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Pharma 50 Spikes

In our annual review of the industry's top Rx sales producers, we weren't surprised to find names tied to the COVID-19 pandemic. But how long will the companies whose sales skyrocketed remain in the spotlight?

After months of anticipating new treatments and vaccines to fight COVID, the world was eager to embrace them. As a result, the companies who came through—notably Pfizer, Moderna, Regeneron, and Gilead, with products that first emerged on the scene in late 2020 and early 2021—have risen in the ranks of our annual list of top pharma companies, based on Rx revenue. In the case of the smaller biotechs, the extra interest caused the companies to spike on our lists. But with few immediate follow-ups on the horizon and demand for COVID vaccines and drugs perhaps waning, it will be interesting to see how long these entrants last in the top half. In comparison, large pharma companies, such as Pfizer, have a pipeline of new products always in the works, so their jump may be more sustainable heading into future lists. But the fact remains the COVID effect on our Pharma 50 this year was substantial.

In this issue, we also take a look at another important area impacting the industry—environmental, social, and governance (ESG) issues. Sandor Schoichet, a co-founder and partner at the Biopharma Sustainability Roundtable, who has written for *Pharm Exec* on a number of occasions on this topic, shares his Top 5 sustainability challenges for the Top 50 Biopharma Companies.

In addition, we revisit another topic of importance to the biopharma c-suite—the growing popularity of expanding “chief” titles. Editor-in-Chief Elaine Quilici first reported on this in her January 2022 leadership column, and expands now to look at the pros and cons of this trend, and what these changes mean for the industry as a whole.

Finally, our executive profile this month centers on Bradford Sippy, CEO of Tremeau Pharmaceuticals, who has held a number of positions in both biotech and Big Pharma. His vision to turn around the once-withdrawn drug Vioxx to help a population with no treatment options tells a story of persistence and patience, and demonstrates his passion for winning. **PE**

Mike Hennessy Jr
President and CEO
of MJH Life Sciences®

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Fresh Talent Awaits, But Must Be Tech-Savvy

As June ushers in a new wave of talent to the industry, we're inclined to look at the changing face of the pharma workforce. Though almost every industry has had to adapt to new ways of doing business over the past two years, pharma has specifically witnessed some marked changes.

From a shift in how sales meetings are conducted to an increased focus on cell and gene therapies, companies are in the process of designing a new legion of innovators to take on the challenges of 21st-century medicine.

According to GlobalData, the rate of pharma companies hiring for roles involving the Internet of Things rose in March. Hiring for cloud roles rose to a 12-month high in the same month. And in April, digitization roles were up from the previous year, while connectivity roles hit an annual high.

In its recent report titled *Transforming the Talent Experience*, Deloitte specifically calls out five trends driving investment in data science: patient centricity, data liquidity, regulatory guidance, shift to value, and growing cost of R&D. As Mathai Mammen, global head of R&D at Janssen Pharmaceutical Companies of Johnson & Johnson is quoted in the report: "Incorporating data science into everything we do is transforming the way that our organization answers the question of 'what is possible,' including the way we conceive of, develop, and provide treatment options to our patients."

With digital infiltrating almost every area of the industry, the next generation of pharma execs needs to be digital savvy. The Deloitte report indicates that by 2025, an estimated 40% of core skills will change for workers. And with an expansive move to

digital across all industries, pharma companies won't just be competing with each other for talent. A scarcity of tech talent will be one of the biggest barriers to overcome, and expanding and upskilling talent should be a top investment priority, according to the report.

The topic of how digital is being integrated throughout the pharma industry has come up in various *Pharm Exec* interviews over the past year or so. I've heard more than once how the traditional role of a chief digital officer (CDO) has changed significantly. Because digital is everywhere, the duties of a CDO could one day simply be absorbed into other roles.

I compare this to my children's elementary school, which eliminated its weekly technology classes a few years ago. The district's reasoning was that technology is such a part of everyday learning, that the general education teachers should be demonstrating basic tech skills, such as how to copy and paste, how to import images, and how to build a PowerPoint deck, into their own daily lessons. Perhaps, by the time this generation hits the job market, they will understand digital has no boundaries.

There's a quote I recently read from late Apple co-founder Steve Jobs. He said: "I think the biggest innovations of the 21st century will be at the intersection of biology and technology. A new era is beginning." Well, that era is here. **PE**

Pharmaceutical Executive's 2022 Editorial Advisory Board is a distinguished group of thought leaders with expertise in various facets of pharmaceutical research, business, strategy, and marketing. EAB members suggest feature subjects relevant to the industry, review article manuscripts, participate in and help sponsor events, and answer questions from staff as they arise.

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By Barbara Ryan

Correction

In our May issue, in the *Emerging Pharma Leader* profile of NS Pharma's Gardner Gendron, an incorrect amount was mistakenly reported for the development of an early access program.

FDA to Continue Inspection Efficiencies After Pandemic

Agency will keep in place new methods adopted during COVID

Although FDA announced in February that it was resuming “normal, routine domestic surveillance” of drug and medical product manufacturing facilities, many of the innovations and modifications for site inspections adopted during the COVID-19 pandemic will continue to play a visible role in agency compliance and enforcement operations. FDA’s Office of Regulatory Affairs (ORA) delayed or cancelled most on-site inspections during the past two years due to travel restrictions and infection concerns, but now seeks to resume active inspections where needed and practical.

This shift, however, does not signal an end to FDA’s wider use of paper document reviews and of virtual site visits, or remote interactive evaluations (RIEs), in ramping up oversight of biopharma manufacturing and research operations. These strategies notably reduced agency inspection costs, while enabling timely detection of compliance issues, and FDA sees value in continuing its expanded reliance on documents and records, on inspection reports from trusted regulatory authorities, and on wider use of remote real-time review of records and plant operations to provide assurance of proper manufacturing and clinical research operations.

Judith McMeekin, associate commissioner for regulatory affairs, pointed out during a presentation sponsored by the Alliance for a Stronger FDA on April 6 that ORA saved nearly \$40,000 in 2020 and 2021, providing resources to develop a foreign travel planning system, expand personnel training, enhance information systems, and upgrade labs. FDA analysts are comparing the benefits and shortcomings of on-site inspections vs. record requests in order to develop criteria for revising or continuing these alternative practices.

More flexible inspection programs could gain from legislation before Congress to reauthorize FDA user fees and update agency operations and policies. The bill includes a provision to clarify FDA’s authority for collecting manufacturing records from medical device makers in advance or in lieu of field inspections and also for clinical study sites under the agency’s bioresearch monitoring program. The measure also clarifies agency use of inspection findings of trusted foreign regulatory authorities in determining the need for preapproval inspections (PAIs). And Congress wants FDA to post

more information on the findings from drug and device inspections, such as warning letters and import alerts.

DEALING WITH RIEs

In response to these developments, FDA has worked to better explain its criteria for selecting and methods for conducting more remote and alternative facility assessments. At the recent FDA Generic Drugs Forum, staffers from the Office of Pharmaceutical Manufacturing Assessment (OPMA) in the Center for Drug Evaluation and Research (CDER)’s Office of Product Quality (OPQ) explained that FDA will weigh the need for an on-site inspection based on a risk-based assessment of product, process, and facility risks. This involves scrutiny of records and other manufacturer information from trusted regulatory authorities.

Such information on a firm’s compliance history, process risks, manufacturing experience, and previous alerts, recalls, and complaints will help determine whether a PAI is needed or if FDA can assess the company’s capacity for risk mitigation and GMP compliance from company and regulator records. When FDA considers an RIE advisable, it will discuss the logistics, scope, and expectations with the manufacturer, request needed documents from the firm in advance, and outline its main questions or concerns and the logistics for conducting a remote facility tour. Such virtual site visits also can help all parties prepare for a future on-site inspection, if warranted, but do not qualify as formal inspections *per se*. They are voluntary for the company, but a refusal to cooperate with an RIE request can delay product approval.

OPMA Staff Fellow Alexander Gontcharov described an RIE for a foreign manufacturing facility using a new unit of operation to produce delayed-release oral drugs. This involved four three-hour sessions with a facility “walk-through” using a laptop on a cart with external cameras and microphones. Another RIE for a new unit producing new ointments and liquid products had three four-hour sessions that used a portable tablet PC with Wi-Fi connections. FDA investigators viewed warehouses, labs, and production areas, as well as document control systems. Inspection findings may be specified in a close-out memo, or FDA may later send a letter identifying difficulties found at the facility and if an on-site inspection is needed. **PE**



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Brand Insights - Thought Leadership from Marketers | Paid Program

Social Media: Your Brand's Best Friend Across Life Cycle

The benefits of including organic social in digital marketing

There has been much debate on the value that social media can bring to a well-developed marketing plan. After all, speech is strictly governed to avoid content that is inaccurate or objectionable. However, no matter where your pharmaceutical company finds itself in its product development process, the advantages of digital marketing—specifically organic social—can add significant value without compromising integrity. According to Statista, the average daily social media usage worldwide has increased to 147 minutes per day in 2022, up from 145 minutes per day in 2021. Even though it appears to be a small increase, the implications are substantial. The sooner you act, the less you'll miss out.

BUILDING THE CORPORATE FOUNDATION

While creating your company's corporate foundation, you first want to confirm which platforms your target customers prefer, and then develop a plan to make yourself visible on those platforms in a relevant and meaningful way. Creating a strong social strategy to establish the brand's identity online comes next. An effective social strategy will assist your brand in reaching its overall business goals. Remember, your social media should be seen as an extension of your sales and business development teams, and as a place to generate more qualified leads.

CLINICAL STUDY PHASE

Once your company has reached the clinical study phase, social media can generate buzz around patient recruitment. According to preliminary data from the *Journal of Medical Internet Research*, social media can increase participation and reduce per-participant cost. By sharing specific content series around recruitment, data, and trial results, your company and brand will be able to reach a new audience online that may not have known about the trial otherwise.

DISEASE STATE EDUCATION & MARKET SHAPING


As your company enters the disease state education and market-shaping phase of development, there are increasing opportunities to prove that both your company and leadership team are experts

in your field. By distributing content across social media that consists of conference coverage and webinar-related news, as well as joining relevant disease forums and groups, your company and brand will more naturally be seen as a thought leader within your therapeutic category. During this stage, you can also co-create valuable social media materials with advocacy groups and non-profits.

BRAND LAUNCH AND ACTIVATION

While your product is newly launched into the market, consistently monitoring social media channels is imperative in staying abreast of what the public says about your brand. This will also present the opportunity to quickly respond to any comments, negative or positive, keeping your brand ahead of the competition. During this stage, content should be shared to both corporate and brand pages. Content should consist of activation tactics, upcoming conferences or events you will be attending, testimonials from new patients or HCPs, and engaging video messages. Interacting on social media with other like-minded accounts during this stage will assist in creating long-term relationships with HCPs, advocacy groups, and distributors. Aligning your social strategy with your selling strategy will help guide messaging overall.

POST-LAUNCH MARKETING

After your brand has been launched, organic social media should continue to play a significant role in your overall marketing strategy. Now is the time to reassess which areas of social media your brand has been successful in, and which areas could use some improvement. In this stage, you should be looking at which channels are—and are not—working for your brand. Post-launch marketing is also an appropriate time to share with the world how well-received your product has been with patients and doctors through testimonials shared on your social pages. Revisiting your following and hashtag strategies is essential to confirm that you are up-to-date on industry best practices. By adjusting your current tactics and adding new ones in, you will set your brand up for continued success. 

A Storm in a Brussels Teacup Could Threaten Drug-Pricing Waters

Group's ideas to change EU pricing rules draw captive audience

REFLECTOR

is *Pharmaceutical Executive's* correspondent in Brussels

Over the past 18 months, a worthy but obscure group of Europeans have labored diligently over a self-appointed task in the face of almost universal indifference and even occasional ridicule. But suddenly, their work has assumed a new and potentially dramatic significance for the pharmaceutical industry.

The group is the Conference on the Future of the European Union (CoFoE), and its recently adopted recommendations, recondite though many of them are, have caught the attention of many national governments in Europe. One of the recommendations could, if developed into legislation, drive a coach and horses through the established models of drug pricing in Europe. The group wants to see changes to the EU treaty to give new competences to the EU in health policy.

The report calls explicitly for equal conditions, universal access, and rights in healthcare for EU citizens, and for the EU to lead the change. According to CoFoE, treatments and medicines across the EU must be “of equal quality and of fair local cost, including through tackling existing fragmentation of the internal market.” It also wants to ensure that public health resources “are not drained by profit-oriented health operators with little-to-no regard for the general interest.” And for good measure, it adds, “Medicines should be universally available, including in poorer countries.”

This might have been no more than a well-meaning theoretical discussion, since the underlying ideas have been circulating widely for decades without shifting the way business is done in Europe, or the way that access is governed by national rules on national prices and reimbursement of medicines. The EU treaty is drawn up in such a way that member states remain free to do almost whatever they want—or can—in terms of fixing drug prices, and the international drug industry has long profited from the ability to divide and rule Europe in this respect, since it is negotiating one-on-one with individual countries rather than the bloc as a whole.

This may be changing. Not only has CoFoE proposed modifying the treaty to give the EU more say in health matters, but key figures and institutions in the European context have grasped with enthusiasm at the idea of a more EU-influenced health policy. European Commission President Ursula von der Leyen told the

European Parliament, “Europe should also play a greater role in health.” The parliament’s institutional affairs committee has already come out in favor of a list of treaty amendments it is aiming to propose, with an upgrade of EU competence for health and healthcare high on the list. Some members of the European parliament want joint purchasing across the EU for all drugs, to drive down prices. According to Véronique Trillet-Lenoir, a French MEP and practicing oncologist, “We could find a common evaluation of what the value of a medicine is. When you negotiate as 27, you are stronger. Once you have decided a common price, you can still decide the reimbursement level country by country.”

The CoFoE proposals ran into early trouble with a group of member states who pushed back against the idea of shifting more power to the center in Europe and rejected the call for in-depth consideration of the ideas. But that was quickly neutralized when a still-more influential group of member states—including Germany, Belgium, Italy, the Netherlands, and Spain—retaliated with a ringing endorsement of continuing discussion on the central themes proposed. And in mid-May, German Chancellor Olaf Scholz told the German parliament that his government was not opposed to treaty change.

A game-changer in this has been the COVID-19 crisis, during which the EU conducted its first joint-purchasing program with companies—initially for vaccines and subsequently for therapeutics. It has demonstrated to many both the desirability and feasibility of common action. Similarly, COVID led to the creation of a centralized European emergency health authority known as HERA to centralize planning and response to health challenges. In parallel, another game-changer has been the Russian invasion of Ukraine, which has brought Europe and the West together on many points where intra-EU dissension flourished in less-threatening times.

None of this directly means a change to centralized and harmonized rules for fixing drug prices, but against the background of a growing chorus of concern among member states, patient groups, health insurers, and healthcare professionals about what are seen as excessive and even extravagant prices charged by an overpowerful drug industry, the stage is set for action on a scale seen as unimaginable only three years ago. **PE**

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Early Input Necessary in Creating Smooth C-Suite Transitions

Tips for surviving a shift in executive roles

Transitions can be a challenge at any level, but when the c-suite gets shaken up, companies need to pay special attention to ensure the handoff is as smooth and effective as possible.

“When a CEO comes in, it’s a little different than traditional onboarding,” says Brad Margus, who is in the midst of transitioning out of the CEO role at Cerevance, a Boston-headquartered biotech focused on central nervous system diseases with research labs in Cambridge, UK. “It’s more about really plugging them into the culture of a company, and getting to a point where the CEO feels ownership and realizes it’s their company now, and they can make it whatever they want. A CEO’s position is different than any other kind of role you bring into the company.”

IDENTIFYING A SUCCESSOR

According to Maurice “Mo” Cayer, PhD, a distinguished faculty member, lecturer, and program coordinator for the MS-Human Resources program at the University of New Haven, research indicates that hiring from the outside, on average, fails more often than promoting somebody from within. The reason is because a company knows more about internal candidates, and that can help balance their assessments of who to promote.

To make use of that “insider” information, companies should look at past reviews and solicit feedback from people who have worked with the candidate. For example, collecting a 360-degree assessment of a vice president of research would include people within the research area, their peers in clinical development, marketing, and regulatory, says Cayer. When conducting these “360s,” he suggests evaluating the following areas, which have been proven to contribute to the success of leaders:

- Can the person lead a successful change initiative?
- Do they have learning agility? Have they learned, for example, new therapeutic or functional areas along their career path?
- Can they work cross-functionally, which is more than being just a team player?
- Are they known to confront performance challenges, or do they sweep them under the rug?
- Do they balance humility with ambition?



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AN EFFECTIVE TRANSITION

Leaders need to look at the long-term needs of the organization, not just the urgent ones. They need to address sustained challenges and ensure that the senior leadership team works together in collaborative, optimizing, cross-functional relationships. Once someone is hired, they should be involved from “day zero,” Cayer says.

Margus agrees new executives should be part of the conversation early on. He sees a transition as a good opportunity to get a fresh perspective on the company’s strategy. “I have seen some boards make a mistake where they try to have all the strategy figured out when the new CEO joins,” he says. “They tell the new guy ‘Here’s what the company needs to do.’ But you have to be careful with that. As executive chair, I’ll be telling the board, ‘Let’s hear what the new guy thinks. Let’s force him to do some thinking about our strategy.’”

Cayer is a big believer in coaching at all levels, but for transitioning an executive role, he feels hiring an external executive or leadership coach is essential. After identifying the development needs from interviews with co-workers and speaking with the target person’s boss, a coach can work with the individual to meet those needs.

It’s also a good idea to have an overlap period, if possible. This might be longer and more supportive for a first-time CEO, but in the case of Cerevance, newly appointed CEO Craig Thompson had already held that position twice before, so Margus plans on just a six-month transition.

Another way Cerevance helped ease its CEO handoff was with a virtual fireside chat. “I interviewed Craig and asked him the kinds of questions I knew people were interested in,” says Margus. “This enabled him to take us through his impressive background while I could also rave about him in a way that he couldn’t as he introduced himself. It was also a chance for people to see—despite the press release—the real interaction and chemistry between [us].”

Thompson realizes the change isn’t just about him; it’s a change for the entire company. “The big takeaway for me is to communicate often and well,” he says. “Communicate expectations, make sure you have a great partner, and if you have a question, pick up the phone and ask.” **PE**



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DE&I in Pharma: Good for People— and Business

How addressing equity gaps can be a boost for brands

Back in 2019, I was running the Global Awards, an international competition focused on health, wellness, and pharma advertising and communications. My considered approach was to have a large, diverse, worldwide jury of peers (creative director level and above), keeping in mind that cultural response to advertising can vary quite a bit—certainly enough to make an impact on scoring. I've always been a proponent of diversity of thought.

As a result, the initial round of judging took place in 21 different countries on six continents. I also made it a point to diversify the judges sitting on the executive jury, who decided which pieces were to be awarded. Half of the executive jury were women, and the chairpersons were also women. This is noteworthy, considering the Three Percent Movement cited only 11% of creative directors worldwide were women in 2019, a number that is now listed at 29%. In 2012, when the Three Percent Movement was started by Kat Gordon, only 3% of creative directors in advertising were women—3%!

What's important is that groups like the Three Percent Movement are pushing for women to be in leadership positions and are doing so successfully. Gordon started the Three Percent Movement as a passion project to elevate women and, of course, spotlight a huge business opportunity in advertising—the lack of female creative leadership and its impact on connecting with an overwhelmingly female marketplace. So, not only was the advent of the movement good for women, but it was good for business.

One can't help to see the parallel when it comes to health equity in the “melting pot” known as the United States. In 2020, according to the US Census Bureau, the most prevalent racial or ethnic group in the US was the White non-Hispanic population at 57.8%. This decreased from 63.7% in 2010. The Hispanic or Latino population was the second-largest racial or ethnic group, comprising 18.7% of the total population. The Black or African American was the third-largest group at 12.1%.

Yet issues persist in terms of hiring and elevating women and people of color, increasing clinical trial diversity, raising awareness of disease, and improving access to healthcare for medically underserved populations. An analysis of FDA data since 2015 detailing clinical trials of cancer drugs found that 24 out of 31

cancer trials had fewer than 5% Black participants. That's really tough to swallow, considering Black women are disproportionately affected, and that's just one example.

This really goes back to Gordon's point, which not only calls for equity, but elucidates the simple concept of knowing your audience and customer base, and establishing a relationship based on trust. And as Walt Geer, chief experience design officer, VMLY&R, said to me, “I always say that the messenger matters—who's delivering these messages matters—because with that comes trust. Why do you think social media influencers are such a big deal, changing the way health and pharma brands are marketing to their audiences now? It's because people trust people that they follow because they are often people they align with.”

It always matters—having people of color working in the pharmaceutical industry, the agencies creating ads and marketing plans, reaching out to advocacy groups, and liaising with healthcare professionals (who are often Black in areas with large Black populations). It's not only for people and good health outcomes, but it's good for business. When you look at health equity in the US and Big Pharma, as well as the inherent opportunity of a quickly changing population in terms of diversity, you must wonder why certain realities still exist, and why some don't for that matter.

My reflection on diversity and the percentage of women in the Global Awards jury is something I'm proud of, of course, but it's just one group. What was truly odd to me at the time was the lack of African Americans working at the executive creative director (ECD) and creative director level of advertising. Geer, who I interviewed a few months ago, is one of 10 Black ECDs in the entire advertising industry, and he is the only one I'm aware of who focuses on health and pharma. “The big five ad holding agencies representing the US have over 360,000 employees,” said Geer. According to Statista, there are approximately 13,700 advertising agencies in the US. I'm not one for hyperbole, but this is mind-blowing.

Many more questions and topics remain, and we look forward to hosting some wonderful guests in a much wider discussion to be had on June 29, when *Pharmaceutical Executive* hosts a DE&I Sales & Marketing Roundtable. A summary of that event will appear in our August issue. **PE**



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Are We Closer Than Ever to a Biotech Bottom?

Some observations point to hope for an upturn

As we live through the steepest and longest bear market in biotech history, historical precedents offer little value in assessing how much lower we could fall or for how long. According to a recent biotech market update from Tim Opler and team at Torrey, over one-third of biotechs have lost 75% of their value since the market peaked in early 2021, over 200 companies are trading below enterprise value, and two-thirds of biotechs have an enterprise value below \$100 million (vs. 36% in November 2021).

That said, it is likely true that we may be closer than ever to a bottom. In fact, the week of May 16 was the first up week for the sector in the seven weeks prior—shockingly, it was actually the top-performing sector.

Perhaps, this may have been ushered in part by the increasingly pervasive fears about an impending recession fed by disappointing earnings reports from leading consumer and retail companies flooded with excess inventory and facing soaring costs. Apparently, customers are trading down to cheaper private-label items and appear to be buying what they “need” vs. what they “want,” and the inventory bulge is in the products that fall into the latter category. Inventory markdown risks are running high.

Giants like Walmart and Target have seen their worst stock declines since 1987 and took a sharp ax to their forecasts. Investors fear it could get worse, as the likes of Costco, Dollar General, and Best Buy report their results.

A rapid acceleration in the economy had investors rotating out of expensive growth stocks (like biotech), while rising expectations for rates penalized long-dated assets, such as the highly risky development-stage biotechs, years away from the market, and serial capital raisers highly dependent on capital markets. With the sputtering in the economy and prevailing expectations for a recession, investors may rotate back into growth, including biotech.




BARBARA RYAN
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GREEN SHOOTS SUGGEST OPTIMISM FOR BIOTECH

While still slow and selective, a window into accessing the capital markets does appear to be opening with IPOs and follow-on offerings picking up. We are hearing that the sector specialists do believe there is opportunity in the carnage, and money appears to be coalescing with a goal of identifying and capitalizing on them. Restructurings are reducing cash burns and ring-fencing lead programs. Firepower among the large-cap biopharmas, according to a report published by EY, is at all-time highs, and M&A, partnerships, and alliances remain a key pillar of growth strategies, particularly as the industry heads into a substantial patent cliff and industry blockbusters face losses of exclusivity. New funds continue to pour into the sector earmarked for investments in the innovation renaissance underway. ATLAS is closing a \$3 billion fund, Sofinnova is bringing in \$1.5 billion from Apollo, along with other VCs and financial sponsors with rising interest in the sector. Flagship and many others have all raised record amounts of capital for investment in biotech.

SMART MONEY LOOKS TO INVEST MORE IN BIOTECH

“This is not 2000, when biotech investors often bet on a one-product company, which by definition is binary. Today, savvy healthcare investors have an opportunity to buy platforms of IP, with multiple paths to value creation, some of which have the potential to provide cures,” says Meghan Fitzgerald, a private equity investor who is also a founder in K2Healthcare Ventures and an active life sciences fund investor. “For those with the right teams to assess the science, it’s a compelling time to roll up assets trading at or below cash.”

Interest in reverse mergers is also growing, which have the potential to create new companies with better funding and broader pipelines. Reverse mergers could consolidate the public biotech space. According to select equity capital market desks, dialogues with prominent funds in the sector are calling for a bottom. Let’s hope they are right. 



Interpreting Deep Neural Networks Toward Trustworthiness

On-demand webinar

Aired: Thursday, April 7, 2022

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www.pharmexec.com/pe_p/neural_networks

SPEAKERS:

Bin Yu

Chancellor's Professor in the Departments of Statistics and Electrical Engineering & Computer Sciences, University of California, Berkeley

Lucas Glass

Vice President, Analytics Center of Excellence, IQVIA

MODERATOR:

Fran Pollaro

Senior Editor, Pharmaceutical Executive

Presented by:

**Pharmaceutical
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Recent deep learning models have achieved impressive predictive performance by learning complex functions of many variables, often at the cost of interpretability. This webinar first defines interpretable machine learning in general and introduces the agglomerative contextual decomposition (ACD) method to interpret neural networks.

Extending ACD to the scientifically meaningful frequency domain, an adaptive wavelet distillation (AWD) interpretation method is developed. AWD is shown to be both outperforming deep neural networks and interpretable in two prediction problems from cosmology and cell biology. Finally, a quality-controlled data science life cycle is advocated for building any model for trustworthy interpretation, and a predictability computability stability (PCS) framework is introduced for such a data science life cycle.

3 Key Take-Aways

- Explores how interpretation of machine learning (ML) and deep learning (DL) models needs to pass reality checks, be useful to an audience, and solve a particular problem.
- Explains two viable deep learning interpretation methods with available codes for utilization.
- Discusses a useful framework for a quality-controlled data science life cycle to ensure trustworthiness of data results.

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Clinical Pharmaceutical Composer

Tremeau CEO Bradford Sippy strikes a new chord with revival of old blockbuster drug—modifying it as a unique treatment for orphan hemophilia condition

By Elaine Quilici



Any musician knows the power of a good arrangement. Sometimes taking the same notes and tweaking them can create a sound that's even better than the original song.

Perhaps it was that insight as a musician which helped Bradford Sippy, CEO of Tremeau Pharmaceuticals, see the potential in a withdrawn drug that was once a blockbuster. An entrepreneur at heart, he recognized the value of Merck's Vioxx and began sketching a plan to turn it into a viable treatment for severe hemophilic arthropathy.

"I've always had an entrepreneurial mindset, but you're not going to start a pharmaceutical company in your dorm room," he says. "There aren't any Mark Zuckerbergs in the pharmaceutical industry."

To achieve his dream of starting his own pharma company, after receiving a BS in chemical engineering from Purdue University and an MBA from New York University, the first part of Sippy's career was dedicated to gaining as much experience in as many different places within pharma as possible. After jobs in manufacturing, logistics, research and development, and sales, and specialized training in intellectual property, he decided to focus on the commercial organization and rose through those ranks. He worked for companies such as Roche, Merck, and Sunovion, then eventually was ready to strike out on his own and started Tremeau in 2016.

"Knowing how the entire industry gets put together and having worked in a variety of different roles, and then having the specific experience in this space all combined to put me in a position to be able to do this," he says.

FINDING THE MUSIC BETWEEN THE NOTES

Sippy began his career at Merck as a salesperson in 2000, with one of his products being Vioxx (rofecoxib). The medicine, approved in May 1999, was a popular cyclooxygenase 2-selective, nonsteroidal anti-inflammatory drug (NSAID) that relieved the symptoms of osteoarthritis, managed acute pain in adults, and provided relief for rheumatoid arthritis in adults and children. However, on Sept. 30, 2004, the company voluntarily withdrew Vioxx worldwide due to safety concerns of an increased risk of cardiovascular events, including heart attack and stroke.

In 2005, Sippy was managing the withdrawal of Vioxx as part of the marketing team. As Merck was publishing all the studies associated with rofecoxib, he came across one for the use of rofecoxib and another COX-2 inhibi-

tor, etoricoxib, in the treatment of hemophilic arthropathy. Prior to that, he had never heard of the condition.

"I remember that day 17 years ago," he says. "It was clear that this was a patient population for which this product would be almost a perfect fit. At that time, it was becoming [apparent] that maybe the withdrawal of Vioxx was a mistake, and I had this aha moment that no matter where you land on the debate around the product, that this is a population that almost anybody would agree is a medically appropriate population for the product, and that there might be other places where it can be used."

Though Vioxx was singled out as being risky, Sippy suggests the spotlight was unjustly shone on the product. He explains that Vioxx unfortunately took the heat for its entire class of drugs, which was experiencing similar issues. "It was not the worst in the category," he says. "But it was the first in the category to really uncover what was an issue with the whole class."

Looking beyond the negative news coverage and sticking to the science, Sippy recognized rofecoxib's unique benefits that are particularly relevant to hemophilia patients. These patients often develop early arthritis because of internal joint bleeds. However, due to that internal bleeding risk, they can't take normal NSAIDs. As a result, they are often treated with opioids to manage their arthritic pain. "Because this can happen at an early age, it's not uncommon to have, unfortunately, a 13-year-old kid taking fentanyl patches with this condition," he says.

As the opioid crisis intensified, it reinforced the need for a new therapy that wasn't addictive.

Sippy saw the potential for rofecoxib, which is an NSAID, like ibuprofen, but doesn't have some of the negative effects of ibuprofen, including the potential to cause ulcers, bleeding, or holes in the stomach or intestine. "It's a great treatment option for somebody with hemophilia," he says. "And, more broadly, in a variety of different diseases where you wish you could take an NSAID, but you can't. We're trying to focus the use of the product in those places."

As Sippy planned his revival of rofecoxib, his experience in intellectual property came in handy. He knew when Merck's patents on Vioxx were going to expire and release into the public domain.

Though he had to wait about 12 years, he was able to build his industry experience further during that time. He left Merck to join Sunovion and advanced there, ultimately running the two blockbuster drugs Lunesta and Latuda. "I was kind of biding my time

and thinking about this,” he says. “Then when the patents expired—and it was the right time for me personally and career-wise—I decided to take the jump.”

As Tremeau further developed rofecoxib, which is now in Phase III clinical trials, Sippy and his team discovered previously unknown properties of the product, which led to several new patents on the updated drug. Developing a therapy for an orphan condition also came with its own exclusivity.

SINGING A DIFFERENT TUNE

Taking a drug synonymous with pharmaceutical risk and turning it into a treatment for hemophiliacs might seem like a messaging challenge, but Sippy had science on his side.

First, he had to separate the perception and reality of rofecoxib. As he dug into the drug studies, it was evident that the root cause of the previous issues was that people were taking the product inappropriately—they were using very high doses only indicated for acute use as a chronic treatment. “The facts are that at normal doses it has a similar [cardiovascular] safety profile to other NSAIDs, but it has unique benefits that could [help] patients like hemophiliacs and other patient populations,” says Sippy.

Another misperception of the drug is that FDA forced it off the market, which is not true; it was a voluntary withdrawal. In fact, FDA is on record saying it was a class effect and that rofecoxib actually had the best gastrointestinal safety profile of any product in the class. “Most people don’t know that,” says Sippy. “They just know the headline, and they don’t realize that the FDA was setting the stage for this product’s potential reintroduction back then.”

Tremeau is defining a specific target for rofecoxib this time around. To avoid mistreatment, it is focusing on places where the product’s unique benefits can be clearly realized. With plenty of effective NSAIDs available, there is no reason for the average person to use rofecoxib. Although the data support that it could be used anywhere in lieu of ibuprofen, Sippy realizes the world doesn’t need a similar drug and wants to focus on the areas where ibuprofen can’t be used.

Sippy also had to address messaging when it came time to secure financing for Tremeau. The traditional way to approach investors is to cast a wide net to ultimately discern who shows the greatest interest and fits best with an investment thesis, then convince people that the science will successfully translate into reality. This wasn’t necessary for Sippy though; the drug was extremely well studied and had been already approved for six indications.

Early on, Sippy recognized that there were people stuck on the negative perception of Vioxx, but others understood the reality of its history, so he used an upfront filter to identify the most fruitful leads. Before he would sign a confidential disclosure agreement with someone or go through any lengthy discussions with a potential investor, he would ask: “What do you think of Vioxx?”

If they hesitated with concerns about the drug’s prior withdrawal and safety issues, he knew there was a low probability of flipping that person.

Fortunately, there were many prominent people in the industry who recognized the reality of the situation. They appreciated that most of the risks typical in pharmaceutical development were already answered through the many studies that had been conducted. This is what happened with the fund that Sippy ultimately ended up working with, which was run by the ex-CEO of Sanofi and the former chairman of PhRMA. “I walked into a room to tell him about our plans, and he said, you can skip the first 20 slides of your presentation, you don’t need to convince me this is a good drug that’s got a place; let’s talk about your strategy to bring it back,” he says.

The one group that probably needed the least convincing that rofecoxib was safe and effective was the hemophilia community. Prior to Vioxx’s withdrawal, it had been a standard of care in this space. Though it didn’t have a formal indication for hemophilic arthropathy—there were no approved drugs for this—it did have indications for similar conditions, such as rheumatoid arthritis and osteoarthritis.

“There were two factions [among those treating hemophilia],” says Sippy. “There were the old timers, people who were in practice when the product was on the market. They thought this was a great idea and were very interested. Then there was the younger generation that was in medical school [during the withdrawal] who never actually used the drug and [questioned] if it had some problems. I used largely the same argument as I did with investors and the FDA, and showed them our minutes, to convince them of the reality of the situation.”

HARMONIZING WITH FDA

Many companies rely on reports that their science works in order to sell their product; it’s years before they get involved with FDA. But Sippy knew his science was solid; he felt it was more important to demonstrate that FDA was on his side. In fact, the first thing he did when starting Tremeau from his kitchen table was setting up a meeting with the agency, because he knew that having formal minutes demonstrating there was a perception and reality gap would be important to convincing stakeholders.

“The world is driven by perception, but the good news is the FDA is driven by reality,” he says. “I had the least difficulty making this case to the FDA, because oftentimes I was quoting them back to themselves. They were very receptive to the idea of what we were proposing.”

When Tremeau submitted an orphan designation for hemophilic arthropathy, it was approved within two months vs. the average six-month wait time for that type of approval at the time. FDA agreed to mitigate the risk of the higher dose and off-label use by allowing Tremeau to develop normal doses. Some of the

greatest challenges arose in developing the Phase III protocol for hemophilic arthropathy.

“We had to do a lot of work with the FDA to have a rescue med and [decide] what’s an appropriate washout period and pain score in order to qualify for the trial,” says Sippy. “It’s quite a complicated trial because of the unique considerations within this patient population.”

ACTING AS MAESTRO

As a leader, Sippy relies on patience and tolerance. He knows that things won’t always go well, so it’s important to have a couple different irons in the fire. “Nothing worthwhile is ever easy or ever certain,” he says. “When I propose things to the group or seek ideas, it always comes with the mindset of let’s give this a try, but let’s manage our expectations as to what’s going to happen and only operate off what we know.”

Sippy’s down-to-earth attitude can be traced back to his humble roots. “I’m not a very formal person,” he says. “I grew up with nothing, I paid my own way through college, I’ve done every menial job you could ever imagine. It’s hard to be too full of yourself when you’ve washed dishes and scrubbed toilets as a job before.”

His employees understand and appreciate his unpretentious leadership style. This comes through at team meetings, where everybody is free to speak. “But you have to back up your ideas and your thoughts,” he says. “Just because you’re a more junior person doesn’t mean that I’m not going to hear you out. Conversely, just because you’re a senior person doesn’t mean I’m going to necessarily accept what you say without rationale.”

Sippy also likes to give people credit for their ideas and believes it fosters an environment of willingness to communicate. Sometimes he will go out of his way in a board meeting to make sure to mention the person on the team who came up with an idea, even when they’re not in the room.

Delving into the “why” of things over the “what” is also important to Sippy. “If we’re picking a strategy or I’m describing a decision, I’ll always say, ‘I want to do this because of X, Y, and Z,’” he says. “By having that habit of communicating the what and the why, it allows everybody to understand what’s going on and then it also allows you intellectual flexibility to change with new information.”

ALWAYS ADDING TO HIS REPERTOIRE

Sippy’s “feverish, inventive mind” is always full ideas. In addition to Tremeau, he helped start another small, pharma-related company in 2019, with a lead product that is consumer-focused. “A few years ago, I became enamored with a type of technology called deuteration, where you substitute deuterium for hydrogen and can modify how a product gets metabolized or absorbed,” he says. “I



Whether it’s drug development or music, Bradford Sippy is always up for a challenge. The self-taught bass guitarist now has original tracks available for listening, including on Spotify (link here: <https://spoti.fi/3GnuINh>).

felt that it had more potential than was probably being used right now in the industry, so I started Lennham Pharmaceuticals up and put some patents I had in there, and it’s now taken on its own life.”

Another creative outlet is Sippy’s passion for music. He was a saxophone player when he was younger, but it wasn’t until his two daughters were in school that he recommitted himself to the art. “We were encouraging them to try piano, and I felt like: What kind of role model am I? I can play. I mean, I’m not Fleetwood Mac, but I was good,” he says. “I decided, if I’m encouraging them to try instruments, maybe I should put my money where my mouth is.”

He contemplated a number of new instruments to take up and ultimately started teaching himself bass guitar. “A big advantage of being a bass player is...everybody needs one,” he says. “The moment I displayed any level of competency, I was being invited by local cover bands [in Boston] and worked my way up.”

As Sippy progressed as a musician, he started learning about music theory and is now collaborating with other artists to create their own music. He recently released his first few tracks on Spotify, iTunes, and other platforms, and has around eight more in the queue.

“One of the things about [music] is you only have 12 notes at the end of the day, but it’s amazing how [you can have] an infinite number of combinations of them—there’s always something new to be done,” he says.

While there are more than 12 elements that go into building chemical compounds, sometimes it takes similar insight to see old drugs in a new light. That’s exactly what Sippy did with Vioxx: He took something pre-existing, analyzed it’s potential with modifications, and turned it into something that people can appreciate in a whole new light. “The base is there,” he says. “It’s just how you arrange it.” **PE**



Source: erika8213/stock.adobe.com

The windfall from COVID-19 vaccines and treatments has shaken up *Pharm Exec*'s latest listing of the top global biopharma sales producers in record-breaking fashion, but a likely leveling off—along with challenging patent and global climates—should shift some of the spotlight to anticipated non-COVID risers and perhaps more definitive maneuvering ahead

By Michael Christel

If 2020 was the “Year of COVID,” as we referred to it in our *Pharm Exec* 50 feature last year—reflecting on the pandemic’s scope and disruption on all facets of life—then 2021 was surely the year of COVID vaccines and treatments. And, through the prism of our latest rankings of the top 50 global biopharma players based on prescription drug sales, one that will go down in the annals of commercial Rx output—even if just a short burst in time when looked back upon decades from now. To illustrate the pandemic’s historic jolt to our annual listing, rearranging several spots in the top half, attention first goes to mRNA vaccine makers Pfizer and Moderna, with the former also delivering significant recent gains from its effective, if not somewhat controversial, antiviral therapy for COVID. In data again provided in partnership with Evaluate Ltd, the rankings, our 22nd, capture most recent full-year drug revenue performance. Company R&D investment totals are also presented, as in previous installments.

Last year, Pfizer recorded overall prescription drug sales of \$72 billion, with \$37 billion of that generated from COVID vaccine Comirnaty, alone, making it the best-selling drug in a single year of all time by a wide margin. Factor in first-quarter revenue of \$13.2 billion for Comirnaty in 2022, and the vaccine is already rivaling the cumulative lifetime sales of many blockbuster medicines. Paxlovid, Pfizer’s COVID pill, which received FDA emergency use authorization in December 2021, posted \$1.5 billion in first-quarter sales and may be poised to become the best-selling non-vaccine ever, if it lives up to Pfizer’s projected guidance of

\$22 billion for 2022 (the company says it is set to produce 120 million treatment courses this year, and according to published reports, it doesn’t have to sell all of those courses to exceed \$22 billion). If the ramped-up manufacturing and totals comes to fruition, Paxlovid would eclipse AbbVie’s Humira’s \$20.7 billion in sales in 2021 as the highest grossing non-vaccine to date. Those prospects have encountered recent headwinds, including the CDC’s warning of a potential COVID “rebound” after taking Paxlovid.

BIG GAINS, BUT WILL THEY SUSTAIN?

Pfizer and Moderna are among a handful of biopharmas that have reaped the rewards of the COVID windfall following successful development projects. Given the aforementioned numbers, it was no surprise that Pfizer vaulted from the eighth spot in our previous company rankings to No. 1 in the newest ledger, posting an increase in Rx sales of 102%. In fact, Comirnaty’s output by itself would rank Pfizer ninth overall. In May, the pharma giant reported the best quarter in the company’s history, with total revenue (not just Rx) of \$25.6 billion; it expects full-year 2022 revenue between \$98 billion and \$102 billion (although Pfizer did cut its earnings per share slightly for the year in adjusted first-quarter guidance).

Sharing the mRNA-platform stage in COVID has been Moderna’s vaccine Spikevax, which propelled the Cambridge, Mass.-based biotech into the Pharma 50 for the first time behind \$17.7 billion in 2021 sales. Moderna secured the 17th spot with \$19.2 billion in total Rx revenue. The company sold \$5.9 billion of its

COVID vaccine in the first quarter of this year, and in its May earnings call maintained the organization's full-year guidance of \$21 billion in Spikevax sales. Of note recently, the marketing authorization for Spikevax in Japan will transfer from Takeda to Moderna starting Aug. 1, the two companies announced in late May.

Driven by its monoclonal antibody treatment, Ronapreve, for preventing COVID symptoms, Regeneron leapfrogged eight spots in the Pharma 50 to No. 20, with an increase of 118% to \$12.1 billion in prescription drug sales. Ronapreve, which was effective against initial COVID variants, posted \$5.8 billion in 2021 sales.

Other notable pandemic-influenced jumps in our rankings include AstraZeneca (AZ), whose vaccine Vaxzevria reached \$4 billion in sales last year, helping catapult the company to a 41.5% increase in Rx sales and two spots up to No. 9; Gilead Sciences advancing one spot to No. 12 (and a spike of 13.4%) behind its antiviral drug Veklury (remdesivir), which recorded \$5.6 billion in revenue; and Johnson & Johnson (J&J), which generated \$49.8 billion in 2021 Rx sales, securing fourth on our list and an increase

of 15.5% from the previous year. The company's COVID vaccine, marketed by its Janssen unit, made \$2.39 billion in 2021.

Perhaps factoring into our rankings next year will be treatments or vaccines cleared for emergency use or expanded use in the US and/or Europe in late 2021/early 2022 from Eli Lilly, Merck, GSK, and Sanofi. (For example, revenue from Lilly's COVID antibodies, bamlanivimab and etesevimab, grew \$660 million in the first quarter of this year; the duo made \$2.2 billion in 2021, and Merck's oral antiviral molnupiravir posted \$3.2 billion in Q1).

The million-dollar (or billion-dollar) question is just how long will these tenacious tailwinds last. The consensus among analysts is that first-cleared products during the pandemic may have already hit their peaks, or will this year, and sales will likely start to dip from there. But proper context should also be weighed in the equation—after all, the pandemic has represented an extremely special and unforeseen circumstance for the life sciences and healthcare sectors, one that triggered an unprecedented response in R&D and ultimately product distribution and delivery; thus comparing

	2021 Rx Sales*	2021 R&D Spend*	2021 Top-Selling Drugs*	
1 Pfizer NEW YORK, NEW YORK [PFIZER.COM]	\$72.043	\$13.829	Comirnaty Prevnar 13 Ibrance	36.853 5.587 5.477
2 AbbVie NORTH CHICAGO, ILLINOIS [ABBVIE.COM]	\$55.041	\$6.518	Humira Imbruvica Skyrizi	20.694 4.321 2.939
3 Novartis BASEL, SWITZERLAND [NOVARTIS.COM]	\$51.128	\$9.041	Cosentyx Entresto Gilenya	4.718 3.548 2.787
4 Johnson & Johnson NEW BRUNSWICK, NEW JERSEY [JNJ.COM]	\$49.821	\$11.781	Stelara Darzalex Remicade	9.134 6.023 3.190
5 Roche BASEL, SWITZERLAND [ROCHE.COM]	\$49.293	\$13.080	Ocrevus Perjeta Actemra	5.532 4.328 3.898
6 Bristol Myers Squibb NEW YORK, NEW YORK [BMS.COM]	\$45.669	\$9.531	Revlimid Eliquis Opdivo	12.821 10.762 7.558
7 Merck & Co. KENILWORTH, NEW JERSEY [MERCK.COM]	\$43.259	\$12.245	Keytruda Gardasil Januvia	17.186 5.672 3.323
8 Sanofi PARIS, FRANCE [SANOFI.COM]	\$38.934	\$6.150	Dupixent Fluzone Lantus	6.214 3.111 2.953
9 AstraZeneca LONDON, ENGLAND [ASTRAZENECA.COM]	\$36.131	\$7.987	Tagrisso Vaxzevria Farxiga	5.015 3.917 3.000
10 GSK BRENTFORD, ENGLAND [GSK.COM]	\$33.443	\$6.573	Triumeq Shingrix Tivicay	2.590 2.369 1.901

Source: EvaluatePharma® May 2022, Evaluate Ltd, www.evaluate.com

How the listings were compiled: 2021 Rx Sales and R&D Spend analyses were provided by life sciences market intelligence firm Evaluate Ltd via its EvaluatePharma® service, www.evaluate.com. Pharm Exec would like to thank EvaluatePharma for assisting in the development of this year's Pharma 50 listing.

PLEASE NOTE: 2021 figures represent prescription pharmaceutical sales from the named company only, and exclude revenues from royalties, co-promotions, etc., as well as sales from

*numbers USD in billions

non-prescription pharmaceuticals. Figures in green are Evaluate Consensus Estimates, and are included where actual reported sales data was not available at the time of generation. Evaluate's Sales and R&D Spend figures represent the fiscal year that ended in 2021. For most American and European companies, that means the year ending Dec. 31, 2021. For many Japanese companies, the fiscal year ending March 31, 2022, was used. Historic averages were used in the conversion of companies' native currency to USD.

the sales of COVID products to other drugs in the traditional sense may not be a fair exercise.

Potential new records after this year, nevertheless, are unlikely in the near future. Editors at Evaluate Vantage interviewed by *Pharm Exec* cite trends such as waning demand for COVID vaccines and drugs, as well as supply challenges and shifts in where future government contracts will predominately originate. “I think most of the developed Western worlds that are able to pay higher prices have already bought their vaccine stockpiles,” says Lisa Urquhart, editor, Evaluate Vantage, who is based in London. “There’s debate [in the UK] on whether or not there’s going to be the need for a fourth vaccine [dose] outside of the immunocompromised and the vulnerable. If the US follows suit and if new strains continue the trend of being more mild, then I think some of the targets around the sales might not materialize. It also means you’re now going to have to start selling outside of the Western world into emerging markets where your margins are going to be much lower.”

The consensus for Comirnaty sales in 2023 is reportedly around \$17 billion. Evaluate projects revenue for Comirnaty and Paxlovid settling between \$2 billion to \$4 billion, respectively, by 2025. In the more immediate setting for Paxlovid, Urquhart points to uncer-

tainties around the number of new contracts signed in the first quarter and how much ground will be needed to make up to meet Pfizer’s \$22 billion full-year target. She also notes the fairly strict use of Paxlovid, with several contraindications, such as with patients with diabetes and hypertension. Consensus for Moderna’s Spikevax, Evaluate says, is around \$2 billion in annual sales by 2026. The company’s post-COVID strategy will be followed closely (Moderna’s pipeline includes a candidate in Phase III trials for respiratory syncytial virus, along with early stage projects for the flu and cancer, and next-generation pursuits in COVID).

AZ executives earlier this year projected a low-to-mid 20s drop for Vaxzevria in 2022 (though the company is active in new R&D antibody pursuits), and in April, J&J reported first-quarter sales of \$457 million for its vaccine, far short of Wall Street’s estimate. The results, attributed to low demand and an oversupply in low-income countries, prompted J&J to pull the vaccine from its revenue projections. Regeneron posted no US sales in the first quarter for Ronapreve after FDA rescinded its authorization in January due to poor performance against omicron. Roche, which markets the drug outside the US in a profit-sharing deal with Regeneron, did report \$636 million in revenue during the period.

	2021 Rx Sales*	2021 R&D Spend*	2021 Top-Selling Drugs*
11 Takeda OSAKA, JAPAN [TAKEDA.COM]	\$29.605	\$4.651	Entyvio 4.865 Vyvanse 2.746 Gammagard Liquid 2.680
12 Gilead Sciences FOSTER CITY, CALIFORNIA [GILEAD.COM]	\$27.005	\$5.226	Biktarvy 8.624 Veklury 5.565 Genvoya 2.879
13 Eli Lilly INDIANAPOLIS, INDIANA [LILLY.COM]	\$25.958	\$7.026	Trulicity 6.472 Humalog 2.453 Bamlanivimab & Etesevimab 2.239
14 Amgen THOUSAND OAKS, CALIFORNIA [AMGEN.COM]	\$23.957	\$4.296	Enbrel 4.465 Prolia 3.248 Otezla 2.249
15 Novo Nordisk BAGSVAERD, DENMARK [NOVONORDISK.COM]	\$22.417	\$2.830	Ozempic 5.366 NovoRapid 2.538 Victoza 2.397
16 Bayer LEVERKUSEN, GERMANY [BAYER.COM]	\$20.119	\$3.716	Xarelto 5.023 Eylea 3.454 Mirena 1.385
17 Moderna CAMBRIDGE, MASSACHUSETTS [MODERNATX.COM]	\$19.167	\$1.826	Spikevax 17.675
18 Boehringer Ingelheim INGELHEIM, GERMANY [BOEHRINGER-INGELHEIM.COM]	\$17.806	\$4.392	Jardiance 3.187 Ofev 2.949 Tradjenta 1.837
19 Viatris CANONSBURG, PENNSYLVANIA [VIATRIS.COM]	\$17.508	\$642	Lipitor 1.663 Fluticasone Propionate; Salmeterol 1.100 Xinafoate 825 Norvasc 825
20 Regeneron Pharmaceuticals TARRYTOWN, NEW YORK [REGENERON.COM]	\$12.117	\$2.864	Ronapreve 5.828 Eylea 5.792 Libtayo 306

Source: EvaluatePharma® May 2022, Evaluate Ltd, www.evaluate.com

*numbers USD in billions, lower numbers in millions

Add to the mix ongoing macroeconomic challenges to navigate, such as the war in Ukraine, supply chain issues caused by China, and global inflation; a volatile M&A and seller valuation climate that has shown little sign of abating; and an impending “patent winter,” which analysts contend will be the most painful period of branded sales erosion in at least 30 years, and the overall picture for the Pharma 50 could turn a bit unsettled as the decade progresses.

ABBVIE'S ASCENT

Spurred by COVID vaccines and therapies, US spending on pharmaceuticals rose 12% last year, according to a report by the IQVIA Institute for Human Data Science, and the rate of new prescriptions for chronic and acute care largely recovered from the 2020 pandemic-sparked slowdown. To that end, several organizations with no COVID products in our rankings delivered solid gains in 2021 Rx sales, none more than the strong surge made by AbbVie. Prescription drug revenue for the North Chicago-based pharma skyrocketed almost \$11 billion to \$55 billion last year, moving AbbVie up one spot to No. 2 behind Pfizer. As mentioned, Humira, the company's flagship, brought in record sales, a number it may eclipse this year before the anti-inflammatory stalwart goes off patent in

the US in 2023 and biosimilar competition begins (the majority of Humira's sales come from the US; it is already off patent in Europe).

While Humira will no longer enjoy \$20 billion-plus totals after 2023, Urquhart doesn't believe sales will fall dramatically in the US like they have in Europe, due to a different reimbursement structure in the US, the greater reluctance of physicians in America to substitute biosimilars for the branded product, and the “patent thicket”-type deals originator companies sometimes enter into.

Combined with Humira follow-ups Skyrizi (IL-23 inhibitor for psoriasis) and Rinvoq (JAK inhibitor)—each enjoying stellar sales climbs since their launches in 2019, the latter continuing to add key new indications and recently showing late-stage promise in Crohn's disease—along with the steady rise of leukemia drug Venclextra, analysts remain bullish on continued AbbVie momentum. In fact, according to extended consensus forecasts collected by Evaluate, AbbVie is expected to become the biggest pharma company by Rx sales in 2028. Roche is projected to be a close second, followed by J&J (which is spinning off its consumer health business next year to focus more on its branded Rx), Merck, and Pfizer.

Amy Brown, Evaluate Vantage's special reports and projects editor, tells *Pharm Exec* that the tandem of Skyrizi and Rinvoq,

	2021 Rx Sales*	2021 R&D Spend*	2021 Top-Selling Drugs*
21 Astellas Pharma TOYKO, JAPAN [ASTELLAS.COM]	\$11.828	\$2.149	Xtandi 4.763 Prograf 1.653 Myrbetriq 1.536
22 Teva Pharmaceutical Industries PETACH TIKVA, ISRAEL [TEVAPHARM.COM]	\$10.468	\$933	Copaxone 1.005 Nifedipine 881 Austedo 802
23 CSL MELBOURNE, AUSTRALIA [CSL.COM.AU]	\$10.444	\$1.072	Privigen 2.635 Hizentra 1.377 Human albumin (CSL) 890
24 Biogen CAMBRIDGE, MASSACHUSETTS [BIOGEN.COM]	\$8.847	\$2.501	Tysabri 2.063 Tecfidera 1.952 Spinraza 1.905
25 Merck KGaA DARMSTADT, GERMANY [MERCKGROUP.COM]	\$8.392	\$2.027	Erbix 1.168 Rebif 1.127 Glucophage 1.023
26 Vertex Pharmaceuticals BOSTON, MASSACHUSETTS [VRTX.COM]	\$7.573	\$3.051	Trikafta 5.181 Orkambi 781 Kalydeco 729
27 Otsuka Holdings TOKYO, JAPAN [OTSUKA.COM]	\$7.368	\$1.989	Abilify MAINTENA 1.188 Rexulti 1.104 Jynarque 916
28 Daiichi Sankyo TOKYO, JAPAN [DAIICHISANKYO.COM]	\$7.261	\$2.354	Lixiana 1.833 Enhertu 583 Injectafer 473
29 UCB BRUSSELS, BELGIUM [UCB.COM]	\$6.395	\$1.928	Cimzia 2.179 Vimpat 1.725 Keppra 1.150
30 Organon ** JERSEY CITY, NEW JERSEY [ORGANON.COM]	\$6.172	\$307	Nexplanon 769 Clarinx 261 Ganirelix Acetate Injection 239

Source: EvaluatePharma® May 2022, Evaluate Ltd, www.evaluate.com

*USD in billions, lower numbers in millions

** Spun off from Merck in June 2021. Consists of three businesses—women's health, established brands, and biosimilars.

together, are expected to bring in \$18 billion by 2026. “Rinvoq’s recent approval in atopic dermatitis was a big one,” says Brown. It was cleared by FDA in January for patients 12 and older with refractory, moderate-to-severe disease who do not respond to oral drugs.

Rounding out the first five spots in our list are Novartis at No. 3, up 8.3% to \$51.1 billion; J&J, as mentioned; and Roche, dropping from the top perch to No. 5, posting a 3.8% increase to \$49.3 billion. Roche, the leader in R&D spend the last two years, remained strong in that area, investing \$13.1 billion, trailing only Pfizer’s \$13.8 billion. Merck and J&J also eclipsed double-digits in R&D spend, at \$12.2 billion and \$11.8 billion, respectively; Bristol Myers Squibb (BMS) was close at \$9.5 billion and Novartis invested \$9 billion. Driven by pandemic investments, the 11 largest Big Pharma companies saw their combined R&D investments jump 11% in 2021, exceeding \$100 billion, collectively, for the first time, according to Evaluate.

On the commercial side, J&J and Roche face notable patent expirations in the coming years—Stelara (\$9.1 billion in 2021 sales) next year and Ocrevus (\$5.5 billion) in 2029, respectively. Roche’s new drug for wet age-related macular degeneration and diabetic macular oedema, Vabysmo, approved by FDA in January, has projected sales

of \$1.8 billion from Evaluate in 2026. In partnership with PTC Therapeutics, Roche also gained a key label extension in May for its spinal muscular atrophy drug Evrysdi, now cleared for use across all ages. Novartis made news in April with plans to restructure its global operations, combining the company’s pharma and oncology units. The move pushed out three c-suite executives and signaled looming layoffs, but was done to boost Novartis’ presence in the US market. Quarterly sales for its heart drug Entresto rose 42% to \$1.1 billion.

The rest of the Pharma 50 top 10, with each one rising or dropping a spot or two, include BMS at No. 6; Merck at No. 7, Sanofi at No. 8; AZ, as mentioned, taking the ninth spot, and GSK at No. 10. Each posted Rx sales increases year-over-year. Of that bunch, BMS is under the most pressure to maintain, with three blockbuster products facing the patent ax—Revlimid (a former Celgene product) this year, Eliquis in 2026, and cancer PD-1 immunotherapy Opdivo in 2028. Merck’s PD-1 standout Keytruda, which posted \$17.2 billion in Rx sales in 2021 and has amassed numerous indications, will lose patent exclusivity in 2028, and its patent for diabetes power Januvia is set to expire next month. Potentially offsetting looming patent loses for BMS could be Camzyos, approved

		2021 Rx Sales*	2021 R&D Spend*	2021 Top-Selling Drugs*
31	Eisai TOKYO, JAPAN [EISAI.COM]	\$5.224	\$1.521	Lenvima 1.704 Humira 467 Halaven 329
32	Jiangsu Hengrui Medicine LIANYUNGANG, JIANGSU PROVINCE, CHINA [HENGRIUS.COM]	\$5.203	\$929	AiRuiKa 1.167 Aitan 477 Pyrotinib 272
33	Sun Pharmaceutical Industries MUMBAI, INDIA [SUNPHARMA.COM]	\$5.091	\$390	Ciprofloxacin Hydrochloride 183 Ilumya 176 Atorvastatin Calcium 114
34	Bausch Health Companies LAVAL, QUEBEC [BAUSCHHEALTH.COM]	\$4.924	\$452	Xifaxan 550 1.645 Ocuvite 351 Wellbutrin XL 264
35	Abbott Laboratories ABBOTT PARK, ILLINOIS [ABBOTT.COM]	\$4.692	\$212	Drospirenone; Ethinyl Estradiol 26 Ademetionine 26 Choline Alfoscerate 17
36	Sumitomo Dainippon Pharma OSAKA, JAPAN [DS-PHARMA.COM]	\$4.602	\$869	Latuda 2.008 Aptiom 223 Galvus 174
37	Grifols BARCELONA, SPAIN [GRIFOLS.COM]	\$4.516	\$420	Gamunex-C 1.572 Flebogamma 1.050 Prolastin-C 884
38	Fresenius BAD HOMBURG, GERMANY [FRESENIUS-KABI.COM]	\$4.362	\$704	Heparin Sodium (FRES) 84
39	Les Laboratoires Servier SURESNES, FRANCE [SERVIER.COM]	\$4.344	N/A	Daflon 500 566 Diamicron 527 Vastarel 497
40	Sino Biopharmaceutical HONG KONG [SINOBIOPHARM.COM]	\$4.206	\$503	Focus V 706 Tianqingganmei 241 Zepusi 215

Source: EvaluatePharma® May 2022, Evaluate Ltd, www.evaluate.com

*USD in billions, lower numbers in millions

in the US in April as the first drug to treat an inherited form of heart failure known as obstructive hypertrophic cardiomyopathy.

Like Novartis, Sanofi and GSK are in the midst of restructuring efforts, with Sanofi focused on pruning its general medicines pipeline, and GSK the spinoff of its consumer health business into an independent company, called Haleon, set to officially launch next month. The new company is the result of GSK and Pfizer combining their consumer health units in 2019. According to published reports, Pfizer intends to exit its 32% stake in Haleon, triggering a \$16 billion inflow of cash. In late May, GSK agreed to acquire clinical-stage biopharma Affinivax for up to \$3.3 billion. The deal will add novel pneumococcal vaccine candidates to GSK's pipeline and support the development of its vaccines and specialty drugs.

Among other top 20 entrants in the Pharma 50, Lilly rose one spot to 13th, with a 15% spike in Rx sales (last month the company won an anticipated approval for its new diabetes drug, Mounjaro, which should rival co-GLP-1 receptor agonist Wegovy, made by Novo Nordisk, and has strong potential in obesity); and Takeda, though down a peg to 11th, posted a 6.1% jump in Rx sales. Two of its top sellers, Vyvanse and Gammagard liquid, were borne out

of acquisitions, reflecting Takeda's pro-M&A slant, Urquhart says, compared to traditional views of Japanese companies on offshore dealmaking, perhaps attributed to Takeda's French-born CEO, Christophe Weber, who has lead the company since 2015.

CLOUDED M&A PICTURE

The slowdown of biopharma M&A has continued through the first half of 2022, with the exception (as of press time), on the semi-large scale, of Pfizer agreeing last month to buy Biohaven Pharmaceuticals for \$11.6 billion. The prospects of a major Pharma 50 reshuffling via M&A are likely slim for the rest of the year, though cash-rich drugmakers could theoretically pull the trigger if biotech valuations improve. Buyers and sellers, for now, seem to be entrenched in a wait-and-see approach, experts say—with both sides perhaps holding more closely to the principle of “cash is king.”

“Two or three of the Big Pharma CEOs at the last quarterlies said, ‘you know, sellers’ valuations in their heads haven’t changed yet,’” says Brown. “Sellers’ expectations need to reset. In the meantime, I think a lot of these big companies are happy to do bolt-on deals. That really is the trend right now.” **PE**

	2021 Rx Sales*	2021 R&D Spend*	2021 Top-Selling Drugs*
41 Shanghai Pharmaceuticals Holding SHANGHAI, CHINA [SPHCHINA.COM]	\$3.980	\$247	Tanshinone IIA 230 Shenmai Injection (SHANPH) 169 Hydroxychloroquine Sulfate 147
42 Alexion Pharmaceuticals CHESHIRE, CONNECTICUT [ALXN.COM]	\$3.804	N/A	Soliris 2,258 Ultomiris 903 Strensiq 473
43 CSPC Pharmaceutical Group SHIJIAZHUANG, CHINA [CSPC.COM.HK]	\$3.781	\$445	Butylphthalide 992 Doxorubicin Hydrochloride 501 Jinyouli 452
44 Menarini FLORENCE, ITALY [MENARINI.COM]	\$3.616	N/A	Bystolic 397 Elzonris 213 Enantyum 189
45 Ipsen PARIS, FRANCE [IPSEN.COM]	\$3.236	\$514	Somatuline 1,341 Trelstar 509 Dysport 487
46 Aurobindo Pharma HYDERABAD, INDIA [AUROBINDO.COM]	\$3.159	\$116	Hydrochlorothiazide; Losartan Potassium 57 Folotyn 53 Penicillin V Potassium 38
47 STADA Arzneimittel BAD VILBEL, GERMANY [STADA.COM]	\$3.097	N/A	Bortezomib 102 Retacrit 102 Apokyn 96
48 Jazz Pharmaceuticals DUBLIN, IRELAND [JAZZPHARMA.COM]	\$3.079	\$506	Xyrem 1,266 Xywav 535 Epidiolex 464
49 Endo International DUBLIN, IRELAND [ENDO.COM]	\$2.990	\$149	Vasostrict 902 Xiaflex 432 Adrenalin Injection 125
50 Kyowa Kirin TOKYO, JAPAN [KYOWAKIRIN.COM]	\$2.959	\$579	Crysvita 780 Neulasta 316 Darbepoetin alfa 203

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Is the C-Suite Getting Inflated?

A flurry of new titles entering the executive ranks has its pros and cons

By Elaine Quilici

If you feel like the c-suite has been expanding with an alphabet soup of titles lately, it's not your imagination. While growing with the times has always produced an evolution of executive titles, it seems now more than ever the industry is creating a new legion of leaders: chief digital officer, chief transformation officer, chief patient officer, chief revenue officer, chief diversity officer, chief innovation officer, chief ethics and compliance officer, chief sustainability officer, chief impact officer, and the list goes on and on.

"I think it's become more of a trend now than [during] other [points] of my career," says Daniel Lawlor, senior vice president, North America human resources and pharmaceutical HR business partner at Teva. "I think a lot of companies are moving away from more traditional job evaluation and job titling structures, which I think is contributing to it. But I also think the recent labor market could be contributing to it as well."



Stephen Brengle

Stephen Brengle, managing director, pharmaceuticals and biotechnology, North America, in WittKieffer's global life sciences practice, agrees that changing environmental factors are contributing to the uptake of some titles. "The reason for the constant expansion is most likely related to the need for companies to shift and address the evolving business needs of developing life-saving therapies, in combination with the dynamic changes occurring culturally within the industry and our environment today," he says.

THE EMERGENCE OF NEW TITLES

Though internal factors, such as a reorganization or a new business focus, can contribute to the creation of titles, there are many external elements influencing the new c-suite. In the case of some nontraditional titles, the driver is sometimes about the company trying to demonstrate to internal and external stakeholders that they're serious about certain issues or concerns.

For instance, shareholders who are focused on revenue would like to see a chief revenue officer, while those promoting a long-term strategic plan would prefer seeing a chief transformation officer. Community members might be more drawn to a company with a chief sustainability officer. When stakeholders review the

company's leadership team and see titles that speak to their interests, it makes them feel as if the company is specifically addressing their particular issues or concerns.

Two popular initiatives these days are patient centricity and diversity, so it's no surprise chief patient officer and chief diversity officer titles are growing in popularity.

"[Patient centricity] is at the forefront of drug discovery and where companies will begin to frame their pipelines in the future," says Brengle. "At the same time, you have chief diversity officers who are focused on creating diverse, equitable, and inclusive work environments where data has already shown that companies that diversify will be more successful in the long run. Patient recruitment is a significant deliverable for a chief patient officer, and with an increased focus on diversity in patient recruitment, you often see this as an area where the two roles intersect in a meaningful way."

Top-ranking titles can also attract employees. Current and prospective workers who are concerned about aspects of the company's culture would appreciate seeing a chief diversity officer; a chief digital officer would be important to those driven by innovation and technology. These "statement titles" demonstrate that the company is more progressive and advanced in those areas.

Lawlor sees the pandemic as another driver of specific titles, such as chief remote officer and chief safety officer, as the workplace has been transformed. Again, creating these top-level positions communicates a commitment to prospective employees that the company takes remote work and employees' health and safety seriously.

"Typically, if things become really important in society, they eventually come into corporate America, and they get reflected in things like titles," says Lawlor.

WHAT'S IN A NAME?

The structure of a company can help decide titles. Some companies, like Teva, are very transparent with their organizational classification to clearly identify hierarchy. "Our company has leaned away from ['chief' titles], because it's part of our culture," says Lawlor. "We still use the traditional titles of executive vice



Daniel Lawlor



Source: vegefox.com/stock.adobe.com

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president, senior vice president, and vice president. When you have a more traditional titling structure, it's very transparent to the organization what level someone's at, and you can imply what pay level they're at as well; whereas, if everyone's using the title chief, it doesn't necessarily mean they're all really paid or titled at the same level."



Hettie Stroebel

Hettie Stroebel, founder and CEO of Launch Excellence Partners, a strategic marketing planning and commercialization advisory firm to the life sciences industry, notices a difference in structure among companies that are platform driven vs. non-platform driven. Those with just one drug or one indication tend to be leaner on top. She says the stage of a company

is also important—startup vs. a more mature company—and the desire to have a blend of functional responsibility and divisional responsibility.

"The company's strategy also often determines what roles they would have," she says. "For example, if you look at the Novartis structure, that is very different than some of the other pharma companies, because of what the organization's strategy is. They were one of the first organizations I saw that had the role of chief strategy officer."

When it comes to startup biotechs, many are more generous with their titles. For instance, in a biotech where there aren't as

“Typically, if things become really important in society, they eventually come into corporate America, and they get reflected in things like titles”

many employees, the one person handling all the marketing might be titled chief marketing officer by default. In addition, a smaller company that can't pay as much as a larger corporation might use the "chief" title as an incentive in a competitive talent market.

Smaller startups also can use titles to attract pharma veterans who may be looking to advance; however, at a larger company, that title can be difficult to come by. "That definitely plays a big role," says Stroebel, who worked for Merck in regulatory and commercial for 28 years before starting her own business. "[I know] many ex-Merck colleagues that now are chief marketing

officer [at a smaller company], where they previously were in a director's role."

THE NEGATIVES OF NOMENCLATURE

One caveat of an expanding c-suite is that too many "chief" titles can lead to title inflation. "This can be problematic over time [because] it dilutes the significance of the title," says Lawlor. "If everyone seems to have the 'chief' title, then it doesn't feel that important anymore to someone who maybe was hired in thinking they were really going to be somebody at the [top] leadership level."

The varying roles and responsibilities of "chiefs" across companies can also contribute to some devaluation—where one chief sustainability officer might manage a department of five people, others may be holding down the fort themselves. The scope of a "chief's" job can greatly vary.

Stroebel worries that creating unique titles can be a disservice to employees in the long run, as it can pigeonhole someone in their career. "Where do they find a similar title again in the industry if it's very unique?" she ponders. "Even in your own organization, [how do you] grow with that particular title? It's very important that [companies] think about the longevity of the role and what that title looks like vs. here's a person and now you make a box for them."

In the context of pay equity, "chief" titles also can hide the true level of individuals in an organization. "My sense is that everyone with 'chief' is not really being paid at the same level or grade [within and between] organizations," says Lawlor. "From that standpoint, it works a little against the aspects of being more transparent with pay."

Ultimately, companies need to think about the sustainability of these titles and really look at why they are adding them. "Is it something that's a fad? Is it because it draws people? Or is it about where their company is—and what will that organization look like in the long term?" asks Stroebel.


Adding new titles also may cause a shuffle of other positions, so companies should be cognizant of the greater companywide impact. "[Adding a 'chief'] must provide a good business case and value to the company," says Brengle.

As the c-suite continues to evolve, there's one last area that could affect titling. From a reputation perspective, many organizations have moved away from using the term "chief" for its connection to Native American terminology. For example, the Washington Redskins were temporarily renamed the Washington Football Team in 2020, until they were officially renamed the Washington Commanders earlier this year. In the public sector in 2020, the city of Duluth, Minn., lobbied to remove the title of "chief" from key job titles, and was successful in one case.

"For me, it's just a question of time before the use of the title



Source: Rawpixel.com/stock.adobe.com

chief gets challenged in corporate America," says Lawlor. "We've seen so many different aspects of diversity and inclusion being embraced in [business], and this could be something that we see coming soon as another aspect of diversity and inclusion." 

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Sustainability Sea Change

The Top 5 ESG Challenges for Pharma

Outlining the most important sustainability-related hurdles facing leading biopharma companies today—and current efforts underway to meet new expectations in advancing this strategic mandate



SANDOR SCHOICHET is a co-founder and partner at the Biopharma Sustainability Roundtable, and director at Meridian Management Consultants. He can be reached at sschoichet@biopharmasustainability.com.

Sustainability is maturing into a core element of long-term business strategy, integrating environmental and social risks and opportunities with conventional financial performance and governance concerns. As I noted in my first column for this magazine, *Biopharma Sustainability Considered Essential* (May 18, 2020; <https://bit.ly/3z7UnIk>), sustainability has a special resonance for the biopharma sector since our common mission is to achieve positive social impact through improved medicines and healthcare.

For this special “Top 50 Biopharma” issue (rankings based on prescription drug revenue), I’d like to offer a current perspective on the Top 5 sustainability-related challenges now facing leading companies, and how their responses may act as pathfinders for the rest of the sector. Most of these challenges relate to internal business processes and culture, or to collaboration and consensus-building with key stakeholders, especially investors, standard-setters, and regulators. For each challenge, I’ve provided key references for the interested reader to learn more, but be warned—sustainability is a deep and fascinating topic and these examples are not comprehensive.

Challenge No. 1 is governance, as it so often is. Integrating environmental, social, and governance (ESG) objectives into a company’s core business strategy, operations, and communications is not easy. Last June, the Biopharma Sustainability Roundtable (BSRT) partnered with Chief Executives for Corporate Purpose (CECP) to produce a Biopharma CEO Investor Forum, where 10 biopharma CEOs spoke about exactly these issues, sharing their varied approaches to sustainable long-term planning.

The impetus for companies to incorporate ESG governance, risk identification, and opportunity assessment into a more expansive view of corporate sustainability is driven by broad social pressure—the UN’s Sustainable Development Goals (SDGs), perceived impacts of climate change, the COVID-19 pandemic, and growing participation by younger generations in wealth management. This, in turn, has driven investors and asset managers to create a wide variety of ESG or impact-oriented funds and portfolios that are

“Lawmakers and regulators are getting involved to ensure that ESG performance information is meaningful and decision-useful for investors and society”

meant to preferentially allocate funds to more sustainable companies. Now, lawmakers and regulators are getting involved to ensure that ESG performance information is meaningful and decision-useful for investors and society. The EU is currently a leader in this evolution, but since all large biopharma firms are global, requirements in one geography will drive widespread operational change.

Challenge No. 2 is simply tracking, contributing, and responding to the rapidly evolving landscape of ESG standards, regulations, and stakeholder expectations. With investors’ growing appreciation of non-financial performance as a key to long-term value creation, a sea change is happening in how companies are expected to measure, track, and disclose their ESG performance. My colleague Myrto Kontaxi, also a partner at BSRT, and Victoria Emerick, executive director and global head for corporate ESG-sustainability strategy and operations at Bristol Myers Squibb, recently discussed the range and progress of standard-setting, international harmonization, and new regulation that will be affecting biopharma companies as guests on *Pharm Exec’s* podcast, *New Guidance for Biopharma Investor ESG Communications* (May 26, 2022; <https://bit.ly/3N7BIkb>).

“The second wave of ESG standards and regulations coming in the next one to two years will expand the range of social impact and sector-specific concerns”


There are several active standard-setting and regulatory development efforts currently underway, including a US Securities Exchange Commission (SEC) proposal to enhance and standardize climate-related disclosures for investors, the first International Sustainability Standards Board (ISSB) cross-sector environmental standards, as well as the first European Sustainability Reporting Standards (ESRS), which will start coming into force next year.

Challenge No. 3 is responding effectively to social, investor, and employee demands for joining the “race to net zero.” All companies need to set and drive toward meaningful science-based targets to achieve cross-sector environmental objectives, especially for decarbonization and other climate-related impacts, and this is where the first wave of new regulatory requirements is focused. Some of the best work in this area is being done by the Science Based Targets initiative, which encourages companies to set targets and report progress based on their actual contributions to the problem and opportunities for improvement, rather than as incremental adjustments to past behavior. Many people—including me—have thought that environmental impacts are not all that important (or material) for the biopharma sector, but recent analyses like *The Carbon Impact of Biotech and Pharma*, from My Green Lab and Urgentum, indicate that we do have a higher-than-expected carbon impact through our Scope 3 supply and delivery chains, and through the power demands for laboratory facilities. As an industry focused on R&D and human health, we should be leading by example.

Challenge No. 4 is developing a working consensus among companies, investors, and standard-setters on how to meaningfully define, measure, and communicate social impacts that are unique to the biopharma sector. The second wave of ESG standards and regulations coming in the next one to two years will expand the range of social impact and sector-specific concerns, which for biopharma includes topics such as affordable access to medicine across markets, equitable participation in clinical trials, and the social and economic value of better healthcare infrastructure. These unique challenges and opportunities are addressed in depth in the latest *Biopharma Investor ESG Communication Guidance 4.0*, released in March, reflecting the outcome of an ongoing direct dialog that’s been running for the last four years between biopharma companies and investors, facilitated by the BSRT. While there’s no perfect recipe book for how companies should set their strategic ESG objectives and communicate their progress, the guidance does define the 12 highest-priority

topics for both companies and investors, along with a growing set of metrics and indicators that are being shared with key standard-setters like the Sustainability Accounting Standards Board (SASB), now part of ISSB.

Challenge No. 5 requires the creation of new business models and external collaborations to meet the needs of developing markets, and to address healthcare problems that are beyond the scope of what any one company can do. Biopharma makes extraordinary investments of time, expertise, and money into new product development, but actually delivering equitable access to medicines for all patients who need them requires a different skillset. One example of innovative thinking in this area is Novartis Access, which offers a collective pricing model for a collection of existing drugs for managing key non-communicable diseases (NCDs) to governments, NGOs, and institutional customers in lower-income countries. Access Accelerated is a complementary effort to bring public and private actors together in an industry-led initiative to improve access to NCD-related healthcare services. Private, public, NGO, and government cooperation will also be needed to mount an effective response to the growing danger of antimicrobial resistance (AMR). More than 700,000 people die each year from infections resistant to most or all antibiotics, yet very few firms are actively developing new drugs in this space due to high costs and limited product lives. The increase in AMR is also a major risk factor for whole segments of current medical practice, including most forms of surgery and cancer treatments that rely on immune system suppression. The REPAIR Impact Fund, set up by Novo Holdings, is a new model for investing in this area, intended as part of a larger coordinated response that includes better medical practices, new diagnostic technology, and government action to create appropriate incentives.

I ended my first column on ESG for *Pharm Exec* by highlighting the concept of a “social license to operate” that recognizes the contributions of our sector and allows us to operate profitable research-based businesses on a sustainable long-term basis. And that’s where I want to end this time as well. How our largest and most visible companies address the five key challenges sketched here will strongly influence the broad social perception of our industry and will set the tone for how the myriad of smaller players are expected to operate. Sustainability is now an essential lens for everyone interested in the long-term value and contributions of biopharma to society. 

Untapped Potential

Regulatory Affairs and Innovation

As regulatory reform continues to evolve in the US and Europe, the role of regulatory affairs is poised to help shape the more personalized treatment landscape on the horizon



STEF SCHUTTE, PharmD
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Across the globe, the healthcare industry is working hard to transform care and accelerate improved outcomes for patients. From the growing importance of real-world evidence (RWE) and emerging technologies for data capture and analysis, to the discovery of new modalities and disease states, this rapid transformation is touching every aspect of our work. As contributors to this period of change, all of us working in biopharma have an opportunity to leverage innovation to enhance the patient experience and evolve the paradigm of care.

The pandemic has also been a profound catalyst for change—the adoption of virtual care solutions, accelerated drug development processes, and heightened levels of collaboration, particularly between regulatory agencies and industry, laid the foundations for new models of engagement.

As the expectation for better and more personalized care grows every day, regulatory affairs (RA) is set to play an increasingly important part in ensuring patients can access the potentially life-changing innovations of tomorrow.

INNOVATION CALLS FOR INDUSTRY AND REGULATORS TO ADAPT FOR THE FUTURE

Historically, clinical development often has been based on known pharmacological mechanisms, with small, stepwise innovations. Today, innovation is increasingly more radical, focused on next-generation therapies for complex or rare diseases, using platforms sometimes for the very first time. It is truly an exciting period of discovery, but also uncharted territory with increased uncertainty of the outcome—for industry and regulators alike.

Regulators, including FDA and the European Medicines Agency (EMA), are already calling for new approaches as we adapt to these novel areas. Harmonization of approach among agencies is underway in some regions, but there is a long way to go before alignment is a global reality. More agile and responsive regulatory systems are needed—not only for realizing the potential of these new therapies for patients but for encouraging future innovation.

“ Harmonization of approach among agencies is underway in some regions, but there is a long way to go before alignment is a global reality ”

For RA, this is an opportunity to demonstrate our strategic impact in enabling organizations to adapt to the complexities of innovative science and the changing regulatory landscape, while continuing to fully explore the optimal use of therapies already available. We have a unique opportunity to inform development strategies, guide decision-making, and enhance our understanding to assess how we can deliver even greater value for patients, today and tomorrow.

RA IS PIVOTAL IN TRANSFORMING PATIENT CARE

As our efforts combine to transform and accelerate care for patients by realizing the potential of novel therapies, RA has learned to pivot quickly. New engagement models have been established, and our response to these evolving approaches is more important than ever.

Early, frequent interactions with a broad group of stakeholders and experts are vital to define and agree on the path forward. Ensuring open, transparent dialogue enables us to facilitate information exchange and share progress, learnings, and insights to ensure the key unmet needs of patients and prescribers are met.

RA has an increasingly central and strategic role as knowledge experts, acting as the link between industry and regulatory

agencies. Being aware of and interpreting regulatory trends ensures we understand how new modalities may be approached by regulators so we can contribute to shaping pathways to expedite their approval for patients in need.

Internally, we share these insights and expertise to guide teams from the earliest stages of discovery through the post-approval setting with strategic, as well as operational, support across the entire value chain.

Externally, proactivity and partnership matter. We foster relationships with regulators and industry associations, as well as together in public-private partnerships, such as the Innovative Medicines Initiative and Innovative Health Initiative. By partnering and pooling resources, we ensure that research results are turned into useful innovations for patients, setting the precedents which will define the industry-wide pathways needed for tomorrow's medicines.

PROPELLING THE INDUSTRY FORWARD

RA professionals continually embrace new possibilities to drive the industry forward. We never stop investigating how to elevate the safety, efficacy, quality, and performance of our innovations, as well as focusing on optimizing the treatments already available, to continually seek new ways to improve patient outcomes.

Together with health authorities, we have a key role in advancing regulatory science—the science and research intended to inform decision-making in a regulatory framework. Our goal is to implement the principles, processes, and tools needed to ensure we are equipped for the future.

This is evident in how we are leveraging enhanced data access and analytics, with the validity of RWE being increasingly recognized by regulators as a tool that can enhance our exploration of alternative data sets with patient-centered outcomes.

A key example is the 2021 FDA approval of a new use for Prograf (tacrolimus) in lung transplantation—considered a significant milestone by regulators. First approved nearly 30 years ago in the US for the prevention of organ rejection in patients receiving liver transplants, a retrospective observational study of more than 20,000 people supported the expanded approval of Prograf for the prevention of organ rejection in adult and pediatric lung transplant patients.¹

This marked the first approval of an immunosuppressant therapy for this use, highlighting the potential of a noninterventional study relying on fit-for-purpose, real-world data to meet regulatory requirements. This demonstrates the impact RA can have by truly listening to and understanding the needs of patients and prescribers, adopting novel data-driven approaches, and working in partnership with regulatory agencies to maximize the value we can deliver to patients.

“ Together with health authorities, we have a key role in advancing regulatory science ”

UNLOCKING INNOVATION POTENTIAL

Addressing unmet needs and bringing new treatment options to patients is never easy, but rapid advances in many areas are helping us to navigate complexity and unlock the potential of health innovation.

RA already makes an important contribution to this—from the earliest stages of drug discovery and development through patients in the real world. However, we know more can be done.

Regulatory reform is ongoing worldwide and, with a more personalized treatment landscape on the horizon, this reform will support industry, regulators, and society alike in realizing the value of scientific and technological discovery. A joined-up, patient-centric approach will not only deliver the novel therapies of today, but inspire and galvanize the innovators of tomorrow. With new perspectives already shaping the future, the full potential of RA is yet to be delivered in transforming value for patients. ^{PE}

Reference

1. <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-use-transplant-drug-based-real-world-evidence>

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The Emergence of the Chief Value Officer in Healthcare

Outlining the implications of this c-suite trend for pharma



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The recent appointment of a chief value officer (CVO) at multiple healthcare systems may represent a nascent trend among healthcare executive management teams—one that gives new prominence to the term “value” and could have implications for the pharma industry.

Across the country, the boards of many newly consolidated healthcare corporations are recognizing that the management of what is now a multibillion-dollar company can’t continue as it did when, just a few years ago, it was a multimillion-dollar enterprise. Legacy senior executives are being replaced with younger and more sophisticated CEOs who understand that the healthcare environment around them is changing and that they must adapt to those changes. Part of that means identifying what needs to be done and tasking people at the executive level to make it happen.

But the flurry of CVO appointments at the executive level is also a statement about the importance of value. It signals that the drive for value needs to come from the top, not delegated further down the organization.

A quick survey of CVO role descriptions at organizations like Nemours, Drexel University Health, and the University of Utah suggests some common themes. Responsibilities for CVOs often encompass both enterprise level and internal change. One branch involves building strategic partnerships at the enterprise level with payers, employers, and physician groups to take on innovative, value-based contracts. Internally, responsibilities are to drive change at the clinical practice level that leverages data-based research to improve outcomes for patients and to build capability to succeed in value-based payment contracts. Often, building population health principles into what the organization is doing is part of the mandate.

This recognition of the growing importance of value in the healthcare context and the elevation of responsibility for

change appears to be a milestone. After years of talking about being accountable for cost and outcomes of care, this may signal that leading healthcare organizations are ready to take the concept seriously.

So, what does this mean for pharma? It may mean that delivery organizations are going to take on more financial risk in contracts with payers and employers—contracts in which they accept the need to make prudent, cost-effective choices in the treatment of patients, to keep them out of the hospital instead of relying just on the revenue they generate once they wind up there. That could mean that a change in prescribing policies and practices, substituting preventive measures for acute care, and increased use of lower-cost solutions before the latest discovery. That could mean that some pharma products see lower utilization unless ways are found to lower their effective cost.

That could involve more use of value-based arrangements by manufacturers—arrangements in which patient response to treatment, based on clear-cut metrics, determines discounts to unit costs. It could also mean lower utilization and slower growth in the uptake of some of the industry’s most expensive products.

This suggests that pharma companies need to take a value-based future more seriously, developing and testing approaches of their own that rationalize the cost of utilization and make the case for superior clinical outcomes that matter to patients. Otherwise, providers may increasingly make decisions that are based on the idea that “good-enough is good enough.”

Individuals and employers are staggering under the cost of insurance premiums that have been inflating regularly for years. It’s clear that the issue of healthcare cost is coming to a head soon, and perhaps some of the people leading healthcare corporations don’t want to be caught by surprise. Neither should pharma execs. **PE**

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