



Working together to unlock the full potential of AI-enabled healthcare



By Robert Cohen

Digital health innovation is creating opportunities to transform healthcare in ways that were difficult to imagine even a decade ago. Medical technology, including AI-enabled devices, is helping clinicians detect diseases earlier, personalize treatments and become more efficient, all of which improves patient experience and outcomes. As leaders across the medtech industry for decades, who currently serve as the AdvaMed Digital Health Tech Board of Directors, we have seen firsthand how innovation can improve patient care and benefit patient outcomes. We have also seen how policy can either accelerate or slow that progress.

Today, there is an opportunity to accelerate clinician and patient access to cutting-edge AI-enabled medical devices. Clinicians and industry innovators lack access to the full spectrum of patient data needed to unlock the full potential of AI-enabled healthcare. Medtech company R&D teams seek

clear and efficient regulatory frameworks and predictable reimbursement pathways that keep pace with these rapidly evolving technologies.

Congress and the White House have an opportunity to advance these medtech AI-enabled innovations by enacting policy changes to facilitate continuum of care patient data access within our healthcare system. It is not an easy task, but if we get these policies right, the benefits for patients and the American healthcare system could be substantial — not just for this generation but for future ones as well.

We can start by building on what is already working well. For decades, the U.S. Food and Drug Administration has evaluated software-driven and AI-enabled medical devices for safety and effectiveness across the total product lifecycle. Today, the FDA has already authorized more than 1,500 AI-enabled medical devices for marketing in the United States.

The FDA should remain the lead regulator for AI-enabled medical devices and should continue to evaluate and adapt its regulatory framework to keep pace with the advances in digital innovation, and the White House and Congress should support the agency's efforts to oversee these rapidly evolving technologies. The agency's expertise gives the United States a distinct advantage in a global race to apply AI in healthcare in ways that can improve patient outcomes and help to drive efficiencies for the clinician, the hospitals, the caregivers and the patients. Healthcare AI is fundamentally different from the consumer-facing tools Americans use every day. AI used to help diagnose disease, guide treatment and support a medical procedure must be evaluated in the clinical context in which patients and clinicians rely on it.

Consistent healthcare data access policies can drive digital innovation that enable clinicians to use technology more effectively, including diagnosing disease and supporting medical procedures, and reducing burdens on health systems already stretched thin.

AI is already a valuable asset for clinicians. It can help reduce medical errors, increase accuracy and precision in surgical procedures, and bring efficiency to workflow and administration. To continually advance and improve, AI must know what “right” looks like, and that is achieved through access to data. In the years ahead, we must be able to get more granular and specific health data. The medtech industry already has adopted protocols to de-identify data and safeguard it, many of which are in use today. With greater data access, accuracy can improve, bias in models can be reduced and digital innovation can advance.

High-quality, representative data are essential to developing, validating, monitoring and improving AI-enabled medical technologies. Patients deserve confidence that their health information is protected and used appropriately, while innovators and clinicians need clear, consistent rules that support interoperability, uniform data standards, and responsible data-sharing practices. A patchwork of conflicting state requirements risks making it

harder to build tools that work safely and fairly across diverse populations and care settings.

Congress should enact a federal privacy framework that protects patients while enabling responsible, uniform data access across a patient's continuum of care. Consistent policies can help clinicians use technology more effectively, support model validation across real-world settings and reduce burdens on health systems already stretched thin by expanding access to good care in rural and underserved areas.

To inform design refinements for surgical procedure patients, doctors and medtech engineers should be able to learn from relevant preoperative, operative and postoperative data. Much of this information exists today, but is often scattered across various locations, with varying levels of access for clinicians and medtech engineers. True data access requires the stitching together of data across a patient's journey in their continuum of care relevant to their surgical needs. The full picture is what will enable AI to drive improvements in the procedure and care. Unlocking that data must go hand in hand with robust privacy protections — including appropriate de-identification and security safeguards — so that patients can trust that their information is handled responsibly.

Governance structures for the responsible use of data are critical to data sharing and advancements in AI, and the private sector has a role to play here. The AdvaMed Digital Health Tech Board is developing voluntary Data Access Principles and Best Practices to promote trust, transparency, responsible data stewardship, and effective collaboration across the healthcare ecosystem. They will reflect a commitment by medtech

companies to use data in ways that advance patient care and outcomes; enable innovation, including AI and advanced analytics; respect privacy and legal obligations across data types; and support collaboration with healthcare providers and facilities. We hope that once public, these Data Access Principles and Best Practices will help build trust and enable greater data sharing and collaboration across the healthcare system to ensure that patients can benefit from this next generation of healthcare.

With thoughtful policy that supports appropriate regulation and responsible data use, AI will continue to help detect disease earlier, personalize treatment, make care more efficient and accessible and improve the lives of millions of people. None of this means lowering standards. It means building the right standards: ones that protect patients, earn clinician trust, recognize the difference between medical and consumer AI and promote the development and evolution of transformative technologies.

We are already using AI-enabled devices, but there is so much more we can do. The medtech industry's AI journey has tremendous potential, but many advances remain limited by barriers to data access. The potential for digital and AI-enabled devices to improve patients' lives and deliver measurable clinical and economic benefits is real. Washington should act now to ensure patients can realize this potential.

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Robert Cohen is chairman of the Digital Health Tech Division Board of Directors at AdvaMed, the largest trade association for medtech and health tech innovators. He is also Vice President, Innovation and Technology, of the Orthopaedic Group at Stryker.



AI Is Already Improving Patient Care



**SMART POLICY
CAN UNLOCK ITS
FULL POTENTIAL**

AI-enabled technologies are already helping detect disease earlier, personalize treatment, and improve patient outcomes. With policies that keep pace with innovation, more patients can benefit from better care across America.



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AI

ON THE HILL

Tech for a better life

We are going to cure cancer. AI will help us do it



By U.S. Rep. Rich McCormick, R-Ga.

We are going to cure cancer. I do not say that lightly. I say it as an emergency room physician who has spent countless years practicing medicine and as a Member of Congress working at the intersection of biotechnology and super intelligence (formerly, “artificial intelligence”). Super intelligence is giving physicians and researchers the ability to analyze medical information at a scale and speed that no human being ever could. Pair that computational power with breakthroughs in biotechnology, genomics and precision medicine, and we are approaching a fundamental shift in how we diagnose and fight disease. Cancer may be where that shift matters most. Cancer is not one disease with one cure. Two patients can develop cancer in the same organ and respond differently to the same therapy. Every tumor carries its own biological characteristics, mutations and vulnerabilities. SI gives us an opportunity to attack these complexities head on. Imagine detecting a tumor before a patient ever develops symptoms. Imagine analyzing a patient’s genetics, pathology, imaging and medical history together to determine which treatment is most likely to work



protected. Physicians must understand the tools they use, and patients deserve accountability when those tools fail. But safety and innovation are not opposing choices. We can protect patients without protecting the status quo. I have spent much of my adult life caring for patients. I know what it is like to stand beside a hospital bed when medicine has exhausted every option it has. SI gives us an opportunity to create new ones.

We have the ingredients to lead: the world’s greatest research institutions, physicians, entrepreneurs, technology companies and biotechnology ecosystem. But our advantage is not guaranteed.

A cancer detected before it spreads. A drug discovered years faster. A treatment designed around the biology of one patient’s tumor instead of the average of thousands of patients who came before them. America has led the world through generation after generation of medical breakthroughs. We now have the opportunity to lead the next one.

If we get this right, super intelligence will not make medicine less human. It will give us more power to save human lives. I believe it can help us finally cure cancers we once thought unbeatable.

Dr. Rich McCormick is a decorated veteran and Emergency Room physician who proudly serves Georgia’s 7th Congressional District in the United States House of Representatives. Congressman McCormick serves on the House Armed Services Committee, Oversight & Government Reform Committee, and the House Committee on Science, Space, and Technology, where he serves as Chairman of the Subcommittee on Investigations and Oversight. As a former AI Task Force member, he is a leading voice on emerging technology policy in Congress.

before the first dose is administered. Imagine researchers searching enormous amounts of biological data for connections that would take human beings years to uncover. These possibilities are no longer science fiction. Researchers are already demonstrating how SI can improve cancer screening by analyzing complex medical samples and helping identify patients at greater risk of serious disease. That means greater consistency, greater scale and, most importantly, earlier intervention. And we are seeing the same transformation elsewhere in medicine. At Children’s Hospital of Philadelphia, physicians are using SI-powered tools built with open-source technology, including NVIDIA’s MONAI medical imaging framework, to create patient-specific models of children’s hearts. Work that once required hours

can now be performed in seconds, helping physicians understand a child’s unique anatomy before a complex procedure begins. Today, we can model a heart. Tomorrow, we can increasingly model disease. By harnessing SI, we can begin to predict how a cancer may progress, identify promising drug targets, match therapies to individual patients and dramatically accelerate the process of developing new treatments. After more than two decades treating patients, that is what excites me most about super intelligence. As a member of Congress, it also makes something else clear: America must lead this revolution. That is why I have made super intelligence and biotechnology priorities of my work in the 119th Congress. I introduced the bipartisan Biotechnology Workforce Alignment Act to better connect American

biotechnology research with the workforce needed to turn scientific breakthroughs into medicines, technologies and companies. I also introduced the Biotechnology Diplomacy Leadership Act to strengthen American biotechnology leadership around the world. We have the ingredients to lead: the world’s greatest research institutions, physicians, entrepreneurs, technology companies and biotechnology ecosystem. But our advantage is not guaranteed. China understands that dominance in technology will translate into economic, medical and national security power. If Washington responds to every technological breakthrough by asking first how we can restrict it, we will hand that advantage away. That does not mean abandoning safeguards. Medical SI must be rigorously tested. Patient privacy must be

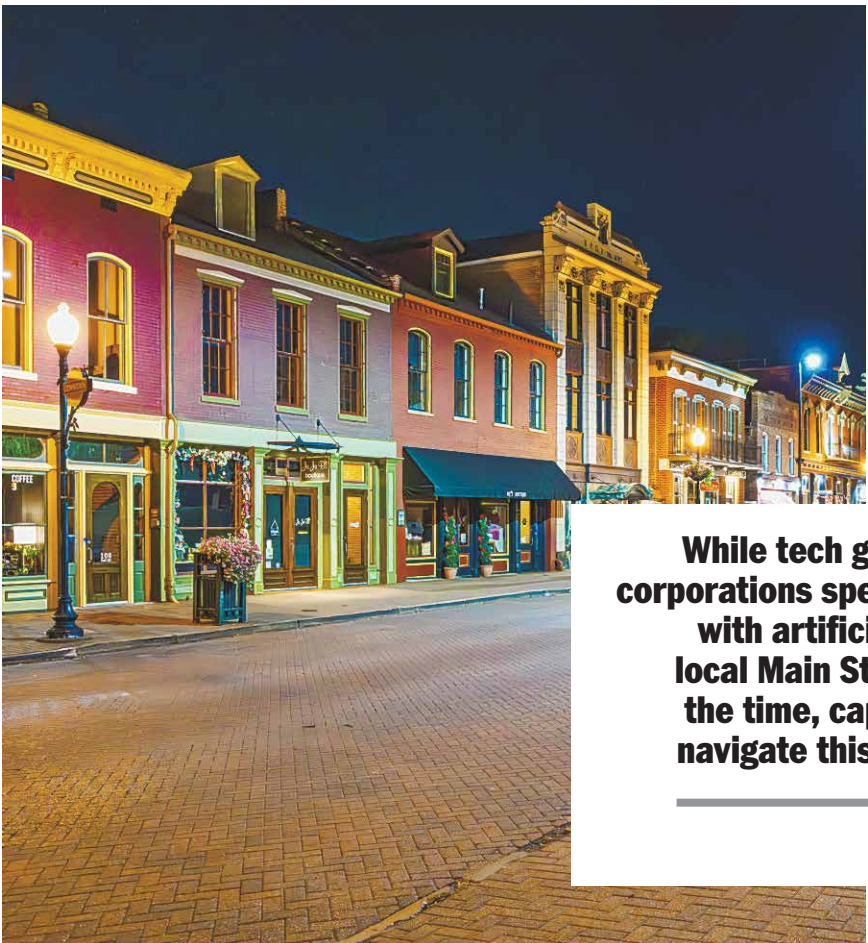
Empowering Main Street: Why small businesses deserve a seat at the AI table



By U.S. Rep. Mark Alford, R-Mo.

Main Street stands at the doorstep of a profound economic transformation. Across our nation — from the historic storefronts of Missouri to bustling commercial corridors nationwide — small businesses are the heartbeat of our local communities. They are the backbone of our economy, driving job creation, fostering local innovation and embodying the American dream. Yet, as a new technological era unfolds, a quiet divide threatens to leave our entrepreneurs behind. While tech giants and Fortune 500 corporations spend millions experimenting with artificial intelligence, many local Main Street shop owners lack the time, capital and resources to navigate this digital frontier alone. Under the capable leadership of our Small Business Committee Chairman — Rep. Roger Williams, R-Texas

— House Republicans are championing policies that level the playing field and ensure that the AI revolution is harnessed by everyone, not just the corporate elite. The technological landscape is moving at breakneck speed, and AI is no longer a distant sci-fi concept. It is already here. Across the country, Main Street business owners are looking for practical ways to optimize their operations, streamline inventory and connect more effectively with their customers. We are seeing real-world examples of this shift emerge across the market. Tools like Meta’s Muse for Small Business and various digital assistant initiatives are demonstrating how generative AI can help local enterprises craft targeted marketing campaigns, design creative assets and manage customer relations in a fraction of the time. For a busy family-owned bakery, a local HVAC technician or an independent hardware store, these capabilities can mean the difference between merely surviving and truly thriving. But knowing that a tool exists is very different from having the guidance to use it effectively. Large corporations can easily hire specialized tech consultants and expensive trial teams to map out their digital transition. A neighborhood retailer working eighty hours a week simply does not have that luxury. To bridge this widening gap, the House passed the AI for Main Street Act, a bipartisan bill I proudly lead. Our legislation is designed to ensure that small businesses are not sidelined in the modern economy. Specifically, the bill empowers the Small Business Administration (SBA) and leverages successful frameworks like America’s



Illuminated historic storefronts along brick-paved Main Street in St. Charles, Missouri.

While tech giants and Fortune 500 corporations spend millions experimenting with artificial intelligence, many local Main Street shop owners lack the time, capital and resources to navigate this digital frontier alone.

Small Business Development Center (SBDC) network to expand guidance, targeted training, and hands-on outreach. By scaling initiatives like the SBDCs’ “AI U” model nationwide, we are giving entrepreneurs access to one-on-one coaching, practical educational resources, and the technical confidence

they need to integrate AI safely and efficiently into their daily workflows. Let me be crystal clear: the AI for Main Street Act is not about replacing people; it is about empowering them. It is about giving a family-owned business in rural Missouri or downtown Kansas City the exact

same opportunity to compete, grow and innovate as a multi-billion-dollar enterprise. Technology should serve as a force multiplier for human ingenuity, freeing up hard-working small business owners to focus on what they do best: serving their customers, supporting their workers, and building strong communities. When we empower our small businesses, we secure the future of American entrepreneurship. We must ensure that the tools of tomorrow are accessible to the local risk-takers and job creators of today. By passing commonsense, forward-looking legislation like the AI for Main Street Act, House Republicans are ensuring that America’s small businesses remain the most competitive, vibrant and resilient engine of economic growth in the world. Rep. Mark Alford represents Missouri’s Fourth Congressional District in the U.S. House of Representatives. He serves on the powerful House Appropriations Committee as well as the House Small Business Committee, where he chairs the Oversight, Investigations, and Regulations Subcommittee.