MARCH 2020

NEWSLETTER – VOL. XV

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INFOCUS

The Challenges Inherent in Healthcare Market Research

By Dan Glass, PhD

Gaining accurate insights into how healthcare markets behave is an aspirational goal of many organizations. Product manufacturers and service providers rely on market research to determine the best strategies to conduct their businesses. And research suppliers, who service both of these organizational types, are directly tied to the practice of generating these insights. Common to all these organizations, though, is the unique challenge in gaining insights that accurately reflect the complexities of healthcare markets. Based on my experience in doing this work over the past twenty years, I have observed three main domains of complexity that contribute to these challenges. These include: 1) the ability to understand and size the true target market, 2) the complex decision-making matrix involving providers, payors, and patients, and 3) the ability to forecast what may occur in the future in a rapidly changing environment. Without thoughtful and careful attention to these challenges, organizations run the risk of making suboptimal decisions, ultimately impacting how healthcare is developed and utilized.

The first domain to consider when highlighting problematic or potentially distorted healthcare market insights is the true size and composition of the target market. Given that healthcare as an industry is designed first and foremost to provide services and care to patients, the research question almost always starts with determining how to define this population. This, however, is rarely a straightforward exercise. The condition of interest may be undiagnosed in many individuals (hypertension being a prime example). Patients who are diagnosed may not be actively followed by traditional healthcare providers. And even when patients are "in the system," their care journey may cross areas of medical specialization, sites of care, and reimbursement channels. These factors make relying on traditional epidemiology estimates of disease prevalence to be potentially distorted, as they often point to a hypothetical market vs. the addressable or "findable" patients that are the true candidates for new products or services. Good market research, then, begins by approaching patient sizing with these challenges in mind, with the goal of understanding the contextual factors impacting how we think about market size. By applying a critical lens to these assumptions, an understanding can be formed about who can be targeted and how big this population might be. Importantly, this work should also consider the uncertainties in one's assumptions and how this might change as you gain more market-based insights.

The next major challenge inherent in healthcare market research is the complex decision-making nexus comprised of the providers of healthcare services, the patients who receive care, and the organizations responsible for managing the reimbursement environment. Depending on the disease state and the uniqueness and innovativeness being offered, each of these constituents may have a varying degree of influence over how a new product or service is ultimately utilized. Recent advances in ultra-rare disease research has pushed the pricing power for novel therapeutics, provided greater access to targeted patient populations, and given providers lifesaving tools in previously orphan markets. In these instances, understanding the clinical utility and safety trade off from the provider perspective takes center stage. In larger markets filled with undifferentiated competitors, understanding the market access environment has become critical to determining how successful a new product launch will be. And for the growing number of consumer-driven healthcare products and services, understanding the unmet need from the patient perspective adds another complex element to the decision-making matrix. Appropriate market research must, then, consider the weight of these various and nuanced voices when studying adoption potential within the healthcare space.

And finally, when it comes to forecasting future demand for new products and services, healthcare market research is especially sensitive to uncertainty. While forecast models are the mainstay of business development, marketing and commercialization teams, and investment firms, the degree of uncertainty in these models is often underappreciated. It is industry standard to forecast product demand ten to fifteen years into the future. These forecasts are, of course, based on what is known at present with the difficult task of predicting what might change in the future. Moreover, this task becomes further complicated by the need to form a complete picture of market demand when based on a hypothetical concept. But forecasts continue to be generated, with many providing actionable and accurate inputs that facilitate important business decisions. These successes, undoubtably, draw from the principles guiding all good market research: to be humble in what can be known specifically, to always be context-specific, to learn from previous mistakes, and to appreciate uncertainty in all that you are studying.

In sum, the study of healthcare markets provides the researcher with many challenges that can lead to a variety of outcomes on the spectrum of accuracy and reliability. For organizations that rely on these inputs, appreciating the complexities inherent in these challenges becomes critical to factoring in the degree of certainty guiding key decisions. These complexities will likely expand as our healthcare ecosystem evolves. This evolution will provide for greater research challenges, but at the same time present opportunities for growth in the field of healthcare knowledge.

Dr. Glass is Managing Director, Global Market Research for the Deerfield Institute.

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Imagining the New Frontier of Health Care Research on Park Avenue South
https://commercialobserver.com/2020/02/jim-flynn-deerfield-345-park-avenue-south-medical-research/

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Deerfield to Create Bold Life Sciences Campus
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Deerfield launches first international venture with $130 million
https://cen.acs.org/pharmaceuticals/drug-development/Deerfield-launches-first-international-venture/98/i2

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Duke University and Deerfield Management Announce Four Points Innovation
https://deerfield.com/news/duke-university-and-deerfield-management-announce-four-points-innovation

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Duke, Deerfield Management Form Four Points Innovation to Invest Up to $130M in Drug Discovery
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R&D Alliance Between Harvard and Deerfield Announces First Project Agreement
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With $65M in funding, UNC spinout Pinnacle Hill backs professor's blood cancer research
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Large-Scale Cell and Gene Therapy Contract Development and Manufacturing Organization to Launch in PA
https://deerfield.com/news/large-scale-cell-and-gene-therapy-contract-development-and-manufacturing-organization-to-launch-in-pa

PHILADELPHIA INQUIRER

Can this investor raise $1.1 billion for building gene therapy factories near King of Prussia?
https://www.inquirer.com/business/phillydeals/philadelphia-biotech-labs-deerfield-king-of-prussia-20200127.html

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Deerfield vaults to the top of cell and gene therapy CDMO game with $1.1B facility at Philadelphia's newest biopharma hub
https://endpts.com/deerfield-vaults-to-the-top-of-cell-and-gene-therapy-cdmo-game-with-1-1b-facility-at-philadelphias-newest-biopharma-hub/

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Philly area developer Brian O'Neill to build cell and gene manufacturing facility in King of Prussia
https://www.inquirer.com/real-estate/commercial/breakthrough-medicines-innovation-labs-king-of-prussia-20200123.html

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Real estate group creating $1.1B gene therapy CDMO at former GSK site
https://www.fiercepharma.com/manufacturing/real-estate-group-creating-1-1b-gene-therapy-cdmo-at-former-gsk-site

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TECHNICAL.LY PHILLY

A cell and gene therapy development center is taking 680K square feet at KOP's Discovery Labs
https://technical.ly/philly/2020/01/24/a-cell-and-gene-therapy-development-center-is-taking-680k-square-feet-at-kops-discovery-labs/

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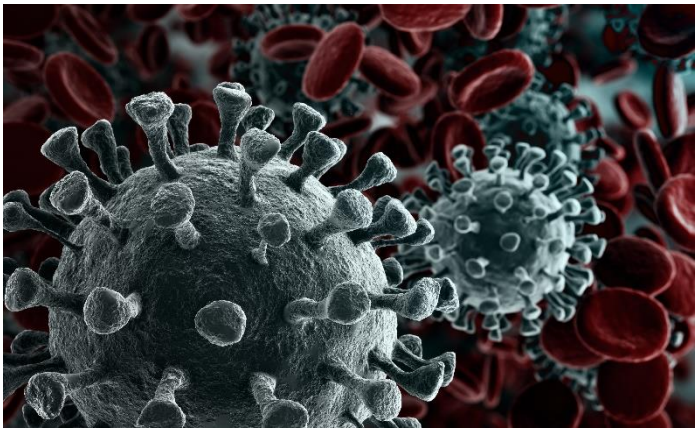
After losing out on big prospect, O'Neill's Discovery Labs takes on cell-gene therapy manufacturing
https://www.bizjournals.com/philadelphia/news/2020/01/24/after-losing-out-on-big-prospect-oneills-discovery.html

RESEARCH BITES

Coronavirus & Preventing Future Viral Epidemics



Around the time the World Health Organization declared the coronavirus spread a global health emergency, and with still many unknowns about the virus, "virus hunter" W. Ian Lipkin, PhD, called for an international prohibition of the sale of wildlife at live animal markets.

An adviser on the 2011 movie thriller "Contagion," and considered one of the world's leading virus experts, Lipkin reportedly just returned from China[1] where he recently visited at the invitation of Chinese health authorities to help assess the risk posed by the virus. He made the same trip 17 years ago when he was tapped to develop a strategy for containing SARS, helping to curtail infections and deaths, as reported by Columbia News[2].

Lipkin blames the packed live animal markets for the outbreak, which he says provides a relatively easy route for the viruses to jump from species into humans. "Such markets were implicated in the emergence of H5N1 influenza (avian influenza) in 1999 and SARS in 2002. The time has come for an international prohibition of the sale of wildlife at live animal markets," Lipkin told Columbia News.

In the interview, Lipkin also offered a reminder that an estimated 70 percent of infections, including HIV/AIDS, Ebola, SARS, MERS, influenza, monkey pox, and Lyme disease, originated in wildlife.

Virologist Vincent Racaniello, PhD, told CUIMC News[3], "It's possible that the virus (COVID-19) will become entrenched in the human population for many years and there will be regular outbreaks. To some degree, we see that with another coronavirus (MERS) in the Middle East. MERS outbreaks continue because there are continuous spillovers from camels (the virus's reservoir) into humans, and people who are asymptomatic can spread the infection. ″

Dr. Lipkin is the John Snow Professor of Epidemiology and Director of the Center for Infection and Immunity at Columbia's Mailman School of Public Health.

Dr. Racaniello is the Higgins Professor of Microbiology & Immunology at Columbia University Vagelos College of Physicians and Surgeons and host of the podcast, This Week in Virology[4].

[1] https://www.crainsnewyork.com/health-care/home-quarantine-travelers-buys-time-new-virus-spreads?
[2] https://news.columbia.edu/news/will-wuhan-virus-spread-us
[3] https://www.cuimc.columbia.edu/news/coronavirus-q-cuimc-experts-explain-what-you-should-know
[4] http://www.microbe.tv/twiv/

One Less Worry for Diabetes Patients Thanks to New CVS Health Plan That Eliminates Out-of-Pocket Costs for Certain Meds

Chain's data suggests RxZERO may increase medication adherence, potentially improving health outcomes and reducing overall medical costs

Recently, CVS Health announced a plan that essentially eliminates member out-of-pocket costs for all diabetes prescription generic drugs, including insulin, according to a company press release.[5]

Dubbed RxZERO, CVS says that the new offering removes member cost as a barrier to patient compliance without increasing the costs for benefit plan sponsors or boosting premiums or deductibles.

RxZERO works by requiring employees with diabetes to use only approved generic medications—instead of brand name—which saves employers around $170 per member, the Company says.

An analysis by the drug chain suggests that nearly 12 percent of their members spend more than $1,000 out-of-pocket annually for branded diabetes medications; average out-of-pocket spending is $467.24.

"Something is really wrong when we have people who are forced to choose between purchasing groceries or their diabetes meds. We applaud CVS for stepping up to the plate and coming up with innovative solutions to address this critical issue and encourage others to do so. Anthem and UnitedHealthcare have already developed similar savings programs," said Alex Karnal, Deerfield Partner and Managing Director. "Such initiatives seem like no-brainers that will lead to reduced healthcare costs overall, and, most important, to improved health outcomes since many more people will be taking their medications."

In related outcomes research, an AbbVie-sponsored study suggested that an autoimmune disease patient support program, which partially helped with medication costs among other services, was associated with greater compliance with adalimumab and reduced total health costs. The study published in an August 2017 issue of the Journal of Managed Care & Specialty Pharma[6].

And from another view, a 2012 study, which appeared in the Journal P&T[7], found that increases in patient cost-sharing was associated with declines in medication adherence and poorer health outcomes.

The American Diabetes Association[8] reports that the total estimated costs for 2017 of diagnosed diabetes of $327 billion includes $237 billion in direct medical costs and $90 billion in reduced productivity. The Centers for Disease Control and Prevention[9] identified diabetes as the seventh leading cause of death in 2015.

5 https://cvshealth.com/newsroom/press-releases/cvs-health-rxzero-solution-eliminates-member-out-pocket-costs-diabetes
6 https://www.ncbi.nlm.nih.gov/pubmed/28737994
7 https://www.ncbi.nlm.nih.gov/pubmed/22346336
8 https://www.diabetes.org/resources/statistics/cost-diabetes
9 https://www.cdc.gov/diabetes/data/statistics/statistics-report.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdiabetes%2Fdata%2Fstatistics-report%2Fdeaths-cost.htm

Deerfield Contributes Insights to Peer-reviewed Study on Access to Life-Saving Drug, Buprenorphine, Examining Growth and Distribution of Waivered Providers

Despite Evidence Showing the Opioid Crisis Disproportionately Affects Rural Areas, Prescriber Growth There Remains Considerably Slower

The federal government is undertaking a number of efforts to increase the amount of buprenorphine prescribers.

While there has been an uptick in the number of U.S. clinicians having waivers to prescribe the potentially life-saving drug, buprenorphine, the total number of waivered prescribers in 2017 still represented fewer than 10 percent of all primary care providers, found a report published online in the January 7 issue of the Annals of Internal Medicine[10]. Buprenorphine, an opioid itself, is used to treat narcotic (opioid) dependence.

Moreover, although rural communities have been shown to be disproportionately affected by the opioid epidemic, the growth in the number of providers having this required waiver certification there remains strikingly low, compared to more urban areas. Authors from the RAND Corporation suggest a need for more targeted efforts to increase access to the medication.

To assess the growth in buprenorphine-waivered providers by region and demographics, the investigators leveraged insights from analysis performed by the Deerfield Institute.

Tapping population estimates from the 2010 U.S. census and total physicians per capita, the researchers calculated the total number of waivered providers per 100,000 from 2007 to 2017. Statistics from the Census Bureau were also used to determine per-capita sociodemographic characteristics.

Over the decade studied, the researchers found that the number of waivered providers, in general, increased from 3.80 to 17.29 per 100,000 persons. Growth rate of waivered providers was markedly slower in small, nonmetropolitan areas, as it was in communities with lower levels of education.

The Food and Drug Administration approved buprenorphine for treating opioid dependency in 2002. According to Kaiser Health News[11], once physicians secure the waiver, they can prescribe buprenorphine in a range of settings[12], including primary care offices, community hospitals and correctional facilities. Compared with methadone, buprenorphine is less likely to result in fatal overdoses.

The authors of the paper are Ryan K. McBain, PhD, MPH, Andrew Dick, PhD of the RAND Corporation in Boston, Massachusetts and Mark Sorbero, MS, and Bradley D. Stein, MD, PhD of the RAND Corporation in Pittsburgh, Pennsylvania.

Dying at Home

In a trend not seen in this country since the early 20th century, more people are dying in the comfort of their own

[10] https://annals.org/aim/article-abstract/2758512/growth-distribution-buprenorphine-waivered-providers-united-states-2007-2017

[11] https://khn.org/news/use-of-buprenorphine-to-treat-opioid-addiction-proliferates-in-california/

[12] https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine

home, rather than at the hospital. The findings, which the authors suggest could inform improvements in high-quality home care, were reported in the December 12, 2019 issue of the New England Journal of Medicine[13].

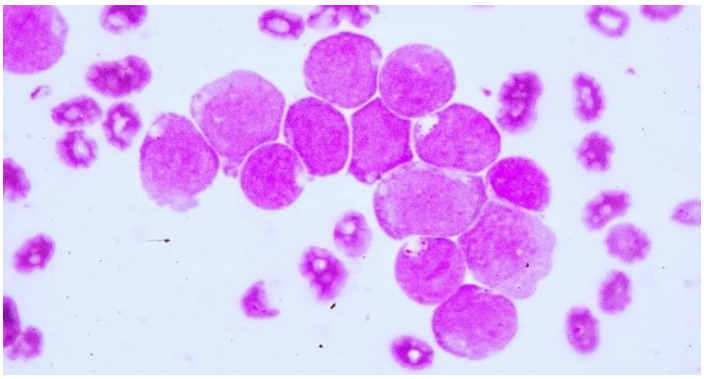
"As a part of the broader shift of care away from hospitals and clinics to the home, people are increasingly choosing to die at home," said Deerfield Partner Julian Harris, MD, MBA. "As the authors suggest, to ensure the highest quality end-of-life care, more information on this experience is needed to inform the development of policies and services that will most optimally meet the needs of patients."

As for a breakdown on the types of patients and where they died, individuals with cancer, according to the article, were most likely to die at home or in hospice. And more often than not, persons with dementia passed away at a nursing home. Not surprising, stroke patients were the least likely to die at home. Ethnic minorities had lower odds of dying at home, as did younger patients and female patients, compared with their white, older and male counterparts.

In 2003, the researchers found, there were 905,874 hospital deaths, representing 39.7 percent of all mortalities. By 2017, that number was down to 764,424, accounting for 29.8 percent of all deaths. To assess data on changes in location of death, the authors reviewed the number of natural deaths recorded for 2003 to 2017 by the U.S. Centers for Disease Control and Prevention and the National Center for Health Statistics. While hospital deaths are still common for the most part, the occurrence is on the decline.

Celgene's Drug is First Maintenance Therapy to Show Clinically Meaningful Improvements in AML

Phase III Trial of CC-486, an Oral Drug that inhibits DNA methylation, Meets Primary Endpoints



Blood smear under microscopy of Adult acute myeloid leukemia (AML). AML is a type of cancer in which the bone marrow makes abnormal myeloblasts, a type of white blood cell.

While targeted therapies, in combination with chemotherapy, have increased the number of patients going into complete remission in acute myeloid leukemia (AML), rates of relapse have not changed and remain the most important cause of treatment failure.[14]

A late-breaking abstract presented late last year[15] at the American Society of Hematology Annual Meeting (Ash), showed that patients with AML who received azacytidine (CC-486) for a prolonged period lived longer than their counterparts on placebo.

"The trial hit the primary endpoint of overall survival (OS) with a 10-month benefit, but what's really notable is that median drug exposure to CC-486 was 12 months," said Deerfield Partner Nick Bishop, PhD. "This is in contrast to typical therapies in AML that rely on a short induction cycle only, and more like other oncology settings where duration of therapy is an important driver of sustained clinical benefit."

[13] https://www.nejm.org/doi/full/10.1056/NEJMc1911892

[14] https://www.hematologyadvisor.com/home/topics/leukemia/treatment-strategies-for-maintenance-therapy-in-acute-myeloid-leukemia/

[15] https://www.targetedonc.com/conference/ash-2019/cc486-maintenance-extends-os-in-older-patients-with-acute-myeloid-leukemia

The 472 AML patients enrolled in the trial, who were in remission following induction chemotherapy, remained in remission longer and survived longer following treatment with the drug. Study participants received either CC-486 or placebo orally for half of a 28-day cycle, along with supportive care until their disease advanced.

Midway through the trial at 41.2 months, survival was significantly improved with median OS at 24.7 months for persons on CC-486, compared to 14.8 months for those who received the placebo. Relapse-free survival (RFS) was also meaningfully extended with median RFS at 10.2 months in the CC-486 arm, versus 4.8 months in the control group. The drug was additionally reported to have a manageable safety profile.

According to the American Cancer Society[16], AML is one of the most common types of leukemia in adults. The 5-year survival rate for people age 20 and older is approximately 25 percent; for people younger than 20, the survival rate is 67 percent.[17]

Newsom's Unprecedented Drug Plan for CA Spurs Debate

California Gov. Gavin's Newsom's proposal to create its own prescription-drug label—in an effort to control costs—was met with a range of reactions based on a review of related news coverage.

Newsom's rationale, according to reports, is that increased competition in the generic market will drive down prices. "The cost of health care is just too damn high, and California is fighting back," Newsom said in a statement.

It was reported that a broad overview of the plan provided by Newsom's office suggests California could contract generic drugmakers to manufacture certain prescriptions under the state's own label. More details are expected to be released in the coming weeks.

A Sample of Reactions

"Frankly, I think it's a ludicrous proposal that demonstrates a profound misunderstanding of generic drug economics. It's like saying you want to go to Post [Consumer Brands] for your Fruity Pebbles and open a supermarket to buy them. It doesn't make sense."

–**Adam Fein,** Chief Executive, Drug Channels Institute
Los Angeles Times

"Consumers would directly benefit if California contracted on its own to manufacture much-needed generic medications like insulin — a drug that has been around for a century yet the price has gone up over tenfold in the last few decades."

–**Anthony Wright,** Executive Director of Health Access California.
PBS News Hour (AP pick-up)

"To save money, California will have to select drugs whose prices have risen substantially that are prescribed often. Too few drugs with low utilization doesn't actually translate into hundreds of millions of dollars to save, so you have to come up with the right trade-off."

–**Pratap Khedkar,** Head of the Pharmaceuticals practice at ZS Associates.
Wall Street Journal

"Other countries control or negotiate the price of drugs, and if there is one state that could do it, it's California, which is the size of a country. A drug company could walk away from Rhode Island. It's much harder to walk away from California."

–**Larry Levitt,** Executive Vice President of Health Policy for the Kaiser Family Foundation
PBS News Hour

[16] https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html

[17] https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics

"It's an interesting idea without there being any specifics. The question is: What is the goal? Is it to decrease aggregate spending on drugs or fix market failures? Just because California makes these drugs, doesn't mean they will make them at a lower cost. They would have to target places where the margin is high. I would be worried about them having the discipline to know which markets to enter."

–**Craig Garthwaite,** Director of the healthcare program at Northwestern University's Kellogg School of Management.
Los Angeles Times

"If Costco can have a Kirkland brand, why can't California have our own generic brand? "I really do think there is quite a bit of merit in having us produce the medications."

–**Democratic Assemblyman Joaquin Arambula** who is also an emergency room doctor from Fresno and chairs the House Budget Subcommittee on Health and Human Services.
PBS News Hour (AP pick-up)

"Will California be able to significantly undercut generic prices? If so, it will shine a light on how much money middlemen take out of the system. If the Governor can truly 'disintermediate' the middleman and offer generics at lower costs, (then) maybe this will be a good model for other states and, perhaps on a larger scale, for the Centers for Medicare & Medicaid Services."

–**Peter Pitts,** Former FDA Associate Commissioner; Current Head of the Center for Medicine in the Public Interest
Stat

"If California enters the market itself, it will face the same market dynamics that have led to generic prescription drug price deflation in the past three years, as well as certain cases of patent abuse that have led to longer monopolies by select brand-name drugs."

–Statement by **The Association for Accessible Medicines**
Wall Street Journal

Applying Lessons Learned from CUNY Workforce Development Programs to Benefit Employers and Higher Education

High-quality postsecondary-employer partnerships are necessary to successfully achieve access to economic advancement for all, advocates the City University of New York (CUNY), Jobs for the Future[18] (JFF) and HERE to HERE[19].

A JFF report[20] titled "Employer Partnerships that Drive Systems Change: Accelerating Change at The City University of New York," was undertaken to identify best practices from existing CUNY employer partnerships and apply these toward other partnerships across the CUNY system, potentially benefiting those entities and higher education at large.

"The report seeks to deepen understanding of the conditions and mechanisms that enable effective partnerships, tell stories of success, highlight key champions, and identify areas for further employer engagement," said Brandi Mandato, Director of Sector Innovation at CUNY, who also thanked Deerfield for being a champion of higher-education partnerships.

[18] https://www.jff.org/
[19] https://www.heretohere.org/
[20] http://ptopnetwork.jff.org/sites/default/files/Employer%20Partnerships%20Drive%20System%20Change-%20CUNY.pdf

Additional takeaways of the report, according to CUNY leadership, include:

- Establish common standards for academic credit;
- A common set of standards for awarding academic excellence, regardless of where the course is housed, must be developed;
- Define student and institutional success more systematically;
- Consistent data collection and sharing are necessary to best align with employers and prepare students.

Shared responsibility for talent development; To achieve program goals, it is necessary to create a coordinated, system-wide structure.

Deerfield's CUNY Fellows program, which is led by Tim Coan, is one such example of a partnership between a post-secondary institution and an employer. Launched in 2015 to help address the economic disparities that exist by increasing opportunities for the underrepresented from diverse communities, the program mentors students, teaching them about healthcare finance.

JFF drives change in the American workforce and education systems to promote economic advancement for all. HERE to HERE links employers, educators and diverse community stakeholders in concerted action to enhance career pathways for young people in low-income neighborhoods. The largest urban postsecondary system in the United States, CUNY is a powerful hub of diverse talent and economic development in New York City.

IP CORNER

U.S. Targets China in Trade Secret Litigation

By Mark Shtilerman, PhD, JD

Trade secrets are a well-known form of intellectual property. Trade secrets protect all forms of information if (a) the information has economic value, (b) the owner took reasonable measures to keep such information secret, and (c) it was acquired by the accused through "improper means", e.g., stolen, or disclosed and used without consent.[21] Reverse engineering, independent derivation, or any other lawful means of acquisition are not considered "improper means".[22]

Trade secrets are traditionally enforced by state courts. However, the federal government has recently taken an interest in preventing and prosecuting the theft of trade secrets. In 2016, Congress enacted the Defense of Trade Secrets Act (DTSA) to allow some types of trade secret cases to be litigated in federal courts.[23] In 2018, the Department of Justice announced its "China Initiative" with the strategic priority of targeting Chinese national security threats.[24] Economic espionage by the Chinese government is estimated to cost the U.S. economy $225-600 billion per year in stolen intellectual property.[25] The DOJ's China Initiative fact sheet specifies its focus on "an enforcement strategy concerning non-traditional collectors (e.g., researchers in labs, universities, and the defense industrial base) that are being co-opted into transferring technology contrary to U.S. interests".[26] This strategic focus has produced numerous actions against academic researchers, who had traditionally been exempt from legal scrutiny.[27] Academic researchers are generally required to assign their inventions to their home institutions with certain rights reserved to the government if their research is funded even in part by any branch of the government. In one such case, which involved false statements and non-disclosure, the trade secret law was violated by the disclosure of government-sponsored or university-owned information without consent of the government or the University. By inventing abroad, or sharing information developed in the U.S. laboratories, researchers breach the trade secret protection and invention assignment obligations, thereby reducing U.S. competitiveness. The breach potentially allowed Chinese institutions to obtain patents on illegally disclosed inventions. Boston-area federal prosecutor Andrew Lelling said that one of the primary goals of the China Initiative is "to sensitize academic institutions to this problem. That's 90 percent of the battle".[28]

Since 2017, the number of new trade secret cases has skyrocketed. And 2018 saw a 30 percent increase in new trade secret cases, driven in part by the DTSA and the China Initiative. "[T]he FBI has about 1,000 investigations involving China's attempted theft of U.S.-based technology, in all 56 of our field offices, spanning almost every industry and sector."[29] Today, more than 90

[21] For example, 18 U.S.C. § 1839 (3).
[22] 18 U.S.C. § 1839(6).
[23] 18 U.S.C. § 1836, *et seq.*
[24] https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-announces-new-initiative-combat-chinese-economic-espionage
[25] 2017 Report by the White House Office of Trade and Manufacturing Policy.
[26] https://www.justice.gov/opa/speech/file/1107256/download
[27] https://www.justice.gov/opa/pr/harvard-university-professor-and-two-chinese-nationals-charged-three-separate-china-related; https://time.com/5596066/emory-fires-chinese-researchers/; https://www.justice.gov/opa/pr/university-kansas-researcher-indicted-fraud-failing-disclose-conflict-interest-Chinese; https://www.tampabay.com/news/health/2019/12/18/moffitt-cancer-center-shakeup-ceo-and-others-resign-over-china-ties/; https://www.justice.gov/usao-nm/pr/former-scientist-los-alamos-national-laboratory-pleads-guilty-federal-court-making-false; https://www.tampabay.com/news/health/2020/01/14/university-of-florida-also-a-target-in-foreign-research-scandal/, and https://www.houstonchronicle.com/news/houston-texas/houston/article/MD-Anderson-fires-3-scientists-over-concerns-13780570.php
[28] https://www.law360.com/whitecollar/articles/1241413/feds-vow-to-go-hard-against-chinese-ip-theft-in-2020
[29] FBI Director Christopher Wray, Feb. 6, 2020.

percent of the DOJ's criminal enforcement of trade secret cases involve China. In contrast, the rate of patent litigation has steadily declined for the past five years from 5,833 new cases filed in 2015 to only 3,580 in 2019.

The theft of trade secrets and the resulting economic damages are very real. However, it is difficult to balance the enforcement of trade secret laws against protections for the free exchange of information that were traditionally afforded to academic research. The academic culture in this country has generally been one of multi-national and cross-disciplinary sharing: academic institutions were always on the forefront of inclusiveness and open access. Many top universities have large groups of foreign students and open campus policy. Students are free to attend all faculty presentations. The restriction of collaborations in academic research could have a chilling effect on innovation. All countries, including the U.S., benefit from the open exchange of ideas that accelerate research. Yet, care needs to be taken in all cross-border transactions, as DOJ prosecutors prepare for another busy year.

BREAK INTO THE BOARDROOM™: BIB BIOS

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

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

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

INTRODUCING...ELIZABETH GARNER, MD

Photo courtesy
Elizabeth Garner, MD

Current Position: Chief Medical Officer of ObsEva SA, a publicly traded women's health pharmaceutical company based in Geneva, Switzerland, focused on the clinical development and commercialization of novel therapeutics to address serious conditions that compromise women's health and overall quality of life.

Previous Roles: Chief Medical Officer, SVP, Agile Therapeutics, Inc.

Vice President Medical Affairs, Women's Health/Preventive Care, Myriad Genetics

Senior Medical Director, Clinical Research, Abbott Laboratories

Director, Clinical Research, Merck Research Laboratories

Education: Harvard Medical School (MD), Harvard School of Public Health (MPH), Mount Holyoke College (AB, Music and Biology)

Key Expertise/Skill Sets: Elizabeth has extensive experience as a strategic leader, having held roles of increasing responsibility in large and small pharmaceutical and diagnostic companies. She is a thoughtful and deliberate decision-maker, and leads her teams with vision, empathy, humility, and resilience. Dr. Garner is an exceptional communicator and is often the face of organizations to internal and external stakeholders, including investors, regulatory bodies, key opinion leaders, and the media. Her skill sets encompass a wide range of areas including clinical trial design and conduct, regulatory strategy, FDA Advisory Committees, NDA and MAA submissions, medical affairs/Key Opinion Leader development, and pharmacovigilance. As an experienced obstetrician/gynecologist and gynecologic oncologist, she is also uniquely positioned to help companies understand both the medical needs and desires of patients and the view of healthcare providers. Elizabeth is interested in using her experience to provide advice and guidance to small and medium-sized pharma companies, and is currently a member of the Board of Directors of Kezar Life Sciences, a publicly traded company developing novel therapies for autoimmune diseases and cancer, and serves on the audit committee.

Professional Interests: Elizabeth has been a longtime advocate for innovation in women's health, in particular around novel therapies and preventive health in areas of serious unmet need, as well as innovative solutions to common yet often under-appreciated problems and challenges women deal with every day. Dr. Garner is also deeply committed to women's career and leadership development, and is frequently invited to speak on the topic. She is a member of the Board of the American Medical Women's Association (AMWA), a founding member of the AMWA Leadership Council, and on the Board of CorStone, an international non-profit organization focused on resilience in girls. She is also a founding member of the organizing committee for Bio NJ's Inspiring Women in STEM annual conference. As a member of the Board of Directors of the Drug Information Association (DIA), she is also interested in supporting the career development of young people in industry as well as the formation of partnerships and collaborations between the academic community and industry to accelerate the translation of scientific discovery to therapeutic reality.

Personal Interests: Dr. Garner's favorite personal interest is her family; she and husband Kelvin are the proud parents of three children, Kenechi, Nkiru, and Ikem. Ikem has autism spectrum disorder, and Beth loves nothing more than spending Saturdays simply hanging out with him at home. A music major in college (piano, voice, and choral music), she loves virtually all genres of music and musical theater. Born and raised in Nigeria, Dr. Garner considers herself a citizen of the world, and finds great pleasure in learning about and working with people from all around the globe.

CAPTURED OUR INTEREST

By Christine Livoti

Utah sends employees to Mexico for lower prescription prices

The state of Utah is paying for public employees to travel to Mexico to pick up certain high cost prescription drugs, as even with the cost of travel and an additional $500 per trip stipend, it is still less expensive than purchasing in the U.S. The program was created in 2018. The state projects it will save tens of thousands of dollars.

https://www.usnews.com/news/health-news/articles/2020-02-09/utah-sends-employees-to-mexico-for-lower-prescription-prices

FDA advances gene therapy guidance

The FDA finalized a series of gene therapy guidance documents and also introduced a new draft guidance on the "sameness" of gene therapy products. The sameness guidance is intended to help manufacturers obtain orphan-drug designation and eligibility for orphan-drug exclusivity when there are multiple gene therapy products targeted for the same disease.

https://www.fda.gov/news-events/press-announcements/fda-continues-strong-support-innovation-development-gene-therapy-products

First ever digital health formulary

Express Scripts published its first ever digital health formulary. The PBM announced last year it would be rolling out the offering in 2020. The formulary includes 15 products related to remote monitoring services and digital therapeutics for diseases, including diabetes, prediabetes, hypertension, asthma, pulmonary disease, depression, anxiety, and insomnia.

https://www.express-scripts.com/corporate/articles/digital-health-formulary-announced

FTC intervention kills proposed merger among NGS players

The proposed acquisition of Pacific Biosciences by Illumina was scuttled by an FTC complaint against the proposed deal. The regulator maintained that the deal would extend Illumina's market monopoly in the US market for next generation sequencing. The companies announced only a few weeks after the FTC complaint that they would be terminating the proposed merger.

https://www.ftc.gov/enforcement/cases-proceedings/1910035/matter-illumina-incpacific-biosciences-california-inc

Johns Hopkins Technology Ventures' Christy Wyskiel shares her insights on female-founded startups

"...As female entrepreneurs, we follow our passion, hone our craft, build a team and, with enough luck, grit and perseverance, magic happens. But we also need champions along the way. To the investment community that is looking for the next great return on investment: The world is not just dudes in fleece vests..."

https://ventures.jhu.edu/news/christy-wyskiel-female-entrepreneurs-baltimore-startup-investing/

DEERFIELD FOUNDATION

The Deerfield Foundation has formed 49 partnerships and invested or committed nearly $49 million for the advancement of children's health in its 10 years, ranging from health clinics in Nepal to a mobile medical home for children in the South Bronx. We would like to highlight here just one of the organizations that we feel is helping us fulfill our mission of advancing healthcare. We are proud to be critical supporters of Lwala Community Alliance.

LWALA COMMUNITY ALLIANCE

Mission — To build the capacity of rural communities to advance their own comprehensive wellbeing.

"The success of our community-led health model has driven us to reject the notion that grassroots health initiatives are not scalable. Local interventions can transform systems of inequity by leveraging the latent capacity of vulnerable communities. We believe that bottom-up solutions matched with research-backed technology are uniquely positioned for systems' change. As such, we leverage partnerships with leaders in global health research to source the most cutting-edge and cost-effective technologies that will save the most lives in our communities."

– **Ash Rogers,** Executive Director

Community Health Workers conducting a routine home visit. Lwala's Community Health Workers develop strong connections with the families they serve.

Partner Since — 2017

Description — Lwala is a community-led innovator operating in Kenya, whose model illustrates that when communities lead, change could be lasting and profound. The entity was founded by a group of community members who mobilized to build the region's first urgently needed health clinic before engaging the research prowess of the University of California, San Francisco (UCSF) and Vanderbilt University to rigorously measure interventions. Today, Lwala is much more than a hospital; the organization has impacted public health locally, making dramatic improvements in the quality of maternal and child health, including a significant reduction in child mortality, a 97% facility delivery rate, and a 300% increase in contraceptive uptake.

2019 Funding — $200,000

2019 Project Funded — **The Obstetric Hemorrhage Initiative**

As part of its community-led health model, Lwala brings traditional midwives into the formal health system, training them as Community Health Workers.

Nearly 99% of deaths from obstetric hemorrhage occur in developing nations. To effect urgent change, Lwala has adopted an innovative intervention called non-pneumatic anti-shock garment (NASG), which has been shown to reduce mortality by 67% related to obstetric hemorrhage[30]. This simple, reusable tool works by constricting blood flow to the lower extremities while redirecting it to vital organs, providing patients with an additional critical 72-hour bridge to securing more formal treatment.

[30] https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-018-0613-5

Project Milestones

- In partnership with a UCSF affiliate and with the use of a trainer-of-trainers model, Lwala scaled its obstetric hemorrhage initiative to 48 facilities, covering 417 healthcare providers in Migori County by January 2020.
- Now, Lwala is working with Ministry of Health and other partners in Migori County to bundle the non-pneumatic anti-shock garment with other lifesaving approaches to create an easy-to-incorporate obstetric hemorrhage package for health workers to deliver.

Also critical to achieving good outcomes, Lwala's community-led efforts have resulted in the following in 2019:

- 82% of expectant mothers attended four or more antenatal care visits in Lwala's innovation hub (North Kamgambo) and 58% attended four or more visits in its expansion site (East Kamagambo), up from 39% in East Kamagambo earlier in the year.
- 98% and 97% skilled delivery rates in its innovation hub and East Kamagambo expansion site, respectively, compared to a 53% county average (Kenya Demographic Health Survey 2014).
- Immunized 98% of children in innovation hub and 81% in expansion site, compared to a county average of 57% (Kenya Demographic Health Survey 2014).

CORRECTION

An item in the December 2019 issue of this Deerfield newsletter misstated the identity of the catcher of a fish at Deerfield's CEO Conference. It was Mike Farrell, not Mike Foley. Mike Foley didn't even fish that day.

IMPORTANT NOTES AND DISCLAIMER

This newsletter is for informational purposes only and does not constitute an offer to sell or the solicitation of an offer to buy any securities, and may not be used or relied upon in connection with any offer or sale of securities, including any investment in a fund managed by Deerfield. Any offer with respect to a Deerfield fund will be made only through a final private placement memorandum and subscription agreement, and will be subject to the terms and conditions contained in such documents. Investment funds are speculative and involve risk of loss. Past performance is not a guarantee of future results. Market conditions may change.

Any specific securities identified and described do not represent all of the securities purchased, sold, or recommended for advisory clients, and the reader should not assume that investments in the securities identified and discussed were or will be profitable. Information provided herein should not be deemed as a recommendation to buy or sell any securities mentioned.

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