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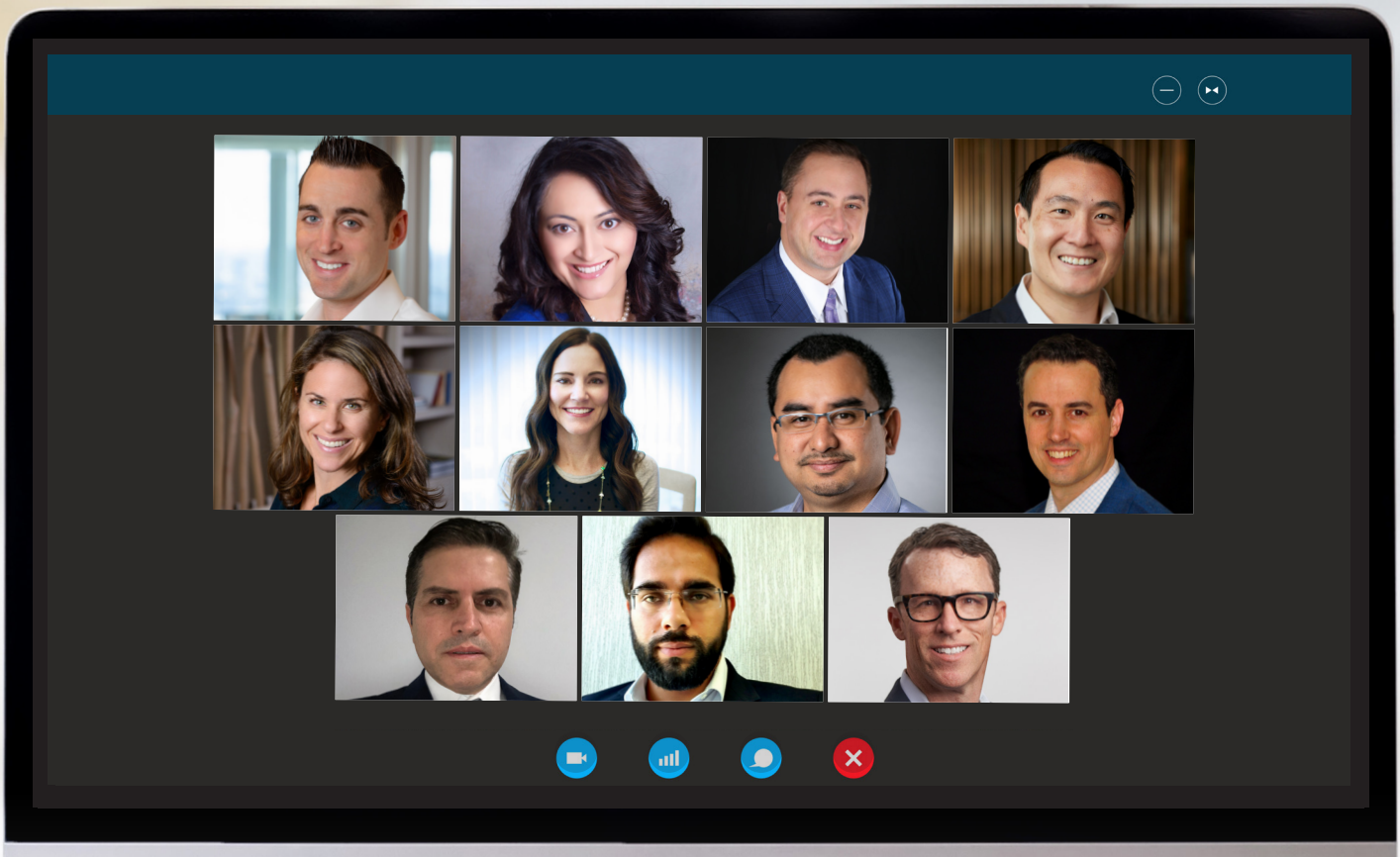

2020 Emerging Pharma Leaders

May 2020
VOLUME 40, NUMBER 5

WWW.PHARMEXEC.COM

Meet the winners.











Pharmaceutical Executive®

Emerging Pharma Leaders

We received more than 100 nominations, and selected 11 people with the most impressive leadership, knowledge, and skills.

These up-and-coming professionals are vital to the future of the pharmaceutical and biotech industry. They've proven that they have what it takes to deal with challenges that will continue to face manufacturers in the coming years.

2020 Emerging Pharma Leaders Awards

- **Lauren D'Angelo** Vice President of Marketing at Urovant Sciences
- **Manuel P. Duenas** Vice President, Global Commercial Operations, Market Access and Pricing at Atara Biotherapeutics
- **Sapan Gandhi** Associate Director, Commercial Strategy and Business Development at Cipla Ltd
- **Dr. Anita Gupta** Senior Vice President, Medical Strategy and Government Affairs at Heron Therapeutics
- **David K. Lee** CEO at Servier Pharmaceuticals
- **Elizabeth (Liz) McGee** General Counsel at Novartis Pharmaceuticals Corporation
- **Andrew Miller, PhD** Founder and Chief Operating Officer at Karuna Therapeutics
- **K. Scott Moore ield, PhD** Chief Business Officer at Boundless Bio
- **Peter O'Neill** Director and Senior Clinical Trial Head at Incyte
- **Craig Serra** Global Head of Strategy and Innovation, Data Operations at Novartis Pharmaceuticals Corporation
- **Rogerio Silva** Vice President and General Manager at PTC Therapeutics

Read more about them:
pharmexec.com/EPL2020

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Master the Science of Success

AFTER A SHORT HIATUS, the *Pharmaceutical Executive* Emerging Pharma Leaders recognition reemerges in this issue. The Class of 2020 features 11 leaders who span large pharma to emerging biotech, as well as roles that lead the various complex and innovative areas across their respective companies. We started the Emerging Pharma Leaders (EPLs) nomination and voting process well before the pandemic and conducted interviews on the cusp of the initial lockdowns. Therefore, we didn't discuss COVID-specific questions. However, we can clearly see how leadership determines the path biopharma companies navigate through not only a very complex and regulated industry, but how leaders can steer through public and global crises.

One of the criteria the judges used to evaluate our EPLs is the actions that nominees took to ensure their path in the C-suite. That determination speaks not only to the desire to lead, but the qualities needed to guide biopharma through difficult times.

Everyone here at *Pharmaceutical Executive* is extremely excited to debut the EPLs milestone with another, the updated look and outlook of the brand, one which was a true collaboration between many departments and our external Editorial Advisory Board. You may have noticed that we also changed the tagline of *Pharmaceutical Executive* to "Master the Science of Success." Though we have had a few taglines in the brand's existence, this one speaks eloquently to you, the audience, and reiterates what we provide you from reading our articles in print or on the web, or engaging with our other media platforms such as enewsletters or webcasts, eBooks or videos, podcasts or virtual events. We are dedicated to providing you with the information and tools you need to lead and succeed in this industry.

We've reimagined the design of the publication to better reflect our audience, as well as the pacing of the articles, so that you know where to find your favorite columns, or easily page to the Executive Profiles or in-depth features. Thank you to our exceptional design staff, Jeff Brown, Ray Pelesko, Marie Maresco, and Maya Hariharan for their talent in transforming our thoughts into a tangible vision.

To our regular columnists who have provided exceptional coverage of the FDA and EU regulatory and government landscapes, we've added four more regular staples. The Financial column is authored by Barbara Ryan, an EAB member and founder of Barbara Ryan Advisors, a capital markets and communications firm she started in 2012 following more than 30 years on Wall Street as a sell-side research analyst covering the US Large Cap Pharmaceutical Industry. Her opinions and expertise are widely sought; she is frequently quoted in the press and appears on CNBC; and she is well-positioned to provide our readers with with the insights and current financial outlook for biopharma.

Sandor Schoichet is well-placed to pen our new Biopharma Sustainability column. In his capacity as Director & Independent Advisor, Meridian Management Consultants, he co-founded the Biopharma Sustainability Roundtable, an annual invitation-only Roundtable and Investor Day. Topics have included sustainability strategy, program management, and enterprise process improvement. Sandor has worked with several life science, IT, and technology development organizations in executive and consulting roles.

Our Technology column is helmed by Julian Upton, P*harmaceutical Executive*'s European and Online Editor. Often writing on the topic already, our go-to tech expert will continue to provide the right balance of know-how with ways companies evaluate success.

Elaine Quilici, our Senior Editor, will contribute a monthly column on Leadership. In the past year, Elaine has taken charge of the PharmExec podcast, as well as writing features and executive profiles. Leadership takes many forms, so this column will be diverse, and it will address, again, the success strategies you can consider for you and your organization.

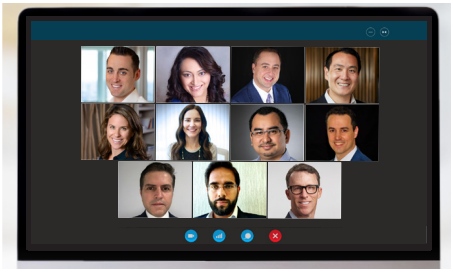
As we move forward with our new design and our new "Master the Science of Success" as our compass, we will continue to bring you the content you've grown to rely on. COVID-19 has impacted many biopharma companies in the short-term, and will continue into the long-term. Our articles will continue to weave lessons learned from the biopharma community as we move onto the next stages of the pandemic. June's annual Pharma 50 issue will also include an article on how large pharma responded to the crisis. Moving into September, the annual Brand Launch issue will tackle how brands were affected overall by the pandemic, whether sales, marketing pivots, or patient access. With Science part of the Success equation, our November Pipeline issue will offer a COVID therapy development section, at which time the landscape will have hopefully dramatically changed.

Please enjoy our new design and branding, and please share your opinions with us. PE

INSIDE THE ISSUE

Executive Q&A

Digital Health



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Pharm Exec Podcasts

Developing a Maternal RSV Vaccine
Kathrin Jansen, head of vaccine R&D at Pfizer, discusses the challenges of creating a new maternal vaccine for respiratory syncytial virus.
bit.ly/3bXa32B

Taking Advantage of Digital Marketing
Chris Paquette of DeepIntent talks about the evolution of digital marketing in pharma and how to approach data and usage in a privacy-first world.
bit.ly/3d61fHN

Twitter Talk

In a pre-COVID-19 study with @IPSOS, a majority of physicians shared they were already starting to adopt digital and connected health tools. @PharmExec shares how they have adapted since.

Sermo, @Sermo
"How Prepared Were Physicians for the COVID-19 Digital Upswing?"
bit.ly/3aWA9I3

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Drive for COVID-19 Therapies Raises Patent and Pricing Issues

Proposals seek to ensure access to any promising treatments

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Fears that biopharmaceutical companies will set too high prices on new therapies and vaccines to protect against the pandemic has spurred proposals to limit patents or set controls on prices of critical medicines. While some members of Congress urge more attention to prices and potential profits on anticipated therapies, international health organizations and national authorities are seeking to ensure access to any promising treatment.

In the US, extensive support for COVID-19 research by the National Institutes of Health, the Department of Defense, and other federal agencies and academic research centers has increased calls for ensuring that future prices consider that significant taxpayer support. Some analysts are highlighting a provision under the Bayh-Dole Act that would enable the federal government to "march in" and seize the patent of a product developed with public research funding if it fails to be made available under "reasonable" terms financially. Similar policies apply to US universities that hold patents on biomedical discoveries from their own labs that advanced due to federal support.

Pharma companies are announcing plans for producing hundreds of millions of doses of any therapy or vaccine found effective against the pandemic, as multiple research programs move from early testing stages to clinical trials. One incentive may be to avoid being unable to supply sufficient quantities of an effective new drug, which could open the door for the federal government to authorize other biopharmaceutical entities to also produce the product.

Meanwhile, international authorities are promoting strategies that support access to new treatments. The World Health Organization (WHO) is considering establishing a voluntary pool to collect patent rights and product testing information that could be shared to develop such products. This mechanism for pooling technologies and information, which was outlined recently by Costa Rican President Carlos Alvarado Quesada, would calculate the cost of clinical trials and other tests, along with public subsidies supporting such efforts, to determine "reasonable and affordable" terms for product pricing to help poorer nations gain access to needed medicines and vaccines.

The existing Medicines Patent Pool (MPP) responded by expanding its mandate to include health technology related to COVID-19. Supported by UNITAID, which funds more than $1 billion in projects to advance global health and biomedical innovation, the MPP has expertise with licensing and IP policies that could advance efforts for ensuring equitable and timely access to drugs and diagnostics for vulnerable populations hit by the pandemic.

These initiatives may gain some industry support as preferable to compulsory licensing actions that have emerged in multiple regions. Canada's COVID-19 Emergency Response Act contains a clause that permits compulsory licensing to address drug shortages during the pandemic. Brazilian lawmakers also have proposed permitting the government to temporarily suspend patents on drugs needed to combat COVID-19 or other similar public health emergency. And a broader "no patent" policy for medicines, diagnostics or vaccines developed to thwart the pandemic was advocated by Doctors Without Borders.

REFORM & TRADE

It remains to be seen if efforts to limit pharma intellectual protections during the pandemic will lead to more targeted patent reform in the US and abroad. Complex IP policies and long exclusivity periods often are blamed for boosting drug prices at home and for delaying access to new biosimilars. Congress has considered legislation challenging brand strategies to limit generic drug competition, but most changes remain on hold.

Meanwhile, patent issues have figured visibly in recent trade negotiations. The U.S.-China trade deal finalized in January includes provisions for the Chinese government to inform pharma firms when a competitor's plan to introduce a generic drug or biosimilar that might infringe on the brand's patent rights. China also says it will extend patent terms in cases where these issues delay marketing approvals. However, companies lost an important protection in the U.S.-Mexico-Canada Agreement negotiated last year when the Trump administration agreed to drop a provision providing 10-year market exclusivity for biologics. PE

A New, Less Friendly Normal Looms for European Drugmakers

Pandemic fallout could spell fundamental business and policy shifts

REFLECTOR
is *Pharmaceutical Executive*'s correspondent in Brussels

While the world faces an unprecedented challenge in the shape of COVID-19, the pharmaceutical industry is facing its own challenge—an unprecedented level of expectation and scrutiny. Why hasn't this huge and hugely profitable industry got any answer to the disease, the world is asking. And if it can't deliver reliable tests and treatments, isn't there something wrong with the system, the world wants to know.

The naivety of the questions may shock. But the widespread public dismay and public disappointment at the current apparent impotence are going to play a powerful role in the inquests on the other side of the pandemic. In Europe, the fallout could mean fundamental shifts both in the pharmaceutical sector and in the policy context.

The stakes are high—and so is the visibility. "Societies will have to live with the virus until a vaccine or treatment is found," stated European Commission President Ursula von der Leyen, as she delivered the EU's proposals for lifting COVID-19 containment measures in mid-April. A compliment to the power of therapeutics, but also turning the attention of the whole of locked-down Europe onto the research community and the healthcare industries. The pressure on the sector has never been so intense.

And this is only the start. Even when treatments or preventive agents are found, any jubilation will rapidly turn to resentment if the prices charged are considered too high, or the patent protection around them limits their availability. Expectations about wide access have been driven by establishment figures as much as by health campaigners. French President Emmanuel Macron insists that medicines and vaccines against the virus must be made available to Africa "without any question of protecting intellectual property or of money." The World Health Organization is exploring the development of a COVID-19 patent pool. António Guterres, the UN secretary general, says a COVID-19 vaccine "must become available and affordable for everyone, everywhere," and "be considered a global public good." The EU's chief diplomat, Spain's Josep Borrell, said: "We must pool resources to produce new treatments and a vaccine, which should be regarded as a global public good." And even the center-right European People's Party group in the European Parliament is urging EU coordination to ensure availability of "hundreds of millions of vaccines."

At the same time, seismic rumblings presage changes in the regulatory and political environment. With cooperation as the new mantra, WHO Europe is urging "strong international cooperation and a coordinated response in the public interest," and EU Health Commissioner Stella Kyriakides has urged G7 health ministers to work together on COVID-19 vaccines development. European authorities are acquiring a new status in centralizing activities hitherto the preserve of national authorities—from observational studies of real-world data for COVID-19 medicines to procurement and stockpiling of therapies, and from investigation of convalescent plasma transfusion to tackling drug shortages. The European Parliament is openly called for EU institutions to be given greater powers to act on health issues, and for repatriation of EU medicines production, and members of the European Parliament are warming to promoting affordable access to medicines, guarantees of public returns on public investment, and compulsory licenses. Even asset managers, pension funds, and insurers are calling for international cooperation within the pharmaceutical industry to combat the virus.

The attention is fuelling earlier criticisms of monopolistic "price gouging"—and Andreas Mundt, head of Germany's powerful antitrust agency, the Kartellamt, has warned: "Companies can work together to get over difficulties caused by COVID-19, but don't you dare go fixing prices." Meanwhile, claims by campaigners multiply that promising treatments in clinical trials could be priced between 30 cents and $3 for a full course.

The biopharmaceutical industry in Europe has constantly reiterated its commitment to collaborative efforts to fight the outbreak. It is likely to find itself, once the outbreak has been successfully fought, working just as hard to defend its former autonomy, as the general determination to make Europe less vulnerable to the next pandemic translates into a new and less friendly normal. A radical review of the political infrastructure and business model for healthcare seems an inevitability for next year—with the prospect of "a new understanding of vaccines and pharmaceuticals as common goods." PE

Competition for Biotech CFOs is Heating Up

Today's go-to options in landing a successful CFO as role evolves

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Finding the right talent to fill leadership positions is never easy. But when the market is flooded with opportunities and the coveted qualifications are specialized, the task becomes a real issue. This is a current concern for many biotech companies looking to fill chief financial officer (CFO) positions. The recent biotech explosion combined with a desired candidate skill set that includes life sciences and capital markets experience has created a demand for a specific type of CFO that simply outstrips the supply.

According to investment banking firm Young & Partners, 2018 was a banner year for initial public offerings (IPOs), with 68 of them worth $7.4 billion. The first three quarters of 2019 followed with 38 IPOs worth $4.3 billion. This indicates a growing number of companies looking to fill CFO positions.

The problem is, traditional CFO skills often fall short when it comes to biotech. Holding the title of CFO at a company that has no earnings but rather spends money to develop potential revenue opportunities is quite different than being a CFO in many other industries. Beyond needing a nontraditional business mind, it requires an understanding of the science involved and an ability to explain that science to others.

"Life sciences is unlike a lot of other industries where you can walk in, figure out the P&L and how the company actually makes money, and communicate that to investors," says Barbara Ryan, founder of Barbara Ryan Advisors and a *Pharm Exec* Editorial Advisory Board member. "At the end of the day, there are just not enough [qualified] people for these opportunities. The question becomes: What can companies do to fill that void?"

There are a variety of approaches organizations can take. One option is to lure a CFO from another successful biotech. Because these CFOs are in demand, however, making an attractive offer can be costly.

A CFO from a less successful biotech might be a better option. A company's disappointing clinical trials or inability to gain more capital could make a CFO eager to find an opportunity with stronger prospects. Of course, the new CFO would need to be introduced to the stakeholders, including investors, analysts, and bankers, which takes time.

In cases where a biotech loses its CFO to another company, it's important to have a strong succession plan so that people below can step in, either temporarily or permanently. This ring of aspiring CFOs can also be tapped for talent, whether they rise from within or outside the company. These first-time CFOs have a history in biotech and have a sense of the job.

Cross-sourcing between biotech and pharma is another possible recruiting route. As pharma has consolidated, aspiring pharma CFOs have had fewer opportunities than in the past. Therefore, these individuals may be more compelled to take a risk to secure the title of CFO. "The risk profiles [of pharma and biotech] are dramatically different, and that can be attractive or unattractive to certain individuals," says Ryan. "Some people actually like the risk and want to take it, and some people shy away from it."

Hiring a CFO from a different industry is another possibility, but it requires an investment in training and education for them to become comfortable enough with the science to communicate about it with investors.

For a candidate well-versed in the capital markets, some companies may look to Wall Street. A pharma or biotech analyst or banker would come with a deep knowledge of the science side and strong relationships with the Street and investors.

"If you hire someone from Wall Street, they may be a better-known entity to your stakeholders, but then you have to train them on the inside stuff," says Ryan. "As first-time CFOs, they will have to learn all of the things they will be responsible for, and having a strong support staff in place can help."

Finally, companies that are private but plan on going public may not want or need a full-time CFO just yet and might consider a virtual CFO company such as Danforth Advisors. Ideal for a transitional situation, these consulting firms provide a CFO who may be working for a handful of companies. After working with a virtual CFO, a company might even pursue that person to join the team full-time when the time comes.

While the competition may be fierce, these myriad options can help ensure an organization hires a successful CFO. All it takes is careful consideration to determine what exactly works best for each individual company. PE

NORM PHILLIPS
Brand Insights Contributor, EVP and Chief Marketing Officer, BioPharm Communications

Brand Insights - Thought Leadership from Marketers I Paid Program

Marketing to HCPs in the New World Order

With sales rep access already in decline, the coronavirus crisis is suddenly thrusting biopharma into an unchartered marketing environment

The current COVID-19 pandemic has taken the world of healthcare provider (HCP) marketing and turned it upside down. Biopharma has had to make instantaneous decisions on how to market in this new environment, who to market to, which tactics to significantly increase, and which tactics to walk away from—all with no historical playbook. We will probably all look back on 2020 as the year that altered the course of pharma marketing more than ever before.

IMPACT ON PERSONAL SELLING AND LIVE EVENTS

Prior to the pandemic, sales rep access to HCPs had already been in decline over the past decade, and now hospital and office visits have been all but eliminated. Sales reps are replacing in-person sales calls with remote details and digital/virtual deliverables to stay engaged with their HCPs. However, HCPs have traditionally not communicated digitally with sales reps to any great extent, so it will be critical for reps to improve their digital communication with HCPs and bring significant clinical value and personalization with their messages.

For now, nearly all upcoming medical conferences, symposia, and dinner meetings have been changed to virtual or cancelled completely. Virtual meetings and webinars are likely to be the way of the future for some time, and biopharma will be searching for new ways to derive the same amount of promotional impact from virtual meetings as from live events.

HCP DIGITAL COMMUNICATION

BioPharm Communications, a leading provider of third-party messaging to HCPs, has seen an increase in unique and total engagement rates with their HCP emails when compared to the pre-COVID-19 timeframe of Feb 10 to March 8. Similar increases have also been noted with Search Ad Clicks and Conversion Rates. It's also important to note that HCP email opt-out rates have declined during the same timeframe.

Until recently, few HCPs have used digital means to communicate with pharma, but there are early indications this is changing rapidly, as HCPs have greatly increased their use of digital resources to obtain drug information traditionally provided by sales reps.

BUDGET ALLOCATION FOR HCP PROMOTION

There is still uncertainty as to whether total promotional spend on HCPs will decrease this year, but it's clear that there has been a significant shift from personal to non-personal promotion. This has been occurring over the past few years as rep access to hospitals and HCP offices has declined, but the shift is rapidly accelerating due to the COVID-19 crisis. Marketers are increasing their spend on digital channels, including email, video, web-based content, banners, social media, and SEO. There has also been a movement from unbranded to branded promotion as marketers want to ensure they are getting maximum value from their promo spend.

KEYS TO SUCCESS WITH NON-PERSONAL PROMOTION TO HCPS

- Provide content to HCPs that is relevant and of high clinical value to cut through the clutter.
- Utilize behavioral data to determine both message and channel affinity of individual HCPs and deploy content accordingly.
- Create personalized journeys to maximize user experience.
- Deliver brand messages through third-party promotional tools that have high familiarity and clinical credibility and, where possible, use opinion-leader derived content.
- Carefully integrate first- and third-party campaigns to avoid viewer overload or unintended "dark periods" with no brand messaging.
- Develop quick-to-market tactics by repurposing existing approved first-party materials in third-party promotional tools with high HCP familiarity and perceived clinical value.
- Develop triggered campaigns providing relevant brand messages based on marketplace events and new access/reimbursement wins, etc.
- Employ advanced technology to improve user experience with virtual/digital engagement. PE

AI: Kickstarting the Race Against COVID-19

Hunting for effective treatments, tools offer support in global fight

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By the time the devastating potential of COVID-19 was really beginning to shake the governments of countries outside China, many international AI drug discovery companies were ramping up efforts to identify existing drugs and new molecules that could be used to treat the virus. At the beginning of February, South Korean company Deargen reported that its deep learning-based model MT-DTI, for example, had revealed the potential of the HIV medication atazanavir to bind and block a prominent protein on the outside of SARS-CoV-2, the virus strain that causes COVID-19. At the same time, Hong Kong-based Insilico Medicine, using AI algorithms to design new molecules that could limit the virus's ability to replicate, published the structures of six potentially effective molecules. In the UK, startup BenevolentAI published a short article in *The Lancet* that highlighted baricitinib (marketed as Olumiant in the US), a once-daily pill developed by Eli Lilly and Incyte and approved for the treatment of rheumatoid arthritis (RA), as the most likely of six compounds that it had identified to potentially block the cellular pathway that allows the coronavirus into cells to make more virus particles.

While worldwide AI efforts to identify treatments are ongoing, BenevolentAI's suggested treatment, baricitinib, moved to the next level on April 11 when Lilly announced that the drug had entered a randomized-controlled trial in COVID-19 patients. "Lilly is moving at top speed and using all available resources to help fight this pandemic," commented Daniel Skovronsky, Lilly's chief scientific officer. Results of randomized-controlled trials of baricitinib for the treatment of COVID-19 in the US, Canada, Denmark, and Spain are expected in the next few months.

BenevolentAI's focus is usually on identifying potential new therapies, but the COVID-19 outbreak saw it concentrate on established medicines that can be quickly moved into clinical trials, Peter Richardson, the company's vice president of pharmacology, told *Pharm Exec*. He added that "life science and technology companies have a duty to mobilize resources for the public good in the current global health emergency." With powerful platforms at their disposal, AI companies are able to act with an urgency that leaves other drug discovery companies looking inert. It took around three days, for example, for BenevolentAI to identify baricitinib as a potential COVID-19 treatment option.

The company set up a team to deploy its tools, models, and algorithms to explore the biomedical "Knowledge Graph" that it has curated over the last five years, and which draws on "vast quantities of mined and inferred biomedical data," to assess treatment options, Richardson explains. Data was pulled from various structured and unstructured biomedical sources, curated, and then fed into the Knowledge Graph, which further contextualized the relevant omics data, clinical data, and scientific literature. With the Knowledge Graph "rich in mammalian biology," BenevolentAI's scientists looked for ways to inhibit the cellular process that the coronavirus uses to infect human cells—the process of endocytosis, whereby the virus attaches to the surface of a cell and is then absorbed inside—rather than focus on drugs that could inhibit the virus directly. Although baricitinib is currently approved for use as an RA treatment, BenevolentAI's studies suggest that it could slow down endocytosis and reduce the ability of the virus to infect lung cells.

Of course, at this point in the crisis trajectory, AI's power is being harnessed to crunch the data and alert drug companies and healthcare systems to potential treatments, rather than being posited as a "solution" to the overall problem. Indeed, in its *Lancet* paper, BenevolentAI cautioned that its findings should not be taken as medical advice about COVID-19 treatment or prevention, but were offered "to assist in the global response" to the virus. It now of course falls on time-honored clinical research methods to establish the safety and efficacy of any particular drug in treating COVID-19 patients (it has been pointed out that baricitinib already carries a warning that the drug could actually make infections worse). But whether or not the new trials achieve the desired results, without AI, says Richardson, we wouldn't know how long it would have taken to identify baricitinib as a contender in the battle against the virus (or, indeed, if it would've been identified at all). One thing we can be sure of is that AI "significantly sped up the process." PE

BARBARA RYAN
is Founder, Barbara Ryan Advisors, and a member of *Pharm Exec*'s Editorial Advisory Board

Biotech in the Age of COVID: The Pain and the Gain

Rocked by pandemic, can companies protect their bottom line?

When I discussed writing a monthly finance column for *Pharmaceutical Executive* with Editorial Director Lisa Henderson a few months ago, I never imagined that my first installment would focus on a once-in-a-100-year storm. COVID-19 dominates all things around the globe, including normally recession-resilient biotech. Leaders in the space have been forced to examine their portfolios under a critical eye, assessing cash burn, access to clinical trial networks, and viability post-COVID-19.

In five short (or long) weeks, the pandemic crashed the economy, US unemployment exceeded 22 million, and retail sales have shown the greatest declines on record. Overnight, we will be living through the largest drop in GDP in history and the biggest increase in unemployment ever. The effects of these steep and rapid shocks will echo well into the future and beyond the near-term period of social distancing that triggered them.

Markets have plunged, interest rates are nearly zero, and Amazon, Netflix, and Zoom are among the "go-to" stocks as the obvious beneficiaries of quarantine.

THE GAIN

The world is counting on biopharma to come up with the therapies and vaccines key to ending this pandemic, saving lives, and reopening economies. First responders are today's heroes, risking their lives on the front lines of a system ill-prepared to protect them and to manage the overflow of COVID-19 patients.

No surprise, biopharma stocks have outperformed the markets due to the prospects for therapies and vaccines, as well as their defensive nature, which make the industry a classic outperformer in an economic downturn. As I write this, the premarkets are soaring on early reports from STAT News of encouraging preliminary results for Gilead's remdesivir against COVID-19. The Nasdaq Biotech ETF is currently trading above its late 2019 and early 2020 highs. In theory, the group has more room to run.

Last month, the NIH announced it was launching a sweeping public-private partnership between federal researchers and 16 big pharma companies called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). The collaboration aims to standardize and prioritize research into drugs and vaccines that have high near-term potential.

THE PAIN

COVID-19, however, will also drive sustained challenges for the biotech industry and, for some companies, threaten their existence. Most development-stage biotechs lack revenues or earnings to fund their businesses, but instead are serial capital raisers highly dependent on capital markets to bankroll their pipelines. Clinical data is often the currency required to tap the markets and raise necessary funds, but new clinical trials and almost everything non-urgent, non-COVID-related is currently shut down or on hold.

Biotechs must evaluate how to extend their cash runways and act with urgency to reprioritize programs, ring-fence critical efforts, and deemphasize, drop, or delay others. Venture debt should be considered where equity financing would be highly dilutive, if even available. "We view the current dislocation as an opportunity to invest in and support some of the best management teams and companies," said Parag Shah, CEO and founding managing director of K2 HealthVentures. Partnering may create options for biotechs as well. Large biopharmas with lots of cash will likely seek to take advantage of the current dislocation to enhance their portfolios.

During and post-pandemic, it is absolutely critical that companies control what they can with intent and precision. That means, along with strategies to extend cash runways, asking the following:

- Is your portfolio still relevant and viable in this new world?
- Does your portfolio have access to a clinical trial network? Many of these will be constrained for a protracted period of time. Those targeting high unmet need, such as drugs/vaccines, will be the first brought back online. Are you one of them?

The bottom line is that programs with questionable value before COVID-19 should likely be repurposed, if possible, or dropped now. An explicit strategic plan is required, one which spans the spectrum and implications of a modest or moderate delay, or an extended delay, with scenario planning around each.

In the words of Maya Angelou, "Hope for the best, prepare for the worst, and be unsurprised by anything in between." PE

Biopharma Sustainability Considered Essential

The commercial and social value of non-financial performance

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A wonderful aspect of biopharma is the confluence of medicine, science, engineering, and business, all working together to advance a deeply shared mission: healthier lives, improving healthcare, and alleviation of suffering. It's been a privilege working with the extraordinary diversity of people that it takes to make our industry work.

My goal in this column is to explore the idea of sustainability in biopharma. As I think of it, "sustainability" refers to a company's non-financial strategy and performance, the elements needed, in addition to a profitable business model, to drive long-term value for all stakeholders. These elements of sustainable business performance are often categorized into Environmental, Social, and Governance (ESG) topics. Sustainability is a perspective that integrates these different elements, one that has grown up in response to a wide range of stakeholder and regulatory concerns, and that is becoming an essential part of long-term business strategy.

The idea of sustainability has been sweeping through the international business world recently, as more and more research shows that effectively managing material ESG challenges also delivers above-average long-term financial returns. (A good point of entry here is *The Comprehensive Case for Business Sustainability* by Tensie Whelan and Carly Fink, *Harvard Business Review,* Oct. 21, 2016. *Sustainability as BlackRock's new Standard for Investing* is the most recent statement on this front, from Larry Fink, CEO of BlackRock).

So, what does "sustainability" mean specifically for biopharma? We're not major emitters of CO2 like transportation, and we don't damage the environment by our operations like resource extractors. Why is this idea essential to our long-term success?

The answer starts with identifying the specific ESG topics that matter most for biopharma companies, and thinking about how they relate to the core mission of our industry. Over the past two years I've helped facilitate a Biopharma Investor ESG Communications Initiative, which brought biopharma and investor representatives together in a collaborative process aimed at improving communications between them. The two groups converged on a shared pool of high-priority ESG topics for the sector. The topics are not ranked, as specific priorities vary widely from one company to another, reflecting different therapeutic specialties and business strategies. The consensus, however, is that all biopharmas should at least address this core set of topics when communicating with investors. The topics include access to healthcare and medicine pricing; business ethics, integrity, and compliance; climate change; clinical trial practices; ESG governance; environmental impacts; human capital management; innovation in therapeutics, diagnostics, and business models; pharmaceuticals in the environment and anti-microbial resistance; product quality and patient safety; risk and crisis management; and supply chain management.

How can these ESG topics help frame our thinking about a challenge like the COVID-19 pandemic, for instance? So far, there's been a huge emphasis on innovation, both in terms of new diagnostics, treatments, and vaccines, and on collaborations that can accelerate R&D or production scale-up. But we need to address a much wider scope—almost every topic has a bearing on our response, and failing to address any of them will diminish the outcome of our efforts and the public perception of our industry for years to come. Take, for example, risk and crisis management. There are already indications that companies with better ESG performance are also doing better handling the crisis. An effective governance model for non-financial performance is the basis for an effective and coordinated response.

Access to healthcare and medicine pricing will have their turn on the frontlines, too, hopefully sooner rather than later. There will be huge pressures to allow early access, and to scale-up not just manufacturing but also equitable global distribution and delivery, while keeping prices low.

There's a concept called the "social license to operate," which refers to the broad social stance on the value of biopharma, and the laws, regulations, and social conventions that allow us to operate profitable research-based businesses on a sustainable long-term basis. What is the social value we'll deliver over the next months and years? Will the outcome be a jumble of high-priced treatments available only in developed markets, or will it be an improved global healthcare system that adds to our resilience and helps put our society back on a healthy footing? PE

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Brand Insights - Thought Leadership Paid Program

The Power of Online Medical Education in Treating Breast Cancer

Staying current with new trends through evidence-based education is critical for oncology care teams

Breast cancer is the most common cancer in women, and accounts for approximately 25% of all cancers in women worldwide. In addition, it is the most commonly diagnosed cancer among women in 140 out of 184 countries worldwide.[1] There are several different subtypes of breast cancer—hormone-receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-positive, triple-negative, and BRCA-mutated—each with different frequencies, outcomes, and precision medicines for treatment.

With the treatment landscape for each subtype rapidly evolving and the high incidence of breast cancer in the population, it is critical that oncologists stay current with the latest scientific understanding of how to screen for and manage the disease when found. Continuing medical education (CME) plays a key role in helping oncologists and other members of the oncology care team stay current with the latest developments in breast cancer by offering evidence-based education beyond what they have learned in medical school and residency.

Online CME is a demonstrably effective option[2] for preparing oncologists to integrate therapeutic discoveries into clinical practice—offering high-value education rooted in science in formats that match oncologists' learning preferences. Some of the therapies oncologists are interested in learning about include cyclin-dependent kinase (CDK4/6) inhibitors, HER2-targeted therapies, poly(ADP-ribose) polymerase (PARP) inhibitors, phosphoinositide 3-kinase (PI3K) inhibitors, and immunotherapy.[3]

"Medical oncology online CME education provides an invaluable resource for healthcare providers, particularly oncologists, with the necessary, timely update in clinical care. This is particularly relevant in breast cancer due to the explosion of new data, recommendations, and FDA-approved agents," said Massimo Cristofanilli, MD, FACP, professor of medicine and associate director of translational research at the Robert H Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine; president of the International Society of Liquid Biopsy (ISLB); and president of the Inflammatory Breast Cancer International Consortium (IBC-IC). "Moreover, we are facing such challenging times due to the current COVID-19 pandemic that we have to start rethinking our current educational and communication models. It is likely that in the future we will see smaller and less frequent conferences and more incorporation of online educational tools."

Each education activity is developed by faculty who are leading oncologists, who work together with Medscape Oncology's medical education directors, clinical strategists, and program managers to deliver high-quality learning solutions designed to accomplish specific educational objectives.

"The rapidly evolving cancer treatment landscape has created a dilemma for practitioners. It is not only essential for oncologists to stay current, but at the same time, more challenging to do so. With the FDA approving cancer therapies and expanding indications at a record pace, the utility of somatic molecular analyses increasing, and increased precision of newly approved drugs, staying current has quickly become a challenge for oncologists," said Gregory A. Vidal, MD, PhD, lead of Breast Research, West Cancer; associate director of Breast Division, West Cancer; and assistant professor at UTHSC. "This is particularly challenging for medical oncologists who practice in the community setting. In breast cancer, we continue to be a leader in the precision approach to treatment. Online CME portals, like Medscape, now play an increasingly integral role in educating and equipping oncologists with the most current data and treatment practices, which allows them to continue to provide the best care to their breast cancer patients."

As oncologists' understanding of breast cancer evolves, clinician education will continue to be of utmost importance, with CME playing a key role. PE

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1. Breast Cancer Research Foundation
2. Medscape internal data, 2019.
3. Medscape Breast Cancer Survey of Oncologists, January 2020, n = 50

2020 Emerging Pharma Leaders

Pharm Exec presents the diverse stories of 11 rising biopharma managers—and how each is poised to help navigate the industry's march into a challenging future

(In alphabetical order)

** From a pool of over 100 nominations, these final selections were judged in a blinded process by four members of Pharm Exec's Editorial Advisory Board.*

A Brand Exceller

Lauren D'Angelo, Vice President of Marketing, Urovant Sciences

By Miranda Schmalfuhs

In 2002, at a young age and early in her career, Lauren D'Angelo was just starting out as a sales representative for AstraZeneca when she quickly found a niche in analyzing numbers. "I wish I could say that I had a deliberate plan in joining the industry, but I really didn't know where it could lead," says D'Angelo. "I was told by many people that because of my outgoing personality, I should try pharmaceutical sales. Little did I know at the time, I was embarking on this amazing journey in an incredible industry that has challenged me and allowed me to grow in multiple ways."

D'Angelo has always been analytical, graduating from Florida State University with degrees in computer science and finance. Her background in sales at AZ, coupled with the available data and tools, allowed her to identify key opportunities for the company and deliver strong sales results. This prompted her to quickly move into the role of business analyst where she helped sales directors identify regional and local opportunities utilizing data, and supported several AZ product launches. Success in that role led to D'Angelo becoming the youngest and one of only two female district sales managers in the company at the time—at just 25 years old.

> **"I enjoy the entrepreneurial spirit and the fewer layers of key decision-making"**

As a district sales manager, she oversaw 12 sales reps and fell in love with leadership. "I'm passionate about developing and helping others achieve their goals, and I genuinely care about the people I lead and my colleagues that I work with," says D'Angelo. "Being able to contribute in some way to their success makes the time and effort worthwhile."

It wasn't until a few years later when D'Angelo was asked to move to AZ's headquarters to join the Crestor brand team that she would discover her passion for marketing. "I love building strategy, developing a deep understanding of what our customers really need, and, most importantly, figuring out how to connect with them to create a unique customer experience," says D'Angelo, who has helped launch 10 products in her career, six of which have become blockbuster brands.

After a decade with AZ, Genentech called, and she found herself moving to California to lead the launch of a hopeful blockbuster. "After almost three years building the brand and preparing for launch, the drug failed in Phase III trials," says D'Angelo. "It was at that time I decided that I wanted to do something different. After spending almost 13 years working in big pharma, I really wanted to try something smaller."

She ended up joining San Francisco-based startup Medivation as its marketing director, oncology and urology, helping launch Xtandi for prostate cancer. D'Angelo discovered that she thrived in a small company environment (Medivation would later be acquired by Pfizer). "I really enjoy the entrepreneurial spirit, the larger scope of roles, and the fewer layers of key decision-making."

In the fall of 2015, D'Angelo moved to Orange County to join Avanir Pharmaceuticals as its marketing head. She rebuilt the team, hiring eight new people in one year. "I have a real passion for identifying, hiring, and developing talent."

Today, as VP of marketing at Urovant Sciences—hired by the former CEO of Avanir as employee number three—D'Angelo says she has enjoyed a true startup experience, watching the company grow to 70 people. "We started with nothing. We had no data, no people, and no knowledge of the market," she says. "I've spent the last two and a half years building out the commercial team, the infrastructure, and collecting key insights to successfully launch our flagship product."

D'Angelo considers herself fortunate for the many career opportunities she's had—experiences that have challenged her and helped her grow as a leader. "No question my goal is to lead a commercial organization one day. But I want it to be with the right company, with the right people, and for the right product," says D'Angelo. "What matters to me right now is the who and the what, not necessarily the title. It's about focusing on the now and being really selective about what's next."

The married mother of a two-year-old boy, with a baby girl on the way, D'Angelo credits her work ethic to her father, who was an entrepreneur. "My dad always loved his job; he worked all hours of the day. I think that's why I've been successful," she says. "When you genuinely love what you do, and you're passionate about it, how can you not be?" PE

Driven By Purpose

Manuel P. Duenas, VP, Global Market Access and Pricing, Atara Biotherapeutics

By Michael Christel

Manny Duenas is a dreamer at his core—nicknamed The Reverend by colleagues for his fiery defense of the mission and motivation of the life sciences industry. In conversation, the executive's orientation often leans toward the philosophical, including thoughtful takes on the human condition, particularly the influence, he believes, every experience—big or small, success or failure—can play in creating and shaping a high-impact career.

"We all have something unique in our backgrounds that will enable us to deliver something unique to the world," says Duenas, currently vice president, global market access and pricing at Atara Biotherapeutics, a San Francisco-based biotechnology company focused on leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop treatments for patients with serious illnesses, including solid tumors, hematologic cancers and autoimmune disease, including multiple sclerosis.

Not yet 40, Duenas's career has progressed rapidly, spanning across industry, management consulting, and venture capital. He's helped spearhead the launch of breakthrough therapies in oncology and HIV, built global access and pricing functions at two large pharmas, and has been a founding commercial leader of two emerging biotechs. At just 25, Duenas was also a founding consultant at PriceSpective, a then-fledgling market access and pricing consultancy, which later would be acquired by the CRO Icon, becoming one of the top pricing/access/commercialization strategy outfits in the biopharma space.

> ***That's the human condition—to be broken. And it's also the human condition to be fixed***

Along the way, Duenas has followed that seemingly simple adage of letting life experience fuel purpose. But, as the married father of one knows all too well, there's often little control over choosing those experiences—and no one personal journey is the same. A native of Guam, Duenas grew up poor, his family part of the Chamorro community, a proud people known "to live interdependently and interact reciprocally." After heading to the states and getting a bachelor's degree in finance and management at the University of Portland, followed by a one-year Fulbright fellowship in Germany, those cultural values aided Duenas in absorbing a series of family health issues and tragedies in the years ahead, culminating in losing his 29-year-old brother just last year.

"You can either sit in the corner and say, woe is me, or you can go out and say, hey, we are uniquely positioned as an industry, as biotechnology to address the absolute worst in the world," says Duenas, who has long dealt with his own chronic, debilitating condition that until recently had him living with what he says was a 30% quality of life. "You talk coronavirus, Ebola, HIV/AIDS, Alzheimer's, autism, diabetes; all of these things are still there. That's the human condition—to be broken. And it's also the human condition to be fixed."

To that end, Duenas's career purpose, he says, has always tied back to one central theme: championing the value of innovative medicines. In recent years, those have included the likes of curative-type specialty drugs, cell and gene therapies, and immunotherapies. Duenas believes the pricing debate, when played out for public and political consumption, has been influenced heavily by a misinformed narrative that does not account for the balance of innovation, reduced cost to the healthcare system, and impact on patient lives throughout the lifetime of the patient.

"In my opinion, you need to measure the value of innovation over generations," Duenas told *Pharm Exec*. "All the people who will benefit and could benefit not only from that specific innovation, but from those innovations that you will enable."

Duenas joined Gilead Sciences in 2013 to help usher its entrance into oncology, enabling the launch of Zydelig, a first-in-class PI3 kinase inhibitor for chronic lymphocytic leukemia (the drug was named ASCO's "Advance of the Year" in 2014). Duenas would later help launch Gilead HIV treatments Odefsey and Biktarvy, the latter with anticipated annual peak sales of $7 billion.

Besides his lens on pricing and value at Gilead, where he

was also involved in the company's 2017 acquisition of Kite Pharma and its CAR-T lymphoma drug Yescarta (priced at $373,000 per dose; one recent study of real-world Medicare claims data suggests that CAR-T therapy may be cost effective by lowering other illness-related expenses), Duenas had stints at Biogen and Genentech in the late 2000s, serving in US commercial operations at each. A few years earlier, before transitioning to industry, Duenas recalls his "baptism-by-consulting fire" at PriceSpective, where, pitching commercialization strategy for targeted therapy blockbusters such as Avastin and Rituxan he presented to Roche executives at the pharma giant's Basel headquarters.

Any hopes of boosting the industry's image, Duenas says, will first require "a real dialogue based on data and facts coming from a place of how best to serve patients and positively impact human life not only now but over time." Duenas attributes what he considers his proudest career accomplishment to this effort. In 2016, he sponsored a modeling study with Avenir Health to quantify the societal benefits of antiretroviral therapy for HIV, where prices have long sparked concern, particularly in the US. The results, published in *Health Affairs* last year, revealed significant value gains during the 1995-2015 period, with 9.5 million deaths and nearly eight million new HIV infections averted and $1 trillion in global economic benefits. The benefit to society across all regions outweighed costs 3.5:1.

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The findings, Duenas says, also identified existing treatment gaps, driving home the importance of Gilead and others continuing to invest in the communities most affected by HIV and boost direct-to-consumer education. Revisiting an earlier theme, Duenas dedicated the article and much of his time with Gilead in honor of his uncle who passed away from AIDS in 2008 after deciding to stop taking his life-saving antiretroviral therapy.

Duenas's interest in the marriage of data and value took root during his first job in the field, a position with @Futures, LLC, a small pharmaceutical marketing agency in Philadelphia. "They were doing some pretty interesting things with advanced analytics and I fell in love with that piece of it," he says, pointing to methods such as discrete-choice modeling, forecasting, Monte Carlo simulations, and other advanced statistics.

Duenas would soon transition into strategy and eventually building commercial infrastructures for hopeful product launches, but those early skills have served him well at each stop, including his current one. Joining Atara in 2018, Duenas, along with his team, has helped to build the company's full commercial capabilities, including global marketing, market access, analytics, and operations—to support what could be the launch of the first-ever allogenic T-cell immunotherapy for an ultra-rare cancer. Atara's lead pipeline candidate is tabelecleucel, currently in Phase III development for patients with relapsed/refractory Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+PTLD).

Duenas spends much of his time contemplating value drivers for tabelecleucel, a process that he says is vastly different from the targeted treatment models he's studied in the past. EBV+PTLD is an acutely life-threatening condition, and patients may present shortly after transplantation or years later (Atara estimates there are several hundred patients in the US each year). Even among ultra-rare disorders, EBV+PTLD is unique in that these patients have to be identified and administered the therapy very quickly.

Solving and accounting for these types of complexities is a reminder of the inherent risks involved in developing and commercializing novel drugs. Duenas says he draws motivation from his career setbacks (including a negative FDA decision on VEGF inhibitor tivozanib for kidney cancer while with AVEO Oncology; the drug did win European approval in 2017)—or "the many times I was told no"—as much as the successes when advising people today. He encourages his team members at Atara to embrace risk and push themselves toward ambitious goals.

"You have to provide opportunities that stretch people into new areas. That funnels down to this philosophy—there's no such thing as failure as long as you keep moving forward and apply your learnings," says Duenas, who earned an MBA from MIT Sloan School of Management in 2010. He envisions himself involved in entrepreneurship or transitioning to the C-suite in the next five to 10 years. "Not everything that we come up with will be right at the start. In fact, we might need to pivot the idea five, 10, 25 times until we get it right. But it's that mental model of if you sit on the sidelines, there's no chance of winning the game; but when you do try, you can succeed." PE

The Holistic View

Sapan Gandhi, Associate Director, Commercial Strategy and Business Development, Cipla

By Julian Upton

From an early age, Sapan Gandhi had his journey to the business side of the life sciences industry mapped out pretty clearly. He studied Biotechnology Engineering at Amity University in India, then earned a postgraduate diploma in Brand Management and Marketing. Gandhi moved smoothly into his first roles as a business development executive at iLife Discoveries and territory business manager at Eli Lilly. Encouraged by his boss, Vinod Nair (then National Sales Manager for Eli Lilly India Oncology), he then completed an MBA at the School of Inspired Leadership in Guragon. Upon joining Cipla as a management trainee in June 2013, however, he was soon faced with a more unexpected path—a chance to move sideways into operations and become the company's manager of supply chain and logistics in Europe.

"Being in operations was something I didn't know I wanted," says Gandhi. And, initially, he was "a bit scared." He had some theoretical knowledge of how the supply chain worked, but no practical knowledge. Still, he didn't hesitate in accepting the offer and moving to Belgium for the role. "I knew it wouldn't be easy, but I was 30, 31 years of age; it was the right time to take a risk, to experiment, to try something new. And I knew it would be helpful in building my career."

Gandhi soon got the hang of operations and started to make his mark as supply chain and logistics manager. He quickly set up efficient processes for negotiating objectively with vendors, for capability building, and for knowledge transfer among the operations team. Gandhi established and managed the Central European distribution Center (CDC) for Cipla Europe and incorporated lean methodology into its inbound logistics. And by implementing continuous improvements in the supply chain process, he targeted key cost-saving opportunities. Ultimately, with the support of a cross-functional team, Gandhi helped to make the company "a multi-million-dollar saving." Of all his career highlights, he says he is probably most proud of what he achieved during this time in operations, in which he effectively set up Cipla's entire supply chain structure in Europe.

> ***"I knew it wouldn't be easy, but I was 30, 31 years of age; it was the right time to take a risk, to experiment, to try something new"***

In 2019, Gandhi moved back to the commercial side of the business, when he was tasked with launching in Europe a value-added generic version of the fixed dose combination of tenofovir/lamivudine for the treatment of HIV. Ironically, given that operations had not been part of his initial career vision, Gandhi would now have to prove that he could be as successful outside of operations. He quickly "developed an advanced level knowledge of the HIV therapy and business," met with key opinion leaders, and worked with the medical affairs and marketing teams to create a scientific case to get the new product included in the European guidelines.

"This helped Cipla to get access to various markets and provide alternative and affordable anti-HIV medicines to many patients," says Gandhi. His efforts helped to complete in 10 months a process that usually takes 18 months.

More responsibility followed. By January this year, Gandhi had become Cipla's associate director, commercial strategy and business development, based in London. He effectively balances three roles within this remit. He is Cipla's country manager for Norway, where he is working to strengthen the company's portfolio. He is also tasked with building Cipla's anti-HIV presence in Europe over the next five to 10 years, to increase visibility and grow Cipla "into a very HIV-focused company in Europe." And Gandhi is looking after the company's OTC business in the UK. "We're working on some very interesting projects there," he says, "such as converting some prescription medicines to OTC medicines, which is a very complex process."

Gandhi seems in no way intimidated by juggling the demands of these different roles. "All the projects I'm working on are at a nascent stage," he says; "this makes them interesting and challenging for me." Gandhi notes that he was well aware when he joined Cipla as a management trainee that he would

be rotated around different functions and exposed to new processes on a regular basis. Indeed, he's glad that "the company kept its promise on that." He has always felt well supported at Cipla, noting particularly the help of his current boss, Anchal Sultania, head of business, Cipla Europe, as well as Christos Kartalis, Cipla's former CEO of Europe and emerging markets, and Anant Atal, former Chief of Staff and Investor relations, in steering his career journey.

Gandhi continues to thrive on new experiences and opportunities for knowledge, even outside work. He is an enthusiastic quiz-taker, for example. In 2013, his team came in fifth out of 200 teams in the city finals of the Tata Crucible Campus Business Quiz in New Delhi, which was broadcast on TV.

Having racked up an enviable list of accomplishments in just over 10 years in the industry, Gandhi's goal for the near future is to work in a position "that offers a good combination of both commercial and operations."

He's keen to take responsibility for the numbers and also for the supply chain or production side, "and help the company grow the next level."

Given Gandhi's adaptability and commitment to getting results, he looks like the right candidate for such a holistic role. PE

Grace Under Pressure

Anita Gupta, Senior Vice President of Medical Strategy and Government Affairs, Heron Therapeutics

By Elaine Quilici

If there's a crisis at hand, Dr. Anita Gupta, senior vice president of medical strategy and government affairs at Heron Therapeutics, is someone we can learn from. She continues to play an integral role in battling the nation's opioid crisis and is currently engaging with leaders on ways to fight COVID-19. Her diverse background in pharmacy, pain medicine, and public policy has placed her in a unique position to bring important ideas to fruition.

After receiving her PharmD from Rutgers University, the New Jersey native briefly worked at Akzo Nobel's Organon before attending medical school at the University of Medicine and Dentistry of New Jersey. She subsequently practiced anesthesiology and pain medicine for more than 10 years, including at the University of Pennsylvania and later Hahnemann University Hospital in Philadelphia. She is currently an appointed member of both the National Academies of Sciences' Global Forum and the National Quality Forum's Leadership Consortium focusing on health policy initiatives, and served on the Anesthetic and Analgesic Drug Products Advisory Committee at FDA.

It was during these experiences that Gupta became an international figure in pain management as a frontline leader of the opioid crisis. When the crisis hit, Gupta's colleagues turned to her as a champion of, and advocate for, patients. She soon became the go-to expert. "I saw I was having an impact but not impact enough. I had a passion to do more. I began to learn how the work I was doing at the FDA tied together with innovation and could drive global impact."

At that point, Gupta was recruited by Heron Therapeutics, a company with a focus on the opioid crisis and oncology. Heron's mission seemed perfectly aligned with her background—making global impact on the opioid crisis, pain, and palliative care. Gupta realized that her earlier work as a PharmD could help drive a successful career in industry.

"Heron has done a lot of work on the opioid crisis and was the first company to develop a non-opioid investigational product that received all accelerated pathway approvals—from fast track to breakthrough designation and priority review. I'm thrilled to work not only on the opioid crisis but [to gain] experience on leading national emergencies."

Dealing with the opioid crisis from various perspectives along the way has been extremely satisfying for Gupta. "It's been a phenomenal journey viewing it from the pharmacist's side when Oxycontin was being developed, to a clinical setting where it was prescribed, then seeing problems turn into serious policy issues, and now coming to the innovation space where we're working to find a breakthrough therapeutic solution," she says. "I've been grateful to be part of it."

One of her proudest moments was being one of the first women anesthesiologists to lead the expansion of naloxone as an opioid overdose antidote through the American Society of Anesthesiologists.

As part of her opioid crisis work, Gupta has worked with many senior government officials in the Centers for Medicare & Medicaid Services, Health and Human Services, FDA, and the White

House. Those relationships led to her being asked to work on the current pandemic. "It's been a great opportunity to help lead and better our understanding of how to handle national emergencies, how to address drug-related issues in governance, in companies, and to be agile when we're dealing with serious public health issues and drug development," says Gupta.

The big and small relationships Gupta has made along the way haven't just provided her with professional advice, guidance, and confidence; they also have yielded benefits to society at large. "I wouldn't be where I am without personal connections and mentoring," she says. "I sometimes look at the relationships I've made and say, 'I'm glad we're friends, because those connections have [contributed to creating] initiatives that have helped.'"

Though people often see her as a leader, Gupta doesn't mind sharing the spotlight. As a mentor herself, she has learned that people often want to lead; they just need to be given encouragement and opportunity. "People don't always know they are [leaders], but identifying them as a leader, giving them course, direction, purpose, and guardrails, and letting them take it from there is important," says Gupta. "Giving people the power to believe in themselves and that the work they're doing is important. As executive leaders, we need to make sure they have a purpose and patient-centric mission."

> ***People don't always know they are [leaders], but identifying them as a leader, giving them direction, purpose, and guardrails is important***

As Gupta advances her career as an executive leader, she plans to continue her dedication to developing global solutions, either in pharmaceuticals or medical devices. In that future, Gupta would love to see increased purpose in the industry. She hopes more people who are public health focused and have scientific know-how will commit their energy to the pharma industry. "We need people on both sides to make a difference and drive change," she says.

Another way to effect change is listening to patients. Gupta learned this in 2017, when she was diagnosed and later cured of a rare disease. That process inspired her to become an advocate for patients whose voices are often unheard. She works closely with the Milken Institute and FDA on elevating the patient's voice while working with drug development. She is also on the board of directors of HealthyWomen, serving communities where women's voices may be minimized.

Gupta is based in California, where she enjoys spending time with family. "I learned a long time ago that work is not everything," she says. "As much as it's important, I believe family and service to humanity come first. I've tried to combine and align that with my work. I tell my kids what I do, and they try to embody that in their life, too." PE

From Vision to Action

David K. Lee, CEO, Servier Pharmaceuticals

By Julian Upton

David K. Lee was still in high school when his mother was diagnosed with metastatic breast cancer. He says he had to grow up fast, help to raise his two younger siblings, and get his driver's license early so he could take his mother to chemotherapy appointments. The experience fueled his desire to "make a big impact on the world" in life sciences. He went on to study biochemistry at Harvard, where he loved the bench work, but on going into medicine it became evident to Lee that "this wasn't quite the way to make the impact I wanted." He was working in a hospital when he decided to go back to Harvard Business School and study for an MBA.

Lee then joined a life sciences consulting firm where he worked with some of the top pharma companies on everything from due diligence to mergers and acquisitions. He ended up joining one of his clients, Novartis, which, he says, "was a fast-moving company, especially for people that wanted to move fast." There, Lee worked in a number of different positions, from clinical development to marketing and market access.

Looking back, one role stands out in particular. During the H7N9 avian influenza outbreak of 2013, Lee was responsible for a cross-functional Novartis team that went from initial cases of patient diagnosis to patient recruitment, vaccination, and final

clinical study results in just eight months. "It was the fastest clinical trial in the history of that of division," he says. "I had a tracker that showed patients being diagnosed on a daily basis; seeing how people's lives were being impacted was hugely motivating for the entire team." While H7N9 was deadlier than COVID-19, Lee's recollections are ominous.

"Every day that you delayed, every day you didn't push forward on the vaccine, people were dying," he says. He also remembers sharply how difficult it was "to have the conversation with government officials on how important it is to be ready for pandemics." He explains, "I don't think you can overprepare. If we had invested the billions that we needed back then, we would not be where we are today." Unfortunately, Lee is not hopeful that "our mindset will be completely changed when the COVID-19 pandemic is over," as we often move on and forget to reflect on the lessons learned.

> ***Once you start delivering great results, you start to build a reputation that will follow you for the rest of your career***

When his Novartis unit was sold to GSK, Lee followed one of his mentors into the oncology business, where he helped to build a company largely focused on hemophilia and immunology that was spun off as Baxalta. When Baxalta was bought by Shire, Lee remained as global head of oncology and was asked also to take on the global genetic disease franchise, which included most of the Shire rare disease products. Following a strategic review at Shire in 2018, it was determined that oncology was non-core to the company, so it was down to Lee to find a home for Shire's oncology assets. In 2018, he brokered a $2.4 billion deal to bring Shire's oncology portfolio to Servier Group and create Servier Pharmaceuticals in the US. Still under 40 years old, Lee was instilled as CEO.

Servier asked Lee to build a full commercial and development entity in the US (the group, despite being present in 149 other countries, had never had a presence there) and build the global oncology portfolio. Eighteen months in, Servier Pharmaceuticals houses therapies such as Oncaspar, a leading first-line treatment regimen for acute lymphoblastic leukemia, and the recently launched Asparlas, which also treats pediatric and young adult patients. Lee found himself in the enviable position of having the freedom to create his own "biotech," while enjoying full parent company support.

"I think we have the best of both worlds," he says. "We're fully cross-functional, with local R&D, and we can be fast and nimble and flexible as a biotech. But we also have the stability of a larger parent company that is financially very stable, that can reinvest a lot in research, and has a lot of fire power."

Lee started Servier Pharmaceuticals "from scratch." It is headquartered in Boston and now has more than 100 employees. It has been an opportunity to build "something that I could truly own," he says, and bring in the people he wants. To achieve this, Lee has been helped by the growing industry recognition of his achievements and leadership.

"I've always insisted on the three Rs: results, reputation, relationships," he says. "With results, you must deliver what you say you're going to deliver, or, even better, overdeliver. With relationships, most of the people I've brought in have worked with me in the past. Relationships are the key that will unlock doors. And reputation—once you start delivering great results, you start to build a reputation that will follow you for the rest of your career. Of those who have come to work with me who didn't know me previously, many knew of my reputation."

Lee continues to put the "three Rs" into practice as he pushes Servier Pharmaceuticals forward. He's busy strengthening the company's relationships and establishing its reputation in the US. Lee's forged "a stellar partnership network," nurturing relationships with academia, venture capitalists, biopharma peers, advocates, and others, and he's architected a "strong presence" at the J.P. Morgan Healthcare Conference and other industry events.

And, of course, he continues to chase results. Lee wants to establish Servier Pharmaceuticals as an oncology leader, growing the company both organically and inorganically (it has the financial clout to pursue M&As). Moreover, he wants it to be "a new kind of pharma company." Globally, Servier is governed by a nonprofit foundation; it doesn't answer to shareholders or a board of directors.

Lee wants "to instill this humanitarian spirit into everything the US company does, fostering an entrepreneurial, free-thinking environment that allows the company to make meaningful improvements in patient care today and in the future."

Perhaps the most important result for Lee—who, after his mother's health battle, wanted to ensure that "no other child, parent, or loved one has to feel that way again"—will be "setting a new bar for patient-centricity." Early in the company's history, he helped to create a Patient Expert Council, which consists of patients and caregivers providing insights "that guide every decision the company makes." Lee observes, "I couldn't imagine, back when my mom was diagnosed with cancer, the amount of therapeutics, the amount of options that would be available to patients now. I wish she'd had all those opportunities and therapeutics. That whole outlook has hugely changed."

As he takes Servier Pharmaceuticals to the next level, Lee will continue to play his part in sustaining and strengthening that change. PE

An Authentic Approach

Elizabeth (Liz) McGee, General Counsel, Novartis Pharmaceuticals Corporation

By Lisa Henderson

Former litigator Liz McGee can honestly say that becoming a lawyer, or working in pharma, was not what she dreamed of doing growing up. Her father, who trained as a lawyer but never practiced, encouraged her to go to law school for the critical thinking skills it provides. And she did—earning a BA from Cornell University and her JD from Fordham University School of Law. After interning at the US Attorney's office in Brooklyn, McGee joined law firm Mayer Brown to work on complex commercial litigations in the areas of product liability, antitrust, and general commercial actions. But after a few years of life in a law firm, coupled with the abundance of research and writing that goes with being a litigator, McGee wanted to engage with the part of law that she really liked—talking through all parts of a problem to find a resolution.

So when contacts from Novartis Oncology inquired if she would be interested in joining their legal team, McGee accepted the opportunity to go in-house. At that time, her mother had cancer, and being that it was an oncology business, she felt she could get passionate about her new job.

"It felt very personal to me," recounts McGee.

Early on at Novartis Oncology, she was identified as someone with talent and high potential and was fortunate to be partnered with an exceptional mentor. Steven Baert, who now serves as chief people and organization officer for the Novartis Group, was paired with McGee, and she says that he was instrumental in helping her make good career decisions that influenced her subsequent roles at Novartis. Those roles ranged from supporting the global oncology and Latin America businesses, followed by serving as vice president and head of US legal, to her appointment as general counsel of Novartis Pharmaceuticals Corporation in 2016 and adding the role of US country head of legal in 2019. McGee now sits on the company's US Pharmaceutical Executive Committee, the US Country Leadership Team, and the Global Pharmaceuticals Legal Leadership Team.

McGee says that outside of the formal mentorship, she's received support from many sponsors in the organization, sometimes unknowingly and surprisingly. But, like other Emerging Pharma Leaders in the past have noted, McGee had direct managers who encouraged her to take on additional responsibility and supported her ability to grow in ways she might not have initially volunteered herself to do.

McGee's promotions to increasing levels of seniority at Novartis are something of which she is proud. "I haven't specifically targeted those positions and said, 'That's what I have to do next,'" notes McGee. "Rather, I've just been very focused on and engaged in whatever role I had at the time," and the results came through.

Those results may be attributed to a key skill she possesses, her ability to be authentic. McGee believes that sometimes, when people achieve senior positions, they can no longer ask questions or think they should have all the answers. McGee disagrees. She believes that being candid and forthright is the way to go. "If I don't know the answer, I'll say I don't know, but I'll go find out. Or I'll check with somebody on my team who knows a lot more about this than I do. Or here's what I think, but I need to think about it a little more," says McGee. "It's not that I'm the smartest lawyer in the room, that I'm the most experienced, that I've been exposed to more issues than anybody else; it's just being authentic."

> ***When I hear that they have gone from behaving like traditional lawyers to behaving like business partners, that makes me proud***

That transparency and honesty also helps McGee when thinking about one of her current challenges: how to structure and manage her team. There are 34 people in the US pharma legal department and she has 10 direct reports and additional responsibilities for the US Novartis entities in her country role. "On the one hand, I don't like hierarchy, but on the other hand, there's value in having a leadership team, so I'm not sure what is best," she admits. But another one of her proudest moments comes when she gets positive feedback on her team members. "When I hear that they have gone from behaving like traditional lawyers to behaving like business partners, and when those people get acknowledged and appreciated in ways that they should, that makes me proud," says McGee.

LET'S GO BEYOND THE PAGES

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A change in the pharmaceutical industry that has benefitted McGee and her legal colleagues is the shift in what is expected from in-house counsel, namely from being a lawyer to being a business partner with a law degree. In the past, McGee believes lawyers existed to rubber stamp commercial plans. But that has changed. "I think industry as a whole is much more mindful of the reputational impacts of everything, and how even the most patient-focused program can be misconstrued by a critic of the industry," says McGee. "Reputation and how we interact with physicians and patients really has become a focal point for the whole industry."

That expectation shift to business partner, vs. purely a lawyer, is something that McGee likes most about her role. "I find myself commenting in conversations or documents that we need to always ensure that the patient is the focal point of all our work."

McGee enjoys running and outdoor sports and spending time with her friends and family (she has a son, 13, and daughter, 11), along with balancing her demanding work. In the future, McGee would like to get involved in Novartis's broader public health-related work in underdeveloped countries. But just as she got to where she is now, McGee doesn't have that move set in stone. PE

Grounded in Science

Andrew Miller, Founder and Chief Operating Officer, Karuna Therapeutics

By Elaine Quilici

It's hard not to get caught up in the spirit of entrepreneurship living in Cambridge, Mass. Whether you're a student at MIT or establishing your own biotech, the air hangs heavy with scientific innovation and the talent to turn theories into therapies.

Dr. Andrew Miller, founder and chief operating officer of Karuna Therapeutics, has a PhD in chemical engineering from MIT. It was the entrepreneurship exposure he received and the connections he made at the school that ultimately forged his path in biopharma. Bernat Olle, CEO and co-founder of Vedanta Biosciences and a 2018 *Pharm Exec* Emerging Pharma Leader, was also in chemical engineering at MIT and the two played intramural soccer together. After joining PureTech himself, Olle introduced Miller to the company. Bob Langer, a co-founder of PureTech and well-known entrepreneur, was a professor of chemical engineering at MIT.

As PureTech focused on venture creation, Miller initially was involved in the scientific aspects of evaluating technologies, IP, speaking with academic investigators, and trying to find interesting opportunities to explore. He also experienced what it meant to turn this process into a business. While working on central nervous system disorders at PureTech, he started focusing on schizophrenia. Miller recognized that the disease had not been moved by many of the new technologies, such as biological and oligonucleotide therapeutics, that were transforming other areas of medicine.

"We're still in a space where we have small-molecule drugs that in many cases follow the same mechanisms of action as some of the first drugs discovered in 1952," says Miller. "So that was an area where there was an obvious need."

Miller cites a lack of understanding about the biological fundamentals of psychiatric disease as part of the problem. Those challenges, combined with more attractive opportunities in other disciplines, such as oncology, caused many pharma companies to discontinue their schizophrenia programs, despite having had successful commercial products in the past. Miller saw that vacuum of activity as a window of opportunity.

The idea for KarXT, Karuna's lead product and the founding of the company, came to Miller while he was at PureTech. The theory was based on clinical data from the 1990s. Miller's intention was to harness the same therapeutic benefit that had been demonstrated previously but to eliminate the side effects that prohibited development. To do this, he combined xanomeline, a novel muscarinic agonist, with trospium, a muscarinic antagonist that does not meaningfully cross the blood-brain barrier.

When Miller transitioned to working full-time at Karuna in 2016, it was relatively seamless due to PureTech's incubation-type business model. As the first and only full-time employee, he had to wear many hats, whether he was prepared or not. Faced with complex scientific, technical, and regulatory issues, he quickly learned how to be an aggregator of expertise and information.

"You become focused on what the organization needs and how to acquire that," says Miller. "Through that process, you cross paths with a lot of people and those experiences are all opportunities to learn."

When Steve Paul joined Karuna as chairman and CEO in 2018, Miller was able to enhance his business acumen further, thanks to Paul's rich industry experience.

"It's been a tremendous opportunity for me to learn from someone who has had success in many aspects of pharma," says Miller. "It gives me a chance in a small company to be exposed to many different aspects of the business and learn a lot."

A scientist at heart, Miller measures his success in terms of lab results. It wasn't until Karuna got successful Phase II clinical trial data last year that his achievement hit home.

"There are many finish lines in biotech, but that data set is something that we were driving toward for so long as the fundamental proof of concept for the idea of KarXT," he says. "It was a turning point in that it transformed an idea we diligently pursued into something where we have a practical timeline and sightline to getting this in the hands of patients. That's a powerful experience and something I take a lot of pride in."

> ***That sense of commitment is something people can be inspired by. We all feel a tremendous amount of ownership and passion for what we're doing***

Miller currently spends half his time on external stakeholder management and the other half on operations. He anticipates his role will change though, as the company transitions into a more mature business.

"It will have to be run a different way and will require different skill sets," he says. "Going forward, everyone's role is going to change. For me, that will mean more involvement in the direct management side, which is something I look forward to."

Though Miller organically found his way into a startup, he realizes making the decision to work in an entrepreneurial environment isn't always an easy choice. There are certainly risks involved, but the way he sees it, there are risks in every career decision.

"If you want to work for a startup, then just go do it," he says. "If you want to get involved in entrepreneurship, look for those opportunities. You could join the largest company or the smallest, and there are risks—there just might be different risks. It's taking a long-term view."

As Karuna enters Phase III development and eventually transitions from R&D into a commercial-stage company, Miller remains centered by the foundation of Karuna, whose name is the Sanskrit word for compassion. "When I look at what we need from a leadership perspective going forward, it continues to be the idea that you do whatever needs to get done," says Miller. "That sense of commitment is something people can be inspired by. [It says] we're all in this together. We all feel a tremendous amount of ownership and passion for what we're doing. It's hard for me to imagine not working in a company like Karuna."

Miller's life outside of work is wrapped up in family activities. He loves spending time with his wife, Michelle, and sons, ages 9 and 7. "It's about seeing our family grow and kids develop," he says. "It has its trying moments, but it's similar to the process of growing our company, with the challenges and new experiences we face. There's such a rewarding aspect in seeing that growth and development."

Connections and Culture

K. Scott Moorefield, Chief Business Officer, Boundless Bio

By Lisa Henderson

In 2019, Scott Moorefield became Boundless Bio's third employee. Like many—through networks, contacts, and personal relationships—Moorefield was tapped by people he knew and previously worked with; the company's Chairman and Co-Founder, Dr. Jonathan Lim; and CEO, President, and Director Zach Hornby, all who Moorefield describes as "amazing people." Boundless Bio itself embodies the core characteristics of what Moorefield has come to believe makes a great organization: great science, people you can trust, and great culture.

But the road to where he is today, his philosophies and dreams for the future, lie in the past, which Moorefield describes as not linear and dotted with pivotal moments. Moorefield was in the seventh grade when his uncle was diagnosed with glioblastoma and died within six months. "It was a defining moment for me, he says. "I was old enough to understand the emotional impact of losing someone to cancer." Moorefield's career path and the choices he has made, though not linear, have oncology as their North Star. This started with his PhD in Molecular Oncology

and Genomic Sciences from North Carolina State University, which led to his post-doctorate work in the epigenetics of glioblastomas and cancer stem cell research at the University of California, San Francisco (UCSF).

It was through his work at UCSF, and taking a class where students pitched company ideas to venutre capitalists, that led to a pivotal moment in his path. He had been on the academic faculty track and now wanted to steer toward business. Moorefield and the team, who he describes as core academics, had an idea to launch a startup. "But we were scientists at heart, and we didn't know a lot about the business side," he recalls. "As you can imagine, there were some decisions that, looking back, I would change, and maybe we could have changed the curve or direction." Even though the company did not succeed, he is proud that he made that jump out of academia and was willing to take on that challenge. "You learn from your successes but you also learn as much from your failures," says Moorefield, noting that they inspired him into a different career direction.

> ***I have found that most people from whom I've sought mentorship advice, from my decision to leave UCSF all the way to leaving Genentech, have come from cultivating relationships. And that means being authentic and honest***

Unlike many of his colleagues, he didn't want to go to business school. It was at this time that Moorefield started his mental checklist of what he'd need for future growth, possibilities, and experiences in business.

His first stop was a consulting position with Campbell Alliance, where he managed brand management/marketing and business/corporate development teams for pharma and biotech clients. After about two years, Moorefield envisioned his next step would be to get operating experience.

He joined Genentech in the biooncology pipeline market planning group, thinking he'd stay two to four years. Nine years later, his career at Genentech spanned early discovery to commercial in a variety of cancers. Moorefield had a key role in launching Tarceva's 1L NSCLC EGFR mutation+ indication, which included driving the strategy for the drug's large salesforce. "It was a rare opportunity to stand in front of 250 people and inspire those people to execute on driving sales for Tarceva and benefitting patients. It was a great experience."

From Tarceva marketing, strategy, and key customers, Moorefield moved up to development project team leader and then global business development director focused on oncology. It was during this time while leading the acquisition of Ignyta that Moorefield met Hornby and Lim. When the opportunity arose to work with the duo and join Boundless Bio, an Arch Ventures portfolio company, Moorefield said that decision was easy. He had spent a lot of time rolling his sleeves up and gaining experience, and now he wanted to be a part of building and driving an organization.

Along the way, Moorefield has developed what he thinks are the three key qualities for leadership: authenticity, transparency, and decisiveness. Leadership qualities also feed into a company's culture, which is very important to Boundless, and Moorefield says he learned a lot about the need for a positive culture at Genentech. "It's very important to have great science, but science can be unpredictable. However, a strong foundation of culture can get you through tough times," he says.

Clearly, you can't have leadership and company culture without staff and employees. That's where authenticity and transparency came into play. "I have found that most people from whom I've sought mentorship advice, from my decision to leave UCSF all the way to leaving Genentech, have come from cultivating relationships," explains Moorefield. "And that means being authentic and honest." He also pays those mentorship experiences forward by helping others. And not necessarily just direct reports, though Moorefield says he is quite proud of people he has mentored that have gone on to do great things.

Reflecting on going from a large biopharma to a small biotech, Moorefield says there is a certain comfort working for a large company because it can absorb the financial challenges and is therefore not as high-risk as the smaller companies. But the industry right now, notwithstanding the potential impact of COVID-19, has a lot of access to capital. Moorefield sees it as a time of tremendous opportunity. "This access to capital allows companies to fund completely new, cutting-edge science, and the funding gives the companies the ability to be creative and the science to breathe, in hopes of developing curative treatments for patients," he says. Moorefield looks back to his time with big pharma as foundational to his experiences, but enjoys where he is now. "I see my longer-term future as doing what's right for Boundless Bio to grow as a company, and then ultimately run an organization myself," he says.

Moorefield has been a competitive cyclist and now competes in triathlons. "There is some kind of a metaphor in cycling, and endurance is the key. Being able to continue with focus and commitment—to power through." PE

Patients at the Fore

Peter O'Neill, Director and Senior Clinical Trial Head, Incyte

By Julian Upton

As he had loved biology in school, Peter O'Neill wanted to be a pre-med student. But when he went to get a blood test before college, he passed out. "So I kind of knew I wasn't going to go to medical school," says O'Neill. Instead, he took an internship as a nursing assistant while studying for his bachelor's degree in biology. "It was an incredible time. I think back to it a lot, even when I'm managing clinical trials today," he says. "Having that patient care experience really helps me with that."

After college, O'Neill secured his first position in the industry, working in clinical operations for the CRO International Pharmaceutical Research. He then took a role at the Beth Israel Deaconess Medical Center in Boston and observed clinical trials from the perspective of a large hospital. He moved on to AAI International and gained trial monitoring experience, but he quickly realized that he "wanted to have more input into the development of the therapies, and you can only get so much of that in a CRO." So, in 2002, O'Neill joined Sanofi-Aventis as clinical project leader. In 2011, he began working for Incyte, a biopharma company whose therapeutic focus spans oncology and inflammation and autoimmunity. Since his move to pharma, O'Neill has played a part in developing and bringing to market several therapeutic agents, most recently ruxolitinib, the first JAK inhibitor approved by FDA.

As Incyte's director and senior clinical trial head, O'Neill is involved in several programs for investigational drugs, helping to determine the strategy for developing and implementing the clinical trials. He also recently led the customization and implementation of new software to digitize and streamline the sharing of safety information with sites and ethics committees. Of all the changes he's seen in the clinical trial space, O'Neill says digital innovations are the most impactful. "There's a lot more information available to us than there was 20 years ago. The databases are more robust; we can now use them to make things more efficient, make them better for patients, and move our clinical trials quicker."

O'Neill welcomes the advance toward remote or decentralized trials. "There are definitely procedures in our protocols that can be done from a patient's home," he explains. "Clinical trials are really intensive for a certain period of time, then there's a long follow-up period. We should be able to allow patients to follow up with telemedicine or have blood draws in their home instead of having to go to the doctor's office. I'm hopeful that that will be part of the future, for the sake of the patients."

O'Neill doesn't drop the word "patient" into his conversation lightly; he remains as passionate about helping patients as he was during his days as a nursing assistant. He doesn't feel that his career can be judged on "successes and failures" in the typical sense, "because sometimes you can work as hard as anybody and might just not be lucky enough to get that approval you're hoping for."

> ***"Patients are our partners. The whole drug development process needs to have patient input from the very beginning"***

Instead, for O'Neill, the reward has always been in improving the patient's lot. And his emotional investment hasn't lessened with time. A couple of years ago, a patient who was suffering from a disease that O'Neill's team were working on came and spoke to his group. "He gave a great speech; he really motivated us," says O'Neill. When the team learned some time later that the patient had passed away, O'Neill was moved to establish a community garden on the roof of the company's headquarters.

"We dedicated it to patients everywhere, to all patients in clinical trials. But it was created mainly with this patient in mind," he says. "We got together a great group of people at my company. We planted the garden, we took pictures, we sang songs. And we cared for the garden all year."

Like many in the industry, O'Neill has been obliged to work from home during the COVID-19 crisis. He's filling his spare time constructively, having enrolled in an online course at Harvard Business School, but one reason he's eager to return to the office is to get back to the community garden. "There were lots of times last year, amid the ups and downs, where many of us went to that community garden and it reminded us of why we do what we do."

O'Neill is also reminded of this purpose when he looks in the mirror. Five years ago, he became a patient himself when he was

diagnosed with malignant melanoma. He was fortunate to catch it early and have surgery, but he was left for some time with a visible facial scar, which O'Neill says, "acted as a reminder of the work left to be done to bring to market therapies for less fortunate patients." The scar is barely visible now, but it continues to motivate him to make patients the center of the drug development process.

"Patients are our partners. The whole drug development process needs to have patient input from the very beginning," he says. "We are all patients at some point in our lives, and yet our industry has sometimes been guilty of putting profit or timelines ahead of the best interest of patients." This is an area "in dire need of more leadership," O'Neill believes. "If we have strong leaders who do the right thing at all costs, then the profits will be an afterthought."

For O'Neill, strong leadership is about being clear about what you stand for. "It's a lot easier to follow somebody if you know what their motivations are, what they're passionate about," he says. "I've always been even more motivated to help leaders and mentors when I've known what's important to them. And I try to do that in my own management and leadership style. I would hope that anyone I work with knows what I'm willing to fight for."

Indeed, you get a strong sense of that after spending just a short time with Peter O'Neill. PE

A Born Problem-Solver

Craig Serra, Global Head, Strategy and Innovation, Data Operations, Novartis Pharmaceuticals Corporation

By Lisa Henderson

There is something in Craig Serra's DNA that can look at a pile of misshapen pieces and know that there is a way to fit them into a complete puzzle. It may not be elegant. It may take time and effort. It may take a lot of perseverance. But he has a gnawing sense that it will work. And, usually, Serra is right.

Serra's stepfather had many health problems including diabetes, hypertension, a below-the-knee amputation, spinal stenosis, neuropathy, and at one point, was unable to walk. He had back surgery to help, but only regressed thereafter, and still could not walk. Instead, he became accustomed to his wheelchair and continued that way for several years.

But Serra had an unrelenting feeling that something was missed. Not that something was done wrong, but that the right people or the right data weren't connected. He began tying together what he considered loose ends—images from one set of doctors, medical records from another—incessantly keeping his stepfather at the center of it all to always have the perspective of the patient. Fortunate to have a close friend who is a renowned neurosurgeon, a preliminary diagnosis of normal pressure hydrocephalus was made, which was missed by over 10 other doctors. The "a-ha!" moment arrived when a high-volume spinal tap was done and within a half-hour, Serra's stepfather was walking for the first time in over two years. "It was like an episode of *House*, without the benefit of Hugh Laurie," he says. "Seriously, I knew there was something there. I was pulling on enough threads and endlessly getting information to synthesize. We were able to solve the problem and he was able to get the permanent surgery to walk again."

Serra didn't consider clinical research as an occupation when he graduated college with a major in psychology and a minor in biology simply because he didn't know it existed. He had done some basic neuropsychiatric research in college, but it wasn't for him. Signing on with a temp agency, it matched his science background, along with his computer skills (entrepreneurial, at 16, Serra had a computer business in addition to working in a pharmacy), with a contract position at Schering-Plough doing support work for senior CRAs. Serra was there for only three months, but between learning what clinical research was and wanting to make a difference, he loved what he was doing.

That mix of passion for learning from others, a natural ability to find solutions, and an inherent knack with complex scenarios describes almost every position Serra has enjoyed in his career, each with steady and growing responsibility.

From Schering-Plough, he went to Pfizer, again in contract work. For two years, he did project management with a small team that operated autonomously. The goal was to find a solution to get data from one system to another. "It was really fun, a great learning experience, with a phenomenal group and a leader who taught me a lot," says Serra. "He is the kind of manager that sees the potential in people and positions them for success."

He was then onto Roche, again with numerous problems to solve that required learning on the fly and working across development, medical affairs, and IT. "The data systems were not working the way they should have and our group was majorly

impacted. With the integrity of clinical trials at stake, the group head saw potential and she let us run with solutions in concert with a lot of stakeholders," he says. "We were doing what we could to hold up a portfolio of studies in the face of incredible technological difficulty. It was a tough job, and I feel fortunate to have worked with extraordinary people who I learned so much from—but only in retrospect did I realize how difficult it was."

After Roche, Serra continued to work in pharma, then at a niche CRO to become head of data and strategic operations. It was here that he learned the challenges of a service provider, which broadened his perspective immensely. Always looking for growth and to be of service, Serra concurrently pursued an MS/MBA dual degree in New York City and became a member of the board for a pediatric brain cancer organization (Cristian Rivera Foundation).

In 2013, Serra returned to Pfizer and was a business process owner (BPO) for clinical data management. While it was a senior role with high accountability, the BPO construct also came without a budget, resources, or direct authority. BPOs had to influence and persuade others, but they also had organizational power to make decisions that could affect thousands and be impactful to senior executives. Admittedly, Serra says it was a very challenging role. "Can't deny it...definitely the most difficult job I've had, by far. I did a halfway decent job with it, but others were much better in that role. My true fun was in leading some transformative and innovative things that are still ongoing there today."

I was pulling on enough threads and endlessly getting information to synthesize

As Pfizer began another restructuring, Serra finished a third graduate degree, this time in pharmacology and toxicology. He departed to another CRO until his next dream job opened up in late 2018 at Novartis. In this current role as global head of innovation for data operations, Serra is accountable for bringing ideas to life and supporting an innovation framework and culture. In furthering his service to the industry, Serra is also on the advisory board of the data and digital company Castor EDC.

His success here, and reflected along his career, can be summed up by one of his nominees: "In 2019, projects were consolidated to focus on those that have transformative potential. He was able to take a take a "too-good-to-be-true" solution, evangelize and socialize it across the organization and ultimately get buy-in across 10-15 verticals, and obtain funding in a very competitive environment. It took him three months to do what it takes other large organizations two to three years."

In the future, Serra sees himself integrating what he has learned and achieved in 18-plus years in drug development to head up enterprise digital strategy, applying it to other large problem areas, and continuing his work to ultimately help people in need. "I don't fit into a neat little box so I tend to be attracted to roles that require a lot of different interests and skills," he says. "And now we have the COVID-19 pandemic as the ultimate catalyst for sustainable change in the way we bring medicine to those in need. We owe it to patients everywhere to deliver that change and I'll be privileged to help do that."

Even though Serra's stepfather passed away five years ago, the example of intuition around his illness influences Serra's career view and advice. "There is no MD after my name, but I was able to figure things out through action, perseverance, and connecting the right people together," he says. "It's a reminder that no matter what anyone's experience, we can all make a positive impact. We just have to decide to do it."

The 'Rare' Educator

Rogerio Silva, VP and General Manager, PTC Therapeutics

By Elaine Quilici

Working in rare disease can present many challenges. Working in rare disease in a developing country like Brazil adds another layer of difficulty. But Rogerio Silva, vice president and general manager of PTC Therapeutics, has been focused on bringing attention to rare, or orphan, diseases in his home country for the past 13 years. And he's making his mark on the community.

According to the nonprofit Global Genes, 400 million people live with one of 7,000 types of rare and genetic diseases around the world. Half of rare disease patients are diagnosed as children,

and 30% of those children don't live past age 5. In a country such as Brazil, where patients don't always have money or access to healthcare, the need to educate and act fast is evident.

Silva began his pharma career at the Brazilian national lab Aché in 1993. He worked there for two years, then moved to Bristol-Myers Squibb. After 12 years, he moved to Shire.

"In 2008, Shire was one of three companies in the rare disease market in Brazil," says Silva. "I remember when I moved, people asked me if I was crazy, because at that time almost nobody knew about rare disease in Brazil."

Nevertheless, he accepted the challenge. Seven years later, the person who interviewed Silva at Shire invited him to join PTC as sales director—and PTC Brazil's first employee. In 2017, Silva became vice president and general manager.

> ***"I remember when I moved, people asked me if I was crazy, because at that time almost nobody knew about rare disease in Brazil"***

"Some global companies have global projects, but usually the general manager doesn't manage the situation," says Silva. "At PTC, I am part of the business. I make decisions, share goals with my team, and discuss with them what we will do. This is something that makes me very proud of working at PTC."

When it comes to communication, Silva believes it's important to be clear about goals. He prides himself in his leadership style, which he says is based on communication, trust, and knowledge. Once employees have a picture of what they want to achieve, he says it's easier to get there.

"Everybody is important to us, and all opinions count," says Silva. "PTC explains goals to everybody, regardless of position, and that has contributed to PTC's growth over the years. Twenty years ago, [CEO Stuart Peltz] developed a product for DMD (Duchenne muscular dystrophy), Translarna. He is responsible for the environment that we have at PTC. People like to work together, people take care of others, and the company works to take care of its employees."

To illustrate this, Silva points out that PTC was one of the first companies in Brazil to allow employees to work from home during the current COVID-19 pandemic.

The importance of the individual is just as valuable when it comes to treating patients. "When I started at PTC, the DMD community was completely different," says Silva. "Some physicians didn't know about this disease. We had no patient advocacy groups supporting patients with this disease. Nowadays, we have thousands of patients identified because of PTC, we have a lot of physicians that know more about the disease because of PTC, and PTC has helped many patients with DMD."

Over the past 27 years, Silva has seen the pharma landscape change dramatically. He cites the impact of technology on treatments as a huge factor. For example, in rare disease, gene therapy has turned conversation from how to treat patients to talking about cures.

Silva also has seen positive changes come from educating people about rare disease.

"Physicians and patient advocacy groups that work with rare disease teach us a lot about how to do something better to help patients," he says. "Physicians who treat rare disease are there truly just to help people, honestly, because they do not receive a lot of money to do that."

PTC also works with patient advocacy groups that support patients. And in a poor country such as Brazil, there are many patients who could use assistance.

"We learn every single day when we talk to patient advocacy groups how difficult it is to have a rare disease in a country that is poor and, unfortunately, doesn't [provide much support to] patients with rare disease," says Silva. "For example, I was talking to someone from a patient advocacy group who said that one patient [delayed] their physician appointment because the father had to choose between eating or paying for the trip to get there."

Finally, given that Brazilians spend an average of three hours and 31 minutes on social media each day—third in the world, according to a January 2020 stat from Hootsuite—the company also uses that as a channel to raise awareness for everybody.

Silva says continuous improvement from within is also necessary. Last year, he attended the Advanced Management Program at Harvard Business School, a business program for senior executives.

"[The program proves] we never know everything," he says. "We have to always improve ourselves. Today I am general manager in Brazil. As a next step, [I'd like to be] general manager in the region in maybe three years, and work at PTC headquarters in five years."

Despite his ambition, Silva still carves out time for his wife, Isabela, and three children, Ana Beatriz, 20; Lucas, 18; and Maria Eduarda, 3. "I love to be with them," he says. "It is completely different when I am with my oldest—I talk about politics, the economy—than when I play with my little girl. I watch movies with my wife, and when I have some time to myself, I like to play and watch soccer. And I love to read—romance, like Shakespeare and Brazilian writer Machado de Assis."

Maybe that is where Silva gets his big heart to help people in need. PE

KATHERINE VANDEBELT
Brand Insights Contributor, Global Head of Clinical Innovation, Oracle Health Sciences

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Field Perspective: Informing the Future of Clinical Research

Gathering a collective view from those involved in clinical trials to better understand the issues and barriers preventing more efficient and effective drug development

When I joined Oracle Health Sciences last year in my role as Global Head of Clinical Innovation, I was fully aware of my first task at hand: to acquire a deeper understanding of the issues and barriers that prevent clinical research from being more efficient and effective in order to help deliver the most value to our customers and the industry.

To accomplish this, I turned to the field in which I myself had been a member of for over 30 years, gathering perspectives from the core contributors to clinical research: study team members, site staff, and patients, which I share along with my insights in the report "Navigating the Changing Clinical Trial Landscape, A Perspective from the Field" (see https://bit.ly/2VL0ixH).

To address cross-functional issues in study design, conduct, and reporting, I approached the study team which revealed a strong desire to "keep the status quo" and appeared to be closely tied to self-preservation. This position was often justified with the claim that regulations were a barrier. However, there was strong support among study team members for improving capabilities within a given work stream, *as long* as they did not result in a significant change to the function itself.

When asked about the top challenges investigator sites face today, a majority of them were related to lack of support from the sponsor or CRO in conducting clinical research, with the main sources of pain tied to delays in the budget and contract process, lack of support for those new to clinical research, and insufficient data collection methods.

Study team members and investigative site staff working directly with patients in clinical trials helped represent the patient perspective. The overwhelming issue related to patient recruitment was the lack of awareness among patients about clinical trials. Not only are they often unfamiliar with what clinical research is, they also don't realize there are clinical trials they could benefit from. Other issues touched upon the treatment of the patient; the lack of support for them; and their lack of ability to provide feedback.

Most importantly, patients want to be treated as humans—not "subjects"—they want to be appreciated and acknowledged during and after the trial.

Finally, to assess the entire clinical trial landscape, I spoke with biopharma leaders to get their perspective on trends in the industry. According to these stakeholders, there is a strong commitment to leverage automation technology that currently exists in the piloting phase to embrace new ways of working that add value, and to promote the use of central IRBs.

As with every journey, navigating the path requires the consideration of potential obstacles. It starts with verifying those issues that are worth fixing and prioritizing the work needed to address them. Some problems are less obvious but their pain is felt often. I wanted to learn what problems really need our attention. I often use the example of a home. The exterior of a home may have an overgrown lawn that needs to be cut, and this problem is easily identified in the community. At the same time, the interior of the home has a hole in the ceiling and water is continually leaking and causing damage and disruption for the residents.

The impact and importance of fixing these two problems is different; one problem is more obvious but less important (the lawn), while the other is less obvious but much more disruptive and painful (the leak). This field research and subsequent report reveal the four "leaks" in clinical research that will be critical to fix.

The goal in sharing these insights is to unify the industry and help each other evolve, so that we can work together to remove the barriers that are slowing down our ability to bring new drugs to market as quickly as possible to patients waiting in need. PE

CFOs Outlook: Forging a Sustainable Future

BDO Managing Director Patti Seymour discusses the key findings from its recent life sciences CFO study—and how change and volatility from COVID-19 will reshape fundamental approaches to business sustainability

By Julian Upton

In January this year, BDO's Life Sciences practice released a study of 100 mid-market chief financial officers (CFOs) in the US. *Sustaining Life Sciences* reported that life sciences CFOs are turning increasingly to outcomes-based arrangements amid growing public pressure to curb product prices and declining return on investment (ROI) from R&D. The BDO report revealed that, amid growing pricing pressures, 43% of CFOs expected a recession by 2021 or sooner, and in response, are pursuing more outcomes-based contracts with providers (53%) and payers (33%). CFOs also advocated a more focused—"and cutthroat"—approach to R&D, with 78% saying their organization is planning to increase R&D spending in 2020, but from a "more refined" perspective. Nearly half (46%) of respondents, for example, had pulled the plug on a research project in the past 12 months because of ROI concerns. The study went on to show that CFOs are looking to focus investment on preventative, more personalized treatments, with diagnostics, consumables, and immunotherapies ranking as the top three areas of research.

> ***For a lot of life science organizations, part of the challenge is that drug pricing regulations negatively impact their business***

The study was based on a survey conducted in the fall of 2019, so there has been an inevitable shift of focus among industry CFOs in the intervening months. Looking at the study in the light of COVID-19, *Pharm Exec* spoke to BDO Managing Director Patti Seymour, MBA, CSCP, who offers further commentary on the relevant points in the face of recent events.

PE: What, initially, did you see as the key messages from the *Sustaining Life Sciences* report from the CFO perspective?

Patti Seymour: There's been a tremendous amount of pressure across the industry to curb drug prices and product prices overall. This isn't new, of course; it's something that the industry has been facing for many years. Many commentators have cited the statistic that 30% of Americans who take a prescription medicine have seen their out-of-pocket expenses increase significantly over the last 12 months. For a lot of life science organizations, part of the challenge is that drug pricing regulations negatively impact their business. While they understand there is an issue, they are concerned about the capping or controlling of prices.

As a result, many of the industry leaders are turning toward outcome-based arrangements as a potentially more sustainable way to move forward. Life sciences companies are looking to advance with these outcomes-based arrangements directly with the provider or with a payer.

If we look at healthcare providers treating diabetic patients, for example, that would involve making sure that patients take their insulin, modify their diets, get their exercise, etc. In other areas, life sciences companies are really focusing their investments on preventative and early-detection measures to help with disease management.

We're certainly seeing significant growth in diagnostics. Consumables and wearables are another growing area. And then there are other types of leading-edge innovative modalities—cell and gene therapy—that the industry is focusing on.

However, as we know, between the fall of 2019 and today, some unexpected things have risen to the top of these leaders' concerns. Not least is supply chain disruption. COVID-19 started in China, which is the second-largest exporter of drugs and biologics to the US. We will certainly begin to feel the implications of those supply chain disruptions in the coming weeks and months.

Those operational challenges are really going to impact lean manufacturing. In theory, lean supply chains are very successful for manufacturers, but this set of circumstances will be very disruptive to that.

PE: How can the life sciences CFO work to promote sustainable industry models?

Seymour: One of the big areas we see are risk-mitigation, disaster-recovery approaches, especially regarding the supply chain. These approaches are fundamentally important in the face of natural disasters, equipment failure, pandemics of course, and other crises. What are the company's plans to continue supplying, or obtain material from another supplier? CFOs play an enormous role in this sense, and this function typically

falls under a CFO's responsibility. They need to be very aware and proactive about their disaster-recovery programs and ensure they are reviewed periodically in the light of all the different things that could happen to their supply chain.

PE: The survey talks about CFO's developing a more "cutthroat approach" to R&D? What is that?

Seymour: The fast-to-failure approach has been pretty common for the last couple of years. By that I mean companies develop a modality and get it into the clinic as quickly as possible to see if the modality and the indication will lead to competitive outcomes in the marketplace. Fast-to-failure approaches allow organizations to begin and end research programs quickly, so they only keep the most promising products in their portfolio and can redeploy scarce resources to promising drugs in their pipeline. One example of this is a company called Biofourmis, a startup that is using biosensors to gather information from patients while their artificial intelligence analytics identifies changes in their health. This process allows the providers and payers to have real outcomes-based data. Drugs and therapeutic modalities are being used in concert with devices and wearables to achieve these outcomes-based ends and allow companies to invest only in those medicines and therapeutics that are actually going to benefit the patient.

PE: We're in an election year—what are CFOs going to be looking at as people go to the polls?

Seymour: As mentioned, outcomes-based frameworks and cell and gene therapy are important. The latter is an exploding area. While they still make up a small percentage of all the therapies being developed, they truly offer transformative possibilities. But they are enormously expensive, so, for our clients, we are following the conversations around how to reimburse them very closely. So, CFOs will obviously be homing in on that in the run-up to the election.

PE: The survey revealed that about 43% of CFOs expected a recession. Today, they might be certain of it. But there was some optimism. How are CFOs planning to weather the oncoming recession?

Seymour: Well, as you point out, this survey was completed prior to what's going on right now. But I think what's going on will force CFOs to be even more laser-focused on the most promising modalities, and to really look at the most innovative technologies and the ones with the best outcomes. CFOs are also looking to other enabling technologies, such as continuous manufacturing. We hope to see more adoption of that, although it is challenging. A lack of equipment and some regulatory issues have hampered efforts in continuous manufacturing.

But the industry and the regulators have been working quite collaboratively to oversee and approve these types of processes, which present something of a paradigm shift in getting products manufactured quickly and cost effectively. Perhaps the COVID-19 situation will further stimulate the adoption of continuous manufacturing because of the need to work quickly to produce diagnostics or therapeutics. PE

> ***[The pandemic] will force CFOs to be even more laser-focused on the most promising modalities, and to really look at the most innovative technologies and the ones with the best outcomes***

Survey: At a Glance

Among the findings in BDO's *Sustaining Life Sciences* survey of 100 mid-market CFOs, the report highlights that:

- Diagnostics—or tools that enable the measurement of biomarkers—is the area of research that companies are planning to invest most significantly in (49%). This is followed by consumables (40%); immunotherapies (40%); gene therapy (36%); cell therapy (32%); and wearables (32%).
- 60% of respondents cited "three to four promising products in their portfolio for commercialization."
- 46% said they would be pursuing a digital strategy in 2020.
- 22% said tax reform was a policy priority in the context of the 2020 presidential election.
- 79% say adoption of continuous processing is "a challenge for them today." The report notes, however, that in part, life sciences companies "have been hindered by complicated regulations around the use of such processes and a lack of equipment needed to implement them." It goes on: "Given the increasing demand to produce specialized treatments at lower costs to the consumer, adoption is likely to quicken in the near-term."

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How Prepared Were Doctors for the COVID Digital Upswing?

Survey spotlights the pandemic-sparked shift in adoption and acceptance of connected health technologies

REENA SANGAR
Global Head of Digital & Connected Health, Ipsos

MATILDA PATERAKI
Research Manager, Ipsos

Before the global outbreak of coronavirus, Ipsos conducted a survey with SERMO (a fieldwork partner), looking at how 1,745 doctors from across 21 countries use digital technologies. Findings from the "Digital Doctor 2020" survey show that while a noteworthy proportion of doctors were already starting to adopt digital and connected health, many were hesitant. With the outbreak of COVID-19, this has all changed.

More recent Ipsos data—taken from 311 interviews with healthcare professionals (HCPs) in the US between March 26 and April 2, 2020—offer an updated perspective from the largest healthcare market in our global study. Although this latest data must be considered directional only due to the base size of the respondents surveyed, it was interesting to note that:

- 80% of the US HCPs surveyed are now taking patient visits using telemedicine.
- 62% are allowing to receive online or telephone details.
- 57% consider the e-details to be effective (among 642 e-details the HCPs evaluated). Note: e-detail was defined as "any non-personal interaction with a pharmaceutical sales representative" such as a telephone call, videoconference (Skype/FaceTime), online video, etc.

Returning to the Digital Doctor 2020 report, although technology had started to be adopted across the globe by primary care physicians, its full potential was yet to be realized. The ongoing outbreak of COVID-19 has prompted a significant amount of inexperienced doctors to use online tools and resources, from telehealth (communicating via videoconferencing) and remote patient monitoring to virtual congresses. Whether these changes are likely to remain and become the "new normal" is difficult to predict, but certainly with doctors experiencing these changes we anticipate a longer lasting impact on the way healthcare is delivered and how technology is viewed and embraced by physicians.

AWARENESS AND KNOWLEDGE OF TECHNOLOGIES PRE-COVID-19

Before COVID-19, there was fairly high awareness of a mix of digital concepts relating to healthcare. However, this did not translate into knowledge. Specifically, in the Digital Doctor 2020 study:

- The top four technologies that the doctors surveyed are most aware of include telemedicine/telehealth (97% awareness, 59% know a lot about it), remote patient monitoring (92% awareness, 41% know a lot about it), artificial intelligence (89% awareness, 31% know a lot about it) and robotics (85% awareness, 28% know a lot about it).
- Technologies that the doctors surveyed are least aware of include chatbots (52% awareness, 16% know a lot about it) and blockchain (44% awareness, 10% know a lot about it).

It seems that although there was a good level of awareness of these technologies, how these tools apply to healthcare —or simply how they work—was still unknown to many doctors at the time of the survey. Now, at a time when so many technologies are being introduced (and advocated) to primary care doctors, it is important to note the level of awareness and knowledge of the various technologies available.

Simple explanations, along with clear benefit statements, will be welcomed when there is such a steep learning curve and a lack of awareness.

THE RISE OF DIGITAL AND CONNECTED HEALTH

The doctors surveyed in the study believe that connected health devices and tools can play a key role in disease and treatment management (83% agree), a figure which increased by seven percentage points since the last wave of this study (Digital Doctor 2017).

Physicians surveyed also agree that connected health devices and tools for patients will form part of treatment plans for certain

health conditions in the future (83%). Agreement with this statement increased by six percentage points since the last study. However, "current usage" of connected health (pre-COVID-19) was not particularly high.

- As shown in the new study, doctors' use of connected health is reported at similar levels for personal (34%) and professional (31%) use. Among those physicians who use connected health devices professionally, the main reasons for doing so are to access information on a disease and how to manage it (57%), and to maintain up-to-date and accurate health records of patients (56%).
- Some doctors surveyed also encourage patients to use these devices, either recommending them a connected health device to monitor their health for self-evaluation (47%) or to review the results over a consultation (46%).

DOES CONNECTED HEALTH EQUAL PATIENT EMPOWERMENT?

Physicians surveyed recognize a number of benefits that connected health devices offer, including patients having access to their data, creating opportunities for early intervention, and having more effective conversations between HCPs and patients.

- Overall, 86% of doctors surveyed agree that connected health devices provide patients with greater access to their own personal health information. Those physicians surveyed who have also recommended a connected health device to their patients also agree that patients have become more interested in their own health data or have control over their weight, diet, and physical activities. However, the physicians also expressed concerns that this "empowerment" of patients can lead to patients misinterpreting data and potentially risk misdiagnosis.

Studies have shown that patient empowerment does lead to patient satisfaction. Providing patients with the option to receive more information about their condition and how they can better manage it does not necessarily mean that they will become, in essence, doctors of themselves. Rather, it provides the opportunity for patients to gather knowledge and participate in decisions about their treatment plan/management.

- Digital Doctor 2020 shows physicians surveyed agree less with statements about the benefits of connected health in relation to the provision of better clinical outcomes, such as reduction of hospital readmissions (56%) or hospitalizations (55%).

The benefits and competitive advantage of connected health devices are that they can help healthcare move from a reactive to a proactive role. Providing patients with the ability to monitor their disease and understand what to do in order to prevent acute reactions means fewer people needing hospitalization or intensive care. Even if a patient is hospitalized, connected health devices will be able to help them manage their conditions after being discharged.

THE RISE OF VIRTUAL CARE/TELEHEALTH

Key study findings regarding telehealth include:

- Around half of primary care doctors surveyed had previous experience with telehealth services.
- A majority are aware of telehealth services, but there remains scope for education as to how these services can benefit doctors and how they can be maximized.
- Around two in five doctors surveyed expect telehealth to play a key role in the future.

Telehealth has long been around but has never been widely adopted. Benefits of using telehealth were always centered around reducing health costs, increasing access to care, and making patients' and doctors' lives easier. Although this would indeed be the case in reality, only 48% of physicians previously claimed to have ever used telehealth. Our more recent survey amid COVID-19 (with 311 HCPs from seven specialties in the US) found that 80% of respondents now use telehealth, suggesting a drastic change in doctors' behavior.

Barriers that countries were facing in terms of adoption of telehealth were regulatory in nature or due to limited technology infrastructure to support secure conversations between patients and doctors. Due to the COVID-19 outbreak, however, things have changed, with new regulations in place in some markets. Specifically, FDA announced it will not object to any change in claims made by medical devices companies to facilitate the use of telehealth. Furthermore, the US federal government has made it easier for patients to get access to their doctors and other caregivers remotely, either via phone calls or video visits.

In these times of crisis, it is paramount to adapt to the new realities as quickly as possible to prevent overburden of the healthcare system. It is widely believed that telehealth is now here to stay, as more and more people gain experience with it and doctors begin to realize its benefits and potential.

RAPID ACCELERATION OF DIGITAL CHANNELS

Reflecting on Ipsos' more recent data gathered during COVID-19, the US HCPs surveyed are now allowing online or telephone details via reps (62%) and 38% have simply eliminated seeing reps at all.

The question remains, why were many doctors still reluctant to widely adopt and use connected health devices pre-COVID-19? We often talk about the benefits that these tools can provide to patients, but less about the benefits that they offer to physicians specifically. Due to unprecedented changes in recent years, such as the increasing number of patients with chronic diseases, growing life expectancy, doctor shortages, and now the global pandemic, huge challenges are facing doctors who have very busy schedules. Value-added solutions, coupled with proper training and supported by new regulations, will accelerate the acceptance and adoption of new digital health technologies. PE

COVID-19: Four Challenges for Issue Management Teams

The key industry areas that will experience downstream pressures in the wake of the coronavirus pandemic

DONNA L. LAVOIE
is President and CEO of LaVoieHealthScience

The fallout from the unprecedented global spread of COVID-19 is only starting to be felt in the life science sector—and without a quick resolution to the crisis, headwinds into the second and third quarters of 2020, and beyond, are likely to be significant. The following are four key areas that will need thoughtful contingency planning from both an operational and communications perspective. Now is the time for companies to consider formalizing their Issues Management Team (IMT) and developing a concrete plan, addressing various levels of crisis/issues to prepare for success.

#1. FUNDING CHALLENGES

With the economy and markets now solidly in bear market territory, funding and liquidity is increasingly top-of-mind with both up-and-coming biotech and established players. Stock market woes are making money tight, and the traditional channels such as face-to-face conferences are grinding to a halt, with the domino effect of industry conference cancellations and postponements. At the same time, company travel restrictions and work-from-home mandates are making roadshows untenable. According to NVCA/Pitchbook, investors have raised more than $210 billion since 2016 and there is ample dry powder in the market to put to work, although there will be a focus on biotech and drug discovery deemed as "essential businesses" versus lifestyle-focused medicines. In this new landscape, companies that are able to pivot to new ways of telling their differentiated story, accepting delays caused by the pandemic, providing transparency, and using unique digital communications in the form of virtual presentations and investor outreach will come out ahead.

#2. REGULATORY AND COMMERCIALIZATION DELAYS

The health system's overwhelming focus on addressing the coronavirus pandemic and capacity strains put on medical professionals, hospitals, and health systems could result in delays in the completion of clinical trials, not to mention recruitment. Focus on combatting the pandemic will also limit key FDA interactions for many companies and potential missed milestones could result in development timelines being pushed out. It is important to get in front of these disruptions and communicate clearly to your key stakeholder audiences and having a framework in place will jump-start your efforts. Many companies have provided updates to investors, clinical site directors, patient groups, and consumers. Those not taking the chance to reset expectations on their product plans are missing both an opportunity for a pass for a potential delay and reenforcing company reputation.

#3. MANUFACTURING & SUPPLY CHAIN DISRUPTIONS

A lopsided portion of active pharmaceutical ingredients (APIs) used in drug manufacturing and components in med tech products and devices are now contracted with China and other Asian countries hard-hit by the coronavirus pandemic. Manufacturing and supply chain disruptions are a very real threat to our industry and have to be addressed clearly to instill confidence. It is somewhat unclear about the direct impact of supply chain delays to the bottom line, although many commercial stage companies have reported that it won't have a material impact on financial results. It has been reported that some companies' China operations are slowly returning to normality and manufacturing alternatives are being sought in India and the European Union.

#4. CANCELLATION OF MEDICAL MEETINGS

Just as industry and investor conferences are being canceled and postponed, so are medical meetings. In the absence of these meetings, it will be incumbent upon companies to develop alternative and compelling virtual or digital means to present their data. Digitally presenting your data and summarizing your poster presentation is one creative way of addressing this and posting to your website. Company executives of all levels must now come prepared to present their data in a new online channel, with perhaps a different set of attendees than the coveted oral presentation at a major medical meeting provides. Be prepared for those presentations to be shared in social media channels. There could not be a more important time to open your digital and social channels, with clear policies in place. PE

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Editorial Director, *Pharmaceutical Executive*

In the last 10 years, an explosion of real-world data has revolutionized the ability for pharmaceutical companies to better understand the market for their products. If used correctly, 'Big Data' can be used to build commercial forecasts of unprecedented fidelity and accuracy.

But constructing big data-enabled forecasts will require a new generation of tools as well as new approaches to forecasting. We examine how new forecasting technologies and workflows enable forecasters to manage the data dump and build forecasts that are more accurate and real-time while considering more factors.

Three Key Takeaways:

- The role of big data, machine learning and real-world evidence in building better forecasts
- Practical steps forecasters can take to manage the data dump and reduce manual data manipulation
- How increased fidelity and accuracy enable better insights

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All we see are insights.