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INFOCUS

Shifting Care to the Home

By Julian Harris MD, MBA



“The Doctor Will See You Now...In Your Home.”

After well over a century during which the majority of care delivery shifted from the home to hospitals, clinics, and nursing homes, we are increasingly witnessing a gradual reversal of this trend. Fueled by a combination of new technology, the rising cost of care in other settings, and personal preferences for the relative convenience and safety of the home, many would argue that this deinstitutionalization of care is long overdue.

Telehealth

While the adoption curve for telehealth has been less compelling than many health care futurists anticipated, a growing percentage of Americans—now at 8 percent—have tried telehealth at least once, and an even larger percentage has expressed openness to considering it in the future. And while millennials have tried telehealth at almost 3 times the

rate of the general population, its potential impact on improving quality and reducing cost may be even greater for seniors, who leverage telehealth for different purposes, such as assistance with medication adherence<sup>1</sup>.

### Remote Monitoring

From digital glucometers, scales, pulse oximeters, and blood pressure cuffs to Alexa devices with health care focused “skills,” a range of technologies has made it possible to better manage a number of chronic conditions in the home, including diabetes, congestive heart failure, and hypertension. Efforts to titrate medications for diabetes and hypertension that previously took weeks can be achieved, at times, in days, because of the much greater volume and frequency of data that can be collected with digitally enabled devices combined with telehealth, enabling clinicians to titrate these medicines much more efficiently than the “start at this dose, and see me back in a week” approach.

Recently, United Health Care announced the acquisition of Vivify, a remote monitoring company that leases to providers tablets connected to Bluetooth enabled devices that allow them to monitor and intervene as patients’ health conditions evolve in the home. Given the massive number of care delivery assets that it has accumulated—from primary care practices to hospitalist groups to ambulatory surgical centers, United clearly sees a wide range of use cases for leveraging remote monitoring as yet another tool to move more care out of the hospital “box” as a cost control and quality improvement mechanism.

### New Payment Models

For commercially insured patients, a number of companies have taken pages from the historic doctor house call model and combined them with GPS-enabled routing protocols, compact, next generation house call kits (which can include a range of diagnostic and lab collection equipment), and clinicians trained to provide a “white glove” level of primary care and urgent care service in the home.

For patients insured by Medicare Advantage plans, a broader range of companies have expanded to provide home-based primary care or to wrap a range of services around patients’

existing primary care relationships. Some individuals served by these plans are relatively healthy, but seek the convenience of home-based care, similar to the commercial population. There is also a subset of socially and medically complex, high-cost patients covered by Medicare Advantage and Medicaid managed care plans who receive their care in the home in part because it may be challenging for them to leave the home for physical, psychological, or economic reasons. Home-based care models have been shown to improve quality and reduce costs for these patients by reducing ED visits, hospitalizations, and hospital readmissions. Given their efficacy in this regard, these companies have contracted with health plans and risk-bearing provider organizations to receive incentive or shared-savings payments that hold them accountable for their performance at reducing or slowing the growth in the total cost of care while meeting pre-defined quality metrics.

### Hospital At Home

Leveraging a combination of telehealth, remote monitoring tools, and in home clinicians (ranging from nurses to physicians, depending on the model), some investor-backed companies and academic institutions are taking the shift in the site of care to the home to its inevitable end-state—the delivery of hospital level care in the home. These companies work with providers and plans to provide care for common conditions like community acquired pneumonia, mild to moderate congestive heart failure, urinary tract infections, and cellulitis that are low-margin DRGs for busy hospitals. In exchange, these hospitals have the ability to care for sicker patients who actually need inpatient or intensive care enough to warrant the higher costs and associated risks of being temporarily housed inside of the hospital “box,” such as opportunistic infections. Hospital at home has been deployed at scale in some European countries for over a decade, and while the uptake has been much slower in the U.S., there is clearly growing interest and momentum in this space and a recognition that it simply has to be one of the features of a future-state health system.

<sup>1</sup> <https://www.americanwell.com/resources/telehealth-index-2019-consumer-survey/>

**Conclusion**

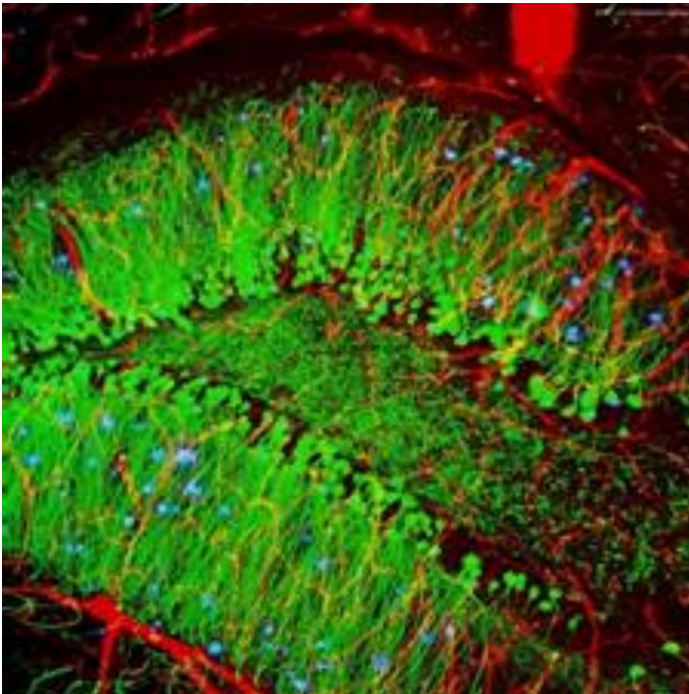
Even if the broader shift to urgent and acute care in the home follows a similarly slow rate of adoption to the one that has been observed in telehealth, over the next 10-15 years, technology-enabled care in the home will become fully mainstream, and the idea of going to clinics or the hospital for many forms of routine care will seem outdated, if not absurd. This shift will force some tough choices, particularly at smaller, community hospitals that may find it challenging to stay afloat without the volume that has sustained the capital-intensive boxes that are modern hospitals. While it may seem counter-intuitive, the shift to the home actually has the potential to create access issues for more complex care where an inpatient stay is required in areas where the reimbursement is not adjusted sufficiently to enable community hospitals that are too big to qualify for critical access hospital status and financing to survive. Overcoming these and other unintended consequences of the shift to the home will require focus and attention, but the positive impact on quality, cost, and the patient experience cannot be understated.

**Dr. Harris is a partner on the health care services and technology teams at Deerfield.**

## DEERFIELD RESEARCH BITES

## Could an APOE-targeted Drug or Gene Therapy be the Answer to Alzheimer's?

*Researchers Not Involved With The Study Suggest That While The Findings Only Involve A Single Case, They Could Potentially Point To A New Approach For Correcting The Disease*



Along with blood vessels (red) and nerve cells (green), this mouse brain shows abnormal protein clumps known as plaques (blue). These plaques are thought to multiply in the brains of people with Alzheimer's and have been long associated with the memory impairment characteristic of the disease. Image courtesy of Alvin Gogineni, Genentech.

Like many generations of her Colombian family before her, the woman likely knew her fate that she was destined to develop Alzheimer's by the time she turned 50. In fact, as a carrier of presenilin-1 (PSEN1), the causative gene for early-onset Alzheimer's, there was nearly a 100% chance she would get it. Only she didn't.

Researchers believe they may know why. In a study published November 4<sup>th</sup> in the journal [Nature Medicine](https://www.nature.com/articles/s41591-019-0611-3)<sup>2</sup>, investigators report that the woman also has two copies of the most common form of the APOE gene—APOE3—but that both of these copies carry an extremely rare mutation called Christchurch, which may be protective.

The woman's brain was functioning very well, say the scientists. She didn't experience any cognitive decline at all until her 70s and was reported to have little brain atrophy and not much tau, the protein that forms tangles in the brain that's considered one of the hallmarks of Alzheimer's.

But quite remarkably, the woman was found to have enormous amounts of amyloid in her brain (the plaques commonly viewed as the other hallmark of Alzheimer's), a finding that carries with it significant implications and potentially raises further doubt about the amyloid hypothesis. Rather than continuing to chase amyloid (or tau) following multiple failed clinical trials and billions of dollars—the research suggests that a medication or gene therapy targeting APOE could have potential.

The APOE4 version of the gene, on the other hand, greatly increases one's risk for late-onset Alzheimer's, the most common form of the disease that affects people age 65 and older.

The early-onset dementia being investigated in the Colombian family is quite rare worldwide. Scientists believe that studying the family will not only help those with this less common form but may provide important insights into late-onset Alzheimer's, the most prevalent form of the disease.

The woman is now entering her late 70s. Dr. Francisco Lopera, the Colombian neurologist who has been closely following for decades her extended Colombian family of about 6,000 people whose members have developed dementia for centuries, is an author of the Nature Medicine paper. He is affiliated with the Grupo de Neurociencias de Antioquia de la Universidad de Antioquia, Medellin, Colombia.

<sup>2</sup> <https://www.nature.com/articles/s41591-019-0611-3>

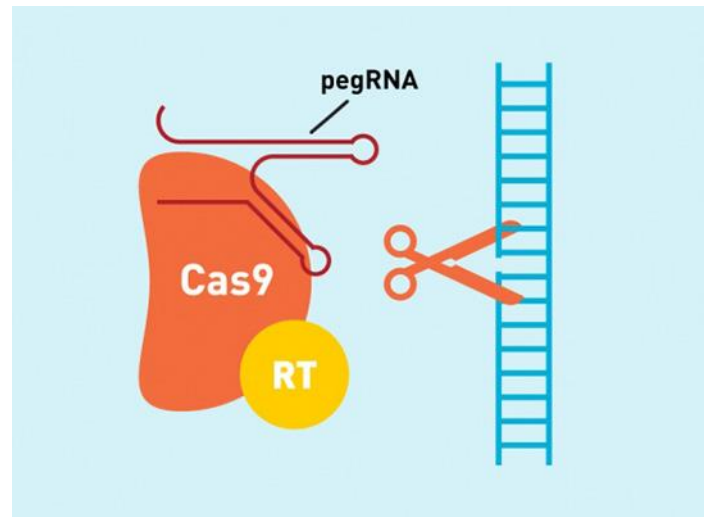
“While these results are very tantalizing, we must keep in mind this is a single case,” says Matt Nelson, VP of Genetics and Genomics at Deerfield. “We should judge this cautiously.” He noted that four members of this extended family with the PSEN1 Alzheimer’s mutation had a single copy of the presumed protective APOE Christchurch variant, but with no delay in disease onset. “Extrapolating cause and effect from one observation is very risky.”

A drug or gene therapy is unfortunately not expected any time soon. Scientists will need to first replicate the protective mechanism in additional cases and support it with further experimental work.

This summary is partially based on the New York Times coverage<sup>3</sup> of the Nature Medicine paper.

## Is Prime Editing Better than Current Methods?

*New Gene-Editing Tool Reported To Be More Precise*



Credit: Susanna M. Hamilton, Broad Institute of MIT and Harvard

“Prime editing”, a new gene-editing approach, has the potential to correct up to 89 percent of known disease-causing genetic variations, according to scientists at the Broad Institute of MIT and Harvard in a paper published in the October 21<sup>st</sup> issue of the journal *Nature*<sup>4</sup>. The research was led by senior author, David Liu, PhD, and first author, Andrew Anzalone, MD, PhD, a postdoctoral fellow in Liu’s lab.

By combining two of the most important proteins in molecular biology—CRISPR-Cas9 and a reverse transcriptase—as well as a new RNA into a single system, the researchers say, the team developed the new CRISPR genome-editing method.

Gene editing involves altering the four bases of the genetic code, designated by the letters A, C, T and G, by deleting them, inserting them, modifying them or some combination of the three.

<sup>3</sup> <https://www.nytimes.com/2019/11/04/health/alzheimers-treatment-genetics.html>

<sup>4</sup> <https://www.nature.com/articles/s41586-019-1711-4>



For the first time, the researchers say, prime editing essentially allows for any changes—whether they be additions, deletions, or replacing any single letter for another—without severing the structure of DNA (the DNA double helix). Unlike previous genome-editing techniques, prime editing uses RNA to direct the insertion of new DNA sequences in human cells.

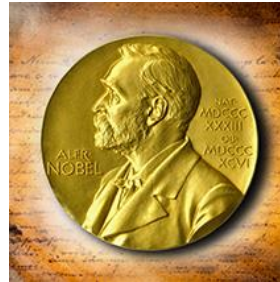
Dr. Lui reportedly offered the following comparison at a press briefing: “If Crispr-Cas9 is like scissors and base editors are like pencils, then you can think of prime editors to be like word processors.”

The research team plans to continue additional testing of prime editing in cell and preclinical models of disease, including investigating delivery mechanisms to provide a potential path for therapeutic applications in people.

Summary adapted from [Broad Institute](https://www.broadinstitute.org/news/new-crispr-genome-editing-system-offers-wide-range-versatility-human-cells)<sup>5</sup> and [WIRED](https://www.wired.com/story/a-new-crispr-technique-could-fix-many-more-genetic-diseases/)<sup>6</sup>.

## 2019 Nobel Prize in Medicine Awarded to Researchers Affiliated with Two Deerfield Academic Partners for Their Discoveries on How Cells Manage Oxygen

*Findings Have Implications For Treating A Number Of Diseases, Including Cancer, Anemia, Heart Attacks And Strokes*



This past October, the Nobel Prize in Physiology or Medicine was jointly awarded to three scientists — William G. Kaelin Jr., Peter J. Ratcliffe and Gregg L. Semenza — for deciphering the mechanism that enables cells to sense and adapt to changes in oxygen abundance<sup>7</sup>. The Nobel Assembly announced the prize at the Karolinska Institute in Stockholm.

### More On The Winners

William G. Kaelin Jr., MD, Jr., the Sidney Farber Professor of Medicine at Harvard Medical School and Dana-Farber Cancer Institute and senior physician in medicine at Brigham and Women’s Hospital, shared at a press conference that he and his late wife had talked about what would happen if he won the Nobel, according to a Dana Farber blog. “It would be too bittersweet, too crushing to receive it without Carolyn,” he said. “Now I like to think she’s looking down and smiling and saying, ‘See, I told you it was going to happen!’”<sup>8</sup>

Gregg L. Semenza, MD, PhD, the C. Michael Armstrong Professor of Medicine at the Johns Hopkins University School of Medicine, recounted in an interview with the New York Times how his life was changed by his high school teacher, Rose Nelson, who taught biology at Sleepy Hollow

<sup>5</sup> <https://www.broadinstitute.org/news/new-crispr-genome-editing-system-offers-wide-range-versatility-human-cells>

<sup>6</sup> <https://www.wired.com/story/a-new-crispr-technique-could-fix-many-more-genetic-diseases/>

<sup>7</sup> <https://www.nobelprize.org/prizes/lists/all-nobel-laureates-in-physiology-or-medicine/>

<sup>8</sup> <https://blog.dana-farber.org/insight/2019/10/it-was-just-surreal-dana-farbers-william-g-kaelin-jr-md-wins-a-nobel-prize-in-medicine>

High School in Tarrytown. “She was unbelievable,” Dr. Semenza recalled in an interview. “She transmitted the wonder and joy of science and scientific discovery. She set me on a course to science.”

At Harvard, Semenza’s plan was to attain a PhD and do research in genetics. But that changed when a close family friend gave birth to a child with Down syndrome. “That shifted me from being interested in genetics as kind of a scientific discipline to thinking about the impacts of genetics on people,” he said.

Kaelin and Semenza shared the prize with Sir Peter J. Ratcliffe, director of clinical research at the Francis Crick Institute in London and director of the Target Discovery Institute at Oxford, who told the Times that he became a medical researcher almost by chance.

#### Why Is The Research Important?

The research has implications for treating various diseases in which oxygen is in short supply — including anemia, heart attacks and strokes — as well as for treatment of cancers that are fed by and seek out oxygen, according to the New York Times<sup>9</sup>.

The Nobel Prize in Physiology or Medicine has been awarded 110 times to 219 Nobel Laureates between 1901 and 2019.

#### A Better Predictor of Antibiotic Efficacy Identified *Findings Could Inform The Development Of New Antibacterial Drugs*



Scientists have long thought that antibiotics work best against fast-growing bacteria versus slow-growing. But a paper published in *Nature Microbiology*<sup>10</sup> by researchers at the Broad Institute of MIT and Harvard and others suggests that another measure altogether—bacterial metabolic state—is a better predictor of antibiotic efficacy compared with bacterial growth rate.

To uncover the relative contribution of growth and metabolism to antibiotic lethality, the research team measured the two in parallel in a diverse group of Gram-positive and Gram-negative species across a broad range of conditions. Nine existing antibiotics were included in the investigation. (Gram-positive and Gram-negative bacteria are distinguished by the structural differences in their cell walls; Gram-negative bacteria are considered more resistant to antibiotics because of their impenetrable cell wall<sup>11</sup>).

The researchers showed that when growth and metabolism are evaluated independently, it is bacterial metabolic state at the time of treatment that best determines antibiotic lethality.

Beyond informing the development of new antibacterial drugs, the scientists say, the findings could point to new ways of enhancing the effectiveness of existing drugs.

“The Broad excels at this type of truly innovative systematic basic research that leads to meaningful translational work and ultimately meaningful clinical advances,” said

<sup>9</sup> <https://www.nytimes.com/2019/10/07/health/nobel-prize-medicine.html>

<sup>10</sup> <https://www.nature.com/articles/s41564-019-0536-0.epdf>

<sup>11</sup> [https://www.diffen.com/difference/Gram-negative\\_Bacteria\\_vs\\_Gram-positive\\_Bacteria](https://www.diffen.com/difference/Gram-negative_Bacteria_vs_Gram-positive_Bacteria)

Deerfielder Bob Jackson, MD. “This paper demonstrates a metabolic-dependent basis for antibiotic-mediated cell death, having potential implications for drug development.”

Adapted from the Broad Institute’s [Research Roundup](#)<sup>12</sup>.

## Genetic Testing Coding Consistency: A Necessary Precursor to Price Transparency



The explosion in clinical genetic testing has brought with it coding variability, an inconsistency in the application of billing codes for commercial insurance reimbursement, according to two recent white papers authored by representatives from Concert Genetics. The papers are titled [Coding Variability in Genetic Testing](#)<sup>13</sup> and [A Coding Solution for Genetic Testing](#)<sup>14</sup>.

The research, which showed that there is little standardization in the way that laboratories bill commercial payors for tests, may not only have implications for overspending for insurers, but also suggests that this inconsistency could create a restrictive reimbursement environment for laboratories, reported the Company.

In addition, the papers demonstrate that inefficiencies in the payment system could make it even more challenging for patients to determine the actual cost of these tests.

To quantify how uniformly (or not) billing codes are being applied in commercial insurance reimbursement, Concert analyzed 2.2 million commercial genetic testing claims from 2016-2018, representing a population of more than 35 million patients.

And to help address coding variability, the Company describes in one of the papers a novel method it developed

<sup>12</sup> <https://www.broadinstitute.org/news/research-roundup-august-30-2019>

<sup>13</sup> <https://www.concertgenetics.com/resources/coding-variability-in-genetic-testing/>

<sup>14</sup> <https://www.concertgenetics.com/resources/a-coding-solution-for-genetic-testing/>



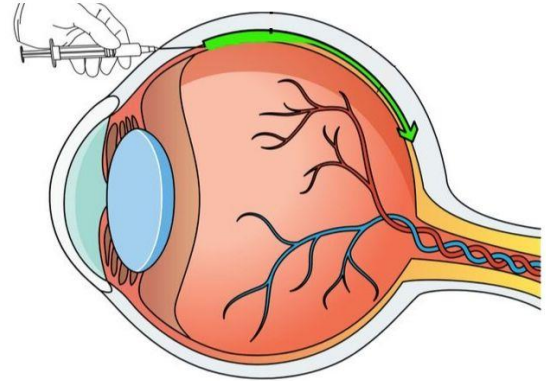
to translate a genetic test into a single code or code combination. This method, the Company says, known as the Concert Coding Engine, relies on finite data elements and generates repeatable output, all without requiring stakeholders to adopt an additional unique identifier. The paper further details the Coding Engine, including the objectives, guiding principles, data inputs, underlying logic, and the limitations of the current implementation.

“Driving genetic coding consistency is important for many reasons. Beyond the value to payors and patients of greater transparency and improved understanding of price and utilization patterns, standardizing genetic coding also has the potential to help drive new clinical insights,” said Deerfielder Leslie Henshaw. “Claims data is increasingly being married with EMR data to deliver a richer view into patient outcomes and treatment efficacy and having a more robust view about specific testing for specific categories of patients may ultimately improve patient care.”

Concert Genetics, a health technology company, has been a Deerfield portfolio company since 2018.

## Scientists Develop New Delivery Method to Get Gene Therapy to the Retina

*Sight-Saving Treatment Tested In Preclinical Models*



Graphical Abstract Credit: Peter Campochiaro

Researchers at Johns Hopkins Medicine have advanced a technique to deliver sight-saving gene therapy to the retina in animal studies. The new approach, if shown to be safe and effective in humans, could offer a new and more permanent therapeutic solution for people with wet age-related macular degeneration (AMD) and other common diseases of the eye.

The findings, which were reported in the August 13 issue of the Journal of Clinical Investigation, further suggest the new method could potentially replace defective genes in individuals with inherited retinal disease.

At present, the gene therapy delivery method available to patients carries some risks. A gene therapy technique currently used to treat Leber congenital amaurosis, an inherited eye disorder, involves a surgical procedure. Surgery poses the potential complications of developing cataracts, among other threats to vision, including retinal detachment.

With the new approach, a tiny needle is injected to deliver therapeutic genes into the space between the white of the eye and the eye's vascular layer, known as the suprachoroidal space, where it then spreads throughout the eye, making its way to the retina. The technique is considered less invasive, since it does not involve detaching the retina.

To test if the injection could effectively deliver gene therapies to the retina—the researchers first needed to determine whether the technique would allow the virus to reach the back of the eye, as part of the experiments. The researchers injected the eyes of animal models with a safe form of a virus modified to carry a fluorescent marker into the suprachoroidal. High-powered microscopes were then used to track the glow across the retina, which was confirmed after one week.

According to the National Eye Institute, AMD is one of the leading causes of irreversible and disabling vision loss in people over age 50. An estimated 10 million Americans have age-related macular degeneration.

Adapted from Johns Hopkins Medicine news release:

[Johns Hopkins Researchers Advance Search For Safer, Easier Way to Deliver Vision-Saving Gene Therapy to The Retina](https://www.hopkinsmedicine.org/news/newsroom/news-releases/johns-hopkins-researchers-advance-search-for-safer-easier-way-to-deliver-vision-saving-gene-therapy-to-the-retina)

<https://www.hopkinsmedicine.org/news/newsroom/news-releases/johns-hopkins-researchers-advance-search-for-safer-easier-way-to-deliver-vision-saving-gene-therapy-to-the-retina>

## IP CORNER

## Reciprocal Education and Respect Through Open Debate

*By Mark Shtilerman, PhD, JD*

China is one of the world's largest and fastest growing economic powers. In 2017, the World Bank reported that Chinese patent filings outnumbered those from any other country in the world. Chinese residential patent filings (i.e., filings by a resident owner or a resident applicant) accounted for 58 percent of worldwide residential patent filings. China has tripled its intellectual property (IP) revenues over the last two years, but this still only accounts for around 1.5 percent of global receipts.<sup>15</sup> The low revenue reflects the lack of confidence that U.S. and European firms have in the fairness of the Chinese legal system, which they accuse of bribery and political influence. Chinese firms are also mistrustful of the U.S. legal system and often decide not to file for patent protection outside of China. Whether due to the vastly different legal systems or cultural differences, there is a persistent mutual mistrust between China and much of the Western world when it comes to IP protection.



As our economy becomes increasingly global, businesses face challenges as they try to protect their intellectual property assets in different countries. Two universities, Berkeley in the U.S. and Tsinghua in China, have tried to mitigate these difficulties by organizing a joint conference between China, the U.S., and other countries. On October 22, 2019, The Berkeley Center for Law and Technology hosted the 2nd Annual Berkeley-Tsinghua Transnational IP Litigation Conference. At the conference, the U.S. and Chinese judges openly debated the pros and the cons of their own and others' litigation systems.

Chinese judges expressed distrust in the U.S. system of jury trials. Besides viewing the jury selection process as cumbersome and inefficient, they viewed juries as unsophisticated laypeople who are poorly suited to understanding complex technologies. Chinese judges fear that the quality of lawyering unduly influences the jurors: jurors are easily swayed by presentation quality, likability of experts, and general trial theatrics. "If we compare, [Chinese judges] are the directors in court, but in a jury system, lawyers and parties are directors of the system," said Hsiung Sung-Mei of Taiwan's IP court. The U.S. judges defended our system suggesting that the juries are capable of weighing evidence and rendering meaningful verdicts. They also suggested that the use of common people on the juries increases confidence in the legal system where common people often mistrust the lawyers.

The U.S. judges expressed concerns with the amount of influence a single person or a single report has on the outcome of a case in China. In contrast to jury trials, Chinese judges appoint and rely on a Technology Investigative Officer (TIO). An appointed TIO hears both sides and prepares a report for the court. While the U.S. rules of civil procedure allow the use of a court appointed expert, this device is rarely used. The Chinese judges believe an impartial third-party expert would be much more qualified to understand the nuances of each particular case rather than a group of jurors.

U.S. judges also questioned ex parte communications between parties and judges that are common under the Chinese system.<sup>16</sup> China's 2001 PRC Judges Law allows non-secret, "authorized" ex parte communications in their courts. Chinese judges feel that ex parte communications expedite proceedings and that judges are sophisticated jurists that are not unduly influenced by one party's arguments. U.S. judges tend to look at this skeptically because U.S. rules explicitly prohibit most ex

<sup>15</sup> Calculated from the authorized use of the proprietary rights associated with patents, trademarks, copyrights, industrial processes and designs including trade secrets, and franchises. Brian Cassidy, *ANALYSIS: Chinese IP Filing Surge Clouds U.S. Receipt Prospects*, Bloomberg Law News (Oct. 27, 2019).

<sup>16</sup> <https://www.chinalawtranslate.com/en/blog-post-on-ex-parte-communications/>

parte communication on the grounds that to allow one party to try to influence the judge without giving the other party the opportunity to respond undermines the fairness of judicial proceedings.<sup>17</sup>

Another concern about the Chinese system is the perception that domestic bias and bribery are common. In rebuttal, Judge Hsiung pointed out that the Chinese patent system provides automatic appeals to the court of last resort. In addition, the cost of litigation in China is much cheaper than in the U.S., making it much more accessible. China views the high costs of U.S. litigation as a major obstacle to efficient dispute resolution. In contrast, the U.S. judges highlighted the transparency and impartiality of their own system. The International Trade Commission (ITC) is a common forum to litigate patent infringement against importers, and its proceedings are public and transparent. The fact that U.S. patent owners win only 58 percent of the cases in front of the ITC is used to indicate the lack of domestic bias.

Although the Berkeley-Tsinghua Transnational IP Litigation Conference did not solve any disputes or change legal systems, the debates did provide a platform to air grievances and genuinely learn the rationale behind other legal systems. The hope is that sincere debate and increased understanding will help alleviate the persistent mistrust between China and the Western world when it comes to IP protection.

<sup>17</sup> The U.S. law allows *ex parte* communications under certain limited circumstances, such as in the cases of domestic violence.

## BREAK INTO THE BOARDROOM™: BIB BIOS

“BiB Bios” is a new, recurring feature in our newsletter. Each issue will profile a different board candidate from Break into the Boardroom’s growing universe of talented alumni. As we have described in past articles, Deerfield, along with its co-founder Oxeon Partners, created Break into the Boardroom (BiB) to help promote greater representation of female healthcare executives on boards within the public, private and non-profit sectors.



To date, nearly 150 highly accomplished, board-ready women have participated in one of our annual programs and, in connection with HLTH (an exciting new healthcare industry event), an additional 100+ women were screened recently and added to our database. It is our objective to help as many of these alumni and HLTH participants as possible find the right board role. As a way of introducing candidates to a broader audience and consistently keeping our program and the importance of boardroom diversity top-of-mind, we have debuted “BiB Bios.”

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](mailto:lhenshaw@deerfield.com) to inquire about meeting Liz Grammar or having us search our database for other candidates with a specific set of skills currently being sought for an identified board opportunity.

### INTRODUCING...LIZ GRAMMAR

**Current Position:** Executive Vice President, General Counsel, Head of Compliance and Head of Human Resources for Ardelyx, Inc., a publicly traded biopharmaceutical company focused on developing medicines to improve treatment for people with cardiorenal diseases.

**Previous Roles:** Liz spent four years serving as outside corporate and general counsel for numerous life sciences companies. Prior to that, she served as the General Counsel for Trine Pharmaceuticals and GelTex Pharmaceuticals.

**Education:** Stanford University Law School, J.D., Boston University, BA in Political Science

**Key Expertise/Skill Sets:** Liz is a strategic and innovative thinker with a passion for developing, articulating and leading the execution of corporate strategy. She is known for having impeccable judgement with a strong, yet diplomatic style in her abilities to motivate and guide teams through complex challenges. Liz has significant experience in structuring, negotiating and managing complex collaborations; advising management and the board on matters related to securities law compliance and corporate governance; and mapping and building corporate structure, talent acquisition and compensation analysis. She is a respected, credible voice in decision-making and establishing governance boundaries. Trained as a lawyer and driven to advance the business interests of the company, Liz thrives on serving as a thought partner and building consensus for positive results.



Photograph courtesy of  
Liz Grammar

**Professional Interests:** Liz has spent more than 20 years working on the advancement of medicines to treat patients with end stage renal disease. She is passionate about the patients and the opportunities that we have as an industry to improve the lives of those patients. While working diligently to support the efforts of the research, clinical and commercial teams within the companies for which she has worked, she also is interested in influencing and advancing policies that will support continued innovation within the life science industry in general and in the renal space in particular.

**Personal Interests:** Liz and her husband, Jeff, have three sons. Her family enjoys every opportunity to connect somewhere around a sporting event, wonderful dinner, or good long hike. She is a dog lover and finds peace walking on the beach anywhere.



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**CAPTURED OUR INTEREST**

*By Christine Livoti*

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**Insurers Get Creative With New Ways To Pay For Costly Gene Therapies**

Large insurers have begun to peel back the curtain on how they will pay for pricey gene therapies, including Luxturna and Zolgensma. Cigna's program, known as Embarc Benefit Protection, is planning to launch in 2020, possibly for as much as \$1.00 per member per month or less. For self-insured employers that are clients of Aetna, CVS will cover the employer's costs that exceed a set threshold for those drugs, and potentially other high-cost drugs.

<https://www.wsj.com/articles/insurers-pitch-new-ways-to-pay-for-million-dollar-therapies-11567677600>

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**Making Clinical Trial Data Public**

Health Canada, the national drug regulatory body of Canada, will be posting clinical study reports to a publicly accessible online portal within 120 days of a decision, whether positive or negative. This differs from the approach taken by the U.S. Food and Drug Administration (FDA), which only makes similar data available for approved drugs, but not for those that are rejected.

<https://www.npr.org/sections/health-shots/2019/10/11/769348119/canadas-decision-to-make-public-more-clinical-trial-data-puts-pressure-on-fda>

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**Collaboration To Advance Therapies For HIV And Sickle Cell Disease**

The NIH and Bill and Melinda Gates Foundation have announced they are joining forces to tackle curative therapies for HIV and sickle cell disease. Each partner will contribute \$100 million over four years, with hopes of advancing therapies into clinical trials within 10 years.

<https://subscriber.politicopro.com/health-care/article/2019/10/nih-gates-foundation-team-up-on-affordable-cures-for-hiv-and-sickle-cell-disease-1811994>

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**FDA Offers More Details On How It Will Regulate Digital Health And Artificial Intelligence**

The FDA has issued new guidance to elucidate how it plans to regulate digital health and artificial intelligence. The agency plans to apply greater review scrutiny to AI decision-support products that would guide treatment of serious or critical conditions, and whose rationale cannot be independently evaluated by doctors. Conversely, things like fitness trackers and wellness apps would not fall under FDA's scrutiny.

<https://www.statnews.com/2019/09/26/fda-artificial-intelligence-digital-health-rules/>

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**New Tools To Find Addiction And Recovery Centers**

Google Maps has added new features that allow users to search for addiction and recovery centers, as well as access to naloxone, the overdose reversal agent. More than 30,000 locations offering addiction recovery services are included in the platform.

<https://www.beckershospitalreview.com/healthcare-information-technology/google-maps-adds-tools-to-help-locate-addiction-recovery-services.html>

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## Foundations Resolve Allegations

Two charitable patient assistance foundations have agreed to multimillion-dollar settlements with the Justice Department to resolve allegations that they violated the False Claims Act. The two foundations join several other biopharma manufacturers who have also paid out settlements related to patient assistance/co-pay programs among Medicare patients in recent years.

<https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare>

## DEERFIELDERS TRADE SPREADSHEETS FOR HAMMERS



## HABITAT FOR HUMANITY

## Trading Spreadsheets for Hammers

For the second consecutive year this past September, Deerfielders took a different path to supporting those in need. Fifteen Deerfielders traded in their pencils and Excel spreadsheets to pick up hammers and operate “heavy machinery” to dramatically impact the quality of life of a family by actually building them a home. Coming from various parts of the firm, the team donated their time and physical might for the New York City chapter of Habitat for Humanity on a construction site in Queens, New York. Not unexpectedly, there was apprehension among some members of our team given that they were trying something completely outside of their comfort zone, which typically does not involve hammers, circular saws and splinters! But much like all investment opportunities that challenge us, our entire team put full effort into the project, working side-by-side to reinforce ceilings and frame-out windows. By the end of the day, the team made tremendous progress with the project slightly ahead of schedule and meaningfully impacting the lives of those less fortunate.

*“It goes without saying that the people at Deerfield give not only through the Deerfield Foundation, but also through volunteerism. Our Habitat for Humanity team gave it their all once again, as we were a part of putting the project ahead of schedule through our diligence, hard work and sweat throughout the day.”*

— Paul Takats



John happily produces the missing two-by-four.



As always, Shumaila nails it.





Nelson says: "We got this!"



Rachel is productive while getting fresh air.



Matthew jumps in to hold up the fort.



Paul leads by example.





Cristina applies her precision.



Kerri's geometrical skills came in handy.



Eddie makes his assessment.



Top to bottom: Vince and Alexis say until next time for a job well done.



## DEERFIELD CEO CONFERENCE STORMS SOUTH CAROLINA



In a serene setting reminiscent of the 1991 movie, “The Prince of Tides,” over 100 CEOs from Deerfield portfolio companies, along with about 50 Deerfielders, gathered for the 2nd Annual Deerfield CEO Conference.

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### The Prince Of Tides

*“I grew up slowly beside the tides and marshes of Colleton; my arms were tawny and strong from working long days on the shrimp boat in the blazing South Carolina heat...I was born and raised on a Carolina sea island and I carried the sunshine of the low country, inked in dark gold, on my back and shoulders. As a boy I was happy above the channels, navigating a small boat between the sandbars with their quiet nation of oysters exposed on the brown flats at the low watermark. I knew every shrimper by name, and they knew me and sounded their horns when they passed me fishing in the river.”*

— From the novel by Pat Conroy

One of the objectives of the three and a half day event, which was held at the Montage Palmetto Bluff in Bluffton, South Carolina, was to inspire and create synergism among Deerfield and its portfolio companies.

The conference also featured sessions on best practices in leadership, such as The Art & Science of Building a Sustainable & Scalable Culture and Regulatory & Reimbursement Strategies in the Current & Rapidly Emerging Environment. And to drive home the point on the importance of diversity and inclusion in the workplace, skits were performed by an engaging team of actors from Steps Drama in a session titled, Inclusive Leadership.

Media training and company pitch coaching sessions were also offered for those wishing to refine their skills in a more private, one-on-one setting.

Pulitzer Prize-winning author and Columbia University physician-scientist, Siddhartha Mukherjee, MD, DPhil, was the keynote speaker. Dr. Mukherjee concluded the conference with an impassioned presentation titled, “Themes from the Future of Medicine,” that delved into artificial intelligence, personalized therapy and gene editing.

The event was not all business and attendees also had the opportunity to enjoy the company of their colleagues from both in and outside of Deerfield during non-traditional activities, including building a prosthetic hand, fishing, shrimping, boating, and bike riding.

## A Few Conference Takeaways...

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### On Success.

*"It's always interesting to meet a start-up with not that much and see where they come."*

— James E. Flynn

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### A Word On Culture.

*"If you develop a good strategy that doesn't work for your culture or is not supported by the right talent, it will fail. You cannot have one without the others. You need all for success."*

— Leslie Loveless, CEO, Slone Partners

*"With enough time and money, your competition can duplicate almost everything you've got working for you...except your culture."*

— Daniel G. Welch, Biotech Leader and Executive

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### Why Serve On A Board Other Than Your Own?

*"Buying into the passion and success of another company is my way of paying it forward and contributing my knowledge. As an industry, we have to regain trust."*

— Jan Berger, MD, President and CEO,  
Health Intelligence Partners

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### On Corporate Ethics.

*"We must be bulletproof—not because we have to, but because we want to."*

— James E. Flynn

## Scenes From The Conference



Left to right: Alexis Cazé and Mike Anderson were all hands on deck as they learned how to build a prosthetic hand for a child in need from materials that were made via 3D printing.

Photo by Karin Eskenazi.



Left to right: Jon Ramos and Jon Stonehouse also lent a hand to the project.

Photo by Matt Campana of Corporate Motivation, LLC.



Elise Wang displays Mike Foley's catch of the day.

Photo by Bill Slattery.



Left to right: Sabah Oney and Terence Karnal shoot the breeze while boating.

Photo courtesy of Terence Karnal.



Gill Addo scores his boat's first shrimp.

Photo by Bob Jackson.





Inverted bridge reflections.

Photo by Bob Jackson.



May River at sunrise.

Photo by Peter Steelman.



Marshland wonders.

Photo by Mark Shtilerman.



River views excursion to dinner.

Photo by Angelo Stornello.





Left behind but not forgotten.  
Photo by Bob Jackson.



Jeff Kaplan and Leslie Henshaw chose an eco-friendly mode of travel to the next conference session.  
Photo by Angelo Stornello.



Scenes from the bike tour.  
Photo by Angelo Stornello and Christine Livoti.



James E. Flynn energizes the room.  
Photo by Angelo Stornello.



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