

House Committee on Public Health Written Testimony by C.M. Schade, MD, PhD Texas Medical Association Sept. 13, 2022

Good morning, Madam Chair Klick and esteemed members of the House Committee on Public Health.

My name is Dr. C.M. Schade, and I am a board-certified physician with more than five decades of experience managing patient pain and specializing in pain management. Thank you for the opportunity to testify today on behalf of the Texas Medical Association (TMA) and its more than 56,000 physician and medical student members. Our testimony is on the impact of illegally manufactured fentanyl (IMF)-related overdoses and deaths in Texas. TMA has been engaged in finding solutions to decrease unnecessary deaths caused by opioid overdoses.

I will cover three main topics:

- 1. The current data on IMF-related overdoses and deaths and why it's time to change course from what has been done up until now to address opioid abuse;
- 2. Potential issues in the current enforcement structure that appear to contribute to use of IMF; and
- 3. TMA's recommendations on potential ways to address these concerns.

In light of current data, it is timely for the committee to take on this serious issue. The "opioid crisis" is no longer just about prescription opioids. Despite some of the strongest state and federal opioid regulations in recent history, opioid deaths continue to rise, and IMF has been identified as the main culprit. The Centers for Disease Control and Prevention (CDC) says "most recent cases of fentanyl-related harm, overdose, and death in the U.S. are linked to *illegally* made fentanyl." The statistics are disturbing:

- The American Medical Association (AMA), in its <u>2021 Overdose Epidemic Report</u>, said opioid deaths related to IMF "topped 56,000" in 2020 and have increased every year since 2012.
- Data from the <u>National Center for Health Statistics</u> show overdose deaths attributed to synthetic opioids, primarily IMF, numbered 71,238 in 2021, up from 57,834 in 2020.
- <u>CDC also says</u> the number of overdose deaths involving synthetic opioids in 2020 was more than 18 times the number in 2013. And this alarming trend is expected to accelerate in light of the COVID-19 pandemic.

¹ See CV, attached as Attachment 1, and cmschade.com.

For context, <u>CDC defines fentanyl</u> as "a powerful synthetic opioid that is similar to morphine but is 50 to 100 times more potent." A <u>tragic billboard</u> recently displayed in Texas, which was purchased by a mother who lost her 22-year-old daughter to an IMF-related death, highlights the serious nature of this issue. It announces "1 pill that's all it took" to take the life of her daughter.



Let me point out: Even as opioid deaths related to IMF rose dramatically, valid opioid prescriptions have continued to decrease. The 2021 AMA report notes 2020 marked the 10th consecutive year with a drop in such prescriptions nationwide, and opioid prescriptions in Texas are even lower than the national average.² This state decrease is likely thanks to the combined, ongoing efforts of the state, the Texas Medical Board, TMA, and other stakeholders.

This decline in opioid prescriptions is a success for Texas in the battle against opioid misuse. Unfortunately, however, there is another side to this issue. While opioid prescriptions are dropping, another serious problem is happening. Many patients cannot get proper, medically indicated prescriptions for pain management. And physicians are hesitant to prescribe medication for pain management because of – whether perceived or actual – overburdensome enforcement actions from state and federal agencies. We have heard some of the following concerns:

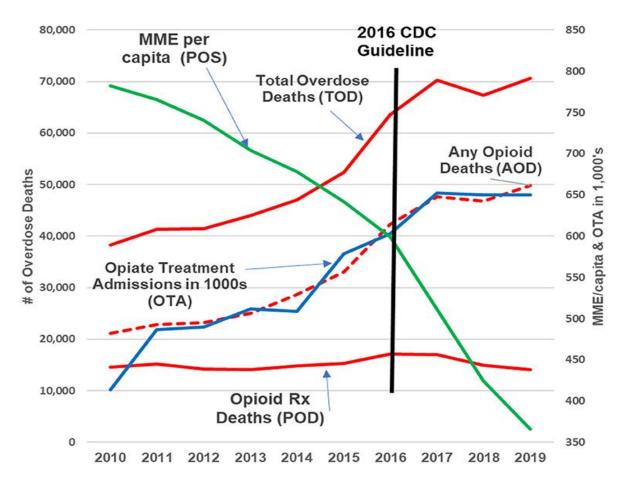
- Patients are having to drive hours to be seen by a physician for pain management because the local
 physician is not registered as a pain management clinic (PMC) or refuses to prescribe opioids over
 concerns about perceived prescribing enforcement.
- As physicians choose not to prescribe opioids or are retiring from the workforce, patients are unable to find a new physician to treat their chronic pain because of physicians' regulatory enforcement concerns
- Many surgeons, emergency department physicians, and others are referring patients to physicians
 who specialize in pain management instead of following standard of care protocols and prescribing it
 themselves.

² <u>Legislative Budget Board Staff Report – ID: 4830 (2019)</u>, page 2 ("Rates of opioid prescribing are lower in Texas than the U.S. average.").

Pain management medications, including opioids, play a necessary role in the practice of medicine. Indeed, <u>new research</u> is questioning the applicability of current prescribing guidelines and previous correlations between opioid prescribing rates and overdose rates in the U.S. <u>The recent study</u> looked at data for 2010 through 2019 and the relationship between prescription opioid sales (POS), measured by morphine milligram equivalents (MME) per capita, and four outcomes:

- 1. Total overdose deaths (TOD);
- 2. Any opioid-related deaths (AOD);
- 3. Deaths tied specifically to prescription opioids (POD); and
- 4. "Opioid use disorder" treatment admissions OTA.

"The analyses revealed that the direct correlations (i.e., significant, positive slopes) reported by the CDC based on data from 1999 to 2010 no longer exist," the authors wrote. Instead, for a "strong majority of states," they concluded, "[t]he relationships between [the outcome variables] and Annual Prescription Opioid Sales (i.e., MME per Capita) are either non-existent or significantly negative/inverse." A graph from the study illustrates this point:



"The green line represents POS, MME/capita; the red lines are opioid deaths (POD, AOD, and TOD); the blue line represents opioid addiction or OTA. Over the past decade, as the green line (prescription opioids) declined by +50%, prescription opioid deaths remained flat while opioid addiction, any opioid and total overdose deaths continued increasing 'exponentially."

TMA Written Testimony Sept. 13, 2022 Page 4 of 7

In my practice, I have seen prescribing pain medication help patients, including in the following scenarios. Please note, I've changed some of the details to protect the patients' privacy. All of the patients in these case histories have been treated in accordance with Texas Medical Board Rule 170 for pain management. This rule provides the guardrails for responsible opioid prescribing. Rule 170 requires using things such as signed pain management agreements, random urine drug screens, checking the prescription monitoring program (PMP), and using multimodal and multidisciplinary treatments to arrive at the lowest effective opioid dose.

- Student Shandra had sickle cell disease, which is an inherited disease with no cure and only symptomatic treatment. It is extremely painful both during crises and chronically. When the red blood cells deform/sickle, they cause blood clots, obstructing blood flow. That tissue then does not get blood and dies, which is painful and debilitating. When I saw Student Shandra at the request of her primary care physician, her pain was out of control, and she was in and out of emergency departments every time she had an attack. I was able to stabilize her with an at-home treatment combination of high-dose prescription fentanyl and antinausea medications, which are typical for cancer patients. She was then able to go to school and enjoy her family by taking her medications at home while avoiding costly and time-consuming treatments in the emergency department. She was stable in my practice for 15 years until she unfortunately died from the disease.
- Bowling Billy is in his thirties, is a semi-professional bowler, and has chronic pancreatitis. Billy was referred to me by his gastroenterologist because of his uncontrolled pain necessitating emergency department visits several times per month, every time he had a pancreatic attack. There is no cure, and the treatment is symptomatic. I was able to stabilize Billy on high-dose methadone and antinausea medications. His painful condition requires 300 to 400 mg of methadone a day. While this is a dose typically used in methadone treatment clinics for opioid use disorder, in this instance, it is an appropriate amount to control his pain. With his pain under control, Billy has won bowling tournaments, rarely has to go to the emergency department, and is an active family man to this day.
- Grandpa Charlie is a 70-year-old retired construction worker with diffuse, painful degenerative changes in his joints and spine. Grandpa Charlie was referred to me by his primary care physician for long-term chronic opioid therapy. If Charlie takes six to eight pain pills a day, he is active, can play with his grandchildren, and work on his small farm. Without the pain medication, he has difficulty getting out of bed and spends the day sitting in pain on his couch. Charlie has been stable with an excellent quality of life for the past 10 years on the same dose of pain medication with no escalation or side effects.
- Farmer Frank injured his back as a 30-year-old and had an unsuccessful spine surgery, leaving him with permanent spinal cord injury and chronic pain. Frank has been stable on daily opioids for four decades. There have been no opioid dose escalations and no evidence of opioid abuse or diversion. He has had a good quality of life. Most importantly, his treatment illustrates that opioid addiction is a disease that is not caused by taking opioids. In my five decades of prescribing opioids for chronic intractable pain, none of my patients has developed opioid addiction.

When patients cannot access medication for pain relief, it creates a dangerous situation. Interference with access to valid pain management prescriptions can encourage patients to seek illicit means, such as

TMA Written Testimony Sept. 13, 2022 Page 5 of 7

illegal fentanyl, to try to manage their pain.³ This of course increases their chance of an overdose or even death. In the past decade, an increased number of patients receiving treatment for chronic pain have committed suicide because they couldn't get their pain medications. It can also be dangerous for physicians. One source reports that "[h]ealthcare and social service workers are five times more likely to experience workplace violence than other workers, and account for three-fourths of all nonfatal workplace injuries and illnesses requiring days away from work." Indeed, a recently reported physician shooting by a patient in Tulsa allegedly arising from concerns involving patient post-operative pain underscores this concern about increasing violence against health care workers.

What all of this information tells us is that (1) the current enforcement structure was not designed with IMF use in mind, and (2) the current enforcement structure may be unintentionally driving patients to use illicit fentanyl and other illegal drugs. It is time for us to reexamine our processes and change course.

TMA offers a few recommendations to address these points:

Establish a workgroup to revisit the current law on certification of pain management clinics and the inspection process for both pain management clinics and non-pain management clinics in Texas Occupations Code Section 168. The current law and underlying rules for entities prescribing pain medication should be revisited. I worked with Sen. Tommy Williams and the Drug Enforcement Administration starting in 2008 until the passage of Texas' PMC certification law in 2010, SB 911 (82R). PMCs were needed at that time to combat pill mill operations, which were prevalent in Senator Williams' district. PMC regulation was helpful at that time because we did not have the robust prescription monitoring program we have today. Based on information we have received from patients and physicians, the law's enforcement structure—particularly the underlying agency rules—has unfortunately deterred many physicians from prescribing qualifying pain medications at all. The perception is that a physician has to be part of a certified PMC in order to treat pain and that all pain patients need to be referred for treatment to a certified PMC. And the current requirements for certification in the rules are administratively burdensome and nuanced, which creates lots of opportunities for minor enforcement violations. For example, the agency rules mandate urine testing for each patient seen by a PMC, even though such testing may not be medically indicated based on the patient's individual facts. In fact, studies have shown "[t]he history of the use of urine drug testing reveals that this testing has at times been punitive and stigmatizing rather than beneficial for either the individual using drugs or the community at large."

Potential enforcement violations pose risks to the physician's medical license. Because of this stigma, even many physicians who are exempt from the law entirely no longer prescribe pain medications, including surgeons for postoperative pain and emergency department physicians treating serious trauma.

I'd like to share with you a saying from the dean of my medical school: "Physicians basically do two things: relieve pain and extend life." To me, this means that the duty to relieve pain and suffering, is central to the physician's role as a healer and is an obligation physicians have to their patients. Suffering is five-dimensional: physical, psychological, financial, religious, and existential. The goal

³ Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions (2009) (section on Treating Patients with Addictive Disorders).

⁴ See <u>AMA Ethics Opinion 5.6</u> ("The duty to relieve pain and suffering is central to the physician's role as healer and is an obligation physicians have to their patients.").

when prescribing opioids or other pain medication is to end suffering. But physicians must prescribe it responsibly. Realistic guardrails are needed to prevent overprescribing, which can lead to abuse. But the guardrails must be tailored carefully to leave enough room on the road to allow for proper prescribing practices to avoid driving patients to seek illicit drugs to manage their pain.

- Syringe services programs. Some parts of Texas, such as Bexar County, have implemented safe and effective strategies to tackle their substance use problems by way of syringe services programs (SSPs), which are "community-based prevention programs that can provide a range of services, including linkage to substance use disorder treatment; access to and disposal of sterile syringes and injection equipment; and vaccination, testing, and linkage to care and treatment for infectious diseases." According to CDC, nearly 30 years of research has shown SSPs to be safe and effective. During the 87th Texas legislative session, House Bill 3233/Senate Bill 2130 sought to allow several major Texas counties and their hospital districts including Bexar, Dallas, El Paso, Harris, and Travis to establish pilot programs to curb substance misuse and prevent the spread of infectious diseases by allowing anonymous exchange of used hypodermic needles and syringes for new ones. Syringes are considered illegal drug paraphernalia under Texas law so the bill would decriminalize them when used as part of a permissible pilot program.
- Prescription monitoring program. We encourage Texas to strengthen the prescription monitoring program by considering funding sources, such as the Opioid Abatement Fund or licensing fees, for the integration software that links the PMP to physicians' electronic health records and the pharmacy-prescribing software. In addition, we recommend that the state authorize and fund the use of effective data mining software that compares pharmacy purchases to pharmacy PMP sales. This will help determine if the number of purchases equals the number of PMP sales as a method to track illegal prescriptions. One software program that has been reported to be effective is the Wholesale Outlier Model offered by Bamboo Health. It has been used in Minnesota and Ohio for several years and was more recently implemented in Oklahoma and Maine. Two other states are in the procurement phase for this program. It helps states to identify pharmacies that are not reporting their dispensing data to the PMP, are purchasing more opioids than they are reporting, and/or have excessively large sales that are disproportionate to their geographic area.⁵
- Education and prevention programs. We recommend providing more information to the public on IMF overdoses caused by counterfeit pills. This can include public service announcements and education in schools, as early as middle school and through university-level programs, about the serious side effects, including death, associated with taking any counterfeit medication and/or abusing IMF or other illegal medications.

⁵ See TMA Policy No. 95.046. Prescription Monitoring Program Integration Into Electronic Medical Records: The Texas Medical Association advocates for (1) prescription monitoring program (PMP) integration into electronic medical records, at no cost to the physician, providing patient-specific information whenever a physician attempts to prescribe a controlled substance, and (2) the integration of the PMP into Texas-based public health information exchanges (currently five), at no cost to the exchanges, so that physicians have one stop for obtaining a patient's health information; see also TMA Policy No. 95.048. Use State Medical Licensing Fees to Facilitate Physician Compliance with the State Prescription Monitoring Program (PMP) Mandates: The Texas Medical Association supports the allocation to the Texas State Board of Pharmacy of funds already being collected through medical licensing fees by the Texas Medical Board to help physicians in complying with Prescription Monitoring Program (PMP) mandates. The funds would be used to cover the basic costs for physicians to access the PMP using prescribing software. This approach would make it easier for physicians to comply with these mandates.

- Encourage equitable access to medication for opioid use disorder. TMA policy "recognizes medication for opioid use disorder as an efficacious first-line treatment for chronic opioid use disorder." We encourage the committee to consider legislation that would make the opioid antidote naloxone available over the counter without a prescription. This Food and Drug Administration-approved medication rapidly reverses an opioid overdose by only attaching to opioid receptors and reversing or blocking the effect of all opioids. According to the National Institute on Drug Abuse, it is a safe medication that only reverses overdoses in people with opioids in their system. We also recommend considering legalization of fentanyl test strips to help prevent fentanyl-related overdoses and deaths. Individuals may not realize they have a counterfeit pill with a lethal dose of IMF in it. Fentanyl strips can help as an important line of defense against this deadly drug.
- Examine sources of funding aimed to support strategies to target fentanyl overdoses. We recommend engaging in the \$4 billion available in the American Rescue Plan to expand access to vital mental health and substance use disorder services, including \$30 million for harm reduction services like naloxone, syringe service programs, and fentanyl test strips. We also recommend accessing the increased federal funding in the National Drug Control Budget for effective opioid substance use disorder prevention, treatment, harm reduction, and recovery.
- Data collection. We encourage the state to develop and implement systems to collect adequate, timely, and standardized data to identify at-risk populations and to fully understand polysubstance drug use and implement public health interventions that directly address removing structural and racial inequities. Steps may include funding in computational neuroscience, basic neuroscience, and clinical therapeutics to develop better models of understanding addiction and targets for therapeutic interventions.
- **Community collaboration.** Finally, we also encourage the committee to consider where the state can collaborate with the U.S. Department of Health and Human Services and community-based agencies and schools to implement a comprehensive behavioral health strategy in response to the landmark Bipartisan Safer Communities Act, which was signed into law June 23, 2022.

With those recommendations, this concludes my written testimony. Thank you for your time, and an appendix has been included for additional information on these issues.

Should you have any further questions, please contact: Laura J. Thetford, JD, associate general counsel, at laura.thetford@texmed.org; Christina Ly, associate vice president, Public Health, at christina.ly@texmed.org; or Michelle Romero, associate vice president, Advocacy, at michelle.romero@texmed.org; or by phone at (512) 370-1300.

⁶ TMA Policy No. 95.049 ("Encourage Equitable Access to Medication for Opioid Use Disorder").



ATTACHMENT 1 – CV

C. M. Schade, M.D., PhD's CV is included below. He is an IMF subject matter expert, Board Certified in Pain Medicine, and has been prescribing opioids for pain in Texas for five decades. He is also the presiding officer of the TSBP PDMP advisory committee, Past President and Board Member of the Texas Pain Society, and a TMA Behavioral Health Committee member. Dr. Schade has authored peer reviewed articles on pain medicine and urine drug testing (see CV below).

C. M. SCHADE, MD, PhD, PE ABA BOARD CERTIFIED IN PAIN MANAGEMENT

ABA BOARD CERTIFIED IN PAIN MANAGEMENT FELLOW OF INTERVENTIONAL PAIN PRACTICE DIPLOMATE:

AMERICAN BOARD OF ANESTHESIOLOGY
AMERICAN BOARD OF PAIN MEDICINE
ACADEMY OF INTEGRATIVE PAIN MANAGEMENT
AMERICAN BOARD OF INTERVENTIONAL PAIN PHYSICIANS
AMERICAN BOARD OF DISABILITY ANALYSTS
LICENSED PROFESSIONAL ENGINEER IN THE STATE OF COLORADO

P O Box 850069, Mesquite, TX 75185

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae

June 1, 2022 Page 1

1. EDUCATION:

B.S. Electrical Engineering and Computer Science University of California at Berkeley	1968
M.S. Electrical Engineering	
Stanford University	1969
Ph.D. Electrical Engineering	
Stanford University	1971
Ph.D. Computer Science (Minor)	
Stanford University	1971
P.E. Licensed Professional Engineer, Colorado	1974
M.D. University of Miami School of Medicine, Miami, Florida	1976
Internship—Internal Medicine	
David Grant USAF Medical Center, Travis AFB, California	1976-1977
Residency—Anesthesiology	
Wilford Hall USAF Medical Center, Lackland AFB, Texas	1977-1979
Diplomate	
American Board of Anesthesiology	1980
Academy of Integrative Pain Management	1989
(Formerly: American Academy of Pain Management)	
American Board of Pain Medicine	1994
(Formerly: Fellow, American College of Pain Medicine)	
American Board of Interventional Pain Physicians	2006
Certificate of Added Qualifications in Pain Management	
American Board of Anesthesiology	1994, 2004, 2014
Senior Disability Analyst and Diplomate	
American Board Disability Analysts	1996
Fellow of Interventional Pain Practice	2004
Certified in Controlled Substance Management	2005
Certified in Coding, Compliance and Practice Management	2005

2. PROFESSIONAL POSITIONS:

Digital Systems Engineer, Berkeley Scientific Laboratories	1965-1966
Assistant Research Engineer, Hewlett-Packard Laboratories	1965-1966
Digital Systems Engineering, Hewlett-Packard Company, Microwave Systems Group	1968-1969
Instructor of Electrical Engineering, Stanford University	1969-1971
Associate Professor of Electrical Engineering, U. S. Air Force Academy	1971-1974
United States Air Force, Lieutenant Colonel, MC, FS	1971-1981
Member, Board of Directors, Rocky Mountain Bioengineering Society	1971-1986
Licensed Professional Engineer, State of Colorado Registration No. 12908	1974 – present

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae

June 1, 2022 Page 2

Technical Director of the Intensive Care Laboratory, Wilford Hall USAF Medical Center Licensed to practice medicine in the:	1977-1981
State of Texas	1978 - present
State of Nevada	1978-2019
Schade Anesthesiology Associates (dba)	1979-1981
Teaching Staff (part time), Wilford Hall USAF Medical Center	1979-1981
Medical Research Officer, USAF Surgeon General's Consultant in CBW,	
& Flight Surgeon Instructor, USAF School of Aerospace Medicine	1979-1981
Anesthesia Consultants (dba)	1981-1988
Chairman, Emergency Room Committee, Charter Suburban Hospital	1981-1983
Member, Executive Committee, Charter Suburban Hospital	1981-1984
Director, Department of Anesthesiology, Charter Suburban Hospital	1981-1988
Vice Chief of Staff, Charter Suburban Hospital	1983-1984
Member, Board of Directors, Charter Suburban Hospital	1983-1984
Medical Director, Department of Physical Therapy, Charter Suburban Hospital	1986-1988
Medical Director, Advanced Orthopedic Services	1987-1988
Faculty, International Spine Injection Society	1992-1994
Member, Medical Executive Committee, Garland Community Hospital	1992-2001
Member, Board of Trustees, Garland Community Hospital	1993-2000
Chairman, Quality Management Committee, Garland Community Hospital	1994-1995
Chairman, Credentials Committee, Garland Community Hospital	1995-1998
Medical Director, Positive Pain Management	1995-1998
Faculty, Current Concept in Pain Management	1995-1997
Vice Chief of Staff, Garland Community Hospital	1996-1997
Chairman, Board of Directors, Patient Advocates of Texas	1996-2006
Chief of Staff, Garland Community Hospital	1998-1999
President-Elect, Texas Pain Society	1998-2000
Member TMA House of Delegates	2000-2020
President, Texas Pain Society	2000-2002
Director Emeritus, Texas Pain Society	2002 - present
Member, Board of Directors, Leland Medical Plaza	2002-2011
Chairman, Board of Directors, Vista Hospital of Dallas	2004-2011
Vice- Chair, KAG Lung Awareness Foundation, Inc.	2009 - present
Pain Medicine Delegate Medicare Carrier Advisory Committee	2013-2017
Chief of Staff, University General Hospital of Dallas	2013-2014
Chairman, Board of Directors, University General Hospital of Dallas	2013-2014
Treasurer, Board of Directors, Complete Picture	2019 - present
Presiding Officer of the Texas State Board of Pharmacy's	•
Prescription Monitoring Program Advisory Committee	2020 - present
RECENT PROFESSIONAL MEETINGS AND REVIEW COURSES.	

3. RECENT PROFESSIONAL MEETINGS AND REVIEW COURSES:

North American Neuromodulation Society annual meeting	2019
TexMed 2019 Best of Practice Management	2019
TexMed 2019 Pain Medicine - Speaker	2019
TMA Winter Conference 2019 General Session	2019
Texas Pain Society 11th Annual Scientific Meeting - Speaker	2019
DEA Practitioner Opioid Symposium	2020
ASIPP 22 nd Annual Meeting	2020
Identifying Human Trafficking in Texas	2020
Texas Pain Society 12 th Annual Scientific Meeting - Speaker	2020
TMB Education Requirements for Opioid Prescribing –CME Speaker (4146 subscribers)	2020
Texas Pain Foundation Pain Management & Prescription Opioids – CME Speaker	2020
TexMed Annual meeting	2021
DEA Practitioner Opioid Symposium	2021
Texas Pain Society 13th Annual Scientific Meeting - Speaker - three sessions	2021
TPS Annual Meeting: Complex Regional Pain Syndrome - Review and Update- Speaker	2021
TPS Annual Meeting: Spinal Cord Stimulation – Review and Update- Speaker	2021
Texas Medical Board- Board Rules on Opioids and Pain Management	2021

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae

June 1, 2022 Page 3

DEA & FSMB Opioid and Diversion Awareness Current State of the Opioid Epidemic 2021

4. MEMBERSHIP ON HOSPITAL STAFFS:

David Grant USAF Medical Center, Travis AFB, California	1976-1977
Wilford Hall USAF Medical Center, Lackland AFB, Texas	1977-1981
Medina Memorial Hospital, Hondo, Texas	1979-1981
Medical Center Hospital, Conroe, Texas	1979-1981
Frio Hospital, Pearsall, Texas	1979-1981
Charter Suburban Hospital, Mesquite, Texas	1981-1989
Leland Medical Plaza formerly known as Garland Community Hospital, Garland, Texas	1982-2003
Garland Memorial Hospital, Garland, Texas	1989-1993
Medical Center at Terrell, Terrell, Texas	2001-2004
Baylor Medical Center, Garland, Texas	2001-2018
Methodist Richardson Medical Center, Richardson, Texas	2003-2017
Vista Hospital of Dallas, Garland, Texas	2003-2011
The Spine Hospital, San Antonio, Texas	2005-2006
Baylor Surgicare at North Garland, Garland, Texas	2005-2018
North Texas Team Care Ambulatory Surgery Center	2012 - present
University General Hospital of Dallas	2013-2014

5. REFERENCES:

Furnished upon request

6. HONORS AND PROFESSIONAL MEMBERSHIPS:

Graduated with "Highest Honors" at the University of California at Berkeley

Graduated number one in my class of Electrical Engineers at the University of California at Berkeley

Phi Kappa Psi Fraternity

Phi Beta Kappa

Tau Beta Pi (Vice President, 1968)

American Medical Association

American Society of Anesthesiologists

Texas Medical Association

Texas Society of Anesthesiologists

Dallas County Medical Society

American Academy of Pain Management

International Spine intervention Society

Texas Medical Foundation, Lifetime member

American Academy of Pain Medicine

Texas Pain Society

American Society of Interventional Pain Physicians

American Board of Pain Medicine

Honorary Member, Texas Spine Society

2004 Healthcare Education Hero of the Year Award

American Board of Interventional Pain Physicians

2012 Texas Physician Practice Quality Improvement Award

International Association for the Study of Pain (IASP)

-CRPS Special Interest Group (SIG)

ASIPP Outstanding Service Award 4-15-16

7. FELLOWSHIPS:

Air Force Institute of Technology Postdoctoral (36-13) Program,	
University of Miami School of Medicine	1974-76
National Science Foundation Fellow, Stanford University	1969-71
Tau Beta Pi Fellow, Stanford University	1968-69
Stanford Fellow, Stanford University	1968-69

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae

June 1, 2022 Page 4

President's Undergraduate Fellow, University of California at Berkeley

1967-68

8. PUBLICATIONS:

Complex Regional Pain Syndrome (CRPS) – Review and Update- Speaker, Texas Pain Society 13th Annual Scientific Meeting 10-23-2021

Spinal Cord Stimulation – Review and Update- Speaker, Texas Pain Society 13th Annual Scientific Meeting 10-22-2021

Texas Medical Board Education Requirements for Opioid Prescribing – Texas Medical Association CME Speaker, (4800 subscribers to date) 3-2022

Pain Management & Prescription Opioids – Texas Pain Foundation CME Speaker 2020

Opioid Overdoses: Not a Prescribing Crisis – An Addiction Crisis. C M Schade, MD, PhD, PE, Dallas Medical Journal, January 2019 16-17

Evidence Based Pain Medicine: A Primer for Primary Care Physicians by the Texas Pain Foundation. Graves Owen, MD; Brian Bruel, MD, MBA; C M Schade, MD, PhD, FIPP; Maxim Eckmann, MD; Erik Hustak, MD; Mitchell Engle, MD, PhD, Baylor University Medical Center Proceedings, January 2018

Urine Drug Testing: Current Recommendations and Best Practices. Graves T. Owen, MD, Allen W. Burton, MD Cristy M. Schade, MD, PhD and Steve Passick, PhD, Pain Physician 2012;15-ISSN 1533-3159

Automatic Adaptation of Neurostimulation Therapy in Response to Changes in Patient Position: Results of the Posture Responsive Spinal Cord Stimulation (PRS) Research Study Cristy Schade, MD, PhD, PE; David Schultz, MD; Nancy Tamayo, DC; Sudha Iyer, PhD; Eric Panken, MS, Pain Physician 2011; 14:407-417-ISSN 1533-3159

The Story of the Texas Pain Society: Formation and Function of the of a Regional Pain Society – Co Author, Pain Practice 2011, Volume 12, Issue 1, 2012, 57-65

Abstract: Physical Activity and Patient Programmer Usage in Spinal Cord Stimulation Patients Cristy Schade, MD, PhD, PE1; David Schultz, MD2; Nancy Tamayo, DC1; Sudha Iyer, PhD3; Eric Panken, MS3 1Center For Pain Control, Garland, TX; 2MAPS Applied Research Center, Edina, MN;3 Medtronic, Inc., Minneapolis, MN

Schade CM, Sasaki J., Schultz D.M., Tamayo N. et al Assessment of Patient Preference for Constant Voltage and Constant Current Spinal Cord Stimulation. Neuromodulation 2010; 13: 210-217

C.M. Schade, MD, D. Schultz MD, N. Tamayo, DC et al Adaptation of Spinal Cord Stimulation (SCS) Intensity in Response to Posture Changes, 2009, Neuromodulation Society, 13th Annual Meeting 2009; Ref Type: Abstract

Schade, C, Sasaki J, Schultz D et al. Voltage versus current stimulation pulse trains in patients undergoing spinal cord stimulation (SCS) trial. North American Neuromodulation Society, 12th Annual Meeting 2008; Ref Type: Abstract

Sasaki J, Schade C, Shultz, D et al. American Academy of Pain Medicine Annual Meeting Abstracts: Preference for voltage or current stimulation pulse trains is not consistent in patients undergoing spinal cord stimulation (SCS) trial (#161). Pain Medicine 2009; 10(1):228

Prevention of Mechanical Failures in Implanted Spinal Cord Stimulation Systems, Neuromodulation, Volume 9, Number 3, 2006, 183-191, co-author.

Pain Management: A Handbook for Texas Physicians, Texas Medical Association, 2006, co-author.

Super Stim – Treating Chronic Neck Pain, MD News, 2005

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae June 1, 2022

Page 5

Spinal Cord Stimulation – Best Practices – Reducing Common Complications, Medtronic DVD, 2005 co-author

Review Article, COADMINISTRATION OF AN OPIOID AGONIST AND ANTAGONIST FOR PAIN CONTROL, 2005 World Institute of Pain, Pain Practice, Volume 5, Issue, 2005 11-17 – co-author

Successful SCS Trials Targeting Chronic Pain in the Low Back, Medtronic 2004, co-author

FLUROSCOPIC SAFETY, Speaker Worldwide Pain Conference San Francisco, CA, July 2000

Active Electrode Screening for Low Back Pain, Speaker Worldwide Pain Conference San Francisco, CA, July 2000

Pursuing Advanced Indications: Complex Back and Leg Pain. The Art and Science of Neuromodulation, Medtronic, 1999, co-author

Guidelines for Implantation of a Percutaneous Spinal Cord Stimulator, 1993.

"Women's G Tolerance," Aviation Space Environmental Medicine, 57: 745-53, 1986, co-author.

"Women's + G_z Tolerance," In: Preprints of the Aerospace Medical Association Annual Scientific Meeting, Washington, D.C., Aerospace Medical Association, 982:24-5, co-author.

"Nitrous Oxide-Oxygen Sedation: USAF Dental Guideline," Aeromedical Review, USAF School of Aerospace Medicine, Brooks AFB, Texas, November 1981, co-author.

"Processing of the Leg Volume Data Obtained on the MO92 Skylab Missions," Instrumentation Laboratory Report, Department of Electrical Engineering, United States Air Force Academy, Colorado, 1974, co-author.

"Manuals for Medical Instrumentation," Instrument Society of American Draft Standard, 1973, coauthor.

"The Adaptive Control of Therapeutic Procedures," Research Animals in Medicine, National Heart and Lung Institute, DHEW Publication No. (NIH) 72-333, 1973, co-author.

"Optimal Regulation of Physiological Systems via Real Time Adaptive Model Synthesis," (TRNo.6792-2), Stanford Electronics Laboratories, Stanford, California, 1971.

"Introduction to Heuristics of Invention and Discovery," SU-DMS-70-T-14, Stanford University, 1969, co-author.

"ADAC-An Automatic System for Measuring Hall Effect in Semiconductors," Hewlett-Packard Journal, November 1966, co-author.

First Interim Technical Report, "Solid State Image Intensifier Panels," DA-44-009-AMC-1250 (T), U. S. Army, Fort Belvoir, Virginia, 1966, co-author.

C. M. Schade, M.D., Ph.D., P.E. Curriculum Vitae June 1, 2022 Page 6

9. PATENTS:

I filed for a Photon Amplifier patent in 1966, and it was patented December 23, 1969, as #3,486,028.

This invention relates to an electronic circuit for amplifying an incident photon signal by taking advantage of the non-linear unidirectional conductivity characteristics of an electroluminescent diode.

In March 1970, Dr. E. E. Loebner and I disclosed an invention relating to a coding for multi-digit number indicating scales for use with time, angular, or linear measuring and/or recording devices.

In October 1993, I filed patent application number 08/453,570 for a surgical x-ray instrument for use in doing cervical discograms. Patent 5531737 was issued on July 2, 1996 for this instrument, which increases safety to the operating physician as well as the patient.



APPENDIX. Research, Resources, and Key Points

- 1. American Medical Association (AMA) Overdose Epidemic Report. Physicians and other health care professionals have reduced opioid prescribing in every state for 10 consecutive years. They have increased the use of state prescription drug monitoring programs (PDMPs) in every state for the past five years. Despite these efforts, drug-related mortality continues to rise. To address the opioid epidemic, the AMA supports increased efforts to expand sterile needle and syringe exchange service programs, decriminalization of drug checking supplies, and (e.g., fentanyl test strips) making naloxone available over-the-counter. This is a key report that first made the argument:

 "Opioid prescriptions decrease for the 10th consecutive year, but deaths continue to increase. It is time to change course."
- 2. Electronic prescription monitoring and the opioid epidemic. This publication highlights concerns with mandating checking of the prescription drug monitoring program (PDMP) every time before prescribing or dispensing controlled substances. According to some research, it may have inadvertently made the opioid overdose problem worse. Mandating PDMP checks has been reported to reduce opioid prescriptions, but unfortunately the resulting supply restrictions have allegedly lead to a significant increase in heroin deaths. Authors also highlight these unintended substitution effects can be mitigated by high opioid use disorder (OUD) treatment facility capacity. Restricting the availability of illicit substances through increased policing and investing in OUD treatment capacity can mitigate the unintended negative consequences of PDMP mandates. This is why, in addition to supply-side restrictions, it is critical that policymakers also consider demand-side solutions such as expanding treatment and rehabilitation capacity.
- 3. Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010–2019. The CDC's guidelines and communications have been questioned as outdated and as misrepresenting the intent of the original authors. This article suggests that, when examining evidence-based solutions, it is important to question flawed data highlighting correlations between prescription opioids sales and opioid treatment admissions and prescription opioid deaths. Further, individualized patient care and public health policy may need to be amended in light of these concerns. See figure 2 on page 3.
- 4. A New Study Finds No Correlation Between Opioid Prescriptions and Drug-Related Deaths. This article provides an excellent review of the research publication by Aubry & Carr (2022), which highlights the contradiction of CDC guidelines by recent data. Aubry and Carr say, relying on those outdated numbers is highly misleading. They say the CDC's advice "should be corrected/updated to state no direct correlation has existed" between prescription opioid sales and drug-related deaths or treatment admissions since 2010, and "individualized patient care and public health policy should be amended accordingly."

- 5. In a World of Stigma and Bias, Can a Computer Algorithm Really Predict Overdose Risk? A Machine-Learning Algorithm Is Being Deployed Across America to Prevent Overdose Deaths. But Could It Be Causing More Pain? There are multiple articles about the dramatic increase in suicides in patients treated for chronic pain that could not get their pain medication after the 2016 CDC guidelines were interpreted as requiring forced tapering of opioids. The latest mortality data strongly question whether America's overdose crisis is still being driven by pill mills, prescription opioid misuse, or doctor shopping. In fact, recent analyses show that the more opioid prescribing declined in certain counties, the growth in overdose death rates became steeper in those areas.
- 6. The Pain Was Unbearable. So Why Did Doctors Turn Her Away? A sweeping drug Overdose Risk Score (ORS) algorithm has become widely adopted as the US handles the opioid crisis. It may only be making the crisis worse. This article highlights a sad but true story that is all too common as patients struggle to manage their pain. The ORS is a proprietary product that has not been peer reviewed and in this case the patient's pet's pain medications increased her ORS, and she was labeled a doctor shopper and denied pain medication.
- 7. Origins of Opioid Crisis More Complex Than Stated. This article is an excellent review of the history of how we have ended up with IMF. Solutions to the U.S. opioid crisis do not lie in continued overregulation of physician prescribing, as promoted in the CDC 2016 guideline and its draft 2022 revision—a concept that now meets Einstein's definition of insanity (doing the same things over and over, while expecting the result to change). Instead, solutions lie in dealing with complex psychosocial and economic factors affecting the overwhelming preponderance of people who use illicit drugs. "There is evidence of a large population of people who use illicit drugs—for example, heroin, cocaine, methamphetamine and various synthetic derivatives—for recreational purposes. Not all of these people have substance use disorders and there is no evidence that people without substance use disorders who use drugs illicitly are contributing significantly to opioid mortality." The notion that even brief treatment with opioids poses a high risk for longer-term opioid use, if not for opioid use disorder, has been definitively put to rest by high-quality studies. And studies of people with opioid use disorder who use heroin have shown that to the extent that they started with opioid pills, opioids were diverted and not specifically prescribed for them by a physician.
- 8. The Opioid Crisis—Not Just Opioids Anymore. IMF deaths are almost always in combination with other substances such as alcohol, methamphetamines (speedball) and/or fentanyl. "The history of the use of urine drug testing reveals that this testing has at times been punitive and stigmatizing rather than beneficial for either the individual using drugs or the community at large." The use of urine drug screens should be based on best practices, not mandated.
- 9. Tulsa Shooting Intensifies Concerns About Violence Against Healthcare Workers. Healthcare and social service workers are five times more likely to experience workplace violence than other workers, and account for three-fourths of all nonfatal workplace injuries and illnesses requiring days away from work." A study published in the *Journal of the American Medical Association* in 2015 reported that an average of nine hospital shootings occurred each year between 2000 and 2005. But over the next five years, the average grew to more than 16 occurrences annually, resulting in 161 deaths. Given that the most recent data show prescription opioids are not the problem, it is time for us rewrite the statutes to encourage physicians to do the ethical thing and treat pain as they have been trained to do without fear of unwarranted enforcement actions.
- 10. <u>President Biden Calls for Increased Funding to Address Addiction and the Overdose Epidemic.</u>
 Budget calls for increased funding for evidence-based prevention, harm reduction, treatment, recovery, interdiction, and supply reduction approaches to save lives. The federal government is

investing billions of dollars into mental health and substance use disorder that Texas collaborate on.	may be able to