DEERFIELD®

JUNE 2016

NEWSLETTER

CONTENTS

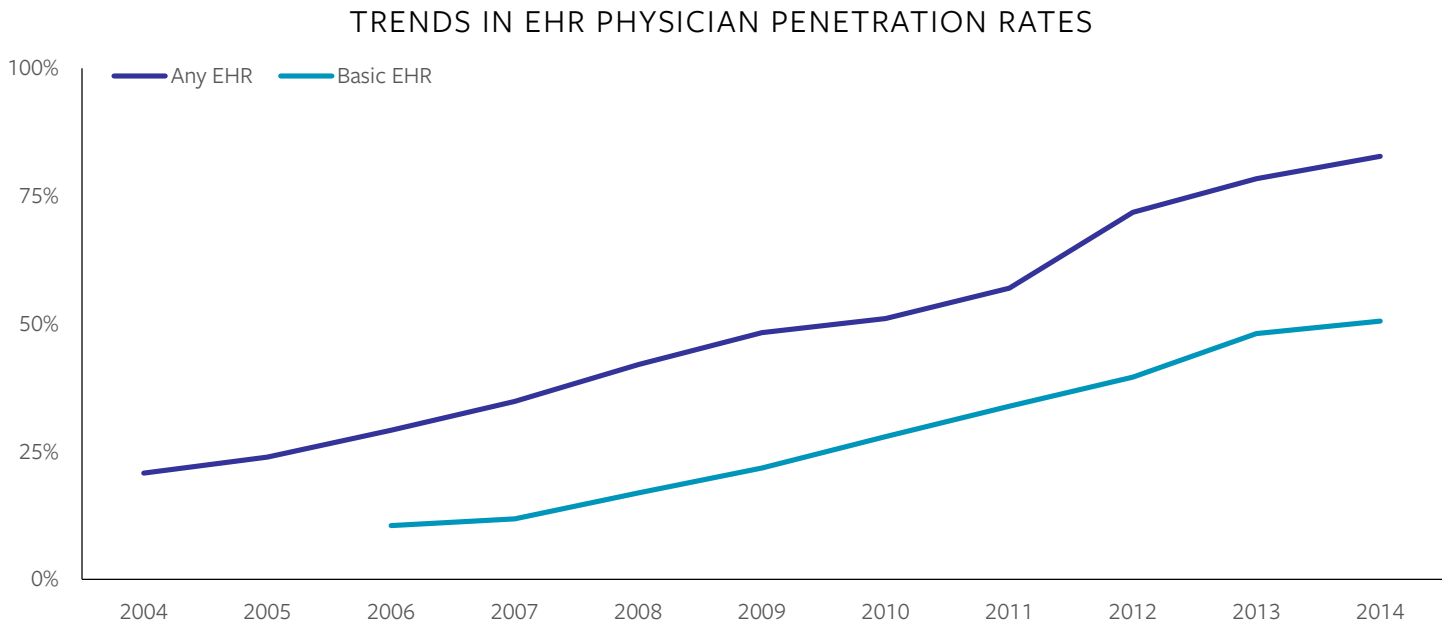
ELECTRONIC HEALTH RECORDS – ON THE CUSP OF SHEDDING ITS AWKWARD ADOLESCENCE

In 2009, in connection with the Health Information Technology for Economic and Clinical Health (HITECH) Act, the government set aside over $30 billion to promote the implementation and use of electronic health records (EHR). The policy objectives at the time encompassed a number of goals including: (1) improving the quality, safety and efficiency of care delivery; (2) engaging patients more fully in their care; (3) improving care coordination; (4) establishing an improved foundation for population health management; and (5) ensuring appropriate security protection for personal health information. Notwithstanding the good intent, significant dollar investment and focused encouragement associated with this initiative, EHR adoption, and its presumed benefits, have been slower than expected to emerge. Seven years and multi billions of dollars later the jury remains out.

On the one hand, great strides have been made in the number of physicians using an EHR. The percentage of providers reporting implementation of at least a basic system has doubled since HITECH was passed, and now stands at just over 80%. On the other hand, it remains highly equivocal as to whether this expanded adoption has improved patient care, enhanced patient and physician satisfaction, or generated promised cost savings. For each of these questions, a quick Google search finds a myriad of conflicting statistics, opinions, and anecdotes, providing ample "evidence" to pronounce HITECH either a resounding failure or an undeniable success.

Rather than weigh in on either side of this debate, or offer what is likely a premature assessment of ultimate potential, I would instead like to flag several areas of both early success as well as concern, and to highlight several future areas of currently unlocked promise. In the area of clear wins, the percentage of physicians e-prescribing via an EHR grew from 7% pre-HITECH to over 70% by the end of 2014. This is important because compared to paper or fax, e-prescribing has been shown to enhance medication safety by improving prescribing accuracy and reducing adverse drug events, and to reduce medication cost through higher generic dispensing rates and more informed drug selection. Similarly, rates of compliance regarding the provision of preventive care and the ordering of recommended vaccinations and lab tests have improved, as has physicians' ability to access patient charts remotely and share information for consults and referrals.

In the concern column, physicians have consistently suffered from productivity drops ranging from 25-33% in the initial phases of EHR implementation and many maintain they have been unable to regain their pre-EHR level of efficiency. EHRs have also introduced new security vulnerabilities despite significant focus on patient privacy protections.



Source:: The Office of the National Coordinator for Health Information Technology. Adapted from HealthIT.gov

More tangentially, providers have expressed concern that the introduction of EHRs into the exam room has detracted from patient-physician interaction and actually reduced the amount of time a physician spends engaged in patient conversation.

This concern, while more pronounced among providers than patients, has even led to the emergence of medical scribes to enter information into the EHR while the doctor interacts with the patient.

Thus, we see the EHR industry continuing to progress, but not without growing pains. As we look ahead, we expect the balance to continue to shift in a positive direction as concerns are addressed and benefits enhanced. We see enormous potential in the area of improved patient engagement. EHRs are highly effective at capturing in-person encounters, but as care expands beyond the walls of the exam room, capturing and tracking what happens between visits will be critical in navigating the transition to population health management and value-based care. A recent industry survey of 500 insured consumers who use mobile/internet-connected health tools revealed that despite the wide-spread adoption of EHRs, 55% of users view them as tools to simply "stay informed." We need to see the pivot of EHRs from providers of information to triggers of action.

Similarly, we see EHRs as a powerful new tool to transform clinical research and public health. Although the healthcare sector has historically trailed other industries such as banking and retail in the use of big data, the richness of information now captured within EHRs holds tremendous promise. New tools are being developed to use EHR data to identify clinical trial candidates, detect disease triggers, validate best treatment regimens, and flag public health threats. Evidenced based medicine, driven by the aggregation of individual data sets and big data algorithms, is starting to get traction and physicians are gaining the ability to assess the likely result of potential treatment alternatives based on data from other patients with the same condition, genetic factors, and underlying traits. Pharma companies are using new datasets and tools to help design trials and identify potential trial participants, and we have already seen that EHR data in combination with historical patterns of flu activity and machine learning algorithms can provide a novel way of monitoring infectious diseases at the national and local level.

EHRs clearly have the potential to touch multiple aspects of healthcare and while change is rarely easy or without unintended consequences, we are confident that EHRs will ultimately improve the cost and quality of care in this country. Achieving these results will require continued collaboration between public and private sectors and ongoing commitment to capturing, standardizing, and integrating the vast array of data generated by patients, providers, payors, employers, and even social media. Providers will need to continue to refine the way in which EHRs are assimilated into their workflow and, most importantly, they and other channel participants will need to learn how to put the new insights enabled by EHRs into practice.

- by Leslie Henshaw

INNOVATE, REGROW, CURE – THE POLITICS OF BIOMEDICAL INNOVATION

When politics and science mix, we all hold our breath.

Several pieces of legislation have been floated in Congress over the past year with the shared objective of encouraging biomedical research and therapeutics.

These follow in the footsteps of other recent legislation designed to speed advances in medicine by modernizing regulatory processes. Even many skeptics of the Washington political process hail some of these efforts, such as Breakthrough Therapy Designation (BTD) and the Generating Antibiotics Incentives Now (GAIN) Act, both implemented in connection with 2012's Food and Drug Administration Safety and Innovation Act (FDASIA), as great successes. In 2015 alone, the FDA approved 45 new molecular entities, which included 10 with BTD and 16 drugs with novel mechanisms of action. Almost half were drugs for rare diseases[1].

Critical to their success, these initiatives were designed through a collaborative process with buy-in from multiple stakeholders – including FDA, patient groups, and industry.

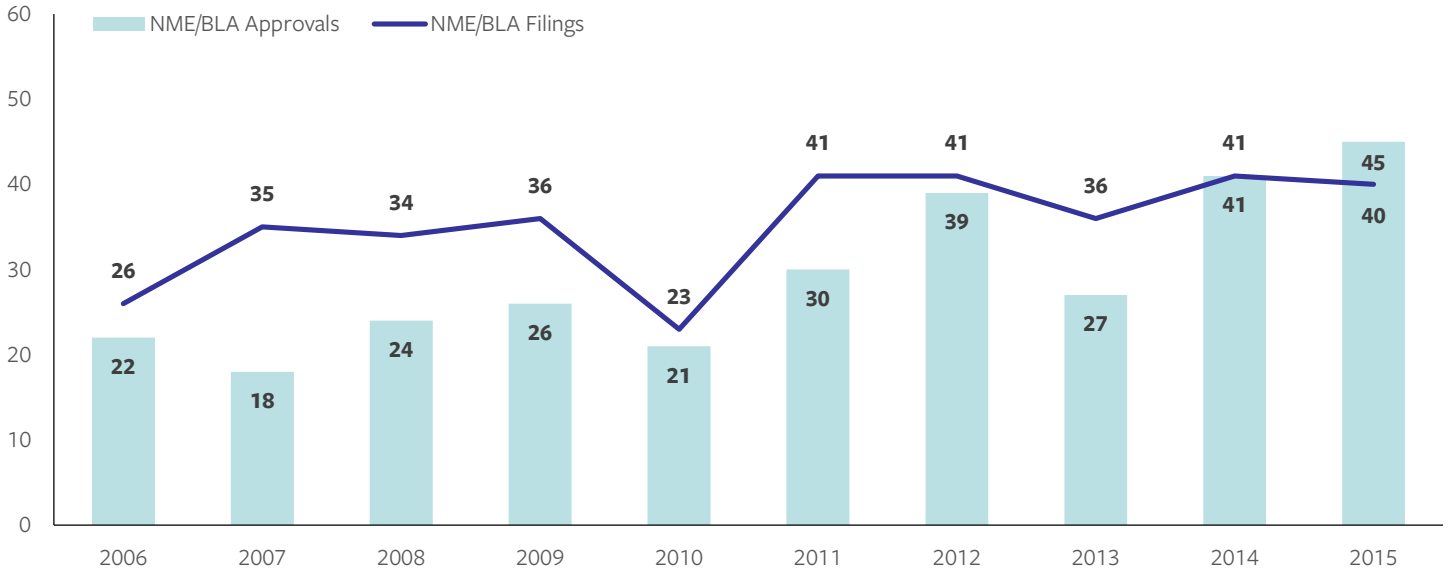
More recently, H.R.6., known as the 21st Century Cures Act, was overwhelmingly passed by the House in July 2015. Its goal is "to accelerate the discovery, development and delivery of 21st century cures[2]." This legislation grew out of a bipartisan process, championed by Representatives Fred Upton (R, MI) and Diana DeGette (D, CO), that carefully constructed something about as close to a consensus as is possible in Washington today. Patient groups, industry, academia, FDA, NIH and other stakeholders all had a voice in constructing a balanced package of reforms designed to enhance the medical innovation ecosystem.

Following in the footsteps of the House, Senate leaders from both parties are advancing the Senate's so-called "innovation legislation," a suite of bills that collectively are that Congressional body's companion to the House's 21st Century Cures. Those bills were discussed across three Senate Health Committee meetings in the first half of 2016, with a total of 19 bills approved by the committee as of April 2016[3].

Like FDASIA in 2012, these bills are the product of efforts to build consensus and alignment across stakeholders, including FDA, and they have the potential to further the advances that grew out of FDASIA.

[1] http://cen.acs.org/articles/94/i5/Year-New-Drugs.html
[2] https://www.congress.gov/bill/114th-congress/house-bill/6?q=%7B%22search%22%3A%5B%2221st+century+cures%22%5D%7D&resultIndex=1
[3] http://www.alexander.senate.gov/public/index.cfm/pressreleases?ID=388C8CAC-698E-4CD0-A4C3-6929EFB9F0BD

CDER NEW MOLECULAR ENTITY (NME) AND
NEW BIOLOGIC LICENSE APPLICATION (BLA) FILINGS AND APPROVALS



Source: FDA analysis[4]. Adapted from FDA.gov

At the same time, it is possible to push too far and too fast in trying to speed new therapies to market. Earlier this year, legislation known as the Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act was introduced into both houses of Congress. REGROW is a bill "to amend the Federal Food, Drug, and Cosmetic Act with respect to cellular therapies[5]" with the aim of supporting regenerative medicines.

A major criticism of REGROW is that it would introduce significant changes that challenge the basic architecture of the new drug approval process. As one example, REGROW would allow for the sale of stem-cell therapies that have been shown to be safe but have not yet been proved effective.

It is perhaps telling that multiple advocacy organizations in the field are opposed to REGROW – these include the Alliance for Regenerative Medicine (ARM), the International Society for Stem Cell Research[6], and most recently, a coalition of 10 patient advocacy groups that wrote a letter to Senator Mark Kirk (R, IL), the bill's sponsor, expressing their shared concerns[7].

ARM noted "We continue to believe the proposal does not contain critical statutory protections for patients[8]," with the patient advocacy coalition similarly noting patient safety could be compromised with the conditional approval pathway stipulated by REGROW, and further, that it would be difficult for FDA to withdraw such products should it subsequently identify safety issues.

The need for new drugs to demonstrate not only safety but also efficacy has been the cornerstone of FDA regulation since the 1962 Harris-Kefauver Amendments to the Federal Food, Drug, and Cosmetic Act, passed in response to the

[4] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm
[5] https://www.congress.gov/bill/114th-congress/house-bill/4762/text?q=%7B%22search%22%3A%5B%22REGROW%22%5D%7D&resultIndex=1
[6] http://www.politico.com/tipsheets/prescription-pulse/2016/05/new-legislation-on-stem-cells-raises-alarm-214069
[7] http://cdn.rarediseases.org/wordpresscontent/wp-content/uploads/2014/11/Letter_to_Senator_Kirk_REGROW_May_24.pdf
[8] http://alliancerm.org/page/government-relations-and-policy

agency's experience with thalidomide[9]. Critics, including FDA officials, have expressed concern that REGROW would upend over 50 years of standard practice at the agency.

Most everyone agrees that there is room to continue to optimize the FDA approval process, and that regenerative medicine represents an area of enormous promise. Efforts to enhance FDA regulation, like the 21st Century Cures process, should be welcomed. But any discussion of eliminating the requirement that new drugs be shown to be efficacious prior to FDA approval should be undertaken only with careful thought and buy-in from key stakeholders across the spectrum, including most importantly FDA itself.

Recent history has shown that Washington *can* act to advance biomedical innovation. But efforts such as REGROW remind us of the dangers of mixing politics with science.

- by Christine Livoti and Jonathan Leff

[9] http://blogs.fda.gov/fdavoice/index.php/2012/02/50-years-after-thalidomide-why-regulation-matters/

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. Full copies of these and other publications are available on the web at Deerfield.com/Institute.

BMC RESEARCH NOTES

BioMed Central
The Open Access Publisher

AWARENESS OF NONALCOHOLIC STEATOHEPATITIS AND ASSOCIATED PRACTICE PATTERNS

SUSAN POLANCO-BRICENO*, DANIEL GLASS, MARK STUNTZ AND ALEXIS CAZE

Abstract

Background: The hepatic manifestation of metabolic syndrome is nonalcoholic fatty liver disease. Patients with nonalcoholic steatohepatitis, the progressive form of nonalcoholic fatty liver disease, have increased risk of fibrosis, cirrhosis and end-stage liver disease. Estimates of prevalence in the United States range from 20–30 % for nonalcoholic fatty liver disease and 2–5 % for nonalcoholic steatohepatitis; however, physician awareness of these diseases is limited. The purpose of this study was to determine the current level of physician awareness and practices in the diagnosis and management of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis within the United States.

Methods: Physicians were asked to participate in an online, 35-question survey about their awareness of various liver conditions and current practices.

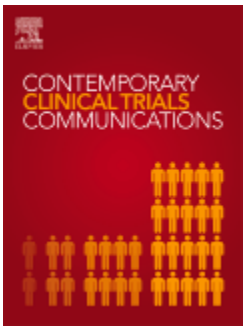
Results: Of the 302 responding physicians, 152 were primary care physicians, and 150 were specialists (comprised of gastroenterologists and hepatologists). More specialists than primary care physicians reported that they were aware of the differences between nonalcoholic fatty liver disease and nonalcoholic steatohepatitis ($p < 0.001$) and that they routinely screened for nonalcoholic fatty liver disease ($p < 0.001$) and nonalcoholic steatohepatitis ($p < 0.001$). Almost half of the responding primary care physicians reported being unfamiliar with the nonalcoholic fatty liver disease and nonalcoholic steatohepatitis differences even though they were aware of both, yet 58 % of those primary care physicians were treating patients with nonalcoholic fatty liver disease and/or nonalcoholic steatohepatitis. In addition, those primary care physicians who reported being unfamiliar with nonalcoholic steatohepatitis were treating an average of 3.7 patients and reported being as likely as familiar primary care physicians to treat new patients with nonalcoholic steatohepatitis. More than half of the specialists used noninvasive diagnostic test to confirm nonalcoholic steatohepatitis, and 10% of the specialists reported treating patients with drugs not recommended by the current guidelines.

Conclusions: Despite reporting they were not familiar with nonalcoholic steatohepatitis, primary care physicians reported they would likely continue to diagnose and manage patients with nonalcoholic steatohepatitis; therefore, more physician education on the recent practice guideline for nonalcoholic fatty liver disease and nonalcoholic steatohepatitis is needed.

Keywords: Nonalcoholic fatty liver disease, Nonalcoholic steatohepatitis, Awareness, Practice guideline, Diagnosis, Disease management, Primary care physicians

CONTEMPORARY CLINICAL TRIALS COMMUNCATIONS

ELSEVIER



IDIOPATHIC PULMONARY FIBROSIS: PHYSICIANS' PERCEPTIONS OF PATIENT TREATMENT WITH RECENTLY APPROVED DRUGS

CELINE AUDIBERT*, CHRISTINE LIVOTI, ALEXIS CAZE

Abstract

Idiopathic pulmonary fibrosis (IPF) is a rare, chronic and ultimately fatal disease for which only palliative treatments existed until recently. Between 2011 and 2015, two new drugs, pirfenidone and nintedanib, were approved in the US and Europe for the treatment of IPF, providing hope for patients. The objectives of our work were to understand physicians' expected use of these new treatments in the US and Europe, and to estimate their potential. To achieve this goal, we conducted surveys amongst US and European Union (EU) pulmonologists caring for patients with IPF. There was a significant difference between EU and US physicians in the treatment of patients with mild disease with pirfenidone; the EU physicians anticipated using pirfenidone for 57% of their patients with mild disease, whereas the US pulmonologists anticipated using it for 34% of their patients (p ¼ 0.01). Regarding patients with severe disease, the US pulmonologists anticipated treating 74% with either pirfenidone (46%) or nintedanib (28%), whereas the EU pulmonologists treated 28% with pirfenidone and anticipated treating 20% with nintedanib. These findings suggest treatment with pirfenidone and nintedanib based on disease severity may vary between US and EU physicians, which may affect patient outcomes.

PLOS ONE

PLOS | ONE

THE PREVALENCE OF PEYRONIE'S DISEASE IN THE UNITED STATES: A POPULATION-BASED STUDY

MARK STUNTZ*, ANNA PERLAKY, FRANKA DES VIGNES, TASSOS KYRIAKIDES, DAN GLASS

Abstract

Peyronie's disease (PD) is a connective tissue disorder which can result in penile deformity. The prevalence of diagnosed PD in the United States (US) has been estimated to be 0.5% in adult males, but there is limited additional information comparing definitive and probable PD cases. We conducted a population-based survey to assess PD prevalence using a

convenience- sample of adult men participating in the ResearchNow general population panel. Respondents were categorized according to PD status (definitive, probable, no PD) and segmented by US geographic region, education, and income levels. Of the 7,711 respondents, 57 (0.7%) had definitive PD while 850 (11.0%) had probable PD. Using univariate logistic regression modeling, older age (18–24 vs 24+) (OR = 0.721; 95% CI = 0.570,0.913), Midwest/Northeast/West geographic region (South vs Midwest/Northeast/West) (OR =0.747; 95% CI = 0.646,0.864), and higher income level (<25K vs 25K+) (OR = 0.820; 95% CI = 0.673,0.997) were each significantly associated with reduced odds of having a definitive/probable PD diagnosis compared with no PD diagnosis. When all three variables were entered in a stepwise multivariable logistic regression, only age (OR = 0.642; 95% CI =0.497, 0.828) and region (OR = 0.752; 95% CI = 0.647, 0.872) remained significant. This study is the first to report PD prevalence by geographic region and income, and it advocates that the prevalence of PD in the US may be higher than previously cited. Further, given the large discrepancy between definitive PD cases diagnosed by a physician and probable cases not diagnosed by a physician, much more needs to be done to raise awareness of this disease.

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.

INTER PARTES REVIEW (IPR) PROCEEDINGS

Inter partes review (IPR) proceedings were introduced by the America Invents Act on September 16, 2012. IPRs were intended to provide a rapid, low-cost alternative to litigation. They allow any party to challenge the validity of an issued patent based on published prior art.

In the pharmaceutical and biotech industries alone, there have been 268 IPR requests to date, indicating widespread use. IPRs make it easier to invalidate patents compared to Federal district court litigation because: (1) the challenged patent is not presumed valid; (2) the burden of proving invalidity is lower in IPRs than in litigation, and (3) the standard for interpreting claim terms is "broadest reasonable interpretation" and thus is more inclusive. However, rather than making the life science industry more predictable, IPRs have introduced increased uncertainty and strategic gamesmanship:

- IPRs are relatively new proceedings and the rules are still evolving.
  - To date, very few requests to amend patents during IPR proceedings have been granted, but the USPTO is now encouraging claim amendments.
  - Substantive testimonial evidence, including expert testimony, is no longer prohibited in preliminary responses from patent owners.
- While the intent of IPRs was to provide an alternative to litigation, practically they provide alleged infringers with an additional chance to invalidate a patent: after nearly a year in litigation, the alleged infringers often file an IPR close to the deadline so that both proceedings run concurrently.
- IPRs and litigations sometimes produce inconsistent outcomes. For example, two patents protecting Novartis's Exelon® patch survived Federal district court litigation and Federal Circuit appeal, but were invalidated in the IPR proceedings.
- Second ANDA filers sometimes strategically use IPR proceedings to interfere with the settlement dynamics established by the Hatch-Waxman litigation scheme.
- Creators of the IPRs did not foresee that financial challengers with no plans to introduce generic drugs would sometimes file for IPRs while shorting the stocks.
- The rate of IPR institutions varies by judge and suggests personal biases.

In the next quarter, these upcoming IPR decisions may be of interest to people monitoring biotech and pharma industries:

- Adcirca (Eli Lilly)
- Copaxone (Teva)
- Effient (Eli Lilly)
- Inomax (Ikaria)
- Prolensa (Bausch + Lomb)
- Xyrem (Jazz)

- by Mark Shtilerman

CAUGHT OUR EYE

Stand Up To Cancer (SU2C) in partnership with American Association for Cancer Research (AACR) have launched "Catalyst" to use funding and materials from industry to accelerate research on cancer prevention, detection and treatment. April 2016
Source: Stand Up To Cancer

The U.S. Supreme Court will hear arguments on a case which could have important implications for the inter partes review system for patent holders. Specifically, the issues of continuing to use the "broadest reasonable interpretation" standard when assessing patent challenges under IPR, and whether the courts can review decisions by the USPTO's Patent Trial and Appeal Board (PTAB) to either institute or accept IPR challenges will be considered in Cuozzo Speed Technologies, LLC v. Michelle K. Lee. April 2016
Source: BioCentury

CMS is looking to change the Medicare Part B payment system in an effort to curb Part B drug spending. Currently, reimbursement for drugs administered in outpatient settings – including physician offices – is tied to the price of each drug, whereby six percent of the average sales price of a drug is added. Some stakeholders argue this method incentivizes the use of expensive drugs over less expensive, although still clinically appropriate drugs. In the newly proposed model, CMS will pay only 2.5 percent, plus an additional fee of $16.80, which will adjust with inflation. This new payment system could begin as early as early fall of 2016. March 2016
Source: FaegreBD Consulting

The FDA is expected to soon make a decision on Sarepta Therapeutics' New Drug Application for eteplirsen for the treatment of Duchenne Muscular Dystrophy, a rare disease of progressive muscle wasting that primarily affects young boys. The drug was recently reviewed at an FDA Advisory Committee meeting which featured several hours of emotional patient and caregiver testimony attesting to the drug's merits. The FDA faces a difficult decision as it weighs this patient input against a small body of clinical evidence – primarily a 12 patient, single center clinical trial – which falls below the agency's usual threshold for clinical evidence. Additionally, the Advisory Committee voted against either accelerated or standard approval pathways for the drug. The Duchenne community, fellow rare disease advocacy groups, and investors all await the high profile decision from FDA, expected later this year. April 2016
Source: The Street

...the story continues...

The company reported in May 2016 that it was informed the FDA would not issue a decision on the company's DMD drug by its earlier intended date. A representative for the FDA did not comment on a new goal date or overall timing for the decision. May 2016
Source: The Wall Street Journal

More than a dozen US states are pursuing a variety of initiatives aimed at providing transparency in drug pricing. New York, California, Massachusetts and Virginia, among others, are drafting new drug price transparency bills, while Ohio and California are offering ballot measures to place price caps on some drugs. Most recently, Vermont Gov. Peter Shumlin (D) signed into law a bill that will annually identify up to 15 prescription drugs where the wholesale acquisition cost has increased by 50% or more over the past five years, or 15% or more over the past 12 months, and which the state spends "significant health care dollars." For companies with such price hikes and that fail to disclose the reasons for those hikes, the state could levy up to $10,000 in penalties. June 2016
Source: Regulatory Affairs Professionals Society

DEERFIELD FOUNDATION

The Deerfield Foundation has formed 32 philanthropic partnerships and has invested over $27 million for the advancement of children's health in its first ten years. It has supported a broad spectrum of 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 Possible Health. For more information, please go to possiblehealth.org.

POSSIBLE HEALTH

Mission:	Possible Health's mission is to provide high-quality, low-cost care to the world's poor. Possible is intent on making a model for patients to realize the right to health by delivering transparent, data-driven healthcare, which it is currently doing for Nepal's rural poor.
Partner since:	2012
Description:	The organizations is pioneering a new approach, called durable healthcare, that brings together the best of private, public, and philanthropic models. Since 2008, Possible has served over 350,000 patients in rural Nepal through hospitals, clinics, and a network of female community health workers.
Total Funding:	Over $1,000,000
The Deerfield Perspective:	Possible Health is a forward thinking, professionally functioning, and data driven organization that has delivered proven and quantitative results for our entire partnership. When the Foundation thinks of organizational excellence in the not-for-profit world, Possible is one of the first that come to mind. Possible has an increasingly growing private/public partnership with the government of Nepal where it is paid for its outcomes. Possible was faced with a difficult decision when many earthquakes hit in 2015 and it rose to the occasion. With full support and backing of the government, Possible was able to expand into a new district, a sign that they are in fact a true partner. Possible relies on resources that are native to the country to deliver healthcare which reduces the cost of the program, but also increases trust among treated patients. The end result, we believe, is that they are building a self-sustaining healthcare system that can withstand change – and growth.
The Possible Perspective:	As an organization trying to change the way healthcare is delivered and paid for in some of the most challenging environments in the world, we are fortunate to have Deerfield as a partner. The Deerfield Foundation has been a key partner that has enabled us to create and pursue a bold vision in Nepal – from investing to build the country's first rural teaching hospital to having the confidence to respond to the country's earthquakes and replicate our model in one of the worst-hit regions of the country. Deerfield's interest and expertise in healthcare has been critical to the success of our partnership, and we hope to continue to find ways to partner beyond the Foundation in the years to come.
Most Recent Project Funded:	Through a $400,000 grant we supported Possible's continued expansion of its original hospital into a 50 bed teaching hospital, increased the scale of its community health program, and ability to make organizational investments to prepare themselves for rapid growth – like establishing the country's first electronic health record and an open enterprise resource planning (openERP) system.
Update:	Although Nepal was badly hit by many earthquakes after our decision to fund the roll out, Possible was able to hit its targets for the original district and expand into a new district in January 2016 where over 46 of the 53 healthcare facilities were damaged or destroyed. There, they are rebuilding 21 clinics and have started operating the central hospital facility for the district in a public-private partnership model.

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