

MANAGING PAIN DURING THE OPIOID CRISIS

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED SIXTEENTH CONGRESS
FIRST SESSION
ON
EXAMINING MANAGING PAIN DURING THE OPIOID CRISIS

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FEBRUARY 12, 2019
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MANAGING PAIN DURING THE OPIOID CRISIS

Tuesday, February 12, 2019

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Burr, Isakson, Collins, Cassidy, Murkowski, Romney, Murray, Baldwin, Hassan, Smith, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order. Senator Murray and I will each have an opening statement and then we will introduce witnesses. After their testimony, Senators will each have a five-minute round of questions. Dan, who is a constituent of mine in Maryville, Tennessee, recently wrote me about his wife who has a rare disease that causes chronic pain. Dan is concerned because it has become more difficult for her to find, access painkillers. This is what Dan wrote, “She is not an abuser, and is doing everything right now; it is harder for her to get the medicine she needs.” Dan’s wife is 1 of 100 million Americans, who according to a 2011 report by what is now the National Academy of Medicine, are living with some pain. That is about 30 percent of Americans—25 million of those, the Academy said, have moderate to severe pain.

A new report in 2018 by the Center for Disease Control and Prevention says, about 50 million Americans have chronic pain. Nearly 20 million of those Americans have high-impact chronic pain. And here is the reality. We are engaged in a massive bipartisan effort to make dramatic reductions in the supply and use of opioids, which is the most effective painkiller that we have. But on the theory that every action has an unintended consequence, we want to make sure that as we deal with the Opioid Crisis, that we keep in mind those Americans who are hurting. We are holding this hearing to better understand the causes of pain, how we can improve care for patients with pain, and where we are on developing new medicines and ways to treat pain.

We know that pain is one of the most frequent reasons that people see a doctor. And according to the Mayo Clinic, the number of adults in the United States with pain is higher than the number of people with diabetes, heart disease, and cancer combined. These Americans need more effective ways than opioids, or other addict-

ive painkillers, to manage pain. Opioids, which are commonly used to treat pain, can lead to addiction and overuse. We know that well.

More than 70,000 Americans died from drug overdoses last year, including prescription opioids, making it the biggest public health crisis in our country, affecting nearly every community. Last year, in the midst of the acrimony of the Kavanaugh hearing, Congress and another part of the Capitol saw 72 different Senators—or 70 Senators offering 72 different suggestions for a comprehensive opioid legislation, which passed the Congress, and which President Trump signed and called the largest single bill to combat a drug crisis in the history of our country. That legislation, from all those Senators, included eight Committees in the House and five in the Senate, included reauthorizing training program for doctors and nurses who prescribe treatments for pain, increasing access to behavioral and mental health providers, encouraging the use of blister packs for opioids such as 3 or 7-day supply, and safe ways of disposing unused drugs.

We also took steps to ensure our new law would not make life harder for patients with pain, but now we need to take the next step to find new ways to help them. First, we gave the National Institutes of Health more flexibility and authority to spur research and development of new, non-addictive painkillers. We also asked the Food and Drug Administration to provide guidance for those developing new, non-addictive painkillers to help get them to patients more quickly. I am pleased to see commissioner Gottlieb's announcement this morning that the agency is developing new guidance's on how FDA evaluate the risks and the benefits of new opioid treatments for patients with pain, and to help the development of non-opioid treatments for pain.

Sam Quinones, a witness at one of our hearings, called new addictive—new non-addictive painkillers the “Holy Grail to solving the Opioid Crisis.” We have backed up those new authorities with substantial funding. Most recently, \$500 million to help the National Institutes of Health find a new non-addictive painkiller.

Second, we included provisions to encourage new pain management strategies such as physical therapy. And third, the new law requires experts to study chronic pain and report to the Director of the National Institutes of Health how patients can better manage their pain. And fourth, the new law requires the Secretary of Health and Human Services to report the impact on pain patients that Federal and state laws and regulations that limit the length quantity and dosage of opioid prescriptions.

Now that we have started to turn the train around and head in a direction that is different on the use of opioids, every one of us, doctors, nurses, insurers, patients, Senators, Congressmen, will need to think about the different ways we treat and manage pain.

There are other things the Federal Government is doing to understand what causes pain and how we treat and manage it. For example, the National Pain Strategy, developed by the Interagency Pain Research Coordinating Committee, which develops recommendations, prevent, treat, manage, and research pain. Through the National Institute on Drug Abuse, the National Institutes of Health HEAL Initiative, researchers are working to better under-

stand pain and why some people experience it differently than others. This will help us find more ways to more effectively treat pain and help get people the treatment they need. For example, physical therapy or exercise may be the best course of treatment for some kinds of back pain.

It may also help us understand why some people can take opioids or manage their pain for years without becoming addicted, while others more easily become addicted. Today, I hope to hear more about how close we are to having non-addictive painkillers and how doctors and nurse can better treat Americans who live with pain. Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much Mr. Chairman. Thank you to all of our witnesses for joining us today.

This Committee has done a lot of important work on the Opioid Crisis that families and communities across the country are facing. I was glad we were able to come together last year to take strong bipartisan steps to address some of the root causes and ripple effects of the Opioid Crisis. I hope we can continue to build on that work. However, today's hearing does offer an important opportunity to take a slightly different perspective on some of the challenges related to the use of opioids, and I hope it can serve as a reminder that while we are working to address substance use disorder and help the families facing it, we cannot forget about the people who are facing pain, both acute and chronic, and we cannot overlook how important it is they get the tools they need to manage their pain and find relief.

For too long, providers were incentivized to think of opioids as an easy and harmless solution to addressing pain, and the lack of understanding about pain management and the risks of opioid prescribing meant health care providers prescribed opioids far more often than was necessary, contributing to the tragic increase in opioid misuse. But that does not mean the solution to the Opioid Crisis is for providers to stop finding ways to help their patients manage pain. We have to find responsible, comprehensive solutions for pain management that ensures opioids are marketed, prescribed, and used responsibly, but at the same time, or within reach for people dealing with chronic pain. It is important to remember that for many people who are elderly, people who have been seriously injured, people with chronic health conditions, or undergoing aggressive health treatments, and people who have a disability, pain seriously impacts their day-to-day lives.

Fifty million people nationwide suffer from pain that persists for weeks or even years. For almost 20 million people, this pain can interfere with their work and daily life activities. Pain management is an absolutely critical quality of life issue for these people and their families. Acute and chronic pain can make it harder to keep a job and earn a paycheck. Even when treated, pain can make it difficult to travel to and from work, and sit at a desk for long stretches of time. And pain does not just affect a person's livelihood, it affects every aspect of their life. Without pain management, patients may not be able to tackle the tasks they need to live independently, by getting dressed, or driving a car, or doing laun-

dry. They may not be able to spend quality time with their loved ones as their pain can make it hard to enjoy a meal with friends or family, or attended a grandkid's soccer game, or even leave the house. Without the right pain management tools, some patients struggle to get a decent night's sleep.

For people living with pain, the ability to get treatments that help them manage it can impact their entire life, and I am very interested to hear from one of our witnesses today to offer her first-hand perspective on this. We appreciate your being here.

It is so important we listen to patients about their health care needs, whether that is finding ways to address that person's pain, or recognizing when asking for painkillers is a result of an addiction, which requires an entirely different form of treatment. Of course, another part of what makes this issue so challenging is that no two people experience pain the same way. Where pain is felt, how it is felt, how severe it is, how long it lasts, and how much it impacts our life, can vary widely from person to person. Pain is not a one-size-fits-all and the tools we use to manage it cannot be either. We need to do more to make sure everyone facing pain is able to get treatment that works for them.

This means ensuring research is done to better understand the biological basis of pain and the factors that determine what might work best for a patient. It means training providers to recognize pain symptoms, to truly listen to their patients' needs, and to consider lower risk, less invasive options before turning to more extreme measures. And it means making sure insurers policy support access to these options rather than incentivizing providers to simply write a prescription for an opioid without taking the time to understand what might work best for that patient. And for some with severe pain, it may mean responsible opioid prescribing, but for many others there are options that will work better and have lower risks of addiction, from other types of drugs that might fit better their needs, to service like physical therapy, to treatments that help address the psychosocial dynamics of pain, like cognitive behavioral therapy to support for modifying their lifestyles in ways that might help manage their pain like through exercise. And it means addressing threats to their health care like the blatantly partisan legal threat from the Republican lawsuit that could strike down protections for people with pre-existing conditions, including people affected by pain.

During our hearing today, I am interested to see what inside our witnesses have to offer about these very complex problems, and what steps we can take to help people get the support they need to manage their pain. For example, what can we do to make sure insurers cover pain management options that patients need, and do so in ways that help them quickly find the treatments that work best for them? How can we tackle the workforce shortage and make sure people in pain are able to find a care provider that can serve them close to their home? What can we do to address health disparities when it comes to pain treatment, and how can we make sure employers understand their obligations to accommodate employees as struggling with chronic pain under the Americans with Disabilities Act, and help them learn how best to support those employees?

As we continue our efforts to respond to this Opioid Crisis and build on the strong bipartisan steps we took last year, I am really glad that we have this opportunity to take a look at another very important angle of this challenge. So, thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. And thanks to you and to your staff for working to create this bipartisan hearing, which is an important follow-up to our work on the opioids bill last year. Each witness will have up to five minutes for his or her testimony. We welcome each of you and thank you for coming. Our first witness is Cindy Steinberg. She is the National Director of Policy and Advocacy at the U.S. Pain Foundation, and Chair of the Policy Council of the Massachusetts Pain Initiative. She was appointed in May 2018 by the Secretary of the Department of Health and Human Services, to serve on the Pain Management Best Practices Interagency Task Force, and she previously served on the Interagency Pain Research Coordinating Committee of the National Institutes of Health. Senator Smith, would you like to introduce the next witness.

Senator SMITH. Thank you, Chairman Alexander. I am really honored today to introduce Dr. Gazelka from my home State of Minnesota. Dr. Gazelka's work represents the health care innovation that is happening in Minnesota and at Mayo Clinic. Dr. Gazelka is the Director of Inpatient Pain Services in the division of Pain Medicine at Mayo Clinic in Rochester, and she is also an Assistant Professor of Anesthesiology at the Mayo Clinic College of Medicine. And she has dedicated her professional life to pain medicine and palliative medicine.

Dr. Gazelka has worked extensively in opioid management, as well as acute and chronic pain management. And most recently, she was appointed by HHS Secretary, Alex Azar, to serve on the Pain Management Best Practices Interagency Task Force—a mouthful and very important work. Dr. Gazelka attended the University of Minnesota Medical School and completed her residency and fellowships at Mayo Clinic College of Medicine. And I think that her professional experience makes her perfectly suited to testify before us today on pain management during—with this Opioid Crisis in front of us. And I know that we are all going to benefit from your expertise, so thank you so much, Dr. Gazelka. And thank you for taking time away from your practice and your patients to be with us today.

The CHAIRMAN. Thanks, Senator Smith. Dr. Andrew Coop is the next witness, Professor and Associate Dean for Academic Affairs of the University of Maryland School of Pharmacy. He is currently researching a new opioid analgesic that may have less potential for abuse and diversion. And finally, Senator Burr, would you introduce our remaining witness.

Senator BURR. Mr. Chairman, thank you for holding this very important hearing. I welcome all our witnesses today, and I have the great pleasure, Mr. Chairman, for the opportunity to introduce Dr. Anu Rao-Patel from Durham, North Carolina. And her current role is Lead Medical Director at Blue Cross, Blue Shield of North Carolina. Dr. Rao-Patel is responsible for making coverage decisions for health care services and prescription drugs for a number of health benefit plans offered by North Carolina Blue Cross. She

has also spent much of her career treating patients with chronic and painful conditions, such as lower back pain and migraine headaches. Dr. Rao-Patel is board-certified in physical medicine and rehabilitation, an active member of the American Academy of Physical Medicine and Rehabilitation and the American Medical Association.

Before moving to North Carolina, Dr. Rao-Patel received her medical training and a medical degree from Louisiana State University. She completed her internship in internal medicine at Earl K Long Hospital in Baton Rouge, and residency training in physical medicine and rehabilitation at Sinai Hospital University of Maryland in Baltimore. I was overly impressed with her background until I found out that her attending physician in her internship was Dr. Cassidy.

[Laughter.]

Senator BURR. I do know that she had a hard-charging attending, as she went through that internship. Dr. Rao-Patel, thank you for all the important work you do on behalf of North Carolina. I look forward to hearing your testimony before the Committee today on how we approach pain management in North Carolina, during a very devastating time of Opioid Crisis in this country.

The CHAIRMAN. Dr. Cassidy, do you have any comment on your former resident?

Senator CASSIDY. It is so gratifying to see someone as a former student do so well, and so I am incredibly proud that you are here. So, I will just limit it at that.

The CHAIRMAN. Thank you, Senator Cassidy and Senator Burr. Now, why don't we begin with Ms. Steinberg. And if each of you would summarize your remarks in about five minutes, we will go right down the line. Ms. Steinberg, welcome.

STATEMENT OF CINDY STEINBERG, NATIONAL DIRECTOR OF POLICY AND ADVOCACY, U.S. PAIN FOUNDATION, POLICY COUNCIL CHAIR, MASSACHUSETTS PAIN INITIATIVE, LEXINGTON, MA

Ms. STEINBERG. Thank you. Thanks for your introduction and thank you for holding this hearing on a really important issue, on pain management. It is a conversation that is long overdue.

My life changed in an instant two decades ago when I was crushed in a serious accident that left me with severe back pain that has never gone away. On an otherwise typical day at my job as a manager at a technology company, I opened my file drawer and unbeknownst to me, moving men had stacked cubicle walls against it. The cabinets and all the walls fell on me, crushing me and causing extensive damage to my back and spine. I was suddenly plunged into a search for relief from an unrelenting, gnawing, burning band of hot coals across my mid-back and the crushing pressure of clenched muscle spasms.

Chronic pain is very different from acute pain. It is relentless. It never ends. I often say, it feels like you are a prisoner in your own body, only you are a prisoner being tortured 24/7, and there is no escape. After a discouraging, difficult and at times demeaning five-year journey of searching for help while trying to hold onto the career that I loved, I finally found a doctor who helped me. Even so,

the pain eventually forced me to give up my career. Out of my own sense of loss and isolation, I decided to start a support group for others living with chronic pain. I was shocked at how many people started showing up for monthly meetings—all ages, men and women, all backgrounds.

Eighteen years later, I am still running that group, and more than 400 people have come to this group in the suburbs of Boston. I learned that my story is everyone's story with pain in America. Though the causes of pain vary, each of us has had the same experience of struggling to find adequate care. Everyone had to see four or five practitioners and go through years of discouraging and expensive trial and error treatments before they could find help.

The scope of chronic pain is enormous. The number of Americans impacted by pain and the human suffering involved, and the cost of the health care system in society is staggering. You have said some of these things yourself. Fifty million Americans live with chronic pain. Twenty million have high-impact chronic pain, which is pain that affects their ability to work, live, socialize on a daily basis. Pain is the number one reason why Americans access the health care system. It is the leading cause of disability in the United States. Pain costs our economy \$600 billion a year in lost productivity and direct medical costs. Despite the impact of pain, we fail as a country to effectively address it. We have underinvested in pain research relative to its burden. Less than 2 percent of the NIH's annual budget has gone to pain research. We still do not understand the basic nor biological mechanism of pain in the human body. Medical students receive an average of 9 hours of pain management training in 4 years. Veterinarians get 87 hours—your pet is getting better pain management often than people do. And less than 1 percent of physicians are specialized in pain management.

In the midst of the Opioid Crisis, there has never been a more important time for policymakers to improve pain management. Some well-intentioned measures to contain the crisis have resulted in unintended consequences for chronic pain patients. We and other groups have heard from thousands of chronic pain patients who have been forcibly tapered off their medications or dropped from care completely by their doctors. This is inhumane and morally reprehensible. Opioids are one treatment among many. They should not be a first-line treatment for chronic pain. Patients with providers must work together closely to carefully balance the benefits and risks for each person.

Nevertheless, for many pain sufferers, particularly those with severe pain, opioids can be a lifeline to lessening their pain. In the near term, we can and must restore balance to opioid prescribing. In the long term, we must invest in the discovery of new, effective, and safer options for people living with pain. There are, however, many steps we can take now to give people with chronic pain the quality of care they so desperately need and deserve. Some examples include reducing insurance cover barriers to ensure that a full range of pharmacological and non-pharmacological treatments, including complementary treatments and medical devices and technology. Promoting reimbursement models that encourage providers to dedicate the time and resources necessary to treat the complex-

ities of pain, promoting individualized, integrative multi-care plans, investing in vital collection and reporting epidemiological data on pain, increasing research into understanding pain in the human body, and investing in ongoing patient support and teaching of self-management skills for living with a chronic illness.

Fortunately, Congress has an excellent policy blueprint for implementing these measures. And that blueprint is the report of the task force that you have mentioned. That report is due out in May, and it has many excellent suggestions that I hope you all implement. Thank you.

[The prepared statement of Ms. Steinberg follows:]

PREPARED STATEMENT OF CINDY STEINBERG

Introduction

My name is Cindy Steinberg and I have lived with chronic pain for more than 18 years. I am also a chronic pain support group leader of 18 years, the Policy Council Chair for the Massachusetts Pain Initiative, and the National Director of Policy and Advocacy for the U.S. Pain Foundation.

Thank you for holding this critical and timely hearing on the state of pain management in the United States, and how the opioid epidemic impacts people living with chronic pain. Our country is facing two public health challenges that are often conflated as one: chronic pain and opioid use disorder.

This is the first of what I hope will be many hearings focused on improving pain management for the tens of millions of Americans who are suffering. It's a conversation that is long overdue. The opioid crisis has only underscored our failure to provide adequate, safe, accessible treatment options for pain relief.

Chronic Pain is an Enormous and Costly Public Health Problem

The number of Americans impacted by pain, the human suffering involved, and the cost to the health care system and society is staggering:

- 50 million Americans suffer from chronic pain, or pain that lasts most days or every day for 6 months or more.¹
- 20 million Americans suffer from high-impact chronic pain, or pain that interferes with basic functioning, including work, sleep and activities of daily living, like personal hygiene and household chores.²
- Pain is the number one reason that Americans access the health care system.³
- Pain is the leading cause of long-term disability in the United States.⁴
- In 2010, pain cost the United States \$560–635 billion a year in direct medical costs and lost productivity.⁵
- People with moderate pain spend an extra \$5,000 a year on health care expenditures than people without pain; those with severe pain spend an extra \$8,000 a year.⁶
- People with chronic pain are four times more likely to experience anxiety or depression,⁷ and 10 percent of all suicide cases involve chronic pain.⁸
- 80 percent of veterans returning from Operation Enduring Freedom and Iraqi Freedom live with chronic pain.⁹

Despite the impact of pain, we have failed as a country to effectively address it.

¹ <https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm>.

² <https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm>.

³ <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=57>.

⁴ <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=57>.

⁵ [https://www.jpain.org/article/S1526-5900\(12\)00559-7/fulltext](https://www.jpain.org/article/S1526-5900(12)00559-7/fulltext).

⁶ [https://www.jpain.org/article/S1526-5900\(12\)00559-7/fulltext](https://www.jpain.org/article/S1526-5900(12)00559-7/fulltext).

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000181/>.

⁸ <https://annals.org/aim/fullarticle/2702061/chronic-pain-among-suicide-decedents-2003-2014-findings-from-national>.

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/20104399>.

- At present, less than 2 percent of the NIH's budget goes to pain research.¹⁰
- Veterinary students spend 3–4 times as many hours studying pain management than students in medical school.¹¹
- For every 8,700 people with high-impact chronic pain, there is only one board-certified pain specialist.¹²
- Patients can only expect to achieve, through their various treatments, an average reduction in pain of only 30 percent.^{13, 14}

Chronic Pain is a Disease of the Nervous System Distinct From Acute Pain

I would like to make an important clarification about chronic pain before continuing any further. Acute pain serves as a normal and vital signal, alerting us that something is wrong and protecting us from further injury, such as the pain of a broken bone or abdominal pain before a ruptured appendix. But when pain continues past six months—regardless of the cause—it transitions into chronic pain. Neuroscience research now shows that chronic pain becomes a disease in and of itself, with measurable changes in the brain, spinal cord, and peripheral nervous system.

Chronic Pain Devastates Lives

Think about the last time you experienced pain. Maybe it was because you whacked your elbow against a cabinet or burned your finger on a hot pan. Do you remember how it took your breath away and commanded your attention? You could not do anything else until the pain subsided.

All of us have experienced physical pain at some point. What is difficult to imagine is pain that never goes away. But I'd like you to envision it. Try to imagine how the pain would impact your daily life, your career, or your relationships.

Chronic pain is relentless agony. It's often described as being imprisoned in one's body and tortured 24/7 with no means of escape. Unlike a serious illness such as cancer, where patients can often receive treatment and resume daily life, victims of chronic pain are often forced to cease life activities in perpetuity. They cannot work, care for their families, or engage in social activities.

This loss of function, productivity, and independence is heart-wrenching. People with chronic pain lose their sense of self. They feel worthless, helpless, and very, very alone.

We Can, *and Must*, Improve Pain Care

The need to improve pain care has never been more urgent. We can and must do a better job in improving pain management by:

- Promoting individualized, integrative, multi-modal care plans.
- Breaking down coverage barriers to a full range of non-pharmacological as well as pharmacological treatments.
- Investing in vital collection and reporting of epidemiological data on pain.
- Improving public, patient, and provider education about pain management.
- Breaking down stigma that creates barriers to proper care.
- Investing in ongoing patient support and teaching of self-management skills for living with a chronic illness and pain.
- Increasing research into understanding the basic mechanisms of chronic pain in the human body and the development of novel safe and effective treatments.

My Story: Learning Firsthand About Pain Care in America

More than 18 years ago, on an otherwise typical day at my job as a manager at a technology company, a stack of unsecured filing cabinets—and the cubicle walls leaning up behind them—fell on top of me, crushing me beneath them. The accident left me with severe, unrelenting back pain that continues to this day.

¹⁰ <https://www.hhs.gov/about/budget/budget-in-brief/nih/index.html>.

¹¹ <https://www.ncbi.nlm.nih.gov/pubmed/21945594>.

¹² <http://www.abpm.org/faq>.

¹³ <https://www.ncbi.nlm.nih.gov/pubmed?term=21704872>.

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3841375/>.

No matter what therapy or medication I tried, I simply couldn't be upright for more than a couple of hours at a time without an enormous increase in pain and muscle spasms. Even aside from my job, it was a struggle to do basic things I had previously taken for granted: bathe my young daughter, and cook dinner for her and my husband. Everything that required being upright was and is still is a challenge. After a discouraging, difficult, and, at times, demeaning five-year journey of searching for help for my pain while trying to hold on to the career I loved, I finally found a doctor who helped me.

Even with a treatment plan, the pain eventually forced me to give up my career. Out of my own sense of loss and isolation, I decided to start a support group for others living with chronic pain. I was shocked at how many people started showing up for my monthly pain group meetings—all ages, men and women, and diverse racial, ethnic and socioeconomic backgrounds.

A remarkably common experience is that everyone has had to see at least four or five health care practitioners before they could find help for their relentless pain, if they ever do, and many did not. There was no one-size-fits-all treatment; what worked well for one person might cause a bad reaction in another. The quest for help was exhausting and frustrating—each person had dealt with having their pain dismissed or downplayed by healthcare providers. It was also expensive: affording treatment could easily drain a family's resources. Living with severe pain most likely means you struggle to work—combine that with high health care costs, and you have a potentially ruinous problem.

It has been 18 years and I am still running this group today. More than 400 people with chronic pain have come to this local group. I knew I was helping these individual lives, but I had to do more. Despite my daily pain and physical limitations, I decided to dedicate all the energy I could to improving pain care in this country.

In 2009, I became Policy Council Chair for the Massachusetts Pain Initiative—an all-volunteer organization that is comprised primarily of healthcare providers who treat individuals with pain and donate their time to the organization and its mission to improve pain care in the Commonwealth. Working together with Massachusetts lawmakers and regulators, I have led our successful efforts to establish pain education and opioid prescribing continuing education requirements for physicians, create pain policies with professional licensing boards, establish a pain specialist consultation service for general practitioners, and require Massachusetts public and private insurers to cover a full range of pain management therapies.

In 2013, the U.S. Pain Foundation asked me to work on Federal pain policy for the organization. U.S. Pain Foundation is a patient organization with thousands of Ambassador advocates and tens of thousands of supporters nationwide that educate, support, and advocate for Americans living with chronic pain. The organization advocates for common diseases like cancer and arthritis, as well as rare or complex conditions like Ehlers-Danlos syndrome, migraine disease, and complex regional pain syndrome; or pain from trauma, like a motor vehicle accident or my own accident.

In my role with U.S. Pain, I advocate for improvements in pain care at the national level.

I am honored to have been appointed to a number of key pain policy committees at the Federal and state level: the Interagency Pain Research Coordinating Committee, the highest ranking Federal pain policy oversight committee chaired by the NIH; the HHS Pain Management Best Practices Interagency Task Force, established by the CARA legislation; a National Pain Strategy Expert Working Group; Massachusetts Governor Charlie Baker's Opioid Working Group; and the Massachusetts Drug Formulary Commission.

Managing Pain During the Opioid Crisis

There has never been a more important time for policymakers to improve pain management in the United States. The focus on the opioid crisis, while absolutely necessary, has resulted in unintended consequences for chronic pain patients, who are being stigmatized for their disease and in many cases, denied medically necessary treatment. Too often, well-intentioned reforms have harmed or unfairly penalized people with legitimate pain.

Conflation of Two Populations

A critical misunderstanding that pervades media coverage of opioids and pain is the conflation of two largely distinct populations—those with the disease of chronic pain and those with the disease of opioid use disorder.

Demographic research on these populations has shown that chronic pain sufferers tend to be largely female and over the age of forty and those with opioid use disorder tend to be largely male and under the age of thirty. These are two largely separate groups with very little overlap.

Repeated research *within the chronic pain population* has found the risk of addiction to be small, on average less than 8 percent¹⁵ and in patients with no history of abuse or addiction, studies have shown the rate of addiction to be between .19 percent to 3.27 percent.^{16, 17}

Speaking from personal experience and from 18 years of helping hundreds of chronic pain sufferers manage their conditions, opioid prescription medications are not the enemy, nor the savior, when it comes to chronic pain.

Opioids are one treatment modality among many pharmacological and non-pharmacological treatments for pain. They should not be a first line treatment for chronic pain and ideally should be used in conjunction other therapies. They should primarily be considered in the case of severe chronic pain, and in the case of moderate pain when other options have failed. When they are prescribed, patients should be carefully screened for risk factors for abuse, like a prior alcohol or other drug misuse or a personal or family history of substance use disorder, and counseled in safe use and storage.

Opioids do not help all pain sufferers and when they do help, they do not completely take the pain away. Nevertheless, they are an important option. For many pain sufferers who take them responsibly and legitimately, they are a lifeline that allows them to have some quality of life and lessen their relentless pain.

Treatments like physical therapy, massage, behavioral therapy, and injections may be helpful, but few insurance plans cover these options fully, if at all. For a person with severe pain who is struggling to work part-time, costs for complementary therapies that are not covered by insurance may cost hundreds of dollars a week, and this is not affordable. Furthermore, people with pain who live in rural areas or have physical limitations that impede travel may have difficulty even physically getting to appointments for non-pharmacological options, like physical therapy or injections.

For patients without risk factors for abuse and where opioids are clinically indicated, it is cruel to take away a treatment option without offering any realistic alternatives.

It is essential that treating clinicians be permitted to evaluate individual benefits and risks for each patient and that all appropriate pharmacological, interventional and complementary therapies remain available.

As a result of well-intentioned measures to contain the opioid crisis, such as restricting the supply of prescription opioids, intense regulatory scrutiny of physicians, the establishment of ceiling doses and day limits on the number of opioids that can be prescribed, legitimate chronic pain patients are being made to feel like criminals simply for seeking relief—many of whom have been on long-term stable doses of their medication for years.

We, and other pain patient groups, have heard from thousands of chronic pain patients who have been forcibly tapered off their medications or dropped from care by their doctor. It's easy to understand why, for many providers, restrictions on opioids have made it simply too burdensome to prescribe them, even when they may be beneficial. Some providers are outright leaving the specialty of pain medicine out of fear, a devastating development given there is already a dire shortage in the field: less than 1 percent of physicians are specialized in pain management. Even if a clinician does continue to prescribe opioids, patients feel like criminals for taking them and are constantly terrified that the slightest misstep might be misconstrued as a sign of misuse or addiction.

This has caused tremendous unnecessary suffering and anxiety, and has led many to contemplate or attempt suicide. As I mentioned earlier, recent research found that at least 10 percent of suicide cases in America involve chronic pain. This number may be surprising to the average person, but not to pain patients, who know the fear and helplessness all too well.

In the near term, we can and must restore balance to opioid prescribing with depoliticized, rational and clear-eyed recognition of the risks and benefits of these

¹⁵ <https://www.nejm.org/doi/full/10.1056/NEJMra1507771>.

¹⁶ <https://www.ncbi.nlm.nih.gov/pubmed/18489635>.

¹⁷ <https://www.ncbi.nlm.nih.gov/pubmed/20091598>.

medications. In the long term, we must invest in the discovery of new, effective, and safer options for people living with pain.

Federal Efforts to Improve Pain Management

Fortunately, the Federal Government has launched several important policy planning initiatives to improve pain management. HHS has included improved pain management as one of its Five Pillars to address the opioid crisis and the FDA has released its Opioid Blueprint and Innovation Challenge to promote the development and use of approved medical technology and non-opioid medication, and the development of new medical devices and non-addictive medications.

In 2016, HHS, under the auspices of the NIH and the Interagency Pain Research Coordinating Committee, released the comprehensive National Pain Strategy. The National Pain Strategy emphasizes the need for patient-centered, integrative pain management practices based on a biopsychosocial model of care that enables providers and patients to access a full spectrum of pain treatment options including pharmacological and non-pharmacological treatments and complementary therapies.

In 2017, the Interagency Pain Research Coordinating Committee and the Office of Pain Policy at the NIH released the Federal Pain Research Strategy, a long-term strategic plan for basic biomedical research to advance our understanding of the neurobiological basis of pain.

Recent Promising Initiatives

I applaud Congress for initiating two of the most promising developments in advancing the science and clinical treatment of chronic pain in 2018. These are the Helping to End Addiction Long-term (HEAL) Initiative at the NIH and the establishment of the HHS Pain Management Best Practice Interagency Task Force.

The HEAL initiative will invest in research on addiction and pain. The goals of the pain research are to understand the process by which acute pain turns chronic, discover novel targets for pain treatments, advance previously discarded pharmaceutical assets for reasons other than safety, develop a pain clinical trials network, and discover biomarkers for chronic pain.

Congress established the HHS Pain Management Best Practices Interagency Task Force in the Comprehensive Addiction and Recovery Act (CARA) with the charter to identify gaps and inconsistencies in best practices for acute and chronic pain management adopted by Federal agencies and propose recommendations to address those gaps and inconsistencies.

Secretary Azar appointed an exceptional group of pain management and substance use disorder experts, including my fellow witness today, Dr. Halena Gazelka, whom I am proud to serve alongside on the Task Force. The Task Force has been ably led by Dr. Vanila Singh, the Chief Medical Officer of HHS who is a well-qualified board certified pain management physician. We have worked hard over a seven-month period to review the literature, discuss and deliberate on each section of the report, consider all the input we received including that of thousands of patients and offer the best possible advice we could provide on the most current consensus on best practices in pain management.

A draft report is currently out for public comment with the final recommendations report due out at the end of May 2019. I strongly encourage Congress to formulate an action plan to implement the best practices recommendations in the report.

Pain Management Policy Recommendations

1. Surveil the national burden of chronic pain through NIH data collection, analysis, and dissemination.

Despite the enormous human and economic impact imposed by chronic pain on our Nation, there is no concerted effort within the government to ascertain and make publicly available high-quality data on chronic pain. National surveillance efforts are needed to evaluate population-level interventions, evaluate the impact of changing public policies, and identify emerging trends and needs. For example, we would expect that our aging population with age-associated pain-producing conditions such as cancer, diabetes and arthritis is leading to substantial increases in the incidence and cost of pain to the Nation. But without data to understand this trend, how can we effectively plan for and manage this burden, as well as contain its cost?

It is critical that Congress create and fund a National Chronic Pain Surveillance System (NCPSS) at NIH to collect epidemiological data to clarify the incidence and prevalence of various chronic pain conditions. The NCPSS would enable NIH to col-

lect data that will: identify trends, subpopulations at risk, and the health consequences of pain in terms of morbidity, mortality, and disability; clarify the incidence and prevalence of pain syndromes differentiated by age, comorbidities, socioeconomic status, race, and gender; and assess direct cost of pain treatment in terms of utilization of medical and social services and indirect costs such as missed work, public and private disability and reduced productivity. Simply put, better data equals better pain policy and better health outcomes.

2. Transform pain treatment through implementation of pain management best practices.

Pain care across the United States is highly ineffective, inadequate and inefficient. Integrative, multimodal pain care based on a comprehensive assessment and an individualized care plan including a combination of non-pharmacological and pharmacological treatments developed and guided by a knowledgeable healthcare provider with input from the patient is best practice, but many barriers prevent access to such care. These barriers include inadequate insurance coverage for pain management services, lack of education and training of physicians and other healthcare providers on core competencies in pain management, time constraints that deter physicians from managing chronic illness, shortages of pain management specialists and lack of research and evidence base on treatment modalities that currently exist, especially which modalities are best for which type of pain and in what combination.

Fortunately, as I noted earlier, Congress, HHS, and the NIH have already authorized and developed two excellent public policy blueprints for improving pain care in the United States: through the National Pain Strategy and the HHS Pain Management Best Practices Interagency Task Force (PMTF). The National Pain Strategy is the Nation's first interagency strategic plan to implement a system of safe, effective, evidenced-based care. HHS released the strategy in 2016, after a nearly two-year period of thoughtful development among six Federal agencies, along with eighty nominated experts from the medical, scientific, patient, and advocacy communities.

Through CARA, the PMTF was charged with identifying gaps and inconsistencies in best practices for acute and chronic pain management, as well as proposing recommendations to address those gaps and inconsistencies. The subsequent report was drafted by a panel of 29 pain management and Federal Government health agency experts selected from an extensive and thorough search throughout the country. The PMTF report, including its recommendations, is currently out for public comment, with the final report due at the end of May, at which time Congress must develop an action plan to implement the recommendations.

3. Invest in pain research at the NIH.

The Federal investment in pain research has been chronically and grossly incommensurate with its human and societal burdens. Very little is known about the prevention, causes, and mechanisms of chronic pain. Substantial initiatives are urgently needed to develop pain treatments without abuse potential. Further, generating high-quality evidence that can guide clinicians and patients in making informed decisions about safe and effective pain management is imperative.

An essential response to the opioid crisis must include an increase in the Federal pain research investment. The cost savings of discovering improved chronic pain therapies will far surpass the increased costs of research. Beyond relieving suffering from both chronic pain and substance use disorder, development of improved pain therapies will spur introduction of innovative products with global markets, increase workplace productivity, and reduce expenditures for Federal entitlement programs such as Medicaid, Medicare, and Social Security Disability Insurance. A meager 1 percent reduction of the United States costs of pain would translate into approximately \$6 billion in annual societal savings.

The recently begun HEAL Initiative is a start, but it is limited in scope to a few specific areas. The Federal pain research budget including the HEAL Initiative pain work still only represents 2 percent of the NIH's annual budget for a disease that affects 50 million Americans and is the leading cause of disability. The Federal Pain Research Strategy, released in 2017 under the auspices of the IPRCC and the NIH Office of Pain Policy, is a comprehensive strategic plan developed using the same thoughtful, inclusive process of work teams comprised of the Nation's brightest medical and scientific experts in the field of pain research. Congress should use this strategy as blueprint to expand and expedite our investment in pain research.

Other Important Policy Recommendations

Although the National Pain Strategy and the HHS Pain Management Best Practices Interagency Task Force Report discuss the recommendations below, among many others, I have chosen to highlight these as priorities from a patient perspective:

- Ensure access to any medically necessary treatment so long as benefits outweigh risks for that individual patient.
- Improve public and private payer coverage for integrative care based on individualized treatment plans, so that patients and their healthcare providers can select from a full range of pain management therapies, including non-pharmacological complementary treatments, novel medical devices and innovative non-addictive pharmacological treatments.
- Provide grants for patient support group networks that educate and empower patients to self-manage chronic pain using a skill-based chronic disease model.
- Invest in large-scale efforts to improve public, patient, physician, and other healthcare provider education in pain management. This is essential to restoring empathy and compassion, eliminating damaging stigma and reducing the tremendous burden of pain and suffering among millions of Americans living with chronic pain.

Summary and Conclusion

I would like to sincerely thank the HELP Committee for holding this hearing focused on pain in America. Chronic pain is the most prevalent, costly and disabling health condition in the United States, yet it remains largely unknown, poorly treated, and misunderstood relative to other prevalent diseases such as cancer, diabetes, and heart disease. It has been called the “hidden epidemic,” and rightly so.

The opioid crisis has revealed decades of underinvestment in research aimed at understanding the mechanisms and treatment of pain, such that we have no completely effective therapies that will eliminate chronic pain and only a handful of good ones that substantially help carefully selected patients. It should come as no surprise that we have had to rely on imperfect treatments for pain relief. While these treatments may help those who use them appropriately, they have led to huge costs for others and society-at-large.

We have also turned a blind eye to the tremendous physical pain of millions of our fellow Americans. These people are your constituents, your families, your friends, and your neighbors. We can and must do better.

As you plan future legislative action, I hope Congress will consider these key points:

- Chronic pain affects 50 million Americans, including 20 million Americans who live with high-impact pain.
- The financial and societal burden of chronic pain is enormous: it costs the United States an estimated \$635 billion annually in terms of lost productivity and health care costs. It is the leading cause of long-term disability.
- Chronic pain is a disease of the nervous system and brain that can and does last a lifetime. It is distinct from acute pain, which is time-limited.
- There is no one-size-fits-all approach to treatment for pain. Individualized care is essential. Patients must work closely with their healthcare providers to weigh the benefits and risks of each option.
- Chronic pain and opioid use disorder are distinct and separate diseases. Many patients use opioids legitimately and safely.
- We must restore access to care and medically necessary treatment for tens of thousands of pain patients who have been dropped from care by fearful and frustrated providers or who have been forcibly tapered off stable doses of opioids that have helped them for years and left to suffer with relentless pain. This is inhumane and morally reprehensible.
- A multimodal, multidisciplinary approach to treatment—that includes both pharmacological and nonpharmacological options—is essential to effective, long-term pain relief. Inadequate insurance coverage, high out-of-pocket costs, and limited availability are significant barriers to effective care.

- Prescribing reform was necessary to address the opioid crisis. However, we must be cautious to ensure that these reforms are thoughtful, balanced, and consider the needs people with opioid use disorder as well as the needs of people with pain.
- Investing in public, provider, patient and policymaker education about acute and especially chronic pain is fundamental to progress in the care, well-being and productivity of millions of Americans.
- Expanding research at the NIH into our fundamental understanding of the mechanisms of pain in the human body is essential to discovering safer, more effective treatments—and someday a cure—for chronic pain, and for reducing reliance on opioids.
- The National Pain Strategy and the HHS Pain Management Best Practices Task Force Report are excellent public policy blueprints for jumpstarting a national commitment to pain care improvements. These initiatives must be funded and implemented.

The American crisis of inadequate treatment of chronic pain demands congressional attention. We have done the work to determine effective next steps; it is now the work of Congress to fund these necessary recommendations. I call on you to commit to an investment commensurate with the scale of this crisis to once and for all solve the enormous problem of pain in America.

[SUMMARY STATEMENT OF CINDY STEINBERG]

My life changed in an instant two decades ago when I was crushed in a serious accident that left me with severe back pain that has never gone away. I was suddenly plunged into a search for relief from an unrelenting, gnawing, burning, searing band of scorching hot coals across my mid-back and the crushing pressure of clenched, spasm muscles tightened like cords running up and down my spine that worsened whenever I was not lying flat.

I have learned that my multi-year search for help is a common story for everyone with chronic pain in America. For nearly two decades, I have led a chronic pain support group, and in recent years I have become involved in a number of efforts to address the dual crises of opioid use disorder and chronic pain in America. My years of experience have taught me that the most vital thing Congress can do is invest in research and improvements in clinical care, commensurate to the economic burden, physical pain, and loss of quality of life and even life itself they can cause.

I call on Congress to consider these key points:

- Chronic pain affects 50 million Americans, including 20 million Americans who live with high-impact chronic pain.
- The financial and societal burden of chronic pain is enormous: it costs the United States an estimated \$635 billion annually in terms of lost productivity and health care costs. It is the leading cause of disability.
- Chronic pain is a disease of the nervous system and brain that can and does last a lifetime. It is distinct from acute pain, which is time-limited.
- There is no one-size-fits-all approach to treatment for pain. Individualized care is essential. Patients must work closely with their healthcare providers to weigh the benefits and risks of each option.
- Chronic pain and opioid use disorder are distinct and separate diseases. Many patients use opioids legitimately and safely.
- We must restore access to care and medically necessary treatment for tens of thousands of pain patients who have been dropped from care by fearful and frustrated providers.
- A multimodal, multidisciplinary approach to treatment—that includes both pharmacological and nonpharmacological options—is essential to effective, long-term pain relief. Inadequate insurance coverage, high out-of-pocket costs, and limited availability are significant barriers to effective care.
- Investing in public, provider, patient, and policy maker education about acute and especially chronic pain is fundamental to progress in the care, well-being, and productivity of millions of Americans.
- Expanding research at the NIH into our fundamental understanding of the mechanisms of pain in the human body is essential to discovering

safer, more effective treatments—and someday a cure—for chronic pain, and for reducing reliance on opioid analgesics.

- The National Pain Strategy and the HHS Pain Management Best Practices Task Force Report are excellent public policy blueprints for jumpstarting a national commitment to pain care improvements. These initiatives must be funded and implemented.

The American crisis of inadequate treatment of chronic pain demands congressional attention. We have done the work to determine effective next steps; it is now the work of Congress to fund these necessary recommendations. I call on you to commit to an investment commensurate with the scale of this crisis to once and for all solve the enormous problem of pain in America.

The CHAIRMAN. Thank you so much, Ms. Steinberg, for making the trip and for being here today. Dr. Gazelka, welcome.

STATEMENT OF HELENA GAZELKA, M.D., ASSISTANT PROFESSOR OF ANESTHESIOLOGY AND PERIOPERATIVE MEDICINE, DIRECTOR, MAYO CLINIC INPATIENT PAIN SERVICE, CHAIR, MAYO CLINIC OPIOID STEWARDSHIP PROGRAM, ROCHESTER, MN

Dr. GAZELKA. Thank you. Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for allowing me to testify today.

My name is Halena Gazelka. I am an anesthesiologist practicing pain medicine at the Mayo Clinic in Rochester, Minnesota. Mayo Clinic cares more than 1.3 million patients annually from all 50 states and from over 140 countries. The needs of our patients range from primary care to very complex and serious conditions. I am honored to serve those in need of both acute and chronic pain care, and palliative care. I am privileged to share my inside as a provider and a leader in an organization that is thoughtfully addressing the pain management needs of our patients.

Pain management is, at its essence, individualized medicine. No patient is the same as another, and therefore each condition, treatment, and surgery has a unique impact with relation to pain. To ensure that patients receive appropriate pain treatment, Mayo Clinic created the Opioid Stewardship Program in 2016, which I chair. Through these efforts, we realized a dramatic reduction in the amount of opioids provided to our patients. Our program evaluated surgical specialties, and we surveyed thousands of patients to develop internal prescribing guidelines, but they are not a replacement for clinical judgment. Using these guidelines, some of our departments have realized a reduction in opioid prescribing of up to 50 percent, all while maintaining a high level of patient satisfaction.

The goal is not only to provide the best care at Mayo but to share our work with others. Our experience has helped other health care organizations improve their pain management, reduce opioid-related morbidity, and decreased diversion.

Established in 1974 in Rochester, Mayo Clinic's Pain Rehabilitation Program has helped bring hope and management strategies to thousands with chronic pain over the past four decades. Similar centers have been established at our Florida and Arizona practices. While pain rehab is very effective, insurance coverage for it is lim-

ited. For instance, it is covered by Medicare but not by Medicaid. Today, I would like to convey four key points to you.

First, dose limits on opioids, such as three and seven-day limits, will not satisfy the acute pain requirements for patients equally. Patients and procedures vary significantly. A patient recovering from the removal of their wisdom teeth will have a very different pain management requirement than a patient recovering from a major orthopedic surgery, or a trauma. These variations are the basis for our procedure-specific and patient-specific guidelines. Chronic pain lasting for months to years typically could be related to cancer or it could be as common as back pain, for example. As the condition and the needs of all, physicians should utilize evidence-based interventions, medical therapy, and restorative therapies to ensure proper management. Typically, patients with chronic pain, particularly when it is not cancer-related, may be better candidates for non-opioid therapies. An individualized approach to care is paramount, and policy should promote the use of effective non-opioid treatments.

Further research is needed to determine why some patients with acute pain develop chronic painful conditions, and to find a means to interrupt that progression. Second, Federal policy should embrace multi-faceted approaches to the treatment of opioid use disorder, including access and prevention. Medicare and Medicaid must develop additional coverage of and reimbursement for non-opioid pharmacotherapies and treatment regimens for chronic pain, to prevent the contact with opioids that may ultimately lead to addiction, particularly for chronic pain where little medical evidence exists in support of long-term opioid use. Other solutions to manage pain may be cost-prohibitive, time-consuming, and lack appropriate coverage by insurers.

The basis of chronic pain management was focused on treating the whole individual with restorative, behavioral, psychosocial, and medical and procedural elements combined appropriately to the patient and the condition. There is not only a paucity of pain management providers and resources but in cases where opioid use disorder does complicate management, not enough treatment programs exist to satisfy that need.

Third, the optimization and standardization of prescription drug monitoring programs should be pursued. While most states currently utilize them, the existing programs are varied and the administrative burden is additive. Nationally, there is a greater need for coordination and consistency across the PDMPs. Finally, we believe that empowering patients is a major key to solving the epidemic. We must increasingly engage patients in shared decision-making and educate them on treatment, risks, and alternatives. We also believe the role of communities and local governments are important. Because opioids provided legitimately by providers are only one facet of this problem, the epidemic will only be solved with a collective approach.

Thank you for the opportunity to join you today and for your efforts in ensuring proper pain management amidst the Opioid Crisis. I am happy to answer any questions.

[The prepared statement of Dr. Gazelka follows:]

PREPARED STATEMENT OF HELENA GAZELKA

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to testify before you today. My name is Helena Gazelka and I am an anesthesiologist practicing at Mayo Clinic in Rochester, Minnesota. Mayo Clinic is a not-for-profit health care system dedicated to medical care, research, and education, where multiple medical experts work collaboratively to find solutions for patients with the most serious and complex illnesses. Our staff of more than 60,000 provide and support care for more than 1.3 million people from all 50 states and 140 countries. The needs of our patients span the spectrum of care—from primary care in the Mayo Clinic Health System to serious and complex conditions in our destination practice.

My specialty is in pain medicine where I have the honor of serving patients who seek pain relief therapies for acute, chronic and palliative care needs. My clinical practice and research focuses on pain medicine, palliative medicine, opioid management, acute and chronic pain management, neuromodulation, intrathecal drug delivery systems, spine care, and cancer pain management. I am an assistant professor of anesthesiology and perioperative medicine; am board certified in anesthesiology, pain medicine, and palliative medicine; and have the privilege of serving as director of Inpatient Pain Services at Mayo Clinic Rochester. I also direct Mayo's Opioid Stewardship Program, which was established in 2016 to oversee prescribing practices across Mayo's enterprise and identify opportunities for improvement.

Recently, I have had the pleasure of serving on the Pain Management Inter-Agency Task Force overseen by the Department of Human Services. Established by the Comprehensive Addiction and Recovery Act of 2016, the Task Force was charged with developing best practices for prescribing pain medication and managing chronic and acute pain. A draft report with recommendations is currently open for public comment and will be shared with Congress later this year.

I am privileged to share my insight as both a pain medicine provider and a leader in an organization that has taken a very deliberate and thoughtful approach to guarantee the pain management needs of our patients are met while ensuring responsible prescribing practices. Mayo has taken a multi-faceted approach to address the drug abuse and opioid crisis across our own enterprise, drawing upon our expertise in integrated clinical care, research and education. Our focus includes embracing a broad range of pain treatment and management tools in our medical practice, where care delivery methods are put through scientific rigor to determine whether they improve patient care and outcomes, as well as developing clinical guidelines that minimize the risk of addiction and abuse with minimal impact on patient experience.

As a pain medicine provider, I can say without reservation that pain management is a very individualized practice of medicine. No patient is the same as another, and therefore each condition, treatment, and surgery will also have unique impact. The scope and length of pain can also vary significantly. To ensure patients continued to receive appropriate pain treatment, the Mayo Opioid Stewardship Program uniquely looked at prescribing practices for acute and chronic pain. This coincided with the development of educational tools for providers and patients, and increased monitoring of opioid prescribing behavior across our organization. The resulting "Mayo Clinic Guidelines for Acute and Chronic Opioid Prescribing" are available to all Mayo care team members and have been shared with external colleagues as well. These recommendations reflect Mayo consensus based on review of existing evidence and guidelines, but are not a replacement for clinical judgment.

The guidelines were developed after extensive research on the existing prescribing practices of our clinicians as well as the experience of our patients. This included a number of activities aimed at better understanding practice behavior and patient experience, such as surveying thousands of patients to comprehend their prescription utilization and needs after being discharged. This combination of examining both clinician and patient behavior was a critically important component of our work as we aim to balance the need to reduce reliance on opioid medications while ensuring that patient needs for pain management are reasonably met. This dyad approach also facilitates the development of effective and relevant education tools that recognizes the current behaviors of target audiences and how to adjust them as necessary.

Early results from the standards developed under our stewardship program have shown significant results in uniform acute and chronic care prescribing practices, improved pain management for our patients, and a drastic reduction in excess opioid availability. As an example, some departments have seen a reduction in opioid prescriptions of close to 50 percent in high-volume surgical practice areas, all

while maintaining a high-level of patient satisfaction with pain management. Mayo researchers continue to study the outcomes of the prescribing practices, including continued engagement with patients, to help identify areas for improvements to optimize care. The goal of this work is to not only provide the best care to patients at Mayo Clinic, but to broadly share our work and learnings with medical experts, educators, and communities so that people can benefit from our expertise. To this effort, we continue to educate future clinicians on responsible and appropriate opioid prescribing practices for chronic pain, illnesses and palliative care as part of planned curricula.

Our stewardship experience has already led to a larger effort with 14 other major health care organizations in Minnesota, working together to improve pain management and treatments for patients, reduce risk of opioid-related morbidity, and decrease opioids available for diversion. This work is now taking place at the Institute for Clinical Systems Improvement (ICSI), in Minneapolis, Minnesota and will yield ongoing information that can inform broader efforts to address opioid use and abuse across entire communities beyond just one organization.

While great efforts are underway to standardize the prescribing of opioids, Mayo Clinic continues to promote non-opioid therapy treatments. Established in 1974 in Rochester, Minnesota, Mayo's Pain Rehabilitation Center (PRC) was one of the first pain rehabilitation programs in the world. The PRC in Rochester has helped thousands of people with chronic pain management over the past four decades, and similar centers were established in 2011 at Mayo Clinic's campus in Jacksonville, Florida, and in 2016 at Mayo's campus in Phoenix, Arizona.

The PRC is staffed with an integrated team of health care professionals trained in many areas, including pain medicine, physical therapy, occupational therapy, biofeedback and nursing. In addition to pain management, the PRC also addresses the psychological needs of all our patients with an array of cognitive behavioral and mental health programs. A major emphasis of the program is the management of chronic pain without the use of opioids, and patients participate in a three-week, full-day program that educates them on effective strategies for addressing their needs with or without prescription medications. We also operate a similar program designed for teens based upon their unique clinical and cultural needs. While we have found the PRC intervention to be a very effective means of addressing patients who cannot or should not utilize opioid therapies, the insurance coverage for this program is limited. The program is covered under Medicare, but it is not covered by Medicaid.

As Congress considers options to address the opioid epidemic that is impacting individuals, families and communities across the Nation, Mayo Clinic would encourage Members to not limit access to appropriate opioid treatment, increase access for patients to alternative pain management therapies, reduce the burden for providers to access prescribing data, and promote public awareness and education on the topic of pain and various treatment options. When considering these options, it is important to recognize at the outset that the needs of patients facing short-term pain, such as those recovering from a surgical procedure, are different than those of patients managing chronic pain, such as those with cancer or complex injuries. Members may want to consider different policy approaches for addressing the challenges associated with these very different populations. For the prior, opioid use as a result of surgeries, procedures or conditions require the most flexibility for physicians to manage and monitor patients. A patient recovering from removal of wisdom teeth will have different pain management needs than a patient with a major orthopedic surgery, and physicians should respond accordingly, and have the ability to do so, to both circumstances.

Chronic pain, however, is generally considered pain that lasts longer than 45 days to three months. The pain could be the result of an underlying medical disease or condition such as cancer or chronic back problem, among many other concerns. These patients can be monitored and providers can be rewarded by utilizing evidence-based care and other guidelines to ensure proper utilization of opioid medications. These patients often present with more complex clinical considerations and their needs may change as conditions evolve. They also may be better candidates for alternative non-opioid therapies that are able to address pain over longer periods of time or offer a cumulative effect that is negligible for patients needing just a few days or weeks of pain relief.

While we strongly believe opioids should be prescribed in the smallest amounts needed, standardized prescribing guidelines and restrictions may not always meet the individual needs of all surgical and complex care patients. An individualized approach to care is a core principle of how Mayo cares for patients. As such, we believe

that the most appropriate policies will encourage responsible behavior, promote the use of effective non-opioid treatments where possible and proactively address high-risk prescribing practices. This approach is the most effective means of addressing the crisis before us without compromising legitimate patient care needs.

Absolute dose limits on opioid prescriptions, such as three-day or seven-day limits already implemented in a number of states will not satisfy the pain requirement for patients equally. Medications, particularly opioid medications, often have to be dose-adjusted to the individual and medical state. For example, a 30 year old 80 kg male recovering from a tonsillectomy will have different pain management needs than a 75 old 50 kg female recovering from hip replacement surgery. Additionally, patients appropriately using medication for non-pain treatment may also be adversely impacted by such policy changes. In essence, the emphasis of prescribing efforts should be to ensure providers are proficient in prescribing the right medication, in the right dose, for the right patient.

Our research on opioid prescribing across a number of specialties shows that there is no one correct limit for post-surgical prescribing. Several factors should be considered by the prescribing physician, such as the degree and complexity of the surgery, rehabilitation requirements, medical co-morbidities, medication interactions, and access to follow-up care (among other issues) when determining discharge prescriptions. Policies considered and implemented should recognize that no surgery—or patient—is identical to any other. As such, prescribers must have the flexibility to develop a care plan that best meets the need of his/her patient while simultaneously prescribing opioids in a responsible manner.

Additionally, the clinical community, payers, patients and regulators need to invest additional effort to develop consistent evidence-based guidelines for opioid prescribing as well as building out the evidence base for non-opioid pain treatments and therapies. While some guidelines currently exist, the wide variation in existing practice patterns demonstrates these guidelines are falling short in providing necessary information and have not been widely adopted. It is imperative that clinical standards and best practices be informed by a strong body of clinical evidence and that stakeholders feel invested in the process of developing those guidelines. These guidelines, in turn, can serve as a fair basis for measuring clinician practice and performance as part of value-based payment for services and other incentives that encourage broader adoption and utilization of practice guidelines at the facility or organization level. Existing performance measurement initiatives, such as the Quality Payment Program, may offer natural opportunities for utilizing such guidelines effectively in the future.

To reduce the reliance on cost-effective opioid treatments, Medicare and Medicaid should develop additional coverage of and reimbursement for non-opioid pharmacotherapies and treatment regimens. There is little medical evidence in support of long-term use of opioids in treating chronic pain, and a number of alternative therapies are not covered or reimbursed in a meaningful way by the Medicare and Medicaid programs. Currently, short-acting opioids are often the least expensive option for pain suffers. But, other solutions preventing Opioid Use Disorders (OUD) such as non-opioid pharmacotherapies and other non-invasive treatments are not covered by many insurers or require large co-payments or cost sharing that is prohibitively expensive for beneficiaries. Interventional treatment options are restricted, but these therapies keep many patients not only off of opioids but contribute to a high functioning status. Understanding that Medicare and Medicaid coverage should be driven by clinical evidence demonstrating the effectiveness of treatment, there may be cases where those standards benefit from greater flexibility. For instance, Congress could direct CMS to exercise greater flexibility under the coverage with evidence development process for Medicare in areas where public health would benefit from broader coverage of emerging therapies.

Opportunities for optimizing existing prescription drug monitoring programs (PDMP) at the national level should also be strongly pursued. Most states are currently utilizing some form of a PDMP to gain greater visibility into physician prescribing and patient behavior. However, there is wide variation in how these programs operate as well as who can access and utilize the information within the program. As an organization serving patients from all 50 states and with facilities physically located in several states, we have observed the need for greater coordination and consistency across programs. Aside from posing administrative difficulties, this inconsistency also leads to gaps in the system that diminish the ability of PDMPs to curtail inappropriate behavior and abuse.

While creating a national PDMP may be one option for reconciling these differences, we are cognizant of the challenges such a program may pose across states

and are concerned that duplication of state efforts could actually complicate this issue further. As such, we encourage the exploration of opportunities to bring some element of uniformity to PDMP policies and operations without adding an additional layer of regulation on top of the existing framework. One approach for undertaking that effort may be to engage with participating Medicare and Medicaid providers in partnership with states to apply consistent standards across the programs.

Furthermore, Federal policy under the Medicare and Medicaid programs should embrace integrated, multi-faceted approaches to addiction treatment, including access. Many patients continue to seek pain management, and thus opioids, in the setting of OUD. Currently, there is not enough availability of treatment programs for opioid addiction to satisfy demand and the increasing role of pain management specialists as the opioid epidemic grows is taxing many communities' available resources. Physician and other referring providers often have few or limited referral options for evaluation and/or treatment. While medically assisted therapy (MAT) for OUD has significant evidence to support its efficacy, the availability of methadone and Suboxone may be unnecessarily limited in some areas and may be financially out of reach for patients and their families with limited coverage. Further, enrolling in the DEA Suboxone program is currently administrative burdensome and significantly limits practice and patients who may be enrolled.

While Congress reviews the various policy proposals to address this crisis, any opportunity to increase public education on the ramifications of opioid addiction, the science of pain and pain management, and non-opioid alternatives and solutions may also prove beneficial by empowering patients. A recent survey conducted as part of the Mayo Clinic National Health Checkup found that a large majority of patients would choose an alternative treatment to opioid pain relievers, but only 25 percent of those surveyed said they have spoken to their provider about alternative treatments. Mayo continues to look for opportunities to educate patients and partners on the impact of various pain management options. Additionally, we engage with local government leaders and law enforcement partners to identify opportunities for increased collaboration, and recently entered a partnership with a public broadcasting partner to develop a public awareness campaign around the opioid crisis. This epidemic will only be solved with a collective approach.

Thank you for the opportunity to join you today, and for your efforts in ensuring proper pain management amidst the opioid crisis. I would be happy to answer any questions and engage further.

[SUMMARY STATEMENT OF HELENA M. GAZELKA]

Mayo Clinic is taking a deliberate, multi-faceted approach to address the drug abuse and opioid crisis across our own enterprise and in our communities, drawing upon our expertise in integrated clinical care, research and education. Our efforts embrace a broad range of pain treatment and management tools in our medical practice, where care delivery methods are put through scientific rigor to determine whether they improve patient care and outcomes, as well as development of clinical guidelines that minimize the risk of addiction and abuse with minimal impact on patient experience. We recognize that this crisis will only be solved with a collaborative approach and appreciate the opportunity to share our experience with you today.

Pain management is a very individualized practice of medicine. No patient is the same as another, and therefore each condition, treatment, and surgery has a unique impact. The scope and length of a patient's pain can also vary significantly. To ensure patients continue to receive appropriate pain treatment while guarding against overprescribing, the Mayo Opioid Stewardship Program, which I chair, was created to review our prescribing practices for both acute and chronic pain to assess how we could best support our clinicians in managing the pain needs of our patients. Paired with the development of educational tools for Mayo Clinic providers and patients and increased monitoring of opioid prescribing behavior across our organization, this initiative allowed us to realize a dramatic reduction in the amount of opioids provided to our patients with minimal complaints.

The resulting prescription guidelines, developed after extensive research on the existing prescribing practices of our clinicians as well as the experience and needs of our patients, are available to all Mayo care team members and are shared externally as well. The recommendations reflect our consensus based on physician data review, extensive patient surveys and existing guidelines, but are not a replacement for clinical judgment. We are continuously talking to the members of our care teams to adjust our protocols and integrated effective workflow tools to support adoption

of recommended practices on the Epic EHR platform deployed across all Mayo Clinic sites last year. Early results from implementation of these efforts demonstrate more appropriate acute and chronic care prescribing practices, improved pain management for our patients, and a drastic reduction in excess opioid availability.

As Congress continues to address the opioid epidemic that impacts individuals, families and communities across the Nation, I would encourage Members to increase access for patients to alternative pain management therapies, refrain from placing one-size-fits-all limits on clinician prescribing, reduce the burden for providers to access prescribing data, and promote public awareness and education on the topic of pain and various treatment options. When considering these options and opportunities, it is important to recognize at the outset that the needs of patients facing short-term pain, such as those recovering from a surgical procedure, are distinctly different than patients managing chronic pain, such as those with cancer or complex injuries.

Thank you for the opportunity to join you today, and for your efforts in ensuring proper pain management amidst the opioid crisis. I would be happy to answer any questions and engage further.

The CHAIRMAN. Thank you, Dr. Gazelka. Dr. Coop, welcome.

STATEMENT OF ANDREW COOP, PH.D., PROFESSOR AND ASSOCIATE DEAN FOR ACADEMIC AFFAIRS, UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY, BALTIMORE, MD

Dr. COOP. Chairman Alexander, Ranking Member Murray, and Committee Members, I thank you for the opportunity to testify today.

My name is Andy Coop. I am the Associate Dean for Academic Affairs at the University of Maryland School of Pharmacy. But I am a chemist. I make new drugs. I was trained over the pond by a guy called John Lewis, who many people have forgotten about. He was the guy who discovered buprenorphine. He trained me that academics are here to make discoveries, but unless those biomedical discoveries are translated to the patient, it is all for nothing. I applaud the Federal funding agencies for that focus on translational research. As we have heard, chronic pain is horrendous. There are figures, there are dollars out there, but we just owe everybody a better solution. There are wonderful, outstanding classes of opioids, and we should ensure the patients that require opioids, get them. But we need to respect them. Just like a big dog; we need to respect them.

But I have been asked today about the new analgesics coming down the pipeline, including, in full disclosure, the compound I am working on. So, opioids, not opioids, there are lots of other options, but what about opioids. Well, first of all, we need to define what we are talking about. If we do not define where we are trying to get, we are never going to get there, which is the reason I do not use the word addiction—it is very hard to define on biological mechanisms. I use the terms dependence and reinforcement.

The two concepts need to be solved when we are developing new opioid medications. Okay, what other? Dependence is when you chronically take a drug, your body adapts, so it becomes normal to have the drug present. You stop taking it, you go into withdrawal. There is only one surefire way of eliminating withdrawal and that is taking more drug. That happens in the clinic to patients. Reinforcement is the high, taking a drug recreationally. It is acute. It is instant. You get high from taking the drug. So recreational seeking of a drug is seeking to get the high. Long-term, chronic is de-

pendence. They are two very different concepts. We need to address both. So—sorry, I got ahead of myself, sorry. We need to solve both.

Think about abuse-deterrent formulations. They are designed so that they cannot be abused on the street. They are used in the clinic. That is great. They will not be diverted, but they will still cause dependence. So, discontinuation would still cause withdrawal. So, what is being done toward this area? We have biased agonists, which is activating one pathway, not another. We have approaches where opioids only go to one place in the body. We have what I am doing and many others—there are many people doing this—where we actually target two biological systems, where the second biological system modulates the first to prevent the dependence under reinforcement.

Many are in development in both academic and industrial laboratories, and it is important to continue this funding, of which thankfully NIDA and the NIH have been wonderful. We need consistent funding. As mentioned by the Chairman, the FDA has a critical role in addressing these drugs. But not only does the FDA need to do this rapidly, it needs to be safe. It is safe and effective. We need to ensure that we do not bring drugs to the market that make things worse. Non-opioid medications. We have gone through some of these. Some that were not mentioned. OTC ibuprofen often works very well for many patients, and we need to remember that.

We have local anesthetics. We have channel blockers. We have capsaicin and non-pharmacological treatments. And yes, we need to do further research, and yes, it is controversial, but we really should look at the potential of cannabinoids. The studies are not out there. If we do not have the studies, we cannot make the decision on the potential of cannabinoids. In my last two minutes, I just want to talk quickly about my profession of pharmacy, my Doctorate profession of Pharmacy. Pharmacist pretty much, often get ignored in this crisis. They are accessible. They are trained. They are doctors. They are able to help with counseling patients on the appropriate medications to use. And one major impact that the Federal Government could make is to expand the prescribing of buprenorphine for medication-assisted treatment to include pharmacists. This is called getting a data waiver, so that the pharmacists, under collaboration, could prescribe buprenorphine and provide the buprenorphine in a very accessible pharmacy.

Thank you.

[The prepared statement of Dr. Coop follows:]

PREPARED STATEMENT OF ANDREW COOP

Chairman Alexander, Ranking Member Murray and Committee Members, I want to thank you for the opportunity to testify today on a matter of critical importance to this country, and I applaud this Committee for continuing to seek to better understand alternatives for pain management that will not lead to opioid addiction. I am Dr. Andrew Coop and I am a Professor of Pharmaceutical Sciences in the University of Maryland's School of Pharmacy. As many of you know, the school is located at the University of Maryland, Baltimore in the city of Baltimore—a densely urban area of this country which has its share of the many challenges US cities face. The scourge of opioid addiction continues to be particularly prevalent in Baltimore despite many relatively successful efforts to lessen its impact. The University, where I have worked for 20 years, is deeply involved in this fight for our citizens' lives. I was trained in England by John Lewis, a name that is not known to many; he was the person who developed buprenorphine, and I have followed him in my personal research efforts, focused on developing non-addictive, non-opioid alter-

natives for pain management to help diminish the number of individuals addicted to opioids due to chronic pain.

With this background, I want to briefly outline the current state of research in finding effective, non-addictive pain compounds, discuss the promise and to offer suggestions on strengthening the administration of pain management compounds. In the interest of transparency, I want to disclose that one of the compounds I will discuss is being developed by ALT Pharmaceuticals of which I am the co-founder along with a colleague from the School of Pharmacy, and I serve as its Chief Scientific Officer.

Let me begin by saying that individuals who suffer from severe and chronic pain deserve our sincere sympathy. Their discomfort is debilitating and even life threatening in some cases, and their addiction to relief brought on by opioids is not by choice in most cases. We owe these individuals a better solution—one that does not come with its own complications and one that, while not curing the condition that brings the pain, enables them to return to a fuller life.

The number of individuals with chronic pain addicted to opioids is significant according to recent data. According to the CDC's National Health Interview Survey (NHIS), an estimated 20.4 percent of U.S. adults—some 50 million people—had chronic pain and nearly 20 million had high-impact chronic pain—pain that frequently limits life or work activities.

Make no mistake, opioids are an outstanding class of drugs for treating pain when used appropriately. All currently approved opioids interact with and activate certain receptors in the brain which gives rise to analgesia (pain relief), and are a gold standard in treating pain when used appropriately. Unfortunately, they also give rise to all the associated side effects, including “addiction” and respiratory depression—it is the respiratory depression (slowing of breathing) that is the major cause of death on overdose. In my work and those of others in the field, we are searching for a compound that will treat the threshold of pain like opioids, but without the dependency of opioids. I attempt to avoid the term “addiction” due to the fact that it is often interpreted differently by different people, and therefore does not allow a scientific approach to the development of new opioids lacking such an effect. If we don't know what our goal is, we will never get there. We need to define terms that can be measured biologically, namely *dependence* and *reinforcement*. They are different and have different mechanisms.

Dependence: Chronic administration of an opioid causes adaptations in the brain—specifically to the *mu receptors*, where they now function as if the opioid is present. On discontinuation of the opioid, the receptors are suddenly functioning without the drug that they adapted to, and this leads to withdrawal. This effect occurs no matter the reason for taking the opioid (for clinical reasons or for recreational reasons), so a patient who has received chronic administration of an opioid to treat pain will have withdrawal just as much as a person taking illicit opioids. The withdrawal effects are severe (like a bad case of the flu) and leads to patient seeking opioids to prevent withdrawal. Both prescription and illicit opioids would attenuate the withdrawal effects (as both work through *mu receptors*), leading to a life of drug use.

Reinforcement: In addition to analgesia, opioids also give rise to euphoria—commonly referred to as a “high”, an acute and instant effect. This effect leads to drug seeking for recreational purposes, and the drugs are usually administered through snorting or by injection for optimal reinforcement. Overtime, as the individual takes opioids chronically, they develop dependence, and drug seeking turns to preventing withdrawal, rather than for reinforcement. As stated, all opioids act through the same mechanism, so prescription opioids are often diverted for recreational use due to their reinforcing properties.

My research, along with that of several others is focused on the development of an opioid lacking both reinforcement (like the abuse deterrent formulations) and dependence. Approaches include biased agonists, opioids that do not enter the brain (peripheral opioids), as well as my approach of designing a drug that activates both *mu receptors* and an additional biological system that prevents the side effects from *mu*. Many are in development in both academic and industrial laboratories, and it is critical that this research continue to be funded. The FDA has a critical role in the approval of such opioids, as we need an approach that will be both rapid in getting the drug to patients, but ensure that the new opioids are indeed safer than the current clinically approved ones. For instance, the drug developed in my laboratory appears to lack dependence in animal tests, but is reinforcing in larger rodents. Thus, although this compound (UMB425) appears promising it is not a panacea, is only half-way to the optimal analgesic, and would almost certainly not be approved

by the FDA, due to the potential for illicit use through its reinforcing properties, something that has happened recently for other new opioids.

An example of effort to create a drug for pain management without the complications of reinforcement is loxicodegol under development by an industrial laboratory.

The efforts to design a drug that would treat the same level of pain as a traditional opioid but would lack both dependence and reinforcement characteristics continue in laboratories across the US, but may take a number of years to reach the prescribing market. Like you, I wish this were not the case, but the research is intense and hopeful. A more rapid approach would be the use of drug combinations, where a lower dose of opioid is combined with another approved drug leading to lower doses of opioid required.

Research is also ongoing to find ways to potentially reduce recreational use of opioids, which is of concern to policymakers and the Nation as a whole as the drug crisis continues. One approach is to focus on the use of “abuse-deterrent formulation”. For example, we can use tablets that prevent removal of the opioid to be diverted for recreational use and injected or snorted, but when taken orally will have the desired analgesic effect. The same is true for using a patch for transdermal drug induction. Taking a drug orally or transdermally leads to less reinforcing effects, as it is the rate of increase in levels that is correlated with reinforcement. Abuse deterrent formulations are a strong step toward the optimal opioid, but, however, do not prevent the development of dependence as that is due to chronic, long-term action of opioid on the brain’s mu receptors—so not yet perfect.

As noted above, opioids should continue to be available to patients for the treatment of severe pain, as they are unsurpassed in their ability to treat chronic pain. That said, we need to ensure patients who require opioids are able to have them prescribed. However, their use should be reduced to a minimum, with education of patients on appropriate use and misuse. This requires a multi-faceted approach to pain management, including education of both patients and prescribers that pain is to be *managed*, rather than eliminated. This requires a team-based approach, where one size does not fit all. We all have experienced pain of some sort, and the first line of defense is to use aspirin, ibuprofen, acetaminophen or naproxen. When these and other over-the-counter medicines fail to relieve our symptoms, we turn to our physicians who may suggest alternative or complementary approaches such as exercise, physical therapy, weight loss, acupuncture, or cognitive behavioral therapy. There are local anesthetics and nerve blockers that are effective for surgical pain, but cost is often an obstacle. Topical capsaicins work well in many cases. Medical cannabis, controversial as it is, has potential, but well-designed studies are lacking. However, these potential sources of relief may not suffice especially for those with high-impact chronic pain and many require more patience and dedication than a pain sufferer can manage, and we ask for more. Many patients have come to expect a prescription of opioids that unrealistically totally eliminates pain when the appropriate goal is to reduce pain to a manageable level. Patient education, counseling, and follow-up care are critical to minimizing the risk of addiction.

I cannot stress enough the importance of prescriber education on opioid prescribing and would hope that this Committee and other interested bodies would continue to push for reducing the number of potentially unneeded opioid prescriptions written. Further, I suggest that patients need to take more personal responsibility for managing their pain before asking one’s physician “for something stronger”.

If I might turn to my own adopted profession and how pharmacists can contribute to reducing addiction. We are behind the counter when a prescription is filled and our prescription records often tell an important story about a particular patient. We are on the front line when opioids are the choice. The opioid epidemic requires an “all hands-on deck” inter-professional team approach to truly combat opioid-related deaths and adequately treat opioid use disorder. Adding to the complexity, mental illness and substance use disorders are often concurrent chronic disorders. We want to make you aware of the unique expertise that specialized pharmacists can bring to this effort. Pharmacists are medication experts and one of the most accessible health care professionals, yet they have been underutilized in fighting this epidemic. Expanding the prescribing of medications like buprenorphine/naloxone to include pharmacists would optimize treatment access and patient care.

Pharmacists are routinely making a difference every day by dispensing medications like naloxone and educating the public about this lifesaving antidote for opioid overdose. They receive years of training to educate patients, manage and monitor medications, including for side effects and drug interactions, and, in some cases, prescribing and administering medications. Allowing pharmacists to practice at the full extent of their education expands access to care. When pharmacists gained the

authority to administer influenza vaccine and other vaccinations, immunization rates significantly increased. As a result, 280,000 pharmacists are trained to administer vaccines. Pharmacists also receive specialized training in various practice areas. For instance, psychiatric pharmacists are uniquely qualified to work with opioid use disorder patients and are experts in medication use and abuse/diversion. Psychiatric pharmacists receive graduate pharmacy degrees and post-graduate residency training in psychiatry and substance abuse. They are eligible to become board certified psychiatric pharmacists (BCPP) by completing required prerequisites and a rigorous national exam.

Most states allow pharmacists to prescribe or adjust patient medications and monitor medication effects in collaboration with a physician through laws permitting collaborative drug therapy management (CDTM) agreements. Patients with substance use disorders and mental illness often require complicated medication regimens. Collaboration between prescribers and pharmacists helps to optimize medication selection, improve safety, and expand access to care, especially in areas with a shortage of health professionals.

Buprenorphine/naloxone is an effective treatment for opioid use disorder. Unlike other medications, including prescription opioids, buprenorphine/naloxone can only be prescribed by a DATA-waivered prescriber, which limits treatment availability. Lack of institutional, mental health and psychosocial support has been cited as significant barriers to prescribing buprenorphine among primary care providers. Pharmacists are not currently eligible to apply to become DATA-waivered. We ask your support and petition for Federal legislative changes which would allow pharmacists participating in CDTM agreements to prescribe buprenorphine/naloxone collaboratively with physicians to further expand access to care and improve treatment outcomes. I strongly recommend that we allow pharmacists to prescribe buprenorphine as part of an overall management of care for opioid use disorder, and gain reimbursement from Medicare. We need a long-term solution to the opioid crisis, but we also need to ensure that current patients have optimal access to medication-assisted treatment.

In conclusion, we must continue to allow access to opioids for those individuals with significant pain while we search for alternative medicines to control pain. Alternatives to opioids are within reach and research funding into such medications must not be threatened if progress is to be made. Policies designed to stem illicit drug use must not jeopardize appropriate health care. Greater efforts into the development of “safer opioids” are warranted. Prescriber and patient education on the use, and possible misuse of opioids for chronic pain conditions must continue and be strengthened. Teams addressing the opioid crisis should include pharmacists.

Thank you.

[SUMMARY STATEMENT OF ANDREW COOP]

Severe and chronic pain is debilitating and even life threatening in some cases, and addiction to relief brought on by opioids is not by choice in most cases. We owe these individuals a better solution—one that does not come with its own complications and one that, while not curing the condition that brings the pain, enables them to return to a fuller life.

My testimony will focus on four main areas:

1. The need to define the biological mechanisms behind addiction, specifically the difference between dependence and reinforcement, and how new opioid analgesics need to address both.
2. Non-opioid analgesic medications that are available, including combinations to lower the amount of opioid, non-pharmacological treatments, and potential new drugs that act through non-opioid mechanisms.
3. The education of both patients and prescribers on the fact that pain management should indeed be considered as management, rather than an elimination of all pain. Opioids should be available to those patients that require them, but their use should be kept to a minimum.
4. Pharmacists are medication experts and one of the most accessible health care professionals, yet they have been underutilized in fighting this epidemic. Expanding the prescribing of medications like buprenorphine to include pharmacists would optimize treatment access and patient care.

The CHAIRMAN. Thank you, Dr. Coop. Dr. Rao-Patel, welcome.

STATEMENT OF ANURADHA RAO-PATEL, M.D., LEAD MEDICAL DIRECTOR, BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, DURHAM, NC

Dr. RAO-PATEL. Good morning. Thank you, Chairman Alexander, Ranking Member Murray, the distinguished Members of the Committee and their staffs for providing me with the opportunity to talk about the management of pain during the Opioid Crisis—I apologize.

My name is Anu Rao-Patel. I am a Lead Medical Director of Blue Cross Blue Shield of North Carolina. My background is in physical medicine and rehabilitation, and prior to joining Blue Cross four years ago, I was in private practice doing chronic pain management and some management of addiction. I continue to remain clinically active. I see patients regularly in addition to my primary role at Blue Cross. I hope to provide unique perspective today to the Committee based on my clinical training and practice as a board-certified physiatrist, my first-hand management of chronic pain, as well as my perspective as a Medical Director at Blue Cross, North Carolina. I have also submitted written testimony, which further expands on my comments. At Blue Cross, North Carolina, we serve close to 4 million customers. We are in every zip code of all 100 counties. The Blue Cross, North Carolina PPO network of health care providers includes 96 percent of medical doctors and 99 percent of general acute-care hospitals. Blue Cross, North Carolina is accredited by the National Committee for Quality Assurance. We are all aware of the scope of the issues with the Opioid Crisis, both the human and the financial toll that it is having.

In North Carolina alone, Attorney General Josh Stein stated that in 2018, four people died every day from an overdose and that between 2017 and 2018 the number of fatal overdoses in North Carolina increased by 33 percent, and that is even with efforts to reduce overdose death by distributing naloxone to reverse narcotic effects. Blue Cross and Blue Shield companies are strongly committed in doing our part to combat the epidemic of opioid use disorder while ensuring patients living with chronic pain get access to appropriate evidence-based treatments. As evidence of this unified commitment, I am listing several examples of things that we cover.

We provide coverage for non-opioid pharmacologic alternatives for pain management including, non-steroidal anti-inflammatories, antidepressants, anticonvulsants, topical analgesics, alpha-2 agonists, and others. We provide coverage for non-pharmacologic alternatives for pain, including physical therapy, occupational therapy, aquatic therapy, chiropractic care, trigger point injections, biofeedback, steroid joint injections, interventional pain procedures, including facet blocks, medial branch blocks, epidural steroid injections, spinal cord stimulators. We cover TENS units, intra-articular hyaluronic acid injections for knee osteoarthritis, Botox injections for migraine and spasticity, as well as others. We have endorsed the CDC guidelines for prescribing opioids for chronic pain, and we are working collaboratively with the prescriber community to implement these, understanding that there is not a one-size-fits-all approach to managing pain.

We support access to medication-assisted therapy, including associated counseling and behavioral therapy. We support a wide avail-

ability of naloxone. We support enhanced operability of prescription drug monitoring systems and encourage providers to access this data before prescribing. As chronic pain is a legitimate and debilitating medical issue, there are many opportunities for physicians to continue to manage pain effectively with or without the use of opioids. Physicians must incorporate the universal precautions in the use of pain medicine for the treatment of chronic pain, including making an accurate diagnosis, informed consent with a patient, treatment agreements, pre and post-intervention assessment to assess pain and function.

The goal of long-term pain management is to support the patient improvement of their function and quality of life as much as possible, despite their ongoing pain symptoms. Opioids are certainly an option to support select patients in managing symptoms and should be prescribed thoughtfully and judiciously as part of a broader pain management regimen. In addition, patients must have realistic and honest expectations of pain management goals, including understanding that in some circumstances elimination of pain in its entirety is not a possibility but certainly a goal.

Providers should continue self-education on appropriate prescribing and in pain management, as well as participation in their state and medical licensing boards on continuing medical education requirements. There must also be increased training in medical school and residency programs on pain, as well as addiction, as well as increased research nationally on pain.

Finally, physicians and payers must understand, as mentioned several times, that there is no one-size-fits-all approach to manage chronic pain, and must incorporate a holistic, multimodal, and thoughtful approach similar to any other chronic medical condition. Thank you again for including me in this discussion. Blue Cross Blue Shield companies share your commitment in addressing America's Opioid Crisis, and ensuring those who are suffering from opioid use disorder, as well as chronic pain, get the care that they need.

Thank you.

[The prepared statement of Dr. Rao-Patel follows:]

PREPARED STATEMENT OF ANURADHA RAO-PATEL

Good morning and thank you, Chairman Alexander, Ranking Member Murray, the distinguished Members of the HELP Committee, and their staff for providing me with the opportunity today to discuss the management of pain during the opioid crisis. My name is Anuradha Rao-Patel, and I am a Lead Medical Director at Blue Cross and Blue Shield of North Carolina (Blue Cross NC). My background is in Physical Medicine and Rehabilitation and prior to joining Blue Cross NC four years ago, I was in private practice providing management and treatment for chronic pain and addiction. I continue to remain clinically active and see patients regularly in addition to my primary role at the health plan. I hope to provide a unique perspective to the Committee today based on my clinical training and practice as a board-certified physiatrist, my first hand management of chronic pain as well as addiction, as well as my perspective as a Medical Director at Blue Cross NC.

Background—Blue Cross Blue Shield Association and Blue Cross NC:

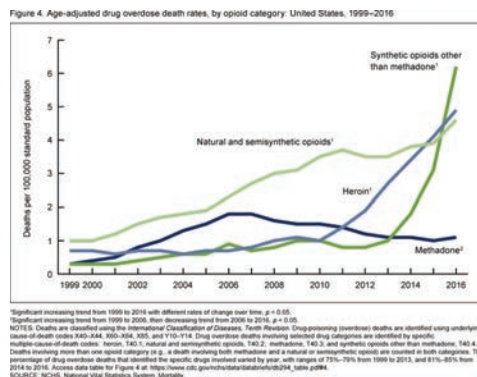
Since 1929, Blue Cross Blue Shield (BCBS) companies have provided healthcare coverage to members in every ZIP code. Blue Cross Blue Shield offers a personalized approach to healthcare based on the needs of the communities where their members live and work. They work closely with hospitals and doctors in the communities they serve to provide quality, affordable health care.

We understand and answer to the needs of local communities, while providing nationwide health care coverage that opens doors for more than 106 million members in all 50 states, Washington, DC, and Puerto Rico. Nationwide, more than 96 percent of hospitals and 95 percent of doctors and specialists contract with Blue Cross Blue Shield companies—more than any other insurer.

At Blue Cross NC, we serve close to 4 million customers and are in every ZIP code of all 100 counties. The Blue Cross NC PPO network of health care providers includes 96 percent of medical doctors and 99 percent of all general acute-care hospitals. Blue Cross NC is accredited by the National Committee for Quality Assurance (NCQA), a not-for-profit organization dedicated to improving health care quality. NCQA is the most widely recognized accreditation program in the United States. We have partnered with our provider network and continue to work collaboratively with other key state stakeholders including North Carolina Department of Health and Human Services (NCDHHS), North Carolina Medical Board (NCMB), North Carolina Medical Society (NCMS), and the North Carolina Attorney General's Office.

Scope of the Issue-Opioid Epidemic:

According to the Centers for Disease Control and Prevention (CDC), from 1999–2017 almost 400,000 people in the United States died from an overdose involving any opioid, including prescription and illicit opioids. They also estimate that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion per year, which includes the costs of health care, lost productivity, addiction treatment, and criminal justice involvement. The National Institute on Drug Abuse (NIDA) estimates that roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them and between 8 and 12 percent develop an opioid use disorder. In North Carolina alone, Attorney General Josh Stein stated that in 2018 four people died every day from an overdose and that between 2017–2018, the number of fatal overdoses in North Carolina increased by 33 percent—and that is even with efforts to reduce overdose deaths by distributing naloxone to reverse narcotic effects.



Blue Cross Blue Shield Findings:

Blue Cross Blue Shield Association (BCBSA), in collaboration with Blue Health Intelligence (BHI), examined opioid prescription rates, opioid use patterns and opioid use disorder among commercially insured Blue Cross Blue Shield (BCBS) members (excluding members diagnosed with cancer or who were undergoing palliative or hospice care). In 2017, BCBSA released a report, *The Health of America* report, illustrating the impact of opioid use and opioid use disorder on the health of Americans.

While progress has been made, there were approximately 241,900 BCBS members diagnosed with opioid use disorder in 2017.

Specific Findings

- Nationally, the total number of opioid medications filled by commercially insured BCBS members has declined by 29 percent since 2013, with sig-

nificant variation among states. Thirty-four states had higher reductions, with Massachusetts leading at 51 percent.

- In 2017, 67 percent of BCBS members filled their first opioid prescription within the CDC-recommended guidelines for both dose and duration. Some states did significantly better than the average, led by Rhode Island at 80 percent, Mississippi at 74 percent and Vermont and Massachusetts at 73 percent.
- When examining total opioid prescriptions for BCBS members in 2017, not just the first prescription, 45 percent of members filled prescriptions within the CDC-recommended dose and duration guidelines, up from 39 percent in 2013.
- In 2016, opioid use disorder claims stabilized, with 6.2 in 1,000 BCBS members diagnosed. The rate dipped slightly to 5.9 in 1,000 members in 2017.

Why Opioids have the Potential for Abuse:

In order to understand why opioid medications have the potential for abuse, one needs to understand what an opioid is and how these medications are metabolized in the human body. Opioids are a class of drugs naturally found in the opium poppy plant. Some prescription opioids are extracted from the plant directly, while others are manufactured in laboratories using the same chemical structure. Opioid medications exert their analgesic effects predominantly by binding to mu-opioid receptors. These receptors are densely concentrated in brain regions that regulate pain perception (periaqueductal gray, thalamus, cingulate cortex, and insula), including pain-induced emotional responses (amygdala), and in brain reward regions (ventral tegmental area and nucleus accumbens) that underlie the perception of pleasure and well-being. Mu-opioid receptors are also located in other regions such as the gastrointestinal tract which explain other side effects of opioids such as constipation and in the brainstem which results in the respiratory depression associated with opioid-overdose incidents and death. Opioid medications vary with respect to their affinity and selectivity for the mu-opioid receptor and there is also variability among the drugs with respect to their pharmacokinetics and bioavailability.

Chronic Pain:

Chronic pain generally is defined as pain lasting three or more months or beyond the time of normal tissue healing. According to the *Morbidity and Mortality Weekly Report* (MMWR) from the Centers for Disease Control and Prevention (CDC), approximately 50 million American adults—20.4 percent of the U.S. adult population—have chronic pain, defined as pain most days or every day for at least the past six months. Age and sex do seem to make a difference, with a higher prevalence among older adults and women. For those with chronic pain, 8 percent (19.6 million adults), report that the pain is bad enough to frequently limit their daily life or work activities. In addition, living with chronic pain can also lead to a variety of health issues, including anxiety and depression. All told, according to estimates cited by the CDC, the bill in the United States for chronic pain totals at least \$560 billion a year in medical expenses, lost productivity and disability programs.

Use of Opioids to Manage Chronic Pain:

Opioids emerged into standard management for chronic pain management in the 1990s. There are many conditions for which opioids have been prescribed including arthritis, low back pain, fibromyalgia, musculoskeletal pain, and in dental issues. The recognition of the role of opioids in the management of acute and end-of-life pain, the inappropriate adoption of World Health Organization (WHO) analgesic ladder designed for use in cancer pain at the end of life, the utilization of pain scales (0–10 scale) to rate level of pain, the refractory nature of persistent pain, labeling pain as the fifth vital sign, and the influence of marketing by the pharmaceutical industry fueled an increase in the popularity of opioids as a treatment for chronic pain. Early studies seemed to provide sufficient evidence to support this approach. In 2013, however, it became evident that the rise in the prescribing of opioids was accompanied by a parallel rise in opioid-related harms, including addiction, overdose, and death. A reevaluation of the early clinical trials suggested that opioid use in clinical practice was neither as safe nor effective as previously believed.

There are a number of systematic reviews on use of opioid therapy for chronic pain. However, evidence on the benefits of long-term opioid therapy is still lacking. There appears to be no data that any one opioid is more effective than another and minimal evidence that opioids differ in their propensity to cause harm. An obvious

limitation is the short duration of many clinical trials and the fact that most clinical trials were monitored and supervised closely and firm conclusions cannot be extrapolated into the long-term use in a clinical practice setting.

Evidence is also lacking regarding the relationship between or the progression from acute to chronic pain, although preoperative chronic pain is thought to be a risk factor. It has also been proposed that inadequate management of acute pain may increase an individual's risk for development of chronic pain.

Alternatives to Opioids to Manage Chronic Pain:

It is important to emphasize and understand that the term “pain management” has not been clearly defined and is generally lacking in research. Oftentimes, the term is used erroneously to denote solely pharmacologic tools, most commonly with the use of an opioid. However, pain management may involve the use of a number of tools—both pharmacologic and nonpharmacologic—to both relieve pain and improve function and quality of life. In my personal experience in clinical practice, patients more often than not equated a referral for pain management with an automatic prescription for a narcotic. Physicians fortunately are in a front-line role and have the unique opportunity to educate their patients on expectations and goals for management of their pain. As chronic pain represents a complex pathophysiologic condition that develops over time, its successful management often requires an equally complex and time-intensive approach. Therefore, combining multiple therapeutic modalities, nonpharmacologic and pharmacologic (non-opioid and opioid) and treating pain holistically by addressing the underlying cause as well as the immediate experience appears to be the best approach. In addition, redirection and emphasis on setting reasonable expectations and establishing mutually agreed-upon goals for the control of chronic pain, with an emphasis on communication and safety is paramount.

Role of the Payer in Management of Chronic Pain:

Blue Cross Blue Shield companies are strongly committed in doing our part to combat the epidemic of opioid use disorder while ensuring patients living in chronic pain have access to appropriate evidence based treatment. As evidence of this unified commitment, I have listed several examples below:

- We provide coverage for non-opioid pharmacological alternatives for pain management including nonsteroidal anti-inflammatory medications, antidepressants, anticonvulsants, topical analgesics, alpha 2 ($\alpha 2$) adrenoreceptor agonists, and others
- We provide coverage for non-pharmacological alternatives for pain management including physical therapy, occupational therapy, aquatic therapy, chiropractic care, trigger point injections, biofeedback, steroid joint injections, interventional pain therapies (facet blocks/medial branch blocks/epidural steroid injections and spinal cord stimulators), TENS unit, intraarticular hyaluronan injections for knee osteoarthritis, Botox injections for migraine and spasticity and others
- We endorsed the CDC Guidelines for Prescribing Opioids for chronic pain and are working collaboratively with the prescriber community to implement these or similar guidelines
- We support access to Medication Assisted Treatment (MAT) including the associated counseling and behavioral therapy
- We support wide availability of naloxone
- We support enhanced operability of prescription drug monitoring programs (PDMPs) and encourage providers to access PDMP data before prescribing

Conclusion:

As chronic pain is a legitimate and debilitating medical issue, there are many opportunities for physicians to continue to manage pain effectively with or without the use of opioids. Physicians must incorporate “universal precautions” in the use of pain medicine for the treatment of chronic pain as excerpted from Gourlay, et al ... 2005 including the following:

1. Make a Diagnosis with Appropriate Differential
2. Psychological Assessment Including Risk of Addictive Disorders
3. Informed Consent
4. Treatment Agreement

5. Pre-and Post-Intervention Assessment of Pain Level and Function
6. Appropriate Trial of Opioid Therapy +/- Adjunctive Medication
7. Reassessment of Pain Score and Level of Function
8. Regularly Assess the “Four A’s” of Pain Medicine: Analgesia, Activity, Adverse Effects, and Aberrant Behavior
9. Periodically Review Pain Diagnosis and Comorbid Conditions, Including Addictive Disorders
10. Documentation

The goal of long-term chronic pain management is to support the patient in improvement of their function and quality of life as much as possible despite their ongoing pain symptoms. Opioids are certainly an option to support select patients in managing symptoms, and should be prescribed with caution if they are effective in low doses and used intermittently as part of a broader pain management plan. In addition, patients must have realistic and honest expectations of pain management goals including an understanding that after an assessment of risk versus benefit in the use of opioids, that pain elimination may not be a possibility. Providers should continue self-education on appropriate and judicious prescribing and in participation in their state medical and licensing boards continuing medical education (CME) requirements. There must also be increased training in medical schools and residency programs on pain and addiction as well as increased research on pain. Finally physicians and payers must understand that there is no “one size fits all” approach to manage chronic pain and it must incorporate a holistic, multimodal, and thoughtful approach.

Thank you again for including me in this discussion. Blue Cross Blue Shield companies share your commitment in addressing America’s opioid crisis and ensuring that those suffering with opioid use disorder and chronic pain get the care they need.

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[SUMMARY STATEMENT OF ANURADHA RAO-PATEL]

- According to the Centers for Disease Control and Prevention (CDC), from 1999–2017 almost 400,000 people in the United States died from an overdose involving any opioid, including prescription and illicit opioids.
- In 2017, BCBSA released a report, *The Health of America* report, illustrating the impact of opioid use and opioid use disorder on the health of Americans.
- According to the Morbidity and Mortality Weekly Report (MMWR) from the Centers for Disease Control and Prevention (CDC), approximately 50 million American adults—20.4 percent of the U.S. adult population—have chronic pain, defined as pain most days or every day for at least the past six months.
- There are a number of systematic reviews on use of opioid therapy for chronic pain. However, evidence on the benefits of long-term opioid therapy is still lacking.
- It is important to emphasize and understand that the term “pain management” has not been clearly defined and is generally lacking in research. Oftentimes, the term is used erroneously to denote solely pharmacologic tools, most commonly with the use of an opioid. However, pain management may involve the use of a number of tools—both pharmacologic and nonpharmacologic—to both relieve pain and improve function and quality of life.
- Blue Cross Blue Shield companies are strongly committed in doing our part to combat the epidemic of opioid use disorder while ensuring patients living in chronic pain have access to appropriate evidence based treatment.
- The goal of long-term chronic pain management is to support the patient in improvement of their function and quality of life as much as possible despite their ongoing pain symptoms.
- There must also be increased training in medical schools and residency programs on pain and addiction as well as increased research on pain.
- Finally physicians and payers must understand that there is no “one size fits all” approach to manage chronic pain and it must incorporate a holistic, multimodal, and thoughtful approach.

The CHAIRMAN. Thank you, Dr. Rao-Patel. We will now go to five-minute round of questions. I am going to try to hold combined questions and answers to five minutes because we have lots of Senators interested in discussion today.

I will begin with Senator Isakson.

Senator ISAKSON. Thank you, Chairman Alexander. Ms. Steinberg, I hate to make you get up off your cot.

[Laughter.]

Ms. STEINBERG. It is Okay. I am used to going back and forth.

Senator ISAKSON. Well, you can tell that you have the same—that part we were talking about, and we appreciate all you are doing to help us learn more about it, and Dr. Coop I appreciate your pronunciation of all those words. I cannot pronounce any of them.

[Laughter.]

Senator ISAKSON. I would like to know the name of the new one you are working—or have you named the new one you are working on?

Dr. COOP. It has got a code number at the moment, UMB425.

Senator ISAKSON. Okay, well that does not help me much.

Dr. COOP. Nope.

[Laughter.]

Senator ISAKSON. I do numbers better than letters anyways, so thank you. But thanks to all of you. I lost a grandson to an overdose and an addiction, and so, this issue is important to me. And so much of the stuff is on the streets now. It is stuff gotten out of medicine cabinets in homes. And it may have come from Mexico, it may have come from Canada, it may have come from somewhere else, but they got them—kids got it in medicine cabinets, and take them, and it causes big problems. My first question, Dr. Patel maybe you would be the best person to ask this or probably all of you would be. Is hydrocodone the most prescribed? Is it the most prescribed pain medicine?

Dr. RAO-PATEL. Yes, it is.

Senator ISAKSON. It is an opioid, is it not?

Ms. STEINBERG. Yes.

Senator ISAKSON. The reason I ask that question is, I had a major back operation 2 years ago, and I mean major, and major pain. And the surgery worked. I had finally to go to surgery and had fusion and all that kind of stuff. But I noticed that I was always getting hydrocodone because I was having dental work done in terms of implants. I was having a back surgery fusion done. And I got so much hydrocodone—it just seemed like I had an excess of it. Is it prescribed more than anything else because it is less addictive than other types of opioid-based pain medicines, or is it just the most popular one?

Dr. GAZELKA. I think that is probably a culture. It is a very popular medication because it has always been combined with acetaminophen and so people have felt that perhaps you would need less opioid with the combination of acetaminophen. It has been sort of culture in dental schools and in other outpatient arenas, particularly to prescribe hydrocodone.

Senator ISAKSON. It is equally as addictive, is it not?

Dr. GAZELKA. It is. Yes.

Senator ISAKSON. But one of you, and I forgot who did it so all of you can address this question, but one of you talked about addiction, and I think that is the problem. I mean I—and you talked about new, encouraging new development. I think, Dr. Coop, you said that. How the pharmaceutical companies and others find replacements for opioid-based painkillers, and to help with the problem. I think that is exactly it. I mean, I think that if we could take all the hydrocodone that is prescribed in America and substitute some new development that does not use opioids as a base, we would solve a lot of our problems on addiction, I think.

Do you know how many pharmaceuticals are actually working on something like that? It may be what Dr. Coop is working on. I do not know, but is there a lot of work being focused on trying to find a replacement for that?

Dr. COOP. I have a list actually here of about 12 different laboratories currently working toward new opioids. But that is just on the opioid space. They are also working on the non-opioids space.

Senator ISAKSON. Yes, the replacement.

Dr. COOP. A non-opioid replacement that does not work through opioid mechanisms.

Senator ISAKSON. I think that is the most important thing. I am convinced opioids—and I am not a physician. I am an expert in having pain, but I think that—

[Laughter.]

Senator ISAKSON. I think the opioids is a problem, and I think that addiction is a problem. If we can find a way to cure addiction or at least reduce dependence and addiction, we will be a whole lot better off. And I think that is what you said. I think that is what you said.

Dr. GAZELKA. If I could just make a comment. I think so much of that legislation and a lot has been concentrated on treating current addiction, which is obviously incredibly important. We have a country full of people who have substance use disorders, but I think that what you touched on is really important—the prevention of future addiction. The contact, preventing contact with pain medications the teenagers are finding in their parents' medicine cabinet or that they are coming in contact with when they have their wisdom teeth removed in high school. And I think that is really going to be essential for future generations.

Senator ISAKSON. Well, I appreciate it. I think so too and having three children, and having nine grandchildren, I see what we get in our medicine cabinet at home for them, and it is important that be managed as well as possible. It keeps kids from getting something and getting addicted to it without us even knowing, and my grandson, who I lost, is a step-grandson, was not with me all his life, but was with me a lot of his life, he was addicted before we knew, before anybody in the family knew what he was getting or where he was getting it from. But it was a medicine cabinet that got him started and the peer pressure that kept him on it, and dependence that caused the problem. So, I appreciate what you said, what all of you said. I appreciate what you are working on, and God bless all of you for doing it.

Dr. GAZELKA. Well, I am terribly sorry for your loss, sir. We do know that 80 percent of people who eventually develop heroin use disorders and other substance use disorders start with a legitimate prescription that someone received, not necessarily themselves. I am sorry.

Ms. STEINBERG. Senator Isakson, I totally support your emphasis on research. As I mentioned, the HEAL Initiative is a great start, but we have underinvested in research. For the number one reason why people go to the doctor, less than 2 percent of NIH's budget was dedicated toward pain. We still do not understand the basic mechanism of pain in the body. So, we really need investment in research commensurate with the burden of pain. And I think we are going in the right direction, but we have to keep going there.

Senator ISAKSON. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Isakson.

Senator MURRAY.

Senator MURRAY. Yes, thank you very much to all the panel. Really, appreciate it. Throughout these Committees, bipartisan work on the opioid misuse crisis, I have heard from people who supported our legislative efforts who are very grateful. But I also heard from some people with disabilities who experience pain and fear that restricting access to treatment could affect independent

living merely because they were unable to manage their pain. So, Dr. Gazelka, maybe you can take this on, have we struck the right balance in our work to reduce misuse but also making sure that treatments are available, which can be really vital for people with disabilities?

Dr. GAZELKA. That is a very good question, and I worry that we have gotten ahead of ourselves with wanting to restrict opioids. A lot of people are now—a lot of providers—are now scared to provide opioids to patients. They have been prescribing them for many years, but that does not necessarily mean that those patients have come in contact with a pain provider who can help them manage their pain with other means. Most opioids in the United States that are prescribed chronically are prescribed by primary care providers, many of them who do not have any education in managing chronic pain. They do not have time to go into the detail that it takes to talk to patients about other options. They do not have access to pain providers, and I think in some ways—I mean, we have done what needed to be done, which is to drastically reduce opioid prescribing, I think, but I worry that we are getting ahead of ourselves with having available and other options.

Senator MURRAY. Okay. Thank you. I know people experience pain in a lot of different ways, but one of the things I am really concerned about is how bias in the health care system can affect a patient's treatment for pain. Despite the fact that women experience pain at higher rates than men, they are more likely than men to receive sedatives or be diagnosed with a mental health condition when they seek treatment for pain. And when it comes to cardiac care, women are less likely to have their heart attack symptoms recognized, or to receive painkillers after cardiac surgery. And, when patients are not listened to, the results can be debilitating, even fatal. So, Dr. Gazelka, maybe I can ask you, have you seen female patients being treated differently than male patients?

Dr. GAZELKA. I have a patient who has not only giving me permission to share her story but has encouraged me to do so. A 60-year-old lady in 2017 went to her local provider in a small town in Minnesota with abdominal pain. She has been very active running before this. As the year progressed, she became less functional. Her primary care provider did not know what else to do for her other than ordering a CT scan of her abdomen and ruling out any difficulty there. She started presenting to the emergency room locally.

After multiple presentations, the emergency room physician sat her down and said Mrs. B, you have chronic pain. You are going to need to go home and figure out how to manage this. She was frustrated, so came two hours to the Mayo Clinic emergency room and eventually ended up on my schedule in the pain clinic. Now talking about bias, I admit that when I saw that on the schedule and I read her history—I just felt a little irritated that morning having to go into the room, but I stood outside of her room and I told myself you are going to listen to her, like this is the first time she has told her story. And I went in and I listened to her, and I ordered an MRI that showed that she had a metastatic lung cancer eating through her rib and the nerves that innervate that area in her abdomen. They had been present for at least a year and ig-

nored because people felt that she was taking opioids. Bias is a significant problem in all areas of medicine. It is a problem in research. It is a problem when we see patients, and it contributes significantly, I think, to the stigma that surrounds the treatment, not only of chronic pain, but of addiction and of mental health disorders. I think it is a significant issue.

Senator MURRAY. I am not sure how we address that but being aware of it is certainly a critical part of it.

Dr. GAZELKA. I think awareness and I think education both for patients and providers, and the public as well.

Senator MURRAY. Yes. And I understand people of color, same—

Dr. GAZELKA. Yes. There are definitely studies that show that, yes.

Senator MURRAY. Ms. Steinberg, I wanted to ask you, can you share your experience in providing a health care provider who helped you manage your pain, and your thoughts on how Congress can help make sure that providers have the tools they need to support patients who live with pain?

Ms. STEINBERG. Yes, I think it is a great question because I have often asked myself after five years, why did it take so long to find somebody, and what was special about this doctor that finally helped me? And it was not anything miraculous and that is, I think, an important message today, which is he empathized with me. He believed me. A lot of people with pain do not get believed because it is an invisible disability. He said, I will work with you to help you find things to manage your pain, but understand that there is no cure now for chronic pain. You probably have chronic pain and you are going to need to learn to live with this, but I will partner with you. He was honest. He was empathetic, as I said, and he worked with me to find things that helped me. We often say in pain management now, if you do a program of several different things, and what I do is I take medication, I limit the amount of time I am up.

Everybody has different limitations on their activities with pain. I do a water-based therapy, physical therapy program, and a land-based program. So, if each thing takes down your pain 15 or 20 percent, it adds up to maybe a 50 or 60 percent reduction in pain, you can live that way. But it is a matter of having doctors have the time to do coordinated care.

Our system is so fragmented now that people go from doctor to doctor. Nothing is coordinated. They try one thing, it does not work, they go to another person because they are desperate. But if we had coordinated care—think about cardiac rehab. Heart disease has been a huge cost for us, right. But we focus on cardiac rehab and said, we are going to have a rehab program that puts everything together, and we have had great success with that. Pain needs something like that. We need that kind of approach. Where there is an integrated care center, doctors have time to provide that care, and you can try different things and have somebody helping you. You are not isolated. It would go a long way to saving a lot of the wasted cost from trying different procedures, and different needles, and different injections—this is what happens to people with pain. So, that is my suggestion. It is not miraculous.

I think we can do this. If we rethink and realign insurance reimbursement, and think about models of care that are creative that way.

Senator MURRAY. Thank you.

The CHAIRMAN. Thank you, Senator Murray. I am going to try to keep the questions and answers to five minutes each since we have—but let me go back to you, recognizing I have only got five minutes, Ms. Steinberg. We have 300,000 primary care doctors in the country. They are the access point for most of us to—whatever else we need. How do we empower them to do a better job, as you just described?

Ms. STEINBERG. That is a great question because I have been working in policy in Massachusetts for at least 11 years now, and I have worked with lawmakers to try some innovative things. And we just passed the law, something that I worked on, which was—patients are being dropped from care right now. You have heard that doctors are afraid to take care of people with pain. And the bulk of people with pain end up, because we have so many millions, being taken care of by primary care physicians, who do not get much training in it. So we try—

The CHAIRMAN. I hate to cut you off, but I have got several questions—

Ms. STEINBERG. Okay, so we tried a program where primary care doctors can call pain management specialist for consultation, free of charge to them. So the state is going to pay for specially trained teams of pain management specialist who can consult with the doctor, so the doctor feels more comfortable handling that patient, they have a network of alternative providers and that is really helpful.

The CHAIRMAN. Thank you. Dr. Gazelka, does the Mayo Clinic have such a system to connect with primary care doctors around Minnesota or other states?

Dr. GAZELKA. We do have a system within our electronic medical record. We allow for eConsults, where a physician or provider can contact a specialty physician and ask for advice to treat that patient and ask if a referral might be appropriate.

The CHAIRMAN. Dr. Coop, this hearing, for an obvious reason is called human nature, you said that one direction is the right direction, but for sure that something is going to happen that could cause you to go in the other direction you did not anticipate, and that is what we are worrying about here today. Let's say I have a loved one who is about to have a serious surgery, how do I think about opioid prescriptions in a state like Tennessee, where the state has said, with our encouragement, three days per prescription? How should we think about opioids? Is there something you do not use it all? I notice that Blue Cross in Tennessee won't reimburse oxycodone, although I do not think that may be true for other opioids, but how should one think about that, looking at it from the point of view of your own family and someone headed toward a painful surgery?

Dr. COOP. My own family takes opioids and I am fully supportive of them taking them. If somebody needs opioids, they should get them. I really do not think—one of the issues is the pendulum is swung way too back to limiting and people suffering from pain. We

need to get to the middle ground, where opioids are used in limited quantities, but we also add all the other approaches that we have had—

The CHAIRMAN. What is a limited quantity? Three days or three weeks?

Dr. COOP. I am not a physician. I cannot answer that, I am sorry.

The CHAIRMAN. Dr. Gazelka, what is a limited quantity?

Dr. GAZELKA. That varies by the patient and the procedure.

The CHAIRMAN. Well, what would a range be?

Dr. GAZELKA. Between—I think three days is very reasonable for emergency room presentations. That is what we have instituted at Mayo and actually throughout the State of Minnesota with other health care organizations cooperating. But I think for a knee surgery, we know from research, that it is about 16 days of opioid that a patient takes. What is appropriate is to educate the patient, perhaps with the participation of a pharmacist. Educate the patient that you should take this for the shortest amount of time possible. The risk for maintaining long-term opioid use increases dramatically at about 10 days of use.

The CHAIRMAN. Dr. Coop, I have about a minute left. What are the one most promising non-addictive painkiller treatments or medicines coming down the road? You can mention your own.

[Laughter.]

Dr. COOP. My own would not be approved. It does indeed cause less dependence and tolerance, but it is reinforcing. So, that is why I say the FDA needs to fully address all these drugs. My drug should not be approved. It would be the worst thing to put onto the market. I am working on the next generation. The drugs that are coming—I mentioned cannabinoids. I really do, and I know that is a controversial topic, but it is great—

The CHAIRMAN. Why is it controversial?

Dr. COOP. The states have legalized, the Federal Government has not legalized. The studies out there have potential, but the studies have been done with no systematic approach. We need a systematic approach—

The CHAIRMAN. You are talking about medical marijuana?

Dr. COOP. Yes, medical marijuana. Sorry, yes medical marijuana.

The CHAIRMAN. We are laymen, most of us.

Dr. COOP. Sorry, I am really sorry. Medical marijuana, yes. I think that has great potential.

The CHAIRMAN. Thank you very much.

Senator Baldwin.

Senator BALDWIN. Thank you Mr. Chairman. As our witnesses have all noted, pain is a complex issue. It is especially true for patients who are struggling with serious conditions, such as cancer, who often need palliative care services to manage painful symptoms from treatment.

My home State of Wisconsin has embraced palliative care as a critical component. It focuses on patients' needs, explains the treatment options, and gives patients and their families a real voice in their care. Many who need palliative services can ultimately recover and continue to live meaningful lives. I have had the honor of working with my colleague, Senator Capito, on bipartisan legislation, the Palliative Care on Hospice Education Act, which would

help grow and sustain the palliative and hospice workforce, to help fill the needs and wishes of patients and their families. Our bipartisan bill passed the House last session with unanimous support, and I look forward to continuing to work with my colleagues on this Committee to advance this measure through Committee this year.

Dr. Gazelka, you stated that Mayo Clinic's clinical guidelines were developed after extensive research on prescribing practices among providers, but also with feedback from patients. I wonder if you could discuss how the Mayo Clinic continues to refine these guidelines for patients with palliative care needs, and what else is really needed to improve the training that palliative care professionals get to provide the best care possible?

Dr. GAZELKA. Well, that is a topic that is near and dear to my heart. I left my practice to go back and do a palliative fellowship at the Mayo Clinic several years ago. I think that palliative care is essential. I think what you said is key. That not all patients who receive palliative care—they are not dying. They are people who have serious medical illnesses, chronic medical illnesses, and often, studies show that they perform better if they receive those types of services. We have a robust palliative care service at Mayo. We are training fellows each year, but it is a new specialty and there is a paucity of providers—way too few. And so, training is really important. Most guidelines including the CDC guidelines another state laws that have been passed, for instance, have exemptions and exclude cancer patients and patients receiving palliative care.

At Mayo, we started out in the same vein, but recognizing that with the treatments for cancer and with a palliative care measures that we are able to provide to patients, that these patients are surviving. They are being cured of their cancer or their cancer is becoming a chronic disease rather than a terminal illness. And so are their risk of addiction is high. It is as high as any other patients who take an opioid medication. And so we have focused efforts on instituting, essentially, the same guidelines within our palliative care clinic, as we have elsewhere in our clinics. Appropriate opioid use, because there are many—I mean opioids, we call it a stewardship program for a reason. They are vital, important. They are the best painkillers around. They have been around for thousands of years and probably will continue. Very important, but we need to be good stewards of them and teach our patients to be good stewards as well. I hope I answered your question.

Senator BALDWIN. The dangerous misuse of opioids at a VA facility in Tomah, Wisconsin a few years back resulted in the tragic death of a marine veteran named Jason Simcakoski. His story inspired me to author the Jason Simcakoski Memorial and Promise Act, again with my colleague Senator Capito, which has been since signed into law. But the law reforms pain management and safe opioid prescribing practices in the VA system including, by creating pain teams that incorporate provider education and expand access to complementary and integrative health services.

Dr. Coop, you noted that the safe use of opioids requires a multifaceted, team-based approach to pain care that includes patient and provider education. Can you discuss what your research has shown to be necessary for such comprehensive care to truly address

chronic pain, and describe the important role that pharmacist play as a part of those teams?

Dr. COOP. The research behind this is that those teams do not always work together. We need to ensure that those teams do work together. There are perverse financial incentives not to work together. So one of the things that we need to do is to ensure that the financial incentives are there to ensure that the team works together so that we educate people and put the money at the front end, so we are not putting the money at the back end.

Senator BALDWIN. Thank you.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator COLLINS.

Senator COLLINS. Thank you, Mr. Chairman. Dr. Gazelka, last year the aging committee held a hearing on opioids and seniors. I think many of us, when we think of the face of the opioid addiction, automatically think of a young person, usually a young male person. However, what our hearing showed is that this epidemic also affects our older adults. And if you think about it, it is not surprising, since nearly half of older Americans do suffer from chronic pain. And the incidence of chronic pain, it increases with age. The Centers for Disease Control estimates that the number of people aged 55 or older treated in emergency rooms for opioid overdoses increased by nearly a third from 2016 to 2017. Now, some research suggests, however, that opioids are really not effective in treating chronic, long-term pain except in cancer patients. First, I want to ask if you agree with that finding.

Dr. GAZELKA. For the most part, yes. However, I have found in my own practice and with other pain for providers is commonly we do use opioids for patients who don't have other options, and many times as patients are aging, they may not have some of the options, such as surgical interventions, procedural intervention, implants, etc., that might be available to a younger patient simply because of their medical comorbidities.

Senator COLLINS. Ms. Steinberg.

Ms. STEINBERG. Yes, I do want to address your question because I talked about the doctor that helped me, and when I went to him, I did not want to take any medication because I had heard horrible things about pain medication. And he tried me on a lot of other things first, like gabapentin, which is common. It made me so tired, I could not function. But he convinced me to try a hydrocodone, Tylenol combination medication, and I tried that medicine, and it helped me, and I never got high from that medicine. I took a relatively low dose of it, but I took that same medicine. It allowed me to function. I still had pain, but it allowed me to function and become the advocate that I could. I took that medicine for 10 years at the same dose. I never had to change my dose. I never got a high, and most people with pain have that experience.

Unfortunately, people with substance use disorder, it is a genetic disease. You often start with tobacco or alcohol or other things, but I want to draw a distinction. I think the misunderstanding is people think every time you take an opioid, you get addicted. I want to draw a distinction between two largely separate populations. People with pain tend to be women over the age of forty. People with substance use disorder tend to be men under the age of thirty.

We are talking largely about two separate populations, and Nora Volkow herself wrote a prominent article that said that people living with chronic pain, people with pain who take the medication for pain, less than 8 percent of those become addicted. That means 92 percent do not.

Unfortunately, it is clear some people do become addicted. I think that you need to make a distinction and understand that for some people, they are helpful, and they are the right thing.

Senator COLLINS. Right and I am not implying that they are not, but there is research that says that for long-term use for chronic pain for many people, that there are better alternatives to opioids—matches the point I was wanting to explore. Dr. Coop, very quickly because my time is almost done. A substance abuse expert has told me that an individual who is given opioids, who is under age twenty, is far more likely to become addicted than someone who is older, because of the brain not being fully developed. Is that accurate?

Dr. COOP. That has been widely studied, yes. And, if you, for instance, look up when people start experimenting with any drug, it tends to be at that age group. The brain is still developing until your early twenties. So, that is why I guess.

Senator COLLINS. It is interesting because you think of young people having their wisdom teeth taken out and being given opioids, and I know that many of the dentists in Maine have switched to strong doses of ibuprofen followed by Tylenol, and alternating at every two hours, and have found that the pain relief is just as effective and safer. And I see two of you nodding your heads.

Dr. COOP. Yes.

Ms. STEINBERG. I think acute pain, particularly in acute pain is where we have had to cut back and should cut back with opioids. And for dental procedures, it is usually unnecessary, and hopefully, they have gotten the message now.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator HASSAN.

Senator HASSAN. Well, thank you, Mr. Chairman and thank you, Ranking Member Murray as well for holding this hearing. Thank you to all of the witnesses for being here. We really appreciate not only your presence but your expertise and your commitment. As you know, New Hampshire has been especially hard-hit by the opioid epidemic, and we also have many patients who are suffering from chronic pain. So we need to make sure that all of our patients have what they need to access care, including those suffering from pain, as well as people who are suffering from addiction and mental health conditions.

But provider shortages in all of those areas is a real issue in my state. For example, Dartmouth-Hitchcock, which is the largest health care provider in New Hampshire, has between 750 and 800 open positions at any time. And the state's community mental health centers have more than 175 vacancies for clinical positions.

This first question is to Dr. Coop and Dr. Gazelka, as faculty of pharmacy in medical schools, I am interested in what you see as the greatest workforce challenges, and your views on the role grad-

uate medical education play in training the next generation of physicians? And a follow-up to that—you can answer both—how could additional residency slots, particularly it feels like pain management, addiction medicine, and addiction psychiatry, improve access to care for patients? So, Dr. Gazelka if you would like to start and then Dr. Coop.

Dr. GAZELKA. I think, it is probably not a popular thing to talk about, but I think the cost of medical school and the loans that students accumulate during the time that they are in their medical training, are cost-prohibitive, in some cases, if you are going into some of the primary care practices and some of the lesser reimbursed practices, which may be such as, primary care psychiatry, addiction medicine, etc. And I think that is a real problem.

I remember at the time that I was in medical school at the University of Minnesota, the Dean came and spoke to our class and said, so many of you are planning to go into specialties, you need to go into primary care, we need primary care physicians in Minnesota. But at the same time, the University of Minnesota Medical School was the most expensive state medical school in the United States at that time. And those considerations have to be taken. And so, I think finding some way to encourage students to go into specialties that are needed, will be important in that regard.

Senator HASSAN. Thank you.

Dr. Coop.

Dr. COOP. Approaching this, specifically from pharmacy, pharmacist, as I mentioned, they are often the most underutilized of health care professionals. They are the medication experts—

Senator HASSAN. Yes.

Dr. COOP. They are. I teach them all about drugs. They are also taught how to counsel patients—how to appropriately counsel patients with medications. One of the biggest issues we have with patients taking medications is actually taking the medication—

Senator HASSAN. Right.

Dr. COOP. Right. If the medication does not get to the patient, it is not going to do any good. So again part of the financial model is reimbursement for those cognitive services, and it is getting those reimbursements for those cognitive services could bring the pharmacist into the health care team, which would expand that access you are talking about.

Senator HASSAN. Well, thank you. And that brings me really to my next question, which was about reimbursement. And again, to Dr. Gazelka, we know it can be a powerful tool to influence the availability of services as well as providers behavior, and that the lack of appropriate reimbursement, to Dr. Coop's point, can create tremendous barriers for patients who need access to a variety of services.

Insufficient reimbursement policies and Federal programs like Medicaid and Medicare, as well as in private insurance can sometimes create barriers to access to therapy and services that can reduce opioid use, including chiropractic services, some surgical interventions, acupuncture, behavioral health programs, and multimodal pain strategies. We have taken in Congress some important steps over the last few years, both in CARA and the Support Act, to help address some of these barriers and certainly, Dr. Rao-Patel

talked about things at Blue Cross Blue Shield is doing to try to eliminate some of those barriers. But, Dr. Gazelka, can you give me some specific, concrete actions that Congress can take related to reimbursement in order to improve patient access to non-opioid pain management therapies and services?

Dr. GAZELKA. I am an interventional pain physician and so I do neuromodulation. I am implanting intrathecal drug delivery systems, spinal cord stimulators, etc. In many cases, it is very difficult to get those covered. I find that Medicare is one of the most difficult, when I have a patient on Medicare, to have access to those therapies. Those therapies are proven in Europe to be extremely useful for chronic angina, for instance, so that patients do not have to pursue further stent placement, etc., or use opioids for chronic headaches, but the coverage for them is poor.

I also think that I have rarely met a pain patient who would not benefit from behavioral and psychosocial management. It is vital that we treat those areas for patients, and they are not covered. In the hospital, we would like to allow patients who are having surgery to have access to non-opioid management. We did a survey recently at the Mayo Clinic showing that 94 percent of patients would choose something other than opioids, acutely after surgery if they could, but we cannot provide acupuncture, we cannot provide massage, we cannot provide extensive physical therapy at sometimes, and restorative therapies for those patients.

Senator HASSAN. Thank you and thank you Mr. Chairman for your indulgence.

Dr. GAZELKA. Thank you.

The CHAIRMAN. Thank you, Senator Hassan.

Professor Cassidy.

[Laughter.]

Senator CASSIDY. Thank you. First, Ms. Steinberg, you are sitting back there, but I remember, and this will set up my next question, I remember having, when I was first year in Congress, having a slipped disc in my neck with radiating pain down my honor distribution, and it was so incredibly painful. I was imprisoned by the pain and all day long I just waited for my every 6-hour dose of Motrin, and I staggered it with my Tylenol, taking something just when I went to bed. And for three or four months, that is all I did and it just sapped my emotional energy. Now as eventually helped by epidural injections, and this sets my next question, Dr. Gazelka, when I looked at the research on epidural—and for people who are not in medicine, they put a needle right there, they injected it and it would give me instant relief that would then wear away—I looked up the data and said it was no good.

The data says, epidural has no long-term benefit in the management of chronic pain. But after my third one, it just went away and never came back. Now, then I looked up the CDC guidelines for management of chronic pain, and they say, going back to Senator Collin's question, that there is really just no evidence of the use of opioids long-term vs. no opioids vs. etc., etc., etc. So it seems like we have a paucity of evidence, and which empirically worked in me, you know N is equal to 1, does not have the evidence to support it. Now briefly comment on that, because then I am going to go to my former student, Dr. Rao-Patel, to ask if Blue Cross is cov-

ering things, which have no evidence, but nonetheless empirically do work in some. So, quickly.

Dr. GAZELKA. Dr. Cassidy, I do not have to explain to you that you can find studies almost to back up whatever you are looking to back up. You have acute pain. Epidurals very effectively manage acute pain, radicular pain. Probably for patients who have spinal stenosis or other types of chronic radicular pain, they may not be as effective. I could tell you that anecdotally from my practice. Do we use them? Yes, because they are helpful to them. Sometimes patients do not have other options available. But definitely for acute pain, those are helpful.

Senator CASSIDY. Now, of course, mine lasted 3 months. Now eventually what my neurosurgeon friend told me is that it is just part of your nerve will die, although I have a little bit of something. It tingles right there. And then after that death—that is a great way to look at it, I would feel better. So, by the way also once read a Mad Magazine as a kid. Give me statistics and I can prove that Rhode Island is bigger than Texas—

[Laughter.]

Dr. GAZELKA. That is right.

Senator CASSIDY. To your point. But Dr. Rao-Patel, will Blue Cross pay for that which evidence suggests does not work, number one. Number two, Dr. Gazelka mentioned all these wonderful things that can be used in lieu of opioids and the, say, post-surgical study. But then my physician friends tell me, hey, you are on a bundled payment, or you are on capitated payment and the insurance company won't give you that bump up for the more expensive drug, or the more expensive procedure. And I see Dr. Gazelka over there vigorously nodding your head yes. So tell us, as it ultimately comes to your decision as you are the manager for Blue Cross, how does that handle?

Dr. RAO-PATEL. Along with her comment, there are studies that show that for acute pain, injections like epidural steroid injections work. Again there multiple times of injections for spinal pain depending on where the pain generator is. And those are things that Blue Cross Blue Shield does cover. Several of the things that we have discussed like physical therapy, occupational therapy, water therapy, chiropractic care, epidural steroid injections, those are all a multitude of things that we cover as a plan without any type of prior authorization. So if a provider feels that this is the appropriate intervention for the patient for their pain, they can go ahead and do the procedure, they do not even have to contact us—

Senator CASSIDY. Now, let me ask though because clearly giving a prescription for opioids would be cheaper than a whole panoply of that which might be less likely to induce—so and it seems like that is the rub, right. If you get an x number of dollars to manage patients, how do you employ that which is significantly more expensive even though long-term there is a benefit?

Dr. RAO-PATEL. Well, I mean our approach at Blue Cross, is, again we have participated with multi-stakeholders at our state-level, including the Medical Board and Specialty Societies on appropriate management and treatment of pain. And our approach has always been a multimodal approach.

Senator CASSIDY. Let me ask, as amounts at a time, and go back to the question of a bundled payment, and I do not know if Blue Cross uses bundled payment but I can imagine in some place, either you do or you plan to, and again my pain management physicians say, listen post-surgically, we can do this or that, but it is more expensive than just giving them a prescription or giving them an injection of an opioid. So, how do we manage that? How do we approach, as policymakers, bundled payments when we know that it may increase the cost to do something, which would decrease the use of opioids?

Dr. RAO-PATEL. Again, the reason that we bundle payments, for example, is to be more cost-efficient overall. So, again, we are again not trying to limit the options that providers have in managing pain, but we are encouraging to use a multimodal approach in terms of management.

Senator CASSIDY. But I am not sure that answers my question because if your cost basis is just getting a prescription for opioids, but the alternative is this—and he is lightly tapping this thing to tell me to shut up, so that will be a question for the record.

[Laughter.]

The CHAIRMAN. Well maybe you could provide some—Senator Murray would like to know the answer. So, we will extend the discussion for Senator Cassidy and ask you if you have any comment on what he just said.

Dr. RAO-PATEL. Yes, again like I said, the things that, for example, that I am aware of that we bundle at Blue Cross in terms of payment, or for example post-surgery, let's say a patient has a knee replacement or a hip replacement the perioperative, the preoperative period and the postoperative period is bundled in a payment in terms of management of that patient. It is more of a payment question that I could get back to you on, in specifically what we bundle in terms of interventional pain management procedures, but there are instances where we do bundle payments in order to contain the cost.

The CHAIRMAN. Thank you, Dr. Cassidy. I think she said she wants to submit some homework to you.

[Laughter.]

The CHAIRMAN. It is terrific to have a United States Senator who has a former resident student as a witness.

Dr. RAO-PATEL. Yes, I feel like I am in his clinic right now, so.

[Laughter.]

The CHAIRMAN. Senator Smith.

Senator SMITH. Thank you, Chairman Alexander and Ranking Member Murray, and I feel a little intimidated following Senator Cassidy because my knowledge of physiology is dramatically less than yours. But I really appreciate this hearing so much and, Ms. Steinberg, I think it is so important that you are here because in this Committee, we all have our personal stories and we are focusing on the policy issues, and some of us have our own experiences with, pain in our families. But to be able to have you bring it down to the reality is extremely helpful so thanks. Thanks so very much.

Dr. Gazelka, I know that when I meet with health care professionals and families all across Minnesota, what I hear over and over and over again is the need for a coordinated approach to

health problems that are complicated, and cannot just be resolved in one way with one provider. And this is—especially when you think of that all the related issues that relate to whatever that one primary diagnosis is, and this is particularly true for pain management, and we know that chronic pain is associated with all sorts of issues like frustration, and stress and depression, isolation and I know that Mayo Clinic understands this so well. Mayo is renowned for the collaborative approach that you bring to all different kinds of health challenges. Not only this challenge, but this seems to be particularly appropriate. So I am wondering if you could just talk a little bit about the connection between pain management and mental health disorders, and the tools that you see. I am interested in getting from you kind of what we ought to be doing at the Federal Government level to encourage that kind of coordinated approach when it comes to pain management in mental health disorders.

Dr. GAZELKA. It is well known. It is well understood that anxiety, depression, and other mental health disorders are far more prevalent in patients who suffer from chronic pain. They are highly prevalent, and so in treating the whole patient with pain, you must treat their anxiety, their depression, or other mental health disorders. I think an excellent example is the Pain Rehabilitation Center at Mayo. It is an integrative approach. It is housed within our psychiatry department, but it involves pain physicians, physical and occupational therapy. It is a multi-specialty. I think we have gotten away from the pain clinics of 30 years ago, where patients would come in and they would essentially see a team. They would see a team that included a physician, that included a psychologist, typically, that included perhaps a physical therapist or someone involved in restorative therapies. And reimbursement for that type of model, I declined.

It became more interesting to do interventional procedures for patients, which are sort of our rapid, fix me now, and I think that a return to that sort of a model of chronic pain management is essential for caring for patients well. And so I think integrating those services is very important. And then addiction medicine. I can tell you, we do so many surgeries a year. I, could not tell you the number, but a lot of patients come in on chronic pain medications and they have issues with addiction. They come in on their buprenorphine, their methadone. Well, how are we going to treat their pain acutely while they are hospitalized? Well, that takes some coordination with our addiction medicine colleagues as well, because just because you have an addiction does not mean you are not going to need a surgery, or need chronic pain management at some point in your life.

Our palliative medicine clinic is full of patients who have developed cancer or some other chronic, or terminal disease even, but they also suffer from substance use disorder. And so, we have had to coordinate care for those patients so that they can have appropriate management for their pain, but also for their substance use disorder or mental health issues.

Senator SMITH. If we think about what we can do at the Federal level to encourage that kind of approach, I guess it gets somewhat to the line of questions that Senator Hassan was asking about how

reimbursements do not support a comprehensive approach, is that fair to—the way reimbursements happen do not support a comprehensive approach, would you say that is true?

Dr. GAZELKA. I think that is true. It is very hard. For one thing, about positive addiction medicine, physicians and providers throughout the United States, beginning with the Mayo Clinic, we do not have addiction medicine services in our hospital. Patients have to see those providers as an outpatient. Reimbursement is poor for that, and at a point where they could be touched and significantly altered in their course. They are not able to have that type of contact.

Senator SMITH. That leads to some much fragmentation.

Dr. GAZELKA. Right.

Senator SMITH. Also, in their care, which is bad.

Dr. GAZELKA. Even talking about buprenorphine cover, for instance. There is so much talk about pharmacists providing buprenorphine, mid-level in NPs, PAs providing buprenorphine. But you cannot just give a patient buprenorphine. Buprenorphine can also be a drug of abuse. You have to give a patient the other addiction management services that they require to be successful.

Senator SMITH. Thank you very much. I know I am out of time, but I appreciate that very much. Thank you.

The CHAIRMAN. Thank you, Senator Smith.

Senator Romney.

Senator ROMNEY. Thank you Mr. Chairman and Ranking Member. I appreciate very much the comments of the panelists, particularly Ms. Steinberg, who has made a real sacrifice in being here. Appreciate your coming here despite that pain. Your testimony, Ms. Steinberg, reminds me of my experience having served as the Governor of the state where you now live, and I once did.

That is, we noted that we were spending a lot of money in Medicaid psychotropic drugs and we could not quite figure out why and determined that most of these drugs are being prescribed by primary care physicians who had very little experience in really deciding what the most effective psychotropic drug might be. And after some consultation we said, we are not going to—Medicaid is going to no longer reimburse psychotropic drugs to young kids unless the doctor prescribing it contacts a physician at the University of Massachusetts Medical School that is a psychiatrist or in that trained field. That does not mean a psychiatrist had to approve the prescription, just they had to have a conversation. And by doing so, we found that the number of prescriptions dramatically came down, and the quality of care, we believed, substantially improved.

I think each of you has spoken about the fact that most of this prescription of opioids is being done by people who are not specialists in the field. And I wonder whether the lack of best practices is not something, which is really affecting the challenges that we are facing, both for those that have chronic pain and for those that are abusing these products. Should we have some mechanism, that one gathers data from all over the country from everybody who is using these drugs to see what the effect is, but number two, a place where physicians go to get consult, if you will, before they prescribe for someone that has chronic pain—prescribe medication for someone with chronic pain. Do we not need to something of that nature,

and how would something like that be structured at a state or national level? I am happy to turn to any one of you that would like to comment on that.

Ms. STEINBERG. The program mentioned is one attempt to do that. We are doing that in a small model, where PCPs can call for a consultation. I think that is a great idea. One thing that is not a good idea, I think, that was tried, I think was in Washington State, so that nobody could get an opioid prescription without having seen a specialist. And it turned out there is like a handful of specialists in the state. And so people with pain who really did need their prescriptions, could not get their medication. They had to go out of state to get their medication. And it was a disaster. So, I really encourage us to think through the way we implement that. Clearly, education is the other side of what you are talking about, and there is an absolute dearth of pain education. We are not training people on what we now know. So medical schools just absolutely are ignoring this.

Senator ROMNEY. The challenge with that is that if you take more time on one subject, that means less time on another subject, and so consult may be a way we need to go. I am going to ask with regards to Blue Cross Blue Shield, are you able to get expertise to the people who are backing these prescriptions?

Dr. RAO-PATEL. To answer your question, I will say, one thing is that often times it needs to be the primary care physician who is managing the pain. Because, for example, in North Carolina with a lot of rural areas, access to a primary care physician can be challenging and access to a pain management doctor can be even more challenging. So we have really—we actually just started working with a new company, Quartet, who is bringing behavioral health and mental health into primary care areas to empower primary care physician. There is also something that you might have heard before Project ECHO, which is a platform that, several Blue Cross plans are already using, which if anything is sort of a ground rounds, if you will, where primary care physicians or any type of physician can call in and seek expertise from people who are addiction specialist or pain management doctors, and it is meant not only for a consultative purpose, but also an educational purpose so that way the physician learns in the future how to manage a patient that way.

Senator ROMNEY. Yes, thank you. Please, please.

Dr. GAZELKA. On that, Senator Romney.

Senator ROMNEY. Yes.

Dr. GAZELKA. We have, on a small scale at Mayo, begun using—we need to leverage telemedicine and electronic medical records, which are now more and more beginning to speak to each other. Finally, at Mayo we have a health record that speaks to—so we can talk anywhere in the country about our patients and look them up. We have developed a controlled substance advisory group where a specialist, such as myself, sits and hears the cases that are brought by primary care physicians. So they bring forth patients with difficult pain management problems, patients with a substance use disorder problems, etc., and we have specialists from all those around, who sit at the table provided by us and then we enter a note in the patient's medical record, stating what the decision of

the panel is. And I think I have visions of expanding that because I think it would be incredibly helpful to primary care providers. Obviously, there are HIPA, restrictions and things like that across various states, but I think it would be great.

Senator ROMNEY. Thank you. My time is up, but I do want Dr. Coop to instruct a system a path forward on cannabis research, but we will save that for another day.

The CHAIRMAN. Thank you, Senator Romney. And of course, if any of you have additional comments that you would like to make to Senators, you can submit those in writing after you leave.

Senator ROSEN.

Senator ROSEN. Thank you, Senator Alexander. Senator Murray and I really appreciate the panelists here. I hope that my acute pain from wrist surgery does not turn into chronic pain, but that is another issue. But what I want to say is before coming to Congress, I stepped back from my career for several years, was a caregiver to my parents and my in-laws. During this time, I became very familiar with the field of medicine known as palliative care, and the relief from pain symptoms, of course, and the stress that specialized care can provide. Palliative care focuses on improving quality of life for those with often life-limiting illnesses, including those in significant pain or having a terminal illness, often in that gap between end-of-cure and end-of-life, like my mother.

Last Congress, I launched a bipartisan Palliative Care Task Force in the House to bring attention to this type of care. I am hoping to do that here. So, I have a couple of questions for you Dr. Gazelka. In your experience, is it common for patients diagnosed with chronic pain, or possibly terminal diagnosis, to have those conversations with their doctors about palliative care as a treatment option, and how can we ensure specifically with primary care physicians that they understand the needs of terminal or long chronic pain patients? How do we do that, possibly maybe requiring ongoing CME for primary care physicians in this area?

Dr. GAZELKA. I think that is a vitally important topic, and not common enough. I think patients make choices that they do not want to make, to come in and have treatment for things that they would not necessarily choose to have treated. 100-year-olds ending up in the ICU with pneumonia or with a hip fracture because no one had a conversation with them that it is okay to be comfortable and to even do this at home, perhaps, on hospice, to be taken care of, or in another nursing facility. And so I think empowering patients to have those conversations with their physicians is vitally important, and training physicians and other providers to have those conversations is really—

Senator ROSEN. Do you think that we could possibly provide that by improving the way we use continuing medical education, maybe requiring this pain management, chronic pain management as an ongoing CME requirement, especially for primary care physicians? Do you think this is something that we could help?

Dr. GAZELKA. I absolutely. I think it would be helpful. We have instituted in our medical school, for instance, a palliative care education program. Very uncommon in medical schools, but people need to have not only an understanding of what patients' rights and preferences might be but know how to have conversations. And

it is the skills of having critical conversations that are vitally important.

Senator ROSEN. But you think to retain board certification possibly in family practice or a primary care physician required, just like we do for mammograms certain requirements or hours, this could be a way we could go?

Dr. GAZELKA. I do. It is being required for opioid right now.

Senator ROSEN. Thank you. I have a question also for Dr. Coop about medical marijuana. In Nevada, we have ranked 13th in the Nation in prescribing opioid painkillers. Our former Governor took action by forming a new state agency, the Opioid State Action Accountability Agency. We do have legalized medical marijuana in Nevada. We have found that using that has reduced the prescriptions for high potency painkillers, and so in your experience, what do you think are the barriers into effective research for the benefits of cannabis treatments, and how can this possibly be an—or can this possibly be a non-addictive approach or alternative to chronic pain, just another tool in the toolbox?

Dr. COOP. I, first of all, think it has great potential to be another tool in the toolbox. I do not think there is ever going to be a one-size-fits-all magic bullet because pain is different in different people. In terms of how to move the research forward in medical marijuana, one of the issues has been because of the unusual legal status, shall we say, in the United States. Research has been limited. There is no consistency between the different types of marijuana, the studies done. So, what we need is good—they are going on. Some are coming but we need more. We need good, consistent, well-designed clinical studies with good, consistent material so that we can fully assess the impact, do not get me wrong, also the potential drawbacks.

Senator ROSEN. Right, like everything else.

Dr. COOP. Right.

Senator ROSEN. Thank you so much.

The CHAIRMAN. Thank you, Senator Rosen.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman, and Ranking Member. Thank you for this conversation this morning. So important, and I really appreciated the back and forth there with Senator Romney, clearly coming from a very, very rural state. When you are dealing with how you respond to patients' pain issues and you do not have access to, perhaps, those alternate pain management technologies, the different therapies that are available, the quick, and easiest, and cheapest, to Senator Cassidy's point, is the prescription drug. And so, this idea of eConsult is really critical. We pioneer a lot in the telehealth space, but making sure again that there will be reimbursement for these consoles is important. And Dr. Rao-Patel, the words that you used where you are empowering the primary care docs, but translate that to me. Do you cover these consults then?

Dr. RAO-PATEL. Yes, we do. We do cover telehealth, and in fact, like I mentioned. One of the things that we are doing—

Senator MURKOWSKI. Telehealth specific to these types of pain management consults?

Dr. RAO-PATEL. Correct. And a lot of behavioral health telehealth as well, as it is used to treat opioid use disorder as well.

Senator MURKOWSKI. Good.

Dr. RAO-PATEL. I guess one of things I was going to mention is that, that is one of the things that we have really developed and are expanding on, at least on our Blue Cross North Carolina program, is increasing access for folks especially in the rural areas that we talked about, to be able to access providers that they would not otherwise be able to through telehealth.

Senator MURKOWSKI. Right. Let me just—I am going to ask one question for all of you here, so you can probably jump in on this Ms. Steinberg. The big conversation over the Christmas and the New Year's holiday back home was what we are seeing with constituents in our bigger population centers, so out of the rural areas but in Anchorage and in Fairbanks, they are being denied prescriptions where the prescription drug is opioid-based. Some of it goes to the bias issue, but it is the pharmacists that are refusing to fill the prescription the doctor has prescribed and we are not—certainly the involvement that we have had with these constituents, it certainly does not appear to be abusive situations, but people who have legitimately been prescribed these pain medications for these debilitating and long-term pain management issues.

I understand that it relates to the recent guidance coming out of CDC, recommending, restricting how much a pharmacy can do and guidance in controlling law, but in an abundance of caution, the pharmacists are saying no we are not going to do this. So, you now have the patient in the middle of a regulatory debate, if you will, and it has caused the lid to be blown off the discussions in my state, and I cannot imagine it is just in Alaska. What are we doing to address this tension now, this conflict between prescriber and the pharmacist? And then ultimately we want to be helping the patient, but we have got a struggle going on and I do not know who is addressing that. Can anyone of you speak to that?

Ms. STEINBERG. There is a terrible of fear out there among all practitioners right now, and they are just—they do not even want to treat people with pain anymore. That is how it has gotten. That bad. And, like your example, I had a doctor from Dana-Farber Cancer Center call me saying pharmacist will not fill my prescription for patients that I have that have really bad cancer, and so it has gotten to a point where—it has just gotten so unreasonable. There is a history out there.

Senator MURKOWSKI. What do we do?

Ms. STEINBERG. I think we need to educate everyone better about this issue. I think we need public education about pain and the fact that pain is a disease itself, so people understand that we are not just talking about acute pain here. Chronic pain is devastating, and for the kinds of things that you are talking about, pharmacists are not getting proper training in that. I do not think anyone is getting enough training in pain.

Senator MURKOWSKI. It is pharmacists who are not getting the training, but you have also said that the physicians do not get enough training.

Ms. STEINBERG. Correct.

Senator MURKOWSKI. Dr. Coop.

Dr. COOP. I was just going to say that folks do view the guidance as being like gospel, so I think those guidance on the quotas, I think they have been taken too far, and that needs to be rolled back. This is one thing that can be done. Yes, all health care professionals could certainly benefit from more education in this area.

Ms. STEINBERG. The other thing I wanted to add to this whole discussion of specialists, and consult, and telehealth, is that we do not have enough pain management specialists. And I know Senator Hassan has left here, but she brought that issue up. There are so few doctors specializing in pain management that it takes people more than a year, in my pain group, to get an appointment with a pain specialist. There is a dearth of them and I do not know in your state, I can just imagine how few there are. So, we are talking about consults and telehealth. There are not even specialists to handle the telehealth. We need to incentivize pain management as a specialty. There is a board certification and there is a dearth of physicians.

Dr. GAZELKA. I just wanted to comment on the unintended consequences of some of the use of the CDC guidelines. There is only number six in the CDC guidelines. It is a very small section talking about acute pain management, that three days, at the most seven days, should be considered for acute pain management. It has been made into law in many states. Many insurers have used this. It is not a problem of pharmacies at the Mayo Clinic, it is a problem of our insurance companies.

We literally are keeping patients in the hospital longer because we cannot get their prescription for discharge pre-authorized so that they can go home to North Dakota or they can go home to Montana. They are staying in a hospital because a physician will give out a prescription for two weeks of opioids, which is what we have decided on, if that is a certain procedure that we have decided that on our guidelines. This has to go too. Their insurance company or pharmacy has to submit it, a patient cannot get a prescription for that link, so they stay in the hospital while we work that out. There have been some significant unintended consequences in multiple of the pharmacies as well. Larger pharmaceutical companies and I have spoken to some of them on the phone, have arbitrarily set 7-day limits on what they will allow patients to have and they cancel the rest of the prescription from the physician. This means more trips back to the doctor for the patient, who may have just had surgery. This means another copay for the patient, who has already paid one copay for their opioid when they need a refill. So, it can be a really significant issue. I respect that.

Ms. STEINBERG. The task force has looked at the CDC guidelines and have some really great recommendations on how they need to be revised. Picking a dosage level is an arbitrary decision. It was not scientifically based and it has now become law, and it has caused all kinds of problems.

Dr. RAO-PATEL. Can I just add one thing to that? I will just say that I think a lot of the issues with the CDC guidelines are just that, I think, it is a lack of education on the part of the physician, as well as the pharmacist in understanding that they are just that, guidelines. That there are going to be patients who will potentially look like outliers and go higher than what CDC recommendations

are, and that might be entirely appropriate for that patient population. So, I just wanted to mention that as well.

Senator MURKOWSKI. Thank you. Mr. Chairman, I know we are well over, but we have apparently revealed something here.

[Laughter.]

The CHAIRMAN. Well, we are all interested in those answers and I think it is worth saying that we considered and rejected the idea of a Federal law establishing 3 and 7-day prescriptions, leaving that to states, and physicians and caregivers to work out. And I think that is proving to be a wise decision, although I hear what you say about CDC. Doctor—not doctor but—

Senator Jones.

Senator JONES. Doctor-Senator would be fine.

[Laughter.]

The CHAIRMAN. Senator Jones. We have a Doctorate from Law School.

Senator JONES. That is right. Thank you, Mr. Chairman and Ranking Member. Thank you all for being here today. One brief comment, I appreciate the comments on telehealth and telemedicine. And we are continuing to have our rural hospitals and providers leave our rural areas, and I have always thought that telemedicine and telehealth is one way to try to keep that. It is only, however, as good as our rural broadband and access to the internet, and that is something that we are, my office, are continuing to push forward and I would—any help on that area to try to get broadband in those areas would be great.

I do want to follow-up though with an area, and I—a lot of times when we ask these questions, people think we are going at it with an agenda. And sometimes we are, sometimes we are not. This is not one of those. But Senator Rosen asked about the research and development using medical marijuana and cannabis, and Dr. Coop, you gave a very good answer. I appreciate that very much, but I would also like to hear from the other three of you on this issue. I do think it is an important topic. It is one that, in the public's mind, it is growing throughout the country. And so, with each of our physicians as well as Ms. Steinberg there, if you would.

We will just start with you, Ms. Steinberg. If you could comment on the pros and the cons of what you see in the developing of medical marijuana, cannabis. The ability to use this alternative, but also the research that would be required to go into it.

Ms. STEINBERG. Yes and actually, cannabis has helped a number of people living with pain. It is another option, as we talked about, in the toolbox. It has helped a significant number of people, but it is not legal in a lot of places and therefore, even where it is legal, as Dr. Coop said, it is not standardized. Doctors need to be the ones prescribing it, but they do not know what they are doing with it. They are not trained with it either. And so without having a real good research base—we are just flying, blind.

Senator JONES. What prohibits the research base?

Ms. STEINBERG. The fact that it is not legal.

Senator JONES. Okay. Just wanted to get that in the record. It is a scheduled substance so that it limits the amount of research considerably that can go on with both the pros and the cons.

Ms. STEINBERG. Yes.

Senator JONES. Yes. Okay, thank you. Dr. Gazelka.

Dr. GAZELKA. I do not think we do know that marijuana is not addictive. I have certainly seen patients who have excessively used marijuana, not medical marijuana perhaps but the pot, and it is believed to be an addictive substance. You have said not that many years ago, we heard that opioids were not addictive, and so I think we have to proceed with caution—

Senator JONES. Right.

Dr. GAZELKA .—as with anything else. I think that inconsistency among the products that are produced with the ratio of CBD to THC, etc., is an important component of this that will factor in when it is being researched. But I think the impediment has been that it is a schedule II—a schedule I substance rather, sorry. It is not permissibly prescribed by providers, but I do think that there may be some significant areas where this may be very useful. I have some palliative medicine patients using it for nausea, appetite, etc. And I think it can be helpful.

Senator JONES. All right, thank you. Yes, ma'am.

Dr. RAO-PATEL. I would agree with that. I think due to limitations, such as the fact that it is illegal in some states as well as on a Federal level, make research difficult. I think a lot of times I have seen patients of mine in the past who were taking opioids and, we did a urine drug screen on and they tested positive for marijuana, and they found that seemed to help more than being prescribed an opioid or any type of adjunctive medicine to do an opioid.

I do think that there is, from a physician's standpoint, I think that there is some potential to the utility of medical marijuana for the management of chronic pain. I will say putting on my other hat as an insurer hat that we obviously only cover procedures and drugs that are FDA approved. So, we would obviously need some clinical evidence to support to be able to cover those kinds of medications.

Senator JONES. Have any of you got any suggestions? Other than short of removing it off of schedule I, which I guess you could do and put some other weird restrictions I guess, what can we do other than—is there anything other than that, that we can do to open up the ability to research the pros and the cons of medical use of cannabis? Or is that the impediment that we have got to try to figure out how to deal with? Dr. Coop.

Dr. COOP. I was going to go into this and I would say that this is a decision that the National Institute on Drug Abuse, with the experts that could know all the confounding factors, it would be something that I think we should charge those guys with—coming up with what is the best way forward.

Senator JONES. Okay. Right. Well, thank you all for your answers and thanks for being here. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Jones. Senator Murray, do you have additional comments?

Senator MURRAY. I just would like to thank all of our panelists for being here today. This has been, I think, really an interesting, and eye-opening, and important hearing and I want to thank all of you for your help today.

The CHAIRMAN. Well, I agree with Senator Murray's sentiments, and I only have one question. Several of you have mentioned, in response to questions from Senators, that what we could do about this is public education. Well, that is what we are attempting to do today. I mean the U.S. Senate is a forum that helps lead the way to recognize opioid abuse and try to deal with it, and we should at the same time try to lead the way to determine whether there are some unintended consequences and whether the millions of Americans who live with pain are not able to deal with pain as a result of the reaction to the effort to stem opioid abuse.

We have heard today that reimbursement policies are important. That primary care doctors and their education is important. We have talked about the most promising non-addictive pain medicine. That has been a priority of Senator Murray in her role as senior Democrat on the Appropriations Committee that deals with health, and this Committee, where we have attempted to push more funds into the National Institutes of Health toward non-addictive treatments and medicines. And Dr. Collins has been here to testify on that and is working in a variety of ways to accelerate that.

We have talked today about pharmacists and what their role might be as we go along, but I wanted to ask one last question about the CDC, the Center for Disease Control recommendations. They are not law. They are not rules that anyone has to follow, but the CDC is enormously respected in states and in the medical profession, and in this environment, sounds to me like, Ms. Steinberg, that your experience of using a low dose of hydrocodone and one other over the counter medicine for 10 years to relieve pain would not fit with the CDC guidelines for your doctor. So what recommendations—my final question would be and you can elaborate if you would like to after you leave, and you can submit it in writing, but each of you, what would be your recommendations about the existing guidelines of the Center for Disease Control guidelines for opioid abuse, and how we can make sure that, while we are dealing with the opioid epidemic, that we do not make it difficult or impossible for people who need opioids to relieve their pain to get them. Let's start with you, Ms. Steinberg.

Ms. STEINBERG. Yes, I think the best thing you can do is have the CDC guidelines revised. They really have been taken as a law. As the CDC is behind them, people think that those are based on strong science and they are not.

The Pain Management Task Force that Congress did wisely create, of pain management experts, is producing a report now and the report specifically reviews the CDC guidelines and makes excellent recommendations on how to revise them. I really think that Congress should ask CDC to revise those guidelines based on the task force report. Dr. Gazelka and I both serve on that task force and they really need to be revised. CDC are not pain experts and they did not use pain experts to create those guidelines, sadly.

The CHAIRMAN. Well the CDC deals with epidemics and obviously, we had an epidemic, but I hear your suggestion and maybe that is a subject for another hearing.

Ms. STEINBERG. NIH is the best place to put pain. NIH has an office of pain policy. The CDC has no pain section. I have done tons of research at CDC to understand why their attitude toward pain

is the way it is. They do not have pain experts. NIH is the place really, that should decide those things. They have the office of pain policy. They know about pain research, and I think they are the best people to make a decision like that and to pull the experts together. They have done the best job with the national pain strategy and with everything else. I really do not think it belongs in the CDC.

The CHAIRMAN. Thank you, Ms. Steinberg. Thank you again for making the effort to come today.

Dr. Gazelka.

Dr. GAZELKA. I think the best thing that could happen with the CDC guidelines is that people understand what they were intended for. They were intended to advise primary care providers, they were not intended to provide hard-and-fast rules. I actually like the CDC guidelines, at the risk of having tomatoes thrown at me. We use those guidelines to form our chronic pain management guidelines at the Mayo Clinic. I think they have a lot of good advice on how you monitor a patient appropriately when you place them on opioids. The doses that are mentioned probably are not scientifically based, as we would prefer that they would be, but they do not say do not use chronic opioids. They suggest doses where you might kind of yellow-light, red-light, become concerned with the use. And so those numbers are concerning somewhat, but I think the basis of the guidelines was sound, as far as the intention of them. Where the numbers came from is probably more questionable.

The CHAIRMAN. Do you see those guidelines as inconsistent with say a decision by Mayo team for knee surgery, 16 days of opioids would be appropriate?

Dr. GAZELKA. Yes, I think that there is very little mention, as I said, of acute pain management. They were not really intended to address acute pain management as much as chronic pain management. They do suggest that you limit to 3 days or 7 days unless there is a compelling reason to do otherwise, and I think that leaves some room for a physician—

The CHAIRMAN. But that is per prescription, right?

Dr. GAZELKA. That is correct.

The CHAIRMAN. It is not for everyone.

Dr. GAZELKA. For acute prescribing. That is right. For a one-time incident or surgery, yes. Not for chronic pain—the guidelines within are different.

The CHAIRMAN. Just for the layperson, which most of us are, what is a short description of a difference between chronic and acute pain?

Dr. GAZELKA. Yes, so we have considered, in the medical literature, typically three months has been used to describe the transition to chronic pain. We use 45 days at Mayo just to allow our surgeons a shorter time that they would be prescribing. But I think between 45 days and three months. Anything over that time is typically considered chronic.

The CHAIRMAN. Dr. Coop.

Dr. COOP. There is not much I can add that has not already been add by my learned colleagues, except that it is the law of unintended consequences and people take these guidelines as law. So

we need to reassess them and we need to remind everyone that they are indeed education and a place to start. That is what we need to do.

The CHAIRMAN. Thank you.

Dr. Rao-Patel.

Dr. RAO-PATEL. Yes, so I will just add this comment and say that I agree with everything my colleagues have said here, but what I will say is that the reason that the CDC made these guidelines, is part of the reason that we have an opioid epidemic now, is because there was a lack of education and knowledge on how to prescribe these medications.

I won't pick on any other specialty but my own. I know they are geared toward primary care physicians, but they can be used for any specialty. And as a physiatrist, I will say that physiatrists used to write a lot of opioids. We write a lot of opioids. A lot of us are interventional pain management doctors. A lot of us do chronic pain management, which is what I did. So I think that the goal of what the CDC was doing is correct, which is that there were not a lot of guidelines on how to prescribe these medicines, so people would go in to their physicians on Monday morning after having a flare-up of their back because they painted their home, and they would come home with a 30-day prescription of opioids, which is not necessary. So I think the intentions were correct.

I think like any other guidelines, they are guidelines. There are going to be people who fall outside of those guidelines and it is entirely appropriate to prescribe outside of them. I think that is where the universal precautions come in, managing chronic pain and making sure that you are assessing a patient's function, a patient's—how they are responding to the pain, or are there any other, risk-benefit ratio, do they have informed consent, etc. And I think like any guidelines, they are open for revision. Just because something was written one month ago, three months ago, six months ago, does not mean that six months from now the guidelines have not changed.

What I would say is that they are a revolving door of guidelines. I think there is certainly room to improve them, to change them, but I do understand the reason that they were written, and a lot of that is the reason that we are here today.

The CHAIRMAN. Thank you very much. This has been a follow-up to what the President described as the most important Federal law to try to fight a public health epidemic. That was the opioids epidemic. But as I mentioned earlier, this Committee, which has as you can see from the personalities on the Committee, has broadly divergent views. Generally left to state physicians and agencies who write guidelines. These decisions about limits on prescriptions, rather than try to write an inflexible Federal law that applied everywhere.

There is plenty of room for discussion and adjustment if adjustments need to be made. We welcome any follow-up comments you would like to make. You can tell by the interest from the Senators today that we are very interested in the topic. The hearing record will remain open for 10 days. Members may submit additional information during that time if they would like.

The CHAIRMAN. Thank you for being here.

The Committee will stand adjourned.

QUESTIONS AND ANSWERS

RESPONSE BY CINDY STEINBERG TO QUESTIONS FROM SENATOR MURRAY, SENATOR CASEY, SENATOR WARREN, SENATOR HASSAN, AND SENATOR MURKOWSKI

SENATOR MURRAY

Question 1. H.R. 6, the SUPPORT for Patients and Communities Act that Congress passed last year to address the opioid crisis, includes several specific provisions requiring CMS and FDA to examine barriers to the development and adoption of non-opioid alternatives, including payment and coverage policy. What do you see as the most significant barrier to further adoption of non-opioid alternatives for pain management? What can be done to overcome or address these barriers?

Answer 1. The most significant barrier to the adoption of non-opioid treatments for chronic pain is cost and the lack of public and private insurance coverage, limited payer coverage, elaborate prior authorization hurdles and high deductibles, co-pays and co-insurance for these therapies. Individuals living with high impact chronic pain, which the CDC and NIH have reported to be 19.6 million Americans either are completely disabled by their pain or can only work part time. Consequently, they are living on very limited budgets and can ill-afford these treatment modalities.

To overcome these barriers, payers including CMS and private insurers should be required to: cover a broader range of treatment options such as acupuncture, massage therapy, aquatherapy, chiropractic, relaxation and mindfulness meditation among others; remove payer limits on physical therapy and occupational therapy allowing physicians to decide when these modalities are needed; and, ensure that payers allow exceptions to lengthy, complicated prior authorization procedures for non-opioid pharmacological treatments.

Question 2. For some people with chronic pain, accommodations provided by an employer can make the difference between staying in the workforce or being forced out. Can you comment on the importance of accommodations for chronic pain in the workplace?

Answer 2. This is a very important issue that could greatly reduce the high rate of disability among those with high-impact chronic pain. There are a myriad of diseases, conditions and trauma including accidents and surgery that result in chronic pain. We now know that when pain continues past 6 months it can become a disease itself of the nervous system and brain that can go on for many years or last a lifetime and can be extremely debilitating. Unfortunately, this information is not understood by the general public and most employers. Because pain is an invisible disability, chronic pain sufferers are often not believed nor accommodated in the workplace. In many cases, due to stigma, pain sufferers are afraid to come forward and ask for accommodations. This is all very unfortunate and wasteful because people with pain want to work, be productive and earn a regular salary.

If employers were incentivized to make accommodations for employees with pain and workers were not afraid they would be penalized for asking for an accommodation, many more people with pain would be able to stay in the workplace and be productive. Often the accommodations needed are not that difficult to implement. For example, individuals with repetitive strain injuries who are unable to use their hands to type on a computer can be accommodated with voice recognition software. People unable to sit for more than a few minutes can be accommodated with a standing desk or those unable to be upright can lie down and use a special table to access a computer. Being able to work virtually from home is another key accommodation that would enable many people living with pain to be productive wage earners.

I firmly believe that an awareness campaign to educate employers and the public about the prevalence of and debilitating nature of high-impact chronic pain and what could be done to be more inclusive of and accommodating to people with such disabilities would more than pay for itself in reduced disability costs and increased productivity.

Question 3. Similar to other health advocacy groups, the U.S. Pain Foundation has received significant funding from pharmaceutical companies and there are multiple open investigations into how the Foundation spent funds it raised from pharmaceutical companies under its former CEO.

Why do you think so many health advocacy groups rely on pharmaceutical funding?

Answer 3. Most patient organizations rely on pharmaceutical funding because it is one of the only sources of funds for these groups. It is unclear to me why health insurers and other industry stakeholders, like medical groups, pharmacies, etc., don't offer much if any support to patient groups. In order to actively raise funds from philanthropic organizations and wealthy donors, non-profits require development professionals. These professionals command high salaries that small non-profits cannot afford. To my knowledge, there is also a significant lack of public and private grants available for patient groups.

US Pain Foundation offers a rich array of educational programs and materials, pain awareness activities and events, support services and advocacy free to patients. US Pain Foundation materials do not promote any specific product. It costs a great deal of money to develop and run these programs. US Pain Foundation's constituents are mostly people with high-impact chronic pain who are disabled by their conditions and have extremely limited funds. They cannot afford to pay membership dues nor pay for educational materials, access to events, support groups or other resources or donate money to the organization.

US Pain Foundation's programs reach thousands of patients every year and provide them with hope, support and information to enable them to better cope with their illness, advocate for themselves and take back control of their lives which many feel they have lost. US Pain Foundation and similar groups are a life-line for tens of thousands of Americans. Would it be better for these orga-

nizations to cease to exist rather than accept funds from pharmaceutical companies?

One suggestion I can make in this regard is for the Federal Government to make grants available to patient groups especially for the development of patient education programs and training programs to train support group leaders to run networks of patient support groups. Having run a support group for 19 years as a volunteer, I have seen firsthand how these programs can provide patients with important self-management skills that help them live happier, healthier and more productive lives despite their conditions. Successful groups save costs in the longrun by helping patients gain control over their conditions to be able to return to work at least part-time as well as take an active role in finding and managing the right set of therapies to keep them functional and engaged, thereby reducing unnecessary healthcare costs. It is very rare for leaders to continue to run a group for years as a volunteer like I have. It costs money to develop training programs, create materials, find good trainers and potential leaders, transport them to a training location, rent a facility, provide meals, etc.

Question 4. Do you think more transparency about where pain advocacy groups' funding comes from would be beneficial to patients and families?

Answer 4. It is always good to know where an organization's funding comes from. US Pain Foundation lists its funders for every program the organization runs on its website. In addition, the organization publicly provides copies of its 2016, 2017 and 2018 Form 990 Information Returns as well as its 2018 Audited Financial Statement which can all be found at (<https://uspainfoundation.org/funding/>).

SENATOR CASEY

Nationally, more than 70,000 people died of drug overdoses in 2017, with the large majority of these deaths caused by opioids. My home State of Pennsylvania had the third highest rate in the Nation in 2017, resulting in nearly 5400 deaths, many hundreds of whom were under the age of 25. Given this ongoing public health emergency, activities to reduce access to opioids are an essential part of the national, state, and local response. However, it is also essential that we do not forget about people who live with chronic pain and that we ensure that they have access to coordinated pain management approaches that meet their specific needs and improve their quality of life. It is also essential that insurers and health care providers both have the tools for and are held accountable for providing appropriate care, and utilize best practices regarding acute and chronic pain relief for adult and pediatric populations. Last, it is crucially important to support research into effective, non-addictive alternatives that do not carry the risks of opioid addiction, overdose, and death.

Response. I appreciate and agree with Senator Casey's observations about the need for balance in opioid policy—ensuring that patients with pain who have a legitimate need for opioids are able to obtain them while at the same time using risk assessment tools to ensure that those who are likely to misuse or abuse them do not.

As Senator Casey has mentioned, it is essential that we utilize best practices for managing acute and chronic pain. Fortunately, the HHS Pain Management Best Practices Interagency Task Force mandated by Congress in the CARA Act has recently released a final report that has been universally praised by stakeholders. The report has many excellent recommendations that I hope Congress will review and consider implementing. Finally, I could not agree more about the need to invest in research at the NIH into our understanding of pain in the human body and finding effective, non-addictive alternatives to opioid medications. Sadly, decades of underinvestment in pain relative to its burden have contributed to the dearth of truly effective options for those who suffer the most severe chronic pain.

SENATOR WARREN

Medical marijuana has the potential to provide therapeutic benefits for patients across the country—including those experiencing chronic pain. Currently, 33 states, the District of Columbia, Puerto Rico, and Guam have passed laws providing for the use of marijuana for medical purposes. This means that there are patients who are using the drug legally under state law to treat chronic pain or illness. However, there is still very limited scientific and population-based research conducted to help improve our understanding of the potential therapeutic benefits of marijuana that could in turn help inform patients and their physicians. In addition, medical marijuana may also be one tool to help mitigate the effects of the opioid crisis, as it is a possible alternative treatment to prescription pain medications. A 2014 JAMA Internal Medicine study showed that in states that passed legislation allowing for the use of medical marijuana, the fatal opioid overdose rate is 25 percent lower than in other states.¹ Some studies have also shown that state recreational marijuana laws may also impact the opioid crisis locally. A 2017 *American Journal of Public Health* study, for example, studied Colorado’s legalization of adult-use recreational marijuana and found that it resulted in almost one fewer opioid overdose death each month and determined that the “legalization of cannabis in Colorado was associated with short-term reductions in opioid-related deaths.”² This is consistent with other data from states that have developed laws for medical or recreational marijuana use. As more states pass laws providing for the use of medical or recreational adult-use marijuana, it is critical that the Federal Government facilitate research on the drug and work to support these state efforts. Doing so could ultimately provide patients struggling with chronic pain access to a safer, more effective treatment without the dangerous side effects of opioid medications.

¹ Marcus A. Bachhuber, Brendan Saloner, Chinazo Cunningham et al., “Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999–2010,” *Journal of the American Medical Association* (October 2014) (online at <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1898878>).

² Livingston, Barnett, Delcher, Wagenaar, “Recreational Cannabis Legalization and Opioid Related Deaths in Colorado, 2000–2015,” *American Journal of Public Health* (October 11, 2017) (online at: <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304059?journalCode=ajph&>).

Question 1. How could we benefit from improved scientific research on the health benefits of marijuana when used to treat chronic pain?

Answer 1. The majority of the research on marijuana supported by the Federal Government in recent decades has exclusively focused on assessing the potential harms of cannabis use. As a result, relatively few studies have addressed its positive benefits. In its 2017 report on the state of cannabis research, the National Academy of Sciences found many promising, but small or limited research projects on the usefulness of marijuana for treating pain, and these areas of research certainly merit further study. It's clear that medical marijuana has positive and therapeutic effects for those suffering from chronic pain. But doctors and patients still lack many details about how medical marijuana, with its many different forms and strains, can be most effectively utilized for this purpose. Millions of patients suffering from debilitating pain, not to mention millions of health care providers, would benefit tremendously from a far more rigorous research agenda focused on marijuana for the treatment of pain.

Doctors are generally hesitant to encourage their patients to try cannabis due to the lack of research on pain efficacy and safety and their own lack of knowledge and experience in prescribing it. Yet many patients who use medical cannabis for pain report positive results in reducing pain, improving function and in some cases, allowing them to reduce other medications including opiates that they have relied on. However, without rigorous research these reports remain anecdotal and are likely to continue to limit more widespread use of medical cannabis for pain control.

Question 2. Has the U.S. Pain Foundation received any stories from chronic pain patients who have utilized medical marijuana as an alternative treatment to opioid medications?

Answer 2. We have heard some patient stories of medical cannabis use as an alternative to opioids but the more common stories we hear are patients who have started cannabis as a way to reduce their opioid use. We frequently get questions about the best way to do this. This is an area where patients could really benefit from research on the best way to transition to medical cannabis for pain relief from other medications.

Question 3. Have there been any efforts to survey patient outcomes?

Answer 3. We are not aware of any such efforts.

SENATOR HASSAN

Question 1. Public reports and previous investigations show that the U.S. Pain Foundation has received millions of dollars from opioid manufacturers. Please provide a table listing all entities that donated \$5,000 or more to the U.S. Pain Foundation in 2016, 2017, or 2018, including but not limited to donations received from individuals, companies and tax exempt organizations. In the table, please list each entity that donated to the foundation, the amount they donated in each year, and the purpose of the donations. **Please note whether the donation was unrestricted or re-**

stricted; in the case of restricted donations, please detail any restrictions.

Answer 1. The U.S. Pain Foundation receives funding from a number of sources, including pharmaceutical companies; this funding enables U.S. Pain to offer programs free of charge to its members. The source of any funding U.S. Pain receives does not influence its mission of educating, supporting, empowering and advocating for the 50 million Americans who live with chronic pain. The U.S. Pain Foundation has filed and publicly provided copies of its 2016, 2017 and 2018 Form 990 Information Returns as well as the 2018 Audited Financial Statement. These documents are available on its website: (<https://uspainfoundation.org/funding/>).

I am a contractor for the U.S. Pain Foundation. I am not an officer nor a board member and do not have access to the detailed financial records you have asked for.

Question 2. For each of the last 3 years—2016, 2017 and 2018—what percentage of the U.S. Pain Foundation’s revenue was generated from payments or donations in excess of \$5,000?

Answer 2. U.S. Pain Foundation receives funding from individual donors, grants, private companies and pharmaceutical companies. As previously mentioned, the source of any funding does not influence U.S. Pain’s mission of educating, supporting, empowering and advocating for the 50 million Americans who live with chronic pain. The U.S. Pain Foundation has filed and publicly provided copies of its 2016, 2017 and 2018 Form 990 Information Returns as well as the 2018 Audited Financial Statement, which can be found on its website: (<https://uspainfoundation.org/funding/>).

Question 3. Press reports indicate that the U.S. Pain Foundation’s activities are currently being investigated, including by multiple entities, including the U.S. Attorney’s Office, the Federal Bureau of Investigation, the U.S. Department of Health and Human Services, the Attorney General for the State of Connecticut, and the Department of Consumer Protection for the State of Connecticut. A previous investigation by the U.S. Senate Homeland Security and Government Affairs Committees revealed that the foundation received a \$2.5 million payment from Insys to operate a patient assistance program, which is now subject to investigation by the U.S. Senate Committee on Finance. Insys has been subject to Federal criminal and civil prosecution for improper marketing of Subsys, and its former CEO recently pleaded guilty to charges of bribing doctors to prescribe opioids.³ **Please provide a list that, to the best of the U.S. Pain Foundation’s knowledge, discloses all entities and offices investigating the foundation, its activities, and any of its current or past employees.**

Answer 3. As I stated in my answer to question 1 above, I am a contractor for US Pain Foundation. I am not an officer nor a board member and do not know the answer to the questions you have asked. I contacted Nicole Hemmenway, the Interim CEO, and she has provided the following response:

³ <https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L>.

In April, 2018, USPF's Board of Directors determined that between 2015 and 2018 its former CEO, Paul Gileno, misappropriated funds. Mr. Gileno was forced to resign, and the Board of Directors then assumed leadership of the organization. USPF immediately reported the suspected fraud to the appropriate authorities, and has cooperated with law enforcement throughout the course of their investigation into Mr. Gileno. The U.S. Attorney's office prosecuted Mr. Gileno for his misconduct and on June 17, 2019 Mr. Gileno pleaded guilty to wire fraud and tax evasion; his sentencing is scheduled for October 29, 2019. USPF is unaware of any other criminal investigation related to the organization. Regarding the U.S. Senate Committee on Finance inquiry, USPF has provided information in response to questions about funding the organization received from pharmaceutical companies, including INSYS. The questions posed here are nearly identical to the ones posed by that Committee.

As a result of ongoing investigations into and lawsuits against pharmaceutical companies across the country, USPF has received and responded to subpoenas requesting information related to its affiliation with those companies. USPF has cooperated in these investigations, provided requested information, and has fulfilled financial reporting requirements. These financial documents have been publicly filed and the organization has made them available on its website.

Question 4. Please list all Federal panels, task forces and committees, in which you have participated, including those in which you were a member, witness or otherwise provided testimony. Please include any involvement you had with work done by the National Academies of Science, Engineering and Medicine.

Answer 4. Advancing the Understanding of the Safe Use of Acetaminophen—panelist.

Interagency Pain Research Coordinating Committee—member.

Health and Human Services Pain Management Best Practices Inter-agency Task Force—member.

Senate HELP Committee Hearing on Pain Management during the Opioid Crisis—witness.

I have had no involvement with any work done by the National Academies of Science, Engineering and Medicine.

SENATOR MURKOWSKI

Question 1. What is your perspective on the reported increase in counterfeit opioids as reported by the Drug Enforcement Administration (DEA) and what impact do you think counterfeit drugs will have on the pain community and/or potentially the opioid crisis?

Answer 1. Counterfeit opioid pills being shipped or smuggled into this country are dangerous and we must do all we can to stop this illicit flow of drugs. The most harmful impact of these illicit drugs are on those with substance use disorder who are obtaining these medications on the street. They are often comprised of illicit fentanyl or illicit fentanyl combined with heroin and are many times more powerful than legal opioid medications.

Counterfeit drugs will have less of an effect on legitimate pain patients who overwhelmingly obtain their medications through legal channels such as pharmacies or hospitals. However, given the difficulty legitimate pain patients are reporting obtaining opioid medications from their physicians and pharmacists who are too frightened to prescribe or dispense them, we have heard a few stories (unverified) of patients who are so desperate for relief from their relentless pain that they have been driven to the street to obtain illicit opioids. We are very concerned about these patients.

Question 2. As early as 2017, the Alaska Pharmacists Association has been raising the issue with me that counterfeit opioids were coming into the country and posing a danger. Neither the Alaska pharmacists nor the licensed healthcare groups here today are part of that illegal distribution, and yet must deal with the consequences. What efforts have you and/or your organization implemented to educate patients about the dangers of counterfeits to combat the increasing amount of opioids being purchased outside of the legitimate distribution channel or on the street by the pain community?

Answer 2. We have not undertaken any such efforts.

RESPONSE BY HELENA GAZELKA TO QUESTIONS FROM SENATOR MURRAY, SENATOR CASEY, SENATOR MURKOWSKI, AND SENATOR SMITH

SENATOR MURRAY

Question 1. H.R. 6, the SUPPORT for Patients and Communities Act that Congress passed last year to address the opioid crisis, includes several specific provisions requiring CMS and FDA to examine barriers to the development and adoption of non-opioid alternatives, including payment and coverage policy. What do you see as the most significant barrier to further adoption of non-opioid alternatives for pain management? What can be done to overcome or address these barriers?

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to respond to additional questions for the record following the February 12 hearing on “Managing Pain During the Opioid Crisis”.

Answer 1. As you noted Senator Murray, thanks to congressional action, efforts are underway to identify barriers to the proliferation of non-opioid therapies for pain management. In response to your two questions, which I will answer in tandem, the ongoing barriers that I see as most critical to the adoption of these treatments are related to education and access. As providers, we must remain diligent in staying apprised of new discoveries and processes established by scientific rigor in order to best understand and utilize non-opioid alternative treatments. We are then able to share this education with our patients so they are best informed of their options. Patients must also be better exposed to information on pain management and expectations for treatments. Opioids have been largely utilized because they are a “quick fix”—meaning pain relief is received in short order, at least initially. But as we now know,

the reward does not exceed the risk as our country continues to face this crisis. Congress should continue to promote medical education to ensure proper understanding of pain and opioid stewardship for providers. Furthermore, Congress should also continue to pursue opportunities to increase public education on the ramifications of opioid addiction, the science of pain and pain management, and non-opioid alternatives and solutions in order to better establish expectations for pain management and empower patients to play a role in their care.

The other primary barrier is access. For some patients, especially those in rural areas, physical access to pain specialists can be limited due to the lack of specialty providers trained in the practice of pain management. In addition, many patients experience an access barrier to non-opioid treatments due to lack of health plan coverage. As a result, the cost of a treatment plan involving opioids may be less costly and more convenient than a non-opioid treatment plan. During my testimony I spoke to the benefit of pain rehabilitation programs, and specifically recognized the impact of the Mayo Clinic Pain Rehabilitation Center (PRC). Established in 1974, the PRC has helped hundreds of people manage their chronic pain without relying on opioids. And while the program is covered by Medicare, it is not yet covered by Medicaid. It should be noted that with the growth of telemedicine, there may also be opportunities to utilize this innovative care tool to meet the needs of patients with limited access, but the coverage for telemedicine services continues to be inconsistent. As non-opioid treatment models and technology continues to evolve, it will be essential that government programs also recognize the importance and efficacy of these options.

SENATOR CASEY

Question 1. Nationally, more than 70,000 people died of drug overdoses in 2017, with the large majority of these deaths caused by opioids. My home State of Pennsylvania had the third highest rate in the Nation in 2017, resulting in nearly 5400 deaths, many hundreds of whom were under the age of 25. Given this ongoing public health emergency, activities to reduce access to opioids are an essential part of the national, state, and local response. However, it is also essential that we do not forget about people who live with chronic pain and that we ensure that they have access to coordinated pain management approaches that meet their specific needs and improve their quality of life. It is also essential that insurers and health care providers both have the tools for and are held accountable for providing appropriate care, and utilize best practices regarding acute and chronic pain relief for adult and pediatric populations. Last, it is crucially important to support research into effective, non-addictive alternatives that do not carry the risks of opioid addiction, overdose, and death.

Answer 1. I could not agree more with your supplemental statements, Senator Casey. While actions are needed to address the opioid and drug abuse crisis that is plaguing our communities, it is essential that those with chronic pain are not adversely impacted. That is why the Committee's attention to this topic is appreciated. As a pain specialist who has the honor of serving those

with acute and chronic pain management needs, I am happy to serve as a resource to you and fellow Members of the Committee as you discuss this important topic.

Question 2. Child and adolescent brain physiology is distinct from that of grown adults, and many research studies have highlighted the increased risk of ongoing addiction to substances when exposed to them prior to adulthood.

- In your organizations, how are current recommendations for acute and chronic opioid use different between adults and children/adolescents?
- What processes do your organizations have in place to help ensure that children/adolescents have reduced exposure to prescription opioids in both the acute and chronic health care setting?

Answer 2. This is a very important question as patients young and old experience pain. Best practices for acute and chronic opioid use between adults and children/adolescents are distinctly different topics and have been assessed and addressed individually. In children/adolescents, except in terminal diagnoses and rare exceptions, standard clinical practice is to minimize opioid exposure. As a result, it is very rare to use opioids for children/adolescents.

At Mayo Clinic, we promote that non-opioids be first line treatment for acute injuries experienced by children/adolescents, when reasonable. This would include surgeries for oral and maxillofacial needs, sports injuries, etc. If it is determined that opioids are appropriate given the patient's needs, they should be prescribed for the shortest duration possible. For chronic pain, we have found that adolescent pain rehabilitation is effective. Mayo's Pain Rehabilitation Center (PRC) operates a similar program designed for teens based upon their unique clinical and cultural needs. Like the PRC program for adults, the adolescent program covers a set of core components but also includes topics specific to teens from a relative point of view. Recognizing that chronic pain can affect entire families, the adolescent program includes programming for parents and siblings to better understand chronic conditions and how to respond to those affected.

Question 3. What are current best practices for helping a chronic pain patient who has received years of opioid medication transition onto alternative therapies?

Answer 3. As alternative therapies are identified for chronic pain patients currently receiving opioid treatment, it is important for patients and providers to explore the various options and discuss the best course of action. Patients must understand the reasoning and rationale for weaning off of an opiate as well as what alternative options may be offered for treatment. Most transitions require that other non-opioid options be implemented in parallel with the termination of opioid therapy. This is very important in order to mitigate a break in pain management for the patient. As alternative options are explored, access for and coverage of these is critical for ensuring a smooth transition prior to the weaning of the opioids. Alternative therapies may include interventional therapies, physical therapy, biofeedback, cognitive behavioral therapy, non-

opioid medications, etc., but access and coverage of these services is not consistent for every patient. Additionally, pain rehabilitation or inpatient weaning may be required, but this is also a more time-consuming and potentially costly process.

Question 4. How can it be determined that this transition is “appropriate” for some patient but not others?

Answer 4. Pain management is a very individualized practice of medicine. As patients and providers discuss when a transition from an opioid therapy to a non-opioid therapy is most appropriate, it may be very beneficial to utilize the expertise of a pain specialist. These specialists receive advanced medical training in all aspects of acute and chronic pain management. The diagnosis for which the opioid is being given is vitally important, as are the other comorbidities of the patient in order for the best treatment plan to be identified.

Question 5. Can you describe what “success” in this process looks like at the Mayo Clinic?

Answer 5. At Mayo Clinic, success of a transition for a patient from an opioid therapy to a non-opioid therapy will likely include a few milestones. These milestones may include, but are not limited to: the patient understanding their diagnosis and treatment options; a primary care provider understanding the diagnosis and treatment options; the patient’s pain being managed with interventions, other medications, surgical procedures, etc.; and psychiatric and psychological comorbidities are well-controlled. The milestones may happen entirely within a primary care practice, or with a pain specialist, or in pain rehabilitation, but it more typically will require a multidisciplinary effort to ensure the needs of the patient are met.

SENATOR MURKOWSKI

Question 1. What is your perspective on the reported increase in counterfeit opioids as reported by the Drug Enforcement Administration (DEA) and what impact do you think counterfeit drugs will have on the pain community and/or potentially the opioid crisis?

Answer 1. While we are taking great efforts to ensure opioids are prescribed in a responsible manner, the increase of counterfeit drugs with contaminants such as fentanyl analogs is contributing to many deaths. Opioids purchased outside of the United States or through illegal means lack quality control. If patients are not candidates for opioid therapy yet still seek them illegally, there may be significant consequences, including overdose and death. Prescribing opioids properly, utilizing alternatives whenever possible, and educating patients appropriately are the best tools providers have to prevent improper and illegal use of opioids.

Question 2. As early as 2017, the Alaska Pharmacists Association has been raising the issue with me that counterfeit opioids were coming into the country and posing a danger. Neither the Alaska pharmacists nor the licensed healthcare groups here today are part of that illegal distribution, and yet must deal with the consequences. What efforts have you and/or your organization implemented to educate patients about the dangers of counterfeits to

combat the increasing amount of opioids being purchased outside of the legitimate distribution channel or on the street by the pain community?

Answer 2. As an organization, we strive to provide appropriate pain management treatments and services. Combatting the use of counterfeit and other illicit substances requires a collective community approach. Through the Mayo Clinic Opioid Stewardship Program, we have constructed provider and patient education tools on the appropriate use of opioids. We believe that education on the proper use of opioids will lead to increased awareness of the risks associated with the inappropriate use of opioids and, hopefully, less illegitimate use.

SENATOR SMITH

Question 1. While we work to address the opioid epidemic, we must not forget that there are millions of Americans who suffer from chronic pain and depend on opioids to manage their pain. Mayo Clinic has always been on the forefront of innovation in healthcare, and their pain rehabilitation programs are the perfect example. The Mayo Clinic's Pain Rehabilitation Center was founded in 1974 as one of the first pain rehabilitation programs in the world. Their pain rehabilitation programs provide three-work courses that deliver holistic pain management therapies to adult and pediatric patients. The Pain Rehabilitation Center created the Mayo Clinic Opioids Stewardship Program to help bring meaningful solutions to addressing the opioid crisis. One of the outcomes of this program was the creation of uniform acute pain and chronic pain opioid prescribing guidelines.

- In your research, you describe how you and your colleagues at the Mayo Clinic worked with multi-disciplinary teams to inform these opioid prescribing guidelines. Can you describe the process behind developing these opioid prescribing guidelines and explain the benefit of having a whole host of providers at the table to inform these guidelines?
- Can you contrast the opioid prescribing guidelines that you developed at Mayo Clinic with the guidelines developed by the Centers for Disease Control and Prevention (CDC)?

Answer 1. As an organization, Mayo Clinic recognized the need to review our opioid prescribing practices. As a result, the Mayo Clinic Opioid Stewardship Program was established. We utilized a multidisciplinary team, including clinicians, allied health personnel, researchers and educators, from across the organization to develop our guidelines for chronic pain management as well as acute care. This was vitally important to ensure that we approached our charge from a wide range of viewpoints and that Mayo's collaborative culture was a core foundation of the guidelines.

Once established, our Stewardship Program reviewed current guidelines (such as those released by the CDC), reviewed available literature on acute and chronic prescribing, reviewed the pre-

scribing practices of our providers, surveyed patients (and continue to do so) to determine their care needs, and developed evidence-based guidelines. These guidelines have been made available to all Mayo care team members and have been shared with external colleagues as well.

Those reviewing our guidelines would find many similarities to the CDC guidelines in terms of restricting opioid use to appropriate indications, limiting treatment duration and dose provided, minimizing risk both with appropriate patient selection and medication selection and how/when to monitor patients who are taking opioids. We do encourage adherence to lowest clinically effective dose and duration of therapy but differ from the CDC on recommendations for prescribing limits (such as three days versus seven days) because patients and procedures vary in requirements for opioid administration. Mayo Clinic strongly believes that any prescribing guidelines should not limit provider discretion, as long as the rationale for the variation is clear and documented.

Question 2. As the opioid epidemic scours the Nation, I have also heard from communities across Minnesota—particularly tribal communities—who are struggling with addiction to methamphetamine.

- What is the relationship between illicit use of methamphetamine and the use of medication assisted treatment for opioid use disorders or acute and chronic pain?
- How is the opioid crisis hiding the rise in methamphetamine use?

Answer 2. This is a very interesting question and not in my area of expertise. Senator Smith, I would be happy to connect you with some colleagues within Mayo who have a greater understanding of substance abuse to respond to this question.

RESPONSE BY ANDREW COOP TO QUESTIONS FROM SENATOR MURRAY, SENATOR CASEY, SENATOR MURKOWSKI, AND SENATOR RICHARD BURR

SENATOR MURRAY

Question 1. H.R. 6, the SUPPORT for Patients and Communities Act that Congress passed last year to address the opioid crisis, includes several specific provisions requiring CMS and FDA to examine barriers to the development and adoption of non-opioid alternatives, including payment and coverage policy. What do you see as the most significant barrier to further adoption of non-opioid alternatives for pain management? What can be done to overcome or address these barriers?

Answer 1. In my role as an educator, I would say that education of both patients and healthcare providers. As stated in my written testimony, there are many pharmaceutical and non-pharmaceutical options, but prescribers require additional training on the options for treating pain. This could be accomplished by (1) increasing pain management education in the curriculums for all healthcare professionals, and (2) education of patients that opioids are not always the answer. My adopted profession of pharmacy is the profession that is most focused on drugs, and utilizing the pharmacists to con-

sult with patients on the options available, and what to expect, is an avenue that has gone primarily unexplored. This covered under the answer for question 2 in appendix A (see page 82).

Question 2. Given your experience as a pharmacist, how can health care teams better integrate pharmacists into pain management? Are you aware of any effective team-based care delivery for pain management used either in practice in the United States or internationally?

Answer 2. A detailed response is provided in Appendix A (see page 82).

SENATOR CASEY

Question 1. Nationally, more than 70,000 people died of drug overdoses in 2017, with the large majority of these deaths caused by opioids. My home State of Pennsylvania had the third highest rate in the Nation in 2017, resulting in nearly 5400 deaths, many hundreds of whom were under the age of 25. Given this ongoing public health emergency, activities to reduce access to opioids are an essential part of the national, state, and local response. However, it is also essential that we do not forget about people who live with chronic pain and that we ensure that they have access to coordinated pain management approaches that meet their specific needs and improve their quality of life. It is also essential that insurers and health care providers both have the tools for and are held accountable for providing appropriate care, and utilize best practices regarding acute and chronic pain relief for adult and pediatric populations. Last, it is crucially important to support research into effective, non-addictive alternatives that do not carry the risks of opioid addiction, overdose, and death.

Answer 1. These are all outstanding points, and an approach that includes pharmacists is included in Appendix A (see page 82). The need to fund research into new analgesics is close to my heart, and one that I fully support. The Federal funding agencies (NH, DOD) are committed to this, and we need to ensure that their budgets are sufficient to allow the studies to continue at a rapid pace.

SENATOR MURKOWSKI

Question 1. What is your perspective on the reported increase in counterfeit opioids as reported by the Drug Enforcement Administration (DEA) and what impact do you think counterfeit drugs will have on the pain community and/or potentially the opioid crisis?

Answer 1. The rise in counterfeit opioids has been well documented, including in the mainstream media (https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users-sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb_story.html?utm_term=.72b7d52b4701). Many are laced with extremely potent opioids, or a range of other pharmaceuticals. The DEA requires the resources to ensure that such tablets are eliminated to the greatest extent possible, but the DEA cannot be everywhere at once. As such, as access to prescription opioids continues to be limited to prevent inappropriate use, more

individuals will turn to opioids purchased from the street. This opens a potential huge public health crisis, as the individuals have no idea what drugs they are actually taking. I feel the only approach is a public information campaign with a focus on:

- A. That opioid abuse is a disease, and there are treatments
- B. Opioids have deadly consequences, when taken inappropriately
- C. Individuals should only take opioids that are specifically prescribed to them. When used appropriately, they are outstanding medications.
- D. Opioids from other mechanisms are of unknown quality, and the potential to be lethal

Question 2. As early as 2017, the Alaska Pharmacists Association has been raising the issue with me that counterfeit opioids were coming into the country and posing a danger. Neither the Alaska pharmacists nor the licensed healthcare groups here today are part of that illegal distribution, and yet must deal with the consequences. What efforts have you and/or your organization implemented to educate patients about the dangers of counterfeits to combat the increasing amount of opioids being purchased outside of the legitimate distribution channel or on the street by the pain community?

Answer 2. Students groups at the University of Maryland School of Pharmacy engage the community regarding all aspects of drug use and misuse. We always stress that medications should only be obtained from legitimate sources and only to take those prescribed to you. However, there is always room to improve our message, I will reassess to ensure that the communications are clear in regards to opioid specifically.

SENATOR BURR

Question 1. While hemp and marijuana are both species of the Cannabis plant family, they have different legal statuses in the United States due to the amount of tetrahydrocannabinol (THC) in each plant—marijuana has a high concentration of THC and hemp has a very low concentration. Due to its naturally low levels of THC, hemp is a legal substance in the United States. When discussing alternative pain management options, you note in your testimony that “medical cannabis, controversial as it is, has potential, but well-designed studies are lacking.” Similarly to marijuana, hemp contains cannabidiol (CBD) which some claim has the potential to help with pain.

Just as researchers believe there is potential in medical cannabis for treating chronic pain, are researchers looking into the use of hemp as an alternative treatment? If so, what type of results and impacts have been observed? If not, what are the biggest barriers and challenges to this research?

Answer 1. Hemp is indeed now a legal substance, as you stated, it contains very little (generally less than 0.3 percent) of THC, the psychoactive in marijuana. The agent in hemp that leads to its actions is indeed proposed to be CBD, and is under extensive investigation as a medication. That CBD does not act on the traditional

cannabis targets in the body is a plus in terms of giving rise to no psychoactive effects, but it is through that receptor that THC yields its pain-killing effects.

CBD was recently approved as a medication to treat epilepsy in a medication called Epidiolex. As I stated in my testimony, much of the research with cannabis is difficult to interpret due to differences in the materials being studied, with natural variability in substances from natural sources. In addition, the type of pain plays a significant role, as it appears that both THC and CBD have potential for different types of pain. A very recent paper showed no pain killing activity from one such source of CBD (<http://dx.doi.org/10.1097/j.pain.0000000000001464>), but another paper showed CBD had activity in treating pain and inflammation of the cornea (<https://doi.org/10.1089/can.2017.0041>). This is typical of the literature where THC is controlled, and CBD was until recently controlled. The actions of CBD are therefore difficult to fully assess, but it does appear that a main mechanism of action of CBD is due to its anti-inflammatory actions (<https://doi.org/10.1002/ejp.818>). Although anti-inflammatory actions are almost certainly not the entire story, inflammation is a major contributor to pain so to CBD has the potential to treat pain. Only well designed clinical trials with standardized materials will allow a full analysis of the scope AND limitations of CBD (and THC) as alternatives to opioids.

RESPONSE BY ANURADHA RAO-PATEL TO QUESTIONS FROM SENATOR MURRAY, SENATOR CASEY, SENATOR MURKOWSKI, AND SENATOR SMITH

SENATOR MURRAY

Question 1. H.R. 6, the SUPPORT for Patients and Communities Act that Congress passed last year to address the opioid crisis, includes several specific provisions requiring CMS and FDA to examine barriers to the development and adoption of non-opioid alternatives, including payment and coverage policy. What do you see as the most significant barrier to further adoption of non-opioid alternatives for pain management? What can be done to overcome or address these barriers?

Answer 1. Blue Cross and Blue Shield (BCBS) companies (Plans) cover a multitude of non-opioid pain treatments and services, including physical therapy, occupational therapy, chiropractic care and other evidence-based therapies. BCBS Plans recommend the following to address barriers to broader use of non-opioid alternatives for pain.

- *Align 42 CFR Part 2 with HIPAA.* The regulations in 42 CFR Part 2 currently impede the exchange of treatment information for patients with substance use disorders (SUD). The policies for sharing SUD records should align with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of healthcare treatment, payment, and operations (TPO) to support safety and the appropriate exchange of information.

Today, Part 2 limits the use and disclosure of SUD records among treating providers and effectively separates an individual's SUD treatment record from the rest of his or her physical and mental health medical records, creating barriers to whole-person, integrated approaches to care. Therefore, clinicians face barriers in making complete clinical decisions regarding choice of medications or whether a particular patient may need additional services or supports to address an underlying SUD. Lack of patient SUD information poses a serious safety threat to patients, including risks from multiple drug interactions and co-existing medical problems. To eliminate this barrier, we recommend the alignment of 42 CFR Part 2 regulations with HIPAA, with appropriate consumer protections.

- *Grant Payers Access to Prescription Drug Monitoring Programs (PDMPs)*. In order to protect patients from overprescribing and protect against fraudulent activities to obtain controlled substances, payers should have access to PDMPs at the state level. Increased information, with appropriate privacy protections, supports the provision of holistic and integrated care. Affording plans access to PDMP data would provide plans with additional information that can be used to identify at-risk individuals. For instance, plans do not receive information on prescriptions paid in cash or by other third-party payers—even though this data is collected by PDMPs. With a clear and complete view of the data, plan sponsors would be better positioned to coordinate care and mitigation strategies across providers and suppliers.
- *Encourage the evaluation of evidence-based, non-opioid pain management therapies by Federal agencies and encourage stakeholders to develop provider licensing standards and accreditation*. Challenges pertaining to clinical application of non-pharmacological therapies include a wide heterogeneity of therapeutic approaches and variations in the skill levels of the providers of the therapies. (For example: There are many different approaches to acupuncture, different kinds of Cognitive Behavioral Therapy and many different schools of yoga and tai chi that can be used) with limited information on the efficacy of the different approaches. There are also unique network challenges due to the lack of standards for the licensing of these providers, raising potential quality of care concerns. Certification of these providers varies across locations and modalities. For instance, acupuncture has licensure requirements in most states in the United States, while yoga typically has no such certifications.
- *Support the chronic pain management infrastructure*. Due to a lack of accessible pain medicine specialists, non-specialists and primary care providers are left to manage some patients with complex chronic pain and

painful conditions. In areas where specialist access is limited, support should be given to improving access through telehealth and other innovative strategies.

- *Promote additional pain management education and resources.* More educational and instructional tools are needed to inform providers, employers, caregivers and consumers about pain management topics, including: the risks of SUD/opioid use disorders, living and working with chronic pain and available treatments. In addition, greater resources should be dedicated to research, particularly for understanding chronic pain, opioid misuse, SUD and the establishment of evidence-based treatment guidelines for neonatal abstinence syndrome (NAS).

Question 2. Developing new treatments and team-based approaches to care for chronic pain are both critical to improve patient outcomes. However, if insurers do not cover these treatments and services, patients will be unable to afford them. In a survey of insurers and providers, researchers at Georgetown University found that, while insurers are taking steps to limit inappropriate use of opioids, insurance plans still do not offer sufficient coverage of alternative treatments and services that may help pain patients.

What are the most common types of non-opioid pain treatments and services that Blue Cross Blue Shield of North Carolina covers for its members?

Answer 2. Chronic pain syndromes are unique to each patient and complex. A one-size-fits-all approach is not appropriate. Management of pain often times requires a multimodal and multidisciplinary assessment and treatment plan.

BCBS of North Carolina covers a multitude of non-opioid pain treatments and services including physical therapy, occupational therapy, chiropractic care, aquatic therapy, facet blocks, medial branch blocks, epidural steroid joint injections, steroid joint injections, TENS units and trigger point injections.

Most BCBS Plans cover similar benefits. Some patients need a variety of pain management treatments and medication to find relief. Plans take a number of steps to help ensure access to the best care for their members:

- Plans assess evidence-based strategies through their medical and pharmacy policies.
- Plans work with providers to look for and review new technology and medications at least yearly in order to offer the best options available.
- Plans support coverage of treatments, both pain relief drugs and nondrug treatments that meet the best clinical practice guidelines and scientific evidence.
- Plans follow, and encourage prescribers to follow, the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain.

When deciding which drugs are on the approved list of non-opioid medications, Plan medical and pharmacy teams consider which

have the best clinical benefit. Other options to manage pain may include:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (such as ibuprofen and naproxen)
- Anticonvulsants (such as gabapentin)
- Tricyclic antidepressants (TCAs) and Serotonin norepinephrine reuptake inhibitors (SNRIs) (antidepressant medications)
- Corticosteroids (steroid injections)
- Skeletal muscle relaxants
- Topical analgesics (cream-and ointment-based pain medications)

Question 3. What steps has BCBS of North Carolina taken to ensure providers within its network are aware of the full range of non-opioid alternatives available to treat pain?

Answer 3. BCBS Plans provide a variety of educational materials and resources to providers and members on non-opioid alternatives.

Specifically, BCBS of North Carolina sends out “Provider E-Briefs” and other communications to providers as well as having case managers reach out to members, especially after certain elective surgeries for additional education.

As another example, Anthem Blue Cross and Blue Shield has collaborated with the National Urban League to implement www.whatsupwithopioids.org which provides educational materials and toolkits that can be used to discuss SUD.

Question 4. What types of prior authorization, step therapy and other utilization management protocols are these alternative treatments and services subject to?

Answer 4. Specific benefits and services and any corresponding utilization management protocols are dependent upon the program (Medicare, Medicaid and commercial insurance), state requirements and benefit plan.

BCBS of North Carolina does not employ utilization management protocols when treating pain through physical therapy, occupational therapy, chiropractic care, aquatic therapy, facet blocks, medial branch blocks, epidural steroid joint injections, steroid joint injections, TENS units or trigger point injections. This approach is similar in other Blue Cross and Blue Shield Plans.

Additionally, Plans routinely examine and update utilization management protocols as more evidence and data become available.

Question 5. How does BCBS of North Carolina ensure that there is an adequate network of providers for the full-range of treatments?

Answer 5. BCBS of North Carolina takes several steps to ensure an adequate network of providers for the full range of treatments.

BCBS Plans routinely use data analytics to identify provider access needs. For instance, at BCBS of North Carolina, our contracting department creates geo-access reports to ensure we meet all regulatory requirements around mileage and number of pro-

viders for primary care and specialties. BCBS of North Carolina has the largest network of providers in the state.

If a member has trouble finding a provider, our customer service providers (CSP) or nursing team will assist that member. In the event a network access issue is identified, our medical affairs team will work to recruit high quality providers in that area.

In specific situations, BCBS of North Carolina may approve coverage for certain services received from non-participating providers. This includes situations where continuity-of-care or network adequacy issues dictate the use of a non-participating provider. Benefits are also available from non-participating providers for emergent and urgent care services.

Question 6. H.R. 6, the SUPPORT for Patients and Communities Act, expands the scope of Medicare coverage of telehealth services for the treatment of opioid use disorder and substance use disorders generally. Does BCBS of North Carolina support or cover telehealth services in this fashion? Why or why not?

Answer 6. Yes, BCBS of North Carolina covers telehealth services and has even expanded Current Procedural Terminology (CPT) codes for treating SUDs. Many BCBS Plans also cover telehealth services for SUD.

It should be noted, however, that BCBS of North Carolina and other BCBS Plans have experienced poor participation by providers in providing treatment via telemedicine. One explanation is that workforce inadequacies mean that SUD and behavioral health providers are at practice capacity and are not able to take additional patients.

Question 7. Has BCBS of North Carolina explored providing telehealth services for other aspects of the opioid crisis, such as mental health services? Why or why not?

Yes, BCBS of North Carolina covers behavioral health through telemedicine and has continued to build out the behavioral health program by supporting primary care physicians by integrating behavioral health into the overall course of care.

SENATOR CASEY

Nationally, more than 70,000 people died of drug overdoses in 2017, with the large majority of these deaths caused by opioids. My home State of Pennsylvania had the third highest rate in the Nation in 2017, resulting in nearly 5400 deaths, many hundreds of whom were under the age of 25. Given this ongoing public health emergency, activities to reduce access to opioids are an essential part of the national, state and local response. However, it is also essential that we do not forget about people who live with chronic pain and that we ensure that they have access to coordinated pain management approaches that meet their specific needs and improve their quality of life. It is also essential that insurers and healthcare providers both have the tools for, and are held accountable for, providing appropriate care and utilize best practices regarding acute and chronic pain relief for adult and pediatric populations. Last, it is crucially important to support research into ef-

fective, non-addictive alternatives that do not carry the risks of opioid addiction, overdose, and death.

In your testimony, you wrote that “Nationally, the total number of opioid medications filled by commercially insured BCBS members has declined by 29 percent since 2013,” and “In 2017, 67 percent of BCBS members filled their first opioid prescription within the CDC-recommended guidelines . . . ” This appears to be progress. However, it is also important to ensure that patients with disabilities—who can have ongoing needs for pain management greater than the general population—are not inappropriately denied effective medical care as a result of these changes.

Question 1. How many of the nearly 4 million enrollees of BCBS of North Carolina are individuals with disabilities?

Answer 1. BCBS of North Carolina does not have that data readily available. However, when looking at BCBSA system wide data and employing a broad definition of disability as any health event that leads to a reduction in healthy living, BCBSA estimates that 40 percent of members incur a disability due to an injury or a musculoskeletal condition (conditions clearly leading to pain) in a given year.

Question 2. What protections or processes did the BCBS of North Carolina system implement to ensure that “flexing” around the CDC guidelines for acute and chronic opioid prescription is accomplished when appropriate for pain management?

Answer 2. BCBS of North Carolina and other BCBS Plans align pharmacy benefit management strategies with the March 2016 CDC Guideline. Plans maintain robust exceptions for clinically appropriate circumstances such as for conditions of cancer or sickle cell anemia.

BCBS Plans use strategies such as pharmacy point-of-sale edits to target new starts (opioid naive patients) and are not designed to abruptly alter current pain management regimens that are working. Plans also utilize the CDC Guidelines as a tool to educate providers who are continuing regimens for consumers with chronic pain. The goal for these edits is to ensure clinically appropriate use of opioids while minimizing the risk of accidental or inadvertent addiction/dependence.

Plans rely on clinical appropriateness and doing what is right for each member. For certain consumers with chronic pain syndrome, opioids are appropriate, allowing the consumer to remain functional and to control pain. As detailed previously in this response, BCBS Plans also provide consumers access to non-opioid options. There are many non-opioid approaches to pain relief which are covered and are used successfully by consumers.

Question 3. How many enrollees have let you know their pain needs are not being met as a result of BCBS of North Carolina implementation of CDC’s guidelines? How are you responding to these concerns?

We do not have a specific measure to answer this question. However, in addition to the protections listed above, BCBS Plans have appeals processes in place if a patient has been denied service. Fur-

ther, Plans continue to educate providers and members on proper opioid use.

Question 4. Child and adolescent brain physiology is distinct from that of grown adults, and many research studies have highlighted the increased risk of ongoing addiction to substances when exposed to them prior to adulthood.

In your organizations, how are current recommendations for acute and chronic opioid use different between adults and children/adolescents?

Answer 4. There are conditions in children such as Sickle Cell disease, cancer and deforming musculoskeletal conditions for which a child's chronic pain must be appropriately and adequately managed. Children differ in how drugs affect their developing bodies, the rate at which the drug is metabolized and side effects of these drugs. A child's pain must be treated holistically, similar to treating adult pain, with a goal of achieving maximum pain relief while preventing the risk of medication misuse and addiction.

Plans have specific utilization management protocols and quantity limits in place for children and adolescents and work closely with network pediatricians to ensure a child's comfort and safety.

We would also like to draw attention to the increase in Neonatal Abstinence Syndrome (NAS) diagnoses. Over the last several years, the United States has seen a significant increase in the incidence of NAS—from 1.5 per 1,000 U.S. hospital births in 1999 to 6.0 per 1,000 U.S. hospital births in 2013. This accounts for a 300 percent increase in infants born with NAS, a postnatal drug withdrawal syndrome that occurs primarily among opioid-exposed infants shortly after birth. In response to opioid use disorders and the associated health risks, BCBS Plans are developing strategies to address substance use before, during and after pregnancy. This strategy includes efforts to optimize pregnancy avoidance or delay for women using controlled substances, effective identification of pregnant women using controlled substances, increased capacity for efficient and effective referral to treatment for pregnant women, and the promotion of standards and consistency of treatment for newborns with NAS.

Additionally, BCBSA recommends that the Substance Abuse and Mental Health Services (SAMHSA) take steps to educate primary care and obstetrical physicians in the safe use of medication assisted treatment (MAT) during pregnancy.

Question 5. What processes do your organizations have in place to help ensure that children/adolescents have reduced exposure to prescription opioids in both the acute and chronic health care setting?

Answer 5. BCBS of North Carolina has taken several steps to reduce childhood exposure to opioids. First, our nurses and case managers educate members on proper use and storage of opioid medications. Second, BCBS of North Carolina has specific utilization management protocols and quantity limits in place for children and adolescents. We have also partnered with local pharmacies in the state for drug take-back boxes across and participate in the annual DEA National Drug Take Back Day.

BCBS Plans continue to encourage providers to educate adolescent patients and their parents and guardians on proper use, storage and disposal of unused medications.

SENATOR MURKOWSKI

Question 1. What is your perspective on the reported increase in counterfeit opioids as reported by the Drug Enforcement Administration (DEA), and what impact do you think counterfeit drugs will have on the pain community and/or potentially the opioid crisis?

Answer 1. BCBS Plans work diligently to ensure members are safe from opioid misuse, deploying a range of strategies to identify and address instances of opioid waste, fraud and abuse as well as diversion including: monitoring of claims for potential fraudulent or abusive behavior; data mining for top prescribers; review of pharmacies when identified for high-volume dispensing of controlled substances; and monitoring cases of potential “doctor shopping.”

At a local level, BCBS of North Carolina has donated \$1 million and has partnered with the Attorney General’s office and NC Department of Health and Human Services on a public awareness and education campaign, not just on the opioid crisis, but also on counterfeit opioids and pain management.

Question 2. As early as 2017, the Alaska Pharmacists Association has been raising the issue with me that counterfeit opioids were coming into the country and posing a danger. Neither the Alaska pharmacists nor the licensed healthcare groups here today are part of that illegal distribution, and yet must deal with the consequences. What efforts have you and/or your organization implemented to educate patients about the dangers of counterfeits to combat the increasing amount of opioids being purchased outside of the legitimate distribution channel or on the street by the pain community?

Answer 2. Please see above response.

SENATOR SMITH

Question 1. Researchers at the Mayo Clinic have found that hospitals and other providers are often driven toward prescribing opioids because they’re relatively cheap compared to other options to treat pain.

Dr. Rao-Patel, you mentioned in your testimony that Blue Cross Blue Shield provides coverage for non-opioid alternatives for pain management. What are some ways we can drive the market toward non-opioid therapies for acute and chronic pain management?

Answer 1. As outlined in our response to Senator Murray’s first questions, BCBS Plans cover and encourage providers and patients to use non-opioid alternatives for pain relief. In our experience, physicians and patients would benefit from increased education on how to manage chronic pain.

Question 2. Has the private sector taken steps in this direction?

Answer 2. Yes, in addition to the examples offered in responses to previous questions, BCBS Plans are working in communities with other local and national stakeholders to educate consumers and prescribers about the risks associated with opioid use and re-

garding coverage for pain-relief alternatives as well as for the treatment of SUD.

Thank you for allowing me to participate in the hearing and offer these additional comments for the record.

APPENDIX A

RESPONSE BY ANDREW COOP TO QUESTIONS FROM SENATOR MURRAY AND SENATOR CASEY

SENATOR MURRAY

Given your experience as a pharmacist, how can health care teams better integrate pharmacists into pain management? Are you aware of any effective team-based care delivery for pain management used either in practice in the United States or internationally?

As Associate Dean for Academic Affairs at the University of Maryland School of Pharmacy, I am acutely aware of the education and training pharmacists receive. Post-graduate education to obtain a Doctor of Pharmacy is rigorous but makes these health care providers uniquely qualified to provide medication-related services, including medication management, screening and risk-factor reduction. Pharmacists provide care in a variety of settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. The types of activities and services pharmacists can contribute to optimizing pain management outcomes can vary depending on the practice setting.

Pharmacist integration into pain management services would be enhanced by addressing current barriers to their inclusion. There is a need for better healthcare team provider and patient/caregiver education and awareness of the enhanced services and expertise pharmacists can contribute to effective pain management in order to improve collaborations.^{1,2} Promotion of successful models beyond the efforts currently underway in the pharmacy profession would help in raising awareness. In addition, integrating community pharmacies into health information exchanges to better facilitate communications and data-sharing is an essential component of team-based care.^{3,4} Yet, the most significant barrier to widespread adoption of the models noted is that payers, including Medicare, provide little reimbursement opportunities for pharmacist-provided patient care services, including pain management-related services. The lack of payment hinders organizations from financially supporting the work of pharmacists within health care teams or contracting with community pharmacies to provide pain management-related services as part of the team. While value-based payment models are changing to facilitate integration of pharmacists, the predominant fee-for-service model remains a barrier to pharmacist inclusion. Effectively addressing these barriers is crucial to health care teams seeking to better integrate pharmacists into pain management.

When these barriers are overcome, integration of pharmacists into pain management services helps fill gaps in care, enhance treatment capacity and options, increase cost savings, reduce pain, improve functionality, improve adherence, reduce adverse events and enhance patient satisfaction, among other benefits. Coordination and alignment of the various pharmacists interacting with patients, team members and caregivers is critical if we are to optimize pain management for the patients served. Appendix B contains a Department of Veterans Affairs (VA) overview of how pharmacists can assist in providing pain management services and addressing the

¹ Fay, A.E., Ferreri S. P., Shepherd, G., Lundeen, K., Tong, G.L. & Pfeifferberger, T. (2018). Care team perspectives on community pharmacy enhanced services, *Journal of the American Pharmacists Association*, 58, S83–S88.

² Doucette, W.R., Rippe, J.J., Gaither, C.A., Kreling, D.H., Mott, D.A. & Schommer, J.C. (2017). Influences on the frequency and type of community pharmacy services, *Journal of the American Pharmacists Association*, 57, 72–76.

³ See Community Pharmacy Enhanced Services Network, *Integrating Pharmacists into the Medical Home Team*, available at: <https://www.communitycarenc.org/what-we-do/supporting-primary-care/pharmacy/cpesn>, last accessed: March 13, 2019.

⁴ See also, Pharmacy Health Information Technology Collaborative, (2018). *Integrating Pharmacists into Health Information Exchanges—Update Version*, available at: <http://www.pharmacyhit.org/pdfs/workshop-documents/WG3-Post-2018-01.pdf>, last accessed March 13, 2019.

opioid epidemic. VA has an excellent practice model that fully optimizes pharmacists' contributions to improved patient care.

Pharmacists can work collaboratively with other members of the patient's health care team in an "embedded" model where the pharmacist sees patients and works at the practice site with other health care team members. Pharmacists practicing in embedded models are usually located in physician office practices, hospital outpatient clinics, and hospitals. Pharmacists in embedded models providing pain management services have defined roles and responsibilities and often work under collaborative practice agreements. These voluntary agreements, permitted in 48 states and the District of Columbia, allow the prescriber to delegate certain functions to the pharmacists beyond the pharmacist's normal practice authority, often prescribing (post-diagnosis), adjusting, or discontinuing medications and ordering laboratory tests. These agreements allow the pharmacist to manage and make adjustments to pain medications resulting in improved treatment outcomes and expanded access to care.

Pharmacists working on pain management teams bring valued expertise focused on optimizing medication therapies by comprehensively evaluating all of the medications that the patient is taking, not just the pain medications. Since patients with pain often have other conditions, the pharmacist's role in coordinating their medications can help to avoid problems arising from multiple prescribers. These pharmacists are also important conduits and coordinators with community pharmacists and other practitioners caring for patients.

Other activities that pharmacists working on pain management teams are involved in include working with physicians and others on the team to provide education on evidence-based guidelines, monitoring pain medication use, working with the health care team to consider non-opioid medications/treatments to control pain, providing opioid and benzodiazepine tapering services, performing risk assessments for substance use disorder or mental health conditions, and facilitating or furnishing naloxone. Pharmacists meet regularly with team members, document in the electronic health record, share information, and communicate with prescribers and other members of the team. Referral processes are often in place for other team members to refer patients to the pharmacist.

Another team-based delivery model involves community pharmacists working with physician practices in a more "virtual" team-based arrangement for patient care services that go beyond traditional dispensing. While not as common as the embedded model, these virtual arrangements often include data sharing and communications agreements and referrals for patient care services. Medicare's Chronic Care Management (CCM) Service is an example where virtual team-based service delivery is occurring that can include aspects of pain management. In addition, some community pharmacists are also partnering with physician office practices to offer opioid tapering services, an aspect of pain management, often using collaborative practice agreements, exploring how they can assist in monitoring for risk of substance use disorder, and providing naloxone.

Highlights of effective team-based care delivery for pain management utilizing pharmacists are noted below:

- A systematic review published in the *Journal of the American Medical Association* indicated that while up to 92 percent of patients studied reported they had "unused" opioids after surgery, utilizing pharmacists in the assessment of opioid prescribing can help minimize the risk of drug diversion.⁵
- Pharmacists can perform a complete review of a patient's medication regimen to optimize therapy and minimize side-effects.
 - As part of this service, they may recommend non-opioid pain alternatives and work with prescribers to provide screening, medication management, monitoring and tapering services.
- A study analyzing the economic impact of opioid-related adverse drug events (e.g. nausea, respiratory complications), estimated over half experiencing an event would have a longer hospital stay resulting in 47 percent higher cost of care for that patient. Involving pharmacists in the process of counseling, discharge, and clinic follow-up of post-operative patients who are prescribed

⁵ Bicket MC, Long JJ, Pronovost PJ, Alexander GC, Wu CL. Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review. *JAMA Surg.* 2017;152(11):1066–1071. doi:10.1001/jamasurg.2017.0831.

opioids can help reduce opioid-related adverse drug events and subsequent health care costs.⁶

- Pharmacists are involved in pain management programs that include monitoring and medication tapering services, work in medication assisted treatment programs, and furnish naloxone where authorized. Research has demonstrated the value of pharmacists in positively impacting patients with chronic pain.^{7, 8}
- Pharmacists' medication expertise helps inform other care team members about safer and alternative prescribing options, and naloxone.^{9, 10} For example, physicians in community practices and the U.S. Department of Veterans Affairs medical settings who received services such as academic detailing from a pharmacist regarding safer opioid prescribing later reported adopting safer prescribing behaviors.^{11, 12}
- Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.^{13, 14, 15} Currently, six states explicitly allow pharmacists to prescribe Schedule II-V controlled substances under a collaborative practice agreement. Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are constrained by Federal law, specifically the Drug Addiction Treatment Act of 2000, from further expanding patient access to MAT.

SENATOR CASEY

Detailed examples of effective team-based care delivery for pain management:

1. Cox, N., Tak, C.R., Cochella, S.E., Leishman E., & Gunning, K. (2018). Impact of Pharmacist Previsit Input to Providers on Chronic Opioid Prescribing Safety.

- Pharmacist's Role: All adult patients with an appointment for chronic pain who were prescribed >50 morphine milligram equivalents (MMEs)/day had charts reviewed by a pharmacist before each appointment; recommendations were sent electronically to the provider before the appointment.
- Results: When comparing outcomes before and after intervention, the mean MMEs/day decreased by 14 percent ($P < .001$), with no change in pain scores ($P = .783$). Statistically significant improvements were noted in multiple other secondary opioid safety outcomes.
- Conclusion: Clinical pharmacists providing previsit recommendations was associated with decreased opioid utilization with no corresponding in-

⁶ E.R. Kessler, M. Shah, S.K. Gruschkus, A. Raju (2013). Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes *Pharmacotherapy*, 33(4), 383–391.

⁷ Cox, N., Tak, C.R., Cochella, S.E., Leishman E., & Gunning, K. (2018). Impact of Pharmacist Previsit Input to Providers on Chronic Opioid Prescribing Safety.

⁸ <https://doi.org/10.1016/j.japh.2017.01.016>.

⁹ See Trotter Davis, M., Bateman, B. & Avorn J. Educational Outreach to Opioid Prescribers: The Care for Academic Detailing, *Pain Physician*, 2017, 20:S147–S:151. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28226336>.

¹⁰ Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135–S140.

¹¹ Larson, M.J., Browne, C., Nikitin, R.V., Wooten, N.R., Ball, S., Adams, R.S. & Barth, K. (2018). Physicians report adopting safer opioid prescribing behaviors after academic detailing intervention, *Substance Abuse*, Apr 2:1-to 7. Available at: <https://www.researchgate.net/publication/324172121-Physicians-report-adopting-safer-opioid-prescribing-behaviors-after-academic-detailing-intervention>.

¹² Gelland, W.F., Good, C.B. and Shulkin, D.J. (2017). Addressing the Opioid Epidemic in the United States Lessons from the Department of Veterans Affairs, *JAMA Intern Med*. 177(5):611–612.

¹³ DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. *J Am Pharm Assoc*. 2015; 55: 187–192.

¹⁴ Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135–S140.

¹⁵ Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, *Mental Health Clinician*, 2013, 3(6), Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135–S140 290–291.

crease in pain scores and increased compliance to guideline recommendations.

2. Genord, C., Frost, T. & Eid, D. (2017). Opioid exit plan: A pharmacist's role in managing acute postoperative pain, *Journal of the American Pharmacists Association*, 57(2), S92–S98.

- Pharmacist's Role: Pharmacist-led opioid exit plan (OEP) for acute postoperative pain management. OEP is a tool and its benefits include medication reconciliation review and prescription drug—monitoring program search before admission, interdisciplinary rounds with the medical team to provide optimal inpatient postoperative pain management, clinical assessment of outpatient prescriptions with opioid discharge counseling, and medication evaluation of prescribed pain regimen and opioid discontinuation status at the post-discharge follow-up appointment. An OEP is a national practice model.
 - This paper summarizes the setup of a new pharmacist-led OEP practice model and the potential role that pharmacists and students can have before admission, during inpatient visits, and during transitions of care for discharge in acute pain management patients.
- Conclusion: A pharmacy pain management team can be key to guiding the appropriate prescribing practices of inpatient opioids and ensure best practices with quantity and quality of opioid prescriptions written on discharge. Future outcomes-based evaluations of the success of this practice model are in progress.

3. Michalets, E., Creger, J. & Shillinglaw, W.R. (2015). Outcomes of expanded use of clinical pharmacist practitioners in addition to team-based care in a community health system intensive care unit, *American Journal of Health System Pharmacy*, 72(1), 47–53.

- Pharmacist's Role: Dedicated clinical pharmacist practitioner (CPP) was made available 5 days per week in multidisciplinary team (trauma surgeon, bedside nurse, care manager, pharmacist, respiratory therapist, and nutrition support professional) rounds in a neurotrauma ICU. A practice agreement was in place to allow the CPP to initiate, modify, or discontinue medications on the hospital formulary and to order pertinent laboratory tests. In addition, the CPP could provide comprehensive medication management for medications administered in the ICU.
 - The pharmacist was responsible for clinical services, participation in the multidisciplinary team, electronic verification of medication orders, participation in emergency-code responses and provisions of clinical services. The CPP assisted with the development of individualized care plans, daily monitoring of patients and precepting of pharmacy student and residents.
- Results:
 - Based on the evaluated national benchmarking data, the estimated cost savings or avoidance associated with these patient encounters was \$2,118,426 over the two-year period. The ROI increased after the CPP expansion, from \$9 per \$1 invested in year 1 to \$18 per \$1 invested in year 2. This doubling of the ROI reflected daily consistency in CPP involvement in NTICU care and provision of more meaningful therapeutic interventions.
 - Comparison of the year 1 and year 2 data indicated a significant increase in the frequency of patient encounters for therapeutic optimization ($p < 0.01$) along with a 29 percent increase in cost savings with the CPP expansion (Table 3). Thus, the addition of two CPPs increased the volume of meaningful interventions. Although not a statistically significant decline, patient deaths decreased by 5.6 per 1000 ICU days during the study.
- Conclusion: With expanded CPP involvement on the NTICU team, there was a substantial increase in therapeutic optimization interventions and a clinically notable reduction in preventable ADEs, as well as an estimated 30 percent increase in associated cost savings.

4. Mathew, S. Chamberlain, C., Alvarez, K.S. & Shah, M. (2016). Impact of a Pharmacy-Led Pain Management Team on Adults in an Academic Medical Center, *Hospital Pharmacy*, 51(8), 639–645.

- Pharmacist's role: Pharmacy pain medication management service (pharmacy pain consult) was provided to certain adult patients.
- Results: Eight hundred twenty-one interventions were made by the clinical pharmacists. Patients displayed a significant reduction in their pre- and post-consult pain intensity scores on a 0 to 10 numerical rating scale (6.15 vs 3.25; $p < .001$). Likewise, a significant reduction in pain intensity scores was seen from pre-consult to pre-discharge (6.15 vs 3.6; $p < .001$). Overall functional improvement, specifically sleep, mobility, and appetite, was seen in 86.6 percent of patients.
- Conclusion: Pain management is an area that provides opportunities for pharmacotherapy interventions. Pharmacists' involvement in pain management on an inpatient consult service had a positive impact on pain scores and improvement in functionality.

5. Boren, L.L., Locke, A.M., Friedman, A.S., Blackmore, C.C. & Woolf, R. (2019). Team-Based Medicine: Incorporating a Clinical Pharmacist into Pain and Opioid Practice Management, *PM&R*. doi: 10.1002/pmrj.12127.

- Pharmacist's Role: A clinical pharmacist was added to a team-based care model in an outpatient Physical Medicine and Rehabilitation clinic in a tertiary hospital.
- Results: A clinically significant reduction in MED with an average decrease of 207 mg was seen after five or more visits with the pharmacist. The pharmacist initiated non-opioid medications at 209 (19.5 percent) unique patient visits. The pharmacist completed 1,197 visits during the study timeframe, increasing physician access by at least 2 additional visits per patient per year. Completion of urine drug screens and medication agreement reviews improved over time ($p < .001$). There was an increase in MED for patients who did not complete this monitoring, while the MED remained stable in those who did complete the monitoring.
- Conclusion: The addition of a clinical pharmacist to an interdisciplinary team managing COT patients resulted in a MED reduction after five or more visits with the pharmacist, improved adherence to best practice standards, optimization of opioid and non-opioid medication therapy, and increased patient access.

6. Chen, J., Lu, X., Wang, W., Shen, B., Ye, Y., Jiang, H., Wang, Q. & Chang, B. (2014). Impact of a Clinical Pharmacists-Led Guidance Team on Cancer Pain Therapy in China: A Prospective Multicenter Cohort Study, *Journal of Pain and Symptom Management*, 48(4), 500-509. (Note: Chinese study)

- Pharmacist's Role: Clinical Pharmacist-Led Guidance Teams provided pre-therapy consultation and drug education to physicians, monitored prescriptions during treatment, and conducted patient follow-up.
- Results: A total of 542 patients were enrolled, 269 in the CPGT intervention group (CPGT group) and 273 controls. Standardization of opioid administration was improved significantly in the CPGT group, including more frequent pain evaluation ($P < 0.001$), more standardized dosing titration ($P < 0.001$), and less frequent meperidine prescriptions ($P < 0.001$). The pain scores in the CPGT group were significantly improved compared with the control group ($P < 0.05$). The incidences of gastrointestinal adverse events were significantly lower in the CPGT group (constipation: $P = 0.041$; nausea: $P = 0.028$; vomiting: $P = 0.035$), and overall quality of life was improved ($P = 0.032$). No opioid addiction was encountered in the CPGT group. Risk analysis revealed that patient follow-up by pharmacists and the controlled dosing of opioids were the major factors in improving treatment efficacy.
- Conclusion: The CPGTs significantly improved standardization, efficiency, and efficacy of cancer pain therapy in China. In a country where clinical pharmacy is still developing, this is a valuable service model that may enhance cancer treatment capacity and efficacy while promoting recognition of the clinical pharmacy profession.

7. Slipp, M. & Burnham, R. (2017). Medication management of chronic pain: A comparison of 2 care delivery models, *Canadian Pharmacists Journal*, <https://doi.org/10.1177/1715163517690540> (Note: Canadian study).

- Pharmacist's Role: In the pharmacists-physician team model, the physician did the medical assessment, diagnosis, and established a treatment

plan in consultation with the patient and pharmacist. The pharmacist then provided the ongoing follow-up including education, dose titration and side effect management and consulted with the physician as needed.

- Results: Both models of medication management resulted in significant and comparable improvements in pain, disability and patient perception of medication effectiveness. Patients in the physician-only group were seen more frequently and at a greater cost. The pharmacist-physician team approach was markedly more cost-effective, and patients expressed a high level of satisfaction with their medication management.
- Conclusion: The pharmacist-physician team model of medication management results in significant reductions of pain and disability for chronic nonmalignant pain sufferers at a reduced cost and is well accepted by patients.

[Whereupon, at 12:02 p.m., the hearing was adjourned.]

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