HEALTHCARE IN THE TRUMP ERA

Navigating the dynamic global and domestic landscape of medicine

- LGBTQ HEALTHCARE IN THE CURRENT ADMINISTRATION
  The impact of new policy changes

- MEDICAL MARIJUANA POLICY: TRUMP’S FATAL CHOICES
  Is Trump’s administration undermining his own vision?

- THE CHANGING FACE OF U.S. INVOLVEMENT IN GLOBAL HEALTH
  Impact of social and domestic values on foreign policy

- THE OPIOID CRISIS: A SMALL DOSE FOR A LARGE EPIDEMIC
  An in-depth look at the health crisis of the decade
Dear Readers,

In our current political landscape, it is nearly impossible to escape news on the “chaotic mess” of policy creation in D.C. With a slew of acronyms (AHCA, BCRA, ACA, etc.), complicated terms (risk corridors, cost sharing reductions, individual insurance, etc.), and a multitude of programs (Medicare, Medicaid, the “exchanges,” etc.) tossed around, it is easy to see why most Americans do not have a full understanding of the debate surrounding their future healthcare landscape. Since most individuals are mainly concerned with the bottom line of their health insurance costs, it is easy to miss not only the origins of the crisis but also the ramifications on other facets of life. Thus, the SYNAPSE Spring 2018 edition seeks to give an accurate image of healthcare policy since the beginning of Trump's presidency, including aiming to declutter the facts from fiction on both sides of the health insurance coverage issue captured by our infographic piece: “Healthcare in the Trump Era: Navigating the Dynamic Global and Domestic Landscape of Medicine.”

This semester, our feature articles explore many sides of healthcare policy, advocacy, reform, and scientific discovery in the recent years with an overall theme of examining how these events shape the image of American healthcare both domestically and abroad. We conducted in-depth interviews to uncover the truth behind the Cuban healthcare system. We examined the impact of healthcare technology developed domestically on foreign countries. We analyzed the current healthcare provisions, or lack thereof, for LGBTQ individuals under the current administration's policies. Touching upon the global, political, innovative, and ethical/cultural aspects of health, our articles seek to expand the way in which we think about health in everyday life. Through these articles, we realized how the American healthcare system still has a significant amount to learn from its counterparts abroad.

In the seventeenth installment of SYNAPSE, we would like to sincerely thank all our members, and each and every member of our Editorial, Design & Layout, and Business/Development/Innovation teams for their contributions this semester and over their collegiate careers. Without the dedication and hard work of our team, the creation of this issue would not have been possible.

Sincerely,
Sebastian de Armas and Victoria Siu
Editors-in-Chief
Interesting in writing for SYNAPSE? Go online to www.upennsynapse.com or email edit.synapse@gmail.com for more information.
THE PROBLEM

Large disparities in access to health resources exist across the globe. While countries like the United States have enough doctors and surgeons to comfortably support their populations, many countries around the world lack access to medical professionals. As a result, millions of people, especially in Africa and Asia, die from medical conditions that are easily treatable if diagnosed at the right time. There is no denying that the world faces a deficit of surgeons. The situation is so dire that in some East African regions, there is only one surgeon for every 100,000 people.5 Furthermore, a World Health Organization (WHO) and World Bank Group report shows that 400 million people do not have access to essential health services globally. Addressing the shortage of doctors and surgeons is no easy task. In fact, it is likely close to impossible to provide the developing world with the infrastructure and support it needs in order to immediately bridge the gap. What if there was a way to connect underserved patients in developing countries with health professionals on the other side of the globe? That is exactly what telemedicine offers.

TELEHEALTH

Teleconsultations provide those suffering from illnesses the opportunity to speak with someone located thousands of miles away who has access to the requisite information to accurately diagnose and potentially treat their conditions. Teleconsulting is currently being implemented in a select few places. People arrive at their “neighborhood centers,” where a nurse or medical worker inquires about the patient’s condition and subsequently connects the patient with a specialist located anywhere in the world. Establishing these “teleconsultation centers” requires only a monitor and a stable internet connection, so it can quickly be scaled up without forcing countries to consume their entire budget1. Moreover, with these teleconsultation centers, health professionals already present in developing countries are now able to perform the lifesaving surgeries and procedures that only an in-person doctor can provide. In other words, it is imperative that doctors in developing nations prioritize and devote their efforts to the most serious cases that require in-person care. Altogether, telehealth digitally transports doctors in regions that already have a surplus of resources to regions that have virtually none.
SUCCESSFUL IMPLEMENTATION OF TELEHEALTH

Recognizing the potential for telemedicine, a number of countries have taken steps towards implementing telehealth systems. The Ghana Health Service and Novartis Foundation are co-operating to develop a nationwide “telemedicine” program by 2019. The roots of this plan lie in a pilot program that began in remote parts of the Ashanti region in 2011. Community health workers, serving around 35,000 people in 30 communities, access specialists from established centers such as Columbia University through a 24-hour teleconsultation center in order to get the medical knowledge they need to properly tend to patients. Preliminary results from Novartis for this project showed that more than half of all teleconsultations could be resolved directly by phone; thus, 31% of patients avoided unnecessary subsequent referrals. Among the cases who were referred, 50% were designated as emergency referrals, and the consultations they received likely saved their lives.

PRELIMINARY RESULTS FROM NOVARTIS FOR THIS PROJECT SHOWED THAT MORE THAN HALF OF ALL TELECONSULTATIONS COULD BE RESOLVED DIRECTLY BY PHONE; THUS, 31% OF PATIENTS AVOIDED UNNECESSARY SUBSEQUENT REFERRALS.

In another part of the world, the Cambodia Consultation Program, also known as the Village Leap Program, is comprised of clinics that are run every other week in villages across northern Cambodia. Health workers are responsible for gathering medical information and transmitting it by email to physicians in the USA. The information is then reviewed and returned back to the center in a timely manner. These consultations are based on text and image-rich clinical documents composed by Cambodian health workers, which are then emailed to physicians in Boston and in Phnom Penh. Clinical recommendations are returned to the health workers within hours of their receipt. Recent studies have shown a diminishing rate of referral to facilities outside the village and a decrease in the duration of chronic medical problems among villagers. Additionally, a randomized survey of patients demonstrated that they are satisfied with the telemedicine service.

Another innovation that has greatly helped healthcare efforts in Africa is a smart vest application called MamaOpe that diagnoses and continuously monitors pneumonia in young children. Pneumonia can often be misdiagnosed as malaria, but through this device, doctors in the US receive the patient’s necessary information to make an accurate diagnosis. According to UNICEF, in Sub-Saharan Africa, pneumonia kills half a million children aged five and below every year. This tragic fact was the inspiration behind the biochemical smart jacket that detects pneumonia three to four times faster than the typical doctor. The jacket, which is only a prototype and has not begun its official national medical examination, could solve the large issue of misdiagnosis.

CHALLENGES

Although the promise that telemedicine offers is undeniable, evident, many issues with this form of healthcare should be addressed. For example, while teleconsulting helps fix the issues that exist in the diagnosis and treatment of simple conditions that are often mishandled, it does not change the fact that there are many procedures that require an intense person to handle. Furthermore, while teleconsulting centers do not need doctors to function, they still require nurses or other professionals to guide patients through this unorthodox form of care. While there are more nurses available than doctors in most countries, there are still not enough personnel to take care of everyone who needs help. Additionally, as Adrian Pacheco, director of the Centro Nacional de Excelencia Tecnológica en Salud, explained, “The biggest challenge is [Internet] connectivity.” The diagnostic centers are ready and available to do more than 150 screenings every day and they do not reach even 50. Without increasing internet access to developing countries, expanding telehealth will remain an impossible goal.

THE FUTURE

In the coming years, as technology advances and the world seeks novel solutions to the decades-old problems facing global health, telemedicine will be at the forefront of the discussion. New teleconsultation centers are being built across Asia and Africa daily, and barriers to healthcare are being slowly broken. However, until we reach this point, it is our responsibility as a society to continue to pursue technologies and ideas that help alleviate the vast disparities that affect the globe.

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References
HEALTHCARE ABROAD:

BY EMMA BOEY

The United States is unusual among advanced industrialized countries in that it lacks a uniform healthcare system for all of its citizens. In 2014, 48% of healthcare spending in the U.S. came from private funds compared to the federal government accounted for 28% of spending. In contrast to this “hybrid” model of healthcare, Cuba, only 90 miles off the coast of Florida, has a universal healthcare system. Cuba’s healthcare system, focusing on healthcare delivery and medical education, has been brought to the forefront of discussion concerning both global health and Cuban international relations. Yet, this seemingly established and accredited healthcare system often has imposed fallbacks on those directly involved — not only the healthcare patients but the providers as well.

Today, Cuba prides itself in not only providing its citizens with free healthcare, but also on spreading health equity to poorer communities around the world via international aid. The Cuban government is known as a large exporter of doctors and healthcare professionals who provide natural disaster relief and bolster medical services in developing countries. Since 1960, over 100,000 Cuban health professionals have served in over 100 countries. Escuela Latinoamericana de Medicina (ELAM) in Havana, Cuba enrolls approximately 19,000 students per year, making the school the world’s largest international medical school. Stemming from Cuba’s state-control over its citizens’ healthcare, a consequence of Cuba’s 1959 socialist revolution by Fidel and Raul Castro, every ELAM student receives a full scholarship from the Cuban government. However, more than 50 years of political enmity, including a United States embargo prohibiting trade with the island, has made it difficult for U.S. media to provide an accurate portrayal of Cuba’s national health system. In actuality, a disparity exists in Cuba between what’s on paper and reality.

TODAY, CUBA PRIDES ITSELF IN NOT ONLY PROVIDING ITS CITIZENS WITH FREE HEALTH CARE, BUT ALSO SPREADING HEALTH EQUITY TO POORER COMMUNITIES AROUND THE WORLD VIA INTERNATIONAL AID.

Enter Dr. Roddy Stusser, a former primary care physician in the Cuban healthcare system during the Cuban revolution. His enduring experience attests to the hardships imposed on Cuban citizens through their government’s healthcare plan, the same system widely acclaimed for its efficacy in delivering quality healthcare to all. “In Cuba, the doctor is a miserable person,” Stusser asserts. “They live in extreme poverty. A lot of doctors want to work abroad because they work with more money and more food. Primary care doctors and other healthcare professionals work with very little technology. They have been using the same medical equipment for the last 20 to 30 years.” Over his career as a regional leader during the Cuban resistance, Stusser began to investigate the statistics published by the Cuban government pertaining to heart disease, nutrition, and neonatal mortality. He found the Cuban government had been omitting data from their published studies. As a testament to their superior healthcare system, Cuba had boasted a decreased infant mortality rate of only 4.3 deaths per 1,000 live births in 2013, compared to 5.90 deaths for the United States. Yet, Stusser vocalizes, the Cuban government chose to exclude that these low rates were compounded with an increased maternal mortality rate.

Many Cuban-trained doctors have become adamant about practicing abroad because of the poor standards of living that exist in Cuba. Until two years ago, doctors were continually paid that of a typical government worker: under $30 a month. Doctors now earn $60 and nurses an average of $40 after increased pressure on the Cuban government to increase wages. “I didn't know that I was going to [work] in the nineties being a slave. I began to wake up to this situation when I went to Nicaragua in 1990. There was a surgeon in the hospital of Managua who was earning $3,500, and I was earning $10 in my pocket… I didn't know that we would be converted by the social justice of the revolution, to the [closest] level of slaves [that] there is in Cuba. Since 1959, we were promised that everything was going to get better, but I only had $10.”

In fact, over 30,000 Cuban-trained health care professionals (most of them physicians) have been sent to Venezuela in a decades-long exchange system that trades medical personnel for oil. Thus, Cuban doctors flee Cuba for a higher wage. Even so, this wage is still usury, meaning that it is easy to liken the work that Cuban-trained professionals do to slavery. And because these professionals received their education for free, the Cuban government has the ability to dictate the terms under which the healthcare professionals work.

Many Cuban-trained medical professionals, tired of being agents of the Cuban government, see potential autonomy through living in the United States as a result of its close proximity to Cuba. Stusser himself became “tired of the harassment with neighbors” and of being held a “hostage in [his] own country.” As result, he looked to come to the U.S., but was prevented from doing so by the Cuban government. For the 73-year-old, the hardest part about getting to the U.S. was receiving the approval from the Cuban “Ministry
of Foreign Affairs and International Relations,” which, according to Stusser, “don’t like people talking about [the] reality” of Cuba. Although he was eventually approved to emigrate out of Cuba, his arrival was ultimately a collaboration of primary care physicians in the U.S., friends, and family.6 Since the socialist revolution, Cuban defects have been traveling to South Florida.

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This mass exodus of Cuban healthcare professionals — where over 6,000 of them (mostly physicians) have left Cuba in the last decade10 — was expedited by the Cuban Medical Professional Parole (CMPP) program of the U.S. Department of Homeland Security, a program in which Cuban medical personnel working in countries excluding the U.S and Cuba could apply for parole at a U.S. embassy or consulate.12 In 2014 alone, the CMPP program enabled 1,278 defected Cubans to come to the U.S. while on overseas assignments.9 As a result of the CMPP program, Cuban healthcare professionals make the roundabout journey through central America in order to reach the U.S. Many Cuban health care professionals relied on the CMPP program to get to the U.S. However, these special Cuban immigrant policies were recently revoked by the Obama administration in January of 2017. The motives behind this sudden halt stem from attempts at reconciliation with Cuba by the U.S. government, a gesture received with mixed feelings importantly, they are caught between the selfless demands that their profession requires and their own personal struggle to make ends meet.

Thus, there is a story of Cubans doing great work in global health and primary care abroad. This is a true story, but it is also a framed story. There are other narratives that entail Cuban doctors practicing in foreign countries in attempts to either triple their income or eventually end up in the U.S. in order to uphold a standard of living. With stricter immigration policies, the future remains unclear for such economic refugees. According to Stusser, the prospect of retaliation in Cuba seems unattainable as he explains that “someone going all day looking for something to eat...doesn't have enough time to change the system where he lives [and is] scared of retaliation [as a result of being] under the control of the government.”6 Under such conditions, the country will continue to feel the repercussions of a system devoid of medical resources as healthcare continues to be supported in this fashion. Cuban healthcare professionals will continue to be caught in the middle of the political and economic struggles of their country. Most im-

References

DR. RODDY WITH DR. JOHN VENER IN FRONT OF THE VEDADO EDUCATIONAL POLYCLINIC.
THE CHANGING FACE OF THE U.S. INVOLVEMENT IN GLOBAL HEALTH

BY SANDY SAMUEL

Global health serves to improve health outcomes and achieve equity in health for all people worldwide irrespective of their socio-economic contexts. The field of global health is a relatively recent phenomenon that began to develop after World War II with the creation of the World Health Organization (WHO) in an attempt to foster global collaboration. Nevertheless, the field truly emerged in its current form in the 1990s primarily due to the HIV/AIDS crisis. The United States has been a major contributor to this field since its inception by either funding established health organizations or founding its own programs. Total U.S. global health funding was $10.4 billion in fiscal year 2017, up from $5.3 billion in fiscal year 2006; the current administration, however, has proposed to significantly cut global health funding for FY 2018.

Through an analysis of U.S. policies in global health beginning from the late 1990s till our modern day, particularly with respect to its global HIV/AIDS policies, it can be argued that the U.S. role in global health has been largely shaped by political, social and economic interests at home.

AFTER WWII:

After WWII, the United Nations was established to create a platform for international collaboration and dialogue. The World Health Organization, the U.N agency concerned with international public health, was formed thereafter in 1948. The U.S. engagement in global health was fueled by several factors, some of which were its successes in identifying ways to eliminate and control many diseases at home and abroad, such as malaria and polio; growing globalization; and the emergence of new infectious disease threats, most notably HIV/AIDS. After the war, the U.S. and the Soviet union were the two major powers on the international stage. Thus, the U.S. had to take on a large commitment, both economically and politically, to implement the agendas set forth by international health organizations. During the Alma-Ata Conference of 1978, many nations, including the U.S., pledged to provide universal healthcare to developing countries. However, this commitment to strive for health for all was soon replaced by a more selective primary healthcare approach that placed the priorities of the wealthy nations first.

1980s- EARLY 2000s

The HIV/AIDS crisis that occurred in the U.S. during the early 1980s prompted the country to launch local and global campaigns against the disease, a major turning point in scaling-up funding for the field of global health that caused it to metamorphose into its current form. It is evident that public health safety concerns at home played a major role in fueling international health programs and channelling much needed funds to developing countries who have been facing the same crisis for decades earlier. Interestingly, the U.S. acted independently of most established international health organizations in its fight against HIV and other epidemics. Instead, it chose to institute its own programs to combat the epidemic locally and abroad. In 2003, the U.S. established the President’s Emergency Plan for AIDS Relief (PEPFAR) which has been a vital driving force behind the global scale-up of HIV care and treatment services, particularly in expansion of access to antiretroviral therapy. This global health strategy aligned with U.S. unilateralist approaches in world affairs, centered on the idea that all global involvement is defined first and foremost by the particularist interest of the United States, rather than committing to common endeavors with other nations. As a result of the HIV/AIDS crisis, public health became a parcel of the new Department of Homeland Security’s U.S. national policy agenda.
Even more recently, the U.S. decided that grants available through the Global Fund to Fight AIDS, Tuberculosis, and Malaria, should have “a new delivery system” rather than relying on UN agencies and the World Bank.\(^2\) Hence, instead of collaborating with other international powers in Europe to address global health challenges, the U.S. took a self-driven approach in first identifying health problems that represented a threat to its homeland security and then by devising its own strategies to channel funds to developing countries facing these epidemics.

In addition, the U.S. often votes in multilateralist global initiatives in a manner that aligns with its own economic interests rather than supporting the mainstream policies. For example, the U.S. is not particularly active in support of the International Framework Convention on Tobacco Control, even though it has some of the most restrictive laws within its own borders.\(^2\) It is evident the U.S. role in global health gradually shifted from engaging in multilateral initiatives through established international health entities to a unilateral approach that put U.S. national interests front and center.

**PRESENT DAY**

The U.S. budget allocated to global health funding has been consistently on the rise in the past years\(^1\), however, this upward trend may soon reverse. Earlier in 2017 and in 2018, President Donald Trump proposed budget cuts to global health spending by 2.2 billion dollars. These cuts would particularly target specific initiatives such as HIV/AIDS, malaria and family planning.\(^6\) It can be argued that the HIV/AIDS budget cuts would disproportionately affect the LGBTQ community-a social group that the administration has previously expressed some negative opinions about.\(^8\)

In addition, other laws pertaining to health services delivery to developing countries have been implemented such as the Global Gag Rule. This law prohibits allocation of U.S. funding to foreign non-governmental organizations that offer abortion services or information about the procedure.\(^7\) It is clear that many of these recent global health policies reflect the new administration’s agenda and priorities with little regard to local contexts of the populations they serve.

**FUTURE TRAJECTORY**

In a time of many health crises, the U.S. must move beyond its current national-interest model in order to strengthen its “soft power” in health and to truly uphold its principles of democracy and equality in the global stage.

In the face of many health challenges, the international community needs a leader to enforce global agendas and priorities and connect all the independent acting agencies particularly that many health issues, such as HIV/AIDS, require a global response and the cooperation of many actors. Only the U.S. has the needed resources and power to be able to take up such a leading role. In other words, the global community expects the United States to take soft power leadership. However, with the Trump administration scaling back its health funding, it is questionable whether global health challenges would be addressed anytime soon.

**U.S. Global Health Funding, FY 2004 - FY 2018 Request (In Billions)**

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**References**


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ORGAN DONATION IN ISRAEL

BY KRISTINA WIRKOWSKI

Whether watching Grey’s Anatomy, getting a license at the DMV, or even talking to friends and family, the subject of organ donation tends to arise in various contexts. This practice has been a central focus of medical officials, due to the life-saving implications that the donation of organs has. While organ donation rates vary in different locations around the world, the Middle East has particularly low percentages. This article will provide an overview of organ donation policy in Israel, which has a reputation for scientific advancement and controversial government policies towards organ transplantation and donation. The diverse religious makeup of this nation will allow for a better analysis of what effects religion has on organ donation levels. Ultimately, it has been shown that factors like poor education and low levels of public awareness contribute more to lower organ donation levels than religious differences do.

BRAIN DEATH - DEBUNKED

Although living donors do contribute organs, such as kidneys or liver lobes, most organs cannot be transplanted if the donor is still alive—this is called cadaveric donation. The act of cadaveric organ donation can happen in two different scenarios: cardiac death and brain death. Brain death occurs when high pressure inside the brain causes swelling, stopping the flow of blood to areas of the brain. When this happens, cells are deprived of oxygen and other necessary nutrients carried through the blood and quickly begin to die. In some cases, the damage from this results in a coma, which can be reversible. When this death happens in certain parts of the brain that control necessary bodily functions, the patient is considered ‘brain dead.’

Although a patient’s brain might no longer be “alive”, as per brain death standards, the human heart can continue to beat for a little while, after which medications and ventilators can help keep the other organs alive. Before the diagnosis is definitive, there are certain standards that must be met. For example, patient nerve function must be evaluated at least twice, six hours apart, and in some cases, further testing, such as electroencephalography (EEG, a test of the brain’s electrical activity) or angiography (mapping of blood flow to the brain to test whether or not the flow is occluded) is performed. ¹

THEOLOGICAL ATTITUDES TOWARDS ORGAN DONATION

As mentioned earlier, not only does the distinction between cadaveric donation and donation after brain death play an important role in technical terms, but it also plays into certain religious attitudes, according to data gathered by the United Network for Organ Sharing (UNOS).

In both Hinduism and the Baha’i faith, there is no prohibition on organ donation, as such a matter is left to each individual’s conscience. Similarly, in Catholicism, organ donation is considered an act of love and of charity, but some stipulations are enforced. For example, organs should not be traded or sold and decisions regarding who should have priority in regard to organ transplantation should only be based on medical conditions. Most Islamic legal scholars and schools of jurisprudence have ruled that organ transplants are allowed, as human life is sacred and must be preserved by any possible means. However, in certain more literal and conservative interpretations of Islam, such as certain schools of Wahhabism, jurists are against organ transplantation or trade of any sort.² In Judaism, organs cannot be removed from a donor until death, which is where the rulings can get complicated. For example, certain conservative Jewish doctrines have ruled that organs can only be transplanted after cardiac death and not brain death since removing a heart that is still beating, regardless of brain function, is seen as murder, which is strictly prohibited.³

MISTAKES OR MISINFORMATION ON THIS SUBJECT ARE TYPICALLY DUE TO A LACK OF AWARENESS AND EDUCATION ABOUT WHAT BEING BRAIN DEAD ACTUALLY MEANS, WHICH IS WHY ORGANIZATIONS THAT PROMOTE AWARENESS SURROUNDING ORGAN DONATION HAVE BECOME INCREASINGLY IMPORTANT THROUGHOUT THE YEARS.

ORGAN DONATION IN ISRAEL

Israel in particular has an interesting history in regard to organ transplantation laws. Prior to 2008, there was no law prohibiting organ trafficking in Israel, and for a while, the Israeli government would actually subsidize medical costs of transplants done abroad. These actions sound great in theory, namely because of low transplant rates in Israel, but what ended up happening was that Israeli citizens would pay organ brokers to procure the organs from donors, have the procedures done, and the brokers would in turn pay the donors much less and make a hefty profit for themselves. This so-called “Transplant Tourism” placed Israeli officials under fire, as the policies in place had inadvertently funneled business into the hands of illicit organ trade rings.⁴

In 2008, the Israeli government officially instituted two laws that curbed such practices – the Cerebro-Respiratory Death Act and the Organ Transplant Act. The Cerebro-Respiratory Death Act aimed to clearly outline the specifics of brain and cardiac death in an attempt to educate the public on the definitions of each of these terms. The Organ Transplant Act was put forth to increase
the number of available organs in Israel and to encourage as many people as possible to register as donors. It introduced a priority system in donors who have already donated, as well as their families, receive first priority on the organ waitlist. Registered donors of three or more years receive second priority, and the immediate families of registered donors receive third priority. Furthermore, this act established compensation for living donors who had to take time off of work, in addition to five years of life and health insurance. Finally, the act established a database of registered organ donors. This unprecedented legislature had almost immediate repercussions, delivering results just five years after it was approved by Israeli Parliament— in two years between 2011 and 2013, the number of living organ donors in Israel increased by 67% when compared with the period between 2008 and 2011. In 2013, there also a significant decrease in Israeli patients who sought transplants abroad, as well as a record breaking number of transplants done in Israel.

What makes Israel such an interesting case is that when asked why they decline to donate their organs, many members of the public cite Jewish law. Specifically, the response tends to be that individuals think that organ donation is outlawed by Jewish law. This instance is one in which religion directly prohibits certain kinds of organ donation. However, it is worth noting that relatively few Jews adhere to such orthodox beliefs. Amongst all of the groups in Israel, only the Haredi minority are conservative enough to completely outlaw organ donation. In fact, donation after cardiac death is almost universally allowed in Jewish doctrine. The notion of not tampering with corpses is outweighed by the opportunity to save a life and is even considered by some groups to be a mitzvah (an act of good done on the basis of religious duty). Therefore, the members of the population who decline to donate their organs on the basis of Jewish doctrine simply assume what the law states, and do not actually know that the aforementioned acts put forth in 2008 were co-written with many Muslim, Christian, and Jewish authorities. This is a clear demonstration of how public misconception, rather than strict religious doctrine, negatively influences rates of organ donation.

SO, WHAT HAPPENS NOW?

Organ donation still remains a heavily debated topic by lawyers, ethicists, religious leaders across the world. Furthermore, it involves a conversation that indubitably has no foreseeable end—citizens will continue to get ill, organs will continue to be necessary, and opinions regarding ethical, legal, and religious ramifications of organ donation will continue to differ. In Israel, legislation not only allows for organ donation, but encourages it by tempting citizens with higher priority for organ donation if the need should ever arise.

With the exception of those who are ultra-conservative, data from this case study suggests that low levels of awareness and education regarding organ donation, including religious and legal doctrine, are to blame for poor donation rates—not religious doctrines in themselves. For this reason, it seems as though the onus must fall not just on governments or organizations like MESOT, but also on religious authorities to clarify official attitudes and policies towards organ donation. Given the fact that there are, quite literally, lives at stake, leaders across the board must work harder to ensure that misinterpretation does not continue to have deadly repercussions.

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In 1996, California became the first state to legalize medical marijuana. Twenty-two states, including Guam and the District of Columbia followed in its footsteps. The medical legalization associated with increased access was driven by citizen support at state level that began to emerge in the early 1970s, particularly with the “baby boomers.” This generation was the first to realize that marijuana was not the evil drug the government had made it out to be, but rather a highly effective medical tool to treat pain. Subsequently, grass roots efforts coordinated at local and state level have promoted political changes. Since then, even the recreational use of marijuana has become legal in some states. In 2012, Colorado and Washington were the first states to take this step, and seven other states and D.C. followed. As these policy changes lead to more public use of the drug, both medically and recreationally, it is meaningful to make the distinction between the two forms clear.

Marijuana has around 100 active components. Of those, tetrahydrocannabinol (THC) is the component found in recreational marijuana which causes the feeling of a “high”. Medical marijuana predominantly contains cannabidiol (CBD), which relieves insomnia, anxiety, spasticity and pain. These CBD dominant strains have little to no THC and do not produce a high. In the United States, medical marijuana is most commonly prescribed to treat chronic pain. Though it is not strong enough to treat severe pain, it is most commonly used for conditions such as multiple sclerosis (MS) and Parkinson’s diseases, in which chronic pain is a side effect.

Currently, under the Marijuana Tax Act of 1937, medical marijuana is legal in 29 states but remains illegal on the federal level. President Barack Obama did not focus on prosecuting medical marijuana distributors. In fact, he put a stop to the violent Bush-era raids of medical marijuana distribution sites. The Obama administration also enacted the Cole Memorandum, establishing a federally hands-off approach in states where marijuana was legal. Also, during his presidency, the Cole Memorandum was enacted, establishing a federally hands-off approach in states where marijuana was legal. While President Trump never directly addressed medical marijuana as a part of his political agenda, he did make an explicit promise to end the opioid epidemic. But, it seems that his administration is pursuing policies that may actually undermine his proposed intentions.

On January 4th, 2018, Attorney General Jeff Sessions rescinded the Cole Memorandum. This change gives federal prosecutors the power to decide whether or not to crackdown on marijuana businesses. The Rohrabacher-Blumenauer amendment to the Cole Memorandum protects medical marijuana programs in states from federal interference. However, if the amendment is not renewed, the federal government could obtain the authority to shut down medical marijuana dispensaries. There is uncertainty with respect to the renewal of the amendment. Though it is hard to tell exactly what the effects of this policy change will be, it is highly likely that due to the increased risk and regulation, many marijuana distributors will leave the business or not enter altogether. Legal dissonance in states where state and federal laws about marijuana conflict creates a great deal of uncertainty for marijuana businesses and sellers. Specifically, these stakeholders face the risk of losing money and being subject to federal prosecution. Overall, the rescindment of the Cole Memorandum will surely lead to a decrease in the distribution of medical marijuana.

These legal changes are particularly interesting to study in the context of the rampant opioid epidemic taking place in the US. In 2015, approximately 52,000 deaths due to addictions to opioids such as oxycontin, Vicodin, heroin and fentanyl were reported. The number of deaths attributed to opioid addiction has increased fourfold since 1999, exceeding the number of deaths due to the crack and AIDS combined. The epidemic can be understood by examining the relationship between physicians and
the pharmaceutical industry in the US. In the 1990s, physicians were under a great deal of pressure to treat patients’ pain, so they turned to the prescription of opioids. Since the US healthcare system measures quality of care based on patients receiving the care that they desire, doctors continued to increase the prescription of opioids. However, the continuous prescription of opioids as the primary method of pain treatment comes with the high risk of increasing the death toll due to the high likelihood of addiction. It is undeniable that relying solely on opioids is not beneficial or sustainable.6

However, a possible solution to this epidemic does exist. Several recent studies have found that medical marijuana could be a replacement for opioids to treat chronic pain, and the transition to prescribing marijuana could have immense implications for the drug epidemic. Strides to exploring the option of replacing opioids with medical marijuana began about 15 years ago.7 Medical marijuana is much safer than opioids because it is much less addictive and impossible to overdose on.3 It was determined that states which permit medical marijuana had 25% fewer opioid overdoses than states where medical marijuana was illegal. This prompted many researchers to investigate a possible relationship between the two drugs. In a study conducted at the University of Michigan Ann Arbor, a small patient population received medical marijuana as an alternative to treat chronic pain, and their opioid use was cut in half due to the substitution. More long term data not based off of a carefully selected patient population is needed; however, these results are very promising and have serious medical and political implications.7

In light of the studies discussing the benefits of medical marijuana in contrast with the policy changes enacted by Attorney General Sessions, it is meaningful to analyze the medical and political implications of the issue in tandem. Through a medical lens, increased distribution of medical marijuana would make a substantial difference in slowing down the opioid epidemic. However, due to the new policy changes, distribution will decrease, and the opioid epidemic could continue to take the lives of thousands. Politically, the implications are even more striking. Trump ran for presidency on the promise that he would work to end the opioid epidemic but has neither generated nor allocated funding for such an initiative. Meanwhile, research suggests that medical marijuana could be a medical tool that could accomplish Trump’s goal for him, with little to no additional funding needed. Unfortunately, with actions such as the rescission of the Cole Memorandum, Trump’s administration seems to be pushing his political objective of ending the opioid crisis further and further out of reach, and the American people will pay the price.

References
LGBTQ Healthcare in the Current Administration

BY SARAH DEVLIN

LGBTQ individuals are some of the most marginalized members in the United States at schools, in the workplace, and also within the healthcare system. LGBTQ health outcomes in the U.S. are far from where they should be, and the current presidential administration is doing little to improve the health of this population.

STATE OF LGBTQ HEALTH

LGBTQ individuals are at higher risk of developing a myriad of health problems. Studies have shown that gay men have higher rates of human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs). Newly diagnosed HIV rates are 44 times higher for gay men than heterosexual men, and this is just the tip of the iceberg in terms of the health conditions disproportionately impacting the LGBTQ community.\(^1,2\)

In terms of mental health, LGBTQ individuals are more likely to suffer from anxiety and depression than those who identify as heterosexual. This is especially pronounced in LGBTQ youth, as they are two to three times more likely to attempt suicide than the general population.\(^2\)

In addition, the LGBTQ population suffers from higher rates of tobacco, alcohol, and drug use; lesbian women are less likely to get preventative cancer screenings; and lesbian and bisexual women are more likely to be overweight or obese.\(^1\) With at least 3.5% of the US population (approximately 11,308,500 people) identifying as LGBTQ, these health problems are no small issue.\(^3\)

IN TERMS OF MENTAL HEALTH, LGBTQ INDIVIDUALS ARE MORE LIKELY TO SUFFER FROM ANXIETY AND DEPRESSION THAN THOSE WHO IDENTIFY AS HETEROSEXUAL.

HEALTHCARE DISCRIMINATION

There are countless stories that demonstrate the healthcare discrimination LGBTQ individuals often face. For example, Jim Confortori, a transgender man, was ready to have a full hysterectomy in 2015 that was deemed medically necessary by his primary doctor. However, he received an email from the hospital informing him that their administration would not allow his surgeon to schedule the surgery there because it was a Catholic hospital. As a result, he needed to get the hysterectomy at another hospital, although it was farther from his home. However, in rural areas or for people who are not well-insured, going to a different hospital is not always an option.\(^4\)


Even when LGBTQ individuals do receive needed healthcare, their providers often miss parts of their care or omit asking important questions. For example, in a study of 1,921 lesbian women and 424 bisexual women receiving gynecological care, just 9.3% of them had been asked about their sexual orientation. Over one-third of the women in the study felt that disclosure of their sexual orientation would change the quality of care they receive from their physician.\(^5\) In another survey, only 15% of lesbian women had been educated about safer sex by their healthcare providers, despite the common misconception that sexually transmitted diseases (STDs), such as herpes simplex and Trichomonas, cannot be transmitted between women.\(^6\)

These instances show that members of the LGBTQ population suffer from a scarcity of resources and lack comprehensive and inclusive healthcare.

LGBTQ HEALTHCARE UNDER THE CURRENT ADMINISTRATION

So far, improvement of LGBTQ healthcare has been very slow. One million individuals in the U.S. have HIV. In late December 2017, the Trump administration discharged the last members of...
the federal advisory council on HIV and AIDS; six of the other members had resigned in June in protest of the administration refusing to let the council pass new policies. Since then, the administration has not hired any new members.7

Later, in January 2018, the Trump administration created a new division under the Department of Health and Human Services (HHS): Conscience Protections for Health Care Providers. The Conscience Protections division would “apply to health care providers who refuse to perform, accommodate, or assist with certain health care services based on religious or moral grounds.” Procedures against moral beliefs include, but are not limited to, abortions, sterilizations, and assisted suicide. The division is meant to stop recipients of federal funding from discriminating against these healthcare providers.8 Healthcare providers may file complaints on the HHS website if they believe they have been discriminated against or have been coerced into violating their conscience or moral beliefs.8 Acting HHS Secretary Eric D. Hargan stated, “Americans of faith should feel at home in our health system, not discriminated against.”

“LICENSE TO DISCRIMINATE”

Many worry that the Conscience Protections for Health Care Providers division will make it easier for healthcare providers to deny care to the LGBTQ population. Omar Gonzalez-Pagan, Confontori’s attorney, is afraid that the new division is giving organizations and individuals “license to discriminate.”4 Patrick Hennessy, a nurse in Baltimore, has witnessed how transgender patients have been treated by the healthcare system in Baltimore — their difficulties receiving care and even overhearing medical providers saying disrespectful things about them — and believes the Conscience Protections for Health Care Providers will make this worse.9

Hennessy believes that healthcare professionals need to provide compassionate care to every single one of their patients, with no exceptions. In an article in The Baltimore Sun, he calls on all nurses to take their roles as patient advocates seriously. He said, “When we see other nurses and medical providers committing a wrong, we speak up. When our elected officials threaten the quality care we provide to our patients every day, we need to speak up too.”9

WHAT SHOULD BE DONE?

Healthy People 2020 is a government organization that creates science-based national health objectives and aims to create social and physical environments that promote health for everyone in the United States. Healthy People 2020 recognized the issues affecting LGBTQ health and recommended implementing specific changes to address them. These recommended changes address the social determinants of health, such as decreasing school bul-

lyering. They also include the physical aspects of health, such as increasing access to providers and offering medical students more training in culturally competent care.1

The organization mentioned that healthcare providers can improve LGBTQ care by asking more inclusive questions such as, “Do you have a spouse or domestic partner?” instead of “Are you married?” They can also ask, “What kind of sexual contact have you had?” to provide relevant safe-sex counseling. In addition, healthcare providers should ask their patients if they have any questions related to STDs.8

If such changes and practices were to be more widely implemented, LGBTQ healthcare disparities would likely decrease, improving health outcomes for LGBTQ individuals.

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When the U.S. Department of Defense (DoD) initially proposed a clause in the National Defense Authorization Act (NDAA) of 2018 that allowed for the use of unapproved medical products, the Food and Drug Administration (FDA) was not pleased. Since the Pure Food and Drugs Act of 1906, the FDA has been a governmental consumer protection agency focused on approving and regulating items for human consumption. In its modern role, the FDA has the authority to facilitate an extensive approval process for pharmaceuticals and medical devices. It has worked to create separate pathways to shorten this lengthy process for drugs that are superior to current treatments or that fulfill unmet clinical needs. In the end, the DoD and FDA made a compromise; they would pass an act alongside, but not as a part of, the NDAA, that created a formal relationship between the two. This piece will cover the important track record of experimentation and approval in both organizations to see how this controversial issue came up in the first place and how it was eventually dissolved.

The FDA has four expedited programs that allow products to get to patients quickly: Priority Review, Breakthrough Therapy, Accelerated Approval, and Fast Track. Fast Track was the first of these programs, tracing its origin to the FDA Modernization Act of 1997 which stated that there was a goal of “Expediting study and approval of fast track drugs.” While Fast Track focuses on approving drugs that address an unmet medical need, Breakthrough Therapy, which stems from the FDA Safety and Innovation Act of 2012, is instead meant for drugs that are substantially better than the currently existing treatments. Additionally, Accelerated Approval allows drugs to be approved based on surrogate endpoints in the data and Priority Review indicates that the FDA intends to act upon an application within half a year. Although these programs are meant to expedite the approval process, they were still not rapid enough to meet the DoD’s clinical needs; in the mind of the DoD, the nature of combat injury in austere environments necessitates quick approval for any and all treatments that could save soldiers’ lives.

Despite the FDA’s extensive reach, it has not stopped the military from utilizing unapproved drugs or other products to support its past endeavors. Alcohol was commonly utilized by different countries to inspire confidence in troops. Various nations outside of the U.S. relied on herbs with hallucinogenic properties at times to give warfighters a sense of fearlessness as they entered battle. For example, European forces supplied cocaine to soldiers during World War I and the U.S. supported the provision of amphetamines to American troops in World War II. Additionally, the Vietnam war saw spikes in the use of marijuana and heroin by deployed troops. Beginning with the Korean War and continuing through the recent First Gulf War, American fighters have been using dextroamphetamine, a powerful stimulant. All of these drugs, with the exception of dextroamphetamine, are illegal substances, indicating that there has been a history of unapproved drug usage for medical or personal reasons amongst military member.

Beyond this illegal drug usage, the military actually conducted hundreds of social and medical experiments on troops between World War I and the 1970s. These troubling experiments were said to be voluntary, but at times they were completed as mandatory orders from superiors. The experiments ranged from racially dividing group members and seeing how they fared under treatments to exposing soldiers to mustard gas and hallucinogens. A group of experiments, called the Edgewood Arsenal Drug Experiments, lasted until 1975 and gave drugs ranging from LSD to PCP, mescaline, and small doses of nerve agents like sarin. The long-term consequences of participation in these tests appear to include the development of cancer and other severe illnesses. Often, these subjects were not informed about which products were tested on them or what risks were involved, which would be a nightmare for the modern FDA.

These types of experiments even took place at our very own home institution of Penn, which housed tests on conscientious objectors during World War II that exposed subjects to hepatitis and fecally contaminated water. Because of this widespread testing, a 2015 class action lawsuit was filed that covered over 70,000 individuals who were affected by these tests. The results of their experiments on individuals make it abundantly clear that the military must avoid offering untested or poorly tested treatments to troops, even if they are meant to be helpful.

**BY RYAN LEONE**

_A Fast Track to War_
The need for a program like this to facilitate DoD and FDA collaboration is apparent, given that the needs of the military to protect troops are immediate and the unapproved use of illegal or unstudied substances can be counterintuitive if it hurts warfighters in the long run. Developing a compromise between the immediate desires of the military after discoveries are made and the thorough concerns for safety and efficacy of the FDA could serve in the best interest of injured soldiers, but it could cause unintended consequences that harm instead.

Ultimately, the final version of the NDAA was passed without this clause to give the DoD independent power for approval, but the issue was addressed in a separate bill. This bill allowed the DoD to request consultation and support from the FDA in putting medical products through an expedited approval process. The components of this collaboration include workshop sessions between the DoD’s Department of Health Affairs and the FDA to evaluate potentially useful products and create a structured document to inform FDA decisions. The Center for Biologics Evaluation and Research (CBER) will conduct the initial phase of research on products for the military since many of them relate to the process of bolstering platelet efficiency or durability in post-combat scenarios. In fact, the initial motivation for this act came from the fact that the FDA had not yet approved the use of a French freeze-dried plasma, leaving it in the pipeline for several years, even when other countries had been able to utilize it for a decade.

The initial proposal to create a separate approval process through the DoD was undoubtedly a bold and arguably unethical one. To usurp the authority of our country’s long-established approval agency would be a controversial move for the DoD, but it could also harm soldiers in the way that previous attempts at unsafe experimentation did. The thorough, bureaucratic system of approval that the FDA has developed over decades is crucial to ensuring that medical products are as safe as we can predict when they reach the hands of consumers. The inherent length in this process has necessitated the need for expedited processes, like those discussed above, and it is clear that this solution of compromise for the DoD is the best way for soldiers to get the high-quality, innovative care they deserve.

References
Interactions between bioethics and politics have become increasingly consequential in shaping the world we live in and the future we are building. Present medical advances are taking us into an unexplored frontier of possibilities and presenting us with ethical considerations that have not needed to be dealt with before. In recent decades, the government has been active in addressing these issues and, presently, the current Trump administration is faced with bioethical decisions that require a great deal of deliberation and foresight as these issues have the potential to impact a large number of people. The Trump administration has possibly seven more years in office and at the rate science is advancing, their decisions will influence the future of medical innovation and the structure of the society we live in.

Since the 1970s, either the President or Congress has commissioned a group of prominent theorists and medical professionals to issue reports and advise the government on bioethical issues. The first bioethics group was commissioned in 1974 under the National Research Act signed by President Nixon. This group, named The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was partially a response to the horrific Tuskegee Syphilis Study, which ended in 1972 after forty years of research. Additionally, the 1973 Supreme Court case Roe v. Wade controversially legalized abortion the year before the commission was officially created. Out of this original bioethics commission first came a report titled “Research on the Fetus” and later the famous “Belmont Report,” which created standards for conducting human experimentation. The guidelines laid out in these reports have been a guiding force in the decision making of Institutional Review Boards (IRBs) for determining whether a study should be approved or not.

This initial commission has been succeeded by several other committees, commissions, and panels, which have issued many reports to guide our government. These reports included recommendations on an updated definition of death, embryology, end of life care, cloning, and stem cell research among other topics. The most recent group was commissioned by former President Obama in November 2009 and came to an end in early 2017. Chaired by the University of Pennsylvania’s President, Amy Gutmann, this commission issued reports on ethical issues relating to whole genome sequencing, the application of neuroscience knowledge to society, and the ethics of cognitive enhancement. Since the ending of this commission, neither President Trump nor Congress has commissioned a new group to advise on potential issues in bioethics.

These commissions are often very progressive and looking forward in the topics they write their reports on. Because of this, Presidents can decide which areas of research and development would be beneficial to promote and which areas may lead to potentially dangerous developments and should therefore have greater regulation. It is as important now as it ever has been for the State to be looking ahead to potential medical developments and the impact they could have on society. As a result, President Trump and Congress would greatly benefit from the commissioning of a group of experts to look into potential bioethical issues in the near-future.
IMPLICATIONS FROM BIOETHICAL ISSUES

One potential bioethical issue that could be researched would be problems resulting from large, possibly infinite, increases in the human lifespan. While the thought of people living for decades, if not hundreds of years, longer seems possible only in a very distant future, it may be possible sooner than many would expect. For instance, surgeons Xiaoping Ren and Sergio Canavero have been planning for the past few years to perform a head transplant on a living human being. If they accomplish this, somebody in an old, sick, or injured body could simply have their head transplanted onto a healthy body and continue to live normally for years until they need a new body.

While a human head transplant may appear to be something worth pursuing, it potentially brings with it several ethical issues and negative consequences that deserve deserving of thoughtful analysis by experts and of appropriate regulation by the State. For example, the State must consider the greater social stratification that could result from this innovation. A head transplant is an expensive procedure; if only those who have accumulated wealth can afford to extend their lives, they will be able to collect greater and greater amounts of money throughout their extended lives without ever needing to create a will and redistribute it to others. With the emergence of the healthcare as a right movement, the State may have to decide whether a head transplant falls under this new right. If it does, the State may need to explore options such as providing government-funded health care to pay for head transplants for citizens unable to afford the doctors’ services themselves. At some point in everyone’s life, a head transplant will become a life-saving procedure and, based off the idea that no one should die because they cannot afford a medical procedure, it seems that this procedure should be made available to all. However, if head transplants were available to all and subsequently everyone could live for a potentially infinite amount of time, then the country and soon the earth itself would face a problem of overpopulation. Consequently, governments would have to propose policies to forcefully stop human reproduction or to limit the amount of years a person can live. In just this one example, our leaders are faced with bioethical and political issues ranging from health care policy to methods of population control.

THE FUTURE OF BIOETHICS AND POLITICS

While the idea of head transplantation may seem absurd, it may now be within the realm of possibility. More importantly, it illustrates a key point: as our medical capabilities have continued to expand and the resulting bioethical issues have multiplied, the presence of bioethics has become increasingly prominent in politics and will continue to be so into the future. Whether it is through policies regulating human experimentation, abortion, stem-cell research, euthanasia, or head transplants, politics and bioethics have become increasingly intertwined in our modern society. Historically, bioethics commissions have been valuable in providing our lawmakers with policy recommendations and, presently, there is still a great need for their guidance in our quickly advancing world. The Trump administration will be faced with a range of highly consequential bioethical decisions and could benefit from the creation of a bioethics commission, or at the very least, a recognition of the close relationship between bioethics and politics.
One major trend that dominated healthcare in 2017 was consolidation of large companies through mergers. A merger is an agreement that unites two existing companies into one new company. In the healthcare world, there are mergers between healthcare systems and insurance providers, both of which affect the delivery of healthcare.

The most common reason for an increase in mergers between two healthcare systems is to form regional hubs. For example Advocate Health Care and Aurora Health Care, two healthcare systems focused in Illinois and Wisconsin respectively merged via the formation of regional hubs. This was also the case with the merger of Princeton HealthCare System with University of Pennsylvania Health Systems, which would lead to Penn Health Systems being the predominant healthcare system in a large region. Regional hubs are areas where health systems grow until there is one major provider left. Healthcare systems prefer such growth strategies, especially in current times, due to rising costs and resources that can be better shared over larger networks since large networks can often consolidate redundant departments such as IT or HR and share resources. They are also pushed towards forming regional hubs to better compete with other systems that are doing the same – thus leading to even faster consolidation of healthcare systems. However, this regional hub structure may not be best for patients. Not only would they have a much more limited range of healthcare options, but experts such as Dr. Altman of the Massachusetts Health Policy Commission, whose research has focused on healthcare mergers, say that institutes saving money doesn’t translate to lower costs and lower spending. Often times, savings for hospitals translate to an increase in hospital budget or savings, rather than direct savings for patients.

Another interesting type of merger is one involving an insurance company. One major proposed merger of this type during 2017 was between CVS Health, a retail pharmacy, and Aetna, an insurance company. The primary reason for this merger is so that CVS can turn pharmacy storefronts into community medical hubs and provide services to Aetna’s 22 million customers. Aetna is interested in this merger because it allows them to move forward and get closer to the community. Some benefits that CVS and Aetna state are that patients can save money since they will be able to go to a CVS instead of to an ER for more basic issues that don’t require specialized/surgical care. They also plan on making healthcare easier to obtain, with better insurance and less paperwork. However, there are several potential problems with such a big merger. One of these is that such mergers would lead to fewer healthcare options for many of Aetna’s customers. Patients would have to accept the quality/cost of given care without having many options to switch providers. This merger is also upsetting those that frequent CVS currently since they would have to expect changes and longer lines in stores.

Many of these mergers, regardless of type, cite increased costs and lower reimbursements as reasons to merge and split costs over larger networks. Another reason for healthcare systems or other companies like CVS to merge could be to stay relevant and competitive as other systems grow larger. Thus, it may be hard to stop similar companies/systems from trying to merge. For patients, in addition to positives such as better care due to higher innovation and resource sharing throughout the now-larger network, there may also be negatives. Although mergers are often thought to lower costs for patients, a rationale that is often cited in favor of merging, previous examples suggest that this may not generally be the case. It is important, but
also difficult, to carefully consider whether these benefits outweigh the costs such as less healthcare choices in a given region.

Fortunately, there are many bodies that play an important role in the merger process for this reason. One of these entities is the Federal Trade Commission which enforces antitrust laws in healthcare markets in order to preserve the benefits of competition and to advocate on behalf of patients. Many experts from health policy commissions also speak on patients’ behalf to ensure that mergers that are approved by the FTC truly are beneficial to customers/society and are not just steps towards monopolized healthcare.

This process of antitrust review starts with the FTC doing a preliminary review of proposed mergers to see if they warrant closer examination. During the preliminary period, parties must wait 30 days before closing their deal. If the waiting period expires or if the waiting period is terminated through approval, the parties are allowed to merge. However, in a select few cases, a secondary, more in-depth review is needed. This review involves parties sending more information about themselves and the proposed action and the FTC comparing this information to existing antitrust laws and multiple statements of Antitrust Enforcement Policy such as the 1996 Statement of Antitrust Enforcement Policy in healthcare to determine whether the action significantly limits competition in healthcare. Once these cases have been reviewed by looking at antitrust rules, the parties may be allowed to proceed if approved or may be blocked from proceeding if it is determined that the action would limit competition in a way significantly harmful to patients.

Despite these external regulations, it is important for patients themselves to stay informed about the many mergers and other changes happening in the healthcare field around them in order to advocate for themselves and ensure that they receive optimal care.

REFERENCES
MEDICAL INNOVATION

BREAKING A MAJOR CLONING BARRIER

BY CHRISTEEN SAMUEL

DOLLY THE SHEEP

In 1996, when Dolly the sheep became the world’s most famous clone, cloning emerged as a promising, largely untapped reservoir for improving our understanding of genetics and development. Although animal cloning can be traced back to several years before Dolly, her cloning was a major scientific breakthrough because it illustrated that DNA from adult cells, despite having been specialized into one specific type of cell, could be used to create an entire organism. The implications of Dolly’s cloning were enormous for pharmaceutical and biomedical research.

RECENT ADVANCES IN CLONING

At the turn of the twenty-first century, more scientists turned their attention to somatic cell nuclear transfer (SCNT), the technique used to clone Dolly, which has since been used to modify and to clone other mammalian species including mice, cattle, pigs, cats, rats, and dogs. SCNT has become widely used in developmental biology as a technique for creating an ovum with a donor nucleus. Unfortunately, cloning of non-human primates by SCNT, which would have more translational implications for humans, has long failed to produce live offspring that can later fully develop.1 In turn, attempts at cloning primates in the last decade have switched focus to other methods, such as a splitting technique, in which an early-stage primate embryo is split into multiple parts creating artificial identical twins. These efforts were limited in that the cells generated using this technique were confined to petri dishes, not fully developed primate individuals. However, in January 2018, scientists in Shanghai, China, led by Chinese Academy of Sciences postdoctoral fellow Zhen Liu, managed to successfully clone monkeys by SCNT using fetal fibroblasts.

LIU ET AL’S STUDY

Liu et al. (2018) used SCNT to remove the nucleus from an egg coming from a healthy macaque donor. This enucleated egg then became the host for a nucleus from a somatic cell, which is any cell in the body besides the gametes. This step essentially paralleled fertilization that would otherwise had happened naturally inside the animal following mating. The resulting embryo was then implanted into a surrogate mother to create an animal that was genetically identical to the nucleus donor. Liu et al. attempted using the nuclei from both adult cells and fetal fibroblasts – a type of cell that is most common in the connective tissues in animals and can synthesize ground substances, such as collagen. While monkeys generated using fetal fibroblasts were healthy, those generated using adult cells died shortly after birth.1 A current explanation for this result is that fetal fibroblasts can be genetically modified in vitro and screened for precise gene editing prior to SCNT.1

TRIUMPH OVER CHALLENGES ASSOCIATED WITH CLONING NON-HUMAN PRIMATES

In previous efforts, a major challenge in cloning non-human primates had been re-creating the characteristic natural process of differentiation during early development. This process essentially requires that only certain genes are expressed in certain cells and not in the others. Researchers have attempted to modify the DNA in the donor nucleus that came from a differentiated cell such that it resembles the DNA of a young embryo that has yet to undergo differentiation. Rewinding this genetic clock is difficult because it necessitates complex chemical methods that need to be fine-tuned for individual species.2 Liu et al. (2018) achieved a breakthrough when they successfully employed epigenetics to reprogram the donor nuclei. Liu’s team temporarily bathed the clone eggs in a substance called trichostatin A, a compound that helped ensure the donor DNA did not cluster such that it became more free for the process of differentiation. Additionally, they also stimulated the eggs to make enzymes that would remove certain chemical tags off the donor DNA. This procedure further freed up locked embryonic genes that were extremely condensed inside the donor nucleus, so that gene expression would become more feasible. In essence, Liu et al. (2018) did not alter the DNA sequence itself, but rather altered the way that individual genes were expressed by modifying the chemical environment of the DNA. This procedure was applied to both the nucleus from the adult cell and that from the fetal fibroblasts of a grown monkey. Liu et al. (2018) believe that the fetal cells were less “hardened” into their cell types than the adult cells, which caused them to be a more appropriate nucleus donor than the adult cells.
IMPLICATIONS OF THIS BREAKTHROUGH

The potential ramifications of this new discovery are immense, as it paves the way for generating numerous primate organisms that mimic the genetic makeup of the nucleus’s donor. Moreover, biomedical researchers could use the exact copies of the same animal to trace more patterns in primates’ genetics and development.  

“For the cloning of primate species, including humans, the technical barrier is now broken,” explains study co-author Mu-Ming Poo, who directs the Center for Excellence in Brain Science and Intelligence Technology at the Chinese Academy of Sciences (3). “However, the reason we chose to break this barrier is to produce animal models that are useful for human medicine. There’s no intention to apply this method to humans.”  

In theory, this study implies that human cloning could be feasible in a matter of months to years. Whether human cloning should proceed, however, is a question of its own.


It is important to note, however, that the procedure used to clone the macaques was not efficient as they involved 79 attempts of implanting embryos into 21 surrogate mothers, and from these a mere six pregnancies were established. From these six pregnancies, only two macaques were cloned successfully. Nonetheless, Liu et al’s study results can potentially unlock novel approaches to studies that aim to find better treatments for genetically based diseases, such as Huntington’s disease and Alzheimer’s disease. It can also be beneficial in cancer research in further understanding the mechanisms governing cell division. Altogether, having access to a large pool of genetically identical research subjects would reduce the variability in results when testing new drugs or other therapies, allowing scientists to reach more concrete conclusions. Therefore, cloning non-human primates can usher in an exciting new era in studies of genetics and development.

References
As researchers investigate more complex problems in healthcare, the interdisciplinary field of bioengineering has become relevant and critical to advancing the status quo. Many of the methods currently used in biomedical research, such as animal testing, are expensive, time intensive, and ineffective in accurately simulating biological processes in humans.1

According to the U.S. Department of Health and Human Services (2018), 30% of drugs that were approved after pre-clinical trials in animals failed during human clinical trials because they were found to be toxic, and 60% were found to be ineffective in humans.2

In addition, the ethics of animal testing have been heavily contested within the scientific community. Organs-on-chips, an emerging field in biotechnology, may provide the tools necessary to decrease the financial and ethical risks associated with drug development and improve our understanding of human physiology.

What are organs-on-chips? Organs-on-chips are microfluidic devices that model tissue and organ functions through culturing living cells. These devices also enable the study of tissue-tissue interfaces and cell-culture microenvironments by allowing for high resolution images and analyses of living cells.3 Although organs-on-chips represent a fairly new area in bioengineering, researchers around the world have already created numerous innovative devices to model physiological processes, disease development, and drug delivery. Research on organs-on-chips arose from the discoveries that cells can be grown on small surface areas and that mechanical forces can be manipulated to affect cell behavior. This led researchers to find that a cell’s microenvironment can be controlled by integrating microfluidics. These findings in Singhvi et al. (1994) laid the foundation for the development of organs-on-chips and galvanized researchers around the world to study the possibility of chip-based models.5 However, it was not until 2007 that the first successful model, a lung-on-a-chip, was developed by Dr. Shuichi Takayama at the University of Michigan.6 This device consisted of microchannels that were engineered on the scale of actual lung airways and used liquid droplets to effectively model the function of mucus in the lung.7 Since then, researchers have created a multitude of organs-on-chips that continue to enhance research methods and have far-reaching applications.

Current progress and applications
Currently, researchers around the world are developing more advanced organs-on-chips, which are facilitating new discoveries. Their research involves the use of microengineering techniques, such as photolithography and micro-contact printing, to create highly structured three-dimensional microenvironments.3 Photolithography is a process in which microscale patterns are transferred to light-sensitive materials through exposure to UV radiation while micro-contact printing is a process that makes use of a master mold to create replica structures in a polymer substrate.3 The microchannels within these devices are generally made of polydimethylsiloxane (PDMS), a type of silicone rubber that is cost-effective, easy to fabricate, flexible, transparent, and permeable to gases.7 Stacked layers of PDMS microchannels, separated by thin, porous membranes, can then be used to model functions of organs. More advanced devices consist of multiple culture chambers connected together with microchannels. Each chamber contains a single type of cell, representing a specific organ, and the device models interactions between organs.8
Organs-on-chips have been developed to study specific physiological functions and disease development by investigating how specific diseases affect physiology. For example, cancer-on-a-chip models are being used to study the growth of breast cancer cells. From the results of experiments using these devices, researchers have found correlations between cancerous cell growth and protein downregulation. The physical transparency of PDMS also allows researchers to gain a better understanding of the mechanisms behind biological processes by taking high resolution images and conducting analyses of living cells.

In addition to having applications in medical research, organs-on-chips have practical applications in pharmacology. While the results of trials using animal models are often inadequate when extending the findings to human, organs-on-chips facilitate drug development by analyzing the interactions of drugs, chemicals, or toxins with cells in various organs. Thus, by more accurately predicting whether a certain drug would be toxic or effective in humans, these devices can reduce the financial costs and potential for harm involved with animal and human trials, thereby making clinical trials more efficient.

LIMITATIONS

With the multitude of advancements using organs-on-chips, it is important to keep in mind that organs-on-chips have limitations. Some functions, such as cognitive processing in the brain, require more complex systems and arise from macroscale interactions within the brain that cannot be simply modeled. In addition, there are limitations in the sensitivity of current micro-engineering techniques. Although advancements in technology have allowed for the creation of more precise models on the micro- and nano-scale, the occurrence of bubbles in microfluidic channels can injure cells and decrease researchers’ control over the chip.

Furthermore, it is important to recognize that simplifications are made when using organs-on-chips; not all types of cells in an organ are represented, as researchers often focus on one type of cultured cell. For example, kidney-on-chip devices consist mainly of kidney tubular epithelial cells in order to better study the micro-scale functions specific to these cells. Whereas not including certain cells may conceal underlying mechanisms, reducing the complexity in the device actually allows for increased resolution in imagining and analyses. Thus, there is an inherent challenge in finding a balance between simplicity and complexity to create the most practical devices. Despite these limitations, the existing research strongly supports the potential of organs-on-chips, and advancements continue to be made in order to overcome these limitations.

THE FUTURE OF ORGANS-ON-CHIPS

On a broader scale, organs in the human body are not isolated mechanisms but are rather all interconnected. Therefore, a future direction is to develop a human-on-a-chip model to study macro-scale interactions within the entire human body. However, as many challenges in current methods and technologies must be overcome first, more immediate future directions for this field include developing advanced chips to more accurately model organ functions, diseases, and cancer progression, as well as interactions among multiple organs. Since organs-on-chips are currently used to model tissue and organ function and to develop drugs, these applications could be integrated in order to create a novel drug to mitigate or cure diseases based on the observed interactions among the drug, disease, and organ functions. Not only can advancements in organs-on-chips allow for better treatments, but they can also revolutionize how treatments and drugs are developed by supplementing clinical trials and enabling more selective procedures for treatments to reach animal testing phases and clinical trials. Ultimately, organs-on-chips are expanding our knowledge of physiological mechanisms in humans by enabling more precise analyses of living cells and have the potential to allow for safer and more humane methods in healthcare, pharmacology, and biomedical research.

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Adenosine triphosphate (ATP) provides the chemical energy needed in most biological processes from metabolic reactions to cellular mechanics, such as photosynthesis and signaling pathways. Hydrolysis of ATP, which cleaves phosphate bonds, is the mechanism by which energy is released to the environment. This results in lower energy derivative forms of ATP such as adenosine diphosphate (ADP) and adenosine monophosphate (AMP). Within biological cells, this chemical reaction often takes place in the vicinity of lipid membranes. Biophysical experiments which utilize X-ray scattering and NMR spectroscopy have indicated that ATP binds to lipid membranes primarily through the adenine ring, leaving the phosphate chains available for hydrolysis. We find that ATP is currently known to play an important role in active transport, cell signaling mechanisms, muscle contractions, and in the synthesis of DNA and RNA, which are all critically important biologically and medically related processes.

However, there remain major gaps in knowledge with regard to ATP, especially the possible role of ATP role in neurotransmission, which could benefit patients diagnosed with Alzheimer’s and Parkinson’s neurodegenerative diseases. Neurotransmitters are chemicals that enable the brain to communicate electrical signals to stimulate activity in specific parts of the body. While this representation does cover most cases of neuronal signaling, studies suggest the possibility of neurotransmitters interacting with the membrane itself. Recent studies suggest that the neurotransmitters γ-aminobutyrate (GABA), glycine (GLY), acetylcholine (ACH), dopamine, and glutamate (GLU) interact with membranes directly, with different levels of affinity. As a result, there is a realistic possibility that other neurotransmitters, such as ATP, have affinity for membranes during interactions in synapses.

Thus, the exact dynamics of ATP and the possible cooperativity between bound ATP molecules is unclear. Using a computational method called Molecular Dynamics Simulations can help to reveal these facets of ATP dynamics, how it binds to lipid headgroups, and the resulting electrostatic charging even at the low concentrations that are typical in biological cells. The important findings that can be found is how ATP electrostatically charges membranes and how this mechanism could affect the transmission of the action potential in neurons. These findings can help with developing new and improved drugs that appropriately target the root cause of neurodegenerative diseases, possibly enabling the development of more permanent solutions for this global health problem.

**MD SIMULATIONS**

Molecular Dynamics (MD) is a computer simulation method designed for studying the motion of atoms and molecules as a function of time. This method was developed primarily for the field of theoretical physics during the 1950s, but is applied today mostly in biological physics, chemical physics, and materials science. In commonly used versions, the trajectory of the atoms in a given system is calculated by numerically solving Newton’s equations of motion for a system of interacting particles. Using information about the position of the atoms, simulations can measures forces between particles and their potential energies, which can indicate how different molecules interact. Because of the vast number of molecules present in a typical system, we employ numerical rather than analytical approximations to simplify the complex calculations. As a result, although these assumptions result in some degree of error, these results can still be used as an analysis tool to examine the time-dependent behavior of a
molecular system.12

APPLICATIONS

Developing new and improved methods of testing research questions is becoming an important aspect of scientific research, and in an environment with ethicality being placed at utmost consideration in clinical research, computational techniques offer a novel possibility of uncovering new treatments for many important medical issues. Given the excellent agreement between simulations and biologically relevant experiments, the information acquired through these computational methods is sufficient to studying more complex interactions without the need for ethical considerations that would otherwise be present in an experimental study. Moreover, this method presents two novel applications, namely, allosteric regulation and molecular docking.

Allosteric regulation is critically important to regulate the binding of enzymes to effector sites that reside in the enzyme’s active site, which can either activate or inhibit a biological process from occurring. This cell signalling pathway is critically important in regulating biological processes such as insulin production, which is an important drug in regulating blood sugar. Moreover, given the limited understanding of ATP’s role in neurotransmission and the regulation of action potentials, developing a detailed picture of these nanoscale interactions can enhance our current understandings on the binding mechanisms and the underlying physics governing life processes. Any disruption in these regulatory mechanisms can cause major problems in the body and in many cases can cause cancers, so developing improved methods to model these activation sites using molecular dynamics simulations will revolutionize research in medically related applications.

Another important application is molecular docking, which is an important process in drug delivery. To develop an in depth understanding on how ligands bind to a molecular counterpart, a key aspect of research is going down to the basics and understanding the structural basis of these binding events, which is an key aspect of molecular dynamics simulations. ATP, especially, is an important energy-carrier molecule and understanding its underlying physical interactions with surfaces, especially cell membranes, will be important in developing a detailed understanding of how the molecular configurations and order are affected by these on and off events. This intricate level of understanding biologically and medically related processes can give rise to better molecular agents in drug delivery.

CONCLUSION

The discussion of the various facets of ATP’s function, neurotransmission, and membrane structure warrants further exploration of the effects that ATP has on membrane order and system size. Further exploration in these avenues, both in theoretical and experimental research, would enable scientists, engineers, and medical professionals to make conclusions regarding the extent to which ATP affects the physical conformation and order of the membrane. These new ideas in basic science can hopefully lead to the implementation of ATP as a therapeutic in treatment of major neuronal disorders that affect millions of elderly people around the globe.

References
The Emergence of Clinical Informatics

BY AHMED FARHAN

Clinical informatics can assist in the healthcare delivery process at several points. When the physician wants to compare radiology or pathology results from an ongoing visit to previous onsite or offsite visits, a research information system or picture archiving and communication system can take in patient identification information and accurately and quickly accomplish the task. If the physicians determine that a patient’s signs and symptoms are not diagnostic for one specific condition, a machine learning algorithm (a program that has the ability to take in data and to improve performance based on previous trials) can either partially or fully make a differential diagnosis. IBM has been developing Watson, their question answering computer system, to utilize a parallel probabilistic evidence-based architecture to assist with second opinions and differential diagnosis. Through this type of program, Watson can use the patient data put into the system by the physician to simultaneously determine the probabilities of several different diseases fitting the patient’s presentation and then give the treating physician a data report with the recommended diagnosis, based on its analysis. Even after the patient leaves the medical facility, a clinical decision support software can monitor the prescription process to provide drug interaction alerts and ensure that the patient is given the correct medication.

Clinical informatics has the potential to bridge the gap between clinical care and medical research today and in the years to come. In modern medicine, electronic health records (EHRs) have made it easier to access and aggregate clinical data. There has been an increasing number of electronic data capture tools to collect patient information, leading to a large number of single-institution and multi-institution databases. For example, Research Electronic Data Capture (REDCap) is one of the more recently introduced data capture software solutions and is already supporting 286 clinical research databases with a growing collaborative network including 27 active partner institutions. Unfortunately, most academic physicians and medical research professionals currently do not have the proper technological tools to make full use of these large datasets. In addition, databases often contain a wealth of information that is useful for several clinical research projects outside of the one they are specifically constructed for. Clinical informatics technology can provide researchers with advanced methods to discover the wealth of information in their large databases while also helping to share and repurpose data sets among research investigators to reduce the costs and inefficiencies associated with clinical research. There has already been an effort by Professor Nicole Grey Weikspof at Columbia University to develop a systematic statistical method of data quality assessment.
for electronic health records. This will allow researchers using secondary data from various sources to assess the completeness, correctness, plausibility, and currency of each data source.

Finally, we must appreciate that the medical profession itself is changing as we enter a new era of mainstream computer integration, automation, and artificial intelligence. This can be most clearly seen through the advent of the medical informatics subspecialty, which was approved for official recognition and certification from the American Board of Medical Specialties on September 21, 2011. Doctors with training in informatics assess the information and knowledge needs of health care professionals, evaluate and refine clinical profession, develop and implement clinical decision support systems, and both manage and advance healthcare information systems such as electronic health records. It is the only medical field where a doctor of any medical specialty can receive training and certification. There are 26 different programs offering a two year ACGME-accredited fellowship with eligibility to sit for the board examination administered by the American Board of Preventive Medicine upon completion of the fellowship. This new field represents an important step towards providing doctors more technical training in computer and information technology. The rise of clinical informatics is also an indication of the growing demand for doctors who can combine patient care with an understanding of informatics conceptions and information technology. In fact, a number of graduates from these fellowships have gone on to hold the growing number of Chief Medical Information Officer (CMIO) position available at hospitals.

Through these examples, we can understand how clinical informatics can help weave technology into three distinct levels of the medical field. It will help bring about efficiency and efficacy in healthcare delivery by providing support in the care delivery process. It will bring exciting solutions to the big data that is taking over medicine, innovating the practice of clinical research at reduced costs. Finally, the field become a subspecialty with great demand and has provided the physicians with an opportunity for concentrated technical training necessary in an age where advanced computer information systems are becoming more integrated into the medical field. In order to advance to the next era of medicine, further research and investments into the field clinical informatics must be made.

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Every year, 7.8 million children are born with a serious birth defect around the world of genetic or partly genetic origin. The pervasive nature of heritable diseases has prompted advancements in gene therapy that are targeting cystic fibrosis, Huntington’s disease, and sickle cell anemia to name a few. This enables scientists and doctors to treat genetically origined diseases at their sources: our genes.

Gene therapy serves two purposes. First, it can introduce foreign genetic material into cells to compensate for abnormal genes. Second, it can give rise to a beneficial protein that the body may be lacking. In a diploid organism, such as humans, there are two copies of each chromosome such that two alleles constitute a particular gene. When one copy is mutated, then a faulty or missing protein is produced. However, gene therapy can introduce a normal copy of the gene to restore the function of the protein. This has been done mainly for diseases caused by single-gene defects, such as cystic fibrosis, haemophilia, muscular dystrophy, thalassemia, and sickle cell anemia.

TECHNIQUE: VIRUSES AS A VECTOR

Gene therapy utilizes viruses to deliver proteins to spur the gene creation process. To be functional, a gene must be inserted into an individual’s genome. A gene that is simply inserted into a cell’s cytosol will not be recognized by the body’s DNA replication machinery. For this reason, a carrier, or commonly known as a vector, is genetically engineered to deliver the gene. Certain viruses are often used as vectors because they can deliver the new gene by “infecting” the cell. A virus is typically used because scientists can manipulate its narrow to leave the host’s genes intact when the virus inserts its genome into the host’s genome. The viruses are modified so they cannot induce a disease or defect when used in people.

A popular class of viruses are retroviruses. They integrate their genetic material (including the new gene) into a chromosome in the human cell. Retroviruses have genetic material in the form of RNA, but they undergo a process called reverse transcription to produce a DNA copy from an RNA molecule. It is carried out by an enzyme in the virus called reverse transcriptase. After this DNA copy is produced and is available in the nucleus of the host cell, it must be incorporated into the genome of the host cell. This process is done by another enzyme carried in the virus called integrase. Integrase has the ability to cut and paste the DNA material into the host’s genome. Once the new genetic material is incorporated into the its genome, the host cell proliferates and its descendants will contain the genetically-engineered gene.

Other viruses, such as adenoviruses, introduce their DNA into the nucleus of the cell, but are not integrated into the genome. This type of vector can be injected or given intravenously into a specific tissue in the body, where it is taken up by individual cells. Alternately, a sample of the patient’s cells can be removed and exposed to the vector in a laboratory. The cells containing the vector are then returned to the patient. If the treatment is successful, the new gene delivered by the vector will make a functioning protein.

ADVANCEMENTS & INNOVATION

Gene therapy has had many advancements in recent years. In March 2017, Bluebird Bio, a biotechnology company, introduced a cure for sickle-cell disease through experimental gene therapy. Sickle-cell anemia is an inherited blood disorder that affects 100,000 people in the United States and millions around the world. Scientists at Bluebird Bio removed stem cells from a boy’s bone marrow and modified them in the lab by introducing copies of a gene to prevent his red blood cells from deforming. When the treated cells were infused into the body, normal red blood cells were produced.

In 2018, the Food and Drug Administration (FDA) approved two treatments, Kymriah and Yescarta, that use a patient’s own immune cells to fight rare types of cancer. Kymriah treats a bone marrow cancer that affects children and young adults, while Yescarta treats a type of lymphoma. These therapies are known as CAR-T therapies that are made by extracting T cells, a subtype of white blood cell, from patients and genetically engineering them to destroy cancerous cells. In recent cases, these therapies
are utilized in a handful of lethal cancers as a last resort when more traditional treatments, like chemotherapy, do not work. Some patients have had remarkable recoveries and remain in remission months or years later.

In December 2017, the FDA approved a Spark Therapeutics’ treatment called Luxturna. It corrects a mutation responsible for a range of retinal diseases that make people to gradually become blind. Spark Therapeutics is a startup biotechnology company founded at the Children’s Hospital of Philadelphia. Luxturna has had a success for two dozen patients who were losing their sight. One young patient claims “Gene therapy has made my world so much more brighter” who went on to describe how he could see the moon for the first time, go out at night, watch facial expressions, and basically live his life more normally instead of waiting for blindness to take over. The treatment in its entirety costs $850,000 per treatment.

**IS GENE THERAPY ETHICAL OR UNETHICAL?**

If gene therapy is limited to bone marrow treatment or blood cell treatment of a human, then the improved gene cannot be inherited by future offspring. However, gene therapy could be targeted to germ cells (egg and sperm cells), which would allow the inserted gene to be passed to future generations. This approach is known as germline gene therapy. While it could spare future generations from having a particular genetic disorder, it might affect the development of a fetus in unexpected ways or have long-term side effects that are not yet known.

Genetic engineering could be used to cure diseases, but also to change physical appearance, metabolism, and even improve physical capabilities and mental faculties such as memory and intelligence. For parents, genetic engineering could be seen as another child enhancement technique to add to diet, exercise, education, training, cosmetics, and plastic surgery.

Athletes might adopt gene therapy technologies to improve their performance. Gene doping is not known to occur, but multiple gene therapies may have such effects. This intervention for non-therapeutic/enhancement purposes compromises the ethical foundations of medicine and sports.

Gene therapy, a multi-opinionated topic, endears significant controversy. The controversy surrounding gene therapy emerged when a gene therapy researcher, James Wilson at the University of Pennsylvania, provided unsafe genetic, experimental therapy to an 18-year-old named Jesse Gelsinger in 1999. Consequentially, Gelsinger died and Wilson was held responsible for the death.

The FDA found that Wilson had violated many of his obligations as the leader of a clinical trial as well. Wilson did not adequately inform volunteers of their risks and continued the trial after seeing certain severe reactions in some patients. For example, the therapy Gelsinger had received relied on an adeno-virus to carry a healthy foreign gene into his own cells. However, Gelsinger’s body mounted a devastating immune reaction to the adeno-virus. Since then, Wilson has been working on turning adeno-associated viruses, which don’t kick off the human immune system as strongly, into gene vectors.

A more recent example of the controversy surrounding gene editing surfaced when a research team sought to repair a genetic mutation known to cause a form of blindness in mice by changing just one DNA letter in the mouse genome. The team was able to successfully correct the targeted mutation in each of the two mice they treated. But they also observed an alarming number of additional DNA changes — more than 1,600 per mouse — in areas of the genome they did not intend to modify. There unknown side effects remain alarming as gene remediation technologies are on the rise.

Others claim gene therapy possesses too much scientific might that it is a field too good to be dismissed. Companies are refining their technologies everyday to make gene therapy more streamlined and accurate for patients. If the side effects of gene editing and cutting are eliminated and the research and development phase of techniques are more regulated, we can all reap the benefits gene therapy offers. After all, to live a healthy life is one that is void of debilitating diseases.

**CONCLUSION**

Gene therapy provides a promising future of alleviating humans from uncontrollable diseases. However, with certain fixes comes consequences if the field is misused with gene doping and human genetic engineering. Gene therapy can only go so far to change the genetic makeup of all future generations. Is this something that humans should develop or is that pushing boundaries?

References:
**Chronic Traumatic Encephalopathy: The degenerative impact of repeated head trauma**

**BY SAAGAR ASNANI**

“He's down! 1…2…3… and the match is over!” The referee raises his voice above the screaming crowds to declare the winner of the latest boxing match. The victor, staggering to the center of the arena after trading blows with his opponent for the past half hour, is unable to stand straight and a little disoriented, or even “punch drunk.”

In the early twentieth century, Dr. Harrison Martland, an American pathologist and former professor at New York University, coined the term “punch drunk” to describe the behavior of certain professional fighters, especially boxers, outside of the arena. Often, the behavior of these athletes quickly deteriorated from being slightly goofy to showing symptoms associated with devastating neurological pathologies such as Alzheimer’s disease. Occurring in disproportionately high numbers among the boxing population, the common name of the “punch drunk” disorder came to be known as “dementia pugilistica,” making reference to this affected population. However, in light of recent diagnoses among children, men and women who have never entered a boxing ring in their lives, a more general name is needed. Thus today, the technical term Chronic Traumatic Encephalopathy (CTE) describes this long-term deterioration of the brain caused by injuries to the head.

**WHAT IS CTE?**

Chronic Traumatic Encephalopathy is a tauopathy, meaning that it is caused by buildups of tau proteins in the brain, eventually leading to brain cell death and degeneration of brain tissue. Tau proteins are commonly found in the neuronal axons in the human body, even those unaffected by any disease. However, multiple instances of head trauma have been linked to the biochemical alteration of tau proteins, which makes it much easier for these abnormal tau proteins to build up or polymerize and results in large depositions of non-functional tau proteins in the brain. These polymerized tau proteins are neurotoxic, causing brain cells to die and brain tissue to atrophy, or waste away. This degeneration of the brain has been linked to the behavioral changes and dementia which are symptoms of CTE.

**WHO IS AT RISK OF DEVELOPING CTE?**

According to the Boston University CTE Research Center, Chronic Traumatic Encephalopathy is often found among people with greater risk for head trauma, particularly football and hockey players, boxers, police officers and soldiers. This is not to say that CTE is only found among those who practice physical contact sports and engage in violent behavior. Anyone with previous sustained exposure to head injuries can be at risk to develop CTE, even if they have not touched a football since high school.

It may seem frighteningly easy to contract CTE, but it actually requires many years’ worth of neurodegeneration to result in the tau protein deposition that leads to the onset of CTE. Physical contact sports players are often the victims of head injuries, explaining the high rate of CTE among these groups. In recent years, there have also been autopsies examining the immediate effects of fatal head injuries on young athletes, and early symptoms of tauopathies — like CTE — have been found in their brains.

**DIFFICULTY OF DIAGNOSIS**

Due to its mechanistic similarity with other tauopathies — like Alzheimer’s disease — CTE is often difficult to diagnose in patients. At first glance, it almost seems like a case of early onset Alzheimer’s disease. However, upon examining a patient’s history and lifestyle, it becomes easier to distinguish the two, since CTE has been clearly correlated to head trauma. The major symptoms of CTE include a steady decline in cognition, memory problems...
loss, lack of coordination, and mood changes. These symptoms all progressively worsen until the onset of dementia, possibly a few years after the first symptoms show.

Because the accumulation of tau depositions in the brain is a slow process, as is the atrophy of brain tissue, CTE can remain hidden for many years after a person has retired from a life of repeated head trauma. Furthermore, since many people engage in the most physically taxing activity in the early part of their lives, CTE is often found in people aged 20-30, especially men. In recent years, there have been many programs seeking to bring awareness to younger populations about the impact of too many concussions and the risks of developing CTE to combat its prevalence among youth.11

Another reason that CTE is so hard to detect among patients is that there are no clear biological markers that one can use in living patients to test for the telltale depositions of tau proteins. The current diagnostic method widely used by doctors is based on patient symptoms alone, since the only way to make a definitive diagnosis of CTE is via autopsy, post-mortem.10 However, this would not be very helpful in diagnosing living patients. In addition, due to the relative obscurity of CTE and its prognosis, very few doctors had a systematic way of diagnosing CTE until fairly recently. In the past few years, there have been a few publications dealing with the clinical diagnosis of CTE that list proposed clinical criteria for symptomatic diagnosis.12 With increased awareness of the disease, greater numbers of doctors are able to recognize CTE and differentiate it from conditions with similar symptoms, like Alzheimer’s and Parkinson’s diseases, since one of the most telltale signals is an athlete’s history of head trauma.

SEARCHING FOR A CURE

For too long, CTE has been thrown under the rug due to a lack of knowledge of its exact mechanism and cause. In addition to the lack of a laboratory-based diagnostic method in living patients, there is also no known cure or medication to slow the progress of CTE.

In spite of this rather dreary reality, Dr. Dichter mentioned new developments in research that may soon allow for systematic laboratory diagnosis and perhaps even treatments for CTE. He talked about “analogs of tau proteins” that can be detected by PET scans and “sophisticated new uses of the MRI” that can detect changes in brain function post-concussion.13 These new techniques may one day help definitively diagnose CTE in living patients, opening new doors in the realm of treatment and care for affected individuals.

For now, the age-old adage that prevention is the best medicine still holds true for Chronic Traumatic Encephalopathy and one can only hope that through educational programs on the degenerative effects of repeated head traumas, people will be discouraged from participating in activities that put them at greater risk. Prudence can go a long way in the prevention of any disease, even one as debilitating as CTE.

THESE NEW TECHNIQUES MAY ONE DAY HELP DEFINITELY DIAGNOSE CTE IN LIVING PATIENTS, OPENING NEW DOORS IN THE REALM OF TREATMENT AND CARE FOR AFFECTED INDIVIDUALS.

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White Coats: Confining Scrubs, Releasing Humanity from Society’s Grip

BY LEAH VOYTOVICH

I spent a semester shadowing and assisting a neurosurgeon in Tel Aviv by performing tasks in the operating room such as helping to prep the patient for surgery and photographically documenting the progression of the operation. From this experience, I learned that medicine is a gateway to social unification. Medicine encourages adversaries to join forces, working together to accomplish a shared goal. A hospital is a unique environment in which such a rarity occurs, more often than one would expect.

I witnessed people who would be complete enemies beyond the confines of the hospital become unified through a shared mission of recovery once they entered the hospital doors.

The hospital I volunteered at is located in the center of political chaos and tension. It attracts many people from Israel’s neighboring regions, mainly Arab territories, for its high quality of care and medicine. The doctors and nurses I worked with treated many Palestinians and Israelis, Muslims and Jews, people who hated Israel, as well as Zionists. I witnessed people who would be complete enemies beyond the confines of the hospital become unified through a shared mission of recovery once they entered the hospital doors.

Due to the multilingual and diverse community in Tel Aviv, the hospital had a number of medical professionals who were specifically trained in interpreting medically-dense conversation in Arabic and Hebrew. Many of these translators, who served as the communicative bridge between medical staff and patients of different origins, came from Palestinian and Arab backgrounds yet worked closely with Jewish Israeli doctors.

While shadowing the neurosurgeon, one of the first patients I encountered was a boy, younger than five years old, who had a brain tumor. His mother, who was understandably extremely anxious at the time, was covered from head to toe in her burqa. His father was also wearing traditional Muslim dress, and all three family members were holding each other’s hands tightly and praying. The religious Jewish Israeli doctor came up to the boy and whispered in Hebrew “I am going to take care of you” in a gentle tone. The boy, not able to understand what the doctor just told him, looked to the translator for guidance. Once he understood, he looked back at the doctor and then to his mom. His mom welled up and cried “thank you” in Arabic. While a palpable tension still existed between the family, particularly between the father, and the doctor, one could sense a realization of the inconsequentiality of such tension and a fresh, deeper, and genuine exchange of respect and sympathy.

Perhaps it is this shared mission, combined with innate human empathy and the absence of choice, that results in an elimination of bias and a newfound appreciation for the people around. The Social Baseline Theory, a theory in psychology that investigates the effects of social interactions and relationships on people’s neurobiological states, serves to provide an additional explanation as to why the doctor-patient relationship can expose the purity of the human condition despite existing initial prejudices. A research article published by the US National Library of Medicine argues the critical role of empathy, providing evidence stemming from empirical and theoretical work in psychology, developmental science, and affective neuroscience. The paper claims empathy to be an innate human capability that has evolved along with the mammalian brain to be able to form and maintain social bonds, necessary for survival and maintenance of overall well-being. Empathy is an inevitable player in the doctor-patient relationship, as respective participants exercise tolerance and cooperation in a relationship that relies on shared decision-making and disclosure of sensitive information. The empathy, however, stems not necessarily from a medical perspective but rather from a mutual understanding and shared struggle. People of opposing backgrounds constantly face the struggle to be open-minded and accepting of others in spite of deeply ingrained prejudices, instilled usually by loved ones such as family members and friends. This internal suffering to overcome prejudice without disappointing those one loves transcends ethnicity and faith and is a suffering that a doctor and a patient of
opposing beliefs can empathize with.

While empathy is naturally instilled in such a doctor-patient relationship, the engendered human connection also results in significant health benefits. The Social Baseline Theory supports the notion that proximity and interaction between individuals diminish cardiovascular arousal, facilitate the development of a relaxed temperament, inhibit the release of stress hormones, reduce threat-related neural activation, and generally promote health and longevity. Furthermore, the Social Baseline Theory suggests that the mere presence of others helps individuals conserve important and often metabolically costly neural and somatic resources. A research study investigating the neurobiology of the Social Baseline Theory conducted at the National Institutes of Health concluded that the brain exhausts much fewer bioenergetic resources when representing a familiar person than it does when representing a stranger. Thus, being with a person with whom one has some sort of relationship conserves various brain resources which can then be applied towards other neuronal functions. After a patient and clinician of potentially opposing backgrounds engage in a human relationship that relies upon great proximity and interaction, they experience positive biological outcomes. Such favorable outcomes may contribute to a newfound and possibly more positive outlook on the other member in the relationship.

Most people see hospitals as places of sorrow, or discomfort at the very least, but a hospital is one of the only buildings where raw, genuine, and beautiful humanity is released from its tight societal grip. When it comes to medicine, political conflicts are forgotten, arguments dissolve, love is reignited, and feelings are exposed. Truth reigns over falsities. Clinicians are both suppressors of illness and gate-openers for unification, working in hospitals that promote both human health and the health of humanity.

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AN ADDICT’S STORY

I never woke up one day and decided that I wanted to become a drug addict.

I was in college and working full-time when I stepped on an earring in my apartment. The earring pierced my left heel, and days later an abscess formed. With fevers above 102.5 F for several days, I went to the ER for treatment...I got IV antibiotics and hydrocodone. The infection cleared, and the pain ceased. I took the extra hydrocodone anyways. It made me feel happy, and dulled the stress of work and school. I started buying OxyContin from someone with a prescription.

Once the makers of OxyContin revealed the abuse-proof formula, the doctor started to prescribe morphine (much cheaper). So, I bought morphine...I graduated college so things weren’t too bad...right?...My addiction progressed to using all day everyday. I couldn’t stop.

THE CRISIS IN A NUTSHELL

In 2016, about one airplane full of people died each month. These deaths were not from airplane crashes. This was the rate at which people were dying from drug overdoses in Philadelphia alone. Nationwide, 11.8 million people misused opioids in 2016. About 2.5 million young adults (18 to 25 years old) admitted to misusing opioids. That’s nearly 1 in 14 young adults. Per the Center for Disease Control and Prevention, 115 Americans die every day from an opioid overdose.

The crisis began in the late 1990s as a result of pharmaceutical companies inaccurately claiming that opioids are non-addictive. Hence, physicians prescribed painkillers without concern of its most powerful side effect—addiction. As Mr. John Cooper, an attorney in the Civil Rights Unit of the City of Philadelphia, says, “addiction does not discriminate.” Young, old, educated, uneducated. Anybody who takes painkillers is susceptible to addiction regardless of demographic.

A LOOK AT AN OPIOID OVERDOSE

Opioids are a class of drugs that bind to receptors that elicit an increased pain tolerance and a sense of euphoria. This includes heroin (an illegal drug), fentanyl, and prescription painkillers (i.e. Vicodin). At very high doses, opioids can be detrimental. Symptoms include delirium, vomiting, pinpoint pupils, slowed or irregular breathing, and respiratory arrest. Depressed breathing is by far the most dangerous since it leads to less oxygen traveling to vital organs and could lead to organ system failure.

SAVE A LIFE

There is an antidote. Naloxone, also known as Narcan, blocks or reverses the effects of opioids. It was developed in September 2013 in collaboration with the National Institute on Drug Abuse (NIDA). It is typically available as either an injection or nasal spray. In November 2016, the FDA approved a nasal spray version for community use. Currently, Naloxone is sold over the counter in all 50 states except for Delaware, Hawaii, Kansas, Maine, Michigan, Nebraska, Oklahoma, South Dakota and Wyoming.

THE POLITICS OF THE OPIOID OVERDOSE

In October 2017, President Donald Trump declared the Opioid Crisis a public health emergency. This gave the secretary of health and human service authority to make grants, conduct investigations, and waive or amend health regulations with the goal of stopping the crisis. However, as drug abuse expert Dr. Andrew Kolodny explains, a public health emergency is not the same as a national emergency. A national emergency would permit the Federal Emergency Management Association (FEMA) to allocate funds towards treatment and prevention of opioid addiction. Most concerning, however, Dr. Kolodny emphasizes that “we haven’t received from the Trump administration is a plan for addressing the problem or a request from Congress for funding.” Despite the Trump administration’s reluctance to announce a national emergency, many federal initiatives have been proposed or passed to allow for a stronger fight against the opioid crisis. In November 2017, President Trump donated his third-quarter salary (roughly $100,000) to aid the Department of Health and Human Services’ opioid programs. Likewise, the Centers for Medicare and Medicaid will allow states to apply for waivers, which would let them use Medicaid to pay for residential drug treatment at certain facilities. At the start of the
The number of opioid overdoses is growing at an alarmingly fast rate and our government is concerned. Politicians understand that their actions today will determine the state of the crisis in the future. Their primary goal is to prevent a downward spiral. Hence, Congress is taking major steps to combat the crisis. One of such interventions is a series of three legislative hearings to discuss potential programs suppress the crisis. The hearings will be led by the Health Subcommittee, which is chaired by Representative Michael C. Burgess M.D. (R-TX). The first round of legislative hearings already occurred on February 28, 2018. Some highlighted bills including the Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act (H.R. 2851), the Safe Disposal of Unused Medication Act (H.R. 5041), the Opioid Preventing Abuse through Continuing Education (PACE) Act (H.R. 2063), and among others. The next two hearings will continue to focus on “helping communities balance enforcement and public safety, public health and prevention efforts, and insurance coverage and payment issues” to promote treatment and recovery.\(^9\) It is evident that until these three aspects are met will our government and communities be prepared to aid those afflicted by the crisis.

### References

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### New Year

President Trump signed the Interdict Act, which gives federal agents more resources to detect synthetic opioids. Finally, Attorney General Jeff Sessions announced a program to repurpose pharmacies and doctors that dispense too many opioids.\(^8\)

The federal government is not the only one responding to the crisis; states are too. For instance, in Pennsylvania, Governor Tom Wolf expanded funding to 45 Centers of Excellence (COE), which are specialized facilities that provide treatment for opioid addiction. He also signed legislation that “limits the number of opioids a patient can receive at emergency rooms to a seven-day supply with no refills.” Furthermore, the Wolf administration is encouraging programs to re-educate physicians in pain management and opioid prescriptions.\(^9\)

Local governments are on the move too. In Philadelphia—the “ground zero” of the opioid crisis—officials are proposing desperate legislation.\(^10\) In January 2018, Philadelphia city officials approved the establishment of Safe Injection Sites.\(^11\) The program stems from concern over the large number of people who have been found overdosed and dead under bridges across Philadelphia. If Philadelphia implements this program, then it would be considered the first American city to do so. The Safe Injection Sites is inspired from similar programs found globally, even as close as in Canada. Logistically, people would bring their own opioids to the sites and inject themselves under the supervision of medical staff. The staff would provide clean needles and equipment as to prevent the spread of communicable diseases, such as Hepatitis B.\(^12\)

Although many constituents have voiced their concerns, the program is meant to be a provocative solution to a very disturbing crisis.

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### 5 STEPS TO SAVE A LIFE

#### Step 1
Identify the overdose

#### Step 2
Call 9-1-1. Make sure to mention that the person is unresponsive and not breathing breathing with difficulty.

#### Step 3
Perform Basic CPR. Ensure that the person’s airway is not blocked and doesn’t experience other complications (i.e. sudden stopping of the heart).\(^13\)

#### Step 4
Follow the instructions on Naloxone packaging. After administering, continue to provide rescue breaths.

#### Step 5
Stay to make sure the person doesn’t go into withdrawal, doesn’t take more opioids, doesn’t go back into overdose, and doesn’t experience other complications.

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GRAPHIC/EMILY XU
HEALTHCARE IN THE TRUMP ERA:
NAVIGATING THE CURRENT DOMESTIC LANDSCAPE OF MEDICINE

BY VICTORIA SIU, JOAN LIM, JENNA HAROWITZ
GRAPHICS BY VICTORIA SIU

The Trump administration has continued its agenda to dismantle the Affordable Care Act and confront the opioid epidemic after one year in office. The Tax Cuts and Jobs Act serves as a precursor for the current shift in policy that favors relaxing regulations for insurance companies and cutting federal deficits. In addition, pressed by the growing public crisis, the administration has allocated funds and created a plan to fight opioid addiction through the “Reduce Demand and Over-Prescription” initiative. This infographic lays out past major events and future effects of Trump’s policies in healthcare.

PRO

Trump’s agenda to dismantle ObamaCare would save costs and allow for consumer choice

- Without a mandate, people who don’t want health insurance will not have to pay for it
- People would be protected from high premiums because government subsidies would rise
- Provides $45 billion for opioid crisis whereas previously it was $2 billion
- Senate version would cut federal deficit by $321 billion by 2026, House by $118.7 billion (accomplished by cutting Medicaid and reducing subsidies that help people pay for health insurance)

CON

Dismantling ObamaCare has long term detriments for public health and the middle class

- No tax penalty: lack of mandate means fewer healthy people are on health insurance which means rates go up since more of the people getting health insurance are unhealthy
- Would allow insurance companies to sell unregulated health policies
- Could cap coverage plans and discriminate against preexisting conditions
- Insurers could convince young and healthy people into cheap, short-term plans which leaves the sicker people buying the ACA-compliant plans, thus driving up prices
Trump signs executive order designed to increase competition and consumer choice for health insurance. New health plans do not have to comply with ObamaCare insurance policies, but low income protected from rate hikes.

October 13, 2017

Republicans attempt to repeal ObamaCare but do not garner enough votes.

March to July 2017

Trump declares the opioid epidemic a national public health emergency.

October 26, 2017

Trump signs the Tax Cuts and Jobs Act to repeal ObamaCare tax for those who do not have health insurance.

December 22, 2017

States are allowed to impose work requirements on Medicaid recipients.

January 11, 2018

Trump administration proposes plan to loosen regulations on short-term insurance.

February 20, 2018

White House pledge support for research in developing vaccine for opioid addiction as part of Trump’s plan “Reduce Demand and Over-Prescription.”

March 19, 2018