

# OCTOBER 2019

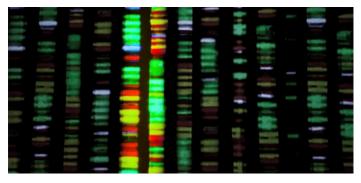
# NEWSLETTER – VOL. XIII

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# INFOCUS

GENOMICS: HOW NEXT GENERATION SEQUENCING MIGHT PLAY OUT AND THE IMPLICATIONS FOR PRECISION MEDICINE BY ANDREW ELBARDISSI, MD



Courtesy of the National Institutes of Health

Precision medicine holds the promise of providing patients with therapies that target the biological mechanism contributing to a particular individual's disease. Historically, the approach to developing novel medicines has lacked the ability to optimize therapy based on specific factors resulting in an individual patient's disease state.

Although many drugs have been approved on the basis of clinical trials run in all patients with a disease, some patients enrolled in those trials have had a strong treatment effect while others had minimal to no effect due to biological diversity. With the advent of next generation sequencing (NGS), we now have the ability to understand the diversity of pathways and patient subsets that make up the broader diseased population. This affords the ability to develop therapies for a given patient that targets their specific genetic alteration. Cancer has been a leading beneficiary of these advances. From a research perspective, biologists can now use next generation sequencing to identify mutations present in patient tumors. Many of these new insights have allowed researchers to further our understanding of cancer biology, although this is only the beginning to the development of targeted therapeutics. In addition to the identification of a novel mutation, researchers and clinicians must advance the science into clinical practice by validating the target through clinical trials in the relevant subset of patients.

This path to clinical validation runs counter to traditional drug development which typically require large trials to prove a drug is effective. With many patient subsets (or mutations) that might exist within a given cancer, it is typically not feasible to run large clinical trials. Yet, despite these challenges, a fundamental understanding of the biology and administration of appropriately targeted therapies has proven adequate by regulators to approve novel drugs. This has resulted in a rapid time to approval, bringing novel therapies to market in record time.

While NGS continues to hold tremendous promise toward the goal of precision medicine, there are a number of practical and technological challenges that currently limit broad applicability. Given the size of the human genome, there is a tremendous amount of data generated per sample of tissue. With existing sequencing technologies, performing whole genome sequencing can take 2-3 weeks due to the processing and interpretation of data. This is a challenge in the clinical setting since patients presenting with cancer may not tolerate a significant delay between diagnosis and therapy.

Additionally, while the cost of whole genome sequencing has come down over time, it can exceed thousands of dollars per sample making it prohibitive to adopt for all patients due to sheer cost. We anticipate that competition and improvement in technology will improve both the speed of a test result and cost thereby making it more accessible to the masses.

NGS also has technical limitations that limit broad clinical applicability. Genomic data derived from NGS technologies are descriptive and static representing a snapshot of the genetic mutations in a small sample of tissue. With cancer being a constantly mutating disease, it is important to keep up with the evolving genetic composition to optimize therapy over time. Additionally, a mutation in one tissue sample may not reflect the broad array of mutations present throughout the entire tumor.

A number of emerging technologies appear to have the potential to address these limitations. Liquid biopsy technologies can identify circulating genetic information, are non-invasive, and can provide a near real-time result, thereby holding the promise of a valuable monitoring and treatment optimization tool. There are also a host of functional genetic and cellular technologies that provide more detailed information as to which mutations are most importantly related to the process contributing to a given patient's cancer.

With the improvements of existing NGS technologies and introduction of novel technologies that can supplement our understanding of cancer biology, we are moving closer to the promise of precision medicine for all patients. Continued investment in the space holds the promise of making

these technologies ubiquitous, low cost, and increasingly informative. Moreover, the speed at which novel biological insights can be tested and validated in the clinical setting are likely to increase rapidly as our knowledge of the underlying biology increases.

## DEERFIELD IN THE NEWS

### DEERFIELD NEWS RELEASE

Deerfield Management Brings Together Scientists, Entrepreneurs and Leading Companies to Form the New York-Based Healthcare Innovation Campus

http://www.deerfield.com/PressRelease.aspx?PressReleaseID=166

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### NATURE BIOTECHNOLOGY

Deerfield builds NYC campus to support life sciences startups https://www.nature.com/articles/d41587-019-00031-6

### WALL STREET JOURNAL

Health-Care Investor to Build Biotech Labs in Nomad https://www.wsj.com/articles/health-care-investor-to-build-biotechlabs-in-nomad-11569495600

Deerfield Management plans to convert an unused office building into drug-research labs

### POLITICO

BIG PLANS – "Health-Care Investor to Build Biotech Labs in Nomad"

https://www.politico.com/states/new-york/newsletters/politico-newyork-real-estate/2019/09/27/nychas-missing-state-funding-317891

### CRAIN'S NEW YORK BUSINESS

Deerfield to build \$635M biotech hub on Park Avenue South https://www.crainsnewyork.com/real-estate/deerfield-build-635mbiotech-hub-park-avenue-south

### CRAIN'S CHICAGO BUSINESS

Health-tech hub Matter expands to New York https://www.chicagobusiness.com/health-care/health-tech-hubmatter-expands-new-york

### YAHOO FINANCE AND MEDCITY NEWS

Deerfield Management to spend \$635M on New York life sciences hub

https://medcitynews.com/2019/09/deerfield-management-to-spend-635m-on-new-york-life-sciences-hub/

### END POINTS

Deerfield bets on New York City, blueprints \$635M biotech hub in midtown Manhattan

https://endpts.com/deerfield-bets-on-new-york-city-blueprints-635mbiotech-hub-in-midtown-manhattan/

### GENETIC ENGINEERING & BIOTECHNOLOGY NEWS Deerfield Plans \$635M New York City Life-Sci "Innovation Campus"

https://www.genengnews.com/news/deerfield-plans-635m-new-yorkcity-life-sci-innovation-campus/

### FIERCE BIOTECH

Deerfield puts up \$635M to create New York City biotech campus <u>https://www.fiercebiotech.com/biotech/deerfield-puts-up-635m-to-</u> <u>create-new-york-city-biotech-campus</u>

### BIOPORTFOLIO

New NYC Life Sciences Campus Expected to Provide 1,400 Jobs https://www.bioportfolio.com/news/article/4096136/New-NYC-Life-Sciences-Campus-Expected-to-Provide-1-400-Jobs.html?utm\_source=dlvr.it&utm\_medium=twitter

### BECKER'S HOSPITAL REVIEW

Matter healthcare incubator opens 2nd location in New York City https://www.beckershospitalreview.com/innovation/matterhealthcare-incubator-opens-2nd-location-in-new-york-city.html

### BUSINESS INSIDER AND BIOSPACE

NYCEDC and Deerfield Management Partner to Create a Life Sciences Campus – MATTER to Create LifeSci NYC's Newest Incubator

https://www.biospace.com/article/releases/nycedc-and-deerfieldmanagement-partner-to-create-a-life-sciences-campus-matter-tocreate-lifesci-nyc-s-newest-incubator/

### GLOBEST.COM

NYCEDC and Deerfield Management Develop Life Sciences Campus

https://www.globest.com/2019/09/26/nycedc-and-deerfieldmanagement-develop-flatiron-life-sciencescampus/?slreturn=20190909153102

### HIT CONSULTANT

Deerfield Management Invests \$635M to Create Healthcare Innovation Campus for Life Sciences in NYC <u>https://hitconsultant.net/2019/09/26/deerfield-management-life-</u> <u>sciences-campus-nyc/#.XZ41pEZKhaR</u>

### NATIONAL REAL ESTATE INVESTOR

10 Must Reads for the CRE Industry Today https://www.nreionline.com/nrei-wire/10-must-reads-cre-industrytoday-september-26-2019

#### WORLD CONSTRUCTION NETWORK

Deerfield Management to invest \$635m to build healthcare innovation campus in US

https://www.worldconstructionnetwork.com/news/deerfieldmanagement-to-invest-635m-to-build-healthcare-innovation-campusin-us

#### CITIZEN TRIBUNE

MATTER to Open in New York City as Part of New Life Sciences Campus

https://www.citizentribune.com/news/business/matter-to-open-innew-york-city-as-part-of/article\_79fceecc-2a10-54da-8777-983bad46c49a.html

# DEERFIELD RESEARCH BITES

# GENERIC DRUG PRICES ARE ACTUALLY FALLING

DESPITE DROP, PATIENTS CONTINUE TO GET HIT WITH HIGH PRICES AT THE PHARMACY FOR REASONS THAT MAY HAVE LITTLE TO DO WITH PHARMA



Courtesy of the National Institutes of Health

As pharma gets slammed for egregious pricing of lifesaving medications and stories continue to make headlines – generic drug prices are actually falling.

That's not to say that consumers aren't still being saddled with high costs at the pharmacy, but a July 2019 paper by the National Bureau of Economic Research (NBER) that reviewed the pricing patterns of generic drugs suggests that other factors may be at play.

Although the U.S. generic prescription pharmaceutical market continues to drive overall prices downward, reductions in pharmacy price are not fully passed to patients, according to the NBER researchers.

One contributing factor to patients not reaping as much of the benefit of the generic price declines, the authors suggest, is the increase in cost-sharing: the practice of insurers offering plans that increasingly shift costs from insurers to consumers.

"Plan sponsors are opting for benefit designs that have consumers sharing a higher percentage of costs. The result is out-of-pocket costs falling less than overall generic drug prices," said Deerfielder Vince Mellet. "Even so, the prices of generic drugs went down." To put these generic price increases into context, the investigators developed two price indices that capture prices of generic prescription drugs paid by consumers of private health insurance plans.

The first, *direct out-of-pocket CPI*, measures consumers' direct out-of-pocket payments to the dispensing pharmacy. The second, *total CPI*, represents the total revenues received by the dispensing pharmacy – the consumers' direct out-of-pocket payments, plus the amount paid to the pharmacy by the insurer on behalf of the customer.

Based on the analysis, the researchers found direct out-ofpocket CPI for generic prescription drugs declined by approximately 50 percent between 2007 and 2016, while the total CPI fell by nearly 80 percent over the same period. The investigators partly attribute the smaller reduction in the direct out-of-pocket CPI, compared to the total CPI, to consumers' increasingly moving away from fixed copayment benefit plans to exclusively coinsurance or a mix of coinsurance and copayments.

While consumers are encountering more cost-sharing that shifts more of the drug cost burden on to them, the researchers report that, on balance in the U.S., consumers have still experienced significant price declines for generic drugs.

Given their findings, the investigators suggest that overall affordability is not the primary issue in the generic drug market and that this segment of the U.S. prescription market is not responsible for the reported growth in prices and spending for prescription drugs overall.

To get the full picture on prices in the U.S. generic prescription industry, the NBER researchers recommend taking a closer look at all components of the entire generic supply chain, from manufacturer, wholesaler, pharmaceutical benefit manager, insurer, to retailer.

To view the full paper, titled "The Price to Consumers of Generic Pharmaceuticals: Beyond the Headlines", visit: <u>https://www.nber.org/papers/w26120</u>

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# DEERFIELD®

# V-WAVE SCORES FDA BREAKTHROUGH STATUS ON ITS HEART FAILURE SHUNT



Courtesy of V-Wave, Ltd.

V-Wave, Ltd., recently announced that it received the prized FDA Breakthrough Designation for its heart failure shunt. Breakthrough designation is one of the highly sought pre-approval stamps that the FDA can place on a device.

According to the FDA's website, it is granted when the device "provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" (than what is currently available). The program aims to provide patients and health care providers with more timely access to medical devices "by speeding up their development, assessment and review," including prioritized review all the way through to market approval.

V-Wave's minimally-invasive implanted interatrial shunt for the treatment of patients with severe symptomatic heart failure is designed to regulate left atrial pressure, the primary cause of breathing difficulty and hospitalization due to worsening heart failure.

"In addition to validation of the potential impact of this technology, breakthrough status will facilitate a timely regulatory review and solve a major issue with medical device investments, namely that reimbursement will effectively be secured immediately upon approval," said Deerfielder, Andrew ElBardissi, MD, who serves on the Company's board of directors. The shunt is currently being evaluated in a global, randomized, controlled, double-blinded, 500 patient pivotal Investigational Device Exemption trial called RELIEVE-HF. The study is enrolling advanced heart failure patients with preserved or reduced left ventricular ejection fraction who

remain symptomatic despite the use of guideline directed medical and device therapies.

An ejection fraction is an important measurement of how well the heart is pumping and is used to help classify heart failure and guide treatment. In a healthy heart, the ejection fraction is 50 percent or higher – meaning that more than half of the blood that fills the ventricle is pumped out with each beat.

According to the Centers for Disease Control and Prevention, nearly 6 million adults in the United States have heart failure and about half of these individuals die within 5 years of diagnosis. Heart failure costs the nation an estimated \$30.7 billion each year.

Achieving this status means that the device also met at least one of the following FDA criteria:

- 1. It represents breakthrough technology;
- 2. No approved or cleared alternatives exist;
- 3. It offers significant advantages over existing approved or cleared alternatives; and
- 4. Availability of this device is in the best interest of patients.

V-Wave, Ltd., a privately held medical device company, has been a Deerfield portfolio company since 2018.

Adapted from company news release: V-WAVE'S INTERATRIAL SHUNT RECEIVES FDA BREAKTHROUGH DEVICE DESIGNATION FOR HEART FAILURE:

http://vwavemedical.com/2019/08/15/v-wavesinteratrial-shunt-receives-fda-breakthrough-devicedesignation-for-heart-failure/

https://www.fda.gov/medical-devices/how-study-andmarket-your-device/breakthrough-devices-program

https://www.mayoclinic.org/diseases-conditions/heartfailure/symptoms-causes/syc-20373142

https://www.cdc.gov/dhdsp/data\_statistics/fact\_sheets/f s\_heart\_failure.htm

# DEERFIELD®

# BROAD SCIENTISTS OUST ALZHEIMER'S RISK GENE IN A LAB DISH BY REVISING DNA



Courtesy of Stephen Dixon/the McGovern Institute

The CRISPR family enzyme CAS13 (pink) uses a special guide (red) to target RNAs in the cell (blue). Broad Institute scientists used a new model of CRISPR, CAS13, to try to eliminate a genetic risk for Alzheimer's disease, they report in the journal Science.

With a newly adapted CRISPR tool, researchers out of the Broad Institute of MIT and Harvard, have stamped out an Alzheimer's threat in cells by revising RNA, rather than permanently editing DNA.

The findings were reported in the July 11, 2019 issue of the journal Science:

https://science.sciencemag.org/content/365/6451/382?r ss=1

Feng Zhang, PhD and colleagues illustrated the promise of the new CRISPR platform, CAS13, by deactivating the APOE4 risk gene and changing it to APOE2, the rarer variant (which is protective and may actually decrease a person's risk for Alzheimer's: Science https://www.sciencemag.org/news/20

14/04/finding-may-explain-why-women-more-likely-

<u>develop-alzheimers</u>). Long viewed as one of the biggest risk factors for Alzheimer's – APOE4 is also associated with the most common form of the disease.

Because protein-coding RNA is transcribed from genomic DNA, this technique offers the potential to correct diseasecausing mutations at the RNA level without the possible risks of making permanent changes to the genome. In addition, in some cell types, particularly postmitotic cells such as neurons, it is difficult to edit genomic DNA using earlier CRISPR approaches. Therefore, CAS13 represents a potential new strategy to treat devastating diseases that affect the brain, including Alzheimer's.

The new advance, called RESCUE for RNA Editing for Specific C to U Exchange, builds on REPAIR, a technology developed earlier by Zhang and his team that changes adenine bases into inosine in RNA. The scientists took the REPAIR fusion and evolved it in the lab until it could change uridine."Development cvtosine to of RESCUE demonstrates the power of protein engineering of natural processes," said Deerfielder Bob Jackson, MD. "The ability of RESCUE to edit from C to U increases the number of pathogenic mutations targetable by RNA editing. It also adds capacity to potentially edit important signaling residues."

CRISPR refers to Clustered Regularly Interspaced Short Palindromic Repeats that occur in the genome of certain bacteria, from which the system was discovered. Often thought of as "molecular scissors", the CRISPR technology enables researchers to remove, add or alter specific DNA and RNA sequences in the genome of higher organisms, with the goal of curing disease.

The Broad has been a Deerfield collaborator since 2017:

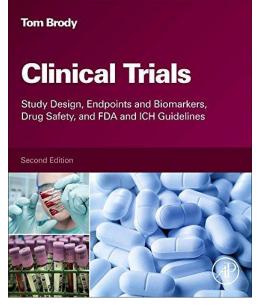
Broad Institute and Deerfield Management launch innovative partnership to tackle serious unmet medical needs

https://www.broadinstitute.org/news/broad-instituteand-deerfield-management-launch-innovativepartnership-tackle-serious-unmet

Adapted from MIT news release:

https://www.eurekalert.org/pub\_releases/2019-07/miotncp070819.php

# ENRICHED ENRICHMENT STRATEGIES IDENTIFIED BY DEERFIELDER MING ZHU, PHD



Courtesy of the National Institutes of Health

In research that could potentially help increase the efficiency of drug development and support precision medicine, Ming Zhu, PhD, identified ways to further enhance FDA-proposed enrichment strategies. Ming presented his findings in early July at the International Chinese Statistical Association (ICSA) conference in China.

In an effort to improve efficiency of drug trials, the FDA first created its enrichment strategy guidelines in 2012: <u>https://www.fda.gov/media/121320/download</u>.

The FDA defines *enrichment* as the "prospective use of any patient characteristic to select a study population in which detection of a drug effect (if one is in fact present) is more likely than it would be in an unselected population." Examples of patient characteristics include demographic, pathophysiologic, historical, genetic or proteomic, clinical and psychological.

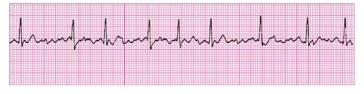
As a part of his analysis to inform on potential areas for strengthening these guidelines, Ming compared the enrichment strategies employed in several clinical trials, while closely reviewing and factoring in the respective study design, the statistical analysis used, along with lessons learned from the trial's success or failure. Among Ming's recommendations are determining the suitability for the disease area in question, adapting quickly from previous studies and enhanced communication with regulatory agencies, when considering an enrichment strategy.

With regard to adapting quickly, Ming discussed a successful phase 3 trial that had benefited from information just released from another trial, pointing to the importance of staying abreast of and acting quickly on related, emerging evidence. In this example, the newly reported data informed on the enrollment of a more enriched study population for the current trial.

Ming emphasized that having early and open communications with regulatory agencies are critical for sponsors in order to secure endorsement of the planned enrichment strategies and statistical methods before undertaking the pivotal trials. As a case in point, Ming cited successful clinical programs that progressed all the way to regulatory submission, only to be rejected when the agency found the enrichment strategies applied to be unacceptable.

He hopes that his research will provide helpful insight into enrichment design and guidance for clinical investigators to develop appropriate strategies toward improved probability of success of clinical trials.

# AFIB TREATMENT ADVANCES PUBLISH IN PROMINENT MEDICAL JOURNALS



Courtesy of the National Institutes of Health

## REAL-TIME FEATURE OF ACUTUS' ACQMAP RESULTS IN IMPROVED PATIENT OUTCOMES

A clinical trial investigating Acutus' AcQMap showed that this novel imaging and mapping system safely guided cardiac ablation resulting in a 12-month freedom from recurrent atrial fibrillation (AFib) in 73 percent of patients with persistent atrial fibrillation.

The results, published in the July 1, 2019 issue of the Journal Circulation: Arrhythmia and Electrophysiology <u>https://www.ahajournals.org/doi/10.1161/CIRCEP.119.00</u> 7233, were first reported earlier this year in a late-breaking trial at the 24th Annual AF Symposium in Boston.

Known as UNCOVER-AF, the trial prospectively studied the safety and efficacy of the AcQMap in 127 patients at 13 sites in Europe and Canada – 98 percent of whom achieved a normal heartbeat upon completion of the procedure.

Characterized as an irregular heartbeat, AFib is the most common type of heart arrhythmia and could greatly increase a person's risk of developing a severe stroke. Cardiac ablation is a procedure that can reduce the risk, yet traditional ablation procedures often fail to achieve longterm absence of AFib, resulting in repeat ablation procedures.

With its precision ultrasound and high definition remapping capabilities, AcQMap helps inform physicians in real time who can strive to improve outcomes by checking their work after each ablation. Adapted from Acutus' news release:

Publication of UNCOVER AF Study in Circulation Demonstrates Impact of Charge Density Mapping During AF Ablation

https://www.prnewswire.com/news-

releases/publication-of-uncover-af-study-in-circulationdemonstrates-impact-of-charge-density-mapping-duringaf-ablation-300883498.html

Acutus has been a Deerfield portfolio company since 2016.

# FARAPULSE PFA SHOWN AS POTENTIAL ALTERNATIVE TO EXISTING ABLATION PROCEDURES

A method of non-thermal field ablation demonstrated safety and efficacy in clinical trials comparing outcomes of the modality to those seen with traditional thermal approaches in patients with paroxysmal atrial fibrillation, or episodic AFib.

The results of the first-in-human trial were reported in an online early version of the manuscript that is slated to publish in the Journal of the American College of Cardiology: <u>http://www.onlinejacc.org/content/74/3/315</u>.

Called pulsed field ablation (PFA), the alternate modality was shown to successfully target heart tissue without damaging adjacent structures like the esophagus or phrenic nerve – a shortcoming of standard ablation therapies, including radiofrequency (via heat) and cryotherapy (by way of freezing).

In 81 patients, 100% of pulmonary veins (PV) were specifically isolated with three minutes of PFA time per patient. Furthermore, long-term remapping procedures demonstrated that the rates of durable PV isolation improved with successive waveform modifications with the most optimized PFA group demonstrating 100% durability.

The rate of primary safety events was low at 1.2%, and with no subsequent primary adverse events during follow-up.

Farapulse has been a Deerfield portfolio company since 2017.

## **IP CORNER**

### LEGAL ANALYTICS FOR COUNSEL SELECTION

BY MARK SHTILERMAN, PHD, JD

When a company enters litigation, it must select litigation counsel. The management of the company would usually call its peers and ask about past experiences, review counsels' fields of technical expertise, evaluate their success rates, and then invite a handful of law firms to make a pitch. The invited attorneys would propose a case strategy and predict their probability of success. The management would then select a counsel based on the presentations given and their personal impressions.

Ex Parte is a start-up formed about two years ago that is trying to change appellate counsel selection for patent cases.<sup>1</sup> The company collects data for every appellate case since 2004 and combines it with a database of all practicing lawyers. It then



Courtesy of the National Institutes of Health

uses a proprietary algorithm to identify a lawyer with the highest probability of success for a specific case. When Ex Parte analyzed the recent appeal by 10X Genomics, the company predicted that an average lawyer would have a nine percent probability of winning the case but hiring one particular litigator would increase the probability of success to 25 percent.

The attorney recommended to 10X Genomics by Ex Parte expressed concerns over the ethical implications of this analysis. For one, the lawyer no longer did patent appeals. Also, according to the American Bar Association's model rules for professional responsibility, lawyers should not create an "unjustified expectation" of a future result based on their part performance.<sup>2</sup> But this is what Ex Parte may be doing – creating expectations of future performance based on past statistics.

In the U.S., the work of Ex Parte is protected by First Amendment rights and companies are not restricted in using its predictions to choose a litigation counsel. However, if a lawyer were to project his own probability of success based on his past record, that would be considered unethical. France has a law completely banning software companies from providing legal and judicial analytics.<sup>3</sup>

Additional concerns revolve over the ability of the software to account for specific facts of the case and the quality of data available from law firm websites. In the case with 10X Genomics, Ex Parte recommended a lawyer who no longer practiced patent appeals because the law firm website had not been updated with his current status. Ex Parte's information may also interfere with the client's relationship with counsel, where the software analysis of the probability of success in a case contradicts the counsel's.

Also, "the law of small numbers" cautions that percentages may appear greatly superior or inferior based on small data sets – the appellate practice is so small that most lawyers only get a few cases in their lifetime. In the example of 10X Genomics, the counsel recommended by Ex Parte had litigated 34 cases, of which 20 were identified as patent appeal cases. The Court of Appeals for the Federal Circuit, which is the sole appellate court for patent appeals, has heard more than 4,000 patent cases since 2004.

With computers infiltrating almost every aspect of our lives, the use of computer-assisted legal analytics is only expected to increase with time. With new technology comes the need to evaluate new ethical considerations. On one hand, making

<sup>&</sup>lt;sup>1</sup> Roy Strom, "The algorithm will hire your patent lawyer now," Bloomberg Law, 8/1/2019.

<sup>&</sup>lt;sup>2</sup> ABA's Model Rules of Professional Conduct, Rule 7.1.

<sup>&</sup>lt;sup>3</sup> Sam Skolnik, "France's judicial analytics ban unlikely to catch on in the U.S.," Bloomberg Law, 6/5/2019.

predictions about future success based on past legal achievements may be considered borderline unethical by the legal community. On the other hand, it can be argued that a company such as Ex Parte merely provides additional information and another viewpoint for clients with which to make informed decisions. Litigations are sometimes driven by unfounded beliefs in the strengths of a company's position, and data from Ex Parte may inject rationality into corporate decision-making and facilitate settlements.

In addition to companies that are entering litigation, Ex Parte's services are also retained by law firms seeking better marketing positions and financial firms that fund litigation. With litigation being a \$100 billion a year industry, any attempt to help quantify outcomes is an understandable goal. The question is whether and where the lines should be drawn for an ethical balancing act.

# BREAK INTO THE BOARDROOM: BIB BIOS

With great enthusiasm, we are introducing "BiB Bios" as 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 it is our objective to help as many of these alumni 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 are debuting "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 <u>lhenshaw@deerfield.com</u> to inquire about meeting Heather Bell or having us search our database for other candidates with a specific set of skills currently being sought for an identified board opportunity.

### INTRODUCING...HEATHER BELL, PHD

CURRENT POSITION: CEO, Turtle Health, new digital fertility startup in stealth mode

PREVIOUS ROLES: SVP, Global Head of Digital and Analytics, Sanofi VP Corporate Strategy at Sanofi and at AstraZeneca Partner, McKinsey & Company

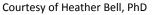
EDUCATION: Harvard, BA history and science Oxford, PhD and post-doc

KEY EXPERTISE/SKILL SETS:

Strategy Digital/organizational transformation Building new global functions/businesses Large company-startup partnerships Communications; bilingual

PROFESSIONAL INTERESTS: Building diverse teams Data-driven decision-making

PERSONAL INTERESTS: Reading fiction Visiting museums Swimming







# CAPTURED OUR INTEREST

## PRICE TRANSPARENCY ON ALL HOSPITALS BY CHRISTINE LIVOTI

The Centers for Medicare and Medicaid Services (CMS) has proposed putting price transparency requirements on all hospitals. The proposal, if finalized later this year for a 2020 effective date, would require hospitals to publicly post both gross chargers and payer-specific negotiated rates for all items and services provided by the hospital. CMS –

https://www.cms.gov/newsroom/press-releases/cms-takes-boldaction-implement-key-elements-president-trumps-executive-orderempower-patients-price

# ARE CHARITY PATIENT ASSISTANCE PROGRAMS MEETING THE NEEDS OF PATIENTS?

A recent publication looked at the characteristics of independent charity patient assistance programs that provide financial assistance to patients taking certain medications. In the study of six independent charity organizations that included 274 patient assistance programs, the authors found that the majority of programs did not provide coverage for uninsured patients, and the medications covered by these assistance programs were generally more expensive than drugs that were not covered. JAMA - Kang S, Sen A, Bai G, Anderson GF. Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs. JAMA. 2019;322(5):422-429. doi:10.1001/jama.2019.9943 -

https://jamanetwork.com/journals/jama/article-abstract/2740721

### INCENTIVES FOR ANTIBIOTICS

There have been multiple recent proposals to incentivize development of antibiotics for antimicrobial resistance. In the United Kingdom, the national payer has decided to test a subscription style model that pays pharmaceutical companies upfront for access to their drugs, rather than based on the volume of antibiotics sold. UK Department of Health and Social Care –

https://www.gov.uk/government/news/development-of-newantibiotics-encouraged-with-new-pharmaceutical-payment-system And in the U.S., CMS has announced it will increase reimbursement for novel antibiotics that are eligible for New Technology Add On Payments. Additionally, inpatient stays associated with the use of antibiotics with activity against antimicrobial resistance will be eligible for higher bundled reimbursement rates. CMS –

https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020medicare-hospital-inpatient-prospective-payment-system-ipps-andlong-term-acute-0

## FDA REPORTED TO BE PRESSURING COMPANIES TO AVOID SHARING WITH PATIENTS HOW THEIR GENES MIGHT INTERACT WITH CERTAIN DRUGS

The Food and Drug Administration has expressed concern at how manufacturers of pharmacogenomic testing deliver test results to patients. These physician-ordered tests may predict how a patient's genes interact with specific drugs. After discussions with the agency, some manufacturers have stopped providing details on specific drugs that may be affected by the patient's test results. STAT News – https://www.statnews.com/2019/08/28/fda-warns-pharmacogenetictesting-companies/

### CVS EXPANDS HOME MEDICATION DELIVERY

CVS will expand its home drug delivery service nationwide after a successful smaller scale pilot program. The program, dubbed CarePass, will be available for \$5 per month or \$48 per year, and will include one-to-two day delivery on eligible prescriptions. FierceHealthcare –

https://www.fiercehealthcare.com/finance/cvs-taking-its-home-drugdelivery-service-nationwide

# BLUE CROSS AND BLUE SHIELD OF MINNESOTA TO COVER INSULIN COSTS AT NO CHARGE NEXT YEAR

Following announcements from both pharmacy benefit managers and drug manufacturers pledging affordability of insulin, the health insurer Blue Cross and Blue Shield of Minnesota has announced it will cover insulin costs at no charge next year for eligible patients in commercial fully insured plans. BlueCross and BlueShield of Minnesota –

https://www.bluecrossmn.com/about-us/newsroom/newsreleases/blue-cross-and-blue-shield-minnesota-cover-insulin-costs-nocharge

## DEERFIELD FOUNDATION

The Deerfield Foundation has formed 42 partnerships and invested or committed nearly \$44 million for the advancement of children's health in its 12 years, ranging from health clinics in Nepal to a mobile medical home for children in the South Bronx. In this newsletter we would like to highlight 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 Many Hopes.

### MANY HOPES



Courtesy of Firefly Imageworks

Courtesy of the National Institutes of Health

Mission Many Hopes rescues children from poverty and abuse in Mombasa, Kenya by providing essential healthcare and education to local children so they can learn to solve the problems that charity alone cannot. It provides them with loving homes and excellent schooling complete with the physical, mental and emotional healing of the whole child necessary for them to excel.

> "We provide healthcare and healing to the whole child. That means physical, mental, emotional and spiritual. Seeing one or two of these areas flourish but others left behind means none are really flourishing. We have seen miraculous healing and children grow in physical and mental strength and grow from bodily and emotionally malnourished girls to powerful confident women you don't want to mess with!"

> > -Thomas Keown, Co-Founder, Many Hopes

Partner Since 2015

Description One trillion dollars of aid has not eradicated poverty in Africa because the primary problem is not funding, but how the money is spent. Many Hopes is raising a generation who have been given the tools to spend the next one trillion dollars differently. This generation of influencers starts in Many Hopes' homes, is accelerated through its school, and is brought to scale through the organization's legislature advocacy in the courts to better protect every child.

Total Funding to Date \$200,000

2019 Project Funded Complete Physical and Mental Healthcare and Nutritious Diet for 150 Orphaned and Abandoned Girls and Boys in Many Hopes' Rescue Homes and School.

# DEERFIELD®

#### Feature Profile ELINAH

At age six, Elinah lost her mother to HIV. She never knew her father. A woman claiming to be Elinah's aunt took her in and promised she would send her to school. Instead, she made Elinah her personal domestic servant. Elinah had undiagnosed epilepsy and so often fell behind in her work and the "aunt" beat her on the same knee every time as punishment. After four years of this unconscionable abuse, Elinah did the most courageous thing she could do. She ran away. Many Hopes found Elinah and took her under their wings. The organization provided her with healthcare, diagnosing and treating her epilepsy, as well as delivered much-needed counseling and schooling. Fortunately, Many Hopes located and prosecuted the abuser. In court that day, 10-year-old Elinah said, "I hope that I can become a lawyer so I can defend other people's rights because someone defended my rights." Elinah graduated law school in 2017 and anxiously awaits the results of her recent Bar exam. She will advocate for thousands. [\*Name has been changed to protect privacy].

### 2019 GRANT

Update Highlight Many Hopes proudly reported that the school that Deerfield helped build and open, the Mudzini School, has attained Cambridge International School accreditation status, making it the exclusive school in the area to achieve this distinction and only one of six on the coast of Kenya. Many Hopes expressed their gratitude to Deerfield for helping to make this possible.

### **Project Milestones**

- Provided four loving homes for 15 Girls, staffed by five house mothers
  - Seven girls attending college
  - Three students accepted into Strathmore, ranked among the best Universities in Kenya, according to Many Hopes

Rather than not having access to any physical or mental healthcare, Many Hopes children, instead, experienced the following:

- 120 preventive care doctor visits supplemented by a nutritional diet, which includes meat, milk, eggs, vegetables and fish grown on Many Hopes' own farm
- 100% of premature infants reached a healthy weight
- 100% of children ages newborn to 5 receive monthly, preventive care doctor visits
- 100% of girls age 3 and older participated in critical group and peer-to-peer counseling to address the trauma they have experienced and to begin the healing process
- Two nutritious meals and snacks were provided every school day to 90 children at the Mudzini School
- 100% of students received physicals

# MEET THE ASSOCIATES

Deerfield launched the Deerfield Fellows program in 2015 to attract college students from the diverse City University of New York (CUNY), who have an interest in pursuing the fields of healthcare or finance for an immersive summer internship experience. Successful Deerfield summer interns are invited to stay through a year-long Deerfield Fellowship; those who most excel in this program become Associates at Deerfield. We are enormously proud of the work of our Associates who we feature here in each issue of our newsletter.

### JULIA SACCAMANO

### WHAT INITIALLY DREW YOU TO THE FELLOWS PROGRAM?

I was initially a chemical engineering major with an interest in pharma, but I found myself enjoying the math classes more so I changed my major to applied math with a minor in economics. This program was unique in integrating my original interest, healthcare, with my strengths, math and economics.

WHAT IN YOUR EXPERIENCE HAS MATCHED YOUR EXPECTATIONS ABOUT BEING A DEERFIELD FELLOW AND NOW AN ASSOCIATE?

Deerfield's highly collaborative and open environment.

### DESCRIBE A TIME OR TIMES YOU FOUND TO BE UNEXPECTED.

Honestly, the entire fellowship was unexpected. Tim would walk in at any time and give us a new task, thing to think about, question to answer, etc. You'd walk in with a plan for your day and leave having done something else entirely.



# WHAT ADVICE WOULD YOU GIVE TO FUTURE FELLOWS?

Ask questions about anything you're uncertain of rather than making assumptions or ignoring it.

WHEN NOT AT DEERFIELD, I CAN BE FOUND: In Astoria at the park, a restaurant, a show, or just spending time with friends at home.

### ONE FUN FACT ABOUT YOU! I'm a cellist and have an electric cello at home.

Photo courtesy of Julia Saccamano

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