Life-Saving Trauma Care for All Americans Act

In addition to the Trauma Care Systems Planning Grants and Regionalization of Emergency Care Pilots there are two other programs contained in the Public Health Service Act (PHSA) set to expire this year and 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 per year in an effort to prevent more trauma center closures by supporting their core missions, curtailing losses from uncompensated care and providing emergency awards to centers at risk of closing. Also, the Trauma Service Availability Grants authorized at $100 million per year are channeled through the States to address shortfalls in trauma services 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. Of course there is no specific Institute that encompasses trauma and the very nature of trauma care crosses several of the Institutes. In 2010, NIH convened a Roundtable on Emergency Trauma Research which identified key research priorities and barriers. Priorities include focusing on the timing, sequence, and the time sensitivity of traumatic injury and treatment effects, assessing the effect of development and aging on postinjury response, and the need to understand why there are regional differences in outcomes after injury. Barriers to

research include a limited number of trained investigators and experienced mentors, limited research infrastructure and support and regulatory hurdles. The Roundtable concluded that the science of emergency trauma care would be advanced by facilitating the following:

> " (1) development of an acute injury template for clinical research; (2) developing emergency trauma clinical research networks; (3) integrating emergency trauma research into Clinical and Translational Science Awards; (4) developing emergency care-specific initiatives within the existing structure of NIH institutes and centers; (5) involving acute trauma and emergency specialists in grant review and research advisory processes; (6) supporting learn-phase or small, clinical trials; (7) performing research to address ethical and regulatory issues; and (8) training emergency care investigators with research training programs."

Reauthorization of the Interagency Program for Trauma Research is imperative to achieve these goals.

PHSA Trauma Programs Designed to Improve Patient Outcomes, and Save Lives and Costs:

All of the PHSA Trauma and Emergency Programs are designed to ensure the availability and effective use of trauma care to save lives, costs and improve patient outcomes. Trauma can happen to anyone, any time and anywhere. As demonstrated by the numerous lives saved during the Boston Marathon bombing and other recent mass casualty events by getting the severely injured to a Level I or II trauma center during the "golden hour." From 1990-2005, 30% of trauma centers closed in large part due to the high level of uncompensated care they provide. Access to timely trauma care has improved in some parts of the nation, but remains unavailable to millions of Americans.

Trauma will continue to occur, despite our best prevention efforts. Unfortunately, access to trauma care is threatened by losses associated with the high cost of treating severely injured patients, including those unable to pay for their care, as well as a growing shortage of trauma related physicians (e.g. trauma, neurological and orthopaedic surgeons) who rely upon trauma centers for the costs of trauma call coverage.

The PHSA trauma programs must be reauthorized because federal investments in trauma systems and centers are essential to improve patient outcomes and provide downstream cost savings. The availability of specialized trauma centers and their effective use through coordinated trauma systems has a close correlation with improvements in mortality and other quality measures. As noted earlier, seriously injured victims treated in Level I trauma centers have a 25% lower risk of death.

The immediate availability of emergency medical personnel and timely access to major trauma and burn centers is essential to saving lives. But lack of trauma care access -- especially in rural areas -- is more often the reality in the United States. Physical distance can be a significant barrier to transporting emergent patients quickly and effectively after first responders have arrived. For example, an accident scene in Mexican Hat, the closest medical facility with a trauma unit was 117 miles away. Five of the victims were treated at this level IV trauma center. The closest level I trauma unit was 190 miles away in Flagstaff, Arizona, and two individuals were treated there and 10 individuals were treated as far as 230 miles away at a level II trauma unit in Grand Junction, Colorado, and three were treated 360 miles away in Salt Lake City, Utah, at a level I trauma unit. Not all of the patients survived. The outcome from a survivable injury should not be a matter of chance.

The public's expectation that trauma care will always be available to them wherever they reside or travel, just as it was on that tragic day in Mexican Hat, has yet to be met. The challenges facing trauma centers, trauma systems and physicians who treat our must vulnerable patients are profound.

Access to Trauma Care is Essential for All Americans

These programs are critical to the efficient delivery of services through trauma centers and the highly specialized trauma teams that staff them, as well as to the development of regionalized

systems of trauma and emergency care that ensure timely access for injured patients to appropriate facilities. A modest investment can yield substantial returns in terms of cost efficiencies and saved lives.

The combination of market pressures and reduced reimbursement, as well as a growing shortage of on-call specialists, could result in additional closures, particularly in rural areas where they are needed the most. Trauma centers typically do not reconstitute once closed, and it takes years to re-establish or develop a new one. It is imperative that federal policy makers address this looming crisis before it deteriorates further.

The PHSA trauma and emergency care programs address the need to improve trauma care by providing seed money to the States to develop and enhance their trauma systems, enhance the availability of services in all geographic locations and to provide support for the existing trauma center infrastructure. Reauthorization of these programs will help to prevent trauma center closures and will drive the development of more efficient regionalized systems of emergency care and transport and enhance trauma research and our ability to most effectively save lives. A modest investment by Congress can yield immense returns in efficiencies, economies of scale and improvement in public health and safety.

Conclusion

On behalf of our trauma and emergency care community, we call upon the Congress to reauthorize these vital programs. Specifically, we urge Congress to reauthorize the Trauma Care Systems Planning Grants; Regionalization of Emergency Care Pilots; Trauma Care Center; Trauma Research and Trauma Service Availability Grants this year. Reauthorization will ensure that support for these vital programs will be able to continue.

Again, thank you for holding this hearing and prioritizing trauma and emergency care as a priority at the beginning of the 114th Congress. Your acknowledgement of the need to ensure that these systems are available to all Americans is greatly appreciated, and we thank you again for your leadership and commitment to these crucial programs. TCAA and our advocacy

partners welcome the progress that has already been made and look forward to working with you. Please contact, Jennifer Ward, RN, BSN, MBA President of the Trauma Center Association of America at (575) 525-9511, if you have any questions or need further information.

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[i] National Trauma Institute. www.nationaltraumainstitute.com. San Antonio, TX.
[ii] Injury Prevention & Control: Trauma Care. www.cdc.gov/traumacare. Centers for Disease Control and Prevention, Atlanta, GA.
[iii] Soni, A. Top 10 Most Costly Conditions among Men and Women, 2008: Estimates for the U.S. Civilian Noninstitutionalized Adult Population, Age 18 and Older. Statistical Brief #331. July 2011. Agency for Healthcare Research and Quality, Rockville, MD. http://meps.ahrq.gov/mepsweb/data_files/publications/st331stat331.shtml.
[iv] MacKenzie EJ, et al. the Value of Trauma Center Care. *J Trauma* 2010; 69: 1-10.
[v] Haas B, Stukel T, Gomez D, et al. The mortality benefit of direct trauma transport in a regional trauma system: A population based analysis. *Trauma Acute Care Surg* Volume 72, Number 6, 2011; MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A national evaluation of the effect of trauma center care on mortality. N Engl J Med. 2006; 354; 366-378
[vi] Haas B, Stukel T, Gomez D, et al. The mortality benefit of direct trauma transport in a regional trauma system: A population based analysis. *Trauma Acute Care Surg* Volume 72, Number 6, 2011.
[vii] Ibid. Mean expenditures per person on most costly conditions among men and women, adults age 18 and older, 2008. For trauma related disorders: $2,475 for women and $2635 for men; for heart disease $3,723 for women and $4,363 for men; and for cancer $4,484 for women and $4,873 for men.

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

STATEMENT OF NATHAN B. FOUNTAIN

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 life-saving 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:]

Nathan B. Fountain, M.D.

Chair, Professional Advisory Board

Epilepsy Foundation of America

Testimony – Committee on Energy and Commerce

Subcommittee on Health

Tuesday, January 27, 2015

Thank you, Chairman Pitts and Ranking Member Green for allowing me to testify on behalf of the more than 2.8 million Americans living with epilepsy and their families. Specifically, as Chair of the Epilepsy Foundation's Professional Advisory Board, I am here to support a legislative initiative that I know is important to this committee and many living with chronic conditions – the reintroduction of last year's *Improving Regulatory Transparency for New Medical Therapies Act.* I have previously spoken to this committee on the importance of this legislation. I was pleased to see that this committee appreciated how vital these changes are to those who need new therapies and look forward to that same support again. The Epilepsy Foundation is extremely grateful for the Committee's leadership for what we believe is not only important, but a reasonable legislative solution that we hope will garner many supporters as it moves towards passage.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 2.8 million Americans with epilepsy. The Foundation fosters the well-being of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. I am pleased to serve as chair of our medical advisors and as a

practicing epileptologist. I would like to share information about epilepsy with this committee, so that you might better understand why our organization is steadfast in our support of this initiative and why we think this is a reasonable and workable solution to current delays for our patients.

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions; it is also called a *seizure disorder*. A person is considered to have epilepsy if they have two or more seizures.[1] Epilepsy is a family of more than 40 syndromes[2] including Dravet syndrome, hypothalmamic hamartomas (HH), and Lennox-Gastaut syndrome (LGS). Dravet syndrome, also known as Severe Myoclonic Epilepsy of Infancy, is a rare and catastrophic form of intractable epilepsy that begins in infancy and includes developmental declines and a higher incidence of sudden unexplained death in epilepsy (SUDEP).[3] HH are benign tumors or lesions in or around the hypothalamus. They can be difficult to diagnose and treat and can lead to daily seizures, developmental delays, and/or precocious puberty.[4] LGS is a debilitating form of childhood-onset epilepsy that is characterized by multiple seizure types, cognitive impairment, and an abnormal EEG.[5]

Epilepsy affects more than 2.8 million Americans[6] and 65 million people worldwide.[7] This condition will develop in approximately one out of 26 people at some point in their lives [8]

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[1] Kobau R, Price P. Knowledge of epilepsy and familiarity with this disorder in the U.S. population: Results from the 2002 HealthStyles survey. *Epilepsia*. 2003;44(11):1449–1454.
[2] National Institute of Neurological Disorders and Stroke. Web site, http://www.ninds.nih.gov/
[3] Dravet Syndrome Foundation. Web site, www.dravetfoudnation.org
[4] Hope for Hypothalamic Hamartomas. Web site, www.hopeforhh.org
[5] LGS Foundation. Web sitewww.lgsfoundation.org
[6] Kobau, R., Yuo, Y., Zack, M., Helmers, S., & Thurman, D. Centers for Disease Control and Prevention, MMWR. (2012). *Morbidity and mortality weekly report* (61). Retrieved from U.S. Government Printing Office website: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6145a2.htm?s_cid=mm6145a2_e

making it the fourth most common neurological disorder in the United States after Alzheimer's disease, stroke, and migraines.[9] This year 150,000 people in the U.S. will be diagnosed with epilepsy[10], with the very young and the very old being the most affected. Currently, 460,000 children under the age of eighteen have epilepsy, and more than 90,000 of them have severe seizures that cannot be adequately treated.[11] Meanwhile, as the baby boomer generation approaches retirement age the number of cases in the elderly population is beginning to soar, with more than 570,000 adults age 65 and above living with epilepsy in the United States.[12] Epilepsy imposes an annual economic burden of $19.2 billion[13] on this nation in associated health care costs and losses in employment, wages, and productivity. Along with the financial costs, epilepsy and its treatment may impact someone's quality of life with side effects such as pain, depression, anxiety, reduced vitality, and insufficient sleep or rest.[14] Depression is significantly linked to epilepsy with more than a third of all people with epilepsy affected by a mood disorder, and people with a history of depression are 3 to 7 times more likely to develop epilepsy than the average person.[15] These side effects are compounded when it is considered that many people with epilepsy live with significant co-morbidities. Research has shown that 25.4 percent of people with autism have epilepsy, as well as 13 percent of those with cerebral palsy, 13.6 percent of those with Down syndrome, and 25.5 percent of those with intellectual

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[7] Ngugi, A., Bottomley, C., Kleinschmidt, I., Sander, J., & Newton, C. (2010). Estimation of the burden of active and life-time epilepsy: A meta-analytic approach. *Epilepsia*, *51*(5), 883-890. doi: 10.1111/j.1528-1167.2009.02481.x

[8] M.J. England et al. / Epilepsy & Behavior 25 (2012) 266–276. Web site, http://iom.edu/~/media/Files/Report%20Files/2012/Epilepsy/epilepsyEBarticleFinal.pdf

[9] Hauser A. Epidemiology of seizures and epilepsy in the elderly. In: Rowan A, Ramsay R, eds. Seizures and epilepsy in the elderly. Boston:Butterworth-Heinemann, 1997:7–18.

[10] " 3 Epidemiology and Prevention ." *Epilepsy Across the Spectrum: Promoting Health and Understanding* . Washington, DC: The National Academies Press, 2012 . Page 111.

[11] Centers for Disease Control and Prevention. *Epilepsy Fast Facts*. Last updated January 16, 2013. Website http://www.cdc.gov/epilepsy/basics/fast_facts.htm

[12] Annual Report 2003: Global Campaign Against Epilepsy, p. 2. Published by World Health Organization, International Bureau for Epilepsy and International League Against Epilepsy.

[13] Begley, op.cit. Reported cost of $12.5 billion for prevalent cases in 1995 is converted here to 2014 dollar value using Bureau of Labor Statistics automated online constant dollars conversion calculator.

[14] From Centers for Disease Control and Prevention. Health-related quality of life among persons with epilepsy. *JAMA*, 2001;285(7):878.

[15] Kanner AM. Depression and epilepsy: A new perspective on two closely related disorders. *Epilepsy Currents*. 2006;6(5):141-46.

disabilities live with epilepsy. The percentage increases when you look at those who have both cerebral palsy and an intellectual disability, with 40 percent living with epilepsy.[16]

Those living with epilepsy also face serious barriers to proper care and first aid. A lack of knowledge about proper seizure first aid exposes affected individuals to injury from unnecessary restraint and from objects needlessly forced into their mouths.[17] Besides poor first aid, those living with epilepsy are also forced to live with uncontrollable epilepsy for an exceptionally long period of time when an effective treatment may be available. On average, it is 14 years between the onset of epilepsy and surgical intervention for seizures that are uncontrollable through medication. American physicians may be unaware of the safety and efficacy of epilepsy surgery, making it among the most underused of proven, effective therapeutic interventions in the field of medicine.[18]

Access to new therapies is particularly important for the 20 to 30 percent of people living with epilepsy who experience intractable or uncontrolled seizures or have significant adverse effects to medication. Patients who have drug resistant epilepsy, defined as a failure to achieve seizure freedom after adequate trials of two tolerated, appropriately chosen and used anti-epilepsy drug schedules (whether as monotherapies or in combination), can develop brain damage or experience other life-threatening effects. As Director of the epilepsy program at the University of Virginia School of Medicine, I am very familiar with the impact of epilepsy for those who

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[16] McDermott S, Moran R. Prevalence of epilepsy in adults with mental retardation and related disabilities in primary care. *American Journal of Mental Retardation*. 2005;10(1):48-56

[17] Repeated surveys by the Epilepsy Foundation, the previously cited CDC report, and numerous other surveys have documented the low level of public knowledge about seizures and epilepsy, including persistent misconceptions about seizure first aid.

[18] Engel,JR Jr. A greater role for surgical treatment of epilepsy: Why and when? *Epilepsy Currents*. 2003;3(2):37–40.

have found seizure control, and those patients who are still searching for the hope that a new treatment may offer.

Sudden unexpected death in epilepsy, known as SUDEP, encompasses non-traumatic, non-drowning related deaths in people with epilepsy that may or may not be associated with a recent seizure, but are not due to prolonged seizures.[19] In definite SUDEP, an autopsy reveals no evidence of an anatomical or toxicological cause of death.[20] As noted in the 2012 Institute of Medicine report, *Epilepsy Across the Spectrum*[21], not only do people with epilepsy succumb to sudden death at a rate over 20 times higher than the general population[22], but SUDEP is also the leading cause of epilepsy-related death.[23] It accounts for the deaths of 40% of people with severe epilepsy and 4% of those with all types of epilepsy.[24] Among people with both cognitive impairments and refractory epilepsy, the cumulative risk of SUDEP can exceed 10%.[25] While much more research is needed into the causes and prevention of SUDEP, the strongest evidence suggests that the occurrence of seizures increases the risk.[26]

The Epilepsy Foundation's SUDEP Institute was established to increase awareness, prevent SUDEP through research, and support people confronting the fear and loss of a loved one. The

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[19] Nashef, L., E. L. So, P. Ryvlin, and T. Tomson. 2012. Unifying the definitions of sudden unexpected death in epilepsy. *Epilepsia* 53(2):227-233.
[20] Ibid.
[21] National Academies, Institute of Medicine, *Highlights from Epilepsy Across the Spectrum: Promoting Health and Understanding* ***A Focus on Mortality and Sudden Unexpected Death in Epilepsy, 2012. Accessed at:*** ***http://www.iom.edu/~/media/Files/Report%20Files/2012/Epilepsy/IOM%20Report%20Highlights%20for%20PAME%20Conference.pdf***
[22] Ficker DE, So EL, Shen WK, et al. "Population-based study of the incidence of sudden unexplained death in epilepsy." Neurology 1998;51:1270-1274.
[23] Tomson, T., L. Nashef, and P. Ryvlin. 2008. Sudden unexpected death in epilepsy: Current knowledge and future directions. *Lancet Neurology* 7(11):1021-1031.
[24] Tellez-Zenteno JF, Ronquillo LH, Weibe S. "Sudden unexpected death in epilepsy: Evidence-based analysis of incidence and risk factors." Epilepsy Research 2005;65(1-2):101-115.
[25] Sillanpää, M., and S. Shinnar. 2010. Long-term mortality in childhood-onset epilepsy. *New England Journal of Medicine* 363(26):2522-2529. Sillanpää, M., S. Lastunen, H. Helenius,
[26] Hesdorffer, D. C., T. Tomson, E. Benn, J. W. Sander, L. Nilsson, Y. Langan, T. S. Walczak, E. Beghi, M. J. Brodie, and W. A. Hauser. 2012. Do antiepileptic drugs or generalized tonic-clonic seizure frequency increase SUDEP risk? A combined analysis. *Epilepsia* 53(2):249-252.

SUDEP Institute carries out SUDEP education and awareness programs for people touched by epilepsy and medical professionals, drives and supports research into the causes of and ways to prevent SUDEP, offers a support network providing counseling, community, and resources for individuals and families affected by SUDEP, and works together with many epilepsy organizations to find the answers to SUDEP and help families with epilepsy. The SUDEP Institute works to provide support to families who have lost a loved one due to epilepsy. They also provide information to medical professionals who work with individuals with epilepsy as well as coroners and medical examiners so they can correctly identify cases of SUDEP. Since the risk for SUDEP is higher in people with recurring seizures, our mission includes improving pathways to new treatments that can bring seizure control to more patients. Delays in access to these potential therapies are clearly against the patients' interest for those with treatment needs and ultimately result in loss of life.

As you can see, a delay in treatment that may control an individual's seizures is not just a mere convenience or a better side effect profile. Seizures inflict potential damage to the brain and this can be especially concerning for children in developmental stages of life. Seizures can increase risk of injury, and ultimately, as shared, can lead to death for some individuals. As I hope you can understand, the concerns from our community about access to new or better treatments is meaningful and important.

When a new treatment receives approval from the Food and Drug Administration the epilepsy community is filled with hope. This hope can be short lived when consumers learn that the product will not reach them or their loved one immediately due to the scheduling process at the

Drug Enforcement Administration (DEA). It is further troubling as a patient advocacy organization that we cannot offer a timeline or explanation of why there is no timeline; nor can we offer a clear explanation of why this delay occurs since DEA review has never changed the drug schedule recommendation. Patients, parents, and families wait and we have no answer other than a bureaucratic process.

The process to schedule a new molecular entity lacks transparency and timelines, and involves many parties including the FDA, the National Institute on Drug Abuse (NIDA), the Assistant Secretary of Health (ASH) in the Department of Health and Human Services (HHS), as well as DEA. Without apparent cause or justification, the time period between initial drug approval by FDA and final scheduling by DEA has been increasing over the years. Between 1997-1999 and 2009-2013, **the average time between FDA approval and DEA's final scheduling increased from an average of 49.3 days to an average of 237.6 days, an almost five-fold increase.**

While the FDA human drug review process is largely transparent, with predictable timelines, the DEA has no set timeline or transparency requirements to make scheduling determinations. Unfortunately, as DEA's unpredictable and often lengthy review occurs, patients are denied access to important medicines that can improve, and in some cases save, their lives.

The Epilepsy Foundation drives education, awareness, support, and new therapies for people and families living with epilepsy. Through the Epilepsy Therapy Project, one of the Foundation's initiatives, we identify and support important new science, translational research programs, and the most promising new therapies, as well as the Epilepsy Pipeline Conference, a leading global forum organized in partnership with the Epilepsy Study Consortium that showcases the most exciting new drugs, devices, and therapies. The Epilepsy Foundation hosts www.epilepsy.com,

the leading portal for people, caregivers, and professionals dealing with epilepsy; and works closely with 48 Epilepsy Foundations affiliates around the country dedicated to providing free programs and services to people living with epilepsy and their loved ones.

Innovation is critical for the Epilepsy Foundation both for patients continuing to live with uncontrolled seizures and those who have more seizure freedom but would like to have fewer side effects from medications. Our focus on innovation, research, and new treatments, devices, and technologies for people with epilepsy is another reason why the DEA delay concerns the Epilepsy Foundation. Due to the unpredictable delay caused by the lack of a timeline for the DEA, companies cannot accurately predict the amount of time they will have left on their patent once the drug goes to market, or the amount of time for which they will have data exclusivity. They cannot accurately predict or plan for their product reaching consumers and physicians. This is a disincentive to innovation in an already challenging area of neurological development.

This bill is a simple solution to the problem and would ensure that drugs will not sit around waiting to be scheduled and patients won't be forced to wait on potentially lifesaving drugs. The reintroduction of this bill would allow more innovative treatments to reach the market and give a clear timeline for drug availability from FDA through DEA.

The Epilepsy Foundation sees no public health reason for these delays; especially after full safety and efficacy reviews and thorough abuse potential analysis by the FDA. We urge all Members to consider full support of the reintroduction of this bill. New products that would benefit from this change would continue to have DEA oversight. We would further argue that epilepsy treatments are not the cause for prescription drug abuse programs, or the public health concern

overall. 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. Now recognizes Mr. Barber, 5 minutes for an 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:]

Statement of
D. Linden Barber, Partner
Director, DEA Compliance and Litigation Practice
Quarles & Brady, LLP

For the U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

Examining Public Health Legislation to Help
Patients and Local Communities

January 27, 2015

Good morning Chairman Pitts, Ranking Member Green, and Members of the Energy and Commerce Subcommittee on Health. My name is Linden Barber, Partner in the law firm of Quarles & Brady and the former Associate Chief Counsel for Diversion Litigation at the Drug Enforcement Administration. Thank you for the opportunity to appear before the Subcommittee to discuss the important issue of preventing the diversion of pharmaceutical controlled substances into illicit channels while ensuring access to these helpful medications for patients with legitimate medical needs.

Little of consequence has changed since April of 2014 when this subcommittee considered The Ensuring Patient Access and Effective Drug Enforcement Act of 2014 introduced by Representatives Blackburn and Marino. The unanimous vote by House of Representatives in favor of the bill is an indicator of the common sense approach embodied in this bill. The proposed legislation will protect access of patients who have legitimate medical needs to pharmaceutical controlled substances which help patients who suffer from the pain of cancer, debilitating diseases and traumatic injuries, and those who suffer from a variety of physical and mental health diseases and disorders. But this bill does more than protect access to controlled substances for patients in need. It protects DEA's important

authority to suspend the registration of a DEA registrant whose conduct poses an imminent danger to public health or safety. Pharmaceutical drug abuse remains a serious national problem that must be addressed. Providing clarity on the legal standard for issuing an immediate suspension remains an important step in addressing this national problem. In the absence of legislation, the executive and judicial branches are likely to continue their decades-long, case-by-case determination on whether a suspension of a registration is appropriate. As the cases discussed in my previous testimony before this Committee, the executive and judicial branches do not always agree on this issue.

While little has changed in the last 10 months, we know more today about the unintended consequences of certain enforcement actions than we did then. For example, we know that some patients with legitimate medical needs find it difficult to locate a pharmacy willing to fill their prescriptions. Although anecdotal at this point, the evidence is mounting that fear of enforcement activity is creating a lack of access to controlled substance medications. Dr. Steven Passik recounts the plight of a breast cancer survivor who suffered chronic pain from a problem with her hip and had an anxiety disorder. Although she used low doses of opiates and benzodiazepines responsibly, her physician refused to continue prescribing

these drugs for her out of fear that he would be violating the law.[1] Dr. Passik noted that this patient suffered not only from the pain of her current malady, but from the fear that should her cancer return, she would have difficulty obtaining appropriate drug therapy to control her pain. Meanwhile, nearly three in four community pharmacists report disruption in their supply of controlled substances causing many of them to turn away patients. Some pharmacists suggested that the lack of supply was a result of "stepped-up DEA pressure [on wholesalers], [who] have set monthly limits on their orders and in some cases stopped shipments altogether."[2]

DEA officials have correctly asserted that the Agency does not set establish limits on the volume of controlled substances a distributor may supply to a pharmacy. However, DEA has required several distributors to establish monthly limits or thresholds on the controlled substances they will distribute. Since DEA does not provide guidance on how to establish those limits, it is reasonable for a distributor to take a conservative approach in establishing these limits since the consequence of distributing what DEA considers too high a volume of controlled substances can be an immediate suspension of the distributor's registration. Even those distributors who are

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[1] "*Opioid Refugees: Patients Adrift in Search of Pain Relief*," by Jody A Charnow, Sep. 4, 2013 at http://www.empr.com/opioid-refugees-patients-adrift-in-search-of-pain-relief/article/310244/.

[2] "Pharmacists Turn Away Legitimate Pain Patients as Wholesalers Limit Shipments of Controlled Substances," by Bruce Buckley, March 1, 2014 at http://www.pharmacist.com/pharmacists-turn-away-legitimate-pain-patients-wholesalers-limit-shipments-controlled-substances-0.

not required by agreements with DEA to establish limits must do so as a practical matter. DEA's regulation requires distributors to detect and report suspicious orders, which include orders of unusual size. DEA has communicated to distributors in letters and conference presentations that they are prohibited from shipping an order that the distributor deems suspicious. Thus, while DEA correctly asserts that the Agency does not establish limits that distributors must impose on customers, DEA has imposed a *de facto* requirement that distributors establish volume limits. I do not advocate that distributors be relieved of their obligation to monitor the orders of their customers. Indeed, it is clear that a highly-regulated system of distribution is essential in decreasing the diversion and abuse of pharmaceutical controlled substances. However, when members of the supply chain limit supply out of fear of being second guessed by DEA or simply to limit the risk of regulatory action, patients suffer. When pharmacists refuse to fill a prescription for fear of being second-guessed by DEA or because they lack supply, patients suffer. In some cases, the legitimate businesses of pharmacists suffer because of the lack of supply. None of these are the intended consequences of the law or DEA's enforcement actions. However, these are the results of a lack of clarity in the law that informs both registrants and DEA on the standards that the

Agency will use when taking the severe step of issuing an immediate suspension.

Perhaps the most significant of the unintended consequences related to the manner in which controlled substances laws are enforced is the rise in the use of and overdose deaths attributable to heroin. The National Institutes of Health reported that some individuals who previously used prescription opiates have turned to heroin because it is cheaper and easier to obtain.[3] I do not advocate that prescribers and pharmacists knowingly permit the misuse of prescription opiates in order to reduce the likelihood that individuals addicted to these medications will turn to heroin. However, it is essential that legislators, policy makers, and the executive branch make informed decisions about how to best address the link between opiate use and heroin use. The lack of availability of prescription opiates causes a certain segment of the population that uses opiates to turn to heroin, which comes from drug dealers, not physicians and pharmacists who are well-positioned to intervene and assist a patient with issues of addiction to or the misuse of prescription opiates. This issue is not directly addressed by the bill. However, it is likely that among the millions of individuals who use opiates for legitimate medical purposes that

[3] "How is Heroin Related to Prescription Drug Abuse?," last update November 2014, http://www.drugabuse.gov/publications/research-reports/heroin/how-heroin-linked-to-prescription-drug-abuse.

some of them are left without access to medication because prescribers, pharmacists, wholesalers and manufacturers have made decisions to limit supply based on the very real risk that DEA will take the severe step of suspending their registrations. It is also a likely but unintended consequence that some individuals who cannot obtain controlled substances for legitimate medical needs will turn to non-pharmaceutical controlled substances like heroin.[4]

The Ensuring Patient Access and Effective Drug Enforcement Act provides a important clarity that will encourage meaningful efforts by members of industry and DEA to take actions that will actually reduce prescription drug abuse and ensure an adequate and uninterrupted supply of medication for those patients with legitimate medial needs. For the convenience of the Committee, I include below portions of my testimony from the hearing on this bill held on April 7, 2014, with updated information where appropriate.

* * * * *

It is vitally important that steps taken to ensure patient access to controlled medications do not undermine the ability of the DEA to protect the public health from the devastating ills caused by the abuse and misuse

[4] It is well-documented that some individuals who use pharmaceutical opiates for ***non-medical*** purposes turn to heroin when price or supply issues make pharmaceutical opiates less accessible.

of controlled substances. The Ensuring Patient Access and Effective Drug Enforcement Act is an Act that addresses both issues by providing clarity in the law and by encouraging collaboration between regulators, law enforcement, health care providers, and the pharmaceutical supply chain.

By providing definitions for two key terms in the Controlled Substances Act, Congress will bring clarity to the regulatory environment. I will focus my comments on defining the term "imminent danger." By defining "imminent danger," Congress can provide clarity that is beneficial to DEA and to the registrants the Agency regulates. How does defining "imminent danger" benefit DEA? The Controlled Substances Act permits DEA to immediately suspend the registration of a registrant whose conduct poses an imminent danger to public health or safety. Unlike other federal statutes, such as the Mine Safety Act, the Controlled Substances Act does not define imminent danger. In the absence of clarity from Congress, the Agency will determine what constitutes an imminent danger on a case-by-case basis. And when a registrant challenges DEA's use of its immediate suspension power, it is ultimately courts that will determine what constitutes an imminent danger. History is instructive, and there is a long history of judicial challenges to the Agency's use of immediate suspensions. Forty years ago, a registrant successfully challenged an immediate suspension

because the conduct that DEA alleged created the danger was not imminent, but was more than seven months old.

More recently, a legal challenge to the Agency's immediate suspension power thwarted the Agency's ability to address illicit Internet pharmacy schemes. In 2005, three pharmacies in Colorado successfully challenged the immediate suspension orders issued by DEA. In early 2006, the U.S. District Court for the District of Columbia ruled that the manner in which DEA processed immediate suspensions deprived the registrants of Due Process. Although the ruling in that case was based on the extraordinary length of time that the registrants had to wait for a hearing, the pharmacy registrants also claimed that the conduct that DEA alleged created a danger had ceased more than a month before DEA issued the suspensions. Having dissolved the suspensions on Due Process grounds, the court did not need to address the troubling allegation that the conduct at issue ceased well before issuance of the immediate suspension orders.

Because of the court's ruling, the DEA and the Department of Justice imposed a hiatus on issuing immediate suspension orders until the immediate suspension process could be restructured to address the Due Process issue that led to the adverse decision from the court. Several months after that decision, I became the Associate Chief Counsel for

Diversion Litigation at DEA and was charged with revamping the immediate suspension process. For more than six months, in the height of the illegal Internet pharmacy schemes that fueled prescription drug abuse, the Agency was effectively stripped of its power to issue immediate suspension orders. Although we fixed the immediate suspension process and, I am proud to say, issued a record number of immediate suspensions in 2007 and 2008, the Agency did not issue immediate suspension orders for more than six months in 2006, during which time millions of dosage units of controlled substances were distributed through illicit Internet pharmacy schemes that could have been dismantled by immediate suspension orders. As a practitioner in this area of the law and an observer of the courts, I am very concerned that in the absence of legislative clarity about the meaning of "imminent danger," courts will intervene and curtail the Agency's powers in a way that will prevent the Agency from being able to effectively address true imminent dangers. Based on more recent challenges to DEA's suspension authority and some troubling and pointed questions about the imminent danger standard raised by the DC Circuit Court of Appeals in 2012, it is, in my opinion, likely that courts will step in to ensure the fair application of the imminent danger requirement in the absence of a clear legal standard that is consistently applied by DEA. Indeed, many of my

colleagues believe that the 2012 case would have resulted in a narrowing of DEA's authority if the Agency had not settled its dispute with the registrant. As a supporter of DEA's mission, I urge this Committee to take legislative action that clarifies the meaning of imminent danger.

The definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act is a common sense standard and is similar to the standard that that Agency used for issuing immediate suspensions employed in the immediate aftermath of the adverse court decision in 2006 previously discussed. Using such a standard the DEA issued a record number of immediate suspensions in 2007 and 2008. Based on that history, I am confident that the definition of imminent danger in the Ensuring Patient Access and Effective Drug Enforcement Act will not inhibit DEA's ability to take swift action to address conduct that poses an imminent danger to the public.

However, the Agency appears to have moved away from using a consistent standard when making a finding that a registrant's conduct poses an imminent danger. In doing so, the Agency invites judicial intervention which could severely limit its powers. The definition of imminent danger in the bill is consistent the plain and ordinary meaning of the term, the definition of that term in other federal statutes, and the case

law that has developed around that term. The clarity of this bill, and the Agency's consistent application of the standard articulated in this bill, will substantially strengthen the Agency's position in the face of legal challenges to its suspension powers.

It is worth noting that in fiscal year 2014 DEA initiated few, if any, immediate suspensions. In the past, DEA has publicized many of its suspensions actions, but a search of public records reveals no indication that DEA has issued immediate suspensions in the last 15 months. The cause of this is unclear. One cause may be the lack of a clear legal standard for the issuance of a suspension. Thus, clarifying the definition of "imminent danger" could serve to empower DEA to issue suspensions that meet a clear legislative standard.

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

has issued immediate suspensions in such contexts. While the Agency surely has a right to address past conduct through normal administrative channels, issuing an immediate suspension for conduct that has stopped is not only contrary to the plain meaning of imminent, it is counter-productive and discourages communication with the Agency.

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

Fostering communication and collaboration between registrants and DEA would be further enhanced by the corrective action plan section of the Ensuring Patient Access and Effective Drug Enforcement Act. A registrant who knows that the Agency will consider corrective action before deciding to revoke or suspend the registrant's registration is more likely to communicate with DEA. Addressing the problem of prescription drug abuse requires registrants throughout the supply chain to bring concerns

about other registrants to DEA's attention. A distributor who grows concerned about a pharmacy's dispensing practices after several months of supplying the pharmacy needs the assurance that DEA will consider any corrective action taken by that distributor in order to encourage the distributor to communicate its concerns to DEA.

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

but also from standard statutory interpretation. Requiring DEA to give a registrant who poses an imminent danger to public health an opportunity to submit a corrective action plan would eviscerate the clear intent of the statute that empowers DEA to issue immediate suspensions to abate an imminent danger.

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

medical needs are being refused controlled medications is disturbing. In the absence of clarity in the law, this trend is likely to continue because registrants will continue to take action to limit supply to avoid the perceived threat of administrative action.

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

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

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

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 pro-

tection 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. OK.

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 and 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 a 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 screen. 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.

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 pace.

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 phar-

macy 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. OK. 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 NASPER. It is one of the major reasons we support NASPER, 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. NASPER 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 a 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 appears at the conclusion of the hearing.]

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. Yes. 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 arm, 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 appears at the conclusion of the hearing.]

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 appears at the conclusion of the hearing.]

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. OK. 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, 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.

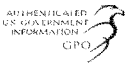
Without objection, so ordered. [1]

Without objection, the subcommittee is adjourned.

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

[Material submitted for inclusion in the record follows:]

[1] The information has been retained in committee files and also is available at *http://docs.house.gov/meetings/IF/IF14/20150127/102844/HMTG-114-IF14-20150127-SD054.pdf.*



HB

113TH CONGRESS
1ST SESSION

H. R. 235

IN THE SENATE OF THE UNITED STATES

FEBRUARY 13, 2013

Received; read twice and referred to the Committee on Health, Education, Labor, and Pensions

AN ACT

To amend the Public Health Service Act to provide grants to States to streamline State requirements and procedures for veterans with military emergency medical training to become civilian emergency medical technicians.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the "Veteran Emergency Medical Technician Support Act of 2013".

SEC. 2. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 314 the following:

"SEC. 315. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

"(a) PROGRAM.—The Secretary shall establish a program consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who completed military emergency medical technician training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to becoming an emergency medical technician in the State.

"(b) USE OF FUNDS.—Amounts received as a demonstration grant under this section shall be used to prepare and implement a plan to streamline State require-

1 ments and procedures as described in subsection (a), in-
2 cluding by—
3 "(1) determining the extent to which the re-
4 quirements for the education, training, and skill level
5 of emergency medical technicians in the State are
6 equivalent to requirements for the education, train-
7 ing, and skill level of military emergency medical
8 technicians; and
9 "(2) identifying methods, such as waivers, for
10 military emergency medical technicians to forego or
11 meet any such equivalent State requirements.
12 "(c) ELIGIBILITY.—To be eligible for a grant under
13 this section, a State shall demonstrate that the State has
14 a shortage of emergency medical technicians.
15 "(d) REPORT.—The Secretary shall submit to the
16 Congress an annual report on the program under this sec-
17 tion.
18 "(e) FUNDING.—Of the amount authorized by section
19 751(j)(1) to be appropriated to carry out section 751 for
20 fiscal year 2014, there is authorized to be appropriated
21 to carry out this section $1,000,000 for the period of fiscal
22 years 2014 through 2018.".
23 (b) CONFORMING AMENDMENT.—Section 751(j)(1)
24 of the Public Health Service Act (42 U.S.C. 294a(j)(1))
25 is amended by striking "There is authorized to be appro-

1 priated" and inserting "Subject to section 315(e), there
2 is authorized to be appropriated".

Passed the House of Representatives February 12, 2013.

Attest: KAREN L. HAAS,
Clerk.

.....

(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. WHITFIELD introduced the following bill; which was referred to the Committee on _____

A BILL

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015".

SEC. 2. AMENDMENT TO PURPOSE.

Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

"(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

"(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

"(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and".

SEC. 3. AMENDMENTS TO CONTROLLED SUBSTANCE MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)—

1 (A) in paragraph (1)—
2 (i) in subparagraph (A), by striking
3 "or";
4 (ii) in subparagraph (B), by striking
5 the period at the end and inserting "; or";
6 and
7 (iii) by adding at the end the fol-
8 lowing:
9 "(C) to maintain and operate an existing
10 State-controlled substance monitoring pro-
11 gram."; and
12 (B) in paragraph (3), by inserting "by the
13 Secretary" after "Grants awarded";
14 (2) by amending subsection (b) to read as fol-
15 lows:
16 "(b) MINIMUM REQUIREMENTS.—The Secretary
17 shall maintain and, as appropriate, supplement or revise
18 (after publishing proposed additions and revisions in the
19 Federal Register and receiving public comments thereon)
20 minimum requirements for criteria to be used by States
21 for purposes of clauses (ii), (v), (vi), and (vii) of subsection
22 (c)(1)(A).";
23 (3) in subsection (c)—
24 (A) in paragraph (1)(B)—

1 (i) in the matter preceding clause (i),
2 by striking "(a)(1)(B)" and inserting
3 "(a)(1)(B) or (a)(1)(C)";
4 (ii) in clause (i), by striking "program
5 to be improved" and inserting "program to
6 be improved or maintained";
7 (iii) by redesignating clauses (iii) and
8 (iv) as clauses (iv) and (v), respectively;
9 (iv) by inserting after clause (ii) the
10 following:
11 "(iii) a plan to apply the latest ad-
12 vances in health information technology in
13 order to incorporate prescription drug
14 monitoring program data directly into the
15 workflow of prescribers and dispensers to
16 ensure timely access to patients' controlled
17 prescription drug history;";
18 (v) in clause (iv), as redesignated, by
19 inserting before the semicolon at the end
20 "and at least one health information tech-
21 nology system such as an electronic health
22 records system, a health information ex-
23 change, or an e-prescribing system"; and

1 (vi) in clause (v), as redesignated, by
2 striking "public health" and inserting
3 "public health or public safety";
4 (B) in paragraph (3)—
5 (i) by striking "If a State that sub-
6 mits" and inserting the following:
7 "(A) IN GENERAL.—If a State that sub-
8 mits";
9 (ii) by striking the period at the end
10 and inserting "and include timelines for
11 full implementation of such interoper-
12 ability. The State shall also describe the
13 manner in which it will achieve interoper-
14 ability between its monitoring program and
15 health information technology systems, as
16 allowable under State law, and include
17 timelines for implementation of such inter-
18 operability."; and
19 (iii) by adding at the end the fol-
20 lowing:
21 "(B) MONITORING OF EFFORTS.—The
22 Secretary shall monitor State efforts to achieve
23 interoperability, as described in subparagraph
24 (A).";
25 (C) in paragraph (5)—

1 (i) by striking "implement or im-
2 prove" and inserting "establish, improve,
3 or maintain"; and
4 (ii) by adding at the end the fol-
5 lowing: "The Secretary shall redistribute
6 any funds that are so returned among the
7 remaining grantees under this section in
8 accordance with the formula described in
9 subsection (a)(2)(B).";
10 (4) in subsection (d)—
11 (A) in the matter preceding paragraph
12 (1)—
13 (i) by striking "In implementing or
14 improving" and all that follows through
15 "(a)(1)(B)" and inserting "In establishing,
16 improving, or maintaining a controlled sub-
17 stance monitoring program under this sec-
18 tion, a State shall comply, or with respect
19 to a State that applies for a grant under
20 subparagraph (B) or (C) of subsection
21 (a)(1)"; and
22 (ii) by striking "public health" and in-
23 serting "public health or public safety";
24 and
25 (B) by adding at the end the following:

1 "(5) The State shall report to the Secretary
2 on—
3 "(A) as appropriate, interoperability with
4 the controlled substance monitoring programs
5 of Federal departments and agencies;
6 "(B) as appropriate, interoperability with
7 health information technology systems such as
8 electronic health records systems, health infor-
9 mation exchanges, and e-prescribing systems;
10 and
11 "(C) whether or not the State provides
12 automatic, real-time or daily information about
13 a patient when a practitioner (or the designee
14 of a practitioner, where permitted) requests in-
15 formation about such patient.";
16 (5) in subsections (e), (f)(1), and (g), by strik-
17 ing "implementing or improving" each place it ap-
18 pears and inserting "establishing, improving, or
19 maintaining";
20 (6) in subsection (f)—
21 (A) in paragraph (1)—
22 (i) in subparagraph (B), by striking
23 "misuse of a schedule II, III, or IV sub-
24 stance" and inserting "misuse of a con-
25 trolled substance included in schedule II,

1 III, or IV of section 202(c) of the Con-
2 trolled Substance Act"; and
3 (ii) in subparagraph (D), by inserting
4 "a State substance abuse agency," after "a
5 State health department,"; and
6 (B) by adding at the end the following:
7 "(3) EVALUATION AND REPORTING.—Subject
8 to subsection (g), a State receiving a grant under
9 subsection (a) shall provide the Secretary with ag-
10 gregate data and other information determined by
11 the Secretary to be necessary to enable the Sec-
12 retary—
13 "(A) to evaluate the success of the State's
14 program in achieving its purposes; or
15 "(B) to prepare and submit the report to
16 Congress required by subsection (k)(2).
17 "(4) RESEARCH BY OTHER ENTITIES.—A de-
18 partment, program, or administration receiving non-
19 identifiable information under paragraph (1)(D)
20 may make such information available to other enti-
21 ties for research purposes.";
22 (7) by redesignating subsections (h) through
23 (n) as subsections (i) through (o), respectively;

1 (8) in subsections (c)(1)(A)(iv) and (d)(4), by
2 striking "subsection (h)" each place it appears and
3 inserting "subsection (i)";
4 (9) by inserting after subsection (g) the fol-
5 lowing:
6 "(h) EDUCATION AND ACCESS TO THE MONITORING
7 SYSTEM.—A State receiving a grant under subsection (a)
8 shall take steps to—
9 "(1) facilitate prescriber and dispenser use of
10 the State's controlled substance monitoring system;
11 "(2) educate prescribers and dispensers on the
12 benefits of the system both to them and society; and
13 "(3) facilitate linkage to the State substance
14 abuse agency and substance abuse disorder serv-
15 ices.";
16 (10) in subsection (k)(2)(A), as redesignated—
17 (A) in clause (ii), by inserting "; estab-
18 lished or strengthened initiatives to ensure link-
19 ages to substance use disorder services;" before
20 "or affected patient access"; and
21 (B) in clause (iii), by inserting "and be-
22 tween controlled substance monitoring pro-
23 grams and health information technology sys-
24 tems," before ", including an assessment";

1 (11) by striking subsection (l) (relating to pref-
2 erence), as redesignated;
3 (12) by redesignating subsections (m) through
4 (o), as redesignated by paragraph (7), as subsections
5 (l) through (n), respectively;
6 (13) in subsection (l)(1), as redesignated, by
7 striking "establishment, implementation, or improve-
8 ment" and inserting "establishment, improvement,
9 or maintenance";
10 (14) in subsection (m)—
11 (A) in paragraph (5)—
12 (i) by striking "means the ability"
13 and inserting the following: "means—
14 "(A) the ability";
15 (ii) by striking the period at the end
16 and inserting "; or"; and
17 (iii) by adding at the end the fol-
18 lowing:
19 "(B) sharing of State controlled substance
20 monitoring program information with a health
21 information technology system such as an elec-
22 tronic health records system, a health informa-
23 tion exchange, or an e-prescribing system.";
24 (B) in paragraph (7), by striking "phar-
25 macy" and inserting "pharmacist"; and

1 (C) in paragraph (8), by striking "and the
2 District of Columbia" and inserting ", the Dis-
3 trict of Columbia, and any commonwealth or
4 territory of the United States"; and
5 (15) by striking subsection (n), as redesignated
6 (relating to authorization of appropriations).

7 **SEC. 4. NO ADDITIONAL FUNDS AUTHORIZED TO BE APPRO-**
8 **PRIATED.**

9 No additional funds are authorized to be appro-
10 priated for the purpose of carrying out this Act and the
11 amendments made by this Act, and this Act and such
12 amendments shall be carried out using amounts otherwise
13 available for such purpose

.....

(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

To amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BURGESS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Trauma Systems and Regionalization of Emergency Care Reauthorization Act".

1 **SEC. 2. REAUTHORIZATION OF CERTAIN TRAUMA CARE**
2 **PROGRAMS.**

3 Section 1232(a) of the Public Health Service Act (42
4 U.S.C. 300d–32(a)) is amended by striking "2014" and
5 inserting "2020".

6 **SEC. 3. IMPROVEMENTS AND CLARIFICATIONS TO CERTAIN**
7 **TRAUMA CARE PROGRAMS.**

8 (a) ALLOCATION OF FUNDS FOR COMPETITIVE
9 GRANTS FOR REGIONALIZED SYSTEMS FOR EMERGENCY
10 CARE RESPONSE.—Section 1232(c) of the Public Health
11 Service Act (42 U.S.C. 300d–31(c)) is amended—

12 (1) in paragraph (1), by striking "and" at the
13 end;

14 (2) in paragraph (2), by striking the period at
15 the end and inserting "; and"; and

16 (3) by adding at the end the following new
17 paragraph:

18 "(3) for a fiscal year after fiscal year 2015, not
19 more than 50 percent of such amounts remaining
20 for such fiscal year after application of paragraphs
21 (1) and (2) shall be allocated for the purpose of car-
22 rying out section 1204.".

23 (b) CLARIFICATIONS UNDER TRAUMA SYSTEMS FOR-
24 MULA GRANTS REQUIREMENTS RELATING TO THE AMER-
25 ICAN BURN ASSOCIATION.—Section 1213 of the Public
26 Health Service Act (42 U.S.C. 300d–13) is amended—

1 (1) in subsection (a)(3), by inserting "and (for
2 a fiscal year after fiscal year 2015) contains national
3 standards and requirements of the American Burn
4 Association for the designation of verified burn cen-
5 ters," after "such entity,";
6 (2) in subsection (b)(3)(A), by striking "and
7 the American Academy of Pediatrics," and inserting
8 "the American Academy of Pediatrics, and (for a
9 fiscal year after fiscal year 2015) the American
10 Burn Association,"; and
11 (3) in subsection (c)(1)—
12 (A) in the matter preceding subparagraph
13 (A), by inserting "and not later than 1 year
14 after the date of the enactment of the Trauma
15 Systems and Regionalization of Emergency
16 Care Reauthorization Act" after "Act of 2007";
17 and
18 (B) in subparagraph (A), by striking "and
19 the American Academy of Pediatrics" and in-
20 serting "the American Academy of Pediatrics,
21 and (with respect to the update pursuant to the
22 Trauma Systems and Regionalization of Emer-
23 gency Care Reauthorization Act) the American
24 Burn Association".

1 (c) CONFORMING AMENDMENTS.—Part B of title XII
2 of the Public Health Service Act is amended—
3 (1) in section 1218(c)(2) (42 U.S.C. 300d–
4 18(c)(2)), in the matter preceding subparagraph
5 (A), by striking "1232(b)(3)" and inserting "section
6 1232(b)"; and
7 (2) in section 1222 (42 U.S.C. 300d–22), by
8 striking "October 1, 2008" and inserting "October
9 1, 2017".

[DISCUSSION DRAFT]

114TH CONGRESS
1ST SESSION

H. R. _____

To amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BURGESS introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Access to Life-Saving Trauma Care for All Americans Act".

1 **SEC. 2. REAUTHORIZATION OF TRAUMA AND EMERGENCY**
2 **CARE PROGRAMS.**

3 (a) TRAUMA CENTER CARE GRANTS.—Section 1245
4 of the Public Health Service Act (42 U.S.C. 300d–45) is
5 amended in the first sentence—

6 (1) by striking "2009, and such" and inserting
7 "2009, such"; and

8 (2) by inserting before the period at the end the
9 following: ", and $100,000,000 for each of fiscal
10 years 2016 through 2020".

11 (b) INTERAGENCY PROGRAM FOR TRAUMA RE-
12 SEARCH.—Section 1261(i) of the Public Health Service
13 Act (42 U.S.C. 300d–61(i)) is amended by striking "2001
14 through 2005" and all that follows through the period at
15 the end and inserting "2015 through 2020.".

16 (c) TRAUMA SERVICE AVAILABILITY GRANTS.—Sec-
17 tion 1282 of the Public Health Service Act (42 U.S.C.
18 300d–82) is amended by striking "2015" and inserting
19 "2020".

20 **SEC. 3. ALIGNMENT OF PROGRAMS UNDER ASSISTANT SEC-**
21 **RETARY FOR PREPAREDNESS AND RE-**
22 **SPONSE.**

23 Section 2811(c)(2)(F) of the Public Health Service
24 Act (42 U.S.C. 300hh–10(c)(2)(F)) is amended by strik-
25 ing "trauma care under parts A through C of title XII"

1 and inserting "trauma care under parts A through D of
2 title XII and part H of such title".

3 **SEC. 4. TECHNICAL CORRECTIONS RELATING TO TRAUMA**
4 **CENTER GRANTS.**

5 (a) CLARIFICATION ON ELIGIBLE TRAUMA CEN-
6 TERS.—Section 1241(a) of the Public Health Service Act
7 (42 U.S.C. 300d–41(a)) is amended by striking "qualified
8 public, nonprofit Indian Health Service, Indian tribal, and
9 urban Indian trauma centers" and inserting "qualified
10 public trauma centers, qualified nonprofit trauma centers,
11 and qualified Indian Health Service, Indian tribal, and
12 urban Indian trauma centers".

13 (b) TRAUMA CENTER GRANTS QUALIFICATIONS FOR
14 SUBSTANTIAL UNCOMPENSATED CARE COSTS.—Section
15 1241(b)(3)(B) of the Public Health Service Act (42
16 U.S.C. 300d–41(b)(3)(B)) is amended—

17 (1) in clause (i), by striking "35" and inserting
18 "30"; and

19 (2) in clause (ii), by striking "50" and inserting
20 "40".

21 (c) CLARIFICATION RELATING TO TRAUMA CENTER
22 GRANTS.—The heading for part D of title XII of the Pub-
23 lic Health Service Act (42 U.S.C. 300d–41 et seq.) is
24 amended to read as follows: "**TRAUMA CENTERS**".

[113H4709]

.....

(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MARINO introduced the following bill; which was referred to the Committee on _____

A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015".

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

1 (1) FACTORS AS MAY BE RELEVANT TO AND
2 CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-
3 TY.—Section 303 of the Controlled Substances Act
4 (21 U.S.C. 823) is amended by adding at the end
5 the following:
6 "(i) In this section, the phrase 'factors as may be rel-
7 evant to and consistent with the public health and safety'
8 means factors that are relevant to and consistent with the
9 findings contained in section 101.".
10 (2) IMMINENT DANGER TO THE PUBLIC
11 HEALTH OR SAFETY.—Section 304(d) of the Con-
12 trolled Substances Act (21 U.S.C. 824(d)) is amend-
13 ed—
14 (A) by striking "(d) The Attorney Gen-
15 eral" and inserting "(d)(1) The Attorney Gen-
16 eral"; and
17 (B) by adding at the end the following:
18 "(2) In this subsection, the phrase 'imminent danger
19 to the public health or safety' means that, in the absence
20 of an immediate suspension order, controlled substances—
21 "(A) will continue to be intentionally distrib-
22 uted or dispensed—
23 "(i) outside the usual course of profes-
24 sional practice; or

"(ii) in a manner that poses a present or foreseeable risk of serious adverse health consequences or death; or

"(B) will continue to be intentionally diverted outside of legitimate distribution channels.".

(b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Subsection (c) of section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) by striking the last two sentences in such subsection;

(2) by striking "(c) Before" and inserting "(c)(1) Before"; and

(3) by adding at the end the following:

"(2) An order to show cause under paragraph (1) shall—

"(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

"(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but no less than thirty days after the date of receipt of the order; and

1 "(C) notify the applicant or registrant of the
2 opportunity to submit a corrective action plan on or
3 before the date of appearance.
4 "(3) Upon review of any corrective action plan sub-
5 mitted by an applicant or registrant pursuant to para-
6 graph (2), the Attorney General shall determine whether
7 denial, revocation or suspension proceedings should be dis-
8 continued, or deferred for the purposes of modification,
9 amendment, or clarification to such plan.
10 "(4) Proceedings to deny, revoke, or suspend shall
11 be conducted pursuant to this section in accordance with
12 subchapter II of chapter 5 of title 5. Such proceedings
13 shall be independent of, and not in lieu of, criminal pros-
14 ecutions or other proceedings under this title or any other
15 law of the United States.
16 "(5) The requirements of this subsection shall not
17 apply to the issuance of an immediate suspension order
18 under subsection (d).".

19 **SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW EN-**
20 **FORCEMENT ACTIVITIES ON PATIENT AC-**
21 **CESS TO MEDICATIONS.**

22 (a) IN GENERAL.—Not later than one year after the
23 date of enactment of this Act, the Secretary of Health and
24 Human Services, acting through the Commissioner of
25 Food and Drugs and the Director of the Centers for Dis-

1 ease Control and Prevention, and in consultation with the
2 Administrator of the Drug Enforcement Administration
3 and the Director of National Drug Control Policy, shall
4 submit a report to the Committees on the Judiciary of
5 the House of Representatives, the Committee on Energy
6 and Commerce of the House of Representatives, the Com-
7 mittee on the Judiciary of the Senate, and the Committee
8 on Health, Education, Labor and Pensions of the Senate
9 identifying—
10 (1) obstacles to legitimate patient access to con-
11 trolled substances;
12 (2) issues with diversion of controlled sub-
13 stances; and
14 (3) how collaboration between Federal, State,
15 local, and tribal law enforcement agencies and the
16 pharmaceutical industry can benefit patients and
17 prevent diversion and abuse of controlled substances.
18 (b) CONSULTATION.—The report under subsection
19 (a) shall incorporate feedback and recommendations from
20 the following:
21 (1) Patient groups.
22 (2) Pharmacies.
23 (3) Drug manufacturers.
24 (4) Common or contract carriers and ware-
25 housemen.

1 (5) Hospitals, physicians, and other health care
2 providers.
3 (6) State attorneys general.
4 (7) Federal, State, local, and tribal law enforce-
5 ment agencies.
6 (8) Health insurance providers and entities that
7 provide pharmacy benefit management services on
8 behalf of a health insurance provider.
9 (9) Wholesale drug distributors.

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
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IB

Union Calendar No. 451

113TH CONGRESS
2D SESSION

H. R. 4299

[Report No. 113–565, Parts I and II]

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2014

Mr. PITTS (for himself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JULY 29, 2014

Reported from the Committee on Energy and Commerce

JULY 29, 2014

Referral to the Committee on the Judiciary extended for a period ending not later than September 19, 2014

SEPTEMBER 19, 2014

Additional sponsors: Mr. BURGESS, Mrs. MCMORRIS RODGERS, Mrs. BLACKBURN, Mr. GINGREY of Georgia, Mr. GRIFFITH of Virginia, Mr. GENE GREEN of Texas, Mr. LATTA, Mr. ENGEL, Ms. SHEA-PORTER, Mr. BUTTERFIELD, Mr. TONKO, Mr. JOHNSON of Ohio, Mr. HARPER, and Mr. COLLINS of Georgia

SEPTEMBER 19, 2014

Reported from the Committee on the Judiciary with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on March 26, 2014]

A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Improving Regulatory Transparency for New Medical Therapies Act".

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

Section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)) is amended by adding at the end the following: "Any such proceedings initiated at the request of the Secretary under this subsection to control a drug or other substance not previously scheduled, where the Secretary has recommended the drug or other substance be placed in schedule II, III, IV, or V, shall be commenced not later than 120 days after receipt of written recommendations from the Secretary. The final rule shall be issued not later than 60 days after the date on which both the public comment period has closed and the drug or other substance is the subject of an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act, unless a hearing on the proposed rule is granted by the Attorney General.".

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

1 *"(i)(1) For the purposes of registration to manufacture*
2 *a controlled substance under subsection (d) of this section*
3 *for use only in a clinical trial, the Attorney General shall*
4 *register an applicant or serve an order to show cause upon*
5 *an applicant pursuant to section 304(c) of this Act not later*
6 *than 180 days after receipt of an application and all infor-*
7 *mation the Attorney General deems necessary to make a*
8 *determination under subsection (d).*
9 *"(2) For the purposes of registration to manufacture*
10 *a controlled substance under subsection (a) for use only in*
11 *a clinical trial, the Attorney General shall, in accordance*
12 *with regulations issued by the Attorney General, issue a no-*
13 *tice of application not later than 90 days after receipt of*
14 *an application and all information the Attorney General*
15 *deems necessary to issue a notice of application. Following*
16 *the close of the comment period and receipt of all informa-*
17 *tion the Attorney General deems necessary to make a deter-*
18 *mination under subsection (a), the Attorney General shall*
19 *register an applicant or serve an order to show cause upon*
20 *an applicant pursuant to section 304(c) of this Act within*
21 *180 days, unless a hearing on the application has been*
22 *granted by the Attorney General pursuant to section*
23 *1008(i) of the Controlled Substances Import and Export*
24 *Act.".*

Union Calendar No. 451

113TH CONGRESS
2D SESSION

H. R. 4299

[Report No. 113–565, Parts I and II]

A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

SEPTEMBER 19, 2014

Reported from the Committee on the Judiciary with an amendment

Written Statement for the Record

Submitted to the House Committee on Energy & Commerce, Health Subcommittee

The Honorable Joe Pitts, Chairman

"Examining Public Health Legislation to Help Patients and Local Communities"

January 27, 2015

Stephen C. Mullenix, R.Ph

Senior Vice President, Public Policy and Industry Relations

National Council for Prescription Drug Programs

Statement

Mr. Chairman and Members of the Committee, thank you for the opportunity to submit a written statement for the record in conjunction with the Health Subcommittee hearing entitled "Examining Public Health Legislation to Help Patients and Local Communities" held on January 27, 2015. We are especially appreciative that the Subcommittee is examining reauthorization of the NASPER program. We appreciate your attention to this critical issue and are pleased to present our thoughts on how to improve the program by allowing states to share information with each other in order to identify at the point of dispensing patients who may be abusing prescription drugs. To assist the Committee, we have included the attached white paper, "*NCPDP Recommendations for Improving Prescription Drug Monitoring Programs.*"

The National Council for Prescription Drug Programs (NCPDP) is the multi-stakeholder problem solving forum for healthcare and American National Standards Institute (ANSI) accredited standards development organization for the pharmacy services sector. NCPDP provides the proven forum and process for diverse healthcare stakeholders to work together for the common good. Industry solutions include standards and guidance for real-time claims adjudication, eligibility verification, payment reconciliation, HIPAA, medication history and patient safety, uniform ID cards, electronic prescribing, electronic prior authorization, REMS and more.

Prescription Drug Abuse

Prescription drug abuse is one of the fastest-growing drug problems in the United States as evidenced by the research of multiple independent and government agencies including the Centers for Disease Control (CDC) and the Office of National Drug Control Policy (ONDCP). The CDC has declared the problem an epidemic with instances of 100 unintentional overdose deaths per day. ONDCP finds that deaths involving opioid prescription drug abuse and overdose occurred four times as much in 2010 as they did a decade earlier. Drug-induced overdose deaths now surpass homicides and car crash deaths in America at a cost of more than $193 billion annually.

Prescription Drug Monitoring Programs (PDMPs)

PDMPs are an important tool in the fight against prescription drug abuse. The Hal Rogers Program and NASPER have allocated critical funds to states in order to develop, maintain and update state databases in order to track the dispensing of these controlled medications. However, in the years since PDMPs were first developed, the prevalence of prescription drug abuse has changed dramatically – it is now a national problem, yet the technology used in state programs has not adapted to effectively combat these new challenges.

While NCPDP strongly supports a renewed emphasis on addressing this issue, simply funding existing programs at higher levels will likely not lead to the desired outcome of decreasing prescription drug abuse. Specifically:

- Traditionally prescription drug programs have focused on combatting incorrect dispensing instead of stopping the abuse before the prescription is filled;
- The current prescription monitoring communication process is systemically burdensome and does not effectively provide information at the point-of-care and in a timely manner across all state lines.; and
- State by state approaches to combatting prescription drug abuse have led to uneven success: the most recent SAMHSA National Survey on Drug Abuse showed that drug-traffickers have moved westward to states with looser restrictions.

NCPDP Supports Systemic PDMP Improvements

Through the use of existing, interoperable industry standards, providers will be able to share real-time information to enable prescribers and pharmacists to make clinical decisions prior to writing and dispensing medications for proactive intervention and to stop abuse before it starts. The burden on providers is reduced by incorporating drug abuse information within their workflows. Prescribers and pharmacists are already using NCPDP standards in their everyday operations to send, receive, and bill for prescriptions, making it easier for them to assess patient risk and ensure access for patients with a valid medical need.

NCPDP's PDMP model is a proactive, sustainable, national solution. The benefits to this approach are numerous:

- Shares real-time information at the point of care anywhere in the country through the use of existing, interoperable industry standards.
- Reduces burdens on providers by incorporating drug abuse information within pharmacy and prescriber workflows, with bidirectional communication.
- Enables prescribers and pharmacists to make clinical decisions prior to writing and dispensing medications for proactive intervention and to stop abuse before it starts.
- Ensures access for patients with valid medical needs.
- Enables individual states to maintain control over its own program.

NCPDP's model effectively addresses deficiencies in current industry PDMPs and provides an onramp for existing PDMPs to optimize value of the programs at both the state and national levels.

We encourage the Committee and its Members to address the national prescription drug abuse problem by adopting advanced and readily available technical solutions as described in the attached white paper.

Thank you, again, for your attention and work on the prescription drug abuse issue. We look forward to working with the Committee and its Members going forward in the implementation of policy and changes to reduce the instance of prescription drug abuse in the United States.

NCPDP Recommendations for Improving Prescription Drug Monitoring Programs (PDMP)

Version 1.0
March 2013

NCPDP™

This white paper details a plan to nationally standardize PDMPs to better track and deter abuse of controlled substance prescriptions. The plan leverages NCPDP's Telecommunication and SCRIPT Standards in use industry-wide. It includes best practices to improve prescriber and pharmacy clinical decision making at point-of-care, and supports real-time access to PDMP data across state lines. It integrates the prescription monitoring process into workflows and provides timely clinical data to prescribers and pharmacists, which also helps ensure access for patients with a valid medical need for controlled substances.

NCPDP Recommendations for Improving Prescription Drug Monitoring Programs (PDMP)

Version 1.Ø

NCPDP recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

NOTICE: In addition, this NCPDP Standard contains certain data fields and elements that may be completed by users with the proprietary information of third parties. The use and distribution of third parties' proprietary information without such third parties' consent, or the execution of a license or other agreement with such third party, could subject the user to numerous legal claims. **All users are encouraged to contact such third parties to determine whether such information is proprietary and if necessary, to consult with legal counsel to make arrangements for the use and distribution of such proprietary information.**

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 1.Ø March 2Ø13
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The writers of this paper will review and possibly update their recommendations should any significant changes occur.

This document is for Education and Awareness Use Only.

1. PURPOSE AND SCOPE

A focus group on Prescription Drug Monitoring Programs (PDMPs) was held in Baltimore, MD on October 18, 2012, facilitated by the National Council for Prescription Drug Programs. Goals and Objectives of the focus group were to identify the current and future issues and needs regarding the exchange of information for PDMPs. Identifying the specific industry challenges and the goals of the PDMPs, providers, prescribers, and regulatory agencies, will allow NCPDP to propose efficient solutions leveraging existing standards and methodologies as well as develop applicable enhancements that would be standardized across the industry.

The focus group included attendees from pharmacies, Pharmacy Benefit Managers (PBMs), intermediaries, prescriber vendors, ePrescribing vendors, software vendors, drug compendia, consultants, state agencies, Federal Drug Administration (FDA), Drug Enforcement Administration (DEA), United States Department of Health and Human Services (HHS), the MITRE group, and NCPDP.

At the request of the PDMP focus group, during the November 2012 NCPDP Maintenance and Control Work Group meeting, the PDMP Task Group was formed, with the initial task of developing this White Paper to: (1) examine the problems; (2) identify future needs; and (3) recommend solutions for PDMP reporting as well as the role of NCPDP. The goals are (1) to complete the white paper and send it to the Office of the National Coordinator (ONC) by March 2013 to coincide with the MITRE contract timeline, and (2) make the white paper available to the industry.

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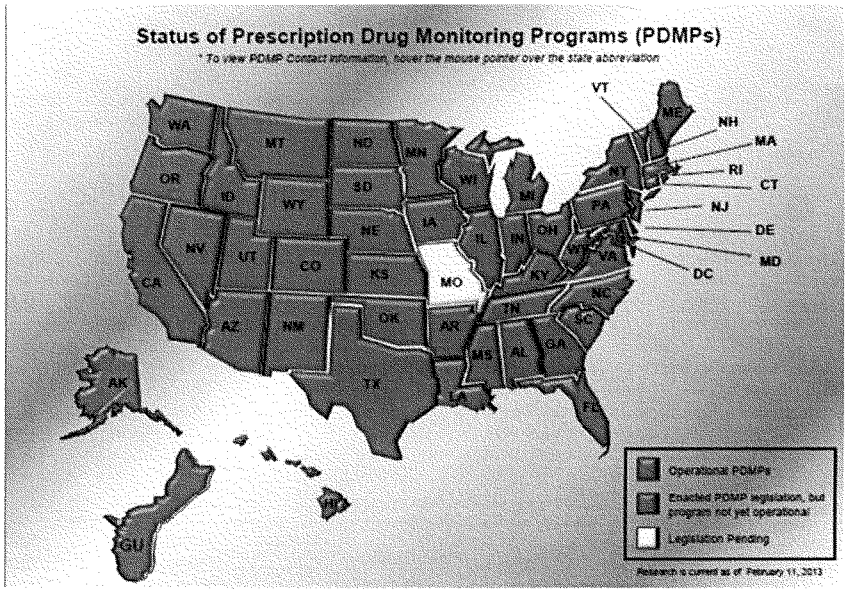
2. BACKGROUND

A PDMP is an electronic database that collects designated data on controlled substances dispensed or prescribed within a given state. The data collected usually includes the names and/or demographic information for the patient, prescriber, and dispenser; the name and dosage of the drug; the quantity supplied; the number of authorized refills; and the method of payment.

As of February 2013, 49 states, the District of Columbia, and one U.S. Territory have enacted legislation that establishes a PDMP. Of those, 43 states have operational PDMPs while 6 other states, the District of Columbia, and Guam have PDMPs that are not yet operational. Illustration 1 below displays the status of the PDMPs across the United States. [1]

Illustration 1
Status of Prescription Drug Monitoring Programs



PDMPs are established and managed at the state level and can vary considerably from state-to-state. Some areas of variation include:

[1] PDMP Training & Technical Assistance Center, Brandeis University. Available at http://www.pdmpassist.org/pdf/pmpprogramstatus2013.pdf

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- **Organizational structure.** Each state determines which agency houses the PDMP and how it is operated.

- **Substances monitored**. PDMPs monitor controlled substance prescriptions and other drugs with potential for abuse. This varies by state.

- **Level of access.** Some PDMPs allow law enforcement to access the database directly; others require law enforcement to obtain a court order or subpoena to access data; and some allow indirect access via a report in response to a request from law enforcement as a part of an active investigation.

- **Solicited and Unsolicited Reporting.** In some states, the PDMP is "reactive" meaning that only solicited reports are generated in response to a query by authorized users such as prescribers, dispensers and other groups with the appropriate authority. PDMPs of other states, in addition to providing solicited reports, are "proactive", generating unsolicited reports when there is reason to suspect that violations on the part of the patients or users have occurred.[2]

- **Purpose and Usage.** The purpose is dependent on user intent and varies by user. Users may be law enforcement, regulatory agencies, state payer programs, researchers and providers.

- **Timeliness of data.** Timeliness of PDMP reporting varies by state—anywhere from monthly to real-time.

- **Interoperability.** State PDMPs vary widely whether information contained in the database is shared with other states. While some states do not have measures in place allowing interstate sharing of information, others have specific practices for sharing. An effort is ongoing to facilitate information sharing using prescription monitoring information exchange (PMIX) architecture. The infrastructure of the PMIX program is based on the National Information Exchange Model (NIEM), which is a data sharing partnership among all levels of government as well as the private sector.[3] The PMIX Architecture utilizes "end-to-end encryption" so that no protected health information can be stored at the hub. The encrypted data leaves the sending state PDMP system and cannot be decrypted until it reaches the receiving state PDMP system.

- **Reporting Formats.** State PDMPs are currently using different versions of the American Society for Automation in Pharmacy (ASAP) data transmission formats.

- **Multiple Work Groups.** The Office of the National Coordinator for Health Information Technology (ONC) has various work groups determining best practices for standardizing the use of PDMP programs.[4]

---

[2] Simeone R, Holland L. Simeone Associates, Inc. (2006, September 1). An evaluation of prescription drug monitoring programs. Retrieved September 7, 2009, from National Alliance for Model State Drug Laws Official Site website: http://www.simeoneassociates.com/simeone3.pdf

[3] Alliance of States with Prescription Monitoring Programs, *Prescription Monitoring Information Exchange (PMIX)*, is available at http://pmpalliance.org/

[4] United States Department of Health and Human Services (HHS), *More doctors adopting EHRs to improve patient care and safety*, available at http://www.hhs.gov/news/press/2012pres/12/20121212b.html

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3. GLOSSARY

ASAP

American Society for Automation in Pharmacy (ASAP) has various versions of different layouts for PDMP reporting.

Authorized Healthcare Professionals

Healthcare professionals involved in patient treatment who may or may not have prescribing or dispensing authority, need access to PDMP data, and have the ability to appoint delegates. These licensed healthcare professionals could include practitioners who work in fields such as medication therapy management, disease management, behavioral health that involves utilization management review and case management, and practitioners such as substance abuse clinicians and psychologists.

Clinical Data

Concepts or terms applying to the clinical delivery of care.

Clinical Decisions

Judgmental process clinicians use to make logical, rational decisions to decide whether an action is right or wrong. *Clinical Decision Support (CDS) is defined as "providing clinicians or patients with clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times, to enhance patient care."*[5]

DEA Number

A number assigned to a health care provider by the U.S. Drug Enforcement Administration (DEA) allowing them to write prescriptions for controlled substances. Legally, the DEA number is solely to be used for tracking controlled substances. It is used by the industry, however, as a general "prescriber number" that is a unique identifier for anyone who can prescribe medication.

Dispenser

Pharmacy or physician authorized to dispense controlled substances

FTP

File Transfer Protocol; commonly used protocol for exchanging files over any network.

Manual Claim Form

Various forms used by the provider of service to submit a claim to the patient's payer or insurer or the state.

NABP

National Association of Boards of Pharmacy

NCPDP

National Council for Prescription Drug Programs

NDC

National Drug Code describes specific drugs by drug manufacturer and package size.

---

[5] *Informatics and Clinical Decision Support*, Kathryn A. Walker, PharmD, BCPS Faculty and Disclosures CE Released: 03/07/2008; Valid for credit through 03/07/2009 accessed February 1 4, 2013 http://www.medscape.org/viewarticle/571099

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NPI

National Provider Identifier is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services.

ONC

Office of the National Coordinator for Health Information Technology

PDMP

A PDMP is a ***statewide*** electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.[6]

Prescriber

A practitioner authorized by state and federal agencies to prescribe controlled substances.

SCRIPT Standard

The NCPDP SCRIPT Standard is used for transmitting prescription information electronically between prescribers, providers, and other entities. The standard addresses the electronic transmission of new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, and other transaction functions. The SCRIPT Standard is named in the Medicare Modernization Act.

SFTP

Secure File Transfer Protocol (also referred to as SSH File Transfer Protocol); provides file transfer and manipulation functionality over any reliable data stream.

SSL

Secure Sockets Layer; cryptographic protocol that provides secure communications for data transfers.

Telecommunication Standard

The NCPDP Telecommunication Standard is used for the electronic submission of eligibility verification, claim and service billing, predetermination of benefits, prior authorization, information reporting, and controlled substance (general and regulated) transaction exchanges. The Telecommunication Standard is named in HIPAA and the Medicare Modernization Act.

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[6] Source, U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control accessed February 27, 2013 website: *http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm*. Accredited to the National Alliance for Model State Drug Laws (NAMSDL) website: *http://www.namsdl.org/home.htm*

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4. THE PROBLEM

According to the Office of National Drug Control Policy, prescription drug abuse is the nation's fastest-growing drug problem, and prescription drug overdose deaths have been classified as epidemic by the Centers for Disease Control and Prevention. An integrated workflow solution to provide a streamlined, standard communication process would enhance the ability of the health care provider to address the epidemic and mitigate patient care risks. The current prescription monitoring communication process is outside the workflow process and systemically burdensome. It does not effectively provide information in a timely manner or evaluations across all state lines and across all pharmacies.

From a pharmacist's and prescriber's perspective, workflow integration and the adoption of national standards is critical to allow the provider to identify potential drug abuse, diversion, and evaluate patient safety risk and to make appropriate clinical decisions before a prescription is written or dispensed.

In addition to a pharmacist's and prescriber's perspective, there are other entities that impact prescription drug monitoring programs, such as emergency departments, pain clinics, dispensing physicians, and ambulatory surgery centers. These entities may provide information for PDMP reporting and may need access to reporting information.

4.1 PHARMACY PERSPECTIVE

From a pharmacy perspective, today's processes for using PMDPs for preventing prescription abuse and evaluating patient safety risk are not adequate. Barriers include:

- Lack of real-time interoperable databases among all the states.
- Lack of a nationally adopted ANSI or other accredited standard for real-time reporting to state PDMP databases.
- Lack of a standard set of data elements and values to make interoperability possible.
- Lack of real-time response for validating accurate data.
- Lack of a real-time response in order to make clinical decisions before the prescription is dispensed. The current process is manual and outside of the pharmacy workflow.

4.1.1 EVALUATION OF PRESCRIPTION DATA

- No standard measurement for evaluating clinical risk among patient and pharmacy history and doctor prescribing data submission and verification.
- Response to data submissions and queries is untimely. As a result, the process of storing the data is inefficient, whereby clinical decisions could be at risk.
- Lack of validation of accurate prescription data elements required for PDMP at the time the prescription is dispensed.
- PDMP alerts are not available within the pharmacy dispensing workflow.

4.1.2 REPORTING/DATA SUBMISSION

- Pharmacy has varying requirements by state for submitting PDMP data. The result is supporting multiple transaction layouts that increase administrative costs,
- If the data submitted is inaccurate or incomplete (i.e. missing patient zip code), the notification and update process is inconsistent amongst the different programs.
- Frequency of data submission varies from state to state:
  - Near real-time-1 state
  - Daily-2 states
  - Weekly-22 states
  - Bi-weekly-11 states
  - Monthly-6 states

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  - Every 6 weeks-1 state
- Data and format requirements vary from state to state. Most states require data formatted in various versions of the American Society for Automation in Pharmacy Standards (ASAP).
- Pharmacy compliance monitoring varies by state.
- Data is not normalized (i.e. address/city/state, one vs. 1)
- Data is delivered using many automated and manual methods (such as):
  - Secure FTP over SSH
  - Encrypted File with OpenPGP via FTP
  - SSL Website
  - Physical Media (Tape, Diskette, CD, DVD)
  - Universal Claim Form submission

4.1.3 ACCESSIBILITY

- Internal security firewalls can prevent access to databases.
- Gaining access to state PDMPs varies widely from state to state.
- Access is unavailable to those participating in the dispensing and clinical processes.
- Pharmacy does not have access to PDMP data within their workflow and must interrupt workflow to access an external database.
- Lack of access to PDMP data across state lines impacts the pharmacy's ability to make accurate clinical decisions.
- Pharmacists providing patient care (clinical services such as Drug Utilization Review and Medication Therapy Management) should have access to PDMP data prior to comprehensive medication reviews.

4.1.4 DATA INTEGRITY

- Gaps in data (e.g. not all Indian Health Services, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

4.2 PRESCRIBER PERSPECTIVE

From a prescriber perspective, the current process for preventing prescription drug abuse is not adequate for addressing the need for improving patient safety. The ePrescribing process is a method to help data verification reporting accessibility but prescription drug monitoring information needs to fit into the prescriber's ePrescribing workflow. Barriers include:

4.2.1 DATA VERIFICATION

- Access to the PDMP data is a manual process and does not fit into the prescriber's workflow.
- Data varies by state, and is inconsistently organized and/or presented.
- Clinical decisions are not integrated into the prescribing process.
- Individual state record look-up often times-out after several seconds.

4.2.2 REPORTING

- Lack of completeness and filtering of data
- Data duplication
- Lack of timeliness in reporting the data makes it difficult for prescribers to make clinical decisions.

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- Data and Format requirements vary by state making it difficult for prescriber vendors consuming the data.

4.2.3 ACCESSIBILITY

- Medication history is not shared real-time on a national level.
- Prescribers are notified of doctor shopping issues outside of their workflow, i.e. email.
- State specific regulations, i.e. California not allowing prescriber access to medication history.

4.2.4 DATA INTEGRITY

- Gaps in data (e.g. not all Indian Health Services, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

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5. IMPROVEMENT RECOMMENDATIONS

By leveraging existing industry standards and processes, several recognized problems are resolved.

5.1 STANDARDIZATION

- Require a minimum set of data elements to be submitted by dispensers systems to the PDMP to be adopted by all states.
- Require one standard transaction format for reporting PDMP, one standard transaction for inquiry and one standard transaction for response.
- Enable accurate reporting of prescriber NPI and DEA numbers.
- Require accurate reporting of all reportable ingredients including compound ingredients.
- Create and adopt a nationally recognized clinical risk score to assist prescribers and dispensers with clinical decisions.

5.2 REAL-TIME REPORTING

- Provide timely access to data as appropriate to all impacted parties for real-time decision making.
- Reduce reporting delays by allowing PDMP type rejections to be corrected at point of adjudication.
- Improve patient quality of care with clinical decision alerts presented at the time of prescription writing or dispensing.
- Enable the exchange of information across states to create a comprehensive picture of prescribing and dispensing patterns.
- Report Date Filled or Date of Service rather than Date Sold (Date delivered or shipped.)
- Eliminate the need for zero reports (no schedules filled).

5.3 CENTRAL DATA REPOSITORY

- Provide PDMPs with more comprehensive multi-state access to data.
- Provide PDMPs with more accurate, timely and consistent data.
- Provide prescribers and pharmacies centralized access to accurate and up-to-date data for clinical and other decision making reasons.
- Provide clinical data to pharmacies and prescribers that are integrated within their workflow.
- Provide data analytics that are more consistent and inclusive.

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6. PROPOSED SOLUTIONS

The task group recommends the following solutions to allow authorized healthcare providers, including prescribers and pharmacists, to make more informed clinical decisions prior to writing and dispensing medications, in an effort to reduce patient prescription drug overdosing and abuse.

1. Adopt a minimum data set and standard transaction format across all states for submission of prescription data to PDMPs.
2. Adopt a minimum data set and standard transaction format across all states for submission of dispensing data to PDMPs.
3. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the prescriber's work flow to enable appropriate clinical decisions before the medication is prescribed.
4. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the pharmacy's work flow to enable appropriate clinical decisions before the medication is prescribed.
5. Leverage the NCPDP Telecommunication Standard to support real-time reporting within the pharmacy's workflow to PDMP state repositories.
6. Leverage the NCPDP Telecommunication Standard to support clinical alerts to the pharmacy prior to dispensing.
7. Leverage the NCPDP SCRIPT Standard RxFill transaction to report to the prescriber and/or PDMP the date the medication was delivered or shipped to the patient.
8. Enable a nationally recognized process to exchange data between PDMP databases.

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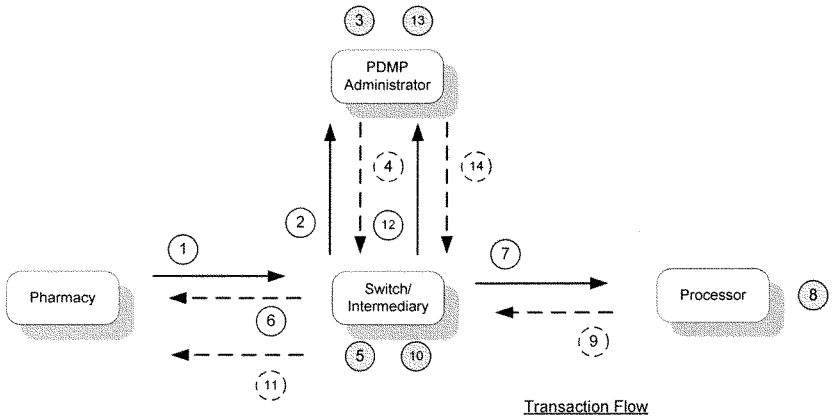
7. FLOW CHARTS

Transaction Flow Sequence
(Pharmacy)



Request Txn.

Response Txn.

Transaction

Processing

Transaction Flow

1 – Billing Request to Intermediary
2 – Billing Request Subset to PDMP
3 – Pre-Processor Editing
4 – Response to Intermediary
5 – Interpretation of Response
6 – Pre-Processor Reject Response
7 – Billing Request to Processor
8 – Adjudication of Request
9 – Response to Intermediary
10 – Interpretation of Response
11 – Response to Pharmacy
12 – Data Delivery Request to PDMP
13 – Accept Response
14 – Data Delivery Acknowledgement

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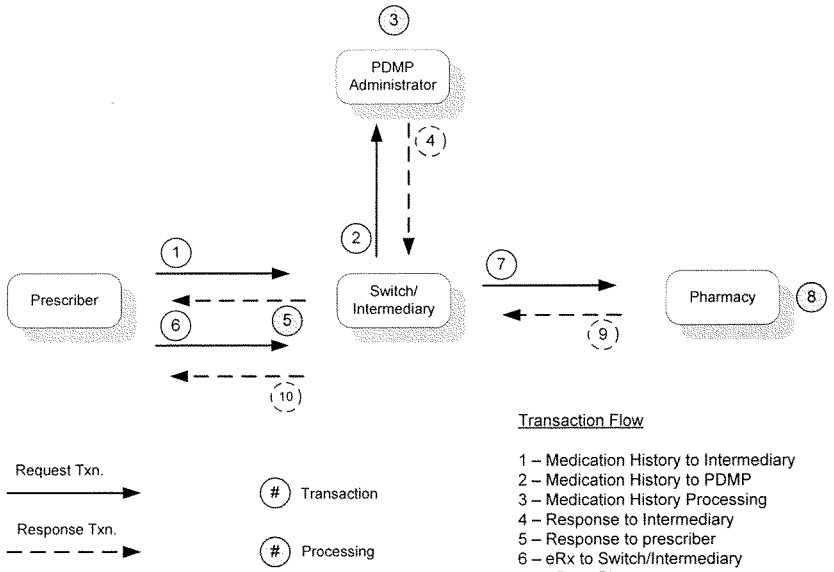
Transaction Flow Sequence
(Prescriber)



Transaction Flow

1 – Medication History to Intermediary
2 – Medication History to PDMP
3 – Medication History Processing
4 – Response to Intermediary
5 – Response to prescriber
6 – eRx to Switch/Intermediary
7 – eRx to Pharmacy
8 – eRx Receipt
9 – Acknowledgement to Intermediary
10 – Acknowledgement to Prescriber

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8. APPENDIX A. HISTORY OF CHANGES

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9. APPENDIX B. LIST OF PARTICIPANTS

Alan Gardner	RxResults. LLC
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Review in Advance first posted online on January 12, 2015. (Changes may still occur before final publication online and in print.)

The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction

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Annu. Rev. Public Health 2015. 36:25.1–25.16

The *Annual Review of Public Health* is online at publhealth.annualreviews.org

This article's doi: 10.1146/annurev-publhealth-031914-122957

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Keywords

prescription drug abuse, heroin, overdose deaths, chronic pain, opioid, addiction

Abstract

Public health authorities have described, with growing alarm, an unprecedented increase in morbidity and mortality associated with use of opioid pain relievers (OPRs). Efforts to address the opioid crisis have focused mainly on reducing nonmedical OPR use. Too often overlooked, however, is the need for preventing and treating opioid addiction, which occurs in both medical and nonmedical OPR users. Overprescribing of OPRs has led to a sharp increase in the prevalence of opioid addiction, which in turn has been associated with a rise in overdose deaths and heroin use. A multifaceted public health approach that utilizes primary, secondary, and tertiary opioid addiction prevention strategies is required to effectively reduce opioid-related morbidity and mortality. We describe the scope of this public health crisis, its historical context, contributing factors, and lines of evidence indicating the role of addiction in exacerbating morbidity and mortality, and we provide a framework for interventions to address the epidemic of opioid addiction.

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INTRODUCTION

Over the past 15 years, the rate of opioid pain relievers (OPR) use in the United States has soared. From 1999 to 2011, consumption of hydrocodone more than doubled and consumption of oxycodone increased by nearly 500% (42). During the same time frame, the OPR-related overdose death rate nearly quadrupled (15). According to the United States Centers for Disease Control and Prevention (CDC), the unprecedented increase in OPR consumption has led to the "worst drug overdose epidemic in [US] history" (58). Given the magnitude of the problem, the CDC recently added opioid overdose prevention to its list of top five public health challenges (13).

Overdose mortality is not the only adverse public health outcome associated with increased OPR use. The rise in opioid consumption has also been associated with a near doubling in visits to emergency rooms for nonmedical OPR use from 2004 to 2011 (69) and in neonatal abstinence syndrome from 2000 to 2009 (57). Moreover, from 1997 to 2011, there was a 900% increase in individuals seeking treatment for addiction to OPRs (66, 68). The correlation between opioid sales, OPR-related overdose deaths, and treatment seeking for opioid addiction is striking (**Figure 1**).

Addiction is defined as continued use of a drug despite negative consequences (1). Opioids are highly addictive because they induce euphoria (positive reinforcement) and cessation of chronic use produces dysphoria (negative reinforcement). Chronic exposure to opioids results in structural and functional changes in regions of the brain that mediate affect, impulse, reward, and motivation (83, 91). The disease of opioid addiction arises from repeated exposure to opioids and can occur in individuals using opioids to relieve pain and in nonmedical users.

Another important feature of the opioid addiction epidemic is the relationship between OPR use and heroin use. According to the federal government's National Survey on Drug Use and Health (NSDUH), 4 out of 5 current heroin users report that their opioid use began with OPRs (54). Many of these individuals appear to be switching to heroin after becoming addicted to OPRs because heroin is less expensive on the black market. For example, in a recent sample of

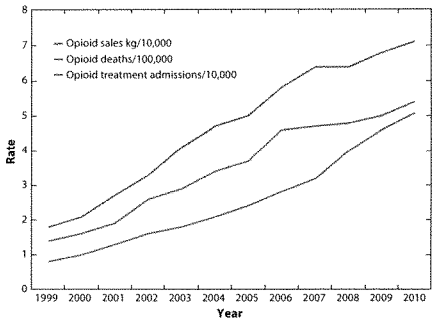

Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain relievers. Source: 10.

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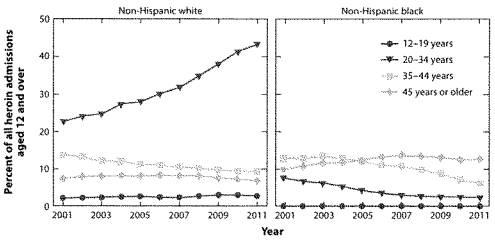

Figure 2

Heroin admissions, by age group and race/ethnicity: 2001–2011. Source: 68.

opioid-addicted individuals who switched from OPRs to heroin, 94% reported doing so because OPRs "were far more expensive and harder to obtain" (16, p. 24).

The increased prevalence of opioid addiction has also been associated with increases in heroin-related morbidity and mortality. For example, since 2001, heroin addiction treatment admissions for whites ages 20–34 have increased sharply (**Figure 2**). During this time frame, heroin overdose deaths among whites ages 18–44 increased by 171% (14).

HISTORY OF OPIOID ADDICTION IN THE UNITED STATES

The current opioid addiction crisis is, in many ways, a replay of history. America's first epidemic of opioid addiction occurred in the second half of the nineteenth century. In the 1840s, the estimated national supply of opium and morphine could have supported a maximum of 0.72 opioid-addicted individuals per 1,000 persons (18). Over the next 50 years, opioid consumption soared by 538%. It reached its peak in the mid-1890s, when the supply could have supported a maximum of ~4.59 opioid-addicted individuals per 1,000 persons. The ceiling rate then began to decline, and by 1920 there were no more than 1.97 opioid-addicted individuals per 1,000 persons in the United States.

The epidemic had diverse origins. Mothers dosed themselves and their children with opium tinctures and patent medicines. Soldiers used opium and morphine to treat diarrhea and painful injuries. Drinkers alleviated hangovers with opioids. Chinese immigrants smoked opium, a practice that spread to the white underworld. But the main source of the epidemic was iatrogenic morphine addiction, which coincided with the spread of hypodermic medication during 1870–1895. The modal opioid-addicted individual was a native-born white woman with a painful disorder, often of a chronic nature.

Nineteenth-century physicians addicted patients—and, not infrequently, themselves—because they had few alternatives to symptomatic treatment. Cures were scarce and the etiology of painful conditions was poorly understood. An injection of morphine almost magically alleviated symptoms, pleasing doctors and patients. Many patients continued to acquire and inject morphine, the sale of which was poorly controlled.

The revolutions in bacteriology and public health, which reduced diarrheal and other diseases commonly treated with opium; the development of alternative analgesics such as aspirin; stricter

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prescription laws; and admonitions about morphine in the lay and professional literature stemmed the addiction tide. One important lesson of the first narcotic epidemic is that physicians were educable. Indeed, by 1919, narcotic overprescribing was the hallmark of older, less-competent physicians. The younger, better-trained practitioners who replaced them were more circumspect about administering and prescribing opioids (5).

For the rest of the twentieth century, opioid addiction epidemics resulted from transient increases in the incidence of nonmedical heroin use in urban areas. After World War II, these epidemics disproportionately affected inner-city minority populations, such as the large, heavily publicized increase in ghetto heroin use and addiction at the end of the 1960s (24, 37).

THE SHARP RISE IN PRESCRIPTION OPIOID CONSUMPTION

In 1986 a paper describing the treatment of 38 chronic pain patients concluded that OPRs could be prescribed safely on a long-term basis (61). Despite its low-quality evidence, the paper was widely cited to support expanded use of opioids for chronic non-cancer pain. Opioid use increased gradually in the 1980s. In 1996, the rate of opioid use began accelerating rapidly (38). This acceleration was fueled in large part by the introduction in 1995 of OxyContin, an extended release formulation of oxycodone manufactured by Purdue Pharma.

Between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants and launched a multifaceted campaign to encourage long-term use of OPRs for chronic non-cancer pain (86). As part of this campaign, Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups, and other organizations (27). In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs.

For example, in 1995, the president of the American Pain Society introduced a campaign entitled "Pain is the Fifth Vital Sign" at the society's annual meeting. This campaign encouraged health care professionals to assess pain with the "same zeal" as they do with vital signs and urged more aggressive use of opioids for chronic non-cancer pain (9). Shortly thereafter, the Veterans' Affairs health system, as well as the Joint Commission, which accredits hospitals and other health care organizations, embraced the Pain is the Fifth Vital Sign campaign to increase the identification and treatment of pain, especially with OPRs. Similarly, the American Pain Society and the American Academy of Pain Medicine issued a consensus statement endorsing opioid use for chronic non-cancer pain (31). Although the statement cautioned against imprudent prescribing, this warning may have been overshadowed by assertions that the risk of addiction and tolerance was low, risk of opioid-induced respiratory depression was short-lived, and concerns about drug diversion and abuse should not constrain prescribing.

Prior to the introduction of OxyContin, many physicians were reluctant to prescribe OPRs on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence (80). To overcome what they claimed to be "opiophobia," physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with "physical dependence." They described addiction as rare and completely distinct from so-called "physical dependence," which was said to be "clinically unimportant" (60, p. 300). They cited studies with serious methodological flaws to highlight the claim that the risk of addiction was less than 1% (28, 45, 52, 59, 62).

In addition to minimizing risks of OPRs, the campaign advanced by opioid manufacturers and pain organizations exaggerated the benefits of long-term OPR use. In fact, high-quality,

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long-term clinical trials demonstrating the safety and efficacy of OPRs for chronic non-cancer pain had never been conducted. Surveys of patients with chronic non-cancer pain receiving long-term OPRs suggest that most patients continued to experience significant chronic pain and dysfunction (25, 76). The CDC and some professional societies now warn clinicians to avoid prescribing OPRs for common chronic conditions (29).

Although increased opioid consumption over the past two decades has been driven largely by greater ambulatory use for chronic non-cancer pain (8), opioid use for acute pain among hospitalized patients has also increased sharply. A recent study found that physicians prescribed opioids in more than 50% of 1.14 million nonsurgical hospital admissions from 2009 to 2010, often in high doses (34). The Joint Commission's adoption of the Pain is the Fifth Vital Sign campaign and federally mandated patient satisfaction surveys asking patients to rate how often hospital staff did "everything they could to help you with your pain" are noteworthy, given the association with increased hospital use of OPRs.

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REFRAMING THE OPIOID CRISIS AS AN EPIDEMIC OF ADDICTION

Policy makers and the media often characterize the opioid crisis as a problem of nonmedical OPR abuse by adolescents and young adults. However, several lines of evidence suggest that addiction occurring in both medical and nonmedical users, rather than abuse per se, is the key driver of opioid-related morbidity and mortality in medical and nonmedical OPR users.

Opioid Harms Are Not Limited to Nonmedical Users

Over the past decade, federal and state policy makers have attempted to reduce OPR abuse and OPR-related overdose deaths. Despite these efforts, morbidity and mortality associated with OPRs have continued to worsen in almost every US state (10). Thus far, these efforts have focused primarily on preserving access to OPRs for chronic pain patients while reducing nonmedical OPR use (89), defined as the use of a medication without a prescription, in a way other than as prescribed, or for the experience or feeling it causes. However, policy makers who focus solely on reducing nonmedical use are failing to appreciate the high opioid-related morbidity and mortality in pain patients receiving OPR prescriptions for medical purposes.

The incidence of nonmedical OPR use increased sharply in the late 1990s, peaking in 2002 with 2.7 million new nonmedical users. Since 2002, the incidence of nonmedical use has gradually declined to ~1.8 million in 2012 (64, 70) (**Figure 3**). Although the number of new nonmedical users has declined, overdose deaths, addiction treatment admissions, and other adverse public health outcomes associated with OPR use have increased dramatically since 2002.

A comparison of age groups of nonmedical OPR users to age groups suffering the highest rates of opioid-related morbidity and mortality suggests that strategies focused exclusively on reducing nonmedical OPR use are insufficient (**Figure 4**). Although past-month nonmedical use of OPRs is most common in teenagers and young adults between the ages of 15 and 24 (65), OPR overdose deaths occur most often in adults ages 45–54, and the age group that has experienced the greatest increase in overdose mortality over the past decade is 55–64 (15), an age group in which medical use of OPRs is common. Opioid overdoses appear to occur more frequently in medical OPR users than in young nonmedical users. For example, in a study of 254 unintentional opioid overdose decedents in Utah, 92% of the decedents had been receiving legitimate OPR prescriptions from health care providers for chronic pain (39).

Middle-aged women and the elderly are more likely than other groups to visit doctors with complaints of pain (4). The development of iatrogenic opioid addiction in these groups may explain why they have experienced the largest increase in hospital stays resulting from opioid user

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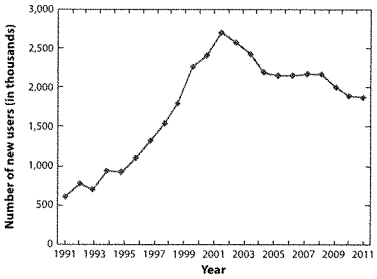

Figure 3

First-time nonmedical use of pain relievers. Source: 64, 70.

disorders since 1993 (56) (**Figure 5**). Over the past decade, white women ages 55–64 have also experienced the largest increase in accidental opioid overdose deaths (12, 15).

Opioid Addiction Is a Key Driver of Morbidity and Mortality

Accidental opioid overdose is a common cause of death in individuals suffering from opioid addiction (36). Although overdoses do occur in medical and nonmedical OPR users who are not

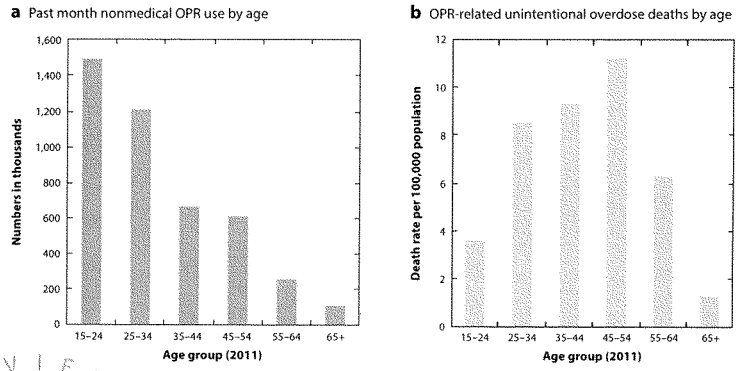

Figure 4

(*a*) Past month nonmedical OPR use by age versus (*b*) OPR-related unintentional overdose deaths by age. Abbreviation: OPR, opioid pain relievers. Sources: 58, 68.

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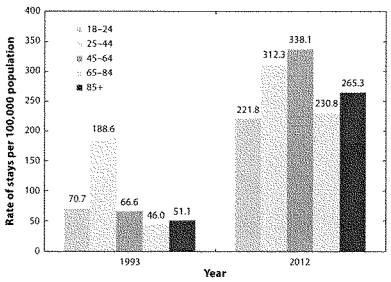

Figure 5

Rate of hospital inpatient stays related to opioid use disorders by adult age group, 1993 and 2012. Source: 56.

opioid-addicted, consistent findings in samples of OPR overdose decedents show that deaths are most common in individuals likely to be suffering from opioid addiction. A study of 295 unintentional OPR overdose deaths in West Virginia found that four out of five decedents (80%) had a history of a substance use disorder (33). Another study found that among 254 opioid overdose decedents in Utah, about three-fourths (76%) had relatives or friends who were concerned about the decedent's misuse of opioids prescribed for pain (39).

The sharp increase in the prevalence of opioid addiction is a key driver of opioid-related morbidity and mortality. The misattribution of the opioid crisis to nonmedical use or abuse rather than to addiction has stymied efforts to address this crisis because it suggests a different set of policies. When the opioid crisis is reframed from an "epidemic of opioid abuse" to an "epidemic of opioid addiction," the strategies required to control the epidemic become clearer.

PREVENTION STRATEGIES

This section organizes strategies for curbing the epidemic of opioid addiction into primary, secondary, and tertiary prevention. Although some specific interventions are discussed, we do not provide an exhaustive list. Rather, our purpose is to demonstrate that prevention strategies employed in epidemiologic responses to communicable and noncommunicable disease epidemics apply equally well when the disease in question is opioid addiction. Interventions should focus on preventing new cases of opioid addiction (primary prevention), identifying early cases of opioid addiction (secondary prevention), and ensuring access to effective addiction treatment (tertiary prevention).

Primary Prevention

The aim of primary prevention is to reduce the incidence of a disease or condition. Opioid addiction is typically chronic, life-long, difficult to treat, and associated with high rates of morbidity and mortality. Thus, bringing the opioid addiction epidemic under control requires effort to prevent new cases from developing.

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Preventing addiction caused by medical exposure to OPRs. The incidence of iatrogenic opioid addiction in patients treated with long-term OPRs is unknown because adequately designed prospective studies have not been conducted. However, opioid use disorders appear to be highly prevalent in chronic pain patients treated with OPRs. A survey performed by Boscarino et al. of 705 chronic pain patients treated in specialty and primary care outpatient centers found that 26% met the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) IV criteria for opioid dependence, and 35% met DSM V criteria for an opioid use disorder (6, 7). A systematic review of studies utilizing opioids for low back pain found that aberrant drug abuse–related behaviors suggestive of addiction occurred in up to 24% of patients on long-term OPRs (50). Many patients on long-term OPRs worry about dependence and addiction and express a desire to taper or cease opioid therapy (76).

To reduce the incidence of iatrogenic opioid addiction, health care professionals must prescribe opioids more cautiously for both acute and chronic pain. Unfortunately, the campaign to encourage OPR prescribing has left many health care providers with a poor appreciation of opioid risks, especially the risk of addiction, and an overestimation of opioid benefits. Despite these risks and the lack of evidence supporting long-term efficacy, OPR prescribing for chronic non-cancer pain increased over the past decade while use of nonopioid analgesics decreased (20). This pattern highlights the need for prescriber education that explicitly corrects misperceptions about OPR safety and efficacy. If clinicians treating pain more often substituted nonopioid analgesics and nonpharmaceutical approaches for OPRs, evidence suggests the incidence of opioid addiction would decline and outcomes for patients with chronic non-cancer pain would improve.

Many prescribers are unaware that evidence of long-term effectiveness for OPRs is lacking and that risks, in addition to addiction, include respiratory depression leading to unintentional overdose death; serious fractures from falls (71, 77); hypogonadism and other endocrine effects that can cause a spectrum of adverse effects (88); increased pain sensitivity (2); chronic constipation and serious fecal impaction (81); and chronic dry mouth, which can lead to tooth decay (79). Providing prescribers with accurate information about opioid risks and benefits could result in more informed risk/benefit appraisals. Indeed, one of the lessons learned from the nineteenth-century opioid addiction epidemic was that physicians were educable. By the early 1900s, aggressive opioid prescribing had become the hallmark of older, less-competent physicians (5).

Several states, including Iowa, Kentucky, Massachusetts, Ohio, Tennessee, and Utah, have passed mandatory prescriber education legislation (89). In addition, the US Food and Drug Administration (FDA) is requiring manufacturers of extended release and long-acting OPRs to sponsor educational programs for prescribers. Unfortunately, some of these educational programs, including those required by the FDA, imply that OPRs are safe and effective for chronic non-cancer pain instead of offering prescribers accurate information about OPR risks and benefits (84). It remains unclear whether or not educational programs such as these will reduce OPR prescribing for common conditions where risks of use are likely to outweigh benefits.

Some opioid manufacturers have reformulated OPRs to make them more difficult to misuse through an intranasal or injection route. These so-called abuse-deterrent formulations (ADFs) may offer safety advantages over easily snorted and injected OPRs, but they do not render them less addictive. Opioid addiction, in both medical and nonmedical OPR users, most frequently develops through oral use (85). Some opioid-addicted individuals may transition to intranasal or injection use, but most continue to use OPRs orally (47). Thus, ADFs should not be considered a primary prevention strategy for opioid addiction.

In 2013, the New York City Department of Health and Mental Hygiene released emergency room guidelines on OPR prescribing (55). Recommendations included in the guidelines call for substituting nonopioid analgesics when possible, avoiding use of extended-release OPRs, and

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limiting the supply to three days. Reducing patient exposure to OPRs and reducing the supply of excess OPRs in the homes of discharged patients may be effective strategies for preventing opioid addiction that can occur from both medical and nonmedical OPR use.

Preventing addiction caused by nonmedical exposure to OPRs. Individuals who use OPRs nonmedically are at risk for developing opioid addiction. Thus, efforts to reduce nonmedical use are an important primary prevention strategy. Adolescents and young adults who experiment with nonmedical use are most likely to obtain OPRs for free from friends or family members who had received a legitimate prescription (70). This information suggests that more cautious prescribing is required to prevent nonmedical use of excess OPRs. Unused OPRs in medicine chests should be immediately discarded or returned to a pharmacy, which became permissible in October 2014 after the Drug Enforcement Administration made a federal regulatory change (82).

Although OPRs have an abuse liability similar to that of heroin (17), they are commonly perceived as less risky. Seventy-three percent of eighth graders surveyed in 2013 perceived occasional use of heroin without a needle as high risk, but only 26% perceived occasional use of Vicodin as high risk (41). Eighth graders also perceived occasional Vicodin use as less risky than occasional marijuana use, less risky than smoking 1–5 cigarettes per day, and less risky than moderate alcohol use.

Individuals who perceive the risk of nonmedical OPR use to be low may be more likely to misuse OPRs. A 2004 survey found that college students who perceive a low level of risk from OPRs were 9.6 times more likely to use OPRs nonmedically, as compared with those who perceive these medications as harmful (3). Although the ability for causal inference from this type of cross-sectional survey is limited, this finding suggests that social marketing campaigns designed to increase perceived harmfulness of OPRs may be an effective prevention strategy.

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Secondary Prevention

The aim of secondary prevention is to screen for a health condition after its onset but before it causes serious complications. Efforts to identify and treat opioid-addicted individuals early in the course of the disease are likely to reduce the risk of overdose, psychosocial deterioration, transition to injection opioid use, and medical complications.

Physicians are frequently the source of OPRs for opioid-addicted medical and nonmedical users (43). Contacts with medical professionals present valuable opportunities for early identification of opioid addiction. However, detection of opioid addiction in OPR users can be very difficult. Opioid-addicted chronic pain patients may demonstrate aberrant drug-related behaviors, such as presenting for early refills. However, some opioid-addicted pain patients, especially those prescribed high doses, may not demonstrate drug-seeking behavior. Opioid-addicted individuals receiving OPR prescriptions are often reluctant to disclose their concerns about addiction with prescribers because they fear being judged, being cut off from a legitimate supply, or being labeled as malingerers for feigning pain.

The difficulty of diagnosing opioid addiction in individuals motivated to conceal their condition suggests that prescribers should seek collateral information before prescribing OPRs. Urine toxicology can be used to verify a patient's self-reported drug ingestion history (53). However, urine toxicology of patients on long-term OPRs is not a reliable strategy for identifying opioid addiction. Urine toxicology cannot determine if a patient is taking extra doses or if a patient is using OPRs by an intranasal or injection route.

Opioid-addicted individuals may receive OPR prescriptions from multiple providers, a practice referred to as "doctor shopping." Doctor shoppers can be identified through use of state

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prescription drug monitoring programs (PDMPs). Some state PDMPs send unsolicited reports to the medical providers of doctor shoppers. Research suggests that unsolicited reports increase prescribers' ability to detect opioid addiction, sometimes prompting actions such as coordinating care with other providers and modifying their own prescribing practices, as well as screening and referring for addiction treatment (78).

Prescribers in most states can consult their state PDMP before prescribing OPRs. PDMPs may be especially useful in emergency rooms and other settings where opioid-addicted individuals feign pain to obtain OPRs. Too often, however, patients identified as doctor shoppers are simply turned away, without hospital staff attempting to link these patients to addiction treatment services. Efforts must be made to help these clinicians understand that drug-seeking patients are suffering from the chronic, life-threatening disease of opioid addiction.

One challenge to PDMP effectiveness has been the low rate of provider use of these data (48). To increase prescriber utilization, Kentucky, Tennessee, and New York passed legislation mandating that prescribers check the PDMP before prescribing controlled substances. Data from these states indicate that PDMP utilization increased rapidly subsequent to the mandate, which correlated with declines in opioid prescribing (KY, TN, NY) and a sharp drop in visits to multiple providers (TN, NY) (35).

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Tertiary Prevention

Tertiary prevention strategies involve both therapeutic and rehabilitative measures once a disease is firmly established. The goal of tertiary prevention of opioid addiction is to prevent overdose deaths, medical complications, psychosocial deterioration, transition to injection drug use, and injection-related infectious diseases. Doing so is accomplished mainly by ensuring that opioid-addicted individuals can access effective and affordable opioid addiction treatment.

Opioid addiction treatment. The need for opioid addiction treatment is great and largely unmet. According to the NSDUH, an estimated 2.1 million Americans are addicted to OPRs, and 467,000 are addicted to heroin (70). Unfortunately, these estimates exclude many opioid-addicted pain patients because NSDUH participants are told by surveyors that "we are only interested in your use of prescription pain relievers that were not prescribed for you or that you used only for the experience or feeling they caused" (67, p. 124).

In 2005, there were an estimated 10 million chronic pain patients receiving daily, long-term treatment with OPRs (8). The continuing increase in opioid consumption from 2005 to 2011 (42) suggests that the number may now exceed 10 million. Applying the prevalence estimates of DSM V opioid dependence found by Boscarino et al. (6) in pain patients taking long-term opioids would indicate that an additional 2.5 million chronic pain patients may be opioid-addicted. Thus, the total number of Americans suffering from opioid addiction may exceed 5 million.

Treatment of opioid addiction includes pharmacotherapies and psychosocial approaches, including residential treatment, mutual-help programs (e.g., Narcotics Anonymous), and 12-Step treatment programs. These modalities may be used as stand-alone interventions or in combination with pharmacotherapy. Psychosocial opioid addiction treatment approaches show value and are an important treatment option (63). However, research with greater specificity and consistency is needed to better evaluate outcomes.

Pharmacotherapies for opioid addiction include agonist maintenance with methadone and partial-agonist maintenance with buprenorphine and antagonist treatment with naltrexone, which is available in a monthly injection. Methadone and buprenorphine work by controlling cravings. Naltrexone works by preventing opioid-addicted individuals from feeling the effects of opioids.

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Naltrexone may be helpful in highly motivated and carefully selected patients. However, patients treated with naltrexone may be at increased risk of overdose death should relapse occur (23).

Multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe and effective treatments for opioid addiction (30, 40, 46, 49, 74, 75). Both buprenorphine and methadone treatment are associated with reduced overdose risk and improved maternal and fetal outcomes in pregnancy (19, 44, 51, 72). Despite strong evidence supporting the use of buprenorphine and methadone, fewer than 1 million Americans are receiving these treatments (87).

Methadone poses a substantially greater risk of respiratory depression than does buprenorphine and can be obtained only from licensed opioid treatment programs (OTPs). The lack of OTPs in many communities presents a major challenge to expanding access to methadone. In contrast, buprenorphine, a partial opioid agonist, has a better safety profile than does methadone and can be prescribed in an office-based setting (26). Barriers to accessing buprenorphine include federal limits on the number of patients a physician may treat, ineligibility of nurse practitioners to prescribe it, and inadequate integration of buprenorphine into primary care treatment. Access to buprenorphine treatment could be expanded if the federal government eased or remove regulatory barriers.

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Harm-reduction approaches. Tertiary prevention strategies also include harm-reduction approaches to improving health outcomes and reducing overdose deaths. In the subset of opioid-addicted individuals who are heroin injection drug users, evidence suggests that access to syringe exchange programs can prevent HIV infection (22). These efforts have been less effective at preventing hepatitis C infection, which is increasing rapidly in young, white IDUs (32).

Expanding access to naloxone, an opioid overdose antidote, can prevent overdose deaths by reversing life-threatening respiratory depression. In the 1990s, syringe exchange programs began distributing naloxone to injection drug users for the purpose of rescuing peers. Evidence shows that clients of syringe exchange programs demonstrated the ability to successfully reverse overdoses when they had been provided with naloxone and training (73). In addition, providing family members of opioid-addicted individuals and nonparamedic first responders with naloxone may be an effective strategy for rescuing overdose victims (21, 90). At present, there are more than 188 community-based naloxone distribution programs in 15 states and the District of Columbia (11).

CONCLUSION

The increased prevalence of opioid addiction, caused by overprescribing of OPRs, has led to a parallel increase in opioid overdose deaths. Efforts to address this crisis that focus exclusively on reducing nonmedical OPR use have been ineffective. Middle-aged and elderly individuals commonly exposed to OPRs for pain treatment have experienced the largest increase in rates of opioid-related morbidity and mortality. Recognition that opioid addiction in both medical and nonmedical users is a key driver of opioid-related morbidity and mortality will result in a more effective response to this public health crisis. Just as public health authorities would approach other disease outbreaks, efforts must be made to reduce the incidence of opioid addiction, identify cases early, and ensure access to effective treatment.

Preventing opioid addiction requires strategies that foster more cautious and selective OPR prescribing. However, if prescribing is reduced without also ensuring access to addiction treatment, the opioid overdose death rate may remain at a historically high level and the use of heroin may continue to increase. Coordinated efforts from federal agencies, state agencies, health care insurers, and health care providers are required to address the needs of millions of Americans now struggling with this chronic, life-threatening disease.

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DISCLOSURE STATEMENT

Dr. Alexander is Chair of the FDA's Peripheral and Central Nervous System Advisory Committee, serves as a paid consultant to IMS Health, and serves on an IMS Health scientific advisory board. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Ms. Hwang is a current ORISE Fellow at the FDA.

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Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on:

"Examining Public Health Legislation to Help Patients and Local Communities"

January 27, 2015
10:15 a.m.
2322 Rayburn House Office Building

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Green, and members of the Subcommittee on Health for the opportunity to share our perspectives on public health issues and policies designed to help patients and local communities. As the face of neighborhood healthcare, community pharmacies and pharmacists play a vital role in promoting the health, safety, and well-being of the American people. The pharmacy community shares the Committee's desire to promote policies that will improve patient outcomes and lead to healthier, safer communities. To that end, we are pleased to offer our support for two pieces of legislation being considered by the Committee today that serve this purpose – the "Ensuring Patient Access to Effective Drug Enforcement Act," (H.R. 471), and the "National All Schedules Prescription Electronic Reporting (NASPER) Authorization Act."

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' 115 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3.3 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and 60 international members representing 22 countries. For more information, visit www.NACDS.org.

The Ensuring Patient Access and Effective Drug Enforcement Act of 2015

NACDS and its members strongly support H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015. This important bill would promote a comprehensive approach to preventing prescription drug diversion and abuse by facilitating policies that enable law enforcement entities to serve the public and act to address prescription drug diversion and abuse, while still maintaining patient access to medically necessary medications. Achieving these related goals is critical to the

development of viable and effective policies to prevent prescription drug diversion and abuse.

This bill is crafted to foster the development of sound policies by directing the Department of Health and Human Services (HHS) to work jointly with the Drug Enforcement Administration and the Office of National Drug Control Policy to assess obstacles to legitimate patient access to controlled substances, and to identify how collaboration between agencies and stakeholders can benefit patients and prevent diversion and abuse of prescription drugs. Moreover, this legislation would require HHS to consult with patient and provider groups, including pharmacies, among other stakeholders. Pharmacies are critical stakeholders in efforts to prevent prescription drug diversion and abuse, and we appreciate the recognition of pharmacies as having important perspectives to share on this topic.

The NASPER Reauthorization Act

While most individuals take prescription medications responsibly, we recognize that the potential exists for controlled substances to be diverted and abused. To help prevent and reduce the diversion and abuse of prescription drugs, NACDS supports federal efforts through the NASPER Reauthorization Act to assist states with funding for state prescription drug monitoring programs. State prescription drug monitoring programs serve important national and state public health goals and warrant federal support.

Over the years, prescription drug monitoring programs have become important tools used to identify and prevent drug abuse, misuse and diversion. Recognizing the important role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support these programs in the 49 states where they have been implemented. Pharmacies submit information on the controlled substances they dispense on a daily or weekly basis depending on the particular state's program requirements. This information includes data on the patient, prescribed drug dosage and quantity, and the prescriber. With the information that is collected, states can conduct confidential reviews to

determine any patterns of potential abuse or diversion. The information also serves as a resource that practitioners can access to make informed treatment decisions.

It is not uncommon for patients to cross state borders for healthcare services. To ensure that practitioners have access to robust prescription drug monitoring program data, states should work to establish interoperability with other states' prescription monitoring programs. Many states are already working to implement interstate data sharing now that standards and data hubs are in place to facilitate this practice. However, where a particular state has not initiated a process to achieve interoperability with other state programs, that state should do so to optimize their prescription drug monitoring program. NACDS appreciates the support that NASPER reauthorization would provide to states toward achieving interstate prescription drug monitoring program interoperability.

Conclusion

NACDS thanks the Subcommittee for consideration of our perspectives on policies that reduce the incidence of prescription drug diversion and abuse. We appreciate the opportunity to work members of Congress, as well as other policymakers, to promote the health and welfare of our patients and all Americans.

January 22, 2015

The Honorable Marsha Blackburn
United States House of Representatives
217 Cannon House Office Building
Washington, DC 20515

The Honorable Tom Marino
United States House of Representatives
410 Cannon House Office Building
Washington, DC 20515

The Honorable Peter Welch
United States House of Representatives
2303 Rayburn House Office Building
Washington, DC 20515

The Honorable Judy Chu
United States House of Representatives
1520 Longworth House Office Building
Washington, DC 20515

Dear Congressmen Blackburn, Marino, Welch and Chu:

We, the undersigned organizations – representing pharmaceutical distributors and pharmacies, – would like to express our support for the Ensuring Patient Access and Effective Drug Enforcement Act of 2015 (H.R. 471). We appreciate your leadership and commitment to working with the healthcare supply chain and law enforcement to combat the inappropriate use of prescription medicines. Your legislation is a timely and thoughtful approach to addressing the drug abuse epidemic.

Millions of Americans depend on prescription drugs to treat and cure illness, alleviate pain, and improve quality of life. Unfortunately, prescription drug abuse is steadily rising. Federal agencies and private parties in the drug supply chain are working diligently to prevent drug abuse and diversion; however, it is also imperative that patients with legitimate pain are able to obtain their prescriptions without disruption. To that end, we believe the legislation will foster greater collaboration, communication and transparency between industry stakeholders and regulators, leading to more effective efforts to combat abuse while protecting patients.

This legislation will clarify key terminology in the Controlled Substances Act to give registrants a better understanding of their responsibilities under the law. This bill will also allow DEA-registered companies to submit corrective action plans to address any agency concerns, creating a more robust and transparent process to address drug diversion with the intention of curtailing unnecessary supply chain disruptions that affect patient access to needed medications. Importantly, the report to Congress will encourage meaningful dialogue to identify how collaboration between agencies and stakeholders can benefit patients and help prevent the diversion and abuse of controlled substances.

We are committed to being part of the solution to this serious public health challenge, working collaboratively with supply chain partners and government officials to address prescription drug abuse and finding ways to slow this epidemic. We commend you for your leadership on this important issue and we look forward to supporting your efforts to advance this legislation.

Sincerely,

American Pharmacists Association
Healthcare Distribution Management Association
National Association of Chain Drug Stores
National Community Pharmacists Association

John M. Gray, President & Chief Executive Officer

January 22, 2015

The Honorable Marsha Blackburn
United States House of Representatives
217 Cannon House Office Building
Washington, DC 20515

The Honorable Tom Marino
United States House of Representatives
410 Cannon House Office Building
Washington, DC 20515

The Honorable Peter Welch
United States House of Representatives
2303 Rayburn House Office Building
Washington, DC 20515

The Honorable Judy Chu
United States House of Representatives
1520 Longworth House Office Building
Washington, DC 20515

Dear Representatives Blackburn, Marino, Welch and Chu:

On behalf of the Healthcare Distribution Management Association (HDMA) and our 34 primary pharmaceutical distributor members, I would like to express HDMA's support for the Ensuring Patient Access and Effective Drug Enforcement Act of 2015. We appreciate your leadership and commitment to working with the healthcare supply chain and law enforcement to combat the inappropriate use of prescription medicines.

HDMA believes the legislation will foster greater collaboration, communication and transparency between industry stakeholders and regulators, especially the Drug Enforcement Administration (DEA). This legislation will clarify key terminology in the Controlled Substances Act to give registrants a better understanding of their responsibilities under the law. This bill will also allow DEA-registered companies to submit corrective action plans to address any agency concerns, creating a more robust and transparent process to address drug diversion with the intention of curtailing unnecessary supply chain disruptions that affect patient access to needed medications. In addition, the report to Congress will encourage meaningful dialogue to identify how collaboration between agencies and stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

HDMA and its primary pharmaceutical distributor members are committed to being part of the solution to this serious public health challenge, working collaboratively with supply chain partners and government officials to address prescription drug abuse and finding ways to slow this epidemic. Again, HDMA commends you for your leadership on this important issue and we look forward to supporting your efforts to advance this legislation.

Sincerely,

John M. Gray
President and CEO

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RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
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COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225-2927
Minority (202) 225-3641

February 25, 2015

Mr. D. Linden Barber
Quarles & Brady LLP
135 N. Pennsylvania Street, Suite 2400
Indianapolis, IN 46204

Dear Mr. Barber:

Thank you for appearing before the Subcommittee on Health on January 27, 2015, to testify at the hearing entitled "Examining Public Health Legislation to Help Patients and Local Communities."

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

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, March 10, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

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

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

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March 9, 2015

Via U.S. Mail and E-mail

The Honorable Joseph R. Pitts, Chairman
Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for calling me to testify before the Subcommittee on Health on January 27, 2015, at the hearing "Examining Public Health Legislation to Help Patients and Local Communities." Attached to this letter are the questions for the record I received from the Honorable G.K. Butterfield and my responses to those questions. Should you or other members of the Committee have additional questions, I would be pleased to respond to those questions.

Very truly yours,

QUARLES & BRADY LLP

[redacted]

D. Linden Barber

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health
Adrianna Simonelli, Legislative Clerk

Attachment

DLB:rs

"Examining Public Health Legislation to Help Patients and Local Communities"
Hearing before the House Energy and Commerce
Subcommittee on Health held on January 27, 2015

Questions for the Record from the Honorable G.K. Butterfield
Directed to D. Linden Barber

Mr. Barber, we've heard from many people about the need to pass the Improving Regulatory Transparency for New Medical Therapies Act to expedite patient access to new medicines. Over the past 15 years, the average time to reach a DEA scheduling decision has increased dramatically.

a) **Mr. Barber, given your prior service in the DEA, what do you see as the main reason for this dramatic increase in review time?**

RESPONSE: The reasons for the increasing delay are not transparent to the public nor were they transparent to me when I was the Associate Chief Counsel at DEA. However, my experience with the Agency leads me to conclude that the primary reason for the increase in the time to schedule new molecular entities is that DEA tends to prioritize its enforcement mission to prevent diversion above its regulatory mission to ensure an adequate and uninterrupted supply of controlled medications to meet the legitimate medical needs of the United States. DEA has communicated to registrants that the Agency is first and foremost an enforcement agency, not a regulatory agency. In light of the enormous problem of prescription drug abuse, this is somewhat understandable. However, it is possible for the Agency to be both a strong enforcement agency and a responsive regulatory agency. A second reason for the increasing delays in scheduling new molecular entities is what appears to be a misunderstanding on the part of DEA about its role in scheduling these entities. The DEA is bound by the medical and scientific findings of the Secretary of Health and Human Services. DEA's role is to examine law enforcement data and information on diversion in reaching a decision about scheduling. With new molecular entities, there is no law enforcement data or history of diversion for DEA to study. Thus, there is nothing within the purview of DEA for the Agency to study that would add anything meaningful to the medical and scientific findings of the Department of Health and Human Services. Searching for law enforcement and diversion-related information on new molecular entities is futile. To the extent that DEA undertakes such queries, the Agency is unnecessarily delaying the scheduling of new molecular entities that are approved by FDA from reaching the market where patients can benefit from these products that FDA has determined are safe and effective for medical use.

b) **How often does the DEA reach a scheduling determination that differs from the FDA's recommendation and what are the leading factors that delay the Agency in making decisions?**

RESPONSE: My review of more than a decade of scheduling decisions on new molecular entities reveals that DEA has without exception adopted the FDA's scheduling recommendation on new molecular entities. The likely factors leading to the delay in DEA scheduling new molecular entities are the DEA's focus on enforcement issues rather than regulatory issues and the Agency undertaking futile inquiries which have proven to add no value to the scheduling process. These factors are discussed more fully in section a, above.

c) **Do you foresee typical circumstances that would prevent the DEA from reaching an interim scheduling determination within 45 days of the FDA's recommendation?**

RESPONSE: The only plausible explanation for DEA requiring more than 45 days to schedule new molecular entities is that the Agency must publish the proposed scheduling action in the Federal Register, provide an adequate period for public comment, and then respond to any comments in the promulgation of the Final Rule scheduling the new molecular entity. These steps are required by the Administrative Procedure Act. However, it would be feasible for DEA to publish a proposed scheduling action within five days of receiving FDA's recommendation since the proposed rules for scheduling new molecular entities are largely boilerplate proposed rules that require little original drafting by DEA. A thirty comment period is typical. Unless the Agency receives an unusual number of comments that raise complicated issues, DEA should be able to publish a Final Rule within ten days of the close of the comment period. Using the timelines above, DEA should be able to schedule new molecular entities within forty-five days of receiving FDA's scheduling recommendation.

However, this process could be even further expedited if Congress amended the CSA and directed DEA to publish its scheduling action on new molecular entities without undertaking the procedures required by the Administrative Procedure Act. The rational for Congressional action along these lines is three-fold: 1) history indicates that DEA always accepts FDA's scheduling recommendation for new molecular entities so there is no value added in DEA delaying scheduling to undertake an independent review of the scheduling decision; 2) once FDA finds that a new molecular entity has an accepted medical use in the United States, DEA has no choice but schedule the drug in Schedule II, III, IV, or V since Schedule I drugs have no accepted medical use in the United States; and 3) DEA has emergency scheduling power under 21 U.S.C. §811(h) which would allow DEA to increase move the new molecular entity to a more restrictive schedule on an emergency basis if information

supported such an action after the substance become available to the public. Taking action to expedite the scheduling of new molecular entities would serve the both purposes of the Controlled Substances Act as reflecting in the Congressional findings of 21 U.S.C. § 801. The public would have timely access to new drugs that are helpful to American people. Meanwhile, placing new drugs in the Schedule recommended by FDA would serve to prevent the diversion and abuse of those drugs as all controlled substances without regard to the schedule of the drugs are subject to significant restrictions and if more restrictive scheduling were necessary based on an imminent hazard to public health, DEA could exercise its emergency scheduling powers.

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