



### REPORT

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#### DIREF

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### HEALTHQUAKE 2019 SUMMIT REPORT

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#### CHAIRMAN'S MESSAGE



The idea for HealthQuake germinated at the Detroit Medical Center—the DMC—a decade ago, when Mike Duggan, now Mayor of a resurgent Detroit, was CEO of a resurgent DMC.

A futuristic discussion among senior representatives of all stakeholders in healthcare—including doctors, nurses, hospital administrators, researchers, employers, payers, policymakers, and investors—was envisaged and finally organized by the Detroit International Research and Education Foundation, DIREF. The first Summit, held in 2017, focused on regenerative medicine as exemplary of the earthquake about to shake the healthcare sector to its core.

#### 2019 Summit Summary

This year's Summit focused on the convergence of genitourinary and associated medicine with the technologies of artificial intelligence and an artificial kidney. In the broader context of the convergence of medicine and technology (the Summit tagline), these technologies were exemplary representatives of two branches of postmodern medicine: Digital and bionic.

From the evidence presented, delegates sought to assess the implications for the healthcare sector as a whole. Considering the continuing acceleration in both the improvement of those technologies and their introduction at the bedside, Dr. Charles Shanley illustrated the convergence of medicine and technology by reference to a point-of-care device that applies machine learning and Raman spectroscopy to the problem of antibiotic resistance and pathogen detection.

Following Dr. Shanley, Dr. Mona Doshi brought delegates up to speed with respect to today's state of the art in the treatment of genitourinary cancers and kidney disease, showing that these two conditions are in fact two aspects of a single complex system. This new understanding has begun to have an impact on the treatment of these conditions, which can only intensify as the technologies described by Dr. Atul Butte and Dr. Shuvo Roy are brought to bear.

Atul Butte has applied big data and artificial intelligence to find the right, precision, treatment for diabetes, a contributor to kidney disease and thus a part of the complex system described by Dr. Doshi. The treatment is personalized for the individual patient and his or her risk factors and predisposition to kidney cancer and disease.

Dr. Roy noted that dialysis has not seen much innovation in the last 50 years, and that while it might save a patient's life in the short term, it does not restore their health. He compared the odds of getting a kidney transplant to winning the lottery. Enter the bioartificial kidney, which is what he told the Summit about.

Following these topical keynotes and discussions, DIREF executive director and futurist David Ellis put the day's discussion in the context of the acceleration of innovation in healthcare, and what it might all amount to a decade from now.

Each of our speakers' talks were followed by discussion among all delegates of the implications. This Report presents an edited synopsis of the day's proceedings. We hope you find it useful, and we look forward to meeting you at HealthQuake 2020.

Sincerely,

J. Edson Pontes, MD HealthQuake Summit Chair

#### **KEY TAKEAWAYS**

- A new weapon in the fight against the existential threat from antibiotic resistance could be on the market within 2–3 years.
- 2. The same tool can identify 30 pathogens in minutes at the point of care, and that number will grow over time.
- 3. Academia has a long way to go in working with the private sector to commercialize such innovations, though successful models exist.
- 4. Kidney cancer and kidney disease are better treated as aspects of a complex single onco-nephrological system.
- 5. Al, increasingly deployed against disease, will be needed to handle the complexities of the onconephrological system.
- 6. Al needs access to the Big Data held in electronic health rrecords (EHRs).
- "Personalized" medicine will ultimately require affordable clinical trials with an N of 1. Example: Type 1 diabetes patients can bypass the health and regulatory systems to conduct (legal) N of 1 trials of a \$250 artificial pancreas on themselves.
- 8. A bioartificial kidney that will begin standard clinical trials in the next 1–2 years will have a major impact on renal disease and cancer patients when it, or something like it, succeeds.
- The hospital industry is as resistant to change as academia and may be more susceptible to customer attrition as Amazon, Google and other tech giants begin to take patients away from them.
- 10. The trends and technologies discussed at this Summit are accelerating so fast that seeing around the corner ahead is going to take not just data but also imagination.

## PANDEMICS WAITING TO HAPPEN



**In healthcare**, clinical caution and prudence are imperative to protect patients in the near term, but to the extent they simultaneously create barriers to rapid-cycle innovation, these guiding principles may appear imprudent in the long term.

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-Dr. Charles Shanley

At the point of care, physicians have a dilemma: To treat or not to treat, with antibiotics, what might or might not be a bacterial infection. It takes two to three days to get a lab test result—too long to risk letting a potential bacterial infection take its own course. But the vast majority of infections are viral, so treating them with antibiotics only serves to increase the antibiotic resistance crisis.

Antimicrobial resistance affects everyone. Surgery is entirely dependent on antibiotics, and pandemics could sweep over the surface of our interconnected globe in the few hours it takes to fly halfway around it.

Raman spectroscopy offers a solution. It identifies the "signature" or "fingerprint" of any material, organic or inorganic, from the unique way in which molecules of the material disperse laser light directed at them. It is used in industry to identify inorganic gases and other materials but has not been used in medicine because the Raman fingerprinting of organic molecules is extremely challenging, requiring sophisticated and sensitive equipment, specialized technologists, complex sample preparation, and countless hours of data collection and analysis.

Raman can reveal information about the phenotypic makeup of the molecule that we have not hitherto been able to get at the point of care during a patient visit. Sophisticated deep learning algorithms applied to the Raman data can accurately differentiate between viruses and bacteria and between antibiotic-sensitive and antibiotic-resistant strains of bacteria.

The big advantage is not having to use special primers and amplification. As well, it becomes very accurate very quickly—something other diagnostic technologies cannot match.

All of this capability has been packaged in a diagnostic device usable by physicians at the point of care, that will do the job in minutes at the point and moment of care, not in hours or days at the lab. The specimen-agnostic device identifies the signature of pathogens in samples and reports its findings to the patient and the doctor on the spot. It will change the behavior of both patient and physician with regard to antibiotics.

After several years of development, the device will be deployed in 2020 initially in veterinary clinics where it will detect crystals in urine, fecal pathogens, and viral and bacterial infections in companion animals.

Beyond clinical application, the device could be used for environmental surface detection, Legionella in water towers, drug discovery, drug development, and more. Raman-based triage will make a world of difference in the developing world, such as in places with ebola outbreaks, where body temperature is still the basis for triage. The current version is a table-top device but future versions are likely to be miniaturized to fit in a briefcase-sized package and even smaller.

The device is already generating substantial research revenue and indirect funding to Wayne State University, which will enjoy long-stream revenue in the form of royalty and profit-sharing arrangements. As such, it represents a new paradigm to integrate the technology development process by bringing clinicians and scientists together to solve important problems.

Universities in general are good at solving problems but not good at commercializing the solutions. To become good at it, they must (1) create win-win arrangements with private-sector partners and (2) drastically reduce the bureaucracy —universities need to be realistic about private sector timelines if they wish to work not just well but at all with private sector partners.

## KIDNEY DISEASE

Two-way relationship between Renal Cancer and Kidney Disease



### Executive Order 13879 of July 10, 2019

### Advancing American Kidney Health

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. My Administration is dedicated to advancing American kidney health. The state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

Sec. 6. Encouraging the Development of an Artificial Kidney. Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department

Source: https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-

**The purpose** of the kidneys is to filter waste products from the blood. They help maintain healthy red blood cells and a healthy heart.

Their failure is catastrophic, with survival rates lower than breast cancer in women, prostate cancer in men, and colon cancer in men and women. Yet people tend to freak out more when told they have cancer than when told they have kidney disease.

Kidney cancer itself is on the rise, along with prostate and urothelial cancers.

#### **Onco-nephrology**

Medical treatment for kidney *cancer* has advanced considerably in the past decade, with newer agents providing longer survival. But ablation therapy, chemotherapy, biologic drugs, and immunological therapy can contribute to kidney *disease*. The recent realization that genitourinary cancers (and their treatments) cause kidney disease *and* that kidney disease causes kidney cancer has shone a spotlight on the reciprocal link between kidney cancer and kidney disease as parts of a single system. Medicine has tended to separate the two, sending patients with kidney cancer to their oncologist and patients with kidney disease to nephrologists—kidney doctors.

Onco-nephrology, which approaches kidney cancers and disease as a whole, is a new and growing field, and a new paradigm in kidney cancer care. It is complex, however, and requires a large medical team of nephrologists, oncologists, radiologists, pathologists, surgeons, coordinators, and others. Eventually AI may be essential to help handle the growing complexity.

#### Dialysis or Transplant or...

Patients with kidney failure have two options: Dialysis or a kidney transplant. Hemodialysis (the kind of dialysis commonly used in the US) is extremely expensive, costing Medicare alone an average of \$90,000 per patient annually, for a total of \$28 billion. Peritoneal dialysis (the preferred kind in the UK, Japan, and other countries with national health systems) is a better and less expensive alternative. However, the two large dialysis corporations that control most of the business in the US profit more from hemodialysis.

The other option, transplant, confers significantly longer survival. Organs are in short supply, so dialysis often serves as a bridge until a compatible organ becomes available. The drawback of transplants is that patients must take immunosuppressant drugs for the rest of their lives.

Apart from the inconvenience and discomfort, rejection medications prevent the immune cells from monitoring for cancer and therefore increase the risk of developing it. For that same reason, patients with a history of cancer have to be cancerfree for 2–5 years before they are eligible for transplant.

The Presidential Executive Order shown on the facing page was issued to tackle these issues. It included a provision to support the development of a third option: An artificial kidney. Within the next 5 years, there is likely to be one (discussed later in this report.)



### BIG DATA

## BIGGER NUMBERS

yotta	Y	<b>10</b> <sup>24</sup>	1,000,000,000,000,000,000,000,000
zetta	Ζ	<b>10</b> 21	1,000,000,000,000,000,000,000
exa	Е	<b>10</b> 18	1,000,000,000,000,000,000
peta	Ρ	<b>10</b> <sup>15</sup>	1,000,000,000,000,000
tera	Т	<b>10</b> <sup>12</sup>	1,000,000,000,000
giga	G	10 <sup>9</sup>	1,000,000,000
mega	Μ	10 <sup>6</sup>	1,000,000
kilo	K	10 <sup>3</sup>	1,000

The common belief is that it takes 10 years and a billion dollars to develop a drug. Actually, the simple arithmetic of dividing the drug companies' R&D spending by the number of successful drugs they bring to market shows a cost of between \$4-12 billion per drug, depending on the company. In an era of personalized medicine, this is probably not sustainable. -Dr. Atul Butte



**If we could** detect and prevent kidney failure earlier, we could eliminate the need for dialysis and transplant in many cases. Artificial intelligence (AI) could help us do that by analyzing the complexities of the condition buried in the big data locked up in electronic health records (EHRs).

In 2014 humanity generated two zettabytes of data (see table on facing page for explanation of *zetta*). The volume of data is doubling annually, so 2019 will end up adding another 64 zettabytes. Quite a bit of that is in the form of YouTube kitten videos, but there is still an enormous and growing amount of useful data.

In the life sciences, many devices, from mass spectrometers to DNA sequencers, generate massive amounts of data, which accumulates exponentially. Big data from billions of DNA samples in biopsies, blood draws, and other sources is now readily available to anyone. How useful is it?

#### Three Examples

#### Example 1. Preeclampsia

Preeclampsia is a major cause of infant and maternal death during childbirth. Tests to detect the condition in time for it to be averted are not available. A team of researchers at UCSF wanted to develop a diagnostic blood test for it. Instead of going to a clinic to try to recruit patients for a study to develop one, the team looked for commonalities in the publicly available data for preeclampsia cases. The search revealed 12 biomarkers. Within 24 months:

- Several academic papers were written and published
- Grants were acquired
- Clinical trials were conducted
- A company was formed to develop and commercialize the biomarkers as a single, reliable blood test for preeclampsia
- The company was acquired by Progenity, a privately held biotech company

In just 24 months, the project went from unseen patterns in public data to commercial acquisition. Anyone could pick another disease needing a better diagnostic—there is no shortage of them and do the same.

#### Example 2. DNA Sequencer

The Human Genome Project succeeded in sequencing the entire generic human genome in 2003 in facilities resembling a factory. That facility has been reduced to a USB device that fits in a shirt pocket.

The cost of sequencing has plummeted from a billion dollars for the first complete sequence to less than a thousand, and the volume of individual human (and animal, and plant, and cancer, &c.) sequencing data is exploding.

The problem is that much of the rapidly accumulating data on genomic differences that lead to disease is locked up in the unstructured text of journal articles. Unlike clinical data from biopsies, blood, and other fluids, genomic data are not available in public databases that can easily be searched and analyzed. 200 geneticists in India were hired to read, curate and analyze 20,000 papers for disease-causing genetic mutations.

That task was automated and a company, Personalis, was formed to commercialize the technique. Personalis raised \$140 million from its IPO in 2018 and has a current market cap of about half a billion dollars.

#### Example 3. Drug Development

Realizing that drug data, as well as disease data, from academic studies was simply being dumped onto the Internet, Dr. Butte and colleagues surmised that if the disease data were run against the drug data—like a match.com for drugs and diseases—they might find new matches.

And they did. The veterinary drug niclosomide, used to treat tapeworms in animals, was found to have some effect against hepatocellular carcinoma, a nasty liver cancer. Because it affects only about 150,000 patients worldwide, of whom very few are in the United States, there has been little effort to develop a drug for it, although sorafenib had been been found to have some effect. Niclosomide worked well in a mouse model, and even better when administered together with sorafenib.

Clinical trials of the synergistic treatment are being planned. Nobody else is working on this cancer, and nobody is working on so many other diseases. Dr. Butte and colleagues raised \$10 million for a startup to tackle such rare conditions, starting with idiopathic pulmonary fibrosis.

The foregoing three examples show what that freely available, and growing, data can lead to. They are just the tip of the proverbial iceberg, the bulk of which lies hidden below the surface in electronic health records (EHRs).

#### **Electronic Health Records**

Doctors mays hate EHRs but they are needed so badly that we pay a handful of EHR companies gargantuan sums—gigadollars on an individual health system basis amounting perhaps to teradollars on a nationwide basis—for them. Sutter spent a billion dollars on one, Partners \$1.2 billion, Kaiser \$4 billion.

Adding insult to injury, health systems pay expensive doctors and nurses as typists just to get patient data into the EHR yet spend next to nothing on mining the data in them. The reason is because the systems do not talk to one another. The reason they do not talk to one another is not technical; rather, it is that each EHR record represents a customer.

It is a tragedy to prevent these data from being used to improve the practice of medicine. It is not enough to collect data in disconnected buckets: The buckets need to be emptied into a lake where the contents can be fished for solutions to problems.

Integrating EHR data across systems is technically not difficult but almost impossible to achieve without a good business justification and model, but such models are possible: For example, the University of California is working with United Healthcare to form a single accountable care organization (ACO) and clinically integrated network and advanced data analytics services.

The results of the analytics will solve problems such as eliminating variations in practice and quality (inevitable across such a large system) and getting a better handle on diabetes. UC Health treats 26,137 diabetic patients and maintains a dashboard that enables administrators and faculty to drill down into their EMR data to know exactly what is going on, in the aggregate or by individual patient, and where action is needed.

The system-wide integrated EMR will mean that:

- Clinical researchers at UC Los Angeles can run a GWAS (genome-wide association study) across UC Health<sup>1</sup>
- Mobile health researchers at UC San Diego can enable patients to contribute data for research
- Community activists and researchers at UC Merced can study environmental factors contributing to health and disease
- Transplant patients at UC Irvine can download all their data across UC Health
- Data scientists at UC Santa Barbara can model the development and predict the prognosis of kidney disease
- App designers at UC Riverside can show patients their choices with chronic kidney disease
- CMOs at UC San Francisco can build predictive models for readmission, test, share across UC Health

<sup>&</sup>lt;sup>1</sup> A genome-wide association study (GWAS) is an approach used in genetics research to associate specific genetic variations with particular diseases. The method involves scanning the genomes from many different people and looking for genetic markers that can be used to predict the presence of a disease. *Source:* https://www.genome.gov/genetics-glossary/Genome-Wide-Association-Studies

- Al researchers at UC Berkeley can build deeplearning models for kidney disease and cancer
- Health services researchers at UC Davis can build predictive models for drug efficacy, and maybe enable pay-for-performance
- Cancer genomics researchers at UC Santa Cruz can study genitourinary and other cancer genomes

The analytics deployed against Big Data in all of these use cases will likely involve some form of AI. In just the last two years, the FDA has approved 30 AI tools and services—up from zero. It is an explosion. The more data to train the AI, the better it gets. The better it gets, the more likely it is to gain FDA approval and to be commercialized. The more AI systems, the more data generated. It is a virtuous circle. The path is clear. All it takes is an unmet need and a clinical champion.



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### INNOVATION

### DIY ARTIFICIAL PANCREAS

Designed to automatically adjust an insulin pump's basal insulin delivery to keep blood glucose (BG) in a safe range overnight and between meals by communicating with the pump to obtain details of all recent insulin dosing (basal and boluses), communicating with a Continuous Glucose Monitor (CGM) to obtain current and recent BG estimates, and issuing commands to the pump to adjust temporary basal rates as needed. It follows the same basic math that a diabetic patient does to calculate a needed adjustment to their BG – but it's automated and more precise in its measurements. Its processor is a \$20 Raspberry Pi computer.

-See https://openaps.org/



HIMSS 2019 Statistics. Source: https://www.himssconference.org/exhibition/ himss19-highlights Medical schools could do some of the big data analytics and should, given that non-academic health systems tend to be limited by what their CIOs see at the massive HIMSS (Health Information and Management Systems Society) annual conference (see facing page). If they do not see it at HIMSS, it does not exist for them.

Academic systems can get their engineers to develop things unseen at HIMSS. But stewardship requires the safe, respectful, and HIPAA-compliant use of data, especially for commercial uses. Many eyes need to be on it—contracting officers and Institutional Review Boards (IRB)<sup>2</sup> made up of Chief Medical Officers, scientists, ethicists, business development officers, and others should meet frequently to guide—not to stifle—innovation.

Patient medical records are owned in the aggregate by health systems, which need policies governing use of patient data for research, administration, operations, logistics, quality improvement, and other functions and purposes. IRB and contracting decisions that take months or even years in some academic systems have been streamlined to as little as two weeks in a few advanced universities. Doing so puts them on the same timeline as potential commercial partners and greatly increases the university's potential for innovation revenue.

#### **Innovation & The Clinical Trial**

Personalized medicine may be on an exponential roll but there is an elephant in the room: The clinical trial. Dr. David Eddy demonstrated digital clinical trials decades ago. No-one can afford to develop and trial a drug just for one or even thousands of individuals, even if there were a way to get a statistically significant sample—which obviously there is not for a one-person drug. [See p. 15.] Clinical trials may nevertheless still improve as EHRs become more integrated and interconnected, enabling more patients to be recruited for bigger trials.

But will hospitals want to undertake them? Today they compete with one another to do trials for the drug companies and the low bids win, so margins range from razor-thin to negative. Most health systems probably don't even know whether they are making or losing money on clinical trials, because they don't know their true costs. It's a mess, but clinical trials will continue to be needed unless we can find an alternative to them.

To put clinical trials in perspective: The pharmaceutical industry spends a total of about \$80 billion a year on R&D, of which clinical trials are just a small portion and a drop in the ocean of the \$4 trillion US healthcare system.

In the mid-1990s a physician group built a registry for hemoglobin a1c. The registry was intended not just to evaluate patient outcomes but also to see how physicians were managing their patient population. Big health data also contain individual physician performance metrics. An efficient system will analyze the data and get to know every patient and every doctor intimately. It alerted one system to the fact that its doctors were prescribing brandname Metformin instead of the generic for many of the system's own employees, and as a result the system saved a million dollars a year.

The DIY Artificial Pancreas project called OpenAPS bypasses clinical trials regulation because each artificial pancreas is built by the patient personally. Over 1,500 are in use among Type 1 diabetes patients and their outcomes are posted online, which is almost as good as (in some ways better than) a clinical trial report.

There has been only one known adverse event since the system was introduced ten years ago, but

<sup>&</sup>lt;sup>2</sup> An IRB is "an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research." https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions

our current broken system kills many more. Patients can see this, and will not stop using the artificial pancreas because of one failure in ten years.

Curiosity also drives experimentation, and the availability of \$20 computers, sensors, mail-order biological samples, and mail-order CRISPR kits enabling anyone to design anything, makes this an experimenter's dream. Unlike the Enlightenment, experimentation is open and affordable to anyone, not just to rich aristocrats. Who knows what cures —and chimeras—will emerge from a garage one of these days?

Of course it is extremely dangerous. In about 2005, Russian barbershops were said to offer stem cell injections to their clients. "In Russia, the Federal Health Inspection Service must approve a clinic's use of stem cell therapy. Several years ago, Russian authorities shut down more than 30 medical institutions illegally carrying out stem cell treatments, but numerous clinics continue to sell stem cell injections under the radar of regulators.

Innovation in distribution of services and products will fundamentally affect healthcare. Walmart put Main Street stores out of business by selling at retail prices lower than the wholesale prices Main Street stores paid to their suppliers. We must not think this cannot happen in healthcare. Today's big health systems are not exactly nimble, but we have the advantage of big data in the EMR and we could be taking advantage of that.

History shows that humanity is never prepared for change. But does it have to be that way?

#### A Clinical Trial With an N of 1 and a Cost of \$3 million

Genome sequencing is often pivotal in the diagnosis of rare diseases, but many of these conditions lack specific treatments. We describe how molecular diagnosis of a rare, fatal neurodegenerative condition led to the rational design, testing, and manufacture of milasen, a splice-modulating antisense oligonucleotide drug tailored to a particular patient. Proof-of-concept experiments in cell lines from the patient served as the basis for launching an "N-of-1" study of milasen within 1 year after first contact with the patient. There were no serious adverse events, and treatment was associated with objective reduction in seizures (determined by electroencephalography and parental reporting). This study offers a possible template for the rapid development of patient-customized treatments. (Funded by Mila's Miracle Foundation and others.)

-Jinkuk Kim, Ph.D., *et al.*: "Patient-Customized Oligonucleotide Therapy for a Rare Genetic Disease." *N Engl J Med* 2019; 381:1644-1652

## BIOARTIFICIAL KIDNEY







Source: https://www.kidneyx.org/

A change in the status quo that persisted over the past 50 years arrived in the form of the Presidential Executive Order reproduced on p. 6. Among other things, it called for the development of an artificial kidney.

An artificial kidney would provide significant benefits over both dialysis and transplant, for more people, at a significantly lower cost. It would not need catheters, dialysate, anticoagulants, or immunosuppressants. It would:

- Mimic the human kidney to provide 24/7 cleaning of the blood for up to at least a month
- Eliminate the build-up of toxins between dialysis sessions
- Eliminate the tether to dialysis equipment
- Decrease the risk of infection and thrombosis by eliminating cannulation
- Provide biological kidney functions that dialysis simply does not
- Not require anti-rejection drugs
- Be far less expensive than dialysis (\$90,000per patient per year) and transplant (\$33,000 for a transplant patient after surgery

The bioartificial (hardware plus human cells) kidney developed by the Artificial Kidney Project, a national project at the University of California at San Francisco and Vanderbilt University, made a key breakthrough in creating a mass manufacturable silicon filter engineered at nanoscale—the size of molecules and even atoms. Unlike dialyzer membranes, they require very little pressure—no more than normal blood pressure, in fact, just like a real kidney, to filter the blood.

Nanoscale engineering enables the filter to eliminate more waste than a dialysis machine. A 1–2-molecule thick layer of non-stick polymer prevents cell adhesion and platelet activation from thrombosis, thereby eliminating the need for blood thinners.

The addition of a biofilter containing real kidney cells allows glucose and insulin to pass through the membrane while preventing BSA and antibodies and 80 percent of inflammatory cytokines. The tissue-engineered kidney cells live for up to 2.5 months on the membrane. With the current prototype of the device, surgery would be required to replenish the filter with fresh cells. It is hoped to increase the interval between surgeries to a minimum of three years.

The prototype artificial kidney is installed in the neck of a pig (see facing page). A Phase 1 clinical trial of parts of the device is planned for 2020/2021. The parts will likely be incorporated in an interim wearable (external, not implanted) artificial kidney or dialysis machine, enabling continuous dialysis.

Materials yet to be developed may improve the filter membranes further, including the ability to control ions and selectively allow specific electrolytes, etc., to pass at low pressures. They might also actively regenerate the membrane surface to prevent clogging. The filter will be in the form of a cassette that can easily be replaced.

The leading dialysis companies want a very low cost per filter cartridge that would be difficult to meet, given that it would have to go through costly separate clinical trials. As well, the established dialysis industry is practically a duopoly, very profitable, with no incentive to change its ways.

The artificial kidney will be of particular benefit to older patients, who are discriminated against by the protocol governing people on the transplant list—for obvious reasons. Younger patients tolerate surgery and do better on the complications infections, for example—that can come from transplant but they are less compliant on dialysis than older patients.

# HOSPITALS

#### **CVS**–Aetna

The merger of CVS and insurance giant Aetna is intended to result in "a community-based integrated model in which doctors, pharmacists, nurses and other health care professionals work together to provide a health care experience that is simpler, more convenient and less expensive."

 Source: https://www.aetna.com/health-care-professionals/newsletters-news/office-linkupdates/news-for-you-december-2018/together-for-you-aetna-cvs-health.html



There is a real probability that a major revolution predicted 19 years ago in *Technology and the Future of Health Care* will be with us by the year 2030.



It's very hard for established industries such as the hospital industry to change business models, especially when—as now—hospitals are still generating most revenue for the big systems. New business models such as the CVS–Aetna model (see facing page) is a trend and a sign that the traditional provider industry stands to lose significant portions of its business.

ICUs and trauma are going to be the future for hospitals. Free-standing emergency departments —downsized versions of hospitals—are already being built.

Established healthcare providers face major threats from Facebook, Amazon, Microsoft Google, Apple, IBM, and even from Big Tech companies in China, all of whom are in hot pursuit of the healthcare consumer.

The industry is not helped by the consumer's mistrust and growing inability to afford its high and often invisible prices. In failing to address the social issues around growing income disparity, society forces young consumers to learn to self-care.

#### Fake Healthcare

The problem is, they can easily be misled by bad information. Information validity is going to become an issue. YouTube is a major source of information for patients, much of it beneficial. But one recent YouTube video claimed that apricot seeds were effective against cancer. It went viral, and within a week one farmer's market ran completely out of apricot seeds. Patients increasingly heed such advice without any discussion with doctors, and even those with insurance are becoming more reluctant to share information with their doctors.

Information generated by AI from a trusted source is by its nature more valid and reliable than opinionated information found on web pages and blogs. As long as we safeguard against the deployment of AIs mischievously taught to misinform, AI will eventually eliminate the misinformation issue.

But it might also obviate a visit to the doctor. There will always be some who believe in any nonsense put out on fringe websites, but most will want, and will learn where to turn for, valid and reliable health advice. Amazon's Alexa, Apple's Siri, Microsoft's Cortana, Google Assistant, possibly IBM's Dr. Watson, and similar offerings from China will probably become the primary care provider for most people.

Trust in the expert opinions of trained and licensed professionals, and in the validity and reliability of the mainly trials-driven evidence on which the better doctors rely, is in decline. We need more data than the typical trial can provide to get to better measures of validity and reliability.

The website PatientsLikeMe is trying to provide them. The world's largest personalized health network began in 1998 as a way to help a family member combat ALS by asking other ALS patients and their families what worked and did not work for them in their particular circumstances, which they were also asked to detail. Since then, PatientsLlkeMe has amassed more than 43 million data points on about 2,800 medical conditions contributed by more than 600,000 patients, based on which it has published over 100 research papers. It also collects actual patient samples.

In sum, the traditional hospital industry faces threats, and certainly faces change, from:

- Non-traditional providers such as CVS/Aetna,
- PatientsLikeMe, and other patient-centered health portals;
- The bioartificial kidney, and other products of bionic and regenerative medicine;
- Digital models of disease processes and patients;
- Quantum computing; and
- The acceleration exponent.

## THE FUTURE

**Such is the acceleration** of innovation that eras have shrunk from millennia to every few years. The discovery of the double helix marked a new era, the sequencing of the human genome marked a new era, CRISPR genome-editing (developed all of five years ago) marked a new era, and on it goes. Before we can get to grips with one era, another starts.

It grows harder to keep up. Older generations get left behind as new technologies make their younger, successor generations more knowledgeable and relevant to the era *du jour* than them. How will Millennial grandparents deal with Generation Alpha grandkids (born after 2014) whose reality will be almost entirely virtual and whose communication may well be telepathic?

In what most of us generalize as the "modern" era, few people work in agriculture any more. In industry, job growth is increasingly consumed by AI-based robotics. Service sector employment too is starting to succumb to AI-driven hardware and software machines. The time will come when humans don't work the land, don't work in factories, and provide only niche, specialized services—which might or might not include healthcare services.

We can all see the changes happening. But our capacity to deny, discount, or ignore evidence until it is too late to prevent potentially catastrophic effects—such as climate change, such as mass unemployment, such as antibiotic resistance seems limitless.

By definition, the emerging AI Revolution (successor to the Agrarian, Industrial, Service, and Information Revolutions) defined by autonomous automation is unlikely to provide new forms of work for people to do, and even if it did, millions of men, women, and children will still suffer in the transition to it.

Increasing numbers of people are already being replaced by AI systems, and we provide very little in the way of a safety net. Where will the 3.5 million (in just the United States) truck drivers—not to mention taxi, Uber, and /Lyft drivers—find work when autonomous vehicles appear on the streets *en masse*, as—barring some global cataclysm they must?

Salvation may come, after much damage has been done, in the form of cyborgism. Human beings will literally *incorporate* AI. It will make us smart enough to figure out how to survive. For one thing, the cyborg will rely in the facts held in its global Internet memory, rather than the confusion, misunderstanding, biases, denial and ignorance of purely human cognition and memory.

Except for trauma and intensive care, ten years from now patients won't need hospitals any more, because they—patients—will be practically a different life form. Like a lizard, they will be able to regenerate a limb if one gets lost.

#### From Health to Superhealth

Telepathy and regeneration will take humanity beyond the traditional concept of health as being whole in body and mind and free from disease and pain. They will sweep us along with the masses responding to extreme makeover programs, demanding bionic bodies not just hale and hearty but beautiful and sensitive and strong as well.

People want more than the health nature provides, and technology is obliging with a future in which chronic ailments such as heart disease and diabetes and obesity will have been eliminated, while acute ailments such as some new strain of exotic disease or a traumatic injury to the body will be quickly fixed. This implies that everybody—that is, everyone who has access to healthcare technology—can be healthy in today's terms.

A future in which human physical, mental, and sensory augmentation are re-defined is a future in which healthcare and its institutions and professions must also be re-defined.

The trend to patient self-care represented by PatientsLikeMe and the DIY artificial pancreas gives people the tools to manage their own healthcare and diagnose and treat themselves. It is empowering people to take responsibility for their own healthcare.

The traditional healthcare providers who manage to stay in business as this trend gathers steam need to know what to provide and whether and how to redefine—reinvent—themselves to provide it. Medical schools need to know what to teach, health insurance plans need to know what to regulate—or not.

#### Q

The future is present today, as it was always present in the past. It exists, as it has always existed and will aways exist, in our imagination.

Imagination is the common denominator for the collective faculty we call myth and the individual

faculty we call dream. It is key to predicting the HealthQuake and its impacts. Had cardiothoracic surgeons dared to imagine the interventional cardiologist, keyhole surgery, and stents, they might have been spared their virtual demise. Their experience, together with the emergence of smartphone apps like Clinic from Face2Gene (see facing page) as reliable, inexpensive, and instantly accessible care providers, should be sufficient to disabuse anyone of the notion that physicians are immune to rapid obsolescence.

When obsolescence starts to affect not just one specialty but the whole spectrum of medicine and its professions, the business of healthcare must and will change drastically.

The question is how fast, how far, and in what direction? We will know more at HealthQuake 2020.





## THE DELEGATES



#### **Invited Delegates**



#### **Gregory Auner**

Founder & Director, Smart Sensors & Integrated Microsystems

Dr. Auner is the founder and director of the Smart Sensors and Integrated Microsystems (SSIM) Laboratory. Originally a unit of the Wayne State University College of Engineering, SSIM became a unit of the Department of Surgery in the School of Medicine. SSIM consists of five inter-connecting laboratories with over 11,000 sq. ft. of

space. His research mostly involves the research and development of biomedical microsystems including implantable vision chips for the blind, an ultrasonic breast cancer detection system (commercialized), and a point-of-care pathogen and disease detector in the process of commercialization for animal use and under FDA fast-tracking for human use. Dr. Auner has over 20 patents.



#### Eran Bashan

CEO, Co-founder, and Chairman, Hygieia, Inc.

Eran has over 20 years experience in leadership, execution, research, innovation, and team building. He co-founded Hygieia in 2008 and demonstrated his ability to bring products from ideation to commercialization. Prior to Hygieia, Eran managed R&D at

OTM Technologies, a startup company focusing on unique optical sensor applications. Prior to OTM, Eran was with Elbit Systems (NASDAQ:ESLT). He also spent several years as a lecturer. Eran started his career in the military as a field officer where he was a Company commander in the Armor Corps. Eran holds a PhD in Electrical Engineering from the University of Michigan.



#### David Bouwman

Professor Emeritus, Wayne State University

Dr. Bouwman is a Clinical member of the Breast Cancer Biology Program at the Karmanos Cancer Center, contributing to the Center's education and dissemination mission. His commitment to cancer research is focused on stimulating medical students,

residents, fellows, and junior surgical faculty to ask questions that result in analysis of clinical experience to identify new knowledge in all phases of breast care from surveillance through risk management to the diagnosis and treatment of clinical breast cancer. He brings extensive clinical experience to this endeavor along with a current knowledge of clinical standards and breast cancer natural history. His main interest is developing new professional talent through education for practitioners in both clinical and translational science areas impacting on breast care.



#### Rosanne Brugnoni

Senior Consultant, Northwood, Inc.

Rosanne (Bommarito) Brugnoni has over 40-years of management experience in hospitals, colleges, and home care industries. At Northwood she is the subject matter

expert for durable medical equipment, prosthetics and orthotics, medical supplies, infusion, home health and ancillary home health care services. Her project management expertise is applied to initiating, planning, executing, controlling and closing projects for Northwood's auto no-fault and workers' compensation clients.



#### Ronald Bukowski

CEO, Bukowski Consulting, LLC

Dr. Bukowski is an emeritus staff at the Taussig Cancer Center and the Cleveland Clinic Foundation. He was recently Professor of Medicine, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University and Deputy Director of the Cleveland Clinic Taussig Cancer Center. He was Director of the Experimental Therapeutics Program at the

Cleveland Clinic Cancer Center, and held the James Zito Chair in Cancer Research from 2001 to 2008. Dr. Bukowski is a fellow of the American College of Physicians and a member of numerous professional societies, including the American Society of Clinical Oncology, and the American Association of Cancer Research. He is a lifelong researcher with interests in new drug development and investigation, as well as biologic response modifiers and the biology of renal cell carcinoma. Currently, Dr. Bukowski is the chairman of the medical committee of the Kidney Cancer Association and chairman of its board.



#### Atul Butte

Chief Data Scientist, University of California

Dr. Butte is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute at the University of California, San Francisco. He is Chief Data Scientist for the University of California Health System and a co-founder of Personalis, a cancer genome sequencing company.



#### Mona Doshi

Professor, University of Michigan

Dr. Doshi is a professor of nephrology and internal medicine at the University of Michigan. She has served as a reviewer for the International Journal of Artificial Organs and for Kidney International, official journal of the International Society of Nephrology.



#### Cynthia Flanigan

Chief Engineer, Vehicle Research and Technology, Ford Research and Advanced Engineering

Dr. Cynthia Flanigan has been with the Ford Motor Company for over 16 years. She worked for nine years in the Plastics Research group within the Ford Research Laboratory, with focus on developing biomaterials such as soy based polyurethane foam,

which led to implementation on seating for all Ford vehicles built within North America. Dr. Flanigan has received several awards such as the R&D100, the SAE International Environmental Excellence in Transportation Award, the Henry Ford Award and several SPE Automotive awards. She leads Ford's Elastomers Research program, including evaluation of renewable and recycled materials for automotive

rubber compounds. Cynthia received Materials Science and Engineering degrees from M.I.T. (B.S.) in Cambridge, Massachusetts and Northwestern University (Ph.D.) in Evanston, Illinois.



#### Heba Gamal

Surgical Oncologist, Cairo University and National Cancer Institute of Egypt

After completing medical school at Cairo University in 1997 Dr. Gamal became the first woman ever accepted into a residency in surgery at the Egyptian National Cancer Institute (NCI), following which she was the first (and to this day is still the only) woman to

be appointed to the NCI–Cairo University faculty to practice and teach surgery. She has served as secretary general of the international annual NCI conference "Bridging Gaps in Oncology" for the past four years and is the NCI's international research coordinator.



#### Jay Greene

Reporter, Crain Communications

Jay is the health care reporter for Crain's Detroit Business. He was born in Sarasota, Fla., and graduated from the University of Florida. He has worked for Crain's a total of 18 years, including 11 years at CDB's sister publication, Modern Healthcare in Chicago.



#### **Elizabeth Heath**

Professor of Oncology and Director of Prostate Cancer Research, Karmanos Cancer Center

Dr. Heath leads the Prostate Cancer Research Team at the Karmanos Cancer Institute (KCI). Her research centers on clinical and translational research trials in genitourinary malignancies. She is also Medical Director of the Infusion Center at the Karmanos Cancer

Center. Dr. Heath is currently the Principal Investigator of the Department of Defense grant supporting KCI/ Wayne State University involvement in the nationally recognized Prostate Clinical Trials Cancer Consortium. She has also served on the Scientific Program Committee of the Developmental Therapeutics-Molecular Therapeutics Committee of the American Society of Clinical Oncology (ASCO) and has served as Program Faculty for the annual Genitourinary ASCO as well as the annual ASCO meetings. She serves on the Board of Directors of the Michigan Cancer Consortium, and has won numerous awards for her work.



#### Shakir Hussein

Transplant Surgeon

Dr. Hussein is an attending physician at the Detroit Medical Center, specializing in transplant surgery for both adults and children. Following medical school in Sudan and residency at the Cleveland Clinic, Dr. Hussein was awarded fellowships in multi-organ transplant (Columbia University Medical Center, New York), liver transplant and hepatic

biliary surgery (ASAN Medical Center, Seoul, Korea), and intestine and multivisceral transplant (University of Pittsburgh Medical Center). He has been a part of the incredible advances made in the science of transplant surgery made in the past several years and conducts research that continues to explore ways to perform less invasive surgery, which is key to helping patients recover quickly.



#### Sérgio Juaçaba CEO, Instituto do Câncer do Ceará

Dr. Sergio is director of the Instituto do Câncer do Ceará and Professor in the Faculdade Rodolfo Teofilo in Fortaleza, Brazil. Under his leadership, the Center has grown to treat some 10,000 cancer patients per year and was first to deploy Watson Health in Brazil. He received his MD from the Federal University of Ceará in Brazil and a Doctorate in

Philosophy from the University of Oxford.



#### Joel Keiper

Chief Strategy Officer, Hygieia, Inc.

Joel's 25 years of diverse healthcare experience help craft and lead Hygieia's strategic portfolio. Joel was previously SVP and CSO for Tenet Healthcare's Midwest region, responsible for overall strategic and capital planning for the

\$3B academic health system which included inpatient, ambulatory and retail growth initiatives, service line development, JVs and divestitures. Joel was also SVP of Business Development at Henry Ford Health System's insurance subsidiary Health Alliance Plan; Senior Consultant with Sullivan Cotter, a national healthcare valuation firm; Director with The Advisory Board Company, a leading D.C. healthcare think-tank; and started his career at Deloitte, advising clients via complex M&A, growth, and technology engagements.



#### Kiran Koya

Researcher, Smart Sensors & Integrated Microsystems Lab

Dr. Koya is a post-doctoral fellow in the Michael & Marian Ilitch Department of Surgery at Wayne State University. His research focuses on the identification of pathogenic biomarkers in bodily fluids through the application of Raman spectroscopy.



#### Anil Kumar

Trustee, Wayne State University

Dr. Kumar has been a practicing urologist in the Metro Detroit area for the past 30 years. He serves as a Clinical Assistant Professor for Michigan State University and as site director for the Urology residency program at Crittenton Hospital. He has been a lifelong teacher and has published numerous articles. Dr. Kumar has been a member of the

board of the Oakland County Medical Society and a member of the Michigan State Medical Society. He is the owner and CEO of the Kumar Surgery Center. He has been Chief of Staff at the North Oakland Medical Center, Chief of Surgery at Crittenton Hospital and is currently Chief of Staff at Ascension Providence Rochester Hospital. He was previously chairman of the board at Doctor's Hospital in Pontiac, Michigan. Dr. Kumar is dedicated to public service with an aim reform healthcare and education.



#### Lillian Preston

President, OurHealth Media Network

Lillian Preston is founder, president and visionary behind OurHealth Media Network, founded in 2004 to address the broad health disparities that exist in our society. Previously Director of Communications for the Detroit Empowerment Zone and Vice President of Marketing for Procurement Resources, an Atlanta based supplier diversity consulting firm. Preston spent the majority of her career working in television as a

producer/director at ABC, CBS and Fox network affiliates, directing news, producing special programs. She was a major contributor to Emmy Award winning productions.



#### Dan Reiner

CEO, Stemcentrx

Dan Reiner is a founder, investor, and/or a director of more than a dozen companies in the public and private sectors, spanning multiple markets from biotechnology to real estate. He was the Founding CEO and Executive Chairman of Stemcentrx, a cancer drug development firm sold to Abbvie for \$5.8+ billion in 2016. Prior to Stemcentrx, Daniel

was Chairman and CEO of telecommunications equipment company World Wide Packets. Daniel was an investor, executive and board member for VaxGen, a spin out from Genentech, which executed on a Phase III clinical trial of an AIDS vaccine. He holds an MBA from Pepperdine University and has undertaken graduate studies in genetics and biochemistry at Wayne State University and the University of California, San Diego.



#### Hermano Rocha

Professor, Federal University of Ceará

Dr. Hermano has a PhD in Public Health from the Federal University of Ceará (UFC) and conducted post-doctoral studies in Applied Epidemiology at Harvard School of Public Health. He is a Specialist in Health Technology Assessment at the Federal University of Rio Grande do Sul in Porto Alegre and in Health Economics at UFC. He is also Master of Public Health at UFC. He is a member of the International Epidemiology Association and

conducts research in various medical and epidemiological areas, with a main focus on maternal and child nutritional health and health technology assessment.



#### Jason Rolls

Transplant Surgeon, Detroit Medical Center

Dr. Rolls is an abdominal organ transplant surgeon at the Detroit Medical Center kidney program, where he also serves renal disease patients with their non-transplant related surgical needs. He received his transplant surgery training at Columbia University, and general surgical training at Cornell University, both in New York, where he grew up. He and his beautiful wife have three wonderful children, and a very large Great Dane.



#### Jerry C. Rosenberg

Transplant Surgeon (retired) and Philanthropist

Dr. Rosenberg was a faculty member of the Wayne State University School of Medicine and former chief of surgery at Hutzel Hospital. He led one of Detroit's first clinical transplantation teams, which performed pioneering transplantation surgeries. He and his wife, Corliss, a former nurse, established the J.C. Rosenberg Endowed Lecture in

Transplantation and Tumor Immunology, now in its fifth year, to teach aspiring surgeons about the field's leading-edge research and innovations. His generous endowment underwrites today's lecture by Dr. Roy on the artificial kidney.



#### Shuvo Roy

Director, The Kidney Project, UCSF Department of Bioengineering and Therapeutic Sciences

Dr. Roy is co-inventor of the world's first implantable artificial kidney. He is a Professor in the Departments of Bioengineering & Therapeutic Sciences and Surgery at the Schools of Pharmacy and Medicine at the University of California, San Francisco.



#### Wael Sakr

#### Specialist-in-Chief of Pathology, Detroit Medical Center

Dr. Sakr focuses on the histopathological and biological traits of preneoplastic changes of the prostate. His work contributed to the current consensus that high grade prostatic intraepithelial neoplasm is a precursor of prostate adenocarcinoma. Dr. Sakr has been actively involved in numerous clinical trials as an expert pathologist. Dr. Sakr is also interested in evaluating genetic changes and expression profiling as markers for cancer

diagnosis and prognosis. In addition, Dr. Sakr is an active investigator on several funded basic research projects on the underlying molecular mechanism of prostate tumor progression and metastasis.



#### Jim Sergi

Chair, CSSi Life Sciences

Prior to founding CSSi LifeSciences Jim held various positions in academic oncology and cancer research and co-founded ProED, a healthcare services and drug development company. ProED was responsible for over 50 successful FDA NDA/BLA and EMA applications and defenses for various drugs, biologics and diagnostic tests, including over 150 medical devices 510(K) submissions. His academic and medical experience

includes Director for the Department of Experimental Therapeutics at the Cleveland Clinic Cancer Center, Associate Professor of Medical-Surgical Nursing at the Case Western Reserve University and Lecturer for Oncology at Cleveland State University. He has authored over 75 scientific and medical publications. Jim serves as an advisor to numerous private equity and venture backed investment firms. Jim is also a scientific reviewer for the NIH SBIR/STTR Commercial Readiness Program and as a mentor to the NIH/NHLBI and the NIH Larta FeedForward programs. He serves as a member of the Global Center for Health Innovation and the NorCoBio Task Forces. In addition, Jim is a frequent speaker focusing on accelerating commercial readiness and value through strategic regulatory and clinical planning.



#### Paul Shaheen Executive Director (retired),

Michigan Council for Maternal & Child Health

Paul Shaheen founded and led the Michigan Council for Maternal and Child Health, where he successfully lobbied the Michigan legislature to protect the health and wellbeing of mothers and children for over 20 years. He is now a University–Community

Senior Fellow at the Michigan State University Office of Outreach and Engagement. In early life served in the Peace Corps in Peru, acquiring passable Spanish in the process.



#### **Charles Shanley**

Founder & Chairman, Seraph Biosciences, Inc.

Dr. Shanley is a vascular surgeon, vice dean for Clinical Affairs at the Wayne State University School of Medicine, CEO of the Wayne State University Physician Group, and Chairman of Seraph Biosciences, creator of the Seraspec®, a portable, point-of-care technology for real-time pathogen and carcinogen detection and identification.



#### Jack Sobel

#### Dean, Wayne State University School of Medicine

A graduate of the University of the Witwatersrand in Johannesburg, South Africa, Dr. Sobel is one of the world's foremost authorities on bacterial vaginosis. He has served as a consultant for the U.S. Centers for Disease Control and Prevention's special committee for recommending guidelines for the treatment of sexually transmitted diseases, and as

president of the Michigan Infectious Diseases Society. He is a member of the National State President's Committee and the Infectious Diseases Society of America's Practice Guidelines Committee. He is chair of the Division of Research in the internal medicine department at WSU, and a professor of Immunology and Microbiology, and Obstetrics and Gynecology.



#### Tony Tedeschi

#### CEO, Detroit Medical Center

Before joining the Detroit Medical Center as CEO in 2017, Dr. Tedeschi served as CEO of Tenet Health's four-hospital Chicago Market as well as CEO at Chicago-based Weiss Memorial Hospital. Prior to joining Tenet, he served as COO of Cook County Health & Hospitals System in Chicago. He earned his medical degree from the University of Illinois at Chicago, his MBA from Chicago-based Northwestern University as well as a master's

degree in public health from the Medical College of Wisconsin in Milwaukee.

#### **DIREF Board Member Delegates**



#### Keith Crain

Chairman, Crain Communications

Mr. Crain is recognized internationally for his contributions in the automotive and publishing industries as publisher and editor-in-chief of Automotive News and Crain's Detroit Business. One of his major accomplishments in his long career was the development of the Automotive News World Congress as an international forum for

global business leaders to meet annually to discuss the most pressing issues facing the automotive industry. Mr. Crain also assisted in the development of the annual North American International Auto Show in Detroit in 1989. He went on to help with the launch of Automotive News Europe's European World Congress in 1997. His services to the automotive world were recognized by his Induction in 2014 into the Automotive Hall of Fame, the single greatest honor in the automotive business. Mr. Crain is active in a myriad civic and professional associations. He is immediate past chairman of the board of the College for Creative Studies, and sits on the boards of The Concours d'Elegance of America, The Detroit Metro Convention & Visitors Bureau, Downtown Detroit Partnership, Gilmore Car Museum, the Automotive Hall of Fame, and the

Detroit International Research & Education Foundation.



### David Ellis

Executive Director, DIREF

Mr. Ellis is a health futurist. He was for several years a regular columnist for *Hospitals & Health Networks Daily*, an online publication of the American Hospital Association, and was futurist at the Detroit Medical Center under Mike Duggan from 2004-2010. Besides *Technology and The Future of Health Care*, which won the 2000 HIMSS Book of the Year

award, Ellis also wrote *Deus ex Machina sapiens*, a book about the emergence of intelligent machines. He now serves DIREF and the Department of Surgery at the Wayne State University School of Medicine.



#### Orlando Padilla

#### President, Padilla Networks

Orlando Padilla provides global public policy, strategic planning and issues management expertise on domestic and international business topics to Fortune 500 clients and new business ventures. He has served on the boards of 18 non-profit organizations and as Senior Advisor to Board members and officers rep-resenting a portfolio potential of 70

Fortune 500/1000 companies in 15 industries. Prior to retirement from a 34 year global career at General Motors, Mr. Padilla's last assignment was Global Senior Director, Public Policy, Corporate & Government Relations with expanded responsibilities for the General Motors Public Policy Center at General Motors headquarters in Detroit. Padilla was named by Hispanic Business Magazine for several years as one of the most influential Hispanics and listed on the Corporate Elite – Top 100 Hispanic Executives and is a founding member of the Hispanic Association on Corporate Responsibility Corporate Executives Forum.



#### Edson Pontes Chairman, DIREF

Dr. Pontes is a thought leader in urologic oncology and one of the pioneers in the diagnosis and treatment of prostate cancer. He retired from the Chairmanship of the Department of Urology at Wayne State School of Medicine in 2012 but continues to practice in his specialty, oncological surgery, at the Karmanos Cancer Institute, the

Detroit Medical Center, and the John A. Dingell Veterans' Hospital. He was formerly Head of International Services for the Detroit Medical Center, where among other duties he oversaw the operation of an international guest hotel and services to visiting international patients and physicians, and before that he served as director of urologic oncology at both the Cleveland Clinic and Roswell Park Cancer Centers. He is internationally recognized as a specialist in genitourinary (bladder, kidney, prostate, testicular) oncology and surgery, and treated French President Francois Mitterand in the 1990s.



#### **Don Weaver**

Chairman Michael & Marian Ilitch Dept. of Surgery

Dr. Weaver is Chair of the Michael & Marian Ilitch Department of Surgery at Wayne State University School of Medicine and Surgeon-in-Chief for the Detroit Medical Center. He is an active clinical surgeon with expertise in surgical oncology and minimally invasive surgery. He has traveled extensively abroad, particularly India, the Middle East, and

Brazil for workshops, lectures and activities of charity. Dr. Weaver is president of the Detroit International Research & Education Foundation.



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