DEERFIELD®

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NEWSLETTER

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GENE THERAPY – THE PRICE IS RIGHT?

Gene therapy tackles disease at its genetic cause by replacing malfunctioning genes. This is no easy feat, requiring the development of technologies that can slip past well-honed cellular defenses without disrupting the normal activities of the cell. Nonetheless, improvements in viruses created for this purpose, manufacturing, and complementary technologies along with greater understanding of disease-causing genetic mutations have led to some remarkable successes in the clinic. Now, approximately 2,000 clinical trials have been completed or are underway, with evidence that dramatic cures may be possible for a variety of diseases with a single dose[1].

Is it finally time for gene therapy to *come on down!* to Contestant's Row? As a result of the clinical successes, a number of observers in the world of healthcare have declared a definitive comeback for the entire field of gene therapy in the last several years[2][3][4]. The number of pipeline candidates suggests that, ready or not, at least one gene therapy is expected to be approved in the US in the next several years.

While patients may be, our healthcare system in many respects is not ready for gene therapy. One of the aspects in which this is apparent relates to pricing. Many in the investment world easily foresee prices in the $1-2 million range. Despite the potential for curative therapies for otherwise devastating diseases such as spinal muscular atrophy, hemophilia, degenerative eye diseases, and other rare immune and inherited metabolic disorders, this may be a challenging price tag for the US system to handle.

Making the conversation more sensitive has been the increasing congressional alarm at industry pricing practices, highlighted by a series of hearings. Concern was evident in the recent EpiPen-demonium, but there are many other instances in the recent past. Valeant Pharmaceuticals and Gilead Sciences executives have both been on the congressional firing line for their pricing practices. In the latter case, Gilead had set its price for Sovaldi, a treatment for hepatitis C, at $84,000. Given that there are millions of people with hepatitis C, this suggested, and became, tens of billions in additional drug spending for payers. With this environmental backdrop it is easy to envision that when several drugs with price tags in the millions start to appear in the marketplace aimed at mortally ill patients with no alternatives, the question of drug pricing ethics will rise again.

[1] http://www.nature.com/articles/mtm201634

[2] http://www.wired.com/2013/08/the-fall-and-rise-of-gene-therapy-2/

[3] http://www.forbes.com/sites/matthewherper/2014/03/26/once-seen-as-too-scary-editing-peoples-genes-with-viruses-makes-a-618-million-comeback/#5a93d4935ac9

[4] https://www.washingtonpost.com/business/economy/gene-therapies-offer-dramatic-promise-but-shocking-costs/2015/11/11/01f11cf0-824b-11e5-9afb-0c971f713d0c_story.html

While at first blush this type of pricing can be hard to stomach, multiple cost effectiveness studies using mathematical models that have long been employed by health systems in Europe have shown therapies such as Sovaldi to be cost effective given the outright cure it provides in almost all cases. Likewise, for many diseases targeted by gene therapy, there is evidence to show that in absence of potentially curative therapies, the healthcare system may already pay $3-400,000 per year, per patient. Assuming these therapies are truly curative, it would take only a few years for these to hit a breakeven point, before bringing overall savings in the longer term.

The high price tag coupled with the one time dosage make it difficult to keep perspective on the long term benefits to the healthcare system. But there are ways that the US system could make the cost more palatable. For instance, payments could be made over time, corresponding to a demonstration that these therapies are actually working – by way of cancers in remission or protein levels, among others. In this manner, it would not be expected that the $2 million dollar check would get written all at once. Instead, among the proposed models for paying for gene therapies is an annuity structure, where a fixed amount is paid incrementally over time, should the therapy demonstrate that it continues to work.

This potential, sensible approach is harder to employ in the US which has a multi-payer system. In European countries, the government is primarily the sole payer, making the long-term logistics of an annuity system more feasible – one payer is responsible for writing those annuity checks over time. In the US, a typical rule of thumb among the payer world is for a particular patient to be covered by a particular payer for only 3-5 years. Why should Payer B continue writing checks for a therapy Payer A first signed-off on? Further, long term outcomes and effects for these therapies are still unknown – if any one of these therapies look more or less effective at 10, 20 and 30 years on – should Payers B, C, D, etc. continue to pay the same fixed amount, or should more or less be paid depending on the magnitude and durability of the therapy, good or bad?

Others purport that sponsors should have some skin in the game and contribute to a risk-sharing agreement, where they will be responsible to foot some of the costs in the event of suboptimal responses. Ultimately the goal is to find a payment structure that will both incentivize sponsors to continue drug development in this space and for investors to continue supporting those sponsors. If not for the aforementioned expectation of gene therapy pricing in the $1-2 million range, investors would be more reticent to maintain, if not ramp up the level of investment in the space, given the multitude of developmental and regulatory uncertainties these therapies still face. Should we fail as a healthcare system to adequately prepare the necessary policy and infrastructure to make these therapies available to the relevant populations, we jeopardize future investment in this extremely promising field.

It is possible that new legislation is needed to create a paradigm that makes all of the above possible, including new payment methodologies and structures through the Centers for Medicare & Medicaid Services, from which private payers could then borrow and follow suit. We would be remiss to not acknowledge the other excellent discussion points raised on this topic by Orkin and Reilly[5].

While the US still awaits its first gene therapy product, the game is on in Europe where the first two gene therapy players have made it down to Contestant's Row. These are Glybera, approved in Europe in 2012 to treat the ultra-rare disease known as lipoprotein lipase deficiency, in which patients cannot properly process fat, and Strimvelis, approved earlier this year in Europe for adenosine deaminase deficiency, which leaves children stricken with this genetic condition unable to fight against infection. Thus far, Glybera's $1 million dollar price tag has been paid but once in the roughly four years since its approval, and with great difficulty, according to a report from earlier this year[6]. The German physician who prescribed the therapy described preparing a stack of documentation to convince the German health administrators to pay for the therapy.

[5] http://science.sciencemag.org/content/352/6289/1059
[6] https://www.technologyreview.com/s/601165/the-worlds-most-expensive-medicine-is-a-bust/

Meanwhile, Strimvelis received a price tag earlier this year of €594,000 (roughly $660,000) and will only be administered at the Italian research institute where it was developed. The Italian Medicines Agency, which will pay for the therapy, stipulated a risk-sharing agreement with GlaxoSmithKline, the drug's sponsor, based on clinical outcomes and that the therapy's performance will be monitored over time. All of this comes despite estimates of only about 15 people per year to be affected across all of Europe[7].

Unfortunately the lack of use of our first two "successful" examples of gene therapy approvals shed light on the clear imbalance between the dozens of potential gene therapy candidates currently being studied, and the massive infrastructural bottlenecks that have allowed for either only a single patient to be treated, or a single center to even possibly think about treating the small universe of appropriate patients. Without the proper structures put in place, at present, it would be seemingly impossible to conceive of treating the relatively small number of patients afflicted with any one of these rare diseases when faced with these issues of pricing and payment. Such an impasse jeopardizes the feasibility of investors to continue to support the development of this promising field.

- by Christine Livoti, James E. Flynn, and Jonathan Leff

DEERFIELD TAKES LEADERSHIP ROLE IN ADDRESSING BOARD DIVERSITY

During the last decade there has been much discussion and analysis regarding the gender imbalance that exists inside of corporate boardrooms. Numerous studies have documented the quantitative and qualitative benefits of boardroom diversity yet the percentage of board seats held by women remains stubbornly low. In the public arena, females make up less than 20% of all board members and in private companies, research suggests the ratio is much lower, due in large part to the shortage of female partners in the venture capital and private equity funds that often control board composition.

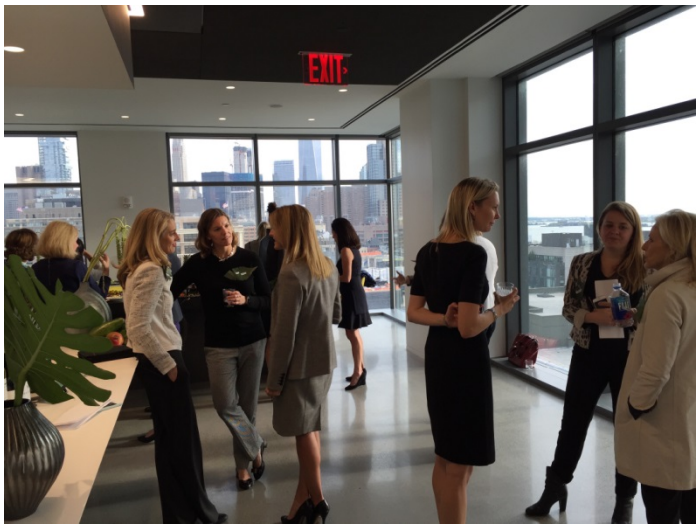

Photo courtesy Oxeon Partners

We believe that effective solutions to this imbalance must address both the demand and supply side of the equation. On the demand side, we believe that companies must be pushed to make a more deliberate and proactive effort to improve gender diversity. A recent analysis by Heidrick & Struggles found, at the current rate of change, it will take 28 years to achieve gender parity in the corporate boardroom. Clearly, we can't rely solely on organic evolution. On the supply side, the pool of women with typically sought after credentials (prior board experience, C-suite title, established network of connections) needs to be expanded. Unfortunately, it is rare for well-intended solutions to simultaneously address both of these challenges. Companies with a professed desire to improve board diversity can't always find an appropriate candidate or convince the nominating committee to look beyond their existing relationships for a fresh perspective. And women need a broader network of connections to recommend them and advocate for them, particularly in the face of such a classic chicken and egg dilemma of needing prior board experience to be considered as a viable boardroom candidate.

[7] https://www.statnews.com/2016/08/03/gene-therapy-price-gsk/

Inspired by several speaking engagements on the topic and the thought already devoted to advancing our Fellows program (which offers local college students from historically under-represented backgrounds on Wall Street a year-long fellowship with a path to full-time employment upon graduation), Deerfield realized that we were uniquely suited to tackling both sides of the problem. In collaboration with Oxeon Partners, a healthcare-oriented executive recruiting and investment firm based in New York, we set about launching an initiative to help prepare qualified women for their first board role and, over time, to help match them with appropriate board opportunities emerging from our portfolio companies. The program debuted earlier this year with a founding class of roughly 30 female senior healthcare executives with an interest in corporate governance. This group participated in a series of four educational sessions designed to support both finding and fulfilling board roles. Participants were also paired with board-experienced mentors and entered into a searchable database that can be mined on behalf of our portfolio companies seeking board candidates with specific skill sets or sector knowledge. In particular, we see real opportunity to take a leadership role in providing board positions in the companies that we form. The feedback from this initial effort has been very positive and we are already beginning to plan the 2017 program. We expect to broaden the list of invited participants and will seek nominations from a number of our public company CEOs as well as from other Oxeon and Deerfield relationships. At this time next year we hope to report back that a number of our alumni have distinguished themselves as valuable boardroom additions for a variety of our investment partners.

- by Leslie Henshaw

PEER-REVIEWED ABSTRACTS

As part of Deerfield's mission of advancing healthcare, the Deerfield Institute is committed to publishing its proprietary research in peer-reviewed, open access scientific journals. Below is a selection of our most recently published work. More information on the Deerfield Institute and full copies of past publications are available on the web at Deerfield.com/Institute.

2016 ASCO ANNUAL MEETING

ASCO University
LIFELONG LEARNING

USE OF FDA-APPROVED VS. LAB-DEVELOPED TESTS IN ADVANCED NON-SMALL CELL LUNG CANCER

CELINE AUDIBERT, MICHAEL SHEA, DANIEL GLASS, MARINA KOZAK, ALEXIS CAZE, RYAN HOHMAN, JEFF ALLEN, ELLEN V. SIGAL, JONATHAN LEFF

Abstract

Background: Molecular testing is central to the management of many cancers. We measured the extent to which FDA-approved and lab-developed tests (LDTs) are used in stage IV adenocarcinoma non-small cell lung cancer (NSCLC) patients, with a focus on EGFR mutations and ALK rearrangements.

Methods: A retrospective chart review of NSCLC patients was conducted between April and September of 2015. A representative sample of US oncologists was asked to complete an online form containing fields for anonymized patient information, including year of diagnosis, whether molecular testing was performed, and if so, which markers were tested, type of test used, and test location. 8,129 NSCLC-treating oncologists in the US were invited to participate in the study. Oncologists were eligible to participate if they personally managed at least 5 NSCLC patients per month, and diagnosed at least one NSCLC patients in the past 12 months

Results: Information on 765 patient records was obtained from the 153 physicians who met eligibility criteria. Histological subtype split was as follows: 76% of patients had adenocarcinoma, 19% had squamous cell carcinoma and 5% had other types. Among the 579 patients with adenocarcinoma, 95% and 84% were tested for EGFR mutations and ALK-rearrangements, respectively. Sample was further reduced to only include patients for which the type of test was known, and whose diagnostic was performed after FDA approval of the relevant test (May 14, 2013 for EGFR and August 26, 2011 for ALK), resulting in 424 patients for EGFR, and 399 for ALK. 87% of adenocarcinoma patients were tested with non-FDA-approved tests for EGFR, and 49% for ALK.

Conclusions: This study highlights the prevalence of non-FDA-approved testing in the treatment of lung cancer. Further evaluation of the comparability of approved and unapproved tests currently being used interchangeably is needed to mitigate uncharacterized variability between tests.

CARDIOLOGY

CARDIOLOGY
International Journal of
Cardiovascular Medicine, Surgery, Pathology and Pharmacology

MODELING THE BURDEN OF ABDOMINAL AORTIC ANEURYSM IN THE USA IN 2013

MARK STUNTZ

Abstract

Objectives: Abdominal aortic aneurysm (AAA) is a pathological condition characterized by an abnormal, localized dilatation of the lower part of the aorta. Due to a lack of data on the natural history of AAA and risk of death from other cardiovascular diseases attributable to AAA, the true number of AAA-attributable deaths may be higher than currently estimated. This study aims to produce more realistic estimates of the burden of AAA.

Methods: A disease-modeling software, DisMod II, was used to assess the AAA burden via a multistate life table. Inputs included population, all-cause mortality, size- and sex-specific AAA prevalence, and relative risk of death estimates for persons with AAA compared with persons without AAA.

Results: There were 2,347,339 prevalent cases of AAA in the USA in 2013 (95% CI: 2,131,964-2,524,116), resulting in 41,371 deaths attributable to AAA (95% CI: 34,090-49,234). Females constituted 21.1% of prevalent cases and 45.2% of deaths, compared with males constituting 78.9% of prevalent cases and 54.8% of deaths.

Conclusions: This work shows that the burden of mortality attributable to AAA is more than twice the current estimates from the American Heart Association. Females account for a disproportionately high percentage of deaths despite constituting a low percentage of prevalent cases.

DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY

BUILDING A DRUG DEVELOPMENT DATABASE: CHALLENGES IN RELIABLE DATA AVAILABILITY

CÉLINE AUDIBERT, MORGAN ROMINE, ALEXIS CAZE, GREGORY DANIEL, JONATHAN LEFF & MARK MCCLELLAN

Abstract

Context: Policy and legislative efforts to improve the biomedical innovation process must rely on a detailed and thorough analysis of drug development and industry output.

Objective: As part of our efforts to build a publicly-available database on the characteristics of drug development, we present work undertaken to test methods for compiling data from public sources. These initial steps are designed to explore challenges in data extraction, completeness and reliability. Specifically, filing dates for Investigational New Drugs (IND) applications with the U.S. Food and Drug Administration (FDA) were chosen as the initial objective data element to be collected.

Materials and methods: FDA's Drugs@FDA database and the Federal Register (FR) were used to collect IND dates for the 587 New Molecular Entities (NMEs) approved between 1994 and 2014. When available, the following data were captured: approval date, IND number, IND date and source of information.

Results: At least one IND date was available for 445 (75.8%) of the 587 NMEs. The Drugs@FDA database provided IND dates for 303 (51.6%) NMEs and the FR contributed with 297 (50.6%) IND dates. Out of the 445 NMEs for which an IND date was obtained, 274 (61.6%) had more than one date reported.

Discussion: Key finding of this paper is a considerable inconsistency in reliably available or reported data elements, in this particular case, IND application filing dates as assembled from publicly-available sources.

Conclusion: Our team will continue to focus on finding ways to collect relevant information to measure impact of drug innovation.

IP CORNER

Intellectual Property (IP) is a vital asset to any emerging company in the healthcare space. Here, we highlight noteworthy trends and events in the IP realm with implications for both young and established healthcare companies alike.

SUPREME COURT LEAVES DIAGNOSTICS INDUSTRY IN LIMBO

In *Mayo Collaborative Servs. v. Prometheus Labs*, the Supreme Court established a standard for analyzing the patent eligibility of diagnostic inventions. The standard does not allow patents for newly discovered laws of nature, nor for any practical applications of these laws if the applications merely use methods already known in the art. The industry fears that such an overbroad holding will have the unintended consequence of rendering truly innovative discoveries unpatentable.

The fears were justified in *Ariosa Diagnostics, Inc. v. Sequenom*, where the Federal Circuit held that Dr. Dennis Lo's invention was ineligible for patent protection under *Mayo*. Dr. Lo discovered that a fetus sheds small DNA fragments into maternal blood. This discovery was revolutionary to the field of prenatal diagnostics. Based on his discovery, Dr. Lo patented a method of detecting fetal chromosomal defects by analyzing maternal blood using standard diagnostic techniques. This test thereby eliminates the need for amniocentesis, which carries a small risk of inducing miscarriage. Sequenom in-licensed Dr. Lo's patent and developed a commercial test, which Ariosa argued was ineligible for patent protection under *Mayo*. The Federal Circuit judges acknowledged the revolutionary nature of Dr. Lo's invention but felt constrained by the rigidity of the *Mayo* standard.

In requesting the Supreme Court review of the Federal Circuit's decision, Sequenom argued that the *Mayo* standard was written too broadly and had the unintended consequences of making numerous diagnostic patents unenforceable and new inventions ineligible for patent protection. The nature of the medical diagnostics industry is such that most inventions would not satisfy the standard as written in *Mayo*. For example, correlations of genotype and phenotype, the presence or absence of a marker and therapeutic outcome, and sensitivity to a particular drug are often viewed as laws of nature not eligible for patents under *Mayo*. Twenty two briefs from industry groups and academics were filed in support of Sequenom. No briefs were filed in support of Ariosa. The Federal Circuit's decision in *Ariosa Diagnostics* was viewed by many as an ideal opportunity for the Supreme Court to narrow its ruling in *Mayo*. Yet, on June 27, 2016, the Supreme Court denied Sequenom's request for review, leaving the diagnostic industry in continued limbo.

With no clarification from the Supreme Court, it is now up to the Federal Circuit to define what falls outside of the sweeping ruling in *Mayo*. Recently, in *Rapid Litigation Management Ltd. v. Cellzdirect, Inc.*, the Federal Circuit decided that a method for producing a pure cell culture for use in diagnostics may still be patentable despite being based on the discovery of a law of nature. It held that the process resulted in a tangible material as opposed to information, thereby placing it out of the scope of *Mayo*.

Additional litigation will be required to fully elucidate the boundaries of the *Mayo* standards. As of now, the diagnostics industry continues to face significant uncertainty.

- by Mark Shtilerman

CAUGHT OUR EYE

The FDA launched a media campaign in June as part of a broader effort to encourage minorities to participate in clinical trials across all medical conditions. The campaign is one part of the agency's larger program "The Year of Clinical Trials Diversity" aimed at more closely matching clinical trials participants to the patients who would ultimately use the approved medicines. Currently, the agency notes most trial participants are white and male. June 2016. FDAVoice blog

Google unveiled a new feature, symptom search, to help users find legitimate information about common health problems and their symptoms. The information, curated by Harvard Medical School and Mayo Clinic experts, seeks to bring an end to "pretty terrifying" responses a simple Google search would provide from the same query criteria. June 2016. The Washington Post

Pharmaceutical giant Pfizer recently dropped $350 million to create a new biotech center in China, which is expected to focus on biosimilar drugs and bio-manufacturing. Slated to open in 2018, this will be Pfizer's third biotech center globally and first in Asia. June 2016. FierceBiotech

In addition to shaking world markets, Brexit is feared to jeopardize EU scientific research funding. While not expected to immediately affect funding of existing research projects, it does create uncertainty around potential research collaborations between U.K. researchers and their European counterparts. Grant funding from the Horizon 2020 fund – a significant source of research funding in the EU – is only available to EU member states of a country that has specifically negotiated access to the program. June 2016. The Wall Street Journal

Patients in the US face the unfair burden of coordinating their own care in a fragmented system, writes Vox. This includes navigating the at times complex web of doctors, managed care organizations, and pharmacies, among other organizations. The cumulative burden raises the issue that patients may ultimately give up on managing their own care. June 2016. Vox

The US Patent and Trademark Office (USPTO) is implementing a pilot program to allow for earlier review of patent applications related to cancer immunotherapy. The move is in support of the White House's Cancer Moonshot initiative. Specifically, the USPTO will advance applications containing a claim or claims to a method of treating a cancer using immunotherapy out of turn for examination if the applicant files an appropriate petition under the program. June 2016. Federal Register

Various research groups are exploring how patients feel about knowing, sharing, and acting on their genetic information. The work follows the falling price and increasing interest in personal genome sequencing. Shared concerns among patients and researchers alike include actionability of genetic information and implications for family members. June 2016. The Wall Street Journal

Compensation in the biotechnology industry is more equal between men and women compared to other industries. The higher proportion of advanced degrees among female executives compared to their male counterparts, including PhDs or higher, is thought to be the reason behind the more equitable pay found in the industry. June 2016. Pitchbook

Commercial institutional review boards (IRB) have slowly displaced most academic IRBs, the organizations which review all research involving human participants. Commercial groups oversee an estimated 70% of US clinical trials for drugs and medical devices, with larger IRBs having already acquired some smaller players. There is debate as to whether these commercial organizations can adequately protect human subjects, and concern around their potential conflicts of interest and profit motive. The FDA reported twice as many violations and problems with commercial IRBs compared to nonprofit boards from 2008 to 2014. July 2016. STAT News

DEERFIELD FOUNDATION

The Foundation has formed 32 partnerships and has invested over $25 million for the advancement of children's health in its ten years. It has supported impactful work 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 The Water Trust.

THE WATER TRUST

Mission:	The Water Trust equips rural villages in Africa to provide children with a healthy environment to grow, starting with access to clean water.
Partner since:	2008
Description:	The Water Trust is an independent nonprofit health organization focused on empowering rural communities to reduce preventable death and disease by creating access to safe water and a healthy, clean environment.
Total Funding:	Over $1,100,000
The Deerfield Perspective:	The Water Trust is a forward thinking, professionally functioning and data driven organization that is taking a leadership role in providing water, sanitation and hygiene solutions (WASH) to the world. Since 2008, The Water Trust has created access to clean water and sanitation for more than 120,000 people, including approximately 60,000 children, through the construction and maintenance of 315 improved water sources and 100 toilets. The impact is significant: the rate of diarrheal disease in a two-week period was reduced from 47% to 5% and families spent 286 fewer hours each year carrying water from distant sources. The greatest challenge to long-term impact is successfully transitioning the operations and maintenance of the improved water sources from International Non-Governmental Organizations to communities. The Water Trust is playing a critical role in testing the viability of different tactics to equip communities to sustainably collect fees, save for future repairs, and contract mechanics. The end result, we believe, is that they are delivering immediate impact for families in need and discovering new ideas to sustain this impact for generations to come.
The Water Trust Perspective:	The Deerfield Foundation has been a critical partner in achieving our success by supporting the implementation of projects on the ground as well as The Water Trust's organizational development. Deerfield has directly supported the construction and maintenance of 80 improved water sources and eight latrines in villages and schools, directly serving 30,291 people, including approximately 16,319 children. Deerfield's organizational support has enabled TWT to connect more than 80,000 additional people, including 46,000 children, with access to clean water and sanitation.
Most Recent Project Funded:	In July of 2016 Deerfield made a 1 year $300,000 commitment to fund the development and implementation of multiple approaches to enhance the capacity of communities to operate and maintain improved water sources. The intent of these funds is to identify a viable model that can be evaluated at scale, and, if successful, replicated by other NGOs and governments.

THE WATER TRUST

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