



# THE RECORD

Interagency Institute for Federal Health Care Executives

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## ***From the Director...***

Over the years we have held Institutes at stormy and unsettling times – politically and meteorologically! These have included 9/11/2001 and Hurricanes Isabel and, most recently, Florence. The 133rd Interagency Institute occurred during one of these significant times. Many faculty members addressed the serious challenges and issues we are facing within the public and private sectors of our health care system, the nation and globally. It is very easy to feel that these negative and frightening trends are overwhelming and irreversible. This is not necessarily so and our faculty made it very clear that what is needed is strong, positive leadership at all levels. VADM Forrest Faison, MC, USN, Surgeon General of the United States Navy, made this point very forcibly in his comments at the Embassy of Australia. A summary of his remarks are included in this newsletter. I hope that the recent graduates and their fellow alumni/ae throughout the federal health services will appreciate the importance and relevance of these challenges and do whatever they can to be the kind of leaders required for the future.

I was especially pleased to observe the small groups in action and to hear their presentations at the 133rd Institute. All five topics are relevant and timely. I think that our readers will find their analyses and recommendations to be stimulating and helpful.

While just a little bit biased, I was very proud and appreciative to be able to hold the ‘Lessons From Other Countries’ session during this Institute at the Embassy of Australia. Ambassador Katrina Cooper, Deputy Head of Mission, and Brigadier Shane Gabriel, Military Attaché and Assistant Defence Attaché, along with their staffs, were most gracious and welcoming. It was a special honor to have Brigadier General Andrew Downes, Surgeon General and Commander Canadian Forces Health Services Group, participate in the Senior Federal Health Leaders Panel, along with the representatives from the US Navy, US Air Force, US Public Health Service and the Department of Veterans Affairs. General Downes is a graduate of the Institute and a strong supporter of our professional development program.

These Institutes could not happen without the support of our Uniformed Services University of the Health Sciences colleagues, the Henry Jackson Foundation, our alumni/ae and the staff of the DoubleTree by Hilton hotel. Janet and I are most grateful.

We strongly encourage the Institute alumni/ae to attend the FHCEIAA Annual Meeting and Breakfast at the 2018 AMSUS Conference at Gaylord National Harbor on November 29, 2018.

With best wishes,

Dr. Richard F. Southby



## Letter from the President, FHCEIAA

Congratulations to the alumni of the 133rd Interagency Institute. I welcome new members to the Federal Health Care Executives Institute Alumni Association. We are pleased that you joined our team and ranks. A special thanks to Delta Dental of California, Health Net Federal Services, LLC, Express Scripts, Inc, and Spectrum Healthcare Resources for their generous support of our Institute dinner, education program and transportation which was held on September 13, 2018, at the Army Navy Country Club, Arlington. It was a truly exceptional dinner, venue and gathering with insightful remarks presented by our guest speaker, Dr. Steve Miller, Express Scripts Chief Medical Officer, regarding, "The Evolving Role of Pharmacy in a Dynamic Healthcare Environment".

Please check out our social media presence on Facebook and revisit for updates. We highly encourage you to use this tool to post your own updates, maintain connections, collaborate and respond. You can locate us by name search or through our direct link: <https://www.facebook.com/Federal-Healthcare-Interagency-Institute-1805076689707896/>

If you have not yet joined FHCEIAA, I encourage you to consider becoming a member. Membership ensures maintaining connectivity and collaborative opportunities to maximize resourcefulness and effectiveness throughout the federal health care system. Additionally, members receive the FHCEIAA newsletter twice annually, their dependent children or grandchildren are eligible to apply for a \$1,500 scholarship, and they are eligible to apply for a \$2,000 professional development scholarship. Also, local members are invited to attend the Institute dinner and all are encouraged to attend the FHCEIAA Annual Meeting. If you have any questions or would like to inquire, kindly contact CAPT (Ret) Gayle Dolecek at [gjdolecek@verizon.net](mailto:gjdolecek@verizon.net).

Administratively, I ask each of you to assure that CAPT Dolecek has your current e-mail address and that you add him to your e-mail contacts in order to avoid FHCEIAA messages ending up in your spam folder.

I invite you to the **FHCEIAA Annual Business Meeting**, being held during the AMSUS Annual Continuing Education Meeting, at the **Gaylord Convention Center, National Harbor MD, on November 29, 2018, from 0645 – 0745**. We will meet in **National Harbor Rooms 2/3**. A Continental breakfast is available for a reduced rate of \$25. You may register as part of the AMSUS registration at <https://amsus18.registerat.com/Home.aspx> or you may call Ms. Janet Neiman at 301-828-1589 to reserve. We hope for a good turn out of Institute graduates to be active participants and make valuable contributions to the discussion.

As always, we want to tap into the energy and enthusiasm of the alumni for fresh ideas on how to advance the organization. **If you are interested in serving as an FHCEIAA board member, kindly express your intent as soon as possible by sending me (Aaron.P.Middlekauff@uscg.mil) or CAPT Dolecek an email.**

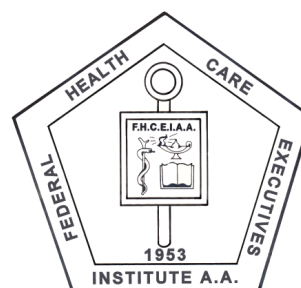
It has truly been my honor and I have been humbled to serve as your president the past two years. I look forward to continue to serve as an active member and synergistically achieving extraordinary accomplishments!

Sincerely,

Aaron

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## “Lessons from Other Countries” - Visit to the Embassy of Australia

As mentioned in the Director’s column, the institute participants were welcomed to the Embassy of Australia on September 18, 2018, by Ambassador Cooper and Brigadier Gabriel. Then the Senior Federal Health Care Leaders Panel included remarks by Brigadier General Andrew Downes, CF; Vice Admiral Forrest Faison, USN; Major General Sean Murphy, USAF; Rear Admiral David Goldman, USPHS; and Dr. Gerald Cox, VHA, followed by a lively Q&A session. In the afternoon, the “Lessons From Other Countries” presentations addressed the health care systems of Australia, Canada, Germany and the United Kingdom. The speakers were Wing Commander Elicia McGinniss, RAAF (a participant in the 133rd Institute); Lieutenant Colonel Andrew Currie, CF (a graduate of the 132nd Institute); Colonel Kai Schlolaut, FRG; Group Captain Martin Ruth, RAF; and Dr. Richard Southby.



### Comments by Vice Admiral C. Forrest Faison, III, Surgeon General and Chief, Bureau of Medicine and Surgery, USN

VADM Faison, a graduate of the Interagency Institute, has been a regular participant in the Federal Senior Health Care Leaders Panel, which has been a highlight at each Institute.

At this Institute, he began his remarks by emphasizing the significant changes which are occurring in the global environment and the world of military health care. Consequently, the most important message for military health care leaders is that new leadership strategies will be required to meet these challenges. The world is changing rapidly and dramatically and old solutions will not be acceptable or effective.

The Surgeon General noted that we came out of Iraq and Afghanistan with a 97% combat survivability rate. Military medicine needs to prepare to maintain this high survivability rate in the next battle, which is most likely to be at sea.

VADM Faison questioned how will the ill and injured be treated when we do not have control of the battle space on shore or on the sea or in the air? He explained that his top priority is to focus on readiness and the ways in which it can be maintained in the next battle space. He emphasized that it is imperative to collaborate with our line commanders to anticipate the next battle space which will be very different from past experiences. This will include identifying singular points of failure, inefficiencies and opportunities to provide the best care to our Soldiers, Sailors, Airmen and Marines. A new kind of leadership will be essential at every level to review current practices and reevaluate the ways combat health care is organized and how it will be delivered in the future.



VADM C. Forrest Faison, III



## The Evolving Role of Pharmacy in a Dynamic Healthcare Environment

Steve Miller, MD

Chief Medical Officer, Express Scripts

Prescription drug prices keep rising – the average price of brand medications increased 232 percent from 2008 through 2017, according to Express Scripts' prescription price index. At the same time, more benefit providers are offering high-deductible and consumer-driven health plans. And some patients are getting stuck in the middle, facing bills they cannot afford for medication they need.

As a society, the U.S. spends more on healthcare overall than other developed nations: Per capita costs are \$9,500 here, compared with an average of \$3,763 average among Organization for Economic Cooperation and Development countries. Yet we have some of the worst healthcare performance, according to a 2017 Commonwealth Fund analysis.

While representing less than 5% of the world's population, the U.S. makes up approximately one-third of global drug spend and more than half of drug manufacturers' profits. When pharmaceutical companies charge as much as they can in the United States, the nation's employers and government programs are forced into no-win situations: cover expensive treatments and suffer the financial consequences, or cut back essential care and leave beneficiaries out in the cold.

Pharmaceutical innovation is good news for patients who need novel treatments, even cures. Gene and cell therapies are true breakthroughs with the potential to cure deadly and life-altering diseases. But even the best medication isn't effective if patients can't access it.

However, a common-sense combination of legislative, regulatory and business actions can fix what's broken and achieve what we all want: a system that provides the best care, at the highest value and lower cost for American consumers.

What we need is a new approach, one that drives the best patient care and value by leveraging advances not just in medicine, but also in technology and consumer behavior.

Doctors' offices of today don't look much different than they did a century ago: An exam table, a sink, a few modest instruments and a way to take notes. We keep building more versions of the same thing in a proliferation of hospital beds and urgent care centers. Yet what patients need and want – as reflected in other areas of their lives – are convenient, easy to use, high-tech approaches to managing health care.

We can do things differently to achieve better results.

### **From Apathy to Adherence: Data Analytics and the Rise of Digital Health**

According to a recent survey by Russell Research, many Americans on medications for chronic diseases are not concerned about missing doses, don't appreciate reminders from their spouse or partner, and think they do a better job than others at taking their medication as prescribed. For this reason, nonadherence to medication continues to be our nation's costliest healthcare challenge, generating \$337 billion in annual medical waste alone. However, Express Scripts' investment in digital health technologies that focus on adherence avoidance continue to yield not only higher savings, but also better health outcomes for those with chronic conditions.

It began with a simple question: "What if physicians could detect when their patients were going to become nonadherent?" With this in mind, Express Scripts developed proprietary, real-time, disease-specific predictive models to identify patients at risk of nonadherence with as much as 94% accuracy. That enables personalized interventions -- delivered by specialist pharmacists -- to help patients overcome the barriers to adherence and stay on their therapy. Through the use of digital health technologies, we see the highest rates of medication adherence across our 80 million members



who use the Express Scripts and Accredo pharmacies, where patients are supported by data-driven resources and specialist pharmacists who understand their medication needs and issues.

To encourage patients to remain adherent, there are approaches such as Mango Health, a mobile health company that provides a daily health management platform. The Mango app helps patients develop healthy habits and manage their medication adherence by tackling the biggest driver of non-adherence: forgetting. It helps people follow their doctors' instructions by making it easy to track the medication schedule and set up reminders, and facilitates ordering prescriptions directly from their device with the pharmacy of their choice. The app also educates patients about their chronic conditions, and offers solutions for caregivers who can track their loved one's medications even when living in different cities.

Another approach to improve adherence and treatment outcomes is through real-time remote monitoring, which helps members and their pharmacists better manage chronic conditions including diabetes, asthma and COPD, and address adherence issues immediately. Remote, Bluetooth-enabled devices such as asthma inhalers and glucose monitors can send real-time data to the care team and flag warning signs to trigger an intervention.

### **Care for the Rare: Gene Therapy**

In addition to digital health platforms, gene therapy has recently received significant attention within the healthcare space – and for good reason. Approximately 4,000 diseases are linked to gene disorders, and many lack any effective treatment. As a result, gene therapy has the potential to treat – and cure – some of the most debilitating diseases patients face.

Unlike traditional drug therapies, gene therapies introduce genetic material into a person's DNA to "edit" and replace faulty or missing genetic material that leads to disease. Unlike nearly all other medications that are repeatedly taken over time, these therapies typically are administered once with the intent to provide long-term benefit, and in some cases, a cure.

Since the first of these therapies to market cover rare conditions, the large cost of R&D must be offset by a small population of patients – and that translates to therapies that cost over \$1 million for a course of treatment. This occurs once and may yield a lifetime benefit, which also means the price hits payers and patients in a lump sum, rather than being spread over years as in a long-term, chronic treatment.

Our system is not set up for very high-cost, "one and done" treatments. So we must explore novel drug management and payment models.

One of the first gene therapies to market, Luxturna™, treats a rare type of inherited retinal dystrophy that causes blindness in children. Its list price is about \$425,000 per eye. In order to help patients and payers manage the cost, Express Scripts worked with the manufacturer and hospitals to put in place outcomes-based rebates, an innovative contracting model and a system for payments over time.

American healthcare isn't perfect, but it's full of opportunities like these to think and act differently on behalf of patients, payers and the sustainability of the system. When pharma companies develop cures, and we can work together to get them into the hands of people who need them, we all win.



Dr. Steve Miller, Senior Vice President & Chief Medical Officer, Express Scripts, was the guest speaker for the 133rd Interagency Institute Participants and Alumni Dinner on September 13, 2018, at the Army Navy Country Club, Arlington, Virginia.

**“MY GENERATION WAS SUPPOSED TO LEVEL AMERICA’S PLAYING FIELD. INSTEAD WE RIGGED IT FOR OURSELVES.”**

Article by Steven Brill, TIME, Vol. 191, No. 2, pp. 32 - 39, May 28, 2018.

**Group Assignment:** Prepare a critical review and analysis of the article cited above. Is Brill’s diagnosis of what ails our society valid? In addition to his optimistic outlook that the ‘new achievers’ will be able to get America ‘back on the right course,’ what additional policies and changes will be necessary to achieve these lofty goals?

**Group Members:** CAPT Wanza Bacon, USPHS, COL Carlene Blanding, USA; CAPT Han Bui, USN; Col Craig Forcum, USAF; COL Robert Kent, USA; Mrs. Andrea Massey, VHA; Dr. Bonita McClenny, VHA; Col Joann Palmer, USAF; Col Vito Smyth, USAF; CDR Phil Timmons, USN; and CAPT Tony Voeks, USN.

**Introduction.** Steven Brill used a perspective of the last 50 years and referred to the US economy as being in a tail-spin. He explained concerns relative to meritocracy. According to Merriam Webster (2018) meritocracy can be defined as a system in which the talented are chosen and moved ahead on the basis of their achievement. Brill explains that “...many of the most talented, driven Americans used what makes America great: the First Amendment, due process, financial and legal ingenuity, free markets and free trade, meritocracy, and even democracy itself, to chase the American Dream. And they won it, for themselves.” (page 35). Further, Brill asserted there are now systems in place that protect the wealthy. He explained, that since the 1960’s, the real polarization that has broken America has been the protected vs. the unprotected, the common good vs. maximizing and protecting the elite winners’ winnings.

The discussion of this economic divide as occurred in America can also be found within the global economy, as this is what America did within the global economy. This is not a stagnant situation of a separation between the 1% and the 99%. The 1% continues to further distance themselves to escalate this issue. A generation of wealth concentrated in fewer and fewer hands where instruments are created to keep the wealth concentrated and used to buy political access continued this concentration where property instead of people was the focus.

**Validity of Diagnosis.** While this diagnosis is valid, the economic situation has been going on for more than 50 years as highlighted in this article. An example goes as far back as the Roman empire. Knowing this, it is evident that this economic divide is not a characteristic of democracy but human nature. People tend to act for short-term self-interest.

While this is a component of what is ailing America, it is not the only thing ailing society. While income/economic disparities are examined in this article, no other disparities are discussed, such as health care disparities. What has transpired is the acceptance of transferring the negative risk of decisions to others. Since 1% could transfer risk to the 99% there is no need for concern because the risk is gone from the 1%. With that being said, everything ailing society can’t and shouldn’t be attributed/blamed on the 1%. A leading factor as to why this is acceptable goes back to the U.S. Supreme Court held in Citizens United, which asserted corporations, Not for Profits, and unions have a First Amendment right to make independent expenditures for communication. As a result, the balance of resources to spend in the political process has shifted away from individuals to corporations and other entities with greater resources to spend (Cornell University Law School, 2018).

**Recommendations.** In reviewing the information in Brill’s article, there are three primary recommendations: Congressional accountability, voter reform and community engagement.

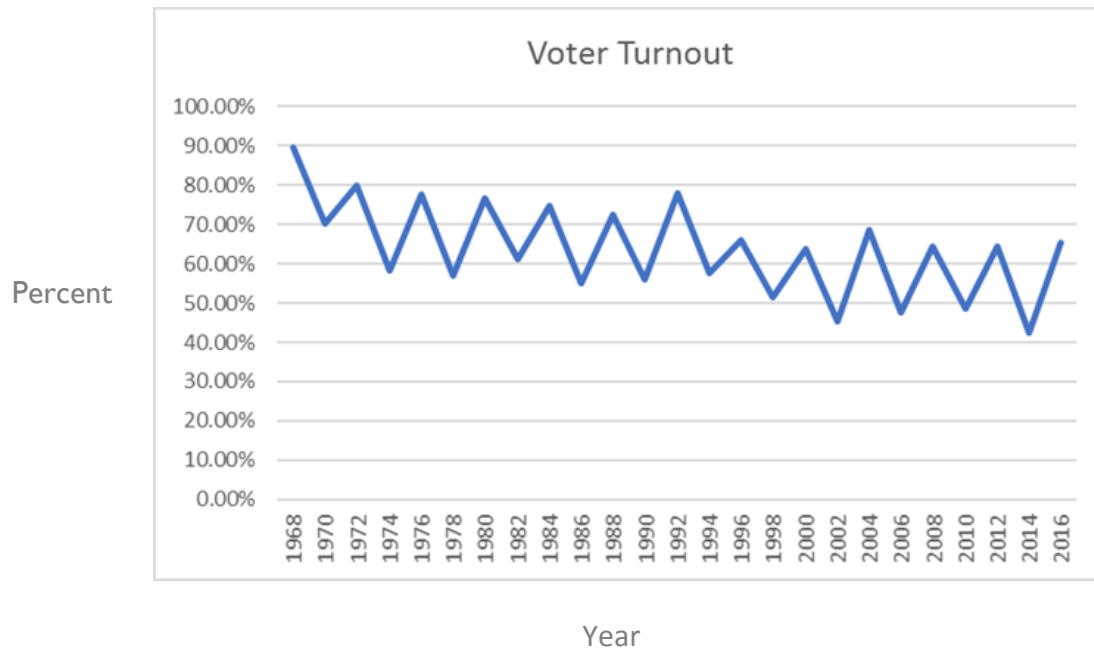
Congressional accountability should be accomplished through increased transparency and policy changes. The policy changes include:

1. Amending the 1995 Congressional Accountability Act to allow for enhanced accountability of those elected to congressional positions.
2. Distribution of power (Federal vs. State) to push the decision-making where appropriate from the Federal level to the states.
3. Campaign finance reform to enforce a limit on campaign donations by large corporations and the 1%.
4. Lobby Reform which should limit the outsized role of lobbyists to defend corporate interests on Capitol Hill.



5. Tax reform to incorporate standardization in tax law and work to eliminate many of the tax loopholes and make the system more equitable for all.

Voter reform should include a review of voter registration trends, voter turnout, voter education (upstream interventions) and redistricting by an independent bipartisan committee. The U.S. has seen a steady overall decline in voter turnout since 1968 as indicated in the chart below (The International Institute for Democracy and Electoral Assistance, 2018).



This decline in voter turnout supports the need for reform as a means for the US society to come together and have ownership in determining the way forward for our country. Consideration must be given to reasons for and ways to decrease the polarization of voters. Voter education should be incorporated into school curriculums starting in middle school. This would include content on Congress, the congressional processes, and ways to become informed and engaged with political issues throughout pre-adolescence into adulthood. While redistricting is something that currently occurs, it is typically lead by the party having control. The recommendation is for the redistricting to be conducted by an independent bipartisan committee which should eliminate gerrymandering.

Finally, community engagement is critical to addressing the lofty goals outlined by Brill. Continuing efforts through education to enhance engagement in the political process, consistent long-term education about the civic process, and education on how to hold politicians accountable should be the foundation of this community engagement.

**Conclusion.** While we acknowledge that these proposals are the tip of the iceberg, we believe that implementation of the recommendations at the grassroots level will assist in rebalancing America and facilitate improvements in the long-term.

#### References:

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## UNIVERSAL HEALTH COVERAGE IN THE UNITED STATES

**Presenting Group Members:** COL Darrin Cox, USA; Mr. Keith Essen, VHA; Col Colleen Forestier, CF; Mr. Mark Henius, VHA; Col Kathleen Jones, USAF; CAPT Paul Jung, USPHS; Col Myron McDaniels, USA; WGCDR Elicia McGinniss, RAAF; CAPT Shawn Ricklefs, USN; Col Michele Shelton, USAF.

### INTRODUCTION

Our group was assigned the unenviable task of addressing some key questions regarding universal healthcare for the United States population. This task was partially based on the Economist article “Universal health Care: An affordable necessity” written by John McDermott in April 2018. It would seem that all questions related to this complex issue can be answered with the simple phrase of “It depends.”

### **Is universal coverage for health care, with all that this implies for access, quality and costs, a worthy and high priority social objective?**

Overall, universal coverage is a worthy social objective, but it may not currently be a high priority social objective in the United States. Given the three elements of access, quality and costs, research has repeatedly demonstrated that universal healthcare overall reduces cost, and improves economic growth. A system of universal coverage is also likely to facilitate effective quality improvement by providing a standardized framework to assess effectiveness of healthcare delivery and practice. However, it remains to be seen whether increased access and improved quality are currently high priority for the US, as evidenced by political activities in recent elections and Congressional efforts to move such proposal and legislation forward. Addressing this issue from an economic perspective may get more traction and be viewed as a higher priority than attempting to address this from a social justice perspective.

### **What services and programs should be covered?**

The determination of what services and programs should be covered under a universal healthcare model can be a particularly challenging task, especially when we know that healthcare is constantly evolving and the factors that affect health are broad and complex. In trying to determine appropriate services and programs, there is a risk of falling into the practice of formulating “lists” which inevitably create an inflexible framework that does not meet the requirements of the constantly evolving health landscape.

The central and overlying theme of what should constitute “baseline programs and services “ needs to consider how these programs and services will influence overall population health and mortality, and what evidence exists to support them. Generally all “necessary care and programs that prevent and treat disease” should be covered. Most countries that offer universal health care coverage include at a minimum; emergency care, primary care, basic surgery, acute in-patient care, preventative health and community health programs, antenatal and pediatric care.

Consideration for covering additional services such as dental, optometry and pharmaceuticals is needed as these are considered basic healthcare by some countries but not in others.

### **How should health and related services be organized, financed, and provided?**

The question of how health services should be organized, financed and provided created a great deal of debate amongst our group, and just as the politicians have not reached a consensus, neither have we (although we do hope our trust score is higher than Congress!).

Overall, while we do agree that the federal government has a role in funding and oversight, the determination and delivery of resources would be more successful if managed at the state level. This would ensure a baseline healthcare standard is met, and would provide the flexibility for each state to tailor care to their population and resource challenges. In addition, a universal healthcare system would only function if contributions through either taxation or other funding mechanisms are applied across the entire population in order to balance the risk pool.

There is no doubt however, that private insurance, either through employer plans or individual plans, would continue to play a key role in the provision of additional options for accessing healthcare.





If the role of the universal healthcare is to focus on population health then the provision of care would need to shift from a specialist focused system to a more primary care based system in order to strengthen the preventative and wellness care components of health and help ensure that specialist resources are being used as efficiently and effectively as possible. However, this shift would create a need for significant down-tasking as well as creative adjustment of the primary care delivery models that currently exist. This would thereby incentivize providers and patients to follow evidence based guidelines and for developing holistic healthcare plans.

### **What are the implications for the education of health professionals?**

The nation would need to rethink what defines a “clinician” and how their skills are effectively used. A system of universal coverage will require significant assessment of its health professional workforce to ensure that the needs of the system are being met. If the health system focuses on increased access to primary care, for example, the workforce development system must develop a plan to produce larger numbers of primary care providers (and conversely stop producing larger numbers of specialists) and ensure the plan aligns the entire education requirement (e.g. additional clinician undergrad slots are aligned with clinical placement availability). An emphasis on high-quality care or interdisciplinary care will require training of health professionals capable of engaging such skills. Meaningful consideration and planning will be required to develop a workforce to match the goals of a universal health coverage system.

### **What are the major obstacles in American society to achieving ‘universal healthcare’?**

The culture of individualism and classic liberalism embedded in the social fabric of American society makes the adoption of universal health care particularly challenging.

Some of the significant obstacles that need to be considered include: Powerful special interest groups, deep-seated ideologies, and a serious misunderstanding of the meaning and role of universal health care, making it difficult for the average person to understand how universal health care would potentially benefit them, their families and the economy. There also exists an overall mistrust of social institutions and the politics associated with them that creates a reluctance to accept any government-directed changes in healthcare.

### **But can these obstacles be overcome?**

It is important to remember that other countries (e.g. Canada, Australia, Germany) that successfully adopted universal health care models also encountered serious opposition and social discord during its introduction, but have managed through education and experience to adjust to a new “norm”, and now consider universal healthcare to be part of their culture. However, most of these countries were navigating a healthcare landscape that wasn’t nearly as complex as the current US “system.”

Many US citizens may not be aware that the US already has health systems governed and managed by the federal government. They provide care to a variety of American populations including military service members, Veterans, American Indians, Alaskan Natives, and those incarcerated in federal prisons. As the US federal health systems continue to improve their processes, the framework of universal coverage may gain more traction with political and business leaders in the coming years. More awareness of this existing and effective federal framework may help pave a path for a broader, more integrated, universal healthcare delivery model in the US that could be replicated and managed at the State level.

## **CONCLUSION**

Healthcare system change in the US will require strong trusted leadership in areas of policy, politics and economics with a singular focus on the economic benefit (not the social benefit) of universal health care. It is very likely that the successful integration of a universal healthcare model will be driven by private industry (e.g. Amazon) rather than by government, but there is little doubt that change will come.

### **Reference:**

John McDermott. Universal Health Care: An affordable necessity. The Economist. April 28, 2018. pp3-12.



## **HEALTHCARE FOR THE VULNERABLE POPULATIONS**

**Presenting Group Members:** Ms. Marcia Bowens, VHA; LTC Lalini Briley, USA; CAPT Alison Castro, USN; Col Robin Fontenot, USAF; CDR Tracy Gualandi, USPHS; Lt Col Steven Lehr, USAF; CDR Jeffrey Martens, USN; LTC/P C.J. Plummer, USA; Col Steven Ward, USAF.

### **INTRODUCTION**

Whether viewed as a right or a privilege, the wellness of any society depends on the quality, accessibility and availability of the healthcare it provides to its members. Quality reflects the appropriateness and effectiveness of the care provided. Access reflects the user's ability to obtain adequate healthcare resources. Access is dependent on affordability and physical location. Availability describes the supply of services. Although many have access to quality care, many do not and are considered vulnerable populations. Vulnerable populations are the disenfranchised. This includes, but is not limited to, individuals with low (or no) income, those in rural areas, undocumented immigrants, the uninsured, the homeless, the elderly, and some Native Americans.

### **BACKGROUND**

The vulnerable populations are traditionally found to have lower levels of general health. They may be less likely to seek primary and preventive care. They may avoid seeking care during the early stages of disease progression, choosing to wait until their disease is advanced. As a result, they may utilize healthcare resources inappropriately, frequenting emergency services for issues that are more appropriately addressed in a primary care setting. The care, when sought, is costlier because of the advanced stages of disease progression.

According to Legatum Institute, a London based research foundation, the health of a nation is measured by three key components: a country's basic mental and physical health, health infrastructure, and the availability of preventative care. The following is the top five of their 2017 ranking of national health:

1. Luxembourg
2. Singapore
3. Switzerland
4. Japan
5. Austria

The U.S. ranked 30<sup>th</sup>.<sup>[1]</sup>

These five countries have universal healthcare systems demonstrating better accessibility, minimum influence by the politicians and government, and controlled drug costs.

In a universal healthcare system, everyone must share a moral imperative to foster health. This requires concerted action by the health sector and other sectors of society, to include the government, community, industry and the individual.

Governments must ensure availability, access, and quality. This includes reforming current healthcare systems to positively impact the health of the vulnerable populations. The federal government's role must include:

- a. establishing national standards for care,
- b. upholding the standards,
- c. creating programs to meet the needs of vulnerable populations, and
- d. providing adequate funding to providers.

Community involvement underscores the notion of partnership and shared responsibility. Health services must commit to delivering high-quality care, while considering the unique challenges of the populations they serve. If not addressed, families and the community assume greater responsibility for the community's health, straining the system.

Industry's role extends beyond innovation. Companies hold a responsibility to comply with national laws, act with integrity, respect human rights, and work against corruption preventing harm. There is a growing social expectation that it is in a company's enlightened self-interest to be part of the solution. Among the benefits to a business are the ability to create new markets, as well as a healthier, more productive society.



Taking personal responsibility for health involves a commitment to adopting a healthy lifestyle, to include frequent exercise and weight control. The ramifications of this responsibility are presently playing out with health insurance companies. Insurance costs less for non-smokers and people who complete weight-loss programs. There are added financial incentives promoting participation in health screening or smoking cessation programs.

**SOLUTION**

As the only industrialized nation without a universal health care system, it is time the nation embraces a solution to serving its most vulnerable members. There are numerous possible solutions. Any solution would require an aggressive outreach to the nation and a bipartisan effort to pass a plan. There is a need to increase the primary care workforce. The Health Services Resources Administration has federal programs to incentivize health care providers by providing loan repayment to clinicians that treat underserved and rural populations through the National Health Service Corps. This program could be expanded to increase the flow of providers into high need communities. The Uniformed Services University of Health Sciences (USUHS) has a program to train United States Public Health Service (USPHS) doctors. USPHS doctors are committed to serving the underserved patient populations. USUHS could increase the number of slots for USPHS officers who are committed to serving underserved populations.

Additionally, the U.S. will need a systematic approach to treat the vulnerable populations. The group proposed two viable approaches. The first is to establish federally funded facilities located in the most vulnerable communities. The Bureau of Primary Health Care (BPHC) currently accomplishes this by funding Federally Qualified Healthcare Centers (FQHCs). FQHCs provide integrated primary care and dental services to patients without regard to ability to pay. BPHC funding for FQHCs could be expanded to increase the number of FQHCs.

A key in the success of the FQHCs is a strong partnership within the community to establish trust, and address healthcare needs. Identifying key community leaders is essential for gaining trust of the vulnerable population. These leaders can help to identify the gaps in access, as well as establish a rapport between the healthcare workers and the community.

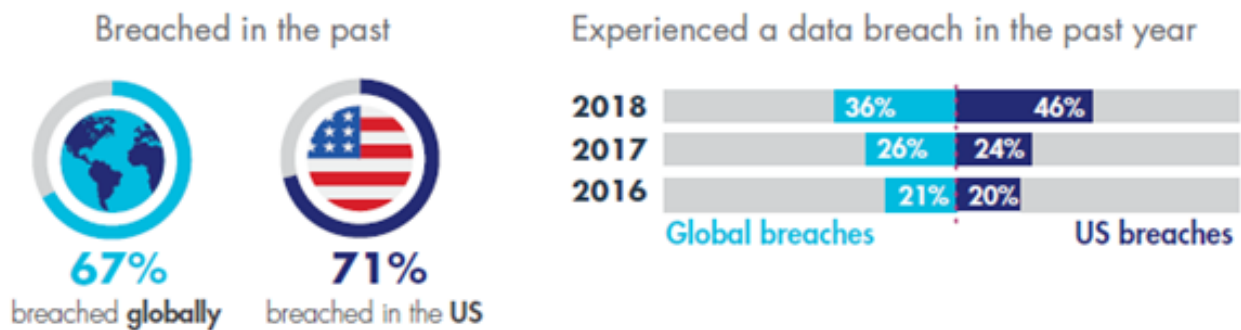
The second approach would expand universal healthcare coverage to all individuals. This was attempted by the Affordable Care Act (ACA). The ACA failed partially because while it provided (mandated) healthcare coverage, it did not constrain costs. Universal coverage with requisite cost-containment could garner bipartisan support. A move from “fee for service” to “outcome-based” payment systems would contain costs. An “outcome-based” system controls expenditures by incentivizing standards of care and dis-incentivizing non-evidence-based treatments.

**CONCLUSION**

These solutions are options. To truly solve the healthcare issue, however, the U.S needs to grapple with reforms in pharmaceutical costs and medical tort reform. More fundamentally, our country needs to determine whether healthcare is an earned privilege or a universal right. Given that we are the most economically viable country on the planet, it is not a question of resources but rather a question of resolve. Until our nation settles this debate, and allocates resources accordingly, care for the underserved will continue to be a challenge.

<sup>1</sup> “The Legatum Prosperity Index, 2017”, The Legatum Institute Foundation, 2017, pp. 10-11.

**DATA BREACH HISTORY**





## HEALTH CARE DATA MANAGEMENT IN THE 21<sup>ST</sup> CENTURY: THE CHALLENGE OF CYBERSECURITY

**Group Assignment:** Good data management is a vital element in health care in order to protect health systems (public and private) and their beneficiaries from cybersecurity threats. How significant are these threats in present day American society? Are we more or less vulnerable than other developed nations? What policies and programs need to be developed and implemented to protect our health data and how should we foster a culture of cybersecurity throughout our society?

**Group Members:** CDR Yasir Bahrani, USN; CDR Janine Danko, USN; Col Stana Ilcus, USAF; Col James Knowles, USAF; Col David Linkh, USAF; COL Michael Ludwig, USA; CDR Brett Maycock, USPHS; COL Christian Meko, USA; LTC/P James Pulliam, USA; Dr. Sheila Sullivan, VHA; CAPT Meredith Yeager, USN.

**Introduction.** Adoption of health care cyber technology is a challenging and intensive process requiring substantial resources for planning, development and implementation. Post-adoption maintenance through software updates and patches is essential to address newly identified threats and vulnerabilities as cyber criminals aggressively pursue and refine new technologies and tactics daily. While health care organizations are devoting increasing attention and resources to cyber security and defense, threats are significant, persistent and evolving.

**Vulnerabilities in the US Health Care System.** The health care industry has become a prime target for cyber attacks, with increasing attacks reported during the last three years. Data indicate that over 100 million healthcare records were compromised during 2015 from more than 8,000 devices in over 100 countries. Data breaches have cost the health care sector more than \$6.2 billion, and 80% of healthcare institutions were hit with two or more data breaches in 2014-2015. The health care industry is prone to cyber attacks due to insufficient spending on prevention. Furthermore, there is a high demand for medical records in the black market where criminals combine patient identifiers with false provider information to file fraudulent insurance claims. Ransomware, another growing threat, involves malware designed to infect a system resulting in a denial of service attack during which the hacker demands payment to release the data. In the first quarter of 2016, there were more than 4,000 ransomware attacks daily, a 3% increase over 2015.

US healthcare data is more vulnerable than that of other developed nations. Over 70% of US companies have been breached vs. 67%, globally. Global interconnectivity, interdependence and a penchant for technologic advancements in the post 9/11 world puts the US healthcare system at particular risk. In the US, 90% of healthcare institutions were subject to cyber attacks from 2012-2015. Unfortunately, 84% of US healthcare providers don't have a cyber security officer and only 11% plan to add one in 2018. According to reported US data, 54% of healthcare providers don't conduct regular risk assessments and 39% don't carry out regular penetrating testing. More concerning, 89% of C-suite respondent's said IT funds for 2018 are focused on business functions, with only a small fraction allocated to cyber security.

**Risk Mitigation and Management Strategies: The Need for Comprehensive Policies and Programs.** There are a substantial number of policies and programs in place to protect health care data across federal agencies. The DoD has published a resource guide referencing 48 instructions or guidelines on developing cybersecurity strategies and managing access to information technology (IT) infrastructure. Additionally, in 2018 the Defense Health Agency (DHA) published a procedural instruction on acceptable use of IT outlining authorized and unauthorized uses. It also provided expectations that 1) each MTF will perform a risk management plan using the risk management framework which will be later validated by DHA, and 2) all MTFs standardize IT equipment to include a process for discontinuing systems that pose a security risk. Another organization addressing this issue is DARPA, which oversees about 250 research and development programs. Its "SafeDocs" initiative aims to provide technological assurance that an electronic document or message is automatically checked and safe to open, while also facilitating generation of safer documents.

The DHA has outlined its goals for the IT shared service, to include delivering trusted IT services, investing in people and optimizing operations. While strong policy is important to establish the security framework, we also need to invest in our IT professionals and infrastructure. This includes developing a robust risk management plan while increasing surveillance, and vulnerability assessments all of which needs to be accomplished in an environment of inter-service collaboration. Another issue is continuity in providing IT services to our medical facilities. Currently there is excessive fragmentation due to periodic changes in contracts and undervaluing the need for IT professionals. If unaddressed,



risks will only proliferate with increased reliance on cloud services, machine learning, advanced robotics, biotech and automated intelligence. These policies and programs notwithstanding, an article in Health Management Technology, aptly reminds us that “security is ultimately a people problem not a technology issue.” This emphasizes that each organization must commit to fostering a culture of cybersecurity.

**The Way Ahead: Establishing and Sustaining a Culture of Cybersecurity.** In the digital age, we rely extensively on the Internet and electronic storage devices. To secure these domains, adoption of a comprehensive cyber hygiene strategy is essential to assure we are protecting and maintaining systems and devices and using cyber security best practices for anything that connects to the web. It also includes organizing security in hardware, software and IT infrastructure, continuous network monitoring, and staff awareness and training. Cultural shifts begin with small victories where positive changes go viral in an organization through personal stories and open dialogue. Cyber hygiene, the practices and steps that end-users take to maintain system health and maintain online security is recognized as a critical element in cybersecurity. Such practices can be incorporated into a routine to ensure the safety of personally identifiable information and other details that could be stolen or corrupted. Campaigns to promote cyber hygiene require public private collaboration and must be actionable and easy to understand and implement by the average user. Notable examples include Stop, Think, Connect, a cyber hygiene campaign developed by the National Cybersecurity Alliance and currently adopted by numerous federal agencies, corporations and US multinational partners. The vision involves providing a low-cost, user-friendly program for enabling immediate and effective defense against cyber attacks. The campaign’s priorities address the vast majority of known cyber threats and can be implemented at multiple levels within the organization:

**Count:** Know what’s connected to and running on your network

**Configure:** Implement key security settings to help protect your systems

**Control:** Limit and manage those who have administrative privileges for security settings

**Patch:** Regularly update all apps, software, and operating systems

**Repeat:** Regularly revisit the Top Priorities to form a solid foundation of cyber security

**Conclusion.** Cyber security of health care systems is a growing challenge in the US despite increasing recognition of risks and vulnerabilities. Near-term and long range actions in the arenas of policy, practice and culture change are needed to establish safeguards ensuring the continued availability, privacy and integrity of health care data.

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STOP | THINK | CONNECT™

STOP. THINK. CONNECT.™ is the global online safety awareness campaign to help all digital citizens stay safer and more secure online. There are a variety of free online safety resources, including tip sheets, videos, posters and memes, that you can download and share. Sub-campaigns include:

- Lock Down Your Login
- Own Your Online Presence
- Keep a Clean Machine



## **GOOD PUBLIC HEALTH: ENSURING THE SAFETY OF FOOD, DRUGS AND MEDICAL DEVICES**

**Group Assignment:** Ensuring the safety of food, drugs and medical devices is an important component of good public health in all nations. Which level of government in the United States has the major responsibility for overseeing the development of standards and enforcing compliance with them in the United States? Where are the gaps in our current procedures and what changes should be considered to deal with them? Are there other nations which have tackled these challenges better than the United States and could their policies and procedures be helpful to us?

**Group Members:** Col Christopher Bird, USAF; Col Terrence Cunningham, USAF; CAPT Victor Diaz, USN; CAPT Cedric Guyton, USPHS; Dr. Katerine Osatuke, VHA; CAPT Marie Parry, USN; Col Kevin Talton, USAF; Mr. Brady White, VHA; CDR Nathan Wonder, USN; LTC Dentonio Worrell, USA.

**INTRODUCTION.** The Food and Drug Administration (FDA) regulates \$1 trillion worth of products a year. It is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, cosmetics, tobacco products and medical devices, including products that emit radiation. The FDA also plays a significant role in our nation's counterterrorism capability by ensuring the security and safety of our food supply except for meat, poultry and some egg products (the U.S. Department of Agriculture's Food and Safety Inspection Service regulates) and fosters development of medical products to respond to deliberate and naturally emerging public health threats.

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, further expanded the FDA's authorities and strengthened the agency's ability to safeguard and advance public health by: giving the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products; promoting innovation to speed patient access to safe and effective products; increasing stakeholder involvement in FDA processes and enhancing the safety of the drug supply chain.

### **Where are the gaps in our current procedures and what changes should be considered to deal with them?**

Over the past 25 years, globalization of drug manufacturing has prompted the FDA to take additional measures to ensure that their drug manufacturing surveillance program kept pace with the evolving landscape and consumers continued to receive safe and effective drug products. The shift to overseas production of U.S. goods, including some drugs and their components in the early 2000s, added new complexities to the supply chain.

A large-scale endeavor, the FDA has attempted to maximize resources around the globe using a risk-based, site selection model to ensure that inspection resources are allocated in the most efficient and appropriate manner. Their model prioritizes inspections to locations where drug manufacturing processes pose the greatest potential risk for problems and patient harm to assure that all products meet the same high-quality standards. As of Fiscal Year, 2017, there were 5,063 human pharmaceutical sites subject to routine surveillance inspection worldwide; 3,025 were foreign-based. For that year, the FDA conducted 1,453 drug surveillance inspections including 762 on foreign soil to ensure manufacturers were following current Good Manufacturing Practice (GMP) requirements and maintaining high quality standards.

Besides the need to maintain a strong drug manufacturing surveillance program with limited resources, additional gaps identified include addressing: the high list price for drugs; government programs overpaying for drugs due to lack of the latest negotiation tools; increasing out-of pocket costs for consumers; and foreign governments free-riding off American investment in innovation. Additional opportunities include: improved communications with domestic and foreign partners; developing collaborative agreements with sister agencies in foreign countries; and improved conflict management, to better understand limitations of sister countries.

### **Are there other nations which have tackled these challenges better than the United States and could their policies and procedures be helpful to us?**

The European Union (EU) has developed a regulatory system supported and coordinated by the European Medicines Agency (EMA). Founded in 1995 and headquartered in London, UK, the EMA is a decentralized scientific agency that coordinates the evaluation, supervision and pharmaco-vigilance of medical products for the 28 nations in the European Union (EU). The EMA also facilitates development and access to medicines and coordinates the assessment of



marketing authorization applications (MAA) via a centralized procedure, monitors safety of medicines across their lifecycle and provides information on human and veterinary medicines to healthcare professionals and patients.

With a staff of approximately 890 employees and an additional access to over 4000 scientific experts among the EU member states, EMA staff do not conduct primary reviews or inspections, as these are conducted by individuals within the health authorities of the EU member states. Rather, EMA's role is to ensure quality and consistency of the decisions in accordance with EU guidance and policies, manage the development of new policies and guidance, resolve crosscutting issues, coordinate necessary training and leverage resources among member states. The same rules and harmonized procedures apply to all the EU member states for the authorization and quality oversight of pharmaceuticals. Investigators from member states perform inspections of pharmaceutical manufacturers to assure that facilities follow EU GMPs.

In addition to the inspections performed by the 28 EU member states, the EMA also relies upon inspections from several different countries in cases where there are Mutual Recognition Agreements (MRAs) in place. Currently, the EMA has fully operational MRAs with Australia, New Zealand, and Switzerland. EMA also has conditional MRAs with the following countries: Israel; Canada and Japan. MRAs allow drug inspectors to rely upon information from drug inspections conducted within each other's borders and enable reallocation of resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe.

FDA collaborative initiatives to include MRAs with the EU and other countries could result in improved efficiency between the U.S. and equivalent foreign regulatory agencies and avoid duplication of inspections. At the same time, leveraging MRAs could free up limited resources to be employed inspecting facilities deemed greater risk to the public health of our citizens.

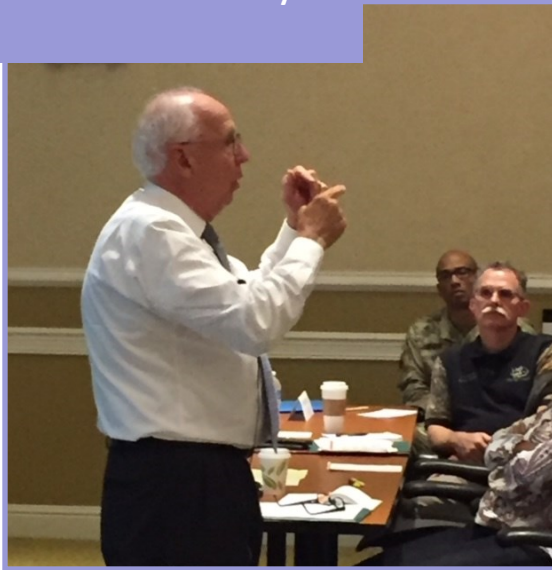
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## **Top Management and Performance Challenges Facing the U.S. Department of Health and Human Services**

1. Ensuring Program Integrity in Medicare
2. Ensuring Program Integrity in Medicaid
3. Curbing the Opioid Epidemic
4. Improving Care for Vulnerable Populations
5. Ensuring Integrity in Managed Care and Other Programs Delivered Through Private Insurers
6. Improving Financial and Administrative Management and Reducing Improper Payments
7. Protecting the Integrity of Public Health and Human Services Grants
8. Ensuring the Safety of Food, Drugs, and Medical Devices
9. Ensuring Program Integrity and Quality in Programs Serving American Indian and Alaska Native Populations
10. Protecting HHS Data, Systems, and Beneficiaries From Cybersecurity Threats

Darrell G. Kirch, MD, (pictured below) gave his final presentation at the Institute as President and CEO, Association of American Medical Colleges, on September 14th. Dr. Kirch has been a popular and respected faculty member of the Institute for many years.



## Plan now to attend!

**The FHCEIAA Annual Meeting and breakfast will be held Thursday, November 29, 2018, from 6:45 - 7:45 AM in the Gaylord Convention Center National Harbor Rooms 2/3, during the AMSUS Annual Continuing Education Meeting, November 26 - 30.**

A Continental breakfast will be available for a reduced rate of \$25. You may register as part of the AMSUS registration at <https://amsus18.registerat.com/Home.aspx> or you may call Ms. Janet Neiman at 301-828-1589 to reserve.

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