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INFOCUS

Why Genetics Matters in Tackling Covid-19

By Matthew R. Nelson, PhD



The novel coronavirus, SARS-CoV-2, has been circulating in people for over nine months now. As of this writing in early September 2020, infection has been diagnosed in more than 28 million people and resulted in over 900 thousand deaths worldwide. The United States has seen more than six million cases and 190 thousand deaths and is among the countries with the highest per capita numbers for both.

This virus has wreaked havoc on our economies and daily lives due to its capacity to spread quickly under normal activities and the consequently high rates of severe disease and death. In 50-year-old adults, over 70 percent of those infected with SARS-CoV-2 will show no or very mild Covid-19 symptoms. However, [about 5 percent require hospitalization and is fatal in approximately 0.2 percent, and the risks go down dramatically in those younger and up dramatically in more elderly¹](#).

¹ <https://www.medrxiv.org/content/10.1101/2020.07.23.20160895v4>

There are many potential causes for the range of infection response and understanding each of them can provide important clues about how to predict those at greatest risk of severe disease and more effectively treat them. Aside from age, which is the single largest risk, other factors influencing severe Covid-19 include male sex, obesity, coronary artery disease, high blood pressure, active cancer, diabetes, asthma, and liver and kidney disease. Another factor of interest is genetics; of both the virus and its human host. Human genetics can be particularly helpful because it is something we are born with, so we can more easily ascribe causal relationships than other factors that we study.

Viral Genetics

SARS-CoV-2 is only the seventh coronavirus known to infect humans. It is closely related to the SARS-CoV that caused an epidemic in 2003, infecting approximately 8,100 and causing 774 deaths. The Mediterranean MERS coronavirus has infected over 2,500 since it was first discovered in 2012 and has killed 862. There are four other coronaviruses that have become endemic in human populations, which are responsible for about 20 percent of common colds. The SARS-CoV-2 genome is made up of 29,903 ribonucleic acid (RNA) bases that code for at least 12 genes needed by the virus to enlist the host molecular machinery to infect, replicate, and then be packaged up to spread to other cells and potentially infect another host. This virus is most closely related to coronaviruses found in bats, where it is believed by most scientists to have made the jump to humans late last year.

The genomes of all organisms mutate and change over time. On average, one or more of the 30,000 RNA building blocks in SARS-CoV-2 mutate every two times it is passed from one host to another. While that is less than half the rate of influenza virus, with so many people infected worldwide, there have been over three million different versions of the coronavirus in just the past nine months. Most of those mutations will result in a virus that is somewhat less capable of infection and illness. However, some result in viruses that

are more easily passed on or make the infected person sicker.

There are many labs around the world that have sequenced over 100,000 viruses isolated from infected patients, tracking the changes that are taking place and taking hold in certain areas. Although we have observed certain forms of the virus becoming more common than others, there is no compelling evidence that any is more dangerous than the original viruses sequenced in Wuhan, China where the first outbreak began. By studying the sequence of the virus, we can better understand how it moves around within and among populations. Using such techniques, researchers showed that an outbreak originating at [a world-wide Biogen meeting held in Boston in late February](https://www.bostonglobe.com/2020/08/25/business/biogen-conference-likely-led-20000-covid-19-cases-boston-area-researchers-say/)² led to over 20,000 infections in Massachusetts by the end of May.

Human Genetics

Our genetics can also contribute to the variability we see in our propensities to become infected and sick or pass the virus on to others. There is very good precedent for this. One well documented example is with human immunodeficiency virus, or HIV, which causes AIDS. HIV infection occurs when it enters immune cells by binding onto the CCR5 protein on the cell surface. About 0.5 percent of people carry two copies of a version of the CCR5 gene that lacks the binding sequence that HIV requires, thus providing them with a high resistance to infection. Such insights can give us clues into how we can develop drugs to protect us from or fight the coronavirus.

Broadly speaking, there are two approaches to investigating the effect that differences in our genes have on disease. One approach, first developed in the late 19th century, involves investigating extreme conditions that appear together in families. For Covid-19, the most straightforward method is to find people who develop severe disease from infection that should otherwise be at low risk. This is even more powerful when this occurs in multiple members of a family. Then we can use the capabilities developed over the past decade to sequence large portions of the affected

² <https://www.bostonglobe.com/2020/08/25/business/biogen-conference-likely-led-20000-covid-19-cases-boston-area-researchers-say/>

participant genomes and identify changes in genes that track with severe disease.

To date, there has been one such discovery published in late July in the [Journal of the American Medical Association](#)³ that found two pairs of young healthy brothers in the Netherlands that ended up requiring mechanical ventilation. By sequencing all 20,000 genes, they found that the brothers from both families had mutations that disrupted the function of a gene called TLR7 that plays a role in a cell's ability to detect viruses and initiate a reaction to curtail their proliferation. This information is helpful in prioritizing new therapeutic mechanisms for early treatment of infection. Such mutations are too rare to deploy as a stand-alone diagnostic. However, within the next decade it will become commonplace for this kind of genetic sequencing to be carried out and included in our health record. In such a situation, that information could be very valuable to identify who should be particularly vigilant in avoiding infection or be first in line for a vaccine.

The second approach to learning how our genes affect our susceptibility and response to infection involves looking for more subtle genetic differences than described above. This approach emerged over the past 15 years as we gained the knowledge and technologies to cheaply measure genetic signposts across the three billion building blocks of our DNA and compare how common those signposts are in thousands to tens of thousands of people with infection or severe illness. This approach is referred to as a genome-wide association study (GWAS) and has been used to find well over 50,000 ways that our genes impact conditions from eye color and height to cholesterol levels and diabetes.

There are several studies and collaborative initiatives around the world seeking to bring together large number of participants with a range of disease severity to find the genes involved. [The first successful GWAS](#)⁴ was published in June with 1,610 Covid-19 hospitalized cases and 2,205 controls from Italy and Spain. They found two regions of the genome associated with risk of Covid-19 hospitalization.

One is in a region of the genome that harbors several genes known to be involved in immune response, where the exact gene involved is still unknown. The other region is responsible for determining our blood type, finding that the A blood type is at higher risk and the O type lower risk of Covid-19.

The [COVID-19 Host Genetics Initiative](#)⁵, which is led by an international group of prominent researchers, is bringing together all such data available around the world to delve deeper into the genetics more than any other study. To date, they have brought together data from over 3,200 hospitalized cases from eight studies and have found three additional genetic regions that may be involved in Covid-19.

This is a remarkable amount of genetic insight for a virus and a disease that is less than one year old. This is made possible by both the tremendous advances in genomic technologies and the willingness of research groups to share data and learnings. Over the next nine months, we can hope that multiple vaccines will be shown effective for curbing infection and disease, and additional therapeutics will improve disease outcomes in those infected. As the genetic research into Covid-19 continues, we can expect this to contribute to new therapeutic approaches that will further reduce SARS-CoV-2 infection to a manageable disease and minimize its impact on individuals and societies.

Dr. Nelson is Deerfield's Vice President, Genetics and Genomics

³ <https://jamanetwork.com/journals/jama/fullarticle/2768926>

⁴ <https://www.nejm.org/doi/10.1056/NEJMoa2020283>

⁵ <https://www.covid19hg.org/>

RESEARCH BITES

Overdose Crisis Endures, Yet Few People Receive Existing Effective Treatment

Even before Covid-19, despite enormous unmet need, life-saving buprenorphine is vastly underprescribed



Approximately half of clinicians authorized to prescribe buprenorphine for opioid use disorder (OUD), one of three medications for OUD, are actively prescribing the medication, according to a JAMA study led by researchers at The Pew Charitable Trusts, Deerfield Management Company, and RAND Corporation.

The research letter, which appeared in the August 24th online issue of [JAMA Network Open](#)⁶, examines national OUD buprenorphine prescribing patterns by Drug Enforcement Administration (DEA)-approved patient limits.

Buprenorphine is considered one of [the most effective therapies to treat OUD](#)⁷. In most circumstances, in order to become an authorized prescriber of buprenorphine to treat OUD, clinicians are required to undergo training approved by the [Substance Abuse and Mental Health Services Administration](#)⁸ (SAMHSA) and receive a special controlled substance license by the [Drug Enforcement Administration](#)⁹. Known as the X-waiver, the license was introduced by the [Drug Addiction Treatment Act of 2000](#)¹⁰. (More details on the steps necessary to become eligible to prescribe buprenorphine for OUD can be found on SAMHSA's [website](#)¹¹).

The authors of the paper point out that federal regulations currently limit these waived clinicians to treating 30, 100, or 275 patients concurrently, with clinicians who are limited to treating 30 or 100 patients having the ability to request an increased limit.

Based on a national analysis of clinician databases from the DEA and SAMHSA, and clinician-level prescribing information from Symphony Health, the authors found that of 55,938 waived clinicians, only 50.9 percent wrote at least one buprenorphine prescription during the 22-month period of April 2017 through January 2019.

Median patient monthly census calculations revealed 275-patient clinicians treated 36.9% of their patient limit, while 100-patient and 30-patient clinicians treated 23.9% and 11.3% of their patient limits, respectively.

“More than 2 million people in the United States have an opioid use disorder, yet few of them receive any type of specialty treatment, including buprenorphine,” said study co-author Alexandra Duncan, senior officer with The Pew Charitable Trusts’ substance use prevention and treatment initiative. “Removing barriers to buprenorphine prescribing can help close this treatment gap and ensure that people have access to the evidence-based addiction care they need.”

In recognition that buprenorphine is an important option for patients because it eliminates the need for the daily clinic visit required of most patients receiving methadone, [NYC Health and Hospitals expanded access](#)¹² to the medication by integrating prescribing into primary care. Additional benefits of buprenorphine are its low potential for abuse and negligible risk for overdose.

“Our finding that about half of doctors who can prescribe buprenorphine aren’t doing so makes clear that increasing the number of patients receiving it is not just about increasing the number of clinicians who can prescribe it,” added co-author Bradley Stein, Director of RAND’s Opioid Policy Center. “We need to focus efforts on increasing

⁶ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683>

⁷ <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/03/23/providers-underuse-oud-treatments-that-significantly-reduce-overdose-rates>

⁸ <https://www.samhsa.gov/>

⁹ <https://www.dea.gov/>

¹⁰ <https://www.naabt.org/data2000.cfm>

¹¹ <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>

¹² <https://www.nychealthandhospitals.org/pressrelease/opioid-addiction-treatment-expands-in-all-five-boroughs/>

reimbursement for buprenorphine's use, educating prescribers, patients, and their families about its effectiveness, and combatting the stigma that hampers the effective treatment of opioid use disorder.”

“Leveraging multiple large databases not only allowed us to confirm earlier evidence that clinicians are prescribing below their patient limits, but also enabled us to continue to peel back the onion on the scope of this problem,” said co-author Jared Anderman, Director of Data Analytics at the Deerfield Institute, a division of Deerfield Management Company. “We are looking forward to continuing to work with the powerful dataset we have created and identifying additional opportunities to make an impact.”

Authors of the study, titled, “Monthly Patient Volumes of Buprenorphine-Waivered Clinicians in the U.S.,” are: Alexandra Duncan (The Pew Charitable Trusts); Jared Anderman (Deerfield Management Company); Travis Deseran (previously Deerfield Management Company); Ian Reynolds (The Pew Charitable Trusts); and Bradley D. Stein (RAND Corporation). The work was funded by The Pew Charitable Trusts and Deerfield Management Company.

In other related news...

Opioid Deaths Surge During Coronavirus, Including in Wisconsin

The State of Wisconsin has been plagued with more than twice as many suspected opioid overdoses during the pandemic, compared with the same period last year, according to the Wisconsin Department of Health Services (DHS).

Not surprisingly, health officials said that this can be attributed, at least in part, to the added stress and anxiety that many people are feeling now.

Early data from Wisconsin emergency rooms revealed that there were 325 suspected overdoses from March through July 13, 2020. As a comparison, there were 150 during the same period last year.

Officials with the Opioid Initiatives of DHS commented in a [news release](#)¹³ that the pandemic hit just as Wisconsin was making progress in getting down the number of opioid-related deaths.

“We know that the pandemic as a whole has caused increased stress and anxiety in just about everybody and anybody,” said Paul Krupski, director of Opioid Initiatives at DHS, during a [video conference](#)¹⁴. “And for individuals who have struggled with substance use and may be currently in treatment for that, this adds an extra layer to the challenges that they are encountering during this pandemic.”

5.4 Million Americans Lost Health Insurance Amid Pandemic, Study Finds



In another byproduct of the pandemic, a record-breaking 5.4 million people who experienced job loss between February and May 2020 also lost their health insurance, according to a [study](#)¹⁵ released recently by Families USA, a consumer healthcare advocacy organization.

The approximate increase in uninsured laid-off workers over the three-month time frame was almost 40 percent higher compared with the highest previous rise recorded during the one-year period of the recession from 2008 to 2009. During that period, 3.9 million adults lost their insurance.

Importantly, the numbers don't count family members who might also have been on those insurance plans.

¹³ <https://www.dhs.wisconsin.gov/news/releases/072220.htm>

¹⁴ <https://apnews.com/c3e331526483cc34d54fae53d5d089d>

¹⁵ <https://www.familiesusa.org/resources/the-covid-19-pandemic-and-resulting-economic-crash-have-caused-the-greatest-health-insurance-losses-in-american-history/>

The report, which is a state-by-state assessment of outcomes of the health crisis on laid-off adults under age 65, found that almost half of the health insurance coverage losses occurred in California, Texas, Florida, New York and North Carolina.

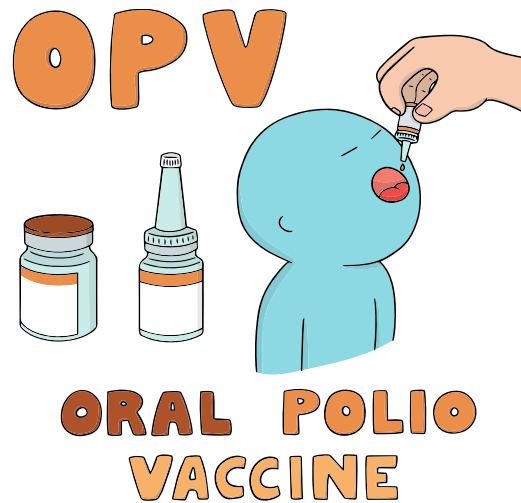
In addition, in eight states, 20 percent or more of adults are now uninsured: Texas, where nearly three in ten adults under age 65 are uninsured (29%); Florida (25%); Oklahoma (24%); Georgia (23%); Mississippi (22%); Nevada (21%); North Carolina (20%); and South Carolina (20%). With the exception of Oklahoma, the author points out, all are among the 15 states with the country's highest spike in new Covid-19 cases during the week ending July 12, 2020.

Stan Dorn, who directs the group's National Center for Coverage Innovation and is the author of the study, told the [New York Times](https://www.nytimes.com/2020/07/13/us/politics/coronavirus-health-insurance-trump.html)¹⁶: "We knew these numbers would be big. This is the worst economic downturn since World War II. It dwarfs the Great Recession. So it's not surprising that we would also see the worst increase in the uninsured."

Definitive data on loss of health insurance coverage will not be available until mid- to late-2021, when the federal government publishes health insurance estimates for 2020.

In his report, Mr. Dorn calls on federal lawmakers to use the next Covid-19 bill as an opportunity to fill in the gap by including protections for comprehensive health insurance.

Until We Have a Covid-19 Vaccine, Might the Polio Vaccine Offer Some Protection?



A co-discover of HIV says that an existing oral polio vaccine and other live vaccines may help protect against Covid-19.

In a recent paper in the journal [Science](https://science.sciencemag.org/content/368/6496/1187)¹⁷, Robert Gallo, MD, along with Konstantin Chumakov, PhD, and their co-authors, propose that live versions of some vaccines, particularly the vaccine against polio, could provide temporary protection against Covid-19.

Gallo, the co-discoverer of the human immunodeficiency virus that causes AIDS, is with the Institute of Human Virology at the University of Maryland; Chumakov is associate director for research at the FDA's vaccine division.

As both the poliovirus and coronavirus are positive-strand RNA viruses, the researchers hypothesize that the polio vaccine may offer the best chance at inducing common innate immunity mechanisms.

The paper points to a number of earlier instances in history where the polio and other live vaccines were shown to induce broader protection against unrelated pathogens, beyond which they were intended.

¹⁶ <https://www.nytimes.com/2020/07/13/us/politics/coronavirus-health-insurance-trump.html>

¹⁷ <https://science.sciencemag.org/content/368/6496/1187>

Some of the nonspecific effects of vaccines against infectious diseases, reported the researchers, may be mediated by interferons and other mechanisms yet to be identified.

Early clinical studies showed that in immunized children, beyond protecting against polio, the polio vaccine reduced the number of other viruses, compared with the control group. According to the paper, more recent studies have also confirmed these broad protective effects of the polio vaccine.

Compared with some other live vaccines, the risk of adverse effects due to the polio vaccine is very low and the vaccine is generally well tolerated. Other benefits of the polio vaccine emphasized by the researchers are its cost-effectiveness, ease of administering, and wide availability.

Importantly, the researchers reported, the oral polio vaccine produces herd immunity effects. Herd immunity is defined by the Centers for Disease Control and Prevention (CDC) as “a situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely.”

“In addition to protecting vulnerable individuals, it could also prevent the spread of the new coronavirus by increasing the proportion of unsusceptible individuals,” wrote the authors.

According to the CDC, an inactivated polio vaccine (IPV) is the only polio vaccine that has been given in the United States since 2000. IPV is given by a shot in the leg or arm, depending on the patient’s age.

The oral polio vaccine (OPV), or live vaccine, is currently used in other countries. Live vaccines produce a strong and long-lasting immune response, say vaccine experts.

Nearly eradicated worldwide, the U.S. has been polio free since 1979.

Pfizer’s Tafamidis at Higher Dose Boosts Survival in Patients with Transthyretin Amyloidosis Cardiomyopathy

At 51 months, 80 mg/day resulted in substantially greater survival, compared with 20 mg/day



New long-term extension data, out of the landmark ATTR-ACT trial, showed a statistically significant difference in survival rates in patients with transthyretin amyloidosis cardiomyopathy (TAC).

Patients who were treated with oral tafamidis at 80 mg/day fared remarkably better than those who received 20 mg/day, with a 30 percent reduction in risk of death in the higher dose group ($p=0.04$). The data was presented recently at the [European Society of Cardiology Heart Failure Discoveries virtual meeting](#)¹⁸.

TAC¹⁹ occurs when transthyretin, a transport protein, becomes destabilized and misfolds, promoting deposition of amyloid fibrils in the myocardium and elsewhere. In the heart, the result is progressive ventricular wall thickening and stiffness, manifest as restrictive cardiomyopathy and progressive nonischemic heart failure.

“The original 30-month endpoint data reported two years ago suggested no difference in overall survival between the 20 mg and 80 mg arms of the study,” said Deerfield Partner Nicholas Bishop, PhD. “The new data are encouraging.”

¹⁸ [https://www.escardio.org/Sub-specialty-communities/Heart-Failure-Association-of-the-ESC-\(HFA\)/Research-and-Publications/HFA-Discoveries](https://www.escardio.org/Sub-specialty-communities/Heart-Failure-Association-of-the-ESC-(HFA)/Research-and-Publications/HFA-Discoveries)

¹⁹ https://www.heart.org/-/media/files/health-topics/answers-by-heart/abh_what-is-atrcm_v2_a

Would You Take A Blood Test for Alzheimer's When There's No Cure?



A new, experimental diagnostic to detect Alzheimer's disease is nearly as accurate as the most definitive method to date to diagnose the disease: autopsy. The research was published in [JAMA](#)²⁰ recently and presented at the Alzheimer's Association International Conference (AAIC).

The blood test, which may be available for clinical use in two to three years, could make diagnosis easier and more affordable, reported the [New York Times](#)²¹.

The investigators found the test to be highly specific, accurately identifying when people with signs of dementia had Alzheimer's instead of another condition.

Beyond clinical assessment, current methods to diagnose Alzheimer's include costly PET scans and spinal taps that are invasive, the latter of which also poses some risk. Both of these approaches detect elevated levels of the amyloid protein, long considered one of the hallmarks of the disease, though there has been considerable debate in recent years questioning the [amyloid hypothesis and greater role of tau](#)²².

The new blood test being studied, in contrast, measures a specific form of the tau protein known as p-tau217. Buildup of tau tangles is additionally thought to correlate closely with cognitive decline. Importantly, the test appears to also identify the presence of amyloid plaques, according to [AAIC's press release](#)²³.

[Research](#)²⁴ suggests some combination of amyloid and tau involvement with amyloid buildup from preclinical through early dementia stages followed by tau-related pathology, the latter driving cognitive deficits and dementia severity.

In theory, such a blood test could potentially be used in the future to predict who might develop Alzheimer's, independent of exhibiting any symptoms. Quite remarkably, the test recognized changes in the brain 20 years before symptoms would occur in a group of people with a genetic mutation for early-onset Alzheimer's.

The ability to diagnose Alzheimer's early has been a key challenge in the development of an effective therapy. Currently, the process of screening participants for Alzheimer's [clinical trials takes years and costs millions of dollars](#)²⁵. At the same time, [concerns](#)²⁶ have been raised that such a test ahead of a cure or an effective treatment would be unethical.

"Early detection and intervention long before a person shows clinical symptoms of Alzheimer's are key. It is at this earliest stage of the disease when it will be most amenable to treatment. The results of this study need to be replicated in more rigorous clinical trials that are expanded to reflect broader and more diverse populations," said Deerfield Partner Zheng Su, PhD. "Also, it's important to keep in mind that hallmarks of Alzheimer's do not necessarily mean that amyloid and tau are causes of the diseases. The jury is still out as to whether they are a cause or a sign of Alzheimer's."

"This test appears to be equally accurate but less invasive than current gold standard diagnostic tests for Alzheimer's disease. Thus, it might be helpful to accurately identify patients suitable for treatment, in a future world where effective disease-modifying therapies for Alzheimer's have been developed," said Deerfield Partner Nicholas Bishop, PhD.

Oskar Hansson, MD, PhD, professor of clinical memory research at Lund University in Sweden, and Eric Reiman, MD, executive director of the Banner Alzheimer's Institute in Phoenix, are senior authors of the study.

The cross-sectional study included 1402 participants from three selected cohorts.

²⁰ https://jamanetwork.com/journals/jama/fullarticle/2768841?guestAccessKey=42d098cb-7eca-4a1c-9d7b-9951b104b003&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=ftl&utm_term=072820

²¹ <https://www.nytimes.com/2020/07/28/health/alzheimers-blood-test.html>

²² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5797629/>

²³ https://www.alz.org/aaic/releases_2020/blood-biomarkers-tau.asp

²⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5536337/>

²⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6118094/>

²⁶ <https://www.npr.org/sections/health-shots/2014/03/09/286881513/alzheimers-blood-test-raises-ethical-questions>

IP CORNER

Licensing IP from State Universities: Special Considerations

By Mark Shtilerman, PhD, JD

Academic institutions generate many early stage innovations then pass them to commercial entities for further development. Revenue is generated through equity, milestone, and/or royalty payments from the commercial firms. Academic institutions in these commercial endeavors are bound by some of the rules applicable to commercial entities. Commercial firms that serve as counterparts in these transactions want assurances that they will be able to enforce such in-licensed IP. If litigation is to be brought, both the patent owner and the licensee are necessary plaintiffs²⁷. State universities present a unique challenge because unlike private institutions, they cannot be forced to become party to litigation in a federal court.

The Federal Rule of Civil Procedure requires patent owners to be plaintiffs in most patent litigations, with only small exceptions for cases when the license is really a sale. Meanwhile, the 11th Amendment of the U.S. Constitution confers sovereign immunity to states. The result is that state-owned universities can assert sovereign immunity to avoid being involuntarily brought into litigation.

This conflict played a central role in a recent case of *Gensetix, Inc. v. Baylor Coll. of Med.* (Fed. Cir. July 24, 2020). William Decker, an employee of the University of Texas (UT), invented a method for modifying immune cells to treat cancer. He assigned his inventions to UT, which in turn licensed his inventions to Gensetix. Decker subsequently moved to the Baylor College of Medicine where he engaged in allegedly infringing activity. Gensetix sued Dr. Decker and Baylor for patent infringement, but UT asserted sovereign immunity and refused to join this litigation. Baylor made a motion to dismiss the case for lack of a necessary plaintiff. Gensetix asked the district court to bring UT into the case as an involuntary plaintiff, but the court refused and dismissed the case. This left Gensetix with no ability to enforce the patents²⁸. Gensetix appealed.

On appeal from the district court's decision, the three judges of the Court of Appeals for Federal Circuit addressed two key questions:

- Is UT protected by sovereign immunity?
- Should the case proceed without UT if UT asserts immunity and refuses to be a plaintiff?

Judge O'Malley	Judge Taranto	Judge Newman
UT is immune	UT is immune	UT is not immune
Proceed without UT	Should not proceed if UT is immune	Proceed without UT

Judges O'Malley and Taranto agreed that precedent set by prior Supreme Court cases requires broad application of 11th Amendment immunity. Judge O'Malley opined that a state university cannot contractually waive the immunity as this right is reserved for the state legislature. In dissent, Judge Newman wrote that when a state enters regular commercial activity, it should be subject to the rules of commerce. After all, UT has collected significant payments from Gensetix under the license. However, this position is not the current law.



²⁷ Fed. R. Civ. Pro. 19.

²⁸ *Gensetix, Inc. v. Baylor Coll. of Med.*, 354 F.Supp. 3d 759 (S.D. Tex. 2018).

The judges also disagreed on whether the joinder of UT is required by Fed. R. Civ. Pro. 19. The rule requires a two-step analysis: (a) whether the party is considered a “required” party: specifically, whether it or other parties will be prejudiced by the judgement in its absence, and (b) whether the joinder is feasible. If the joinder is not feasible, “the court must determine whether, in equity and good conscience, the action should proceed among the existing parties or should be dismissed.”²⁹

Judges O’Malley and Newman ruled that the joinder is not feasible, but that the case should proceed because “Gensetix is without recourse to assert its patent rights because UT cannot be feasibly joined.” These judges also looked at the totality of rights transferred to Gensetix and commented that the interests of UT will be adequately protected by Gensetix. Judge Taranto felt bound by the Supreme Court precedent that gave extreme weight to sovereign immunity and dissented on this issue. As a result, the case will proceed in district court without UT.

Although this case proceeds, its legal underpinnings are shaky as evidenced by the fractured decision. Baylor is expected to appeal to the full Federal Circuit or the Supreme Court. The law may change depending on the composition of the panel of the Federal Circuit and the specifics of subsequent cases. The case highlights the legal uncertainty over the ability to enforce IP licensed from state universities. Companies that license IP from state universities should be aware of this issue regarding sovereign immunity.

²⁹ Fed. R. Civ. Pro. 19.

BREAK INTO THE BOARDROOM™: BIB BIOS

“BiB Bios” is our way of introducing candidates to a broader audience and consistently keeping our program, Break into the Boardroom, and the importance of boardroom diversity top-of-mind. It is our objective to help as many of these alumni as possible find the right board role.



We are committed to connecting our featured candidates with company boards that could benefit from their expertise. Please reach out to Leslie Henshaw at lhenshaw@deerfield.com to inquire about meeting Ms. Nicole Latimer or having us search our database for other candidates with a specific set of skills currently being sought for an identified board opportunity.

INTRODUCING... NICOLE LATIMER

Current Position: CEO, Medrio, a privately held company that accelerates clinical trials through innovative, intuitive, cloud-based software.

Previous Roles: CEO, StayWell, a digital health and wellbeing information company acquired by WebMD

SVP, The Advisory Board Company, a best practices research and technology company now part of Optum/United Healthcare

Education: University of Michigan (MBA & MHSA), Dartmouth College (BA, English)

Key Expertise/Skill Sets: Nicole is a data-driven executive who optimizes commercial functions and scales operations within HCIT companies. She uses her knowledge of clinical workflows as well as clinician and patient behaviors to inform product management, market positioning, and customer relations. An advocate for interoperability, Nicole has partnered with major EHRs and has developed FHIR apps used within inpatient and ambulatory environments. Nicole also has extensive experience evaluating and integrating technology acquisitions, including consumer-facing applications.

Professional Interests: Nicole is passionate about using technology and information to streamline processes and improve outcomes within the healthcare and life sciences industries. Always seeking to balance the high-tech, high-touch duality of healthcare, Nicole also has interests in clinician, patient and employee engagement.

Personal Interests: When not continually feeding her teenage sons, Nicole finds perpetual frustration in her golf game, pure joy on a ski slope, and tranquility in a well written book.



Photo courtesy of Nicole Latimer

CAPTURED OUR INTEREST



By Christine Livoti

UK launches subscription payment scheme for antibiotics

In an effort to bolster treatment options for serious infections, the UK's National Health System (NHS) has launched a new payment model that will provide upfront payments to manufacturers for their antibiotics based on their value to the NHS rather than on how much is used. Two drugs will undergo value assessments by the National Institute for Health and Care Excellence (NICE), the UK's cost effectiveness body, throughout 2021. NICE will use an adapted-valuation method for antimicrobials to determine the level of the subscription payment.

Pharmatimes

http://www.pharmatimes.com/news/uk_launches_worlds_first_subscriptionstyle_payment_model_for_antibiotics_1342470

Pfizer sues to extend co-pay assistance to federal insurance programs

Drugmakers can offer direct financial assistance to patients or donate to charity programs that help defray out-of-pocket drug costs. However, legislation prohibits the use of such assistance for patients covered by government insurance like Medicare and Medicaid. Pfizer recently sued in New York District court over its heart drug Vyndaqel in order to get more legal clarity around what is known as the anti-kickback statute which governs the practice.

FiercePharma

<https://www.fiercepharma.com/pharma/pfizer-sues-to-help-vyndaqel-patients-raises-constitutional-question-against-anti-kickback>

CMS proposing to make permanent many telehealth changes introduced under Covid

In its annual rule-making process that governs payment rates for Medicare and Medicaid, CMS has proposed to keep many of the changes to telehealth first introduced during the Covid-19 public health emergency. Specifically, it will finalize coverage for particular telehealth services not only by physicians but also a range of mid-level practitioners. After reviewing public comments, the agency will settle next year's rule by November.

CMS

<https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-4>

NYC Covid antibody data sheds light on hardest hit neighborhoods

The New York City Department of Health released findings from the 1.5 million antibody tests conducted citywide since mid-April. The Bronx and Queens thus far have shouldered a heavier burden of infections, with antibody positivity rates hovering around 30 percent, compared to less than 20 percent for Manhattan. The data may have implications for which communities reach herd immunity earlier.

New York Times

<https://www.nytimes.com/2020/08/19/nyregion/new-york-city-antibody-test.html>

Third patient death reported in gene therapy trial

A clinical trial being conducted by Audentes and Astellas in X-linked myotubular myopathy reported its third patient death. The gene therapy was seen as promising for the rare disease. Thus far, the three patient deaths appear to be in older patients treated at higher doses, with pre-existing liver injury. The program now remains on clinical hold by the FDA.

Endpoints

<https://endpts.com/derailed-gene-therapy-study-reports-3rd-death-as-safety-and-durability-issues-cloud-a-booming-field/>

Florida abruptly cuts ties with Quest over delays in reporting Covid testing results

The Florida Department of Health announced it would be immediately severing ties with Quest Diagnostics for the performance of Covid testing. At issue was a delay by Quest in reporting 75,000 test results to public health authorities going back to April. The lab giant accepted blame and attributed the missing results to a technical issue.

Quest

<https://newsroom.questdiagnostics.com/COVIDTestingUpdates>

BCBS NC looks to bolster primary care

Insurance provider BCBS NC announced the launch of its Accelerate to Value program in response to the financial struggles imposed on independent primary care practices related to Covid-19. The program, open to independently owned primary care practices in North Carolina, includes financial support by BCBS NC by making payments to participating practices, based on 2019 revenue, in an effort to improve financial stability in 2020 and 2021. These payments will begin by September 2020. In exchange, participating practices must participate in BCBS NC's value-based care program.

BCBS NC

<https://mediacenter.bcbsnc.com/news/blue-cross-nc-launches-comprehensive-program-to-help-independent-primary-care-practices-stay-in-business#>

DEERFIELD FOUNDATION

The Deerfield Foundation has formed 56 partnerships and invested or committed over \$50 million for the advancement of children’s health in its 13 years, ranging from health clinics in Nepal to a mobile medical home for children in the South Bronx. We would like to highlight here just one of the organizations that we feel is helping us fulfill our mission of advancing healthcare. We are proud to be critical supporters of The Family Center.

THE FAMILY CENTER

Mission To strengthen families affected by crisis, illness or loss to create a healthier and more secure present and future for their children.

Partner Since 2008

Description The Family Center was founded in 1994 after four women who, while working at the NYC Department of Social Services, saw a gap in services addressing the needs of families affected by HIV/AIDS. Little was being done to prepare the children for death, mourning and rebuilding their lives. With these families in mind, the organization was established to give children a secure future by providing comprehensive legal and social services under one umbrella.



On an outing at the Young Architects Program at MOMA (pre-Covid)
Photo credit: Marya Gilborn

The scope of services offered by The Family Center has continued to evolve. In May 2020, The Family Center received a grant from the federal government to become a Certified Community Behavioral Health Center and in turn will provide an even greater level of integrated services. This new programming will incorporate primary medical care and substance abuse treatment services for children, teens and parents/caregivers into the agency’s existing model of comprehensive services.

2019-2020 Funding \$85,000 + \$16,800

2019-2020 Project Funded [Project Bienestar and Covid-19 Emergency Funding for Client Families](#)

2019-2020 Grant

Update Since early 2019, The Family Center has been working on an initiative called Project Bienestar, which provides trauma treatment and case management support to trauma-impacted immigrant children who recently arrived in the U.S. and who came alone or were separated from their families or guardian at some point along the journey.

As of December 2019, The Family Center has screened and assessed 69 immigrant young men and women for trauma exposure, which is 69 percent of the goal of 100 children before November 1, 2020. The Project Bienestar’s staff have already provided 29 children and teens with evidence-based trauma-treatments and/or

case management services; this is over 70 percent of the projected goal of serving 40 immigrant young women and men by November 1, 2020. In January 2020, by partnering with a Pathways High School social worker, who counseled immigrant students, the organization was able to help 19 Bangladeshi teens who were negatively impacted by a suicide in the NYC Bangladeshi community. The 19 men met as a group with the social services staff of Project Bienestar once a week for 10 weeks for mental and behavioral treatments. The Covid-19 pandemic, however, disrupted this schedule of meetings.

[Covid-19 Emergency Funding for Client Families:](#) Many clients of The Family Center experienced unprecedented financial hardships due to the Covid-19 pandemic. The Deerfield Foundation contributed \$16,800 to The Family Center to help relieve some of the financial burden of 168 of the Center's client families. The families were selected based on the following parameters:

- Income level - All live on incomes that fall far below the federal poverty threshold
- Food security assessment - As done by direct staff worker
- Housing stability assessment - As done by direct staff worker
- Medicaid eligibility - All are on Medicaid or The Family Center is actively working to enroll them

Feature Profile **MARIA***

Maria was a 16-year-old girl from Guatemala, where she had lived her entire life with her father and stepmother. At age 12, Maria was kidnapped by a local gang and held for several days while different gang members took turns abusing her. While she was eventually released and returned home, the local authorities could not protect her and the kidnapping and abuse became a pattern for the next several years. When Maria arrived in the U.S. alone after a grueling journey north, she was put in a federal detention center for six weeks. When she came to The Family Center, she was living with her mother, who had been living in Brooklyn for nearly all of Maria's life. Maria had an intense fear of crowds and experienced daily migraines, jaw pain and blurred vision. Unable to speak English or figure out the subway system, she had also stopped attending school.

Upon enrolling Maria in Project Bienestar, a Family Center social worker began visiting Maria's home and teaching her how to take the subway. Her social workers also intervened to secure her a place at the Brooklyn International High School where she could receive special ESL instruction. Her social worker connected Maria with a doctor for the first time in her life and coordinated with her court-appointed immigration attorney to testify to the trauma Maria had experienced. All the while, Maria's Family Center social worker was also providing specialized, Trauma-Focused Cognitive Behavioral Therapy. While Maria was initially improving—experiencing a reduction in somatic symptoms and attending school regularly—the Covid-19 pandemic has been very difficult for her and her mother. This is one Family Center client family that was grateful to receive the \$100 stipend as part of The Deerfield Foundation Covid-19 Relief Grant to the Center.

* Name and other minor details changed by The Family Center to protect their client's confidentiality.

Website

www.thefamilycenter.org

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