

UPSKILLING THE MEDICAL WORKFORCE: OPPORTUNITIES IN HEALTH INNOVATION

HEARING BEFORE THE COMMITTEE ON SMALL BUSINESS UNITED STATES HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS SECOND SESSION

HEARING HELD
NOVEMBER 13, 2019



Small Business Committee Document Number 116-058
Available via the GPO Website: www.govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE
WASHINGTON : 2020

HOUSE COMMITTEE ON SMALL BUSINESS

NYDIA VELÁZQUEZ, New York, *Chairwoman*
ABBY FINKENAUER, Iowa
JARED GOLDEN, Maine
ANDY KIM, New Jersey
JASON CROW, Colorado
SHARICE DAVIDS, Kansas
JUDY CHU, California
MARC VEASEY, Texas
DWIGHT EVANS, Pennsylvania
BRAD SCHNEIDER, Illinois
ADRIANO ESPAILLAT, New York
ANTONIO DELGADO, New York
CHRISSY HOULAHAN, Pennsylvania
ANGIE CRAIG, Minnesota
STEVE CHABOT, Ohio, *Ranking Member*
AUMUA AMATA COLEMAN RADEWAGEN, American Samoa, *Vice Ranking Member*
TROY BALDERSON, Ohio
KEVIN HERN, Oklahoma
JIM HAGEDORN, Minnesota
PETE STAUBER, Minnesota
TIM BURCHETT, Tennessee
ROSS SPANO, Florida
JOHN JOYCE, Pennsylvania
DAN BISHOP, North Carolina

MELISSA JUNG, *Majority Staff Director*
JUSTIN PELLETIER, *Majority Deputy Staff Director and Chief Counsel*
KEVIN FITZPATRICK, *Staff Director*

CONTENTS

OPENING STATEMENTS

Hon. Nydia Velázquez	Page 1
Hon. Steve Chabot	2

WITNESSES

Dr. Matthew Conti, Orthopaedic Surgery Resident, Hospital for Special Surgery (HSS), New York, NY, testifying on behalf of the American Academy of Orthopaedic Surgeons (AAOS)	4
Dr. Ingrid Zimmer-Galler, Associate Professor of Ophthalmology, Founding Clinical Director of the Office of Telemedicine, Johns Hopkins University School of Medicine, Baltimore, MD, testifying on behalf of the American Academy of Ophthalmology	6
Dr. Nancy Fahrenwald, PhD, RN, PHNA-BC, FAAN, Dean and Professor, Texas A&M University, College of Nursing, Bryan, TX, testifying on behalf of the American Association of Colleges of Nursing	8
Mr. Michael Hopkins, RN, CEO & Founder, True Concepts Medical, Centerville, OH	9

APPENDIX

Prepared Statements:

Dr. Matthew Conti, Orthopaedic Surgery Resident, Hospital for Special Surgery (HSS), New York, NY, testifying on behalf of the American Academy of Orthopaedic Surgeons (AAOS)	25
Dr. Ingrid Zimmer-Galler, Associate Professor of Ophthalmology, Founding Clinical Director of the Office of Telemedicine, Johns Hopkins University School of Medicine, Baltimore, MD, testifying on behalf of the American Academy of Ophthalmology	34
Dr. Nancy Fahrenwald, PhD, RN, PHNA-BC, FAAN, Dean and Professor, Texas A&M University, College of Nursing, Bryan, TX, testifying on behalf of the American Association of Colleges of Nursing	40
Mr. Michael Hopkins, RN, CEO & Founder, True Concepts Medical, Centerville, OH	46
Questions for the Record:	
Questions from Hon. Troy Balderson to Dr. Matthew Conti and Responses from Dr. Matthew Conti	59
Questions from Hon. Troy Balderson to Dr. Nancy Fahrenwald and Responses from Dr. Nancy Fahrenwald	64
Additional Material for the Record:	
Letter from the Healthcare Leadership Council	68

UPSKILLING THE MEDICAL WORKFORCE: OPPORTUNITIES IN HEALTH INNOVATION

WEDNESDAY, NOVEMBER 13, 2019

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,

Washington, DC.

The committee met, pursuant to call, at 11:32 a.m., in Room 2360, Rayburn House Office Building. Hon. Nydia Velázquez [chairwoman of the Committee] presiding.

Present: Representatives Velázquez, Finkenauer, Kim, Chu, Evans, Delgado, Craig, Chabot, Balderson, Hern, Hagedorn, Stauber, Burchett, Joyce, and Bishop.

Chairwoman VELAZQUEZ. The Committee will come to order.

I thank everyone for joining us this morning, and I want to especially thank the witnesses who have traveled from across the country to be with us here today.

On this Committee we are focused on ensuring that cities and towns across the country have a vibrant and growing main street. Small firms, with their innovations and character, create jobs that lead to healthy and sustainable local economies.

As we all know, an essential part of any community are the doctors and nurses who are relied upon in every corner of our country to keep us healthy. However, many people forget that these health care professionals are themselves small businesses.

They are relied upon to care for our families, while also taking on the challenge of operating a business. Not only do they face capital challenges, they also face the increasing costs of interacting with insurance companies, larger student loan burdens, and a growing patient population. Challenges such as these have led to a declining physician workforce which has disastrous effects for many Americans in underserved and rural communities.

In fact, by 2030, the Association of American Medical Colleges expects the workforce shortage to expand to over 100,000 doctors nationwide. The greatest need will be for primary care physicians who face the test of caring for every kind of patient and illness. They have become the first, and in many cases, only source of care for millions of Americans.

Luckily, advancements in technology are changing the face of medicine. Like every other industry, health care is undergoing a rapid transformation, and these emerging technologies are changing the way we think about health care in this country.

Telemedicine is allowing providers to take appointments over video chat and perform virtual visits with patients many miles away. It is not only making it easier for patients to access care, it

leads to better health outcomes by giving doctors the ability to remotely monitor their patients. In fact, telemedicine services are already being offered at 46 percent of rural community health centers and we should be expanding their funding to ensure access to care for our rural communities. Other technologies, like robots, are improving minimally invasive surgeries, allowing for more precision, safety, and a quicker recovery time.

Health information technology, such as electronic health records, is helping providers sort and transfer important health information to specialists that can advise them on treatment. Technology like this helps doctors and nurses become more efficient, cut costs, and improve quality for their patients.

For these technologies to be fully realized, we will need highly skilled physicians, nurses, and even administrators to make our healthcare system more efficient while still delivering quality care.

Unfortunately, formal curricula in virtual care and telehealth has not been widely incorporated into medical and nursing schools. Despite the availability of simulators and virtual reality to provide the opportunity to train surgeons for procedures without using patients, there are few training programs in this area.

Medical technology advancements provide a great opportunity to expand access to health care and save lives, but the complexity of these technologies requires investments in training programs to upskill medical professionals. If we poorly train, or neglect to train, our health care providers to adapt to new developments in medical devices and practices, we risk negating the potential benefits of this technology and put patients at risk.

This is why we are here today. It is clear that this technology has the potential to dramatically alter the industry. What we need to realize is, if it is done correctly, it can incentivize doctors to open practices in rural areas. It can help nurse practitioners provide care where physicians are unable and consult with specialists when needed. It can empower those in the home health care space, many of whom are small businesses.

Emerging technologies in health care can be the great equalizer allowing smaller, independent practices to treat more people and cut the cost of doing business.

To do this we need to ensure proper training. Whether through new and innovative ways of training physicians during school or upskilling nurses as they progress in their careers, providers need this training to avoid confusion and uncertainty in the face of change.

I look forward to hearing from our expert witnesses who have direct experience in training to use these technologies and developing curriculum for that training.

I would now like to yield to the Ranking Member, Mr. Chabot for an opening statement.

Mr. CHABOT. Thank you, Madam Chair.

Health care is a critical and constantly changing field with new technologies emerging every day. The advanced technologies of artificial intelligence, AI, robotics, and telehealth or telemedicine, are trending now. Each of these areas presents new solutions to old problems but do not come without cost. It is important to weigh the positives and negatives with each advancement. That is why we

are here today, to discuss the effects of these innovative forces on the healthcare industry.

Larger companies seem to dominate the emerging technologies of AI and telehealth. We need to understand how small businesses fit into this picture and what we can do to support the small firms already in these fields. It is not just the trending technologies that can have great impact on our healthcare workforce. Some solutions may seem smaller but can have an equally great impact. These changes tend to be led by small businesses or one entrepreneur with a big idea.

Such technologies can reduce costs, streamline workflow, improve delivery of care, enhance patient experience, and most importantly save lives. The time and effort saved can then be spent on patient care and additional training for healthcare workforce and a whole range of other things.

We must find ways to reduce waste and increase positive outcomes for patients and providers. This can only be done when innovators are able to create and develop products, technologies, and procedures that are properly and efficiently tested and proven to be effective. Small businesses can play a key role in all of these areas.

We are very fortunate to have a very strong and esteemed panel here today. I think we all look forward to hearing their testimony.

And Madam Chair, thank you for calling this hearing, and I yield back.

Chairwoman VELÁZQUEZ. Thank you, Mr. Chabot. The gentleman yields back.

If Committee Members have an opening statement prepared, we will ask that they be submitted for the record.

I would like to take a moment to explain the timing rules. Each witness gets 5 minutes to testify and each Member gets 5 minutes for questioning. There is a lighting system to assist you. The green light will be on when you begin, and the yellow light will come on when you have 1 minute remaining. The red light will come on when you are out of time, and we ask that you stay within the timeframe to the best of your ability.

I would now like to introduce our witnesses.

Our first witness is Dr. Matthew Conti, who currently serves as a PGY-4 at the Hospital for Special Surgery in New York City. He received a B.A. in economics and premedical studies from the University of Notre Dame and spent a year studying at Oxford before going to medical school at Cornell University. He is the founder of Our Hearts to Your Souls, a nonprofit organization that has provided free shoes and foot care to more than 40,000 homeless men and women across the U.S. for the last 15 years. Thank you, Dr. Conti, for being here today. I welcome you.

Our second witness is Dr. Ingrid Zimmer-Galler. Dr. Zimmer-Galler is an associate professor of ophthalmology at the Johns Hopkins Wilmer Eye Institute and is the medical director of its Frederick location. She is also the executive clinical director of the Johns Hopkins Office of Telemedicine. Thank you for being here today.

Our third witness today is Dr. Nancy Fahrenwald. Dr. Fahrenwald is the dean and professor at the Texas A&M Univer-

sity College of Nursing. Throughout her career she has been recognized as one of the 30 most influential deans of nursing in the United States. She earned her master's in nursing from the University of Portland, and her Ph.D. in nursing from the University of Nebraska. Thank you for being here.

I would now like to yield to our Ranking Member, Mr. Chabot, to introduce our final witness.

Mr. CHABOT. Thank you, Madam Chair.

A graduate of the University of Cincinnati, UC, with a Bachelor of Science in Nursing, Michael "Mick" Hopkins is the CEO and founder of True Concepts Medical Technologies (TCMT) in Centerville, Ohio. Mr. Hopkins developed the ideas for TCMT's products with the support of Dr. Arash Babaooff, a coworker from the Cincinnati Children's Hospital, one of the greatest children's hospitals in the country. They developed new syringe technologies after witnessing waste in multiple areas of health care. Mr. Hopkins holds four U.S. patents for technologies developed and has multiple internationals pending. His business has been named 2019's Most Promising Startup by the Quality and Safety Education for Nurses International Forum, and we welcome him here today and look forward to the testimony of all four of the witnesses. Thank you.

Chairwoman VELÁZQUEZ. Dr. Conti, you are now recognized for 5 minutes.

STATEMENTS OF MATTHEW CONTI, M.D., ORTHOPAEDIC SURGERY RESIDENT, HOSPITAL FOR SPECIAL SURGERY; INGRID ZIMMER-GALLER, MD, ASSOCIATE PROFESSOR OF OPHTHALMOLOGY, FOUNDING CLINICAL DIRECTOR OF THE OFFICE OF TELEMEDICINE, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE; NANCY FAHRENWALD, MD, PHD, RN, PHNABC, FAAN, DEAN AND PROFESSOR, TEXAS A&M UNIVERSITY, COLLEGE OF NURSING; MICHAEL HOPKINS, RN, CEO AND FOUNDER, TRUE CONCEPTS MEDICAL

STATEMENT OF MATTHEW CONTI

Dr. CONTI. Chairwoman Velázquez, Ranking Member Chabot, and members of the Committee, thank you for the opportunity to testify before the House Committee on Small Business. I offer this testimony on behalf of the American Association of Orthopaedic Surgeons, which represents 18,000 orthopaedic surgeons and 5,000 orthopaedic residents nationwide, as well as our musculoskeletal patients. I am honored to share my perspective on the role innovation plays in the field of medical education as well as my current experience as an orthopaedic resident at one of the top surgical hospitals in the country.

I would also like to thank the Chairwoman, Ranking Member, and members of the Committee for your continued focus on issues important to physicians this Congress. Past hearings on prior authorization, student loan debt, and challenges to private practices have drawn great attention to some of the issues negatively impacting patient care, especially in areas where patient choice and access is decreased. These truly are small business issues, and we are grate-

ful that this Committee is continuing to examine them with your specialized expertise.

I am currently serving as an orthopaedic surgery resident with 1-1/2 years left in training at the Hospital for Special Surgery (HSS) in New York City. As a resident at HSS, I have been able to further my surgical training, as well as to pursue opportunities in research that I hope will advance the field of orthopedics.

HSS is a special place for residency training. As a top nationally ranked hospital for orthopaedic surgery, residents at HSS have access to a range of new technology, innovative techniques, and experiences that those at smaller or more rural institutions may not have as part of their graduate medical education curriculum. I am fortunate to be able to train in such a unique environment.

In addition, this year I was selected as one of two AAOS resident advocacy scholars which has allowed me to gain a broad overview of national issues affecting health care.

As we discuss technology and innovation, surgical simulation quickly rises to the top of the list in terms of its importance and ability to effectively teach residents the skills needed to become successful surgeons. Whether it be through high-tech simulation tools or through cadaveric specimens, the surgical simulation work where I can practice techniques multiple times before treating patients has been one of the most valuable learning experiences I have had during my residency.

Virtual reality technology is another tool being used with increasing frequency and success for surgical simulation in graduate medical education. New advances in this technology allow for both visual and haptic or touch feedback recreating the feel of an actual surgery. However, significant improvements in haptic feedback are necessary in order to make virtual reality more closely mirror true operating room experiences.

When discussing innovation in technology, I also want to call attention to the issue of rural access. Patient access to specialty care is becoming an increasing challenge for patients across the country, but particularly so for those in rural areas. While telehealth has opened doors in many specialties, allowing patients in rural areas with limited medical professions to access needed medical care, there is still much to be done in the field of orthopedics.

AAOS supports efforts to ensure rural providers have the resources and tools necessary to provide quality care via groundbreaking technologies and methods.

Finally, the U.S. Federal Government invests significant funding into graduate medical education at hospitals who choose to sponsor residency programs. The health and welfare of patients is linked to the knowledge and skills physicians develop during their medical and surgical residencies.

I cannot emphasize how important this is to produce qualified and competent healthcare providers to care for me, you, and our families and friends. Funding for graduate medical education spots has been capped to control costs since 1997, forcing hospitals in states to find creative ways to fund their residency programs and the technical investment that advances their students' opportunities.

AAOS supports at a minimum maintaining current funding levels for graduate medical education, which are necessary to ensure future stability and access to a strong, diverse healthcare workforce.

I would be remiss in my testimony if I did not mention the incredible burden that medical student loan debt places on medical students and their families today. As the number of specialists in rural areas declines and the physician work shortage continues to pose challenges to patient access, the crushing pressure that this debt puts on physicians very much influences their choice in where they obtain a residency and ultimately practice afterwards.

AAOS supports common sense reforms like H.R. 5734, the Resident Deferred Student Interest Act, or REDI Act, which would allow interest-free deferment on student loans for borrowers serving in a medical or dental internship or residency program.

I would like to thank Chairwoman Velázquez and others on the Committee who have already expressed their support for this important legislation through their co-sponsorship. We greatly appreciate the Committee's interest in this and other healthcare topics and hope to continue to serve as a resource going forward.

Thank you so much for the opportunity to speak with you today.

Chairwoman VELAZQUEZ. Thank you.

Dr. Zimmer-Galler, you are now recognized for 5 minutes.

STATEMENT OF INGRID ZIMMER-GALLER

Dr. ZIMMER-GALLER. Chairwoman Velázquez, Ranking Member Chabot, and members of the Committee, I am honored to be testifying before you today on behalf of the American Academy of Ophthalmology. I am an associate professor of ophthalmology at the Johns Hopkins Wilmer Eye Institute. I also served as the founding clinical director of the Office of Telemedicine at Hopkins for the past 3 years. I serve on the American Academy of Ophthalmology's Telemedicine Task Force, and recently, I was invited to join the World Health Organization's Digital Health Roster of Experts.

I am excited to share and discuss with you today the promise of telemedicine, both in ophthalmology and more broadly, and to highlight the culture shift that is already occurring among patients and providers as telemedicine is being recognized as a new tool to deliver health care.

In July of 2016, the Johns Hopkins Office of Telemedicine was launched, and since then we have performed over 18,000 telemedicine encounters with 63 different programs. Our telemedicine programs include both image and data-sharing consults between providers or between a provider and a patient and live interactive video visits. Additionally, we have remote patient monitoring programs for patients with chronic disease that promote lower healthcare costs by allowing early intervention for patients who are declining, and thereby reducing the costs for hospital readmission and emergency department visits.

Telemedicine can benefit institutions, healthcare systems, patients and providers by expanding access to care, lowering the total cost of care, and improving the quality of care in rural and urban areas.

The challenges and burdens on patients from rural areas to access care can be significantly alleviated with virtual care. Imagine the challenges for someone at work who receives a call from their elderly parent who is not feeling well and their specialist is at an academic institution several hours away. Imagine the convenience that exists today, the reality that exists today of using a video visit to loop in the family caregiver, the patient, and the patient's specialist to allow the patient to stay at place at home and allow the family caregiver to continue staying at work.

Millennials who are very comfortable with digital technology not only want to receive their care virtually and use technology to receive their care but they want to have providers that will provide care to them at the right time, the right place, and the right care.

Similarly, telemedicine can be extremely helpful for patients with limited mobility, including the wheelchair bound. For example, neurologists at Hopkins offer follow-up video visits at home to patients with ALS or Lou Gehrig's disease. These are patients who may not be able to walk and sometimes are on a respirator. And again, imagine how much easier it is so for caregivers to have that patient have a video visit from home rather than transporting them with all of their medical equipment.

Numerous examples of successful telemedicine programs exist in my specialty in ophthalmology with the earliest being in the realm of diabetic retinopathy screening. Early detection of diabetic eye disease is key to allow intervention before permanent damage and vision loss occur. The effectiveness and success of these diabetic retinopathy screening programs with telemedicine can be measured by the many programs that are in place across the U.S. and internationally. Both the veterans' healthcare system and the Indian Health Service have large national telemedicine diabetic retinopathy programs which have significantly improved access to care across the U.S.

Digital health and virtual care are rapidly changing and evolving and evolving, and the workforce will need to keep up with advances to bring this technology to patients and providers. A typical telemedicine workforce will involve staff of various education and skill level. Staffing, as well as their additional training or upscaling for telehealth roles is critical as these individuals are the ones that will likely determine the success of the program.

There are multiple recommended staffing roles for successful telemedicine programs which are detailed in my written summary of my testimony.

In spite of the promise of telemedicine, policy barriers on both the state and the Federal level continue to contribute to its limited use. A major barrier to telehealth adoption is the lack of consistent reimbursement for virtual care. Medicare and Medicaid dictate their own policies on coverage of services, types of services allowed, and the setting where they may occur. With individual state policies added to this, we have a patchwork quilt of telehealth laws and regulations across the United States making it difficult for programs and providers to keep abreast of what they can and cannot do.

An additional major policy barrier inhibiting adoption and widespread use of telemedicine is licensing of providers. Current regula-

tions require that providers are licensed in the state where the patient is located. Applying for licenses in multiple states is time-consuming and costly. The American Academy of Ophthalmology has supported action to facilitate multi-state physician licensure for those looking to provide telemedicine services outside of their home state. And the Interstate Medical Licensure Compact currently offers qualified physicians an expedited pathway to licensure.

On behalf of the American Academy of Ophthalmology and the ophthalmic community, I thank you for your time in allowing me to discuss my work in this field and the benefits of telemedicine.

Chairwoman VELAZQUEZ. Thank you.

Dr. Fahrenwald?

STATEMENT OF NANCY FAHRENWALD

Ms. FAHRENWALD. Thank you, Chairwoman Velázquez, Ranking Member Chabot, and members of the Committee, for the opportunity to provide testimony on how we, in academic nursing, are re-envisioning the education of the next generation of nurses and nurse leaders to thrive in an ever-changing healthcare system.

I am Nancy Fahrenwald, dean and professor at Texas A&M University College of Nursing. I also serve as the Chair of the Government Affairs Committee of the American Association of Colleges of Nursing (AACN). AACN represents 825 schools of nursing, 543,000 baccalaureate and graduate students, and more than 45,000 faculty members.

With over 20 years of experience in nursing education, I have witnessed firsthand how innovation impacts healthcare delivery. I have also seen how technology and innovation have supplemented and enhanced education so that students can become effective and proficient practitioners. I have experienced how academic nursing, and nurses in general, have been early adopters of these advances, not only in practice, but also in the way that we educate our students.

As we continue in this era where there are rapid changes in technology, health professions schools, like Texas A&M, are including clinical simulation, virtual reality, telehealth, and other technology-based education platforms within the curriculum to prepare tomorrow's practitioners. Today, as the dean of the College of Nursing at Texas A&M, I collaborate with other A&M health profession schools to educate our students in the largest and most geographically diverse clinical simulation laboratories in the state, the Clinical Learning Resource Center.

At the center, students have hands-on experience making decisions about patient care as if it were real, while also allowing faculty to remediate, debrief, and educate students on best practices. Nursing students are able to prepare for skills, such as learning to administer a medication independently or to take care of something as complex as a cardiac arrest or a post-partum hemorrhage. In fact, our center has high-fidelity, full-bodied computer program mannequins that can simulate a range of responses. They can bleed, have dynamic heart rates, and even birth babies.

Other emerging technologies, such as augmented and virtual reality may be used to enhance the educational experience, for example, by putting on 3D goggles, the student can see through a man-

nequin or they are able to practice procedures such as insertion of a feeding tube or conducting a physical exam. Other mixed technologies allow students to virtually enlarge, turn, or rotate organs with their hands. These types of high-tech innovations once dreamed up in science novels are now cutting-edge tools that provide students an immersive, comprehensive, and live-action learning experience without the fear of harming a live patient.

In other nursing programs we are also seeing an emergence of entrepreneurship laboratories or innovation classes. So often, our students and faculty have an idea but they may need a software expert or an engineer to translate that idea into tangible healthcare solutions.

Adopting and integrating health and healthcare technologies beginning in the educational setting is imperative as nurses are at the forefront of care. The need for highly educated nurses is only expected to grow. The U.S. Department of Labor estimates that by 2028, the demand for registered nurses, or RNs, is expected to increase 12 percent nationally, and the demand for most advanced practice registered nurses (APRNs) sometimes serving as the only care practitioner in rural and underserved areas is expected to grow by 26 percent.

Whether nurses are providing care in hospitals via telehealth, through managed care clinics, schools, federally qualified health centers, or even establishing their own small businesses, pairing the products of health and healthcare innovation with foundational nursing principles is imperative for upscaling the future healthcare workforce. I am grateful for the opportunity to be here today to discuss ways that we are doing just that in academic nursing.

Chairwoman VELÁZQUEZ. Thank you very much.

Mr. Hopkins?

STATEMENT OF MICHAEL HOPKINS

Mr. HOPKINS. Thank you, Chairwoman Velázquez, Ranking Member Congressman Chabot, and to all the members of the Committee for this opportunity to testify before you today. It is an honor to be here.

My name is Michael Hopkins. I am the CEO and founder of True Concepts Medical Technologies located in Dayton, Ohio. I am here today to share with you how innovations from the bedside can have a global impact.

For the past 24 years, I have worked as a critical care nurse focused on emergency medicine and trauma. This, coupled with 25 years of design experience, has led me to develop a series of next generation dual-syringe technologies which have the capability to save the U.S. healthcare system billions of dollars while improving patient outcomes.

We have developed three separate standalone dual-syringe technologies, each a business unto itself. The patented safe syringe for better delivery of life-saving cardiac medications to the heart, Recon pen, a dual-syringe technology for the reconstitution of dry powder medications, and the patented dual-syringe technology, Diversion, for the best practice collection of blood cultures.

Due to time constraints, I will only be highlighting Diversion today.

True Concepts Medical Technologies is a medical device innovation engine that delivers novel, manufacturable solutions based in clinical experience. Our devices are designed by clinicians for clinicians with a focus on areas that have significant morbidity and mortality such as sepsis and sudden cardiac arrest. Our goal is to save lives and reduce healthcare costs with intelligently designed solutions that eliminate the opportunity for human error.

To better understand the solution, we must first appreciate the scope of the clinical problem. Sepsis is the body's overwhelming and life threatening response to infection that can lead to tissue damage, organ failure, and ultimately death. Each year, nearly 1.7 million individuals in America develop sepsis and 270,000 die as a result. One in three patients who dies in a hospital dies of sepsis, making it the leading cause of death in U.S. hospitals.

Sepsis kills more Americans than breast cancer, lung cancer, and opioid overdoses combined.

At \$27 billion annually, it is the leading cost of hospitalization. However, 80 percent of sepsis deaths may be averted with rapid diagnosis and appropriate treatment. Rapid diagnosis starts with the proper collection of blood cultures which have long been the gold standard in confirming infectious etiology and guiding anti-microbial therapy.

However, current blood culture collection techniques are highly flawed leading to delayed or misdiagnoses. Nearly 40 percent of all positive blood cultures are considered false positives, making an accurate and timely diagnosis of sepsis very difficult.

Annually, the U.S. healthcare system spends billions of dollars treating 1.5 million false positive blood cultures as a result of contamination that occurs during the collection and processing of the blood cultures. With just over 40 percent of the U.S. population receiving some type of government assisted health care, the financial impact to the U.S. Government is \$3 billion annually and accounts for upward of a million unnecessary inpatient hospital days.

The three main sources of contamination include skin preparation, subsurface bacteria, and human factors. Of particular significance, subsurface bacteria colonize beneath the skin in the sebaceous glands and the subsurface portions of the hair follicles where antiseptics are not effective.

Recent research has demonstrated by isolating the initial 2 mLs of blood, 2 milliliters of blood during a peripheral collection of blood cultures you can reduce contamination by 92 percent, dramatically reducing false positive blood cultures.

Our solution is the patented dual-syringe technology Diversion as seen on page three of our written testimony before you. Diversion isolates the initial 3 milliliters of blood from the rest of the sample within a single syringe ensuring contaminate free blood culture collection. A novel plunger design with an integrated transfer device allows the user to transfer collected blood from the syringe to the blood culture bottles via closed system minimizing the opportunity for contamination and all but eliminating false positive blood cultures.

We received our first utility patent for Diversion within a year of filing, as well as receiving clean reviews on our international application. Recognizing the impact that this technology can have

globally, we have filed patents in the European Union, Canada, Mexico, India, Israel, Japan, and Hong Kong. With minimal training and without change to existing workflows, Diversion will significantly improve timely, accurate diagnosis of sepsis, saving lives and reducing the financial burden on the U.S. healthcare system.

Chairwoman VELAZQUEZ. Thank you very much. We appreciate all you have shared with us this morning.

I will begin by recognizing myself for 5 minutes.

Dr. Zimmer-Galler, a large problem for our rural doctors and population is that often there is no full physician network. There may be a general practitioner in the area but perhaps not a full network of specialists. Can you explain how clinician-to-clinician telemedicine, especially in something like ophthalmology can benefit patients who may not have full access to health care?

Dr. ZIMMER-GALLER. Yes. So the beauty of telemedicine is that you really can bring specialty care to any area, whether it is a rural area of any geographic location. Typically, in rural communities this works best by having a network where the clinicians or a small community hospital where they work together with a larger tertiary care center and it is very simple to then find the appropriate specialist provider and consults can be done between providers using video technology. But these consults can also be very simply done with data sharing, transferring the medical record and then having the specialist return their recommendations to the local provider.

Chairwoman VELÁZQUEZ. Thank you.

Dr. Fahrenwald, the AMC projects that by 2030, we could have a physician shortage of upwards of 100,000. The main shortage will be in primary care and the hardest hit will be our rural and under resourced urban communities. Can you tell me how nurse practitioners can help fill that gap?

Ms. FAHRENWALD. Thank you for your question.

Nurse practitioners are educated to provide varying levels of care depending upon their specialty. The family nurse practitioner is the role that is most often assigned or appropriate for rural and underserved areas. They can see patients across the lifespan. Preparation of family nurse practitioners at schools and colleges of nursing across the country is at the graduate level with a minimum number of clinical practice hours required with patients across the lifespan in order to sit for a national certification exam.

These practitioners are often the providers in the rural areas that provide that critical access. They are also small businesses. Keeping people in these rural areas to access care so they are able to maintain their businesses in town or their farms in local communities, these providers, educated at the graduate level, either the masters or the doctor of nursing practice level in nursing, are safe, qualified health professionals whose outcomes are excellent in terms of quality, cost-effective primary care.

Chairwoman VELAZQUEZ. Is this how telehealth can help nurse practitioners open their own practices in collaboration and coordination with physicians and specialists using telehealth?

Ms. FAHRENWALD. Thank you for that question.

All health care is delivered as team work. Regardless of the setting, we work in teams for the best patient outcomes. That includes

when we practice in rural and undeserved areas where our nurse practitioners might be the only healthcare provider present. Access to other providers who can provide consultation that keeps patients from having to be seen in other settings and to travel for that care, but also to provide the confidence in the assessment of that provider is critical. Those consults can be with another nurse practitioner. They can be with a specialist. Certainly, the access to telehealth care has provided phenomenal support for these providers in the rural area and ultimately for the patients.

Chairwoman VELAZQUEZ. Thank you.

Dr. Conti, much of the equipment you use for training costs hundreds of thousands of dollars, if not millions. How can we make this equipment more accessible to surgeons that are not accepted to a residency program at such a forward-thinking institution?

Dr. CONTI. Thank you, Chairwoman.

At the Hospital for Special Surgery where I am, a lot of our simulations and our BioSkills Education Laboratory is funded through both government research grants, but also through private industry. So not all surgical simulation needs to be high cost. For example, the American Association of Orthopedic Surgeons provides orthopedic video lectures online that allows residents and surgeons who have not seen a procedure before be able to practice or at least view the procedure online. And that is a very low cost way for residents to get involved in simulation. Other ways are to have a lab that has saw bones or cadaveric specimens or to just work more closely with mentors. All of those things can be done in a more cost-effective way. And the AOS finally has courses that are put on for residents and the courses are sometimes free to residents. And as long as the resident can make travel arrangements and take time off for work, they can fly to these courses and learn the newest simulation techniques. So these are some of the ways that we can bring simulation to residents and attendings.

Chairwoman VELAZQUEZ. I have other questions but my time has expired.

Now we recognize the Ranking Member, Mr. Chabot.

Mr. CHABOT. Thank you, Madam Chair.

Mr. Hopkins, I will go with you first.

You mentioned the difficulties that you had in securing capital in order to move forward on your products and those things. Could you review with us sort of the process that you went through to secure that funding, and did you ever consider trying to get some help from the SBA, or did that ever enter your mind?

Mr. HOPKINS. Thank you for the question.

We have relied solely on friends, family, and physicians. Dr. Babaoft has been instrumental in connecting us with individuals who have expressed an interest in investing in us. We have been able to come a very long way with very little to this point. We are in our second round of funding, and again, we are leaning on friends, family, and physicians for that round. In the state of Ohio, we have a unique way of trying to raise money because as being an early stage medical startup the risk is much higher. And so many investors do not want to take on that risk. So we have been fortunate enough to be paired with Tech Dayton, which is the entrepreneur center. It is an entrepreneur services program out of the

state of Ohio, and they provided us with resources, business mentorship, build a website, did a market analysis for us for free through government grants. But it is more the connections that they have made that has led us here today actually to be in front of you all.

Mr. CHABOT. Thank you very much.

Dr. Fahrenwald, I will go to you next. How does healthcare innovation fit in to addressing the shortage of doctors and nurses, and how does small businesses fit into that as well?

Ms. FAHRENWALD. Thank you for your question.

Healthcare innovation provides a platform to offer care. People need care where people are. We prepare the healthcare providers to provide that care in the settings where people need it using the technology that is available. If that technology is not available we encourage and support entrepreneurial behavior on the part of our students or providers in order to improve access to care. It varies by state what nurse practitioners in particular as our primary care providers that we educate are able to do depending upon regulation of their practice by state boards of nursing. Certainly, in many of the rural states in this country, practice regulation has changed because of access to a nurse practitioner being the only provider or even a certified nurse midwife being the only provider in a very rural and remote area and wanting to retain them.

Technology and innovation have allowed these providers to be able to have the support they need to be successful when they are presented with a myriad of surprising situations that they may have not been exposed to before. In our simulation laboratory right now we are training nurses from across the state of Texas in how to perform examinations of people who have experienced violence, either child abuse, elder abuse, or sexual assault. Preparing them in that simulation setting so that when they are out there in their rural practices and encounter those situations they can provide safe, competent trauma-informed care.

Mr. CHABOT. Thank you very much. I appreciate it.

Dr. Zimmer-Galler, telehealth obviously is marked as a suitable alternative to in-person care for those in all communities. My question would be relative to rural communities. How might the lack of access to high-speed internet affect this alternative, and what would you suggest that we on this Committee or Congress work on relative to that?

Dr. ZIMMER-GALLER. So thank you. That is an excellent question.

Absolutely—

Mr. CHABOT. All my questions are excellent, by the way. Just kidding.

Dr. ZIMMER-GALLER. Absolutely. Access to broadband is something that for many types of telehealth services is required. But I would also venture to say that there are few geographies left in the world where there is not access to broadband. Perhaps one of the bigger challenges that comes is in communities in disparate communities where there is perhaps access to broadband but the patient does not necessarily have the means. They may have a cellphone but they do not have the means to have data coverage

with that cellphone. So we do have to be careful that we do not introduce disparity by bringing telehealth in.

But remember, a lot of telehealth can also be done with very low broadband requirements. When we are simply sharing data, that takes much less broadband, much less width than if you are trying to do a video visit. So it certainly does not always have to have a video visit.

In terms of providing care, being able to actually see the patient and see how they look, interact with them, yes, a video visit adds a tremendous amount of information but it is not always necessary to get very good telehealth opportunities.

Mr. CHABOT. Thank you very much.

My time has expired, Madam Chair.

Chairwoman VELAZQUEZ. His time has expired.

Now we recognize the gentleman from Pennsylvania, Mr. Evans, Vice Chair of the Committee.

Mr. EVANS. Thank you, Madam Chair.

Dr. Zimmer-Galler, I still would like to follow up on what was just said. Would telehealth and telemedicine help address physician shortages and healthcare disparities among the disadvantaged populations?

Dr. ZIMMER-GALLER. Absolutely. For example, one of the things that one of the programs that we have at Hopkins is to provide pediatric specialty care to the Eastern Shore of Maryland where there is very little access to any type of specialty care. And these are communities that have relatively few means and ability to even bring children to a tertiary center. Many of these families are single parent families, and for them to take time off of work to bring a child to Baltimore or to a large center where you have specialists, such as pediatric rheumatology or pediatric endocrinology, that obviously can be a huge burden. But working with county health departments, these children can come to a facility where they can actually then have a facilitated video visit with a specialist and then we can provide that care with really the family needing to have relatively few additional things other than to bring the child to the health department.

Mr. EVANS. Unfortunately, Pennsylvania is one of only a handful of states that have been unable to pass legislation to require insurance companies to reimburse telemedicine services at the same rate as in-person services. There is currently a bill in the Pennsylvania Senate which seems to have large opposition of the industry. Can you, Doctor, again, in your testimony, you stated a major barrier to telehealth adoption is the lack of consistent reimbursement of virtual care. Can you describe the challenges healthcare professionals face when getting reimbursed from insurance companies for telehealth or telemedicine services?

Dr. ZIMMER-GALLER. Yes. Thank you.

So there are certainly many states that have not yet passed parity laws, parity regulation that requires that payers will cover for telehealth services. But it is not only the coverage, it is the amount that is reimbursed that is also an issue. So it is definitely one of the barriers. It is difficult for us to ask providers to do things if there is no reimbursement, obviously. And with telehealth, even with relatively simple telemedicine programs there is certainly

some cost associated with that. And so it does become a huge challenge. You know, where there is no money, there is no mission. So unfortunately, reimbursement is a problem, not just from commercial payers but also from our Federal and state for Medicare and Medicaid.

Mr. EVANS. Have any of the other panelists run into a similar problem?

None have run into a similar problem as just described? Have you, Dr. Conti?

Dr. CONTI. At the Hospital for Special Surgery, I work with many attendings, and so I have a chance to see the schedule of many different orthopaedic surgery attendings. And I would say that time and physician burnout is a very significant problem in medicine right now. And so to finish up your clinic day or your OR day and then to see patients at the end of that day for 15 or 20 minutes for each patient via a telehealth medicine visit and then to not be reimbursed for that would be, I think, very difficult for many of the attendings who I have worked with.

Mr. EVANS. I thank you, and I yield back the balance of my time, Madam Chair.

Chairwoman VELAZQUEZ. The gentleman yields back.

Now we recognize the Ranking Member of the Subcommittee on Economic Growth, Tax, and Capital Access from Oklahoma, Mr. Hern.

Mr. HERN. Thank you, Madam Chairwoman, Ranking Member Chabot, and our witnesses for being here today to discuss this very important topic.

As a member who represents a rural state, I appreciate the hearing on the anticipated shortage of doctors and to discuss on how to prepare to overcome this worrisome trend.

However, I will tell you that I find it a little bit troubling that some of my colleagues claim to support innovation and also, you know, against this shortage, but also supporting Obamacare which according to the Nonprofit Tax Foundation, in 2013, took \$35 million out of innovation. Between 2013 and 2015, took 22,000 out of innovative areas and the medicine field. And given that one of the pillars of Obamacare funding is the Medical Device Tax, which stifles innovation, is critical to support of Obamacare and to also claim that you support innovation. I find it interesting. We have a lot of those kind of things happen in Washington, D.C.

I am hopeful that my colleagues across the aisle can realize this and take actions to start advocating for policies that will actually help spur innovation as you all describe how important that is to the future of health care.

That said, the Trump administration recently released a report that shed some light on this topic titled "Reforming America's Healthcare System through Choice and Competition." One major conclusion that came from the report was that reduced competition among clinicians leads to higher prices for health care and reduce choice. Specifically, the report states that "scope of practice restrictions limit provider entry and ability to practice, and when this happens, these undue restrictions are likely to reduce healthcare competition and harm consumers."

The report also points out that advanced practice registered nurses, physician assistants, pharmacists, optometrists, and other highly-trained professionals can safely and effectively provide some of the healthcare services as medical doctors.

This is something I would like to ask each of you. I will start with Mr. Hopkins.

Do each of you think that at least some of our doctor shortage problems, and it is going to continue to grow based on a meeting I just had this morning, might be effectively addressed by assuring that all of our licensed providers operate at the top of their education and training?

Mr. HOPKINS. I see not only a shortage in physicians but also a shortage in the nursing practice. But to answer your question, I believe that a physician should be working up to their capabilities to meet the requirements.

Mr. HERN. Dr. Fahrenwald?

Ms. FAHRENWALD. Yes, thank you for your question.

All healthcare professions should be practicing at their full scope of practice authority. In the best interest of Americans is that the providers of their care are able to perform the care, and much of that care can be reimbursed by the Federal Government and safe. For example, CMS regulations allow for billing for some wellness visits in older adults. Those visits can be handled by a registered nurse in a primary care setting. They do not have to be a physician. Our colleagues practicing at the full scope are able to manage the complex pyramid of care where the most complex patients need to be managed by our physician colleagues. The day-to-day primary care that most of us need can be managed by many of these other healthcare providers as you have mentioned, including advanced practice registered nurses. But certainly, the role of all healthcare providers working together as a team in addressing our healthcare needs in this country is important.

Mr. HERN. Thank you.

Dr. Zimmer-Galler?

Dr. ZIMMER-GALLER. Thank you.

When it comes to telemedicine, there are actually a number of restrictions in place on the state level and the Federal level in terms of which type of licensed providers can actually provide telemedicine services. So there are regulations that prohibit, if you will, some licensed providers from practicing at the top of their level if you pull telemedicine into the picture because the regulations actually do not allow certain providers to provide care by telemedicine.

I would like to also add just a quick comment on the shortage of healthcare professionals, that we do need to start looking at how to tie technology into this, for example, with artificial intelligence. The FDA last year cleared the first autonomous AI device in the U.S. and it was actually for identification of diabetic retinopathy referable disease using AI. And so here we are taking a huge public health problem, screening patients with diabetes for diabetic retinopathy. If we were to actually screen every patient in person, we do not have the healthcare personnel to do that. If you tie AI into this, you can actually alleviate a lot of that public health problem with lack of providers.

Mr. HERN. Thank you.

Dr. Conti, I would love to have gotten your thoughts on this but Madam Chair, I yield back.

Chairwoman VELAZQUEZ. The gentleman yields back.

Now we recognize the gentleman from Minnesota, Mr. Hagedorn, for 5 minutes.

Mr. HAGEDORN. Thank you, Madam Chair. I appreciate the opportunity. It is nice to see the witnesses here. Thank you for your testimony.

I am just going to add a little bit to Congressman Hern, what he said about regulations. The doctors and technicians and others that I talk to, nurses, will say that increased costs in the medical field are maybe 35 percent higher because of needless regulations. AMA came out and said maybe 25 percent. So I think we should be focusing on some of the things that government does in these areas in order to drive up costs that just should not be borne at all. So I think we could eliminate a lot of the problems right there with some common sense.

I would also like to talk about another aspect of this. If we are worried about doctor shortages and we are worried about providing health care in rural parts of the country, I represent Southern Minnesota, a very rural district. It includes the preeminent institution of medicine in all the world, the Mayo Clinic; right? A great spot. Also, some terrific rural hospitals. The New Ulm Medical Center was voted the number one rural critical access hospital in the whole country. So we have some good things.

But if anyone thinks that we move toward more government reimbursement, Medicare for all, single payer, things of this nature and you think that these hospitals and the models are going to survive, they will not. The Mayo Clinic is going to be harmed, as are the rural hospitals. And almost everyone I talked to in the rural hospitals will say you are going to have massive consolidation. They are just going to disappear completely and you are going to have people in rural areas having to travel 50, 75 miles, maybe more in some cases, just to get care. So that is just going to exacerbate the problem because there is no way you can convert all this, have massive government reimbursement, and think the reimbursements are going to go up or stay the same. They are going down. And everybody knows that. I think we should just, you know, that is a bigger problem than some of the things that we are talking about today.

Dr. Zimmer-Galler, I was touched by what you said about ALS patients. I happen to have a friend who went through that and I can attest that when you take someone to the doctor, and sometimes those things could be done at home, it is way better for someone, for instance, for ALS. As much as you try to care for someone, there are accidents. People fall. They end up going to the doctor and having to be dealt with with a broken arm or a deep bruise or something like that which is going to take a long, long time to heal, if ever. Whereas, if somebody could do the telemedicine or have even a home healthcare provider be out there to do tests, fit them for braces, things like that, that would be a much better deal.

So obviously, the broadband is a big deal. Regulations in these areas. What specifically do you think the Federal Government should be doing today in order to move that alone?

Dr. ZIMMER-GALLER. So with the ALS example, that program, actually, most of those patients are self-pay patients because Medicare, for example, does not reimburse, in most instances, for a few specific diseases they do, but in most instances Medicare does not reimburse for telehealth visits, video visits from home.

So the restrictions on not just geographic areas but actually the site where the patient is located, the restrictions on where telehealth services are covered, those are areas where I think we really could work to alleviate some of the regulatory burden and allow more people to have access to new ways of having healthcare delivered that are much easier for many of these, especially the chronically ill patients.

Mr. HAGEDORN. Thank you.

And sometime I think people get a little backwards. They think as far as rural areas, the reimbursement should be lower because it costs less to live there and all those things. But actually, the reimbursement should be higher. It should be higher because a lot of people have to travel distances, especially in home healthcare and things like that. It should be higher because it is sometimes tougher to attract talent to live in rural communities when they have opportunities to be paid even more money in the urban areas. Does anybody have a thought about that? It is just the opposite of what people think. We should actually be having much higher reimbursements in rural areas than we do in the urban areas. Anyone?

All right. We will leave it—

Dr. ZIMMER-GALLER. I will speak. Congressman, I will answer that question.

I cannot speak to higher but I can say that rural health clinics, nurse practitioner-owned rural health clinics are reimbursed at parity and that is a good thing. I recently visited a rural health clinic in Texas. A nurse-managed clinic in a very small rural town where patients are driving to these visits on their lawnmowers or on their horse.

Mr. HAGEDORN. Interesting.

Dr. ZIMMER-GALLER. The care that is offered there is life-saving care that provides access for the people in that area where they have not had access for 100 years.

Mr. HAGEDORN. How about that? Thank you. I appreciate that. I yield back.

Chairwoman VELÁZQUEZ. The gentleman yields back.

Now we recognize the gentleman from Minnesota, Mr. Stauber, Ranking Member of the Subcommittee on Contracting and Infrastructure for 5 minutes.

Mr. STAUBER. Thank you, Madam Chair. And I appreciate this opportunity to have a conversation.

Thanks to the witnesses. It is difficult from my angle to see the names, but I will just say, Mr. Hopkins, you identified yourself as a nurse. Can you tell me, in your profession, approximately what percentage of the time are you filling out paperwork that has been put before you due to regulations?

Mr. HOPKINS. At the hospital I currently work at and formerly worked at we had EPIC, which was a computer, electronic computer charting system. It does take a fair amount of time.

Mr. STAUBER. Can you just give me a percentage when you say a fair amount of time?

Mr. HOPKINS. Working in the emergency department I would probably say 20 percent of the time.

Mr. STAUBER. Do you think that the rules and regulations that are put upon our entire health care can be part of the problem?

Mr. HOPKINS. Yes. We do have a lot of kind of checks and balances that we need to do when we are checking the patients in. Certain questions that really do not have to do with what is going on with the patient.

Mr. STAUBER. Yes. So you as a healthcare professional could probably put the pertinent questions that need to be put forth to the patient; would that be correct?

Mr. HOPKINS. Correct.

Mr. STAUBER. Thank you.

I do want to talk about, so I represent Minnesota's 8th Congressional District. It is a rural district. It goes all the way up to the border of Canada. And my colleague, Mr. Hagedorn talked about the rural component of health care. We need to stay competitive and we need our healthcare clinics and hospitals to stay open.

One of the things that we have talked about is telemedicine and telehealth. And one of you mentioned that broadband is pretty much across the country. In my mind that cannot be further from the truth. There are at least 26 million Americans that do not have that. So I think the ability to take that technology and make us competitive, deploy rural broadband that is dependable and high speed is critically important for rural America.

And I will give you an example. If you are in Grand Marais, Minnesota, which is from close to the Canadian border, if you have one sheriff deputy in that whole country and there is a mental health crisis, an individual is going to harm himself or others or a danger to himself or others, they have to drive 160-some miles to Duluth, Minnesota, to get care when they leave their county without any law enforcement protection. So the ability to have that telemedicine, that telehealth, that rural broadband so the doctor in Duluth, Minnesota can see that patient in Grand Marais rather than taking all that time, there is a whole slew of things that can be helped with telemedicine and rural broadband. And I think it would probably be safe to say that that doctor would probably want to physically see on the screen the patient to see how he or she is acting and responsive to the questions.

So that is just one example that we are getting that happens every day in rural America. And through your profession, you can help guide that and give us that technology into rural America. And I think there are rural members on this Committee, Small Business Committee that understand that we need to make sure that our rural hospitals are competitive. We need good quality healthcare professionals in rural America. And this is one of the ways that we can do it. And we can talk about billing with Medicare and Medicaid, and I think it is important. That is a good discussion to have because as the young doctor said, they should be

reimbursed after a long day if they are going to do some telemedicine or some telehealth. I think for me I just appreciate the conversation about the technologies out there. Let's use it. Let's have the opportunity to move the health care forward in an affordable way and make that health care personable.

In rural Minnesota, we have elderly people that have to come out in the cold to go see their doctor and they could just as well do it via telehealth and telemedicine. It would be easier on the patient and the family members that have to take time off or relatives to drive them.

So Madam Chair, I was opining on some of my opinions, and I appreciate that I used my 5 minutes up. I appreciate your professionalism and your coming here and giving us your testimony from your worldly experience. And to the young doctor, I wish you nothing but the best.

Thank you, Madam Chair.

Chairwoman VELAZQUEZ. The gentleman yields back.

Now we recognize the Chairwoman of the Subcommittee on Rural Development, Agriculture, Trade, and Entrepreneurship from Iowa, Ms. Finkenauer.

Ms. FINKENAUER. Thank you, Madam Chair.

And thank you so much to all the folks who came here to testify today and bring your expertise. I know it takes a lot to get here.

So I represent Northeast Iowa. I have 20 counties in my congressional district. Seventeen of my 20 counties are very rural. And so one thing that we have been hearing a lot about is are facilities struggling to recruit enough providers. This is obviously especially challenging in Iowa, not just because of the location issues for some folks but also because we have some of the lowest Medicare reimbursement rates in the country which is something that we have been working on a lot to address and fix. And actually, just a couple weeks ago I found out that a clinic in Waukon, Iowa, up in the Great North I like to call it in my district, will be closing its doors next month. Their main issue, they cannot find the doctors. They have one doctor right now and cannot find enough providers to staff the clinic. And back in September, also not that long ago, just a few months ago, we heard a hospital in Marshall County has closed their OB/GYN unit making it actually the 34th hospital in Iowa to stop delivering babies and offering comprehensive care to new moms since the year 2000.

The shortage of healthcare providers has long been a factor in these closures, and at the Federal level, I know we need to take a multi-pronged approach to address these workforce shortages. We need to recruit more doctors, obviously, in our rural areas, and in the meantime, we need to make sure that the medical practices in rural areas can keep serving patients with the number of providers they already have. I am especially concerned right now about the access to health care for our new moms, especially, again, given the stat I just gave you all. Women in general need weekly appointments towards the end of their pregnancy, and this can be hard on women who live in rural areas and may be forced to drive an hour each way to their appointments.

When it comes to maternal health care, I know that telehealth is one way to improve access. I helped introduce, actually, the bi-

partisan Rural MOMS Act which would put great funding toward telehealth projects that will expand access to maternal healthcare services. And then, you know, this was one of the things that I started talking about when I have been out there around the district, and recently, just a few weeks ago, I was visiting a hospital in Grinnell and started talking to the nurses in the OB/GYN unit and asking them what they thought. And you know, if they had any ideas about what we should be looking at. And actually, one of the nurses just flat out said a dream that she would have is that there would be some mobile unit that could go out there and actually either stop at a worksite where there is moms who had just recently given birth who are back at work quite frankly too soon, or moms who are getting ready to have birth as well, making sure that they are getting the care that they need, or just getting out there, again, to folks who just cannot make it in because they do not have the transportation. You name it. There is a number of issues here.

So that was one idea that she had. And I thought it was actually quite a good idea. And I know Dr. Zimmer-Galler, you work a lot on these issues, especially with the new technologies and with telehealth. Do you have any ideas and ways to expand services to our rural healthcare facilities, especially some of these smaller practices? And then do you have any ideas, too, any of the panel, about what new technologies could do and things that we should be looking at to really, you know, make sure we are doing everything we can here and actually, listening to the people on the ground who are living it every day?

Dr. ZIMMER-GALLER. So one aspect that we have not really talked about with telemedicine that can be very helpful for rural areas to attract and to retain providers that are there is using telemedicine to alleviate some of the feeling of isolation that providers have. When you are the only person there and you are taking care of pretty much everything that walks in the door, obviously, that can be something that is a daunting task. If you know that there is always someone that you can reach out to if you have a network in place, that you can reach out to a specialist or to another provider and you are able to call on them, not only does that help you take care of that patient but it also helps to allow for education that maybe the next time that provider will better be able to deal with that same problem. And again, it takes away a lot of that very scary sense of isolation if you are the only provider for hours' drive around. So I think that is an area where we really need to think of telehealth as well to support physicians or providers from that standpoint.

Ms. FINKENAUER. Does anybody else have any—

Mr. HOPKINS. Yes. I think when it comes to creating medical devices, with nursing shortages, physician shortages, you need to create devices that are going to allow clinicians to work smarter with less opportunity for error. So just as I spoke about the Diversion syringe that we have, the technology, being able to eliminate one and a half million false positive blood cultures and saving the U.S. healthcare system \$3 billion, just the government side of it, having those funds to reallocate and put into other innovations that are coming from the bedside would be very helpful.

Ms. FINKENAUER. Well, thank you all again for being here. I really appreciate it.

And with that, my time has expired.

Chairwoman VELAZQUEZ. Her time has expired.

Now we recognize Dr. Joyce from Pennsylvania, Ranking Member of the Subcommittee on Rural Development, Agriculture, Trade, and Entrepreneurship for 5 minutes.

Mr. JOYCE. Thank you, Madam Chair.

And thank you to our expert witnesses from leaving your practices, your training, and coming here.

I represent south central Pennsylvania, Pennsylvania 13, which is a 10-county region that starts in the east in Adams County where Gettysburg is, you can identify it by that, and travels to the west to where Flight 93 went down. Until December of last year I was a practicing physician. I trained at Johns Hopkins Hospital. I did internal medicine followed by a specialty program in dermatology where I completed as chief resident.

I listened with great interest of the issues that you bring because those are issues that allowed me to step up and run for the United States Congress. The number one issue in south central Pennsylvania that I ran on was health care. And that continues to be an issue today.

In the first days of being a member of the United States House of Representatives, I started the Homegrown Healthcare Initiative, addressing issues that you and I both realize are incredibly concerning. In Pennsylvania, we have 11 medical schools, and yet, in south central Pennsylvania there are none. And there is a paucity of medical students in the medical facilities. So with one of the medical schools we have partnered and have started a Homegrown Healthcare Initiative where students who are from these communities can rotate in their third and fourth years, in their clinical years, and be part of the communities where often they were born, where their parents or siblings work, where they can return to the roots and establish medical connections. And we know, Dr. Conti, as you pointed out, that in your training you often stay in those areas. Your number was within a 100-mile radius of where you do your residency you see those residents stay. We need to allow those students to return to south central Pennsylvania and reconnect with the communities where they grow. And there are ways that the Homegrown Healthcare Initiative can be enhanced by the telemedicine Dr. Zimmer-Galler that you talk about. I think it is so important that those lines of education are not only opened but expanded, where individuals who are training in rural settings as medical students and as physicians and fellows can connect with the experts at places like Johns Hopkins or at HSS, at these top learning institutions which quite honestly I had the privilege to train at. And unless we encourage this to occur, we are going to see a continued decreased number of physicians in the rural areas that Representative Finkenauer just mentioned, that we all face in our areas.

So my first question is for you, Dr. Zimmer-Galler, to address, please, how the innovations of telemedicine, and I as a board certified dermatologist and a board certified internist realize how important that is. But in ophthalmology, you talked about the ability

to diagnose diabetic retinopathy which is certainly a big issue leading to blindness in the patients with diabetes. Talk to me, please, how we can open those dialogues of training in telemedicine with people in rural areas who are training to take care of the underserved?

Dr. ZIMMER-GALLER. Thank you.

So yes, that is certainly a huge challenge. And again, you know, everything kind of comes back full circle. The barriers are still, I think everybody recognizes the potential, what we can do, the good we can do with using telehealth. The problem in getting it to have more widespread adoption really, the root of that is the regulatory burden. The reimbursement issue, the licensure issues. Those are actually really the hardest, the biggest problems.

The medical students, the residents that are in training today, they are very much into all of the technology, obviously, and I think we are starting to see more training that comes through medical schools and residencies where our physicians in training are exposed to telemedicine and how it can be used. But we need to do a much better job of actually then taking that and bringing that back to the rural communities.

Mr. JOYCE. Thank you very much.

Dr. Conti, you are closest to having been in medical school most recently. Was telemedicine part of your medical education as a medical student?

Dr. CONTI. Where I went to medical school we did not do any telemedicine training. I went to medical school in New York City, at Cornell, so it is a large metropolitan area. There are not very many rural communities where I went to medical school.

Mr. JOYCE. Were there patients who did not have access to be at Cornell that might have benefited from telemedicine?

Dr. CONTI. I think so. I think that we on the Upper East Side, there are a large number of older patients who even going just a few blocks back and forth from the hospital can be a real burden to those patients.

Mr. JOYCE. And if I might interrupt—

Dr. CONTI. Sure.

Mr. JOYCE.—because I want to continue this line. During your residency training—you are PGY-4; correct?

Dr. CONTI. Yes.

Mr. JOYCE. And is there an opportunity to see and evaluate patients via telemedicine for you as a resident?

Dr. CONTI. We do not see and evaluate patients via telemedicine with any of the subspecialties that we rotate through. And I think part of that is because we have patients from all over. And because of the regulatory burden, people have decided not to, because a lot of our patients are from Connecticut and New Jersey, people have decided not to engage in telemedicine.

Mr. JOYCE. Thank you for those concise answers.

I think this is an important part of our journey in the Small Business Committee to realize that this is an avenue that clearly needs to be expanded, and we should be working together, bipartisan as we do here, working for our patients and working with the physicians.

Thank you again to our expert witnesses.

Chairwoman VELÁZQUEZ. Thank you, Dr. Joyce.

Thank you all for being here today. I know that you might think telehealth is to cover for your work that you need to do while you are absent from your practices. Thank you so much for being here and for the wealth of information that you have provided.

It is apparent that the pace of change in medicine is rapid and that those changes have the potential to increase access to health care while reducing costs. Whether it be the concentration of health services, lack of access for rural America, or the impeding doctor shortage, technology can solve many of the issues within our health care system. For that to happen, training programs are needed in telehealth and a curriculum must be incorporated to train the next generation of health providers.

I look forward to working with my colleagues on both sides of the aisle to address these workforce challenges in the health care industry, and we are going to be looking into reimbursement, and regulations.

Mr. JOYCE. Licensure.

Chairwoman VELÁZQUEZ. Regulations.

I would ask unanimous consent that Members have 5 legislative days to submit statements and supporting materials for the record.

Without objection, so ordered.

This hearing stands adjourned. Thank you.

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

[Dr. Ingrid Zimmer-Galler and Mr. Michael Hopkins did not submit their responses to questions from Hon. Troy Balderson in a timely manner.]

APPENDIX



U.S. House of Representatives
Committee on Small Business

"Upskilling the Medical Workforce: Opportunities in Health Innovation"
November 13, 2019

Testimony of Matthew Conti, M.D.

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc

Chairwoman Velazquez, Ranking Member Chabot, and members of the Committee, thank you for the opportunity to testify before the House Committee on Small Business. I offer this testimony on behalf of the American Association of Orthopaedic Surgeons (AAOS), which represents 18,000 orthopaedic surgeons and 5,000 orthopaedic residents nationwide, as well as musculoskeletal patients. I am honored to share my perspective on the role innovation plays in the field of medical education, as well as my current experience as an orthopaedic resident at one of the top surgical hospitals in the country.

I would also like to thank the Chairwoman, Ranking Member, and members of the Committee for your continued focus on issues of importance to physicians this Congress. Past hearings on prior authorization, student loan debt, and challenges to private practices have drawn great attention to some of the issues negatively impacting patient care, especially in areas where patient choice and access is decreased. These truly are small business issues, and we are grateful that this Committee is continuing to examine them with your specialized expertise.

I am currently serving as a PGY-4 orthopaedic surgery resident at the Hospital for Special Surgery (HSS) in New York, NY. As a resident at HSS, I have been able to further my surgical training as well as to continue research on clinical outcomes. I received the Orthopaedic Research and Education Foundation (OREF) and the HSS Surgeon-in-Chief grants for a project focusing on adolescent idiopathic flatfoot deformity. I am an active member of the American Orthopaedic Foot and Ankle Society (AOFAS) Young Physicians Committee. I am also the founder of Our Hearts to Your Soles, a non-profit organization that has provided free shoes and footcare to more than 40,000 homeless men and women across the United States for the past 15 years.

Growing up with a father who is an orthopaedic surgeon, I developed an interest in his practice at a young age. I wanted to pursue a career in a field in which I could help others, and I thought the best way to do that would be through a career in medicine. In medical school at Weill Cornell Medical College in New York City, I spent time performing clinical research with my mentors at HSS, Dr. Jonathan Deland and Dr. Scott Ellis, who encouraged me to pursue orthopaedics. The opportunity to significantly improve and preserve a patient's quality of life motivated me to apply for a residency position in the field of orthopaedic surgery.

The Role of Surgical Simulation in Resident Education

HSS is a unique and special place for residency training. As the top nationally ranked hospital for orthopaedic surgery (for the 10th consecutive year)¹, residents at HSS have access to a range of new technology, innovative techniques, and experiences that those at smaller or more rural institutions may not have as a part of their graduate medical education (GME) curriculum. I am very fortunate to be able to train in such a unique environment.

As we discuss technology and innovation, surgical simulation quickly rises to the top of the list in terms of its importance and ability to effectively teach residents the skills needed to become successful surgeons. Whether it be through high-tech simulation tools or through cadaveric specimens, the surgical simulation work I've done inside the HSS lab has been one of the most valuable learning experiences I have had during my residency.

Surgical simulation has become so increasingly important to GME, that in 2013 the American Board of Orthopaedic Surgery (ABOS) and the Accreditation Council for Graduate Medical Education (ACGME) Residency Review Committee (RRC) for Orthopaedic Surgery implemented simulation and motor skills requirements for resident education.

Bioskills labs provide residents with the ability to simulate surgical procedures, familiarize themselves with surgical equipment and instrumentation, and learn new or innovative techniques that will enhance their ability to treat patients. At HSS, residents like myself have access to the Bioskills Education Laboratory (BSEL) which allows for exposure to and additional training on some of the top technologies in orthopaedics. Studies show that the skills learned during lab simulations transfer successfully to the OR, citing that residents trained with the simulator to perform an arthroscopic knee performed significantly better in key measurement categories than those trained with traditional surgical instruction.² However, labs of this nature come at a huge expense to the hosting institution, often containing millions of dollars' worth of surgical equipment, instrumentation and technology. Less well-funded labs also have decreased access to cadaveric specimens, making it more challenging for residents to utilize them as a surgical simulation tool.

Virtual reality (VR) technology is another tool being used with increasing frequency and with increasing success for surgical simulation in GME. In one study of general surgery residents, trainees who were randomized to participate in VR training were 58 percent faster and had

¹ Hospital for Special Surgery. HSS Nationally Ranked No. 1 in Orthopedics by U.S. News & World Report for Tenth Consecutive Year, Hospital for Special Surgery, 30 July 2019, <https://news.hss.edu/hss-nationally-ranked-no-1-in-orthopedics-by-usnews-world-report-for-tenth-consecutive-year/>.

² Cannon, W. Dilworth, MD, et al. "Improving Residency Training in Arthroscopic Knee Surgery: JBJS." The Journal of Bone and Joint Surgery, Bone and Joint Journal, Nov. 2015.

three times fewer errors in their first attempt at performing laparoscopic cystectomies.³ New advances in this technology allow for both visual and haptic (touch) feedback recreating the feel of an actual surgery. However, significant improvements in haptic feedback are necessary in order to make VR technology more closely mirror true OR experiences.

In the field of orthopaedics, simulation has been particularly successful when used to recreate arthroscopy and minimally invasive surgery, two of the most modern surgical techniques residents are learning. Simulation can be done repeatedly, on-demand, and without patient risk – potentially lowering complication rates and costs to the health care system in the long run. Additionally, technology in VR has advanced significantly, now providing tactile feedback to the operator which enables the resident to develop a touch for the surgery that previously couldn't be learned without a live patient or a cadaver. The aim of all simulation tools is that residents are able to train and reach an acceptable level of proficiency before they perform surgery on real patients.

Personally, the Bioskills Education Laboratory has provided me with numerous opportunities to advance my surgical skills in a safe setting. Time spent working with cadaveric specimens has allowed me to try new surgical techniques that can then be applied in the operating room to improve patient care. I have also found the arthroscopic surgical simulator useful to learn how to adjust my hands in space. In arthroscopic surgery, the arthroscope, or camera, is placed inside the joint. In order to effectively use an instrument such as a shaver in the other hand, a surgeon must learn to triangulate his or her hands so that the camera and instrument can be adjusted while inside a joint. This had led to greater efficiency as a resident in the OR. I find that my time in the OR with attending surgeons is more useful because I have already learned basic skills and am ready to learn more advanced techniques.

The Role of Medical Specialty Societies

Facilities and programs like that at HSS, are able to provide students with increased opportunity to utilize these technologies. But as mentioned above, students in GME at smaller or more rural institutions may not have access to the same simulation and VR techniques. That being said, simulation does not need to be overly expensive or complex to be effective. The utilization of sawbone exercise or even modeling suturing techniques on pigs' feet can be a simple opportunity to engage through surgical simulation. Companies have now begun offering

³ Grantcharov TP, et al. "Randomized Clinical Trial of Virtual Reality Simulation for Laparoscopic Skills Training." NCBI, British Journal of Surgery Society Ltd. Published by John Wiley & Sons, Ltd., Feb. 2004, <https://www.ncbi.nlm.nih.gov/pubmed/14760660>.

simulation technologies for an annual fee plus hourly usage and annual maintenance fees. This approach allows for institutions to receive the latest technology upgrades each year while greatly reducing their share of the hardware costs. Surgical simulation courses or labs presented through a resident's medical specialty society are often offered at a reduced cost to those in GME and can provide a similar experience to the courses offered in bioskills labs at larger academic institutions.

AAOS has worked in collaboration with the American Board of Orthopaedic Surgery (ABOS) and orthopaedic subspecialty organizations like the Arthroscopy Association of North America (AANA) to develop programs like the Fundamentals of Arthroscopic Surgery Training (FAST) program to teach residents arthroscopic surgical techniques in a cost-effective, clinically based, and hands-on way. The goal of the program is to eventually develop an accessible system of teaching tools that enables residents to practice arthroscopic surgery skills at home, with more expensive simulation devices available at the residency program and hospital levels, and ultimately, state-of-the-art and highly sophisticated VR equipment at regional centers where skills testing is performed.⁴ My hospital even requires residents to attend an arthroscopic surgical skills course prior to graduation. Additionally, partnerships like that of AAOS and the Orthopaedic Trauma Association (OTA) continue to task simulation teams with the development of new, cost-effective simulation tools to be used at institutions that may not have access to the newest technologies. Hopeful outcomes of these simulation development teams include the identification of subsets of procedures that can be effectively simulated in the academic setting as well as simulation "toolkits" which can be implemented by teaching institutions at a number of levels.

Medical specialty societies like AAOS also offer residents and fellows a variety of virtual resources that further their advancement of specific procedures and techniques. AAOS frequently hosts webinars, specifically targeting residents and also offers its members a full library of virtual training materials through the AAOS Orthopaedic Video Theater (OVT). This library of videos allows resident members to view high-quality, peer-reviewed educational video content which demonstrates the latest surgical techniques and procedures in an on-demand fashion that can be accessed anywhere. Virtual resources like this can be used to augment simulation, although they are not a standalone substitute or alternative.

Rural Access and Telehealth

Rural access to specialty care is becoming an increasing challenge for patients across the country. While telehealth has opened doors in many specialties, allowing patients in rural areas

⁴ Leahy, Maureen. "Using Simulation, Metrics to Improve Orthopaedic Surgical Skills." Submit Form, AAOSNow, Dec. 2012, <https://www5.aaos.org/aaosnow/2012/feb/clinical/clinical9/>.

with limited medical professionals to access needed medical care, there is still much to be done in the field of orthopaedics.

Traveling to orthopaedic appointments can present significant challenges for patients that telehealth can help alleviate. Telehealth in orthopaedics can range from routine postoperative care for patients to remote viewing of a patient's injuries and radiographs. By allocating resources to regions with specialist shortages, Congress can help alleviate the costs for both providers and patients.

AAOS supports efforts to ensure rural providers have the resources and tools necessary to provide quality care via groundbreaking technologies and methods. Continued innovation through new technologies represents the best approach to expanding the health care workforce into underserved areas. Unfortunately, the Rural Healthcare Program's funding is capped at \$400 million annually. The convergence of limited rural access to specialists, the overall challenges of rural healthcare (especially for seniors), and the aging population presents an even greater need to fund and utilize innovative new telehealth tools. As more and more federal programs create avenues for virtual participation (such as the Merit-based Incentive Payment Systems' new "virtual groups"), greater investment in the technological infrastructure to participate in these programs can help increase quality patient care and reduce costs.

When it comes to residents, statistics show that students typically go on to practice full-time in the location of their residency. For example, one study found that more than half of physicians who complete their residency in family medicine practice within 100 miles of where they trained.⁵ Therefore, it is essential that residency programs in rural areas have adequate resources and funding to continue to maintain their GME slots and can continue to attract and retain residents to their programs.

As I apply for fellowship, I have found that many orthopaedic residents already have signed their first job contract before finishing residency. These residents typically sign contracts either in their hometown or at the institution where they did their residency. Providing residency programs in rural areas with funding and access to innovative technology will allow them to recruit high-level medical students to be residents who may ultimately stay to practice in that location.

The Physician Workforce Shortage

⁵ E. Blake Fagan et al., "Migration After Family Medicine Residency: 56% of Graduates Practices Within 100 Miles of Training," *American Family Physician*, vol. 88, no. 10 (November 15, 2013), p. 704.

The U.S. federal government invests significant funding into GME providing hospitals who choose to sponsor residency programs with funding to cover some of the costs of resident's salaries, as well as the costs of extra medical tests that residents may order as a part of their training. These costs account for almost two-thirds of spending by the Department of Health and Human Services (HHS) on health workforce⁶.

The Medicare program provides financial support to medical training slots (residencies) in two ways: direct graduate medical education (DGME) payments to hospitals to cover costs directly related to educating residents, and indirect medical education (IME) payments to cover the higher costs of teaching hospitals. The number of residency slots that count towards DGME and IME payments were capped in 1997, even though medical schools have increased the number of doctors they are training to meet the demand of caring for a growing elderly population. In fact, over the past decade, undergraduate medical education has expanded nationwide by more than 30 percent, greatly outpacing the growth in residency slots. We are now facing a tipping point where some U.S.-trained medical school graduates may not have a first-year residency position available to them in the United States.

The health and welfare of patients is linked to the knowledge and skills physicians develop during their medical residencies. As we talk about innovation and technology in GME, there is a fundamental limit to the amount of advancement that can occur if medical school graduates are not able to find placement in a residency position. Funding for GME spots has been capped to control costs since 1997, forcing hospitals and states to find creative ways to fund their residency programs, and the technological investment that advances their students' opportunities. As a result of these trends, it is becoming more difficult for teaching hospitals to cover their costs and invest in new technology for program participants.

AAOS supports at a minimum maintaining current funding levels for GME, which are necessary to ensure future stability and access to a strong, diverse health care workforce. AAOS also supports the following GME principles:

- GME training should be expanded in ambulatory and community sites to reflect the current and evolving practice of medicine;
- A portion of the financial support for GME training in community and ambulatory settings should be distributed to the educational sites or programs where the training occurs;

⁶ U.S. Government Accountability Office (GAO), Health Care Workforce: Comprehensive Planning by HHS Needed to Meet National Needs, 16-17, December 11, 2015, <http://www.gao.gov/products/GAO-16-17>; hereinafter, GAO Health Workforce Planning Report.

- There should be greater accountability and transparency for Indirect Medical Expenditures in order to achieve national health care aims and objectives. Reevaluation of the funding process of GME is necessary to ensure equity, proper distribution of specialties, location, and geographical distribution of residents;
- GME funding for the Teaching Health Centers (THC) and Children's Hospitals should be stabilized with dedicated ongoing funding;
- New curriculum is needed to address health care delivery system change and patient and population-centered GME;
- There should be a further national effort to coordinate and engage underrepresented minority students in health care professions and medical careers. Public support for GME should be leveraged to encourage physician specialists to locate in otherwise underserved regions and communities.

As a current resident, I recognize the extreme importance of funding these slots to ensure a viable health care workforce in the years to come. While we can continue to discuss the importance of innovation and technology in GME, funding these slots is an essential component that allows the practice of medicine to evolve and new, young physicians to learn in a supervised environment where they can learn from leaders in the field of medicine.

Student Loan Debt

I would be remiss in my testimony if I did not mention the incredible burden that student medical loan debt places on medical students and their families today. The average medical student graduates with approximately \$200,000 in debt, with those graduating from private institutions averaging more than \$300,000⁷. As the number of specialists in rural areas declines and the physician workforce shortage continues to pose challenges to patient access, the crushing pressure that this debt puts on medical students very much influences their choices on where they obtain their residency and ultimately practice afterwards.

AAOS supports common sense reforms like H.R. 5734, the Resident Deferred Student Interest (REDI) Act which would allow interest-free deferment on student loans for borrowers serving in a medical or dental internship or residency program. The 75 percent of residents who carry education debt upon graduating medical school watch their loan burden multiply during residency due to the continued accrual of interest. The REDI Act would help ease that burden so that young doctors can focus on building their skills and caring for patients. I would like to thank Chairwoman Velazquez and others on the Committee who have already expressed their support for this important legislation through their cosponsorship.

⁷ Budd, Ken. "7 Ways to Reduce Medical School Debt." *AAMC*, 9 Oct. 2018, <https://www.aamc.org/news-insights/7-ways-reduce-medical-school-debt>.

Conclusion

I would like to again thank the Chairwoman, Ranking Member, and members of the Committee for the opportunity to testify today regarding innovation in GME. AAOS strongly supports policies that will allow for the additional funding and support of GME programs and the residents who participate in them. I would also reiterate our support for resources that will allow smaller and more rural institutions to invest in technology, equipment and programming that can further the skillsets of their residents. Finally, the expansion of GME slots as well as the passage of legislation like the REDI Act will only further the field of medicine as it advances and changes. We greatly appreciate the Committee's interest in this and other health care topics and hope to continue to serve as a resource going forward.



AMERICAN ACADEMY™
OF OPHTHALMOLOGY

20 F Street NW
Suite 400
Washington DC
20001-6701

P.O. Box 7424
San Francisco, CA
94120-7424

T: +1 202.737.6662
www.aao.org

Testimony of Ingrid Zimmer-Galler, MD
American Academy of Ophthalmology
Before the U.S. House of Representatives Small Business
Committee Hearing on "Upskilling the Medical Workforce"
November 13, 2019

Chairwoman Velazquez, Ranking Member Chabot, and members of the Committee, I am honored to be testifying before you today on behalf of the American Academy of Ophthalmology. My name is Ingrid Zimmer-Galler, and I am an Associate Professor of Ophthalmology at Johns Hopkins Wilmer Eye Institute. I also served as the Founding Executive Clinical Director of the John Hopkins Office of Telemedicine for 3 years and serve on the Academy's Telemedicine Task Force. The Academy is the world's largest association of eye physicians and surgeons and seeks to protect sight and empower lives by setting the standards for ophthalmic education and advocacy for our patients and the public.

I am excited to share and discuss with you today the promise of telemedicine, both in ophthalmology and more broadly, and to highlight the culture shift that is already occurring among patients and providers as telemedicine is being recognized as a new tool to deliver health care. My initial work with telemedicine began two decades ago with research on diabetic retinopathy assessment by remote retinal imaging to address the challenge of vision loss due to poor compliance with recommendations for annual eye exams to screen for diabetic eye disease. We implemented one of the first large-scale telemedicine diabetic retinopathy screening programs in the US, and, over a decade, more than 175,000 imaging encounters were completed in 17 states and several countries resulting in a significantly improved diabetic retinopathy screening rate in multiple geographies. This early work led to my involvement with the American Telemedicine Association (ATA) where I served as chair of the Ocular Telehealth Special Interest Group followed by four years on the ATA Board of Directors. More recently, as the clinical leader and strategic advisor for all Johns Hopkins telemedicine efforts, my work focused on incorporation of telemedicine across a large health system and into all medical specialties. Additionally, we are now incorporating artificial intelligence into telemedicine diabetic retinopathy screening programs in adults and children.

John Hopkins Office of Telemedicine:

The Johns Hopkins Office of Telemedicine was launched in July 2016 and was purposed with the strategic deployment, support and coordination of the delivery of clinical services by telecommunications technology initially within the Hopkins healthcare enterprise and now also to national and international external markets. The office oversees the implementation of telemedicine services including building any required technology infrastructure and integration with the electronic medical record. The office assists in coordinating clinical activities, evaluating and advising on relevant research studying clinical outcomes and the efficiency of telemedicine. The office staff also work closely with legal, payor and compliance teams of experts to ensure a coordinated approach to telehealth across John Hopkins Medicine. Participation with government affairs on national and state levels in policy development for telemedicine is another important role for the office of telemedicine. The approach to virtual care at Johns Hopkins has been to use standardized and scalable methods to create solutions and alternative options for health care delivery to our patients. The goal is to allow clinicians to follow similar workflows regardless of whether the patient is being seen in person or virtually.

Our Office of Telemedicine has 6 full time staff including a physician medical director, a nurse program manager, an administrative director, two project managers, and a technology coordinator/software engineer. As of Oct 2019, there are 63 live telemedicine projects at Johns Hopkins in 56 different sub-specialty areas. Over 18,000 total telemedicine encounters have been performed since inception of the office of telemedicine. Telemedicine programs at Johns Hopkins include asynchronous or store-and-forward projects, which generally involve sharing images and other data as consults between providers or between a patient and provider not in real time, and synchronous live interactive video visits between providers or between a patient and a provider. Additionally, remote patient monitoring of patients with chronic disease such as diabetes, congestive heart failure and lung diseases can reduce overall health care costs by reducing hospital readmissions and avoidable emergency department visits.

Some examples of our asynchronous projects include:

- Diabetic retinopathy screening while patients are visiting with their endocrinologist allow acquisition of retinal photographs which are interpreted by a specialist remotely. More recently this has been incorporated with near simultaneous interpretation of the images by artificial intelligence.
- E-visits for simple low-acuity problems allow patients to send a message with or without an image to their provider through the patient portal. The provider responds to the patient via the patient portal typically the same day. This is a more cost-effective and convenient alternative to an in-person office visit which also saves the avoided in-person visit time for a patient with a higher acuity problem.

A few examples of synchronous telemedicine projects at Johns Hopkins include:

- Video consults which provide ophthalmology specialty care to a community hospital that does not have ophthalmologists on call thereby avoiding transfer of most patients with eye problems to a tertiary care hospital.
- Video visits are also an option in the emergency department for patients with lower acuity problems allowing them to see a provider virtually sooner than the potentially long wait for an in-person visit with an emergency care provider.
- Video visits for specialty care which is being provided to rural areas without access to specialists. Care for patients with hepatitis C, including access to life-saving drug treatments, is now available to communities in western Maryland that have no infectious disease specialists. Similarly, pediatric specialty care including endocrinology and rheumatology is now available to communities on the eastern shore of Maryland which are hours away from any such specialists. These specialty care video visits take place in the local community health departments and are facilitated by the local staff.

The Benefits of Telemedicine & Ophthalmology Successes:

Telemedicine can benefit institutions, healthcare systems, and providers by expanding access to care and improving the quality of care in both rural and urban settings. The challenges and burdens on patients from rural areas to access care include transportation and time required for travel which can be significantly alleviated with virtual care. Small rural hospitals and healthcare facilities are able to offer a wide range of quality specialty and subspecialty care with telemedicine even when it is not feasible to staff these facilities with specialist providers. Providing care locally and allowing patients to stay in place in their community rather than transferring the patient allows tertiary care center beds to remain available for those in need of more critical care. Additionally, this helps reduce rural provider isolation by allowing the providers to work as a team, offering support and sharing knowledge. Similarly, telemedicine can be extremely helpful for patients with limited mobility including the wheelchair bound and patients in skilled nursing facilities who have difficulty being transported for health care visits. For example, neurologists at Johns Hopkins offer follow-up video visits at home to patients with amyotrophic lateral sclerosis (Lou Gehrig's disease) who may not be able to walk and may be on a respirator.

Numerous examples of successful telemedicine programs exist in ophthalmology with the earliest being in the realm of diabetic retinopathy screening. In most geographies diabetic retinopathy remains the leading cause of vision loss in working-age adults in part due to poor compliance with recommendations for regular eye examinations. Early detection of diabetic retinopathy is key to allow intervention before permanent damage and vision loss occur. The effectiveness and success of diabetic retinopathy screening with telemedicine can be measured by the many programs in place in the United States and internationally. Large national

telemedicine diabetic retinopathy programs are in place throughout the Veterans Affairs (VA) health system and the Indian Health System. In the United Kingdom, diabetic retinopathy is no longer the leading cause of blindness in adults in part due to a national diabetic retinopathy telemedicine program. In 2018, a cloud-based artificial intelligence (AI) algorithm used to detect referable diabetic retinopathy was cleared as the first autonomous AI device to be marketed in the United States without the need for a clinician to review the images or results. This greatly enhances opportunities for early disease detection in patients with diabetes in the primary care environment even in areas where access to retina specialists may be limited.

Other successful uses of telemedicine in ophthalmology include remote screening for retinopathy of prematurity (ROP) which addresses another public health concern in the United States. Despite good treatment options, babies continue to go blind from ROP due to the lack of available physicians who are able and willing to diagnose and manage this disease. Using a wide-angle digital retinal camera to capture images that are interpreted by a remote expert helps to overcome geographic challenges and expert provider shortages. By complementing traditional ROP management, telemedicine allows it to be done more efficiently and with fewer in-person examinations which also expands the reach of individual providers. The VA is using an ocular telehealth program to expand basic eye care services for veterans which is especially useful for veterans in rural areas with limited access to specialty eye care. With this program, veterans in rural areas can undergo eye-disease screening at a community-based outpatient clinic as part of their local primary care visit. Veterans who need follow-up care can see an ophthalmologist at a VA medical center or in the local community.

Opportunities for Growing the Medical Workforce:

While the core functions may be similar, telemedicine program structures vary significantly, and no two telemedicine programs will look exactly alike. A typical telemedicine workforce will involve staff of varying education and skill level. Staffing, as well as their additional education and training for telehealth roles, is critical as these individuals are the ones that will likely determine the success of the program. Some of the recommended staffing roles for a successful telemedicine program include:

- Physician medical director who serves as liaison for medical staff and the institution's leadership and provides clinical guidance to the telehealth providers
- Administrative director who guides the telemedicine team, handles administrative aspects of implementation, and serves as the primary advocate for the program within the health system
- Program coordinator with clinical experience, such as a nurse, who leads project managers and all aspects of telehealth clinical services such as staff and provider training, service coordination and process development.

- Project manager(s) who works closely with clinical departments to develop workflows and provide support pre- and post-implementation
- Site coordinator(s) at the originating site where the patient is located who serves as the main point of contact and is the local distributor of telemedicine information
- Technology coordinator who serves as the primary contact for hardware and software issues including immediate response to troubleshoot connectivity and equipment issues when clinical services are being provided
- Nurse or staff presenter at the originating site who facilitates the virtual clinic visit, assists the patient and interacts with the remote provider as needed
- Clinical champions in the various specialty departments, who may not be part of the telemedicine team, are vital to encourage and support providers new to telemedicine technology.

Major Barriers for Widespread Telemedicine Adoption:

In spite of the promise of telemedicine, policy barriers on both the state and federal level continue to contribute to its limited use. A major barrier to telehealth adoption is lack of consistent reimbursement for virtual care. Federal reimbursement is centered on Medicare. Medicare restricts where telehealth services can take place both geographically and originating site-wise, the type of provider who may bill for telemedicine services, and the type of service that can be billed (primarily synchronous services). Although some exceptions for very specific conditions exist, Medicare limitations, which are largely statutorily dictated, have impeded the growth of telemedicine. Existing legislation in the Senate, the Screenings for Eye Evaluation, Monitoring, Observation, Review, and Examination (SEE MORE) Act, would lift originating site restrictions. Other inroads are being made and recently Medicare has moved to allow reimbursement for remote communication technology, chronic care management and remote patient monitoring.

Medicaid policies on the state level are generally more progressive but each state dictates their own policies resulting in a patchwork quilt of telehealth laws and regulations across the United States. Frequently limitations on coverage of services and the settings where they can occur remain. Most state Medicaid programs reimburse video visits, a few reimburse asynchronous visits and some reimburse remote patient monitoring. However, each state has their own limitations and restrictions. Commercial payers tend to embrace telemedicine but their policies also vary across states. Many states have parity legislation which mandates payers to reimburse for telehealth delivered services. However, often parity is only dictated for coverage of services and not in payment amount. Importantly, payment policy on the federal or state level does not typically recognize and compensate for the cost of initiating a telemedicine

program, paying instead only for the work and practice expense of a presumed mature technology.

An additional major policy barrier inhibiting adoption and wide-spread use of telemedicine is licensing of providers. Current regulations at the state level require that providers be licensed in the state where the patient requesting telemedicine services is located (medicine occurs where the patient is located). Applying for licenses in multiple states can be time-consuming and costly. The American Academy of Ophthalmology has supported action by the Federation of State Medical Boards to facilitate multi-state physician licensure for those looking to provide telemedicine services outside of their home state. The Interstate Medical Licensure Compact currently allows qualified physicians who wish to practice in multiple states with an expedited pathway to licensure. More than half of all states have joined the compact and are issuing licenses through the process. Similarly, a licensing compact allows nurses to practice in more than 30 compact member states without having to obtain another state license.

State regulatory boards also are increasingly developing regulations, policies and guidelines on the use of telehealth which creates an additional layer of rules with which providers must comply. Other concerns and potential barriers that need to be addressed include malpractice coverage, privacy and security issues, prescribing, broadband access and credentialing and privileging.

Closing Remarks:

On behalf of the Academy and the ophthalmic community, I thank you for your time in allowing me to discuss my work in this field and the benefits of telemedicine. I look forward to your questions.

DISCLOSURE OF FEDERAL GRANTS OR CONTRACTS

Between 2013 and 2015, the American Academy of Ophthalmology (AAO) received funding from the Agency for Healthcare Research and Quality (AHRQ) under the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Program, to disseminate the Registry for Glaucoma Outcomes Research (RiGOR) study findings through the use of social media tools.

AAO is a 501c (6) educational membership association.

**Testimony Prepared for the U.S. House of Representatives Committee on Small Business
Upskilling the Medical Workforce: Opportunities in Health Innovations
November 13, 2019**

**Submitted by: Nancy Fahrenwald, PhD, RN, PHNA-BC, FAAN
Dean and Professor, Texas A&M University, College of Nursing
Government Affairs Committee Chair, American Association of Colleges of Nursing**

Thank you, Chairwoman Velázquez, Ranking Member Chabot, and members of the Committee for the opportunity to provide testimony on how we, in academic nursing, are re-envisioning the education of the next generation of nurses and nursing leaders to thrive in an ever-changing health care system. I am Nancy Fahrenwald, Dean and Professor at Texas A&M University College of Nursing, which educates over 400 students enrolled in undergraduate and graduate nursing programs at two geographic locations in Texas. In addition, I also serve as the Chair of the Government Affairs Committee at the American Association of Colleges of Nursing (AACN). AACN, represents 825 schools of nursing, 543,000 baccalaureate and graduate students, and more than 45,000 faculty members.¹

With over twenty years of experience in nursing education, I have witnessed firsthand how innovation impacts health care delivery. I entered into the field of academic nursing at the birth of the digital age, when this amazing thing called email had just begun to be used in earnest. I have seen how technology and innovation have supplemented and enhanced nursing education so that students can become effective and proficient practitioners. I have experienced how academic nursing, and nurses in general, have been early adopters of these advances, not only in practice, but also in the way we educate the future nursing workforce.

In 2016, Professor Klaus Schwab, founder of the World Economic Forum, heralded the arrival of the Fourth Industrial Revolution, a new era of technology-driven change.² This new “revolution” is marked by rapid changes in technology.³ Health professions schools, like Texas A&M University College of Nursing, are increasingly including clinical simulation, virtual reality, telehealth, and other forms of technology-based educational platforms within the curriculum, to prepare tomorrow’s practitioners and caregivers. Today, as Dean of Texas A&M University College of Nursing, I collaborate with other A&M health professions colleges to educate our students in the largest and most geographically diverse clinical simulation laboratories in the state. In this setting, health care students are refining their skills in a highly specialized environment that allows them to work in hospital, clinic, and community settings and with patients from birth to adulthood.

In other nursing programs, we are also seeing an emergence of entrepreneurship laboratories or innovation classes.⁴ For example, nursing students and faculty, with an interprofessional and

¹ American Association of Colleges of Nursing. (2019). “Who we are.” Retrieved from: <https://www.aacnnursing.org/About-AACN>.

² Schwab, K. (2019). The Fourth Industrial Revolution. Retrieved from: <https://www.britannica.com/topic/The-Fourth-Industrial-Revolution-2119734>.

³ Ibid.

⁴ Duke Nursing: Advancing Innovation Research and Clinical Practice. “Creating Pathways for Innovation.” Summer 2019, Volume 15, Number 2. Retrieved from: https://nursing.duke.edu/sites/default/files/documents/summer_2019_dukenursing.pdf.

interdisciplinary lens, are working on prototypes and even developing products, using 3-D printers and laser cutters, to put new innovations into production and advance the future of healthcare and nursing.⁵ So often our students and faculty have an idea, but may need a software expert or engineer to translate that idea into a tangible health care solution. We recognize that need and are seeing programs partner in unique ways to bring these creative and impactful innovations to fruition.

Adopting and integrating health and health care technologies, beginning in the educational setting, is imperative as nurses are at the forefront of health care throughout the country. The need for highly educated nurses is only expected to grow. In fact, by 2028, the demand for Registered Nurses (RNs) nationally is expected to increase 12%, representing an employment change of 371,500 nurses.⁶ Further, the demand for most Advanced Practiced Registered Nurses (APRNs), sometimes serving as the only primary care practitioner in large rural and underserved areas, is expected to grow by 26%.⁷ This demand on the workforce is coupled with the fact that in the next three years it is projected that 70,000 baby boomer RNs will retire annually.⁸ In Texas, one of the country's fastest growing states, nursing workforce supply and demand reports predict a 20% deficit of full-time RNs and a 25% shortage of nurse practitioners by 2030, equivalent to almost 60,000 professional nurses and over 6,000 nurse practitioners.^{9 10}

The growing demand for RNs and APRNs presents a unique opportunity for the academic programs that prepare the future nursing workforce to answer the call. We need to ensure that students are able to rise to the challenge and as AACN outlined, are "adaptable, creative individuals able to work with diverse populations while being agile to respond to the fluctuating business needs and reimbursement realities."¹¹ Whether nurses are providing care in hospitals, nurse-managed health clinics, schools, or federally qualified health centers, or even establishing their own small businesses, pairing the products of health and health care innovation with foundational nursing principles is imperative for upskilling the future health care workforce. I am grateful for the opportunity to be here today to discuss ways that we are doing just that in academic nursing.

Integrating Innovation into Nursing Education

Access to online education and new technologies have become a standard in nursing education and are

⁵ The Ohio State University College of Nursing, "The Innovation Studio at Ohio State." Retrieved from: <https://nursing.osu.edu/offices-and-initiatives/office-innovation-and-strategic-partnerships/innovationstudio>.

⁶ U.S. Bureau of Labor Statistics. (2019). Occupational Outlook Handbook- Registered Nurses. Retrieved from: <https://www.bls.gov/ooh/healthcare/registered-nurses.htm>.

⁷ U.S. Bureau of Labor Statistics. (2019). Occupational Outlook Handbook- Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners. Retrieved from: <https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm>.

⁸ Buerhaus, Peter, Lucy Skinner, David Auerbach, Douglas Staiger, et al. 2017. "Four Challenges Facing the Nursing Workforce in the United States." *Journal of Nursing Regulation*, Volume 8, Issue 2.

⁹ Rosewicz Barb, Biernacka-Lievestro, Joanna, Newman, Daniel. "Western, Southern States Gain Residents the Fastest." February 27, 2019. PEW. Retrieved from: <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/02/27/western-southern-states-gain-residents-the-fastest>.

¹⁰ Texas Center for Nursing Workforce Studies, Texas Department of State Health Services. "Nurse Supply and Demand Projections, 2015-2030." October 2016. Retrieved from: [file:///C:/Users/RStevenson/Downloads/SupplyDemandReport_ExecutiveSummary%20\(1\).pdf](file:///C:/Users/RStevenson/Downloads/SupplyDemandReport_ExecutiveSummary%20(1).pdf).

¹¹ American Association of Colleges of Nursing. "AACN's Vision for Academic Nursing- Executive Summary." January 2019. Retrieved from: <https://www.aacnnursing.org/Portals/42/News/White-Papers/Vision-Academic-Nursing.pdf>.

only growing. According to AACN's Vision for Academic Nursing, "increasingly, a design-build approach is being used with pairing of faculty with an instructional designer to promote innovation and effective teaching methods in the classroom."¹² These methods help address, "limited resources, rising education costs, and demands to expand enrollments as well as diverse student learning styles."¹³ Nurses are required to have skills and knowledge across a wide-variety of practice settings, to keep up with continually changing and evolving healthcare systems, and to provide high-quality patient centered care across the lifespan continuum. Academic nursing is at the forefront of technological innovation to ensure that these competencies are met.

Educational Experience: The Use of Modern Technology to Simulate Real World Environments

Throughout my experience, I have seen revolutionary technologies incorporated into the nursing curriculum. From electronic health record platforms to simulation labs and adaptive learning to virtual reality, these technologies expand critical thinking skills in a safe, simulated environment, facilitate learning and growth for the nursing students, and improve patient-centered care.

In fact, one of the most remarkable changes to nursing education in the last decade has been the introduction of virtual simulation. According to a 2017 Wolters Kluwer survey, virtual simulation is currently used in 65% of nursing education programs, and that number is expected to grow.¹⁴

At Texas A&M University, we have a Clinical Learning Resource Center (CLRC), which advances the knowledge of our students through interprofessional clinical simulation, including through virtual reality software programs, partial task trainers, human patient simulators operated remotely, simulated clinical care environments, and standardized patients.¹⁵ For example, at the CLRC, a nursing student could "clock in" to experience a myriad of different care delivery environments, such as a rural clinic or even a telehealth setting. Clinical simulation laboratories, like ours, are places where simple and complex care scenarios are created to ensure students are exposure to the technologies that exist in health care and to particularly high-stakes healthcare events.

Through these environments, students have the hands-on experience of making decisions about patient care as if it were real, while also allowing faculty to remediate, debrief, and educate students on best practices. Nursing students are able to prepare for scenarios they may face in practice. It could be simple skills, such as learning to administer medication independently or documenting without a co-signer. The training could also be as complex as caring for a patient experiencing cardiac arrest, post-partum hemorrhage, or sepsis from infection. Students may experience these scenarios all by using technology, standardized patient models, or manikins.¹⁶ In fact, our CLRC includes full-bodied computer-

¹² | American Association of Colleges of Nursing. "AACN's Vision for Academic Nursing- Executive Summary." January 2019. Retrieved from: <https://www.aacnnursing.org/Portals/42/News/White-Papers/Vision-Academic-Nursing.pdf>.

¹³ Ibid.

¹⁴ Wolters Kluwer, "65% of Nursing Education Programs Adopting Virtual Simulation." Retrieved from: <http://healthclarity.wolterskluwer.com/nursing-education-programs-virtual-simulation.html>.

¹⁵ Texas A&M University, "Clinical Learning Resource Center (CLRC) Mission and Vision." Retrieved from: <https://health.tamu.edu/clrc/mission-vision.html>.

¹⁶ Aebersold, M., (April 3, 2018) "Simulation-Based Learning: No Longer a Novelty in Undergraduate Education" *OJIN: The Online Journal of Issues in Nursing* Vol. 23, No. 2. Retrieved from: <http://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol->

programmed manikins that can simulate a range of responses.¹⁷ They can bleed, have dynamic heart rates, and even birth babies. *The Importance of Simulation in Nursing Education* outlines, "Nursing students who take part in education programs involving simulations perform less medical mistakes in clinical settings, and are able to better develop their critical thinking and clinical decision-making skills."¹⁸ Simulation labs allow students to be confident and competent practitioners. According to the Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health Care System*, one of the recommended strategies to improve patient safety is through interdisciplinary team training, such as simulation.¹⁹

Other emerging technologies, such as augmented and virtual reality, may be used to enhance the educational experience and prepare future nursing workforce for the realities of their career. Some schools are investing in virtual anatomy tables that allow students to visualize human anatomy by 'virtually dissecting' patients.²⁰ By putting on 3D goggles, the student is able to see through the manikin and the different layers of their anatomy. They are able to practice procedures, such as inserting a feeding tube or conducting a physical exam.²¹ Other mixed reality technology can enlarge, turn, or rotate organs with the movement of your hand or show how ultrasound beams go through a human.²² These types of high-tech innovations, once dreamed up in science fiction novels, are now cutting edge tools that provide students an immersive, comprehensive, and live action learning experience, without the fear of harming a live patient.

Earlier this month, I was celebrating the work of our forensic nursing faculty and their outstanding master's and certificate education programs, cutting-edge research, and statewide outreach. The A&M Board of Regents recently approved the College of Nursing as a Centers for Excellence in Forensic Nursing. In our curriculum, we prepare forensic nurses, through simulated scenarios, to identify and treat patients who have experienced traumatic episodes, such as elder abuse, sexual violence, or human trafficking. We teach them how to talk with these patients and document the care based on protocol. At the conclusion of the simulations, we debrief with the students to discuss these training exercises. As a result, when faced with similar experiences in our communities, they are ready and able to step in and provide safe, trauma-informed, and evidence-based care. At a social event where we were discussing our center, a casual conversation resulted in one community member explaining to me, "I remember

[23-2018/No2-May-2018/Articles-Previous-Topics/Simulation-Based-Learning-Undergraduate-Education.html#Colleges.](#)

¹⁷ Texas A&M University, "Clinical Learning Resource Center (CLRC) Mission and Vision." Retrieved from: <https://health.tamu.edu/clrc/mission-vision.html>.

¹⁸ Eyikara E, Baykara Z. The Importance of Simulation in Nursing Education. Retrieved from: <https://eric.ed.gov/?id=EJ1141174>.

¹⁹ Kohn LT, Corrigan JM, Donaldson MS, editors. *To err is human: building a safer health system* A report of the Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC: National Academy Press; 2000. <https://www.ncbi.nlm.nih.gov/pubmed/25077248>.

²⁰ Choi, J. (2013, February), *Jack Choi: On the virtual dissection table* [Video file]. Retrieved from https://www.ted.com/talks/jack_choi_on_the_virtual_dissection_table.

²¹ Aebersold, M., (April 3, 2018) "Simulation-Based Learning: No Longer a Novelty in Undergraduate Education" *OJIN: The Online Journal of Issues in Nursing* Vol. 23, No. 2. Retrieved from: <http://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-23-2018/No2-May-2018/Articles-Previous-Topics/Simulation-Based-Learning-Undergraduate-Education.html#Colleges>.

²² CAE Healthcare. Limitless learning. Retrieved from: <https://caehealthcare.com/hololens/>.

being in that situation, and it was the nurse that allowed me to survive.” That is what this education is for, to be ready to meet people where they are and deliver high-quality personalized care.

Another aspect of our innovative training is in telehealth. Telehealth services are integral, especially in geriatric and post-operative care, and can reduce cost burden, increase quality of care, and lessen disruptions for patients.

As I prepare students to meet today’s healthcare challenges, such as an aging population and the rural realities of Texas, telehealth technologies play a large role.²³ Through our curriculum, we are able to simulate those real-world scenarios and telehealth conversations. We work with our nursing students to be able to ask the right questions to help facilitate high-quality, patient-centered outcomes. Keep in mind, it is not just about the patient themselves, but also their environment. For example, we teach our students to ask questions like, do they have a place to fill a prescription? What type of caregivers do they have in their community? Do they have access to transportation? By allowing that patient to stay in their home, or not drive hours to a healthcare facility, we are meeting them where they are, while remaining that trusted patient advocate.

Maintaining and Enhancing Federal Involvement through Title VIII Nursing Workforce Development Programs:

As you can see, technology is a major driver of change. One way the federal government is helping to facilitate and support that change in nursing education is through the Title VIII Nursing Workforce Development Programs. For over fifty years, the Nursing Workforce Development Programs (Title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.]) have consistently and continually sustained the supply and distribution of highly-educated nurses by strengthening nursing education at all levels, from entry preparation through graduate study.

Nursing schools across the country are working to meet the rising demand and educate all qualified applicants interested in the profession. Though a 3.7% enrollment increase in entry-level baccalaureate programs was reported in nursing in 2018 by AACN, “this increase is not sufficient to meet the projected demand for nursing services, including the need for more nurse faculty, researchers, and primary care providers.”²⁴ Each of the programs that comprise Title VIII have a unique mission aimed at promoting nursing care in all communities, especially in vulnerable and underserved areas. For example, the Nurse Faculty Loan Program, helps ensure we have faculty to prepare the nursing students of today to be innovative leaders in the healthcare workforce of tomorrow. According to AACN’s report on 2018-2019 Enrollment and Graduations in Baccalaureate and Graduate Programs in Nursing, U.S. nursing schools turned away more than 75,000 qualified students in 2018 and pointed to a shortage of faculty, clinical sites, and clinical preceptors as the primary reasons for not accepting all qualified applicants into their programs.²⁵

Title VIII programs help fund the innovations, which are at the cutting edge of our profession. They allow us to provide training, scholarships and loans, while helping to ensure we have a robust, diverse nursing pipeline. In my prior role as the flagship college of nursing dean in a rural Midwestern state, Title VIII

²³ Pew Research Center. (2010). Baby Boomers Retire. <http://www.pewresearch.org/fact-tank/2010/12/29/baby-boomers-retire>.

²⁴ American Association of Colleges of Nursing. (2019). Nursing Shortage Fact Sheet as of April 5, 2019. Retrieved from <https://www.aacnnursing.org/Portals/42/News/Factsheets/Nursing-Shortage-Factsheet.pdf>

²⁵ Ibid.

funds allowed our college to purchase simulation technologies and educate our faculty in developing new pedagogies. The faculty also created simulation scenarios for students that our rural nursing colleagues told us were important, such as farm injuries and emergency care of children injured in a rollover of an all-terrain vehicle.

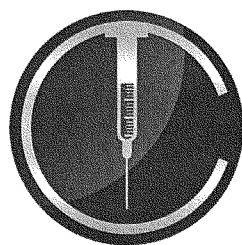
We commend the House of Representatives for passing H.R. 728, the Title VIII Nursing Workforce Reauthorization Act, to ensure these programs continue to provide much needed federal support to nursing education and practice throughout the country. While we continue to work to move this vital legislation forward, we wanted to highlight the important role these grants and programs play in sustaining and enhancing our educational innovations. In that same light, we urge Congress to continue to increase funding for these vital nursing education programs through the annual appropriations process. Reauthorization, and continued funding, of Title VIII Nursing Workforce Development Programs, will ensure that nursing education, and the nursing workforce, continues to maximize new technologies, integrate health care innovation, and prepare for the ever-changing needs of our patients.

Adaptability and Agility: Innovations on the Horizon

While our curriculum may not be based in business, we are on the frontlines of health care and are utilizing innovative technologies to create advancements in delivery systems and address the social determinants of health, while working to minimize health disparities. Our students work in all healthcare settings, small businesses and large health care systems alike, and in every community nationwide.

While integration of these skills is necessary and is redefining the way that nurses are educated and how they practice, we remain steadfast in our foundational principles of putting patients first. As AACN leadership highlights, technological advances “will not replace the need for nurses or faculty, nor decrease the demand for humanistic, compassionate interaction with students and patients.”²⁶ As we enter this new frontier, we are preparing nurses to enter the workforce more competently and confidently than ever before.

²⁶ Cary, Ann and Deborah Trautman. “Rounds with Leadership: Artificial Intelligence.” American Association of Colleges of Nurses.” Retrieved from: <https://www.aacnnursing.org/News-Information/News/View/ArticleId/22796/Rounds-with-Leadership-11-28-18>.



TRUE CONCEPTS
— MEDICAL TECHNOLOGIES —
DESIGNING A SAFER TOMORROW

The Committee on Small Business

Upskilling the Medical Workforce
Opportunities in Health Innovation

November 13th, 2019

Business Summary

True Concepts Medical Technologies (TCMT) is a medical device innovation engine that delivers novel and manufacturable solutions based in clinical experience. Our devices are designed by clinicians for clinicians with a focus on areas that have significant morbidity and mortality such as sepsis and sudden cardiac arrest. Our goal is to save lives and reduce healthcare costs of care with intelligently designed solutions that eliminate the opportunity for human error.

TCMT was formed in early 2017 by Michael J Hopkins, a registered nurse with 24 years of experience in critical care, emergency medicine, and trauma. Coupled with 25 plus years of design experience he has developed a series of next generation dual-syringe technologies which have the potential to save the US healthcare system upwards of a billion dollars, while improving patient outcomes. Partnering with Dr. Arash Babaoff in June 16th, 2017, we filed two US patents and two PCT (Patent Cooperation Treaty) patent applications for which we received notification of clean reviews, placing us on the Patent Prosecution Highway. Within a year of filing we received two US patents. We currently hold three US utility patents and have several continuation patents in process. We have filed international-ly in the EU, Canada, Mexico, India, Israel, Japan, and Hong Kong.

As a small business medical device startup in the state of Ohio raising capital has its unique challenges. We have relied on friends, family, and physicians to secure our initial raise, with 70% of our investment coming from physicians who see the immediate need for these technologies. We've been frugal and have accomplished a great deal. Relationships with other small local businesses have been the key to our progress. Pixel & Timber, an industrial design firm in Cincinnati, Ohio was able to streamline our initial designs and create beautiful CAD models for us. 3D-Technical solutions, located in Dayton, Ohio then took those models and created our alpha prototypes. Minco Tool & Mold, a family owned business in Dayton, Ohio has refined our initial design and is developing molds to prepare us for manufacturing. Regulatory Mark, a FDA regulatory consulting firm in Cincinnati, Ohio prepared a robust regulatory report which has prepared us for FDA 510k submission. The relationship with The Entrepreneur Center (TEC) in Dayton, Ohio that has led us here today to testify before The Committee On Small Business. In August 2018 we became a client of the entrepreneur services program (ESP) which has provided us with valuable resources and connections. In May 2019 we were invited by the QSEN Institute at Case Western Reserve University to participate in "Evolving Ideas in Healthcare" highlighting new medical device technologies, where 150 nursing leaders from across the nation evaluated and our dual syringe technologies the "Most Promising Innovation for Quality & Safety", further validating the need to bring these technologies to the bedside. Many of the participants were asking how they go about purchasing our technologies for their institutions.

Sepsis is the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure, and death. Populations that are at greatest risk include the most vulnerable: children, the elderly, those with chronic illnesses, and those with a weakened or impaired immune system. With 30 million cases of sepsis recognized worldwide, every three seconds someone dies of sepsis. Of the 8 million annual deaths internationally, 3 million are pediatric deaths, making it the leading cause of pediatric deaths worldwide. One in three patients who dies hospital, dies of sepsis, making it the leading cause of death in US hospitals. Sepsis kills more Americans than breast cancer, lung cancer, and opioid overdoses combined. At \$27 billion annually it is the leading cost of hospitalization.

However, 80% of sepsis deaths may be prevented with rapid diagnosis and appropriate treatment. Rapid diagnosis starts with the proper collection of blood cultures, which have long been the gold standard in confirming infectious etiology, identifying the etiologic agent, and guiding antimicrobial therapy.

Current blood culture collection techniques are highly flawed, leading to sepsis misdiagnosis or delayed diagnosis. In the US, there are 45 million blood cultures drawn annually of which 8% are positive. Up to 40% of those positives are considered false-positives, making an accurate and timely diagnosis of sepsis very difficult.

Annually, the US health care system spends billions of dollars treating 1.5 million false-positive blood cultures (FPBC's) as a result of contamination that occurs during the collection and processing of blood cultures. With 40.7% of the US population covered by Medicaid (19.4%), Medicare (16.7%), and Veterans Affairs (4.6%), the financial impact to the US government is \$3 billion annually and accounts for upwards of a million unnecessary inpatient hospital days. The three main sources of contamination include skin preparation, subsurface bacteria, and human factors. Up to 20% of bacteria remain after preparing the skin with Chlorhexidine prior to venipuncture. More significantly there are subsurface bacteria that colonize beneath the skin in the sebaceous glands and the subsurface portions of the hair follicles where antiseptics are not efficacious. Human factors also play a role in contamination, occurring during the assembly of supplies/devices, the preparation of the skin, palpation after the skin has been prepped, and waste tube handling.

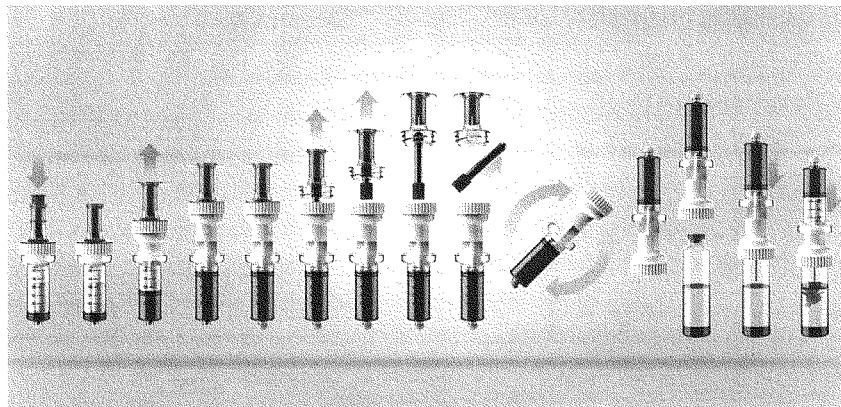
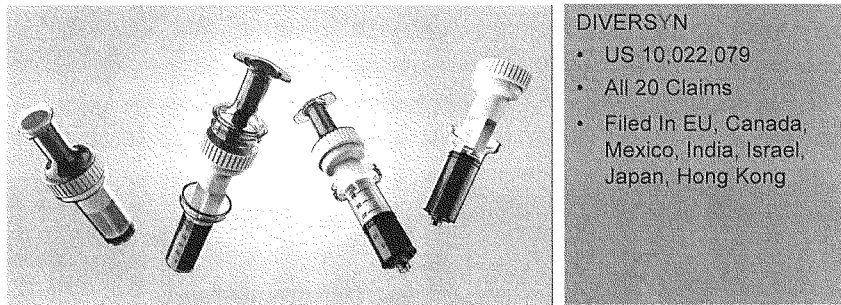
Recent research by Patton & Schmidt has shown that isolating the initial 1.5- 2 ml of blood during the peripheral collection of blood cultures reduces contamination by up to 92%, dramatically reducing false-positive blood culture rates¹

Patients with false-positive blood culture are admitted to the hospital an additional number of days, subjected to unnecessary laboratory procedures and placed on broad spectrum antibiotics, further putting them at risk for dangerous secondary C-difficile infection. Excessive use of antibiotics is the main cause for the spread of antibiotic-resistant bacteria. Decreasing unnecessary antibiotic use is essential in combating increasing antibiotic-resistant micro-organisms. Overall, 1.5 million FPBC's result in millions of unnecessary additional hospital days significantly impacting healthcare expenditures and the US economy.

6. Patton RG and Schmidt T. Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique. *Journal of Clinical Microbiology*, December 2010, p. 4501-4503 Vol. 48, No. 12

Customer Solution: DIVERSYN

DIVERSYN isolates the initial 3 ml of blood from the rest of the sample within one syringe, ensuring contaminate-free blood culture collection. A novel plunger design with an integrated transfer device allows the user to transfer collected blood from the syringe to blood culture bottles via a closed system, minimizing the opportunity for contamination, and all but eliminating false-positive blood cultures. The initial 3 ml of blood is sent to the clinical laboratory for other blood tests and a Procalcitonin level, whose concentration has been found to be elevated in sepsis. Owing its specificity to bacterial infections, Procalcitonin (PCT) has been proposed as a pertinent marker in the rapid diagnosis of bacterial infection, especially for use in hospital emergency departments and intensive care units. The use of PCT measurements to efficiently treat patients with antibiotics has been shown to decrease patient hospital stay. With proper training and without change to existing workflows, DIVERSYN will significantly improve timely, accurate sepsis diagnosis.





US010022079B2

(12) **United States Patent**
Hopkins

(10) **Patent No.:** **US 10,022,079 B2**
(45) **Date of Patent:** **Jul. 17, 2018**

(54) **SYRINGE SYSTEMS AND METHODS FOR BODILY FLUID COLLECTION AND SAMPLING**

(58) **Field of Classification Search**
CPC A61B 5/150251
See application file for complete search history.

(71) Applicant: **Michael Hopkins**, Springboro, OH (US)

(56) **References Cited**

(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

U.S. PATENT DOCUMENTS

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

4,340,068 A 7/1982 Kaufman
9,155,495 B2 10/2015 Bullington et al.
2007/0073267 A1 3/2007 Muller
2010/0286609 A1 11/2010 Mahurkar
2011/0009830 A1 1/2011 Kosinski et al.
2012/0016313 A1 1/2012 Nalesso et al.
2012/0220950 A1 8/2012 Carlyon
2014/0163419 A1 6/2014 Bullington et al.

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

OTHER PUBLICATIONS

(21) Appl. No.: **15/624,467**

(22) Filed: **Jun. 15, 2017**

(65) **Prior Publication Data**
US 2017/0360342 A1 Dec. 21, 2017

Related U.S. Application Data

(60) Provisional application No. 62/350,341, filed on Jun. 15, 2016.

(51) **Int. Cl.**
A61B 5/15 (2006.01)
A61B 5/153 (2006.01)
A61B 5/154 (2006.01)

(52) **U.S. Cl.**
CPC *A61B 5/150251* (2013.01); *A61B 5/15003* (2013.01); *A61B 5/153* (2013.01); *A61B 5/154* (2013.01); *A61B 5/150221* (2013.01); *A61B 5/150351* (2013.01); *A61B 5/150992* (2013.01)

Thomas, Shane; International Search Report and Written Opinion of the International Searching Authority, issued in International Application No. PCT/US2017/037789, dated Sep. 6, 2017; 9 pages.
Thomas, Shane; International Search Report and Written Opinion of the International Searching Authority, issued in International Application No. PCT/US2017/037778, dated Sep. 6, 2017; 11 pages.

Primary Examiner — Daniel Cerioni

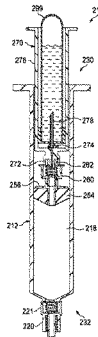
Assistant Examiner — Yasmeen S Warsi

(74) *Attorney, Agent, or Firm* — Ulmer & Berne LLP

(57) **ABSTRACT**

Embodiments of a syringe-based device for procuring bodily fluid samples can include a housing having a port that can be coupled to a lumen-defining device for receiving bodily fluids, an actuator mechanism retained at least partially within the housing, the actuator mechanism including a pre-sample reservoir, a plunger operably coupled with pre-sample reservoir, a plunger cap, a plunger tube, a valve, a plunger seal, an a selectively attachable collection vial for capturing a bodily fluid sample.

20 Claims, 26 Drawing Sheets



Customer Problem: Failed Systems in the Delivery of Emergency Medications

Current delivery of Adenosine and Epinephrine to the central compartment is flawed, inefficient, and ineffective. Three main factors are responsible: failed delivery systems, inadequate flush, and the pharmacologic properties of the medications. We can improve the first two factors to ultimately impact the third.

Adenosine is the medication of choice to treat supraventricular tachycardia (SVT). SVT is defined as an abnormally rapid heart rhythm having an electro-pathologic substrate emerging above the bundle of His (atrioventricular bundle) causing the heart to escalate to rates often higher than 200 beats per minute. If vagal maneuvers are unsuccessful administration of adenosine is necessary. With a half-life of less than ten seconds, adenosine must be administered by rapid IV push followed by a 20 ml normal saline flush. However, 90% of healthcare clinicians fail to administer an adequate volume of normal saline following adenosine administration.

Furthermore, we lack a standardized delivery method for adenosine. Current methods are archaic at best, with many institutions using a three way stopcock method which involves lengthy setup time (5-7 minutes) followed by a delivery system that offers multiple opportunities for failure. Pre-hospital delivery methods include two syringes with needles into one port or administering adenosine through an existing IV line then squeezing the IV fluid bag to push the adenosine to the heart.

These same problems also hold true for epinephrine delivery during sudden cardiac arrest. Worldwide there are > 135 million cardiovascular deaths each year and the prevalence of coronary heart disease is increasing. In the United States, >500,000 children and adults experience a cardiac arrest and < 15% survive. Epinephrine is the primary drug given in all causes of cardiac arrest. It is used for its potent vasoconstrictive effects and also for its ability to increase cardiac output.

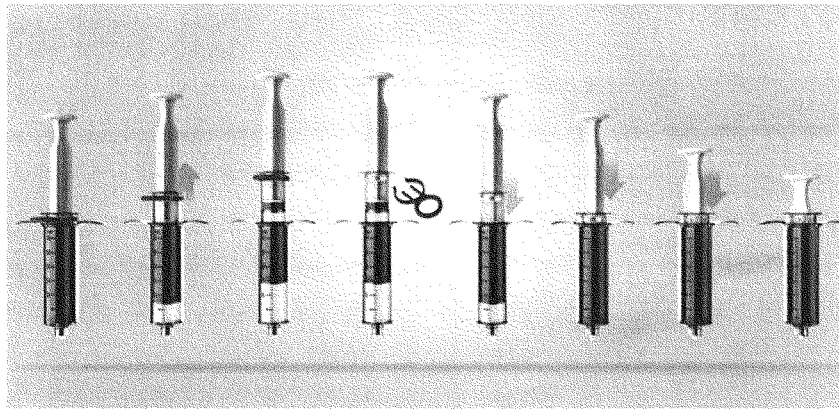
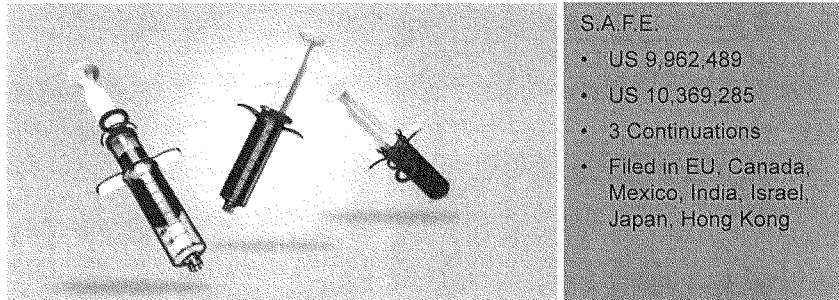
The American Heart Association recommends a 20 ml normal saline flush following the administration of 1 mg of epinephrine to ensure delivery into the central compartment. During sudden cardiac arrest the heart isn't pumping, high quality CPR only circulates 30% of blood volume and 64% of blood resides in the systemic vasculature. In a average sized adult, administration of epinephrine (1mg in 10 ml) through a peripheral intravenous line followed by a 5 or 10 ml normal saline flush does not result in epinephrine reaching the heart; rather it is rapidly absorbed into the bloodstream before it can have a positive impact on the heart. With its potent vasoconstrictive properties, it becomes even more difficult for subsequent doses to reach the heart.

Customer Solution: S.A.F.E. Syringe Technology

S.A.F.E. Syringe is a dual action syringe prefilled with 1mg of Epinephrine & 20 ml of normal saline flush ensuring a Safer, more Accurate, Faster, and more Effective delivery of Epinephrine. The clinician simply removes the S.A.F.E. syringe loaded with 1 mg of Epinephrine from the packaging, pulls red safety tab, attaches syringe to patients line and administers 1 mg of Epinephrine, followed by 20 ml NS flush in one fluid motion, getting Epi to the heart from the start.

Further applications for this technology include but are not limited to:

- Adenosine 6 mg & 20 ml Normal Saline Flush
- CLEANZE: 10 ml Normal Saline Flush & 5 ml of 10 Unit Heparin for the maintenance of Central Venous Catheters
- Rapid Sequence Intubation Medications
- S.A.F.E. Mini, a 10ml dual action syringe prefilled with 5 ml of Normal Saline. Clinicians are able to draw up and administer drug of choice followed by a 5 ml Normal Saline





US009962489B2

(12) **United States Patent**
Hopkins

(10) **Patent No.:** **US 9,962,489 B2**
(45) **Date of Patent:** **May 8, 2018**

(54) **SYRINGE SYSTEMS AND METHODS FOR MULTI-STAGE FLUID DELIVERY**

(71) Applicant: **Michael Hopkins**, Springboro, OH (US)

(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(h) by 0 days.

(21) Appl. No.: **15/624,593**

(22) Filed: **Jun. 15, 2017**

(65) **Prior Publication Data**
US 2017/0361019 A1 Dec. 21, 2017

Related U.S. Application Data

(60) Provisional application No. 62/350,341, filed on Jun. 15, 2016.

(51) Int. Cl.
A61M 5/19 (2006.01)
A61M 5/315 (2006.01)
A61M 5/32 (2006.01)
A61M 5/178 (2006.01)
A61M 5/31 (2006.01)

(52) U.S. Cl.
CPC *A61M 5/19* (2013.01); *A61M 5/31513* (2013.01); *A61M 5/31596* (2013.01); *A61M 5/32* (2013.01); *A61M 2005/1787* (2013.01); *A61M 2005/3128* (2013.01); *A61M 2202/04* (2013.01)

(58) Field of Classification Search

CPC *A61M 5/19*; *A61M 2005/1787*; *A61M 5/31596*

USPC 604/191
See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

4,340,068 A 7/1982 Kaufman
9,155,495 B2 10/2015 Bullington et al.
(Continued)

OTHER PUBLICATIONS

Thomas, Shane; International Search Report and Written Opinion of the International Searching Authority, issued in International Application No. PCT/US2017/037789, dated Sep. 6, 2017, 9 pages.

(Continued)

Primary Examiner — Nathan R Price

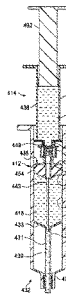
Assistant Examiner — John Doubrava

(74) Attorney, Agent, or Firm — Ulmer & Berne LLP

(57) ABSTRACT

Embodiments of a syringe-based device for delivering fluid include a housing, a port, the port being positioned at about the distal end of the housing, a plunger assembly, the plunger assembly including, a plunger seal, a valve, and a cannula, a first fluid reservoir, where the first fluid reservoir retains a first type of fluid, a syringe including a syringe body, a syringe port, a plunger, and a second fluid reservoir, the second fluid retaining a second type of fluid, and where the syringe transitions from a first configuration in which a first portion of the first fluid type is delivered through the port, to a second configuration in which the second type of fluid in the second fluid reservoir is delivered through the port, to a third configuration in which a second portion of the first fluid type is delivered through the port.

20 Claims, 23 Drawing Sheets



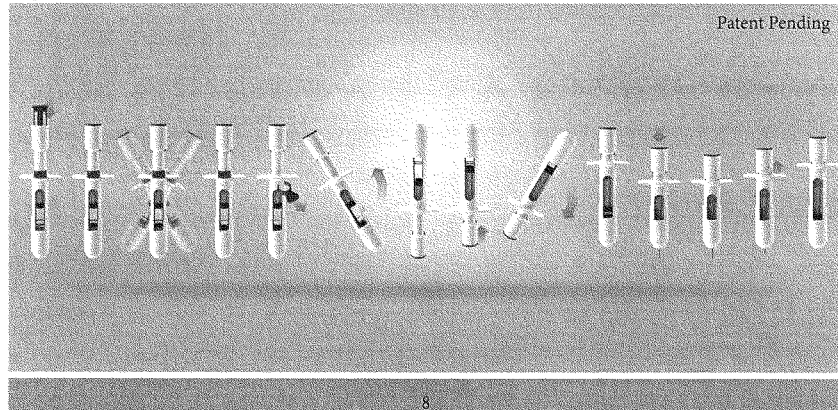
Customer Solution: RECON Pen

RECON PEN is a dual-chamber, prefilled, single-dose injection device for the accurate reconstitution and administration of lyophilized medications/vaccines/biologics. Designed with the end user in mind, this device is simple, intuitive, compact, and lightweight yet durable, ensuring accurate administration of vaccines in house-to-house campaigns by low skilled healthcare workers and self-administration of next-generation, long-acting, injectable contraceptives by patients at home or in other non-clinical settings.

Below is an accurate visual representation of RECON PEN's sequence of operation (Fig. 1). Once the RECON PEN is removed from its packaging, the user depresses the red plunger allowing 0.5 ml of sterile water to enter the glass cylinder where the MR/contraceptive lyophilized powder is located. The red plunger snaps into place once fully depressed. The user then agitates the RECON PEN until MR/contraceptive dry powder is fully reconstituted. The red locking tab is then removed, the PEN is inverted and the plunger is advanced to the red line, purging any residual air. By re-inverting the PEN after prepping the proper dose and firmly pressing the PEN onto the injection site, the guard retracts and the needle injects into the patient. The user depresses the plunger fully, administering vaccine/contraceptive. The guard automatically covers the needle after injection and locks into place, disabling the needle, and the PEN is ready for disposal.

With the reconstitution fluid located within the plunger mechanism outside of the syringe (body), liquid is securely separated from the glass cylinder where the lyophilized powder is located, keeping the powder stable in its dry form until reconstitution is initiated. The red safety tab prevents the user from prematurely depressing the main syringe plunger, accidentally expelling the vaccination/contraceptive prior to completing reconstitution. The needle guard not only disables the needle, but also protects against accidental needle stick injuries and transmission of Hepatitis B & C as well as HIV.

Fig. 1





US010369285B2

(12) **United States Patent**
Hopkins

(10) **Patent No.:** **US 10,369,285 B2**
(45) **Date of Patent:** **Aug. 6, 2019**

(54) **SYRINGE SYSTEMS AND METHODS FOR MULTI-STAGE FLUID DELIVERY**

(71) Applicant: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/948,471**

(22) Filed: **Apr. 9, 2018**

(65) **Prior Publication Data**

US 2018/0221577 A1 Aug. 9, 2018

Related U.S. Application Data

(63) Continuation of application No. 15/624,593, filed on Jun. 15, 2017, now Pat. No. 9,962,489.
(Continued)

(51) **Int. Cl.**
A61M 5/19 (2006.01)
A61B 5/15 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61M 5/19** (2013.01); **A61B 5/15003** (2013.01); **A61B 5/153** (2013.01); **A61B 5/154** (2013.01); **A61B 5/150221** (2013.01); **A61B 5/150251** (2013.01); **A61B 5/150351** (2013.01); **A61B 5/150992** (2013.01); **A61M 5/31513** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC **A61M 5/19**; **A61M 2005/1787**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,832,682 A * 5/1989 Sarnoff **A61K 9/0019**
604/137
2004/0171984 A1 * 9/2004 Greenfield **A61M 5/284**
604/82

(Continued)

OTHER PUBLICATIONS

Stephen Sheehan, Sagent Pharmaceuticals's Sequential Syringes, Medgadget (Sep. 29, 2008), https://www.medgadget.com/2008/09/sagent_pharmaceuticals_sequential_syringes_1.html.

Primary Examiner — Nathan R Price

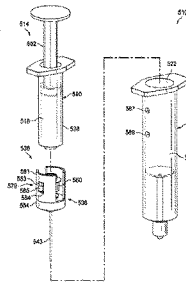
Assistant Examiner — John A Doubrava

(74) *Attorney, Agent, or Firm* — Ulmer & Berne LLP

(57) **ABSTRACT**

Embodiments of a syringe-based device for delivering fluid include a housing, a port, the port being positioned at about the distal end of the housing, a plunger assembly, the plunger assembly including, a plunger seal, a valve, and a cannula, a first fluid reservoir, where the first fluid reservoir retains a first type of fluid, a syringe including a syringe body, a syringe port, a plunger, and a second fluid reservoir, the second fluid retaining a second type of fluid, and where the syringe transitions from a first configuration in which a first portion of the first fluid type is delivered through the port, to a second configuration in which the second type of fluid in the second fluid reservoir is delivered through the port, to a third configuration in which a second portion of the first fluid type is delivered through the port.

18 Claims, 23 Drawing Sheets



Our Team



Michael J Hopkins RN II, BSN
CEO/Founder
True Concepts Medical Technologies

Michael has 24 years of critical care experience, recently retired from Cincinnati Children's where he worked in emergency medicine and trauma. He also has 25 + years of design experience and currently holds three US patents with multiple US & International patents pending.



Arash Babaoft, MD
CMO/Human Factors
True Concepts Medical Technologies

Dr. Babaoft has worked in the pediatric emergency setting for over 21 years and as an adolescent medicine specialist for nearly four years at Cincinnati Children's Hospital in. He has volunteered in over 60 international missions on five continents with various organizations. He has been instrumental in raising capital and the growth of True Concepts Medical Technologies.



Timothy J Hopkins, R.Ph, MBA.
Advisor/Business Development
True Concepts Medical Technologies

In his 26 years of progressive experience within pharmacy industry, Tim Hopkins played critical roles at PillPack, Inc., Omnicare, Inc. and WellPoint, Inc. In his most recent position as President and CEO for Resource Global Health, his focus is providing consulting services in the healthcare space.

Scientific Advisory Board



Joe Thomas, R. PH
Intellectual Property Expert
Chair of Ulmer & Berne's Life Sciences Group

Mr. Thomas's unique background as a licensed pharmacist, a member of the patent bar, an author of peer-reviewed scientific literature, and clinical researcher gives him a deep understanding of the science behind his clients' work.



Mary Beth Privitera, PhD
Human Factors Expert

Dr. Privitera holds an appointment as Associate Professor at the University of Cincinnati, working collaboratively among the Colleges of Medicine, Engineering and Design. She is the Director of the Medical Device Innovation and Entrepreneurship Program at the University of Cincinnati.



Sean Barnett, MD
Chief of Surgery Dayton Children's

Dr. Barnett is an associate professor at the Boonshoft School of Medicine, Chief of the Division of Pediatric Surgery, and the Chairman of the Department of Surgery at Dayton Children's Hospital. Coupled with his devotion to the surgical treatment of children, he has a keen interest in medical device design with experience in all aspects of development.



Frank Pokrop, BS
FDA Regulatory Expert

Mr. Pokrop has over 20 years of experience in regulatory affairs and manufacturing experience with parenteral drugs and medical devices. Formally designated liaison between industry, FDA, trade and standards associations and patient safety groups, he is experienced with domestic submissions and international product registrations.

Thank You

Michael J Hopkins
CEO/Founder
True Concepts Medical Technologies

(513) 568-2703
trueconceptsmedical@gmail.com

Hearing Questions Congressman Troy Balderson

Questions for Drs. Fahrenwald and Conti:

- 1) Thank you all for being here today; I think this is an excellent opportunity for us to understand some of the roles and responsibilities small medical practices have in our communities.

I believe I have a rather unique perspective on this discussion, as two members of my family (both my mother and daughter-in-law) work as nurses. I understand the hard work they put into both their patients and their field.

I believe one of the most critical components of this conversation centers around the impact rural broadband has for so many of these rural communities. And I'm glad that both of you included this issue in your statements. Given this, would each of you please walk us through the role rural connectivity could play in your respective fields?

Dr. Matthew Conti: Thank you for the question Congressman Balderson. I think rural connectivity plays a huge role in the ability of a practice to engage in telemedicine. Without access to high-speed internet, along with other relevant technologies, a physician and his team are not able to participate in most telemedicine activities. This can be problematic for rural areas where access to

specialty physicians is limited as well as limited broadband connectivity. Critical infrastructure and related financial and resource investment are required for rural practices to engage in telemedicine activities.

- 2) Continuing on from that, how can we work to ensure the safety of patients who are undergoing non-surgical telehealth procedures?

Dr. Matthew Conti: Telemedicine has great potential but must be practiced following clinical guidelines for the safety of patients. Evidence-based clinical guidelines must continue to regulate patient care in the telemedicine space.

In the field of orthopaedics, telemedicine has been utilized with success for pre- and post-operative care, particularly for patients in rural or low access areas. These visits typically are focused on simple follow-ups, routine post-operative visits, surgical discussions, wound checks, and MRI/lab result reviews. Telemedicine is not frequently used in the field to evaluate new patients, as those visits typically require the physical examination of the patient with a physician in-person. Complex and difficult cases must continue to be evaluated in the office setting to minimize risk and maximize surgical outcome for the patient.

Physicians who are practicing telemedicine to treat patients outside of their state of residency must also be familiar with

the licensure laws in the patient's home state, and also with any restrictions that the patient's home state places on the type of entity through which healthcare services may be rendered.

Questions for the panel:

- 1) As this is the Small Business Committee, we have heard from countless witnesses about the time and effort it takes to run a small business.

What can this committee do to ensure the nation's non-medical small business owners (i.e., farmers and ranchers) are benefitting from telehealth and telemedicine? I've talked with so many small business owners back home who simply cannot take a day off to drive the long distances into town for basic medical care. How can we better serve these Americans?

Dr. Matthew Conti: Critical investments in the technology and infrastructure required for physicians to provide telemedicine are essential in order to offer those services to patients in rural areas. Additionally, appropriate renumeration is required to incentivize physicians to be active participants in programs such as telemedicine. Education and outreach are also critical components to ensure the success of such programs as many of the patients who would be best served by these technologies either 1.) are not aware of their existence and 2.) aren't as

technologically savvy and may need additional support in learning or to utilize these services.

While telemedicine partially addresses the lack of access faced by those in rural areas, we also need to target the larger issue of a lack of providers living and starting practices in these areas. The increasing cost, growth of regulations, and administrative burden required to run a practice is an increasingly common challenge for those attempting to open a private practice in a rural area. Student loan debt is another factor that often deters physicians from relocating after residency to areas where patient volume and reimbursement may be lower than in more populous urban centers. We need to work on minimizing these issues while also incentivizing physician practice in rural areas to address the root cause of these access issues for farmers, ranchers, and others living in more rural areas of the country. While telemedicine is a useful tool in caring for patients, it does not serve as a true substitute for providers in many circumstances, and we must continue to work to ensure access to specialty physicians for those in rural/underserved areas.

- 2) Our hearing today has offered great insight into the challenges our rural communities face when trying to provide care. However, I also represent the great city of Columbus and want to touch on the impact these telehealth services could have in urban settings.

Do you believe an increase in the utilization of telehealth services in urban settings can help deliver quality care while providing cost savings? Would it be helpful to your practice(s) if Medicare would pay for remote programming of medical devices as a telehealth service?

Dr. Matthew Conti: We believe that there are merits to employing telehealth in a variety of practice environments, both urban and rural. Telehealth can be helpful for patients who have mobility issues and are unable to safely travel to a physician office following a procedure post-operatively. It can also offer the ability to remotely monitor patient recovery, pain management, wound care, etc. These applications would apply in both urban and rural settings providing quality care and potential cost savings for patients, physicians and the healthcare system.

Hearing Questions Congressman Troy Balderson

Questions for Drs. Fahrenwald and Conti:

- 1) Thank you all for being here today; I think this is an excellent opportunity for us to understand some of the roles and responsibilities small medical practices have in our communities.

I believe I have a rather unique perspective on this discussion, as two members of my family (both my mother and daughter-in-law) work as nurses. I understand the hard work they put into both their patients and their field.

I believe one of the most critical components of this conversation centers around the impact rural broadband has for so many of these rural communities. And I'm glad that both of you included this issue in your statements. Given this, would each of you please walk us through the role rural connectivity could play in your respective fields?

Dr. Nancy Fahrenwald's Response:

Broadband connectivity elevates all aspects of life in rural America, including education, business, and health care. Access to health care via telehealth is one example. In academic nursing, we embrace telehealth education as a way to educate the future nursing workforce, both registered nurses (RNs) and advanced practice registered

nurses (APRNs) like nurse practitioners. In many states, the nurse practitioner is the primary care provider who is serving rural areas and accessing a team of experts or colleagues for consultation as needed. While this work can be accomplished with the telephone, broadband enhances the telehealth component. In academic nursing, we are working diligently to ensure that telehealth care, and other technological innovations and tools, are at the forefront of our active learning strategies to assure the readiness of the workforce to provide care in all areas, including rural and underserved communities.

- 2) Continuing on from that, how can we work to ensure the safety of patients who are undergoing non-surgical telehealth procedures?

Dr. Nancy Fahrenwald's Response:

Patient safety is a top priority in nursing education, the nursing profession, and the healthcare community. Our nursing workforce is educated on safety standards, many of which apply across all types of care delivery, such as protected health information about patients, or thorough assessment. Further, academic nursing is utilizing and incorporating technological innovations, such as telehealth and simulation labs, into the education platform to ensure key competencies are met and that students develop into confident and competent practitioners.

Questions for the panel:

- 1) As this is the Small Business Committee, we have heard from countless witnesses about the time and effort it takes to run a small business.

What can this committee do to ensure the nation's non-medical small business owners (i.e., farmers and ranchers) are benefitting from telehealth and telemedicine? I've talked with so many small business owners back home who simply cannot take a day off to drive the long distances into town for basic medical care. How can we better serve these Americans?

Dr. Nancy Fahrenwald's Response:

We can better serve rural America by educating healthcare providers, including RNs and APRNs. In addition, the Committee and Congress could also better serve Americans by continuing to fund and reauthorize programs that are vital to educating the future and current nursing workforce, including Nursing Workforce Development Programs (Title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.]).

- 2) Our hearing today has offered great insight into the challenges our rural communities face when trying to provide care. However, I also represent the great city of Columbus and want to touch on the impact these telehealth services could have in urban settings.

Do you believe an increase in the utilization of telehealth services in urban settings can help deliver quality care while providing cost savings? Would it be helpful to your practice(s) if Medicare would pay for remote programming of medical devices as a telehealth service?

Dr. Nancy Fahrenwald's Response:

Telehealth services are integral in all healthcare settings and can reduce cost burden, increase quality of care, and lessen disruptions for patients. Preparing nursing students to utilize this technology is vital to ensure we are meeting patients where they are, while remaining that trusted patient advocate. As a nursing educator, I cannot speak to practice issues or Medicare payment models.



November 13, 2019

The Honorable Nydia Velázquez
Chairwoman
Small Business Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Steven Chabot
Ranking Member
Small Business Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Velázquez and Ranking Member Chabot:

Thank you for holding a hearing on "Upskilling the Medical Workforce: Opportunities in Health Innovation." The Healthcare Leadership Council (HLC) appreciates the opportunity to share its thoughts with you on this important issue.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

As you know, America faces a physician shortage upwards of 100,000 physicians by 2030, which could disproportionately affect rural and underserved communities. This will be detrimental to the care and well being of Americans across the United States. To ensure that physicians have the training they need, Congress should increase funding for Graduate Medical Education (GME) and increase the number of residency positions in both primary and specialty care. HLC urges Congress to pass the Resident Physician Shortage Act, which would increase the number of GME slots by 15,000 total or 3,000 per year. Additionally, Congress should pass the Advancing Medical Resident Training in Community Hospitals Act, which would raise the GME caps for hospitals that have inadvertently and unknowingly established medical resident training programs with

artificially low levels. Legislation such as the Opioid Workforce Act that would increase the number of GME positions in addiction medicine should also be approved by Congress.

Beyond training more physicians, opportunities in innovative healthcare practices offers another method to proactively address the shortage. HLC believes telemedicine and mobile health offer solutions for rural providers and underserved communities. Telemedicine offers providers a way to serve their patients at lower costs and helps reduce the time it takes patients to receive care—particularly specialty care. Telehealth lessens isolation and provides support to the rural health workforce while addressing provider shortages. Additionally, there are barriers such as restrictive reimbursement and regulatory policies that make it challenging to utilize telehealth. HLC urges Congress to support S. 773, the "Telehealth Innovation and Improvement Act" which would allow providers to test telehealth delivery models without regard to the limitations on the type of service provided, geographic areas or location of the patient.

Thank you for the Committee's work on improving workforce shortages in America. HLC looks forward to continuing to collaborate with you on our shared priorities. Should you have any questions, please do not hesitate to contact Debbie Witchev at (202) 449-3435 or dwitchev@hlc.org.

Sincerely,



Mary R. Grealy
President